Federal Court  Cour fédérale

Date: 20150720

Docket: T-1598-13

Citation: 2015 FC 875

Ottawa, Ontario, July 20, 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

JUDGMENT AND REASONS

[1] In this application, 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 Minister of Health [the Minister] from issuing a Notice of Compliance [NOC] to the respondent, Apotex Inc. [Apotex], for approval to sell its generic version of tadalafil [APO-Tadalafil] until after the expiry of the Canadian Patent 2,226,784 [the 784 Patent] on July 11, 2016.

[2] Tadalafil is used, among other things, to treat male erectile dysfunction (or ED), a condition that affects a substantial number of men. Lilly markets tadalafil under the brand name CIALIS. The 784 Patent is listed against CIALIS on the Patent Register maintained by the Minister under sections 3 and 4 of the *PMNOC Regulations*.

[3] Apotex sought an NOC from the Minister for approval to sell its Apo-Tadalafil product and, by virtue of section 5 of the *PMNOC Regulations*, was required to address the 784 Patent. It did so in a Notice of Allegation [NOA] that it served on Lilly on August 16, 2013. In its NOA, Apotex raised several grounds that it did not pursue during the hearing of this matter.

[4] Following receipt of Apotex' NOA, on September 27, 2013, Lilly filed the present application to prohibit the Minister from issuing an NOC to Apotex for Apo-Tadalafil.

[5] Apotex does not contest that its Apo-Tadalafil product would infringe Claims 1, 2, 4, 9, 12, 14, 15 and 18 of the 784 Patent. Thus, infringement is not in issue in this application. Validity of the 784 Patent, however, is in issue.

[6] By the time of the hearing, Apotex had narrowed the grounds in support of its invalidity claim to two. It first asserts in this regard that the 784 Patent is invalid because it is an impermissible double patenting of the invention claimed in the earlier 2,181,377 Canadian Patent [the 377 Patent] that Lilly is similarly licensed to use and which likewise pertains to tadalafil. Second, Apotex says that the 784 Patent is invalid for insufficiency because it fails to provide guidance on how to produce hydrate forms of the compounds claimed in the 784 Patent. In addition to these invalidity arguments, Apotex also asserts that Lilly lacks standing under the *PMNOC Regulations* to bring this application as it has failed to show that there is a proper chain of title to the 784 Patent in its favour.

[7] This is the second PMNOC case involving the 784 Patent. On January 7, 2015, my colleague, Justice Yves de Montigny, issued reasons in *Eli Lilly Canada v Mylan Pharmaceuticals ULC*, 2015 FC 17, 249 ACWS (3d) 191 [*Mylan Tadalafil*] in which he dismissed Mylan's prohibition application because he found Mylan's allegations of invalidity to be unjustified. Some of the arguments advanced by Apotex in this case are similar to those advanced by Mylan in *Mylan Tadalafil* and some of the evidence in the two cases is similar.

[8] For the reasons set out below, I have reached the same conclusion as Justice de Montigny and have determined that Apotex' allegations of invalidity are unjustified. I have also found its other argument regarding Eli Lilly's alleged lack of standing to be without merit and have accordingly concluded that an order prohibiting the Minister from issuing an NOC to Apotex for its tadalafil product should issue.

I. Background

[9] To put the issues in this case into context, it is necessary to briefly review some of the science behind the 748 Patent.

[10] ED is defined as the inability to sustain an erection sufficient to allow for penetration of a man's partner. An erection occurs when blood flows to and remains in the penis, causing it to become rigid. The penis contains two compartments on either side of the urethra, called the *corpora cavernosa*, which are comprised of blood vessels and smooth muscle tissue. Smooth muscle is also found in other locations throughout the body, including in the lungs, the tissue surrounding the vasculature and in the gastro-intestinal tract. Smooth muscle tissue can relax and contract; however, this occurs involuntarily as smooth muscles are controlled by the body's autonomic nervous system.

[11] In the penis, in its flaccid state, the smooth muscle in the *corpora cavernosa* is contracted, which allows blood to flow into and out of the *corpora cavernosa* at approximately the same rate. When an erection occurs, the smooth muscle in the *corpora cavernosa* relaxes, which restricts the veins flowing out of the penis and causes the *corpora cavernosa* to fill with blood and become engorged. Thus, contrary to what one might expect, it is the relaxation of the smooth muscle *corpora cavernosa* that enables an erection.

[12] Smooth muscle relaxation results from a series of complex biochemical reactions that occur along intercellular communication systems, termed “pathways”. One pathway involved in the erectile process is the NO/cGMP pathway. The 784 Patent is directed to this pathway.

[13] In the NO/cGMP pathway, two different processes occur. In the first, nitric oxide or NO is released principally by the non-adrenergic non-cholinergic [NANC] nerves in the penis following sexual stimulation. NO is termed a “first messenger”, and it enters the smooth muscle cells or interacts with receptors on the cell surface, causing an intercellular reaction. Inside the smooth muscle cells of the *corpora cavernosa*, this reaction eventually results in the production of a “second messenger” called cyclic guanosine-3′, 5′-monophosphate (or cGMP). cGMP causes the smooth muscle in the *corpora cavernosa* to relax, which enables an erection.

[14] The second process in the NO/cGMP pathway involves the breakdown of cGMP by a class of enzymes called phosphodiesterases or PDEs, which convert cGMP into its non-cyclic form called guanosine-3′, 5′-monophosphate or GMP. In contrast to cGMP, GMP does not cause smooth muscle relaxation. Thus, when cGMP converts to GMP in the cells of the *corpora cavernosa*, an erection is lost and the penis returns to its resting state.

[15] There are several types of PDEs present in the body. It is now known that the primary one that acts to convert cGMP to GMP in the *corpora cavernosa* is called PDE V.

[16] Tadalafil operates so as to restrict the production of PDE V. When this isozyme is suppressed, cGMP is not converted to GMP in the *corpora cavernosa* (or the conversion is

slowed). When sexual stimulation occurs and the NANC nerves in the penis release NO, an erection will tend to be maintained if there is insufficient GMP in the *corpora cavernosa* to cause the smooth muscles to contract. Thus, through suppression of PDE V, which acts to create GMP, tadalafil helps to maintain an erection.

[17] Tadalafil was first developed for use in the treatment of hypertension and cardiac disorders. It is a derivative of tetracycline and was first synthesized in laboratories of Laboratoire Glaxo, a predecessor to GlaxoSmithKline [GSK France], in France in 1993.

[18] Tadalafil was first claimed in the British Patent GB No. 9401090.7, the international precursor to the 377 Patent, which was filed on January 21, 1994. The 377 Patent was filed in Canada on January 19, 1995 and claims a priority date of January 21, 1994, the date of filing of the British Patent. The 377 Patent was published on July 27, 1995. The 377 Patent claims several compounds, including tadalafil, pharmaceutical compositions and use of these compounds in the treatment of disorders where the inhibition of PDE V is thought to be beneficial. The 377 Patent does not name ED as one of these disorders or discuss ED in any way.

II. The 784 Patent

[19] The 784 Patent was filed in Canada on July 11, 1996, claims a priority date of July 14, 1995 and was published on February 6, 1997. It is entitled “Use of cGMP-Phosphodiesterase Inhibitors to Treat Impotence”. It relates to the use in the treatment of ED of some of the compounds claimed in the 377 Patent. Dr. Daugan, an employee of GSK France, the successor to

Laboratoire Glaxo, is the inventor of the 784 Patent (and was also the inventor of the 377 Patent). The 784 Patent discloses the same *in vitro* tests that were disclosed in the 377 Patent.

[20] Justice Yves de Montigny aptly summarized the import of the 784 Patent in *Mylan Tadalafil* in the following terms:

> [12] According to the specification part of the disclosure, many different drugs have been shown to induce penile erection but are only effective after direct injection into the penis, and are not approved for ED. […]
>
> [13] The specification goes on to describe the compounds of the invention (tadalafil and 3-methyl tadalafil), and states that these compounds, "unexpectedly", have been found to be useful in the treatment of ED. "Furthermore the compounds may be administered orally, thereby obviating the disadvantages associated with i.c. administration" (pp 3-4 of the Patent).
>
> [14] The gist of the invention is described in the following way:
>
> > It has been shown that compounds of the present invention are potent and selective inhibitors of cGMP specific PDE [i.e. PDE V]. It has now been surprisingly found that human corpus cavernosum contains three distinct PDE enzymes. The predominant PDE has further surprisingly been found to be cGMP PDE [i.e. PDE V]. As a consequence of the selective PDE V inhibition exhibited by compounds of the present invention, the subject compounds can elevate cGMP levels, which in turn can mediate relaxation of the corpus cavernosum tissue and consequent penile erection.
> >
> > ('784 Patent, p 4)
>
> [15] Oral administration is said to be the "preferred route", because it is the most convenient and avoids the disadvantages associated with intracavernosal (i.c.) administration, but the drug can also be administered sublingually or buccally. Oral dosages of the compound for curative or prophylactic treatment of ED are said to be in the range of from 0.5 to 800 mg daily, the actual dosing regimen being determined by a physician. For human use, the compounds will be administered in admixture with a

> pharmaceutical carrier selected with regard to the intended route of administration: "For example, the compound may be administered orally, buccally or sublingually, in the form of tablets containing excipients such as starch or lactose, or in capsules or ovules either alone or in admixture with excipients, or in the form of elixirs or suspensions containing flavouring or colouring agents" ('784 Patent, p 5).
>
> [16] The '784 Patent includes data from two *in vitro* tests on tadalafil and 3-methyl tadalafil. The first test shows that, when in proximity to the PDE V enzyme, the compounds inhibit its activity. The second test shows that the compounds can penetrate and prolong the cGMP response in rat aortic smooth muscle cells. Taken together, these data indicate that the compounds are potent inhibitors of PDE V *in vitro*. The Patent also states that the compounds were shown to be highly selective inhibitors of PDE V over other PDE enzymes, but does not provide these data. The '784 Patent contains no *in vivo* testing or clinical studies of any of its compounds.

[21] The 784 Patent has 28 claims; those in issue are reproduced in the Appendix to these Reasons. There is no dispute between Apotex and Lilly on the construction of these claims.

[22] Claim 1 claims the compounds to which the Patent is directed and sets out their chemical formulae. It includes physiologically acceptable salts or solvates of the claimed compounds. It claims a pharmaceutical composition comprised of these compounds for the curative or prophylactic treatment of ED in a male animal.

[23] Claim 2 claims a pharmaceutical composition comprising two of the compounds falling within Claim 1, namely, tadalafil and 3-methyl tadalafil or a physiologically acceptable salt or solvate of the two compounds for the treatment of ED in a male animal. Claims 3 and 13 claim these compounds where the solvates are hydrates. The parties concur that the term "solvates" as used in Claim 2 (and subsequent claims) includes hydrates. A solvate is a physical form of a

chemical compound that is a crystalline solid containing a solvent incorporated within the crystal structure. A hydrate is a solvate in which the incorporated solvent is water.

[24] Claim 4 claims the compositions of Claim 2 for use in human males.

[25] Claim 9 claims the use of tadalafil for manufacturing a medicament for the curative or prophylactic treatment of ED in a male animal.

[26] Claim 12 claims the use of tadalafil, 3-methyl tadalafil or a physiologically acceptable salt or solvate of the two compounds for the treatment of ED in a male animal. Unlike Claims 2, 4, 9 and 15, Claim 12 is not limited to a particular pharmaceutical composition but rather more broadly claims the use of the compounds or their physiologically acceptable salts or solvates for the prophylactic or curative treatment of ED in a male animal.

[27] Claim 14 adds to Claims 9 through 13 that the male animal is human.

[28] Claim 15 claims the use of the compositions of Claims 1, 2 and 4 for the treatment of ED in a male animal.

[29] Claim 18 is dependent on Claims 9 to 17 and claims compounds, medicaments, compositions and combinations of formulations that are used or adapted to be used orally. When one combines Claim 18 with Claims 12 and 14, the claim is made to the use of tadalafil, 3-methyl tadalafil or a physiologically acceptable salt or solvate of the two compounds in

treating ED in human males upon oral administration. This is the narrowest of the Claims at issue in this application.

III. The Issues

[30] As noted, three issues arise in this application, namely:

1. Is the 784 Patent invalid for double patenting over the 377 Patent?
2. Is the 784 Patent invalid for insufficiency?
3. Does Lilly lack standing to bring this application due to a defect in the chain of title?

IV. The Witnesses

[31] Lilly filed affidavits from six fact witnesses and five experts. Apotex filed evidence from two fact witnesses and four experts.

[32] More specifically, Lilly filed the affidavit of a law clerk (to adduce relevant documents) and of Drs. Daugan, Grondin, Martins and Kral as well as from Jennifer Smith and Patrick Desbiens as fact witnesses and of Laëtitia Bénard and Drs. Goldstein, Kennedy, Wuest and Brock as expert witnesses. Dr. Kennedy's evidence is no longer relevant as it relates solely to the issue of sound prediction, which Apotex raised in its NOA but dropped in its Memorandum and is no longer in play.

[33] As noted, Doctor Daugan is the inventor of the 377 and 784 Patents and is a French pharmaceutical researcher employed by GSK France. In his affidavit, he describes his involvement in the development of tadalafil as part of a research project to identify PDE V inhibitors for the treatment of hypertension and congestive heart failure. He recounts that a patent was filed when tadalafil was first developed (GB Patent No. 9401090.7, the international version of the 377 Patent). After this patent was filed, and after seeing literature on the use of PDE V inhibitors in treating ED, discussions with colleagues at Laboratoire Glaxo and early clinical trials of tadalafil, he says he began to consider that tadalafil could be used to treat ED. He says that at this point the second patent – the international version of the 784 Patent – was filed.

