Federal Court  Cour fédérale

Date: 20200910

Docket: T-1627-16

Citation: 2020 FC 816

Ottawa, Ontario, September 10, 2020

PRESENT: The Honourable Madam Justice St-Louis

BETWEEN:

ELI LILLY CANADA INC., ELI LILLY AND COMPANY, LILLY DEL CARIBE, INC., LILLY, S.A. and ICOS CORPORATION INC.

Plaintiffs/Defendants by Counterclaim

and

MYLAN PHARMACEUTICALS ULC

Defendant/Plaintiff by Counterclaim

AND BETWEEN:

Court File No. T-1631-16 (T-1639-16)

ELI LILLY CANADA INC., ELI LILLY AND COMPANY, LILLY DEL CARIBE, INC., LILLY, S.A. and ICOS CORPORATION INC.

Plaintiffs/Defendants by Counterclaim

- and -

TEVA CANADA LIMITED

Defendant/Plaintiff by Counterclaim

AND BETWEEN:

Court File No. T-1623-16 (T-1624-16)

ELI LILLY CANADA INC., ELI LILLY AND COMPANY, LILLY DEL CARIBE, INC., LILLY, S.A. and ICOS CORPORATION INC.

Plaintiffs/Defendants by Counterclaim

- and -

PHARMASCIENCE INC. AND LABORATOIRE RIVA INC.

Defendants/Plaintiffs by Counterclaim

AND BETWEEN:

Court File No. T-1632-16

ELI LILLY CANADA INC., ELI LILLY AND COMPANY, LILLY DEL CARIBE, INC., LILLY, S.A. and ICOS CORPORATION INC.

Plaintiffs/Defendants by Counterclaim

- and -

APOTEX INC.

Defendant/Plaintiff by Counterclaim

PUBLIC JUDGMENT AND REASONS
(Confidential Judgment and Reasons issued August 6, 2020)

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I. Introduction

[1] This decision relates to infringement actions of Canadian Patent No. 2,371,684 [the 684 Patent] by the Plaintiffs (hereinafter collectively referred to as "Lilly") against each of four Defendants, Mylan Pharmaceuticals ULC, Apotex Inc., Teva Canada Limited, and Pharmascience Inc.-Laboratoire Riva Inc., and related counterclaims of invalidity by each of the Defendants.

[2] The reasons exposed in this case will be filed in each of the other three related cases. Additional reasons, pertaining to the litigation between Lilly and Apotex Inc. in regards to Canadian Patent No. 2,492,540 Patent [the 540 Patent] are exposed in *Eli Lilly Canada Inc. and als. v Apotex Inc.*, 2020 FC 814. In the 540 Patent additional reasons, I repeat certain elements and sections of these reasons in order to allow their reading on a stand-alone basis.

II. Procedural background

[3] Lilly initially sued each of the four Defendants in independent actions for infringement of patents related to tadalafil. Each of the Defendants denied infringement and counterclaimed for a declaration of invalidity of the patents asserted against them. Over the course of these proceedings, Lilly has asserted four patents against the Defendants: (1) the 684 Patent, which expired on April 26, 2020, and relates to a dosage form of tadalafil; (2) the 2,379,948 Patent, which expired on April 26, 2020, and relates to a formulation comprising tadalafil; (3) the 540 Patent, which will expire on July 14, 2023, and relates to a manufacture process for making tadalafil; and (4) the 2,226,784 Patent [the 784 Patent] which expired on July 11, 2016, and relates to the use of tadalafil to treat erectile dysfunction [ED].

[4] On September 8, 2017, Prothonotary Tabib, at the request of the parties, bifurcated the actions as between liability and quantification phases. As per Prothonotary Tabib's Order, the liability phase addresses the following issues: (i) whether the patents have been infringed by the Defendants; ii) whether the patents are valid; (iii) except for paragraphs 9, 28–36, 37–42 and 175 of Apotex's Amended Statement of Defence and Counterclaim which shall be addressed in the quantification phase, whether Lilly are entitled to declaratory relief, injunctive relief, and delivery up; and (iv) Lilly's entitlement, if any, to elect as between damages and an accounting of profits (except as it relates to paragraphs 28–36 of the Defence).

[5] On July 3, 2019, Prothonotary Tabib granted Lilly leave to amend their Statements of Claims, whereby only claims for infringement of the 684 Patent against all Defendants, and

claims for infringement of the 540 Patent against Teva, which was subsequently withdrawn, and against Apotex, were maintained.