[34] Dr. Grondin is employed as a researcher by GSK France. His affidavit describes his role in supervising the early *in vitro* experiments on tadalafil. Like Dr. Daugan, he describes the decision to file the international version of the 784 Patent after researchers predicted that tadalafil – initially developed to treat hypertension and congestive heart failure – could also be used to treat ED. He says this decision was based in part on the review of the patent application relating to sildenafil, which is better known under its brand name, VIAGRA.

[35] Pfizer filed a patent application for sildenafil that was published before the priority date of the 784 Patent. More specifically, PCT Application No. WO 94/28902 [the 902 Application] has a publication date of December 22, 1994. The Canadian version of this Patent, CA 2,163,446, was filed May 13, 1994. Sildenafil is chemically distinct from tadalafil, but like tadalafil, is a potent and selective PDE V inhibitor and is used to treat ED. As is more fully

discussed below, in *Teva Canada Ltd v Pfizer Canada Inc*, 2012 SCC 60, [2012] 3 SCR 625 [*Sildenafil SCC*], the Supreme Court of Canada held that an NOC should issue for a generic version of sildenafil because the allegations of insufficiency made with respect to the Canadian version of the 902 Application were justified, since the Patent failed to disclose that sildenafil was the compound claimed in the patent that was effective to treat ED.

[36] The next Lilly witness, Dr. Martins, is a pharmacologist and a specialist in cGMP and PDE enzymes. In his affidavit he describes his experience in the preparation of the recombinant PDE V enzymes for the research leading up to the 784 Patent. His evidence is not central to the issues that remain in play in this application.

[37] Jennifer Smith is counsel at Eli Lilly Canada and appends to her affidavit the 1997 Amendment to the Collaboration Agreement between Glaxo Group Limited, Glaxo Wellcome Inc. [Glaxo U.S.] and ICOS Corporation [the 1997 Amendment] that Lilly claims is the document pursuant to which rights in the 784 Patent were assigned from Glaxo Group Limited and its affiliates to ICOS.

[38] Patrick Desbiens is the President of GSK France. In his affidavit he states that in 1997 Laboratoire Glaxo was an affiliate of Glaxo Group Limited within the meaning of the 1991 Collaboration Agreement by and among Glaxo Group Limited, Glaxo U.S. and ICOS [the 1991 Collaboration Agreement] that was amended by the 1997 Amendment.

[39] Dr. Kral is the co-inventor of another patent pertaining to tadalafil, Canadian Patent No. 2,379,948 [the 948 Patent], which is a formulation patent. In her affidavit she describes her involvement in the research and introduces two early research reports that she reviewed in the context of her work leading up to the 948 Patent.

[40] In terms of Lilly's experts, Laëtitia Bénard is a French lawyer and offers the opinion that, under French law, the rights to an invention made "during the course of a mission" by an employee hired to invent under an employment agreement belong to the employer. The implication is that the rights to the tadalafil patents, for which Dr. Daugan is the named inventor, automatically transferred to his employer, Laboratoire Glaxo.

[41] Dr. Brock is a urologist, specializing in ED. He teaches at and is the Program Director for the Urology Residency Training Program at the University of Western Ontario. He is currently the Secretary of the Sexual Medicine Society of North America, the Vice-President of the Canadian Urology Association and the Scientific Chair of the Society for the Study of the Aging Male. He is the author of over 150 publications, 25 book chapters, numerous abstracts and the recipient of more than 20 research awards from national and international research organizations. He has spoken widely, and his work in urology and erectile dysfunction has been acknowledged through his role as section editor of the Canadian Urology Association Journal, as well as through his participation as an editorial board member of numerous other scientific journals. Dr. Brock was accepted as an expert in respect of issues similar to those that arise in this case in *Mylan Tadalafil* and in two sildenafil cases: *Pfizer Canada v Novopharm*, 2009 FC 638, 76 CPR

(4th) 83 (Kelen J), rev'd on other grounds in *Sildenafil SCC*, and *Pfizer Canada v Apotex*, 2007 FC 971, 61 CPR (4th) 305 (Mosley J), aff'd 2009 FCA 8, 72 CPR (4th) 141 [*Sildenafil NOC*].

[42] Dr. Brock consults for many pharmaceutical companies, including Lilly. He was involved in the clinical trials of sildenafil and was also the lead investigator for several Phase II clinical studies undertaken by Lilly in conjunction with tadalafil. He sits on the advisory board of Lilly. He also participated in the press briefings when tadalafil was revealed by Lilly and, during the course of these briefings, sat alongside the senior executives of Lilly as part of the company's team.

[43] In his affidavit, Dr. Brock offers opinions on the issues of double patenting, sound prediction and insufficiency. In terms of double patenting, he opines that the 784 Patent is not invalid for double patenting over the 377 Patent. Regarding same invention-type double patenting, he believes that the two patents do not claim the same invention. Regarding obviousness-type double patenting, he believes that the person skilled in the art would not consider the inventive concept of the 784 Patent to be obvious. The other issues discussed in his affidavit are no longer in play as Apotex dropped its allegations related to sound prediction and to the particular argument regarding insufficiency that Dr. Brock references in his affidavit.

[44] Dr. Goldstein is also a urologist, specializing in sexual dysfunction. 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. Like Dr. Brock, 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. Like Dr. Brock, he was accepted by this Court as an expert in respect of issues similar to those that arise in this case in *Mylan Tadalafil*.

[45] In his affidavit, Dr. Goldstein offers opinions on the issues of double patenting, sound prediction and insufficiency. In terms of double patenting, he opines that the 784 Patent is not invalid for double patenting over the 377 Patent as he believes the claims of the 784 Patent are novel and inventive over the claims of the 377 Patent. The other issues discussed in his affidavit are no longer in play as Apotex has dropped them.

[46] Dr. Wuest is a Professor of Chemistry at the Université de Montréal and possesses a Ph.D. in chemistry from Harvard University. His research focuses on design, synthesis, structure and properties of molecular materials. He is a member of several advisory boards and selection committees associated with the award of prizes in chemistry, has published and delivered a myriad of peer-reviewed papers and has received several research grants.

[47] In his affidavit, Dr. Wuest provides an opinion on insufficiency and expresses the view that once a person skilled in the art had made the compounds to which the 784 Patent pertains,

that person could solubize them, attempt to crystallize them in the presence of water under a variety of conditions and carry out routine variations of these conditions to form hydrates. He thus expresses the view that the 784 Patent is not invalid for insufficiency for lack of directions regarding the production of hydrates of tadalafil and 3-methyl tadalafil.

[48] As for Apotex' witnesses, the fact witnesses include a law clerk, who merely appends documentation to her affidavit, and Duane Terrill, the Associate Director, Regulatory Affairs at Apotex, who explains in his affidavit the somewhat circuitous route by which this application came to be. His evidence is not relevant to the issues that remain to be decided in this application.

[49] Apotex' expert witnesses are Dr. Corbin, Dr. Burnett and Dr. Warrington, who speak to the issue of double patenting, Mark Eisen, a patent agent who opines on the chain of title issue, and Dr. Trout, who opines on the insufficiency issue.

[50] Dr. Corbin is a biochemist and is currently a Professor Emeritus in the Department of Molecular Physiology and Biophysics at the Vanderbilt University School of Medicine in Nashville, Tennessee. Previously, he was a Professor and Assistant Professor at the same university. Over the course of his career, Dr. Corbin has sat on various editorial boards and editorial advisory boards, including for the Journal of Biological Chemistry, received multiple research grants and has published widely in various peer-reviewed journals and presented numerous papers at conferences. He discovered PDE V and has studied the effects of sildenafil, vardenafil and tadalafil on PDE V.

[51] The portions of his affidavit that are relevant in this application deal with the issue of double patenting. He offers the opinion that the 784 Patent is invalid for obviousness-type double patenting, taking the view that a person skilled in the art with the common general knowledge (at July 11, 1996 or July 14, 1995) would not have required inventive ingenuity to bridge the gap between the subject matter disclosed and claimed in the claims of the 784 and 377 Patents.

[52] Dr. Burnett is a urologist specializing in sexual medicine. He is currently the Patrick C. Walsh Distinguished Professor at the Department of Urology at Johns Hopkins University School of Medicine in Baltimore, Maryland. He is also the Director, Basic Science Laboratory in Neurology, Sexual Medicine Fellowship Program and the Sexual Medicine Division in the Department of Urology at John Hopkins Hospital. He has published nearly 200 peer-reviewed articles, several non-scientific articles and editorials, two books and 42 book chapters and has served in an editorial capacity for numerous journals and reviews. He is a member of several professional organizations, advisory committees and review groups.

[53] In his affidavit, Dr. Burnett opines on the double patenting issue and offers the opinion that a person skilled in the art with the common general knowledge at the date(s) he was asked to consider (July 14, 1995 and July 11, 1996) would not have required inventive ingenuity to arrive at the subject matter disclosed and claimed in the claims of the 784 Patent in light of the subject matter claimed in the 377 Patent.

[54] Dr. Warrington is a medicinal chemist with a Ph.D. in pharmaceutical chemistry from the University of London. He worked from 1965 to 2005 for Smith Kline & French Laboratories

Ltd. and successor companies, SmithKline Beecham Pharmaceuticals and GlaxoSmithKline R&D Ltd. [collectively, SmithKline]. From 1986 to 1992, he led SmithKline's research program on PDE enzyme inhibitors. Following his retirement from SmithKline, Dr. Warrington held the positions of visiting professor in the Chemistry Department at the University of Durham and member of the steering committee of that university's Biological Sciences Institute. He also sits on the advisory panel and the commercialization advisory panel of the University of Strathclyde and has chaired special committees associated with micro- and nanotechnologies, proteomics and high throughput technologies. In addition, he has served as a consultant to a range of pharmaceutical companies and has co-authored approximately 40 scientific publications dealing predominantly with medicinal chemistry.

[55] In his affidavits, Dr. Warrington opined on construction of the 377 and 784 Patents, double patenting, utility and sound prediction. In terms of double patenting, Dr. Warrington offers the view that the skilled person would not have required inventive ingenuity to arrive at the subject matter of Claims 1, 2, 4, 9-12, 14, 15 and 18 of the 784 Patent in light of the subject matter of Claims 10, 13 and 19 of the 377 Patent and the common general knowledge assessed as of the dates he was given (July 14, 1995 and July 11, 1996). His opinions on utility and sound prediction are not relevant in this application as Apotex has not pursued these allegations.

[56] Dr. Trout is a Professor of chemical engineering at the Massachusetts Institute of Technology and holds a Ph.D. from the University of California at Berkeley in chemical engineering. He has frequently spoken on pharmaceuticals and pharmaceutical processing and regularly teaches a course on pharmaceutical crystallization to industry. He has published over

135 papers in refereed journals and has served as reviewer for several journals. His research is related to pharmaceutical development and manufacturing, with particular emphasis on pharmaceutical crystallization and nucleation (or the first step in crystallization).

[57] In his affidavit, Dr. Trout opines that the 784 Patent does not teach how to prepare hydrates of tadalafil or 3-methyl tadalafil and that a skilled person would not be able to prepare hydrates of these substances having regard to the common general knowledge. He thus offers the view that the 784 Patent is invalid for insufficiency.

[58] Finally, Mark Eisen is a patent agent who provides evidence on the chain of title issue. He deposes that Dr. Daugan signed an assignment of his rights in the 784 Patent to ICOS Corporation, effective January 19, 1998, and that this assignment was registered by the Canadian Intellectual Property Office [CIPO] on April 6, 1998. He also deposes that no other assignment of rights in respect of the 784 Patent was filed with CIPO.

V. Is the 784 Patent Invalid for Double Patenting over the 377 Patent?

[59] I turn now to assessment of the first ground of invalidity asserted by Apotex, namely, that the 784 Patent is invalid for double patenting over the 377 Patent.

A. *General Principles Applicable to Double Patenting*

[60] The doctrine of double patenting, as developed by Canadian courts, prevents a patent holder from “evergreening” its patent by obtaining a second patent for the same invention for

which a patent has already been granted. Typically, double patenting is asserted as a ground of invalidity where, like here, the first patent is not yet published at the priority date of the second patent and therefore cannot be considered in an obviousness analysis. Under section 28.3 of the *Patent Act*, RSC 1985, c P-4, the obviousness analysis is temporally limited to the claim date, i.e. the priority date of the patent in issue – where there is an international filing under the Patent Cooperation Treaty – or to one year prior to the Canadian filing date, where there is no priority claim made in the patent. Section 28.3 of the *Patent Act* provides in this regard:

Invention must not be obvious	**Objet non evident**
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.

[61] In the leading case dealing with double patenting, *Whirlpool Corp v Camco Inc*, 2000 SCC 67, [2000] 2 SCR 1067 [*Whirlpool*], Justice Binnie described the policy behind the doctrine of double patenting in the following terms at para 63:

> The prohibition against double patenting relates … to the "evergreen" problem … The inventor is only entitled to "a" patent for each invention: *Patent Act*, s. 36(1). If a subsequent patent issues with identical claims, there is an improper extension of the monopoly.

[62] In *Whirlpool*, the Supreme Court held that double patenting requires comparison of the claims in the two patents of the patent holder and that there are two sorts of double patenting: same invention-type double patenting and obviousness-type double patenting.

[63] In same invention-type double patenting, the claims in the subsequent patent are identical to or coterminous with the claims in the earlier patent. As Justice Roger Hughes noted in *Merck & Co v Pharmascience*, 2010 FC 510 at paras 117-124, 85 CPR (4th) 179 [*Finasteride*] and *Bristol-Myers Squibb Canada Co v Apotex*, 2009 FC 137 at paras 173-175, 74 CPR (4th) 85, the inquiry in this type of double patenting is akin to the anticipation inquiry and involves asking whether the patent holder has claimed the same invention as claimed in the earlier patent.

[64] Obviousness-type double patenting is a broader concept and involves determining whether the claims in the subsequent patent are patentably distinct from those in the first patent or, in other words, involve a non-obvious invention over and above that claimed in the first patent. As Justice Binnie noted in *Whirlpool*, above, obviousness-type double patenting "is a more flexible and less literal test that prohibits the issuance of a second patent with claims that are not 'patentably distinct' from those of the first patent" (at para 66).

[65] A classic case of this sort of double patenting arose in *Commissioner of Patents v Farbwerke Hoechst Aktiengesellschaft Vormals Meister Lucius & Bruning*, [1964] SCR 49, 41 CPR 9 [*Farbwerke*] where the subsequent patent claimed a diluted form of the medicine identified in the earlier patent. There, Justice Judson held at page 53 that the claims of the second patent were not patentably distinct from those in the earlier patent because the addition of a common excipient to increase bulk did "not result in a further invention over and above that of the medicinal itself".

[66] Conversely, in *Apotex Inc v Sanofi-Synthelabo Canada Inc*, 2008 SCC 61 at paras 112-115, [2008] 3 SCR 265, selection of one of the compounds that was particularly efficacious from among hundreds of thousands falling within the scope of an earlier *genus* patent was found not to constitute obviousness-type double patenting because the second compound was patentably distinct from the larger *genus* claimed in the original patent as it possessed advantages that were not claimed in the earlier patent.

[67] In *Whirlpool*, in addition to delineating the bounds of the doctrine of double patenting, the Supreme Court also underscored that a purposive approach to claims construction is required when construing patent claims. This requires identification by the court, with the assistance of expert evidence, of the essential elements of the claims as they would be understood by a person skilled in the art to which the patent is addressed. Thus, the words used in the claims are not to be read merely in a grammatical sense but, rather, must be interpreted knowledgeably through the eyes of a skilled reader and in the context of the specification as a whole so as to arrive at an interpretation that is, according to the Supreme Court, neither too benevolent nor too harsh and

that is thus fair to both the patentee and the public. Therefore, while the specification cannot be used to expand or contract the claims, it may, where necessary, be used to construe the claims of a patent (*Whirlpool*, above, at para 49; *Consolboard Inc v MacMillan Bloedel (Sask) Ltd*, [1981] 1 SCR 504 at 520, 122 DLR (3d) 203 [*Consolboard*]).

[68] Thus, to recap, in order to assess a claim of double patenting, the court must undertake the following three-step inquiry:

- First, it must set out what is claimed in each of the patents, construing the claims, if necessary;
- Second, the court must determine if the claims in the two patents are identical. If they are and the same invention is claimed, the second patent will be void for same invention or coterminous double patenting; and
- Finally, if the inventions claimed in the two patents are not identical, the court must then go on to determine if the invention claimed in the later patent is inventive or patentably distinct from the invention claimed in the earlier patent. If not, then the second patent will be void for obviousness-type double patenting.

B. *Disputes Between Lilly and Apotex in Respect of Double Patenting*

[69] In the present case, application of the foregoing analytical framework gives rise to three principal points of dispute between Apotex and Lilly.

[70] First, they disagree on how the claims in the 377 Patent are to be construed, with Lilly arguing they should be construed narrowly and Apotex arguing they should be construed more broadly.

[71] Second, they disagree as to the date at which the obviousness-type double patenting inquiry is to be conducted. Lilly says it should be undertaken at January 21, 1994, the priority date of the 377 Patent, the earlier of the two relevant patents in this case. Apotex, on the other hand, argues that it should be undertaken at February 6, 1997, the publication date of the 784 Patent, the later of the two relevant patents in this case. They, however, agree as to the outcome of the analysis undertaken at each of these dates.

[72] More specifically, if the relevant date for purposes of the inquiry is the earliest possible one, i.e. January 21, 1994, the priority date of the 377 Patent, Apotex conceded in oral argument that the claims of the 784 Patent would not be obvious over the claims of the 377 Patent because the common general knowledge of the skilled person – through whose eyes the Patents are to be construed – had not advanced enough to render the claims of the 784 Patent obvious by January 21, 1994.

[73] On the other hand, if the relevant date for assessing obviousness-type double patenting is the latest possible one posited, i.e. February 6, 1997, the publication date of the 784 Patent, Lilly does not contest that the claims in the 784 Patent would be void for obviousness-type double patenting and, indeed, called no evidence to counter Apotex' expert evidence that the common

general knowledge of the skilled person to whom the 784 Patent is addressed had advanced to such a degree by February 1997 so as to render the claims of the 784 Patent obvious.

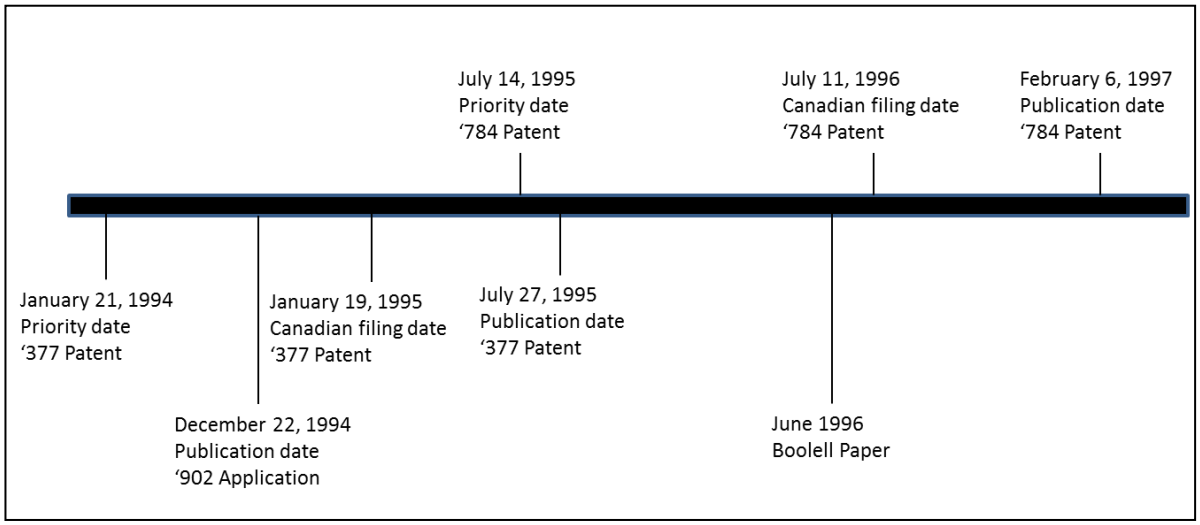
[74] Thus, if obviousness-type double patenting is assessed at January 21, 1994, the parties concur that the 784 Patent is not void for obviousness-type double patenting. Conversely, if the analysis is undertaken as of February 6, 1997, they agree that it would be void for obviousness-type double patenting.

[75] The parties, however, diverge as to the outcome of the obviousness-type double patenting inquiry if the relevant date for assessing the issue falls somewhere between January 21, 1994 and February 6, 1997. This is their third area of disagreement.

[76] Lilly says that if the relevant date for assessment of obviousness-type double patenting falls between January 21, 1994 and February 6, 1997 – and particularly if it is July 14, 1995, the priority date of the 784 Patent – then the 784 Patent is not invalid for obviousness-type double patenting as the common general knowledge of the skilled person had not advanced by that date to a sufficient extent so as to require such a conclusion. Lilly asserts in this regard that the only relevant piece of prior art that became public between January 21, 1994 (when Apotex concedes that its allegation of obviousness-type double patenting fails) and July 14, 1995 is the publication of Pfizer's 902 Application for sildenafil. Lilly argues that even if the 902 Application falls within the common general knowledge of the skilled worker (which it does not admit) it still would not make the claims of the 784 Patent obvious, and Lilly's experts offer evidence as to why this is so.

[77] Apotex and its experts take the opposite point of view and assert that the 902 Application and other pieces of prior art render the claims of the 784 Patent obvious or non-inventive and thus that if the relevant date for assessing obviousness-type double patenting is July 14, 1995 (or later), then the 784 Patent fails for obviousness-type double patenting. Apotex and its experts further say that if a later date is chosen for evaluation of its allegations of obviousness-type double patenting – namely July 11, 1996, the Canadian filing date of the 784 Patent – then its arguments are even stronger as a further key piece of prior art was published in June of 1996, namely the article "Sildenafil: an orally active type 5 cyclic GMP-specific phosphodiesterase inhibitor for the treatment of penile erectile dysfunction" by Boolell *et al*, *International Journal of Impotence Research* 8(2): 47 [the Boolell article]. In this article, Pfizer made additional disclosures about sildenafil, including identifying the compound that was tested and found to be efficacious in the treatment of ED when administered orally, providing details of the clinical trials undertaken by Pfizer and explaining the mechanism of action by which sildenafil was thought to function. This centres on the fact that Pfizer determined that the principal PDE responsible for penile erections is PDE V, that sildenafil is directed to the NO/cGMP pathway and is a potent and selective PDE V inhibitor. Apotex and its experts assert that these details would make the claims of the 784 Patent obvious as tadalafil was a known compound and was also known to be a potent and selective PDE V inhibitor. They accordingly say that it was obvious after the publication of the Boolell article that tadalafil would function like sildenafil and be useful in treating ED.

[78] To help keep these various dates in mind, it is useful to depict the different dates that could be potentially chosen in the following fashion:



C. *Assessment of Double Patenting in Mylan Tadalafil*

[79] Identical issues to the three that separate Apotex and Lilly in respect of double patenting in this case were considered by Justice de Montigny in *Mylan Tadalafil*. He found Mylan’s allegations of same invention-type and obviousness-type double patenting were not justified.

[80] In terms of construction, Justice de Montigny construed the relevant claims of the 377 Patent and 784 Patent.

[81] With respect to the 377 Patent, it appears that the parties asserted only Claim 10 of that Patent as being relevant and Justice de Montigny’s analysis accordingly mentioned only this Claim specifically. He construed Claim 10 of the 377 Patent to be “a claim to one compound, tadalafil, as a PDE V inhibitor” (para 130). Later on in the Judgment, though, he wrote more broadly and stated that “[t]he 377 Patent does not contemplate the use of tadalafil to treat ED, rather, this is precisely the monopoly claimed in the ‘784 Patent” (para 131).

[82] In terms of the 784 Patent, the parties in *Mylan Tadalafil* relied on the same claims as are in play in this case. Justice de Montigny found that, at its narrowest, the 784 Patent in Claim 18 claimed the use of tadalafil or 3-methyl tadalafil in treating ED in human males upon oral administration, and used this construction for the purposes of the double patenting analysis.

[83] Regarding same invention double patenting, Justice de Montigny held that the inventions in the two patents were not the same. He determined that the 377 Patent claimed the compound tadalafil as a PDE V inhibitor for various uses not including ED, whereas the 784 Patent claimed the use of tadalafil to treat ED. Because they claimed different uses for tadalafil, he found that the two patents did not claim the same invention and thus that the claims were not coterminous.

[84] With respect to obviousness-type double patenting, Justice de Montigny found that the 784 Patent was not obvious over the 377 Patent. In *Mylan Tadalafil*, as here, the parties disputed the date for assessing obviousness-type double patenting. Justice de Montigny assessed obviousness-type double patenting at the priority date of the 377 Patent, and, in the alternative, at the priority date of the 784 Patent. In the absence of clear authority, he referred to the purpose of the double patenting doctrine and determined that the appropriate date is the priority date of the first patent, stating as follows:

> [133] There was much discussion with respect to the correct date for a double patenting analysis. There is very little authority on the subject, and the issue is not even addressed by the Supreme Court in *Whirlpool*, above. This is understandable, given that the analysis is confined to a comparison between the claims in two patents, and does not involve an inquiry into the prior art as would be the case if the alleged invalidity rested on an argument of obviousness. Viewed in this light, the evolution of the science between the two patents should be of no consequence in an obviousness-type double patenting analysis: contrary to the position taken by the

> Respondent, the question is not whether the use of tadalafil to treat ED was obvious in light of the '377 Patent, in which case admissible prior art would be relevant, but whether the claims of the '784 Patent disclose novelty or ingenuity over the '377 Patent. To resolve that question, the Court (with the help of the persons skilled in the art) must look at the first patent in the context of what was known at the time, with a view to determine whether the claims in the second patent are patentably distinct from those of the earlier patent. Since the rationale behind this ground of invalidity is the prohibition against an improper extension of the monopoly granted by the first patent, the Court must ascertain whether the invention claimed in the second patent could or should have been included in the first patent.
>
> [134] If, as Mylan would have it, the relevant date was to be the priority date of the second patent (in this case, July 14, 1995), the obviousness-type double patenting analysis would morph into a pure obviousness analysis, with the added benefit that the timing requirements of section 28.3 of the *Patent Act* would be circumvented. It is quite telling that Mylan's written and oral argument relied heavily on the framework for obviousness developed by the Supreme Court in *Sanofi-Synthelabo*, above. To be fair, both sides have at times confused the issue, and all four experts were instructed to consider the issue of double patenting as of July 14, 1995. For the reasons already given, this priority date of the '784 Patent cannot be the relevant date. One cannot read into the claims of the first patent more than what would have been understood by the person skilled in the art at the claim date when comparing the claims of the second patent to those of the first patent. If the focus is to be on the claims, as the Supreme Court teaches in *Whirlpool*, information published after the claim date of the first patent is of no use to determine whether the claims of the second patent are patentably distinct from the claims of the first one. This is indeed what my colleague Justice Hughes found in *Finasteride*, above, where he held that certain documents published immediately before the claim date of the second patent rendered the invention non-obvious, but nevertheless determined that these documents were non-existent as far as the obviousness-type double patenting inquiry was concerned.

[85] Justice de Montigny found that as of January 21, 1994, the priority date of the 377 Patent, the use of tadalafil to treat ED was not obvious and could not have been included in the 377

Patent. Therefore, he held that the use of tadalafil to treat ED was a novel element over the 377 Patent and thus concluded that the 784 Patent was not an "evergreening" of the 377 Patent.