[6] Prothonotary Tabib also then granted Lilly leave to add, against all Defendants, claims for the infringement of the 784 Patent by reason of the manufacturing, importing and stockpiling of tadalafil for ED, prior to the expiration of the 784 Patent, and springboard damages flowing from that infringement. As a condition for granting leave to amend, all issues of validity, infringement and quantification relating to the 784 Patent were bifurcated and will be the subject of a separate trial after the determination of the liability issues for the 684 and 540 Patents.

[7] Although the actions have not been consolidated, they have been case managed together and proceeded together to trial for the liability phase, with hearings conducted from December 5, 2019 to February 7, 2020. Although the actions regarding the two patents at issue have not been bifurcated, the parties all agreed to the trial being divided in two separate components. The first component pertained to the liability phase of the 684 Patent, which involves all four Defendants, presenting a common case, and the second component pertained to the liability phase of the 540 Patent, which involves Apotex as the sole Defendant.

[8] The parties have not disputed that the law is the same in both components of the trial, although surprisingly, and as I will outline in the discussion regarding anticipation, Lilly presented different versions of the principle guiding the disclosure requirement of the anticipation analysis in each components.

III. The pleadings and results

[9] The Plaintiffs in this action are Eli Lilly Canada Inc. (Eli Lilly Canada), Eli Lilly and Company, Lilly Del Caribe, Inc., Lilly, S.A. and ICOS Corporation Inc.

[10] Eli Lilly Canada has a principal place of business in Toronto Ontario. Eli Lilly and Company has a principal place of business in Indianapolis, Indiana. Lilly Del Caribe, Inc. has a principal place of business in Caroline, Puerto Rico, and is incorporated in the Cayman Islands. Lilly, S.A. has a principal place of business in Madrid, Spain. ICOS Corporation Inc. has a principal place of business in Indianapolis, Indiana.

[11] Eli Lilly Canada markets 2.5mg, 5mg, 10mg and 20mg strengths of tadalafil tablets in Canada under the brand name CIALIS, for the treatment of (a) erectile dysfunction (ED) in men; (b) signs and symptoms of benign prostatic hyperplasia (BPH); and (c) treatment of ED and the signs and symptoms of BPH. Eli Lilly Canada also markets a 20mg strength of tadalafil tablet under the brand name ADCIRCA for the treatment of idiopathic pulmonary arterial hypertension (PAH) in the specified conditions.

[12] The Defendants are generic drug makers. Mylan Pharmaceuticals ULC has a principal place of business in Etobicoke, Ontario. Apotex Inc. has a principal place of business in Toronto, Ontario. Teva Canada Limited has a principal office or place of business in Toronto, Ontario. Actavis Pharma Company amalgamated into Teva Canada Limited, effective January 1, 2017,

and Teva assumes all liabilities of Actavis prior to the amalgamation. Pharmascience Inc. is based in Montreal, Quebec, while Laboratoire Riva Inc. is based in Blainville, Quebec.

[13] In July 2016, each of the Defendants received a Notice of Compliance (NOC) for its version of tadalafil with CIALIS tadalafil as the Canadian Reference Product: Mylan-Tadalafil, Apo-Tadalafil, Teva-Tadalafil/Act-Tadalafil, and PMS-Tadalafil/Riva-Tadalafil. In 2016, after the 784 Patent expired, the Defendants entered the market by selling or by offering for sale their generic version of tadalafil in 2.5mg, 5mg, 10mg and 20mg tablets, except for Riva who has offered for sale and sold 5mg and 20mg tablets in Canada.

[14] In 2015, Apotex received a NOC for Apo-Tadalafil PAH 20mg tablets with ADCIRCA tadalafil as the Canadian Reference Product.

[15] Lilly assert that the Defendants have made, imported, used, sold or offered for sale tablets with the patented unit dosages and infringed or induced the infringement of Claim 10 (as it depends on Claim 9, as it in turn depends on Claims 3–6), and Claims 13–16 of the 684 Patent [the asserted Claims]. Lilly seek a declaration that the Defendants are infringing and inducing infringement, and have infringed or induced infringement of the asserted Claims of the 684 Patent, a declaration that the 684 Patent is valid and subsisting to expiry, a declaration that Lilly may elect as between damages and an accounting of profits, declaratory relief, injunctive relief and/or delivery up, and costs.