[86] In the alternative, Justice de Montigny assessed double patenting at the 784 Patent's priority date, July 14, 1995. He found that even as of this date the use of tadalafil to treat ED was not obvious over the 377 Patent. In this regard, he held that the major advance between 1994 and 1995 was the publication of the 902 Application, Pfizer's patent for sildenafil. Justice de Montigny found that the 902 Application did not render obvious the use of tadalafil for the treatment of ED for two reasons. First, he noted that the Supreme Court of Canada determined that the Canadian equivalent of the 902 Application was invalid for being deliberately obscure because it did not disclose which compound was effective and that the 902 Application was even more obscure, listing nine possible compounds as possibly being effective but stating that only one of them had been shown to be effective in treating ED. Justice de Montigny therefore concluded that the 902 Application contained insufficient information to make the use of tadalafil to treat ED obvious. Second, he determined that the 902's teaching—that a PDE V inhibitor could be taken orally to treat ED—was counterintuitive to the common general knowledge about PDE V inhibitors at the time. Therefore, Justice de Montigny concluded that the 902 Application did not render obvious the use of tadalafil to treat ED even as of July 14, 1995. As this was the only relevant piece of prior art that was made available between January 1994 and July 1995, Justice de Montigny concluded that even at the alternate date of July 14, 1995, the 784 Patent was not void for obviousness-type double patenting.

D. *Comity*

[87] Lilly argues that I should follow Justice de Montigny's determinations as to the date for assessing double patenting and his assessment of obviousness-type double patenting but that I should adopt a narrower construction of the claims in the 377 Patent. Apotex, on the other hand, says that I should not follow any of Justice de Montigny's determinations, submitting that he erred in several respects in *Mylan Tadalafil*.

[88] The doctrine of judicial comity applies to the legal, as opposed to the factual, findings made by Justice de Montigny in *Mylan Tadalafil*. This doctrine provides that a judge of a concurrent court should follow previous legal determinations unless the subsequent judge concludes that a departure is necessary and that there are cogent reasons for the departure. Generally, such reasons involve more than a simple disagreement with the previous judge's legal finding and would instead arise where the subsequent judge concludes the former judge gave insufficient consideration to binding authority, new contrary intervening authority has arisen since the date of the first judge's determination, the determination was unconsidered or the subsequent judge determines that a significant injustice would flow if the previous ruling were to be applied.

[89] In *Apotex v Allergan*, 2012 FCA 308 at para 48, 105 CPR (4th) 371 [*Brimonidine*], Justice Marc Noël (as he then was) detailed the scope of the doctrine of comity in the context of an NOC proceeding in the following terms:

> [48] It is up to the judges of the Federal Court to determine how this doctrine is to be applied to their decisions. I note in this respect

> that different considerations may arise depending on the jurisdiction being exercised. I have in mind, for example, immigration where decisions of the Federal Court are final in the absence of a question being certified … However, the general view appears to be that the conclusions of law of a Federal Court judge will not be departed from by another judge unless he or she is convinced that the departure is necessary and can articulate cogent reasons for doing so. On this test, departures should be rare.

[90] To similar effect, Justice James O'Reilly noted in *Apotex v Pfizer Canada*, 2013 FC 493 at para 14, 114 CPR (4th) 270, aff'd 2014 FCA 54, 117 CPR (4th) 401 [*Azithromycin*]:

> [14] Based on the idea that the law should be consistent and certain, this doctrine dictates that decisions of judicial colleagues should be followed "in the absence of strong reasons to the contrary" (*R v Northern Electric Co Ltd, et al*, [1955] 3 DLR 449 (Ont HCJ), at para 41). "Strong reasons to the contrary" does not simply mean better arguments. Justice Michael Phelan set out what this phrase actually means:
>
> > (a) subsequent decisions have affected the validity of the impugned judgment;
> >
> > (b) it is considered that some binding authority in case law or some relevant statute was not considered; and
> >
> > (c) the judgment was unconsidered, a *nisi prius* judgment given in circumstances familiar with all trial judges, where the exigencies of the trial require an immediate decision without opportunity to fully consult authority. (*Altana Pharma Inc v Canada (Health)*, 2007 FC 1095, at para 36).

[91] Likewise, in *Glaxo Group Ltd v Canada (Minister of National Health and Welfare)* (1995), 64 CPR (3d) 65, 103 FTR 1 (FCTD) [*Glaxo Group*], Justice John Richard (as he then was) cited with approval the following passage from the decision of the British Columbia Court of Appeal to define the scope of application of the doctrine of comity (at 67-68):

The principle of judicial comity has been expressed as follows:

> The generally accepted view is that this court is bound to follow a previous decision of the court unless it can be shown that the previous decision was manifestly wrong, or should no longer be followed: for example, (1) the decision failed to consider legislation or binding authorities which would have produced a different result, or (2) the decision, if followed, would result in a severe injustice. The reason generally assigned for this approach is a judicial comity. While doubtless this is a fundamental reason for the approach, I think that an equally fundamental, if not more compelling, reason is the need for certainty in the law, so far as that can be established. Lawyers would be in an intolerable position in advising clients if a division of the court was free to decide an appeal without regard to a previous decision or the principle involved in it.
>
> (*Bell v. Cessna Aircraft Co*. (1983), 149 D.L.R. (3d) 509 at p. 511, 36 C.P.R. 115, [1983] 6 W.W.R. 178 (B.C.C.A.).)

[92] The doctrine of comity rests on the principle that there can only be one correct answer to a legal question. The doctrine also effects the important policy objective of ensuring jurisprudential consistency (*Brimonidine*, above, at paras 43-46; *Azithromycin*, above, at paras 11-14; *Glaxo Group*, above, at 67-68).

[93] As noted, the doctrine applies only to legal findings and does not apply to factual determinations made in an earlier case as, invariably, there are factual distinctions between cases, even when they are very similar and involve the same contract or patent. Thus, the legal findings made in *Mylan Tadalafil* attract the doctrine of comity but the factual findings or findings of mixed fact and law do not. It is therefore necessary to determine which of Justice de Montigny's relevant findings are legal in nature.

[94] Apotex and Lilly concur that Justice de Montigny's construction of the 377 and 784 Patents are legal determinations as is his finding on the appropriate date for undertaking the obviousness-type double patenting analysis. They also agree that his assessment of the prior art and conclusions regarding the lack of obviousness at either January 21, 1994 or July 14, 1995 are factual determinations or findings of mixed fact and law to which the doctrine of comity is inapplicable.

[95] I agree with them. It is well-settled that patent construction is a matter of law (*Whirlpool*, above, at paras 61, 76; *Brimonidine*, above, at para 50; *Western Electric Co v Baldwin International Radio of Canada*, [1934] SCR 570 at 572, 4 DLR 129; *Weatherford Canada Ltd v Corlac*, 2011 FCA 228 at para 24, 95 CPR (4th) 101 [*Corlac*]). Similarly, the determination of the date for conducting the obviousness-type double patenting analysis is a pure legal issue whereas the conclusion reached by Justice de Montigny regarding non-obviousness is a factual finding (see *Brimonidine*, above, at para 50: a finding of obviousness is one of fact).

[96] Thus, the doctrine of comity applies to Justice de Montigny's construction of the 377 and 784 Patents and to his finding that the obviousness-type double patenting analysis is to be conducted as of the priority date of the 377 Patent. It does not apply to his conclusion regarding non-obviousness. For the first two issues, therefore, I should reach the same conclusion as Justice de Montigny unless I determine that there are cogent reasons to conclude otherwise.

E. *Construction of the 784 and 377 Patents*

[97] Turning to the first of the issues to which comity applies, namely, construction of the relevant claims in the Patents, in the present case, as in *Mylan Tadalafil*, there is no difficulty with the construction of the 784 Patent. The case at bar, as *Mylan Tadalafil*, may be decided based on the narrowest of the claims at issue, namely, Claim 18 as it depends upon Claims 12 and 14. As noted, Claim 18, through dependence on Claims 12 and 14, claims the use of tadalafil, 3-methyl tadalafil or physiologically acceptable salts or solvates of the two compounds in treating ED in human males upon oral administration. Apotex and Lilly have both used this construction either explicitly or implicitly in their arguments.

[98] The dispute between them lies with respect to the construction of the 377 Patent. On one hand, Lilly says that the claims of that Patent are to be read without reference to the ability of tadalafil to inhibit PDE V, whereas Apotex would read into the claims (and in particular into Claim 13) the use of tadalafil to treat ED. They both therefore say that Justice de Montigny erred in his construction.

[99] The relevant claims in the 377 Patent, relied upon by the parties in this case, are Claims 10 and 13. They provide the following:

> 10. (6R,12aR)-2, 3,6,7,12,12a-Hexahydro-2-methyl-6-(3,4-methylenedioxy-phenyl)-pyrazino[2',1':6,1]pyrido[3,4-b]indole - 1,4-dione [tadalafil]; and physiologically acceptable salts and solvates thereof.
>
> […]
>
> 13. (6R,12aR)-2,3,6,7,12,12a-Hexahydro-2-methyl-6-(3,4-methylenedioxy-phenyl)-pyrazino[2',l':6,1]pyrido[3,4-b]indole-

> 1,4-dione [tadalafil], or a physiologically acceptable salt or solvate thereof, for use in the treatment of stable, unstable and variant angina, hypertension, pulmonary hypertension, chronic obstructive pulmonary disease, congestive heart failure, renal failure, atherosclerosis, conditions of reduced blood vessel patency, peripheral vascular disease, vascular disorders, inflammatory diseases, stroke, bronchitis, chronic asthma, allergic asthma, allergic rhinitis, glaucoma or diseases characterised by disorders of gut motility.

[100] Lilly is correct in noting that these claims do not mention the fact that tadalafil and 3-methyl tadalafil are PDE V inhibitors. (Nor is this fact mentioned in any other of the claims in the 377 Patent.)

[101] The specification, however, speaks at length about the ability of tadalafil to suppress PDE V. Indeed, the opening paragraph of the specification notes that the invention:

> relates to tetracyclic derivatives which are potent and selective inhibitors of cyclic guanosine 3′, 5′-monophosphate specific phosphodiesterase (cGMP specific PDE) having utility in a variety of therapeutic areas where such inhibition is thought to be beneficial, including the treatment of cardiovascular disorders.

(The parties concur that "guanosine 3′, 5′-monophosphate specific phosphodiesterase (cGMP specific PDE)" is PDE V.)

[102] The specification continues, after describing the compounds of the invention, by noting that "compounds of the present invention are potent and selective inhibitors of cGMP specific PDE" and thus that the compounds are "of interest for use" in treating conditions where "inhibition of GMP specific PDE is thought to be beneficial" (377 Patent, p 6). The specification also provides that "as a consequence of the selective PDE V inhibition exhibited by the

compounds of the present invention, cGMP levels are elevated", which gives rise to a number of potential uses for the compounds. These are said to include:

> treatment of a number of disorders, including stable, unstable and variant … angina, hypertension, pulmonary hypertension, congestive heart failure, renal failure, artherosclerosis, conditions of reduced blood vessel patency (e.g. post-percutaneous transluminal coronary angioplasty), peripheral vascular disease, vascular disorders such as Raynaud's disease, inflammatory diseases, stroke, bronchitis, chronic asthma, allergic asthma, allergic rhinitis, glaucoma and diseases characterized by disorders of gut motility (e.g. irritable bowel syndrome).
>
> (377 Patent, pp 6-7.)

[103] In addition, the specification sets out test results which demonstrate that several of the claimed compounds, including tadalafil, are potent and selective PDE V inhibitors (see in particular Examples 121 and 122, pp 74-77 of the Patent).

[104] Based on the foregoing, Justice de Montigny determined that the inventive concept of the 377 Patent was the ability of the claimed compounds to act as PDE V inhibitors and thus construed Claim 10 as a claim to tadalafil as a PDE V inhibitor based on a purposive construction of the Claim.

[105] I see no error in this determination. While the claims of a patent are the starting point in construction, the case law teaches that, where necessary, they must be read in the context of the specification as a whole to ascertain their import, as, indeed, the Supreme Court held in *Whirlpool*, as discussed above at paragraph 67 of these Reasons (see also *Consolboard*, above, at 520; *Free World Trust v Électro Santé Inc*, 2000 SCC 66 at para 31, [2000] 2 SCR 1024 [*Free World Trust*]).

[106] When one reads Claim 10 in the 377 Patent in light of the specification, the importance of the ability of tadalafil to inhibit PDE V is apparent; indeed, this is the essence of the invention claimed in the 377 Patent. Thus, I see no error in construing Claim 10 as encompassing tadalafil as a PDE V inhibitor. This construction applies equally to Claim 13, where tadalafil is claimed for a number of uses. Therefore, both Claims 10 and 13 of the 377 Patent are to be construed by incorporating the notion that tadalafil is a PDE V inhibitor. I therefore reject the construction proposed by Lilly for the same reasons advanced by Justice de Montigny.

[107] Apotex, however, says that this does not go far enough and submits that I should in addition read into Claim 13 the treatment of ED as one of the uses to which the 377 Patent extends. It makes two arguments in support of this assertion.

[108] First, it says that this issue was not addressed in *Mylan Tadalafil* as Justice de Montigny focused only on Claim 10 of the 377 Patent in his analysis. Apotex thus submits that the doctrine of comity would not prevent me from adopting its interpretation of Claim 13 in the 377 Patent as this issue was not addressed by Justice de Montigny.

[109] Second, and in the alternative, Apotex submits that even if Justice de Montigny decided the issue, he erred in his interpretation because he interpreted the 377 Patent as of its priority date as opposed to its publication date, which has been firmly established by the Supreme Court of Canada and the Federal Courts as the date in respect of which patents are to be interpreted, relying in this regard on *Whirlpool*, above, at paras 55-56, and *Free World Trust*, above, at para 54.

[110] Apotex says that as of July 27, 1995, the publication date of the 377 Patent, the common general knowledge of the skilled worker to whom the 377 Patent is addressed had advanced such that it was known and accepted that PDE V inhibitors were effective in treating ED and that ED was known to be a vascular disease. It relies in support of this assertion principally on the 902 Application for sildenafil and another patent application (PCT Application No. WO 94-29277) made by SmithKline Beecham PLC on June 14, 1993 and published December 22, 1994 [the 277 Patent], which it says are to be read in the context of several earlier articles dealing with ED. Apotex say that in light of this prior art, a skilled reader would understand Claim 13 of the 377 Patent as including ED among the potential uses claimed and that the Claim should accordingly be construed as claiming ED as one of the disorders that tadalafil is useful in treating.

[111] I see no merit in Apotex' assertions for several reasons.

[112] In this regard, contrary to what Apotex argues, I do not believe that Justice de Montigny construed the 377 Patent as of its priority date. Nowhere in his Judgment is this date indicated to be the date in respect of which the construction exercise was carried out. He rather used the priority date as the date for assessment of obviousness double patenting. This is not inconsistent with construing the Patent at a later date. Moreover, his construction rests not so much on the state of the common general knowledge at any given date but, rather, on the words chosen by the inventor in the Patent, which do not claim ED but do claim a host of other ailments as potential uses for tadalafil. Thus, contrary to what Apotex asserts, I do not believe that Justice de Montigny construed the 377 Patent as of its priority date.

[113] As for the assertion that Justice de Montigny construed only Claim 10 as opposed to Claim 13 of the 377 Patent, while it is true that he only mentions Claim 10 specifically in his Judgment, I do not believe that his Reasons can be read this narrowly. Rather, I believe that he determined more broadly that the 377 Patent did not extend to claim the use of tadalafil for the treatment of ED. He wrote as follows at para 131:"[t]he '377 Patent does not contemplate the use of tadalafil to treat ED".

[114] Thus, contrary to what Apotex asserts, I believe that Justice de Montigny determined in *Mylan Tadalafil* that both Claims 10 and 13 of the 377 Patent are to be construed as not extending to the treatment of ED. The doctrine of comity therefore applies to his construction and requires that I follow it unless I am convinced that there are cogent reasons to conclude otherwise.

[115] I am not so convinced, as I concur with Justice de Montigny's construction. Indeed, I believe that the omission of ED as one of the potential uses for tadalafil from the specification in the 377 Patent is telling because the Patent lists a host of other potential uses for the drug in the specification and the claims. The omission of ED must in such circumstances necessarily lead to the conclusion that the 377 Patent is not to be construed as extending to the use of tadalafil to treat ED.

[116] I also find that this construction is supported by the expert evidence in this case. I note in this regard that Apotex' only expert clinician, Dr. Burnett, opined that the 377 Patent contemplates the treatment of a wide variety of conditions, but that "[e]rectile dysfunction is not

amongst the conditions described in the 377 Patent" (Burnett affidavit, para 182, AR p 2861). To similar effect, Lilly's expert Dr. Brock agrees and states in his affidavit that "[n]one of the claims of the '377 Patent relate to the treatment of erectile dysfunction" (Brock affidavit, para 34, AR p 214). On the other hand, Apotex' expert Dr. Warrington posits - rather cryptically - that ED would have been considered a "vascular disorder", which is one of the disorders named in the 377 Patent, and therefore that ED is included in the list of uses in Claim 13 of the 377 Patent (see Warrington affidavit, paras 174, AR p 2928). However, I give this opinion little weight in comparison to those of Drs. Brock and Burnett, since this is an opinion about clinical uses for tadalafil, which falls within Dr. Brock's and Dr. Burnett's expertise, but outside Dr. Warrington's expertise as a medicinal chemist.

[117] I therefore conclude that I should adopt the same construction advanced by Justice de Montigny in *Mylan Tadalafil* and accordingly determine that Claims 10 and 13 of the 377 Patent are to be construed as including tadalafil as a PDE V inhibitor but not as including ED as one of the potential uses for tadalafil.

F. *Same Invention-type Double Patenting*

[118] The foregoing construction leads to the conclusion that the 784 Patent does not constitute same invention double patenting over the 377 Patent as the relevant claims in the 784 Patent claim the use of tadalafil and 3-methyl tadalafil or their salts or solvates to treat ED but those in the 377 Patent do not.

[119] Apotex suggests that Lilly cannot argue there was no same invention-type double patenting in this case as it called no evidence on the issue, and it is therefore not in play. I reject this submission as the issue is one of construction, a matter for the Court, and thus not one in respect of which evidence is required. Moreover, contrary to what Apotex says, Lilly *did* call evidence on the issue as Dr. Brock addresses the absence of same invention-type double patenting at paragraphs 33-34 of his affidavit.

[120] Thus, for these reasons, I conclude that the allegation that the 784 Patent is invalid for double patenting over the 377 Patent through same invention-type double patenting is unsubstantiated.

G. *Date for Assessment of Obviousness-type Double Patenting*

[121] Turning to the next issue to which the doctrine of comity applies, namely the selection of the date in respect of which the obviousness-type double patenting assessment is to be undertaken, Apotex says that Justice de Montigny erred in failing to recognize and follow the binding authority in *Whirlpool*. It asserts that in that case the Supreme Court of Canada held that the date for assessing obviousness-type double patenting is the publication date of the later patent and that Justice de Montigny accordingly erred in holding that there was no authority on the point and also erred in selecting the priority date of the 377 Patent as the relevant date for undertaking the assessment of obviousness-type double patenting.

[122] With respect, I do not believe that the Supreme Court of Canada made any such determination in *Whirlpool*. Rather, in that case the Supreme Court only ruled on the relevant

date for undertaking the construction of a patent, but did not decide the date in respect of which the obviousness-type double patenting analysis is to be undertaken.

[123] More specifically, with respect to construction, Justice Binnie held in *Whirlpool* at para 55 that construction of the claims in a patent is to be undertaken as of the publication date of the patent. For the patents in suit in *Whirlpool*, that date was the issuance date as they were all issued under the former *Patent Act*, RSC 1970, c P-4. In *Whirlpool*, Justice Binnie in addition confirmed that the publication date is likewise the date for construction of patents issued under the current version of the *Patent Act.*

[124] With respect to obviousness-type double patenting, the Court's decision in *Whirlpool* turned on an evidentiary point. Justice Binnie held that the trial judge had erred in accepting the evidence of the inventor's expert, who had too much knowledge of the details of the invention to have stood as a proxy for the skilled person to whom the patents in suit were addressed (at paras 70-71). The Court also held that the trial judge did not err in rejecting the evidence of the alleged infringer's expert because he had no knowledge of any of the technology at issue in that case throughout the entire period in question (paras 72-74). In result, the Supreme Court affirmed the decision of the trial judge based on the presumption of validity enshrined in section 45 of the old *Patent Act* because there was simply no reliable evidence called as to obviousness.

[125] In so holding, Justice Binnie did note at para 55 that Whirlpool had argued that the relevant date for assessment of double patenting was the publication date of the latest patent. In addition, Justice Binnie appears to have assessed the sufficiency of the evidence as of that date,

but, in my view, the date-related comments made by Justice Binnie in *Whirlpool* do not decide the issue of when the obviousness-type double patenting analysis is to be undertaken. These comments are non-binding *obiter dicta* as the case turns on the evidentiary point. In addition, to the extent that there is any discussion of dates in the Court's assessment of obviousness-type double patenting in *Whirlpool*, the discussion is fleeting. Therefore, I do not believe that Justice de Montigny erred in holding that the "issue is not even addressed by the Supreme Court in *Whirlpool*".

[126] Further, I agree with the policy reason advanced by Justice de Montigny in *Mylan Tadalafil* as being the basis for the rejection of the Canadian filing or publication dates of the 784 Patent (July 11, 1996 and February 6, 1997, respectively) for the conduct of the obvious-type double patenting analysis as selection of either of these dates would circumvent the temporal limitations in section 28.3 of the *Patent Act* and expose the patentee to prior art that arises after the claim date of the later patent. This would effectively place an inventor with an earlier unpublished patent at a substantial disadvantage in respect of the date for assessing prior art as compared to any other person who might have made the same invention. I agree with Lilly that such a result should not be countenanced as it would discourage inventors from publicizing their inventions after the claim date while their applications are still pending.

[127] Professor Norman Siebrasse, in his blog ("Date for Assessing Obviousness-Type Double Patenting Is Priority Date of Earlier Patent" (23 January 2015), *Sufficient Description* (blog), online: <http://www.sufficientdescription.com/2015/01/date-for-assessing-obviousness-type.html>) agreed with Justice de Montigny's rationale regarding the circumvention of the

timing requirements of section 28.3 of the *Patent Act*, noting that "[t]he judicially created obviousness type double-patenting cannot be used to do an end-run around a clear statutory provision".

[128] I therefore conclude that Justice de Montigny did not err in rejecting July 11, 1996 and February 6, 1997, the Canadian filing or publication dates of the 784 Patent, for the conduct of the obviousness-type double patenting analysis. When these two dates are eliminated, only two others remain in contention, namely, the priority date of the 377 Patent or the priority date of the 784 Patent.

[129] I believe that a sound argument could be made for the selection of July 14, 1995, the priority date of the 784 Patent, as the appropriate date for the conduct of the obviousness-type double patenting analysis in this case because of the respective timing of the invention claimed in the 784 Patent as compared with the alleged advances in the common general knowledge of the skilled person to whom the 784 Patent is directed.

[130] In this regard, as counsel for Lilly conceded during argument, there are two ways in which a subsequent patent could be void for obviousness-type double patenting and thus two ways in which it could be found to constitute impermissible evergreening.

[131] On one hand, a patentee could under-claim in its initial patent, divide the invention and seek to extend the monopoly period by filing a subsequent patent before the first one is published. In such circumstance, the relevant inquiry involves assessment of what was known at

the point in time for assessing obviousness in respect of the first patent. This is what the defendant argued had occurred in the *Whirlpool* case as it asserted that the invention in the latest patent was obvious when the earlier patents were filed (which, under the regime then in force, was the date for undertaking the obviousness inquiry in respect of a patent).

[132] Conversely, a second type of impermissible evergreening concerns the addition of obvious amendments. This is akin to the "non-inventive bells and whistles" rationale exemplified in *Farbwerke*, above. Particularly in the context of pharmaceutical patents involving a new use for an existing compound or class of compounds, there could be a situation where the common general knowledge advances after the claim date of the first patent that would render the new use claimed in the second patent obvious as of the claim date in the second patent, resulting in the later patent being an impermissible evergreening through extension based on obvious amendments to the initial patent. In such circumstance, I believe a sound argument may be made for the selection of the priority date of the second patent as being the date in respect of which the assessment of obviousness-type double patenting should be undertaken.

[133] The present case falls into the second of the above two possible scenarios and thus I believe that a sound argument exists for the selection of July 14, 1995, the priority date of the 784 Patent, as the date in respect of which the obviousness-type double patenting analysis should be undertaken.

[134] However, even if this date were selected, the 784 Patent would nonetheless not be void for obviousness-type double patenting over the 377 Patent because, for the reasons set out below,

as in *Mylan Tadalafil*, the evidence in this case demonstrates that even if the assessment of double patenting is to be undertaken as of July 14, 1995, the double patenting allegation is not justified.

[135] The issue of the correct date for undertaking the double patenting analysis is therefore moot as the same result obtains if the analysis is undertaken as of the priority date of either the 377 Patent or of the 784 Patent. Given the comity principle and the lack of authority on the point, I prefer not to make a firm determination on the point as under either of the two possible dates the same result obtains.

H. *Obviousness-type Double Patenting*

[136] I turn, then, to assessment of obviousness-type double patenting. As noted, *Whirlpool* teaches that this assessment involves comparison of the claims in the two patents and asking if the claims of the latter are patentably distinct in light of the claims made in the former patent. This inquiry requires the determination of the state of the common general knowledge of the person skilled in the art to which the patents are directed, as *Whirlpool* also teaches. This, in turn, requires assessment of the evidence and ascertaining which portions of the prior art would have formed part of the skilled person's general knowledge as of the relevant date and whether such art renders the new claims made in the second patent non-inventive over the claims in the first patent.

[137] Here, the difference between the relevant claims in the 377 and 784 Patent, as I have construed them, involves the use of tadalafil, 3-methyl tadalafil or their pharmacologically

acceptable salts or solvates to treat ED, which is claimed in the 784 but not the 377 Patent. Both Patents, however, claim tadalafil and 3-methyl tadalafil as potent and selective PDE V inhibitors. Therefore, the issue becomes whether it was obvious that these compounds – as potent and selective PDE V inhibitors – could be used to treat ED.

(1) As of January 21, 1994

[138] Apotex concedes that as of January 21, 1994, this use was not obvious. This concession is significant as much of the evidence of both parties' experts in this case deals with prior art published before January 21, 1994.

[139] Even if this concession had not been made, like Justice de Montigny in *Mylan Tadalafil*, I would have determined that the use of tadalafil or 3-methyl tadalafil to treat ED was not obvious as of January 21, 1994 and thus prefer the evidence of Lilly's experts in respect of this point as I believe it is fairer to the relevant prior art relied on by both sides' experts in this case.

[140] In this regard, I concur with Lilly's experts that as of January 21, 1994, it was not known which PDE isozyme was principally involved in mediating an erection and that it was generally thought that the administration of any vasodilator orally to treat ED would be inadvisable because it would create a risk of dangerous hypotension.

[141] As Drs. Brock and Goldstein note, in the early 1990s, knowledge of the NANC pathway in the *corpora cavernosa* developed from *in vitro* research, but this research did not render obvious the use of a PDE V inhibitor to treat ED. An *in vitro* experiment in which zaprinast

(another PDE V inhibitor) was applied to penile tissue showed that the NANC pathway mediated the relaxation of the smooth muscle tissue in the *corpora cavernosa*. However, this experiment by itself did not provide the basis to establish that administration of a PDE V inhibitor would be useful in the treatment of ED (see Brock affidavit, paras 116-133; Goldstein affidavit, paras 107-119; commenting on Rajfer *et al*, "Nitric oxide as a mediator of relaxation of the corpus cavernosum in response to nonadrenergic, noncholinergic neurotransmission" (1992) 326:2 *New England Journal of Medicine* 90, Potter Exhibit C, Doc #21). Justice de Montigny and Justice Mosley also found that the experiments detailed in the Rajfer paper did not lead to the use of a PDE V inhibitor to treat ED (see *Mylan Tadalafil* at paras 140-41; *Sildenafil NOC* at paras 89-98).

[142] Similarly, other basic research had identified the role of three PDE isoenzymes in the *corpora cavernosa* and speculated that PDE inhibitors may be useful in treating ED, but this research did not identify the specific role of PDE V or definitively establish that a PDE V inhibitor would be effective to treat ED (see Brock affidavit, paras 141-146; Goldstein affidavit, paras 98-100; commenting on Taher *et al*, "Cyclic nucleotide phosphodiesterase activity in human cavernous smooth muscle and the effect of various selective inhibitors" (abstract) (1992) 4 (Suppl 2) *International Journal of Impotence Research* 19, Potter Exhibit C, Doc #24).

[143] I also note that one of the key pieces of prior art relied on by Apotex, namely, the 1993 Ph.D. thesis of Bush ("The role of the L-arginine-nitric oxide-cyclic GMP pathway in relaxation of corpus cavernosum smooth muscle", University of California at Los Angeles, Potter Exhibit C, Doc #48) concluded, based on similar *in vitro* experiments on *corpus cavernosum* tissue, that

the elucidation of the mechanism of relaxation in the *corpora cavernosa* set the groundwork for future studies of the mechanism of erection, which might have clinical uses in the treatment of erectile dysfunction. However, Dr. Bush framed this possibility as a future direction of research; I therefore agree with Dr. Brock that the skilled person would not conclude from this paper that a specific cyclic GMP PDE inhibitor would successfully treat ED (Brock affidavit, para 187). Dr. Goldstein's evidence also supports this point: he opines that the Bush thesis suggests that pharmacological treatment of ED was still "somewhere in the future" (Goldstein affidavit, para 136, AR p 172), and that the thesis did not suggest oral administration of any compound to treat ED (para 140).

[144] Moreover, in 1994, most experts believed that oral administration of a PDE V inhibitor to treat ED was not possible due to concerns about hypotension. Dr. Goldstein opines that "[i]n 1994, a skilled urologist would have understood that a drug could not be administered systemically for the treatment of ED, as it would not be possible to deliver a sufficiently high concentration of the drug to the penis to effectively and reliably relax the vascular smooth muscle without having an effect on the other smooth muscle in the body (e.g. hypotension)" (Goldstein affidavit, para 49, AR p 147). In fact, because a smooth muscle relaxing drug was expected to relax smooth muscle throughout the body, including in the vascular system, such a drug would be expected to lower blood pressure, and thereby cause rather than treat ED (Goldstein affidavit, para 72, AR p 153). In a 1993 review article, Kenneth J. Murray summarized the then recent research on the potential uses of PDE V inhibitors in treating human disease ("Phosphodiesterase VA Inhibitors" (1993) 6:3 *Drug News and Perspectives* 150, Potter Exhibit C, Doc #40). Only one PDE V inhibitor (zaprinast) had been tested in humans, but not as

a treatment for ED. Testing of zaprinast in rats and dogs showed that zaprinast lowered blood pressure. Similarly, the 1992 National Institutes of Health Consensus Statement on Impotence concluded that the use of oral therapies to treat ED should "be discouraged" until further evidence was available (p 9, AR p 2291).

[145] Thus, the evidence in this case, just like in *Mylan Tadalafil*, establishes that as of January 21, 1994 the claims of the 784 Patent were patentably distinct from those of the 377 Patent. I note that Justice Mosley evaluated similar evidence in a similar fashion in *Sildenafil NOC*.

(2) As of July 14, 1995

[146] In terms of the second date that I have determined could be relevant, namely July 14, 1995, there are three documents that Apotex alleges are relevant that it says would have formed part of the relevant prior art and would have been within the knowledge base of the skilled person to whom the Patents are directed. These are the 902 and the 277 Patents as well as a document entitled "Pfizer's Public Affairs Briefing: Press Reports on Clinical Trials of UK-92,480" (Potter Exhibit C, Doc #66, AR p 1052) [the Briefing document].

[147] The Briefing document may be disposed of summarily as there is no evidence that it was ever publicly disclosed as, indeed, Dr. Corbin conceded during his cross-examination (Corbin cross-examination, AR p 5657). Moreover, the document on its face suggests that it was destined for an internal readership at Pfizer. I therefore conclude that the Briefing document does not form part of the prior art that would have fallen within the common general knowledge of the

skilled person to whom the 784 Patent is directed and is accordingly irrelevant to the obviousness-type double patenting analysis.

[148] Likewise, whatever may have been said about sildenafil during briefings held by Pfizer prior to July 14, 1995 cannot form part of the common general knowledge because Dr. Goldstein testified during cross-examination that attendees at such briefings were required to sign non-disclosure agreements, which confirms the private and non-public nature of the information disclosed during the briefings (Goldstein cross-examination, AR p 4496). These meetings were held at the American Urological Association in the spring of 1994. Dr. Burnett and Dr. Goldstein were in attendance (see Burnett affidavit, para 131; Burnett cross-examination, AR pp 5793-98; Goldstein cross-examination, AR pp 4496-98). While Pfizer disclosed during these meetings that it was testing a compound for oral administration to treat ED, Apotex has not established that Pfizer disclosed to attendees the identity of the compound it was testing as Dr. Burnett testified that he could not recall specifically whether the identity or formula of the compound was disclosed (Burnett cross-examination, AR pp 5793-98). In any case, the meetings were confidential, and were attended by only a "handful" of invited elite urologists (Goldstein cross-examination, p 4497). Therefore, the information disclosed during these meetings cannot be said to be within the common general knowledge of the skilled person.

[149] As concerns the 902 and 277 Patents, Lilly disputes that either would have come to the attention of the skilled person to whom the 784 Patent is addressed.

[150] All the experts define that skilled person as an amalgam of clinicians and pharmaceutical scientists. Lilly's expert Dr. Brock defines the skilled person as either a medicinal chemist or pharmaceutical formulator and a clinician such as a urologist (Brock affidavit, para 21, AR p 211). Dr. Goldstein defines this person as having an advanced science degree or a medical degree and experience in a lab where PDEs were being studied or experience treating patients with erectile dysfunction (Goldstein affidavit, para 160, AR p 180). Similarly, Apotex' expert Dr. Warrington defines the skilled person of the 784 Patent as including "a team of pharmaceutical scientists seeking to discover a therapeutic drug (medicinal chemists, biochemists, biologists and pharmacologists) … The skilled person would also include urologists and other physicians who treat patients with erectile dysfunction" (Warrington affidavit, para 26, AR pp 2881-82). Dr. Burnett opines that the skilled person of the 784 Patent is a team comprising a urologist, a pharmacologist, a chemist, and a formulator (Burnett affidavit, para 144, p 2852).

[151] Drs. Brock and Goldstein are urologists, and they both testified that they do not read patent applications like the 902 or the 277 Application (Brock cross-examination, AR pp 4903-04; Goldstein cross-examination, AR pp 4480-81). Dr. Burnett, Apotex' only expert urologist, also testified that he does not read patent applications and had not seen the 902 Application when it was published, although other specialists such as medicinal chemists might read patents (Burnett cross-examination, AR pp 5786-88). Lilly therefore argues that neither Application would have fallen within the common general knowledge of the skilled person to whom the 377 and 784 Patents are addressed.

[152] Apotex disagrees. Dr. Warrington testified that medicinal chemists regularly read patent applications like the 902 and 277 Applications (Warrington affidavit, para 181, AR p 2930). Since the experts agree that a medicinal chemist is part of the skilled person team, Apotex thus argues that these Applications would fall within the common general knowledge of the skilled person in this case.

[153] I accept Apotex' position on this issue as Lilly's argument is unsupported by the evidence and ignores the skill set of the skilled person, which includes a medicinal chemist (as its own expert, Dr. Brock, agrees). Therefore, because the evidence establishes that medicinal chemists routinely read patent applications like the 277 and the 902 Applications, I find that the 277 and 902 Applications would have been within the common general knowledge of the skilled person to whom the 784 Patent is directed as of July 27, 1995.

[154] However, in my view, these Applications do not render the use of tadalafil, 3-methyl tadalafil or their salts or solvates to treat ED obvious.

[155] Only one expert—Dr. Warrington—says anything about the 277 Application, which tends to indicate that it is largely irrelevant. Dr. Warrington does little more than mention the Application in his affidavit: he notes that the 277 Application is the final patent application of a research program at SmithKline that ended in 1992 and that the 277 Application discloses a group of compounds as PDE V inhibitors (Warrington affidavit, paras 67, 81).

[156] Having reviewed the Application, I find it adds nothing of importance to the common general knowledge of the skilled person as concerns the invention claimed in the 784 Patent. The 277 Application contains only a single oblique reference at page 1 of the specification to the potential use of some of the claimed compounds to treat ED. There is no claim to the use of the compounds to treat ED, there is no clinical data at all, and there is no test data related to the treatment of ED (see Warrington cross-examination, AR p 5850). The reference to ED in the 277 Application in no way suggests that tadalafil or 3-methyl tadalafil could be used to treat ED.

[157] As concerns the 902 Application, Dr. Brock discusses the Application in very general terms only by stating that as of July 14, 1995, the skilled person would have understood that "further research was required before making any conclusions about what approaches would be useful in the treatment of erectile dysfunction with a PDE V inhibitor …[and that] the person of skill in the art at that time would not say to themselves that it was self-evident that tadalafil or 3-methyl tadalafil could be used to treat [ED]" (at para 231 of his affidavit, AR pp 273-74). In his affidavit, Dr. Goldstein provides a lengthier discussion of the 902 Application and reaches the same conclusion, noting that the state of the art understanding of the physiology of penile erection was counterintuitive to the claims of Pfizer's patent. He continues in his affidavit by noting that, while the claims in the 902 Application served as a prototype for an orally effective therapy, they did not provide a rational basis for the development of other PDE V inhibitors. He also opined that the potency, selectivity and safety of other PDE V inhibitors with chemical structures different from that of sildenafil could not have been predicted (Goldstein affidavit, para 16, AR pp 137-138). Moreover, Drs. Brock and Goldstein noted on cross-examination that the 902 Application failed to disclose which of the nine potential compounds in the Application

had been found to be effective in treating ED, nor did it disclose the clinical data supporting the claim about the compound's efficacy in humans (Brock cross-examination, AR pp 4910-11; Goldstein cross-examination, AR p 4521).

[158] In addition, both of Lilly's experts noted that even after the publication of the 902 Application several researchers continued to investigate other options than the administration of a PDE V inhibitor to treat ED. Researchers continued to experiment with direct injections and locally-applied topical formulations. A 1995 article by Morales specifically addresses sildenafil, and voices "concern" that any orally administered PDE inhibitor would cause general systemic side effects throughout the body (Morales *et al*, "Oral and topical treatment of erectile dysfunction. Present and future" (1995) 22:4 *The Urologic Clinics of North America* 879 at 882; see Goldstein affidavit, para 52, AR p 148). Both Dr. Goldstein and Dr. Brock opine that the continuation of this sort of research shows that the use of a PDE V inhibitor to treat ED was not obvious. Lilly argues that the concerns about systemic effects of PDE V inhibitors were only finally put to rest in 1996, with the publication of the sildenafil clinical data in the Boolell article.

[159] On the other hand, Drs. Corbin, Burnett and Warrington reach the opposite conclusion and opine that as of July 14, 1995 the use of tadalafil or 3-methyl tadalafil to treat ED was obvious. Drs. Corbin and Warrington discuss the 902 Application in their affidavits, but each, to a greater or lesser extent, conflates the contents of the 902 Application with the subsequent information contained in the Boolell article by intimating that the 902 Application disclosed that the compound found to be efficacious for treating ED was sildenafil, and referring to clinical data not disclosed until the Boolell publication (see Corbin cross-examination, AR pp 5682-83;

Warrington cross-examination, AR pp 5876-77). For his part, Dr. Burnett acknowledges that the effective compound is not identified in the 902 Application, but says that he was personally aware of its identity at the time (Burnett affidavit, para 131, AR p 2848). Given his work in the area – and attendance at the Pfizer briefings – Dr. Burnett possesses more knowledge than the skilled person to whom the 784 Patent is addressed. Thus, his knowledge that sildenafil was the effective compound claimed in the 902 Application does not establish that the skilled person would have likewise possessed this knowledge.

[160] In this regard, as noted, the 902 Application does not identify which preferred compound was shown to be effective. Rather, it discloses only that one of nine compounds was effective to treat ED when administered orally. It also, however, states that several compounds had been tested and all were shown to have been potent and selective PDE V inhibitors (902 Application, pp 9-10). Given the lack of disclosure of which compound was efficacious in the face of a claim that several were shown to inhibit PDE V, it cannot be said that it was obvious that all PDE V inhibitors would be effective to treat ED. I therefore concur with Justice de Montigny that the 902 Application did not render the use of tadalafil, 3 methyl tadalafil or their salts or solvates to treat ED obvious. It was not more or less self-evident that merely because tadalafil and 3-methyl tadalafil are potent and selective PDE V inhibitors they would be effective to treat ED. In short, there is no statement in the 902 Application that all PDE V inhibitors will be effective to treat ED, and, absent such a statement, it is not obvious that tadalafil and 3-methyl tadalafil would be effective.

[161] Moreover, both before and after July 14, 1995, many of those who were studying and attempting to find a cure for ED continued to look for other options and continued to express real concerns about the potential side-effects of an orally administered PDE inhibitor. This research is discussed at para 158 of these Reasons. These concerns and research underscore the inventive nature of the claims made in the 784 Patent.

[162] I therefore concur with Lilly and its experts on this point and conclude that as of July 14, 1995 the claims of the 784 Patent were patentably distinct from those in the 377 Patent.

[163] Apotex has suggested that I should disregard the evidence of Lilly's experts on these points given the close relationship between them and Lilly (particularly in Dr. Brock's case) and given the fact that their experts were not "blinded" to the contents of Apotex' NOA when they expressed their opinions. In support of the latter point Apotex cites my decision in *Teva Canada Innovation v Apotex*, 2014 FC 1070 at paras 94-97, 252 ACWS (3d) 322 [*Teva*] as well as the decision of Justice Rennie in *AstraZeneca Canada v Apotex*, 2014 FC 638 at para 321, 244 ACWS (3d) 180, aff'd 2015 FCA 158 [*AstraZeneca*].

[164] I find no merit in these assertions.

[165] The recent decision of the Supreme Court of Canada in *White Burgess Langille Inman v Abbott and Haliburton Co*, 2015 SCC 23, 383 DLR (4th) 429, indicates that the evidence of Drs. Brock and Goldstein is admissible regardless of their relationship with Lilly (as, indeed, Apotex conceded). Having carefully reviewed the transcripts of their cross-examinations, where their

opinions were vigorously tested by counsel, I can see no indication of partiality or bias on the part of either Lilly expert. Moreover, their evidence on the 902 Application and its import coincides best with the content of that Application, and, thus, there is an objective basis for preferring it.

[166] Insofar as concerns the allegation regarding lack of "blinding", Apotex has tried to apply the decisions in *Teva* and *AstraZeneca* out of context. There, the experts whose credibility was found to be wanting based their construction of the patents in suit with a view to infringement and were able to come to their opinions based on the information in the generic company's NOA. In *Teva*, this led to an especially tortured construction. In *Teva* and *AstraZeneca*, the approach taken was found to undercut the experts' credibility as it led to an improper results-oriented opinion. Neither case can be read for the position that Apotex sought to advance here, namely, that in any case where one party blinds its experts but the other does not, the former's evidence is to be preferred. Rather, these two decisions must be limited to the facts that arose in these cases.

[167] There is accordingly a sound basis for agreeing with Drs. Brock and Goldstein regarding the inventive nature of the relevant claims in the 784 Patent when non-obviousness is assessed as of July 14, 1995.

[168] I therefore conclude that Apotex' allegations of double patenting in this case are not justified.

VI. Is the 784 Patent Invalid for Insufficiency?

[169] Apotex next alleges that the 784 Patent is invalid for insufficiency because it does not provide enough information to enable a skilled worker to prepare a hydrate of tadalafil. As noted, many of the relevant claims in the 784 Patent include solvates of tadalafil or 3-methyl tadalafil, and it is common ground between the parties that a solvate includes a hydrate. Thus, several of the relevant claims in the 784 Patent extend to hydrates of tadalafil.

[170] Apotex and its expert, Dr. Trout, take the position that the disclosure of the 784 Patent is insufficient to enable a skilled person to make a hydrate of tadalafil. More specifically, Dr. Trout opines that as of July 1996 (and indeed up to the date he swore his affidavit) the formation of a hydrate of any given compound must be investigated empirically and there is no way to predict whether a given compound could form a hydrate. As the 784 Patent provides no directions as to how to formulate a hydrate, Apotex says that it is void for insufficiency.

[171] Lilly disagrees and its expert, Dr. Wuest, provides the opposite opinion. Dr. Wuest offers the view in his affidavit that as of July 1996, when the 784 Patent was filed, a person skilled in the art to which the 784 Patent is directed would be familiar with techniques of crystallization "conducive to the formation of hydrates" (Wuest affidavit, para 27, AR p 197). He further expresses the view that the 784 Patent teaches the skilled person how to make tadalafil and 3-methyl tadalafil and that "[o]nce the compounds were made, a person skilled in the art could then solubize them and attempt to crystallize them in the presence of water in a variety of conditions" (at para 28). He also notes in his affidavit that it would be part of routine

experimentation for a person skilled in the art to adjust conditions to favour the formulation of hydrates and that a person skilled in the art would know how to vary these conditions if initial attempts to produce a hydrate of tadalafil or 3-methyl tadalafil were unsuccessful.

[172] As Lilly correctly notes, the 784 Patent discloses a general method for solvent formulation at page 9 of the Patent. Dr. Warrington, an Apotex expert witness, who, like Dr. Wuest, is a medicinal chemist, agreed on cross-examination that the method for solvent formulation disclosed at page 9 of the Patent could well produce a hydrate of tadalafil or 3-methyl tadalafil (Warrington cross-examination, AR p 5888). Dr. Wuest agreed with this point of view during his cross-examination. Moreover, he remained unshaken during his cross-examination that a skilled organic or medicinal chemist would be able to vary reaction conditions, through routine experimentation, to enable hydrate formulation of tadalafil (Wuest cross-examination, AR pp 4759-4764).

[173] Apotex is correct in asserting that there must be sufficient disclosure in a patent to enable a skilled person to replicate the invention claimed in the patent as sufficiency of disclosure is part of the basic patent bargain: the inventor is granted exclusive rights in their invention in exchange for disclosure of the invention, as the Supreme Court noted at para 32 of *Sildenafil SCC*, above (see also *Consolboard*, above, at 519-520; *Free World Trust*, above, at para 13; *Apotex Inc v Wellcome Foundation Ltd*, 2002 SCC 77 at para 37, [2002] 4 SCR 153; *Cadbury Schweppes Inc v FBI Foods Ltd*, [1999] 1 SCR 142 at para 46, 167 DLR (4th) 577). The requirement for sufficiency is found in subsection 27(3) of the *Patent Act*, which provides the following:

Specification	**Mémoire descriptif**
(3) The specification of an	(3) Le mémoire descriptif doit

invention must	:
(*a*) correctly and fully describe the invention and its operation or use as contemplated by the inventor;	*a*) décrire d'une façon exacte et complète l'invention et son application ou exploitation, telles que les a conçues son inventeur;
(*b*) set out clearly the various steps in a process, or the method of constructing, making, compounding or using a machine, manufacture or composition of matter, in such full, clear, concise and exact terms as to enable any person skilled in the art or science to which it pertains, or with which it is most closely connected, to make, construct, compound or use it;	*b*) exposer clairement les diverses phases d'un procédé, ou le mode de construction, de confection, de composition ou d'utilisation d'une machine, d'un objet manufacturé ou d'un composé de matières, dans des termes complets, clairs, concis et exacts qui permettent à toute personne versée dans l'art ou la science dont relève l'invention, ou dans l'art ou la science qui s'en rapproche le plus, de confectionner, construire, composer ou utiliser l'invention;
(*c*) in the case of a machine, explain the principle of the machine and the best mode in which the inventor has contemplated the application of that principle; and	*c*) s'il s'agit d'une machine, en expliquer clairement le principe et la meilleure manière dont son inventeur en a conçu l'application;
(*d*) in the case of a process, explain the necessary sequence, if any, of the various steps, so as to distinguish the invention from other inventions.	*d*) s'il s'agit d'un procédé, expliquer la suite nécessaire, le cas échéant, des diverses phases du procédé, de façon à distinguer l'invention en cause d'autres inventions.

[174] In *Sildenafil SCC*, the Supreme Court of Canada confirmed the earlier jurisprudence laying out the test for sufficiency of disclosure: "[t]he description must be such as to enable a person skilled in the art or the field of the invention to produce it using only the instructions

contained in the disclosure" (*Pioneer Hi-Bred Ltd v Canada (Commissioner of Patents)*, [1989] 1 SCR 1623 at 1638, 60 DLR (4th) 223; cited in *Sildenafil SCC* at paras 51, 71). The specification must define the precise and exact extent of the exclusive property and privilege claimed; if the skilled person is required to do a minor research project to discover the true invention, then the disclosure is insufficient (*Consolboard*, above, at 520; *Sildenafil SCC* at paras 70, 74).

[175] Here, the dispute as to the sufficiency of disclosure about how to make hydrates is an evidentiary one. I prefer the evidence of Dr. Wuest on the point as I agree with Lilly that his expertise is more relevant to this issue than that of Dr. Trout, who possesses a degree in chemical engineering as opposed to chemistry. Moreover, to a certain extent, Dr. Wuest's opinion on the point is corroborated by the answers given by Dr. Warrington on cross-examination, noted above. In addition, there is no reason to doubt Dr. Wuest's credibility. Contrary to what Apotex asserts, Dr. Wuest's evidence is not undercut by his evidence in another Federal Court proceeding, *Merck & Co v Apotex* (Federal Court file T-568-03). I find he provided a more than adequate explanation for the difference between the compounds involved in that case and this case during his cross-examination and re-examination in this case. Having reviewed the transcript of his cross-examination and re-examination, it is my view that Dr. Wuest answered the questions put to him in a forthright manner that is consistent with his role as an expert. I therefore believe that there is no reason to discount his evidence.

[176] I thus find that there is adequate disclosure in the 784 Patent to enable the production of solvates of tadalafil and 3-methyl tadalafil and that, from there, the skilled person, relying on his or her common general knowledge, would be able to create and if necessary modify reaction

conditions so as to favour hydrate formation. Thus, there is, in my view, adequate disclosure in the 784 Patent and Apotex' allegation of insufficiency is therefore not justified.

VII. Does Lilly Lack Standing to Bring this Application Due to a Defect in the Chain of Title?

[177] I turn finally to Apotex' argument about lack of a proper chain of title to the 784 Patent, which it alleges must result in the dismissal of this Application as it claims that Lilly lacks standing to seek a prohibition order from this Court.

[178] Apotex refined its arguments on this point during the hearing and submitted that Lilly failed to comply with subsection 6(4) and paragraph 4(4)(*d*) of the *PMNOC Regulations* and alleged that this failure equated to a lack of standing. Subsection 6(4) of the *PMNOC Regulations* requires a first person to join the patent owner as a party to a prohibition application made under section 6 of the *PMNOC Regulations* if the applicant is not the owner of the patent. Paragraph 4(4)(*d*) of the *PMNOC Regulations* requires a first person, who makes an application to have a patent included on the Patent List, to make a statement in its application that it is either the patentee, or has a licence to use the patent, or has the consent of the patent owner to have the patent included on the list.

[179] Apotex asserts that Lilly has failed to establish that ICOS, as opposed to GSK France, is the owner of the 784 Patent. It therefore says that Lilly ought to have joined GSK France as opposed to ICOS as a party to this application under subsection 6(4) of the *PMNOC Regulations*. It also argues that the statement Lilly filed under paragraph 4(4)(*d*) of the *PMNOC Regulations* was false because Lilly was licensed to use the 784 Patent by ICOS, but ICOS, according to

Apotex, does not own the 784 Patent. Apotex says that Lilly's alleged failures to comply with subsection 6(4) and paragraph 4(4)(*d*) of the *PMNOC Regulations* means that Lilly lacks standing to have commenced this application, which, accordingly, must lead to its dismissal.

[180] Apotex says that the affidavit of Laëtitia Bénard establishes that under French law Laboratoire Glaxo owned the 784 Patent. Ms. Bénard opined that under French law, inventions made in the "course of a mission" belong to the employer unless the employment contract provides otherwise. Dr. Daugan made the invention claimed in the Patent while carrying out his employment duties as an inventor for Laboratoire Glaxo. Dr. Daugan deposed that his employment contract with Laboratoire Glaxo contained no provision about intellectual property (Daugan affidavit, para 37, AR p 104). Therefore, under French law, title to the 784 Patent initially rested with Laboratoire Glaxo. Lilly agrees with this assertion and, indeed, filed Ms. Bénard's affidavit to make precisely such a point.

[181] Where the parties part company concerns what happened after that. Lilly says that in the 1997 Amendment, Laboratoire Glaxo transferred its title in the 784 Patent to ICOS. Ms. Smith, legal counsel for Lilly, appended a copy of the 1997 Amendment to her affidavit.

[182] In this Amendment, Glaxo Group Limited, Glaxo U.S. and their Affiliates assigned and transferred to ICOS all right, title and interest in and to a number of substances, including tadalafil and 3-methyl tadalafil and in all patents pertaining to the inventions claimed in a number of patents and patent applications, including the 784 Patent (see Smith Exhibit A, AR pp 2084-85).

[183] The 1997 Amendment further provides that the "Affiliates" to which that Agreement pertains are defined in the same way as that term is defined in the earlier 1991 Collaboration Agreement. Lilly has not produced a copy of the 1991 Collaboration Agreement but, rather, has filed the affidavit of Patrick Desbiens, the President of GSK France, who deposed that in 1997, Laboratoire Glaxo (the predecessor of GSK France) was an Affiliate of Glaxo Group Limited within the meaning of the 1991 Collaboration Agreement.

[184] Lilly submits that the foregoing establishes a proper chain of title from Laboratoire Glaxo to ICOS. Apotex disputes this, arguing that the 1997 Amendment is not properly before the Court because it is hearsay when deposed through a lawyer's affidavit. In addition, it says that Mr. Desbiens' evidence should be rejected because the qualification of Laboratoire Glaxo as an "Affiliate" is a legal question and Mr. Desbiens, who is a non-lawyer, cannot provide reliable evidence about the issue.

[185] Apotex in addition relies on the fact that Dr. Daugan subsequently signed an assignment in favour of ICOS, which was filed with CIPO. Apotex argues that this assignment should be viewed as akin to an admission that the chain of title Lilly asserts is insufficient as otherwise the assignment from Dr. Daugan would be superfluous. Apotex also says that the failure of Lilly to file the 1997 Amendment with CIPO supports its assertion that this Amendment did not result in the transfer of title of the 784 Patent from Laboratoire Glaxo to ICOS.

[186] Apotex' claims on the chain of title issue thus centre on the alleged insufficiency of Lilly's evidence. Apotex filed no evidence of its own to support its allegation that GSK France remains the owner of the 784 Patent.

[187] In support of its assertions, Apotex relies on the decisions in *Merck Frosst Canada Inc v Canada (Minister of National Health and Welfare)* (1997), 74 CPR (3d) 131, 132 FTR 60 (FCTD) [*Merck Frosst*] and *Parke-Davis Division, Warner-Lambert Canada Inc v Canada (Minister of Health),* 2002 FCA 454, 22 CPR (4th) 417 [*Parke-Davis*].

[188] In *Merck Frosst,* the applicant licensee failed to file any evidence to support the existence of a licence agreement in its favour and Justice Muldoon found this deprived it of standing to commence a prohibition application under section 6 of the *PMNOC Regulations*. An opposite conclusion was reached in *Parke-Davis* as the applicant was found to have filed sufficient evidence to establish the existence of a licence in its favour and had joined the patent owner as a party to the prohibition application, who did not contest the right of Parke-Davis to use the patent in suit in that case.

[189] Both *Merck Frosst* and *Parke-Davis* involved markedly different situations from the present case as the issue in those cases involved whether the applicants had established they were licensees. Thus, in neither case was the legitimacy of an assignment from the original patentee to a subsequent putative patent owner, whose patent was registered under the *Patent Act*, in issue. This distinction is important because Apotex, unlike the respondents in *Merck Frosst* and *Parke-Davis,* asserts that ICOS is not the valid owner of the patent in suit in this case. However, the 784

Patent has been registered under the *Patent Act* and the registration indicates that ICOS owns the 784 Patent. Apotex is therefore attacking the validity of the 784 Patent, but has done so indirectly by asserting that it is only challenging Lilly's standing. When one examines Apotex' claim, though, it becomes apparent that what it is actually asserting is that the 784 Patent, itself, is invalid because ICOS does not own it.

[190] I agree with Lilly that Apotex cannot challenge the validity of the ownership of the 784 Patent in this fashion in an Application such as the present. In *Corlac*, above, the Federal Court of Appeal noted at paras 141 and 142 that:

> It is well established that Canadian patent law is entirely statutory in nature. It is derived from the Act and the regulations enacted under it … [citations omitted] the Act and Regulations are described by this Court as a "complete code."
>
> The grounds for attacking the validity of a patent are delineated in the Act. Specifically, they relate to: utility, section 2; novelty (anticipation), section 28.2; obviousness (inventiveness), section 28.3; and sufficiency of disclosure, subsection 27(3). In addition to validity grounds, a patent can be found to be void if the conditions of subsection 53(1) are met.

[191] Apotex has not asserted any of these grounds in this case. While the issue examined in *Corlac* was different than that raised by Apotex in the present case, I believe the Court's reasoning in *Corlac* applies by analogy here and, as decided in *Corlac*, a party cannot seek to undermine the validity of an issued patent by raising a ground of invalidity outside those contemplated by the *Patent Act*.

[192] I also concur with Lilly that this situation is somewhat akin to that considered in *Apotex Inc v Wellcome Foundation Ltd*, [2001] 1 FC 495, 10 CPR (4th) 65 (FCA), aff'd 2002 SCC 77,

[2002] 4 SCR 153. There, the plaintiff in an infringement action sought to rely on an assignment to it of the rights to a patent that was not registered with CIPO. Subsection 50(2) of the *Patent Act* requires that all patent assignments be registered, and the defendant argued that the failure to file the assignment in that case deprived the plaintiff of standing to commence the infringement action. The Federal Court of Appeal disagreed, as section 51 of the *Patent Act* provides that failure to register the assignment only voids the assignment against subsequent assignees, and not against any third party, noting at para 100 that:

> Having regard to both sections [50(2) and 51], it is clear that a purpose of registration under subsection 50(2) is to secure an assignee's priority as against subsequent assignees. Failure to register will deprive an assignee of priority against subsequent assignees and, as between them, an unregistered assignment is "void". However, there is no indication that failure to register renders the assignment void for any other purpose.
>
> (emphasis in original)

[193] Thus, I find that Apotex' challenge to ICOS' ownership of the 784 Patent cannot succeed as Apotex cannot contest ICOS' ownership of the 784 Patent by alleging that Lilly lacks standing as a first person under the *PMNOC Regulations*.

[194] Subsidiarily, even if this were not the case, I believe that, contrary to what Apotex asserts, Lilly has established its standing to bring the present Application for prohibition because it has established that there was an assignment from Laboratoire Glaxo to ICOS of ownership of the invention claimed in the 784 Patent.

[195] In this regard, I find the 1997 Amendment to be admissible even though it is appended to the affidavit of Ms. Smith, in-house counsel at Lilly. As Ms. Smith did not author the 1997

Amendment, the document is *prima facie* hearsay if introduced through her. In *R v Smith*, [1992] 2 SCR 915, 94 DLR (4th) 590 and *R v Khan*, [1990] 2 SCR 531, 113 NR 53 [*Khan*], the Supreme Court of Canada established that there is a principled exception to the admission of hearsay evidence, which allows for its admission if the proffered evidence meets the twin criteria of reliability and necessity. In *Khan*, the Supreme Court noted that as concerns the necessity criterion for the admission of hearsay, a party seeking to have evidence admitted need establish only that it is reasonably (as opposed to absolutely) necessary that the hearsay be admitted (at 546).

[196] Here, I find the twin criteria of reliability and necessity to be met.

[197] In the circumstances of this case, I find the evidence to be reliable as the 1997 Amendment was appended to the affidavit of a solicitor, who is an officer of the Court, and thus has an ethical obligation to be completely truthful. The document was drawn from Lilly's corporate database of agreements, which ought only contain accurate versions of agreements, and on its face it is a complete agreement. There is, moreover, no suggestion that the Amendment is anything other than that which it purports to be.

[198] As for necessity, I find this criterion to be met as the manner in which Lilly produced the 1997 Amendment is by far the most practical and preferable way for the evidence to be brought before the Court in a prohibition application under the *PMNOC Regulations*. Requiring Lilly to do what Apotex alleges Lilly should be required to do – namely file affidavits from the signatories of the 1997 Amendment merely to file the document with the Court – would serve no

purpose other than unduly lengthening and adding to the expense of this litigation, which has already spawned a record that is thousands of pages long, much of which was ignored by the parties in their submissions. Such a result is undesirable and unnecessary, especially when one recalls that prohibition applications under the *PMNOC Regulations* are intended to proceed in a summary fashion.

[199] Thus, I find that Lilly has established that Glaxo Group Limited, Glaxo U.S. and ICOS signed the 1997 Amendment and that under that Amendment, Glaxo's Affiliates assigned their rights in the subject matter of the 784 Patent to ICOS.

[200] I also find that Lilly has established that Laboratoire Glaxo is an Affiliate of Glaxo Group Limited through the affidavit of Patrick Desbiens and disagree that his evidence should be disregarded because he is not a lawyer. In short, I find the president of a company to be competent to provide evidence about whether the company he heads is bound by an important commercial agreement.

[201] I therefore conclude that Lilly has established a proper chain of title to the 784 Patent in its favour. This determination is in no way undercut by the fact that Dr. Daugan signed an assignment in favour of ICOS that was filed with CIPO nor by the fact that the 1997 Amendment was not filed with CIPO. Given the arguments made by Apotex (which presumably have been raised elsewhere), it was prudent for Dr. Daugan to sign the assignment. His doing so, however, was unnecessary in light of the nature of his employment, the content of French law and the terms of the 1997 Amendment, which, as I have found, were effective to transfer title in the 784

Patent to ICOS. As for the documents that were filed with CIPO, Lilly filed documents with the International Bureau, which issued a notice of change in ownership of the Patent on October 10, 1997 that was filed with CIPO (see Potter Exhibit F, AR p 1675). Thus, CIPO was in fact notified of the change in ownership.

[202] I therefore find this final argument of Apotex to be unduly technical and entirely without merit. I thus conclude that Lilly does possess standing to bring this prohibition application.

VIII. Conclusion and Costs

[203] It follows that this Application must be granted. 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, Lilly shall file its costs submissions, of no more than 15 pages, within 15 days of the release of my Judgment. Apotex shall have 15 days following receipt of Lilly's submissions to file its responding costs submissions, which likewise shall be limited to 15 pages. Thereafter, within 5 days of receipt of Apotex' responding submissions, if it chooses, Lilly may file reply costs submissions of no more than 5 pages.

JUDGMENT

THIS COURT'S JUDGMENT is that

1. The application is allowed;

2. The Minister of Health is prohibited from issuing a Notice of Compliance to Apotex until the expiry of Canadian Patent No. 2,226,784;

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

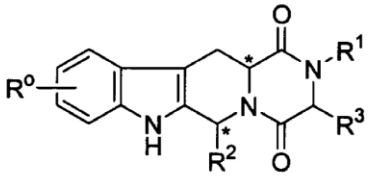
4. No costs are awarded for or against the Minister.

"Mary J.L. Gleason"
Judge

Appendix

Claim 1

A pharmaceutical composition for the curative or prophylactic treatment of erectile dysfunction in a male animal, comprising a compound of formula (I):



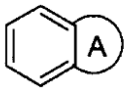
(I)

or a physiologically acceptable salt or solvate thereof, wherein:

R0 represents hydrogen, halogen or C1-C6alkyl;

R1 represents hydrogen, C1-C6alkyl, C2-C6alkenyl, C2-C6alkynyl, haloC1-C6alkyl, C3-C8cycloalkyl, C3-C8cycloalkylC1-C3alkyl, arylC1-C3alkyl or heteroarylC1-C3alkyl;

R2 represents an optionally substituted monocyclic aromatic ring selected from the group consisting of benzene, thiophene, furan and pyridine, or an optionally substituted bicyclic ring



attached to the rest of the molecule via one of the benzene ring carbon atoms, wherein the fused ring A is a 5- or 6-membered ring which may be saturated or partially or fully unsaturated and comprises carbon atoms and optionally one or two heteroatoms selected from the group consisting of oxygen, sulphur and nitrogen; and R3 represents hydrogen or C1-C3alkyl, or R1 and R3 together represent a 3- or 4-membered alkyl or alkenyl chain, together with a pharmaceutically acceptable diluent or carrier.

Claim 2

A pharmaceutical composition for the curative or prophylactic treatment of erectile dysfunction in a male animal, comprising a compound selected from the group consisting of:

(6R,12aR)-2,3,6,7,12,12a-hexahydro-2-methyl-6-(3,4-methylenedioxyphenyl)-pyrazino[2',1':6,1]pyrido[3,4-b]indole-1,4-dione or a physiologically acceptable salt or solvate thereof; and

(35,6R,12aR)-2,3,6,7,12,12a-hexahydro-2,3-dimethyl-6-(3,4-methylenedioxyphenyl)-pyrazino[2',1':6,1]pyrido[3,4-b]indole-1,4-dione or a physiologically acceptable salt or solvate thereof,

together with a pharmaceutically acceptable diluent or carrier.

Claim 3

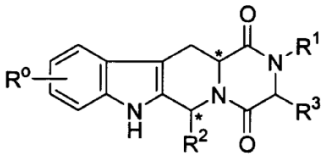
The composition according to claim 1 or 2, wherein the solvate is a hydrate.

Claim 4

The composition according to any one of claims 1 to 3, wherein the animal is human.

Claim 9

Use of a compound of formula (I):



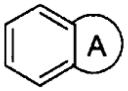
(I)

or a physiologically acceptable salt or solvate thereof, wherein:

R0 represents hydrogen, halogen or C1-C6alkyl;

R1 represents hydrogen, C1-C6alkyl, C2-C6alkenyl, C2-C6alkynyl, haloC1-C6alkyl, C3-C8cycloalkyl, C3-C8cycloalkylC1-C3alkyl, arylC1-C3alkyl or heteroarylC1-C3alkyl;

R2 represents an optionally substituted monocyclic aromatic ring selected from the group consisting of benzene, thiophene, furan and pyridine, or an optionally substituted bicyclic ring



attached to the rest of the molecule via one of the benzene ring carbon atoms, wherein the fused ring A is a 5- or 6-membered ring which may be saturated or partially or fully unsaturated and comprises carbon atoms and optionally one or two heteroatoms selected from the group consisting of oxygen, sulphur and nitrogen; and

R3 represents hydrogen or C1-C3alkyl, or R1 and R3 together represent a 3- or 4-membered alkyl or alkenyl chain,

for manufacturing a medicament for the curative or prophylactic treatment of erectile dysfunction in a male animal.

Claim 12

Use of a compound selected from the group consisting of:

(6R,12aR)-2,3,6,7,12,12a-hexahydro-2-methyl-6-(3,4-methylenedioxyphenyl)-pyrazino[2',1':6,1]pyrido[3,4-b]indole-1,4-dione or a physiologically acceptable salt or solvate thereof; and

(3S,6R,12aR)-2,3,6,7,12,12a-hexahydro-2,3-dimethyl-6-(3,4-methylenedioxyphenyl)-pyrazino[2',1':6,1]pyrido[3,4-b]indole-1,4-dione or a physiologically acceptable salt or solvate thereof,

for the curative or prophylactic treatment of erectile dysfunction in a male animal.

Claim 14

Use according to any one of claims 9 to 13, wherein the animal is human.

Claim 15

Use of a composition according to any one of claims 1 to 4 for the curative or prophylactic treatment of erectile dysfunction in a male animal.

Claim 18

Use according to any one of claims 9 to 17, wherein the compound, medicament, composition, combination or formulation is used or is adapted to be used orally.

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-1598-13
STYLE OF CAUSE:	ELI LILLY CANADA INC. v APOTEX INC. AND THE MINISTER OF HEALTH AND ICOS CORPATION
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