[16] The Defendants individually assert that they have not infringed any of the asserted Claims of the 684 Patent. They initially raised the *Gillette* defence (*Free World Trust v Electro Santé Inc*, 2000 SCC 66 [*Free World Trust*]), to submit they were simply doing what was taught by the expired 784 Patent, and also submit there can be no infringement because the patent is invalid. They counterclaimed, seeking a declaration that the 684 Patent or the asserted Claims are invalid, as well as costs.

[17] On November 26, 2019, the parties have jointly outlined the issues as follows:

a) Whether the parties are proper parties and have standing to bring this action;
b) Whether the Plaintiffs are estopped against re-litigating the findings in *Eli Lilly Canada inc v Mylan Pharmaceuticals ULC* 2015 FC 125 due to issue estoppel, collateral estoppel, comity and/or abuse of process;
c) Construction of Claim 10 as it depends on Claim 9, as it in turn depends on Claims 3–6, and Claims 13–16 of the 684 Patent;
d) Whether any of the asserted Claims are infringed;
e) Whether the *Gillette* defence applies;
f) Whether the asserted Claims are invalid by reason of
    i. Overbreadth: are the asserted Claims broader than either the invention made by the named inventors of the 684 Patent or the invention disclosed in the specification of the 684 Patent?
    ii. Double patenting: are the asserted Claims invalid on the bases of same invention and/or obviousness-type double patenting in view of the subject-matter of Claims 1–28 of Canadian Patent No. 2,307,101?
    iii. Anticipation: does Canadian Patent Application No. 2,226,784 and/or PCT Application No. Wo 97/03675 anticipate the subject-matter of the asserted Claims?
    iv. Obviousness: would the subject-matter defined by the asserted Claims have been obvious on the claim date to a person skilled in the art?
    v. Non-patentable subject-matter: does the subject-matter defined by the asserted Claims relate to non-patentable subject-matter (*ie*, a mere discovery and/or a method of medical treatment)?
    vi. Lack of sound prediction/no demonstration utility: have the requirements of either demonstration or sound prediction of utility as of the filing date of the 684 Patent been met?
    vii. Inutility/inoperability: does the subject-matter defined by the asserted Claims in fact possess utility?
    viii. Insufficiency: does the 684 Patent satisfy the requirements of subsection 27(3) of the *Patent Act* R.S.C., 1985, c. P-4 [the Patent Act]?

g) Whether the Plaintiffs are entitled to elect as between damages and an accounting of profits;
h) Whether the Plaintiffs are entitled to declaratory relief, injunctive relief and/or delivery up.

[18] At the start of the trial, the Defendants abandoned the issue of standing. Regarding infringement, only Lilly's expert evidence has been adduced, and the Defendants have not asserted the *Gillette* defence in closing. It thus appears clear that, if the asserted Claims of the 684 Patent were valid, all the Defendants would have infringed.

[19] At opening, the Defendants indicated that their allegations of invalidity on the grounds of overbreadth, lack of sound prediction or demonstration and inutility/inoperability are asserted only in the event the asserted Claims are construed to include the side effect advantages (transcript of December 5, 2019 at page 20). Likewise, the Defendants indicated their allegation of non-patentable subject-matter is asserted only if the Court construes the asserted Claims in the 684 Patent as implicitly including a maximum daily dose (transcript of February 3, 2020 at pages 207–208).

[20] At closing, the Defendants did not address their allegations of invalidity on grounds of overbreadth, double patenting, lack of sound prediction/lack of demonstration, inutility/inoperability, and insufficiency.

[21] Lilly, in their Closing Memorandum, did counter the Defendants' allegations of overbreadth and inutility/inoperability. Finally, at closing, Lilly no longer seek an injunctive relief, nor the delivery up of infringing drugs.

[22] In brief, and for the reasons exposed hereinafter, I find the 684 Patent is not a selection, and that the asserted Claims are anticipated and obvious, and are thus invalid.

[23] However, if I am wrong and the asserted Claims were valid, then all Defendants will have infringed or induced infringement of the asserted Claims of the 684 Patent.

IV. Tadalafil

[24] The drug substance at the heart of these proceedings is tadalafil. It is known as a phosphodiesterase (PDE) 5 inhibitor. The first approved PDE5 inhibiter was sildenafil, commercialised by Pfizer under the brand name Viagra, and approved in Canada on March 9, 1999. Tadalafil is the second in class PDE5 inhibiter drug product.

[25] In brief, tadalafil works to promote the relaxation of the penis' smooth muscle, which, somewhat counterintuitively for a layperson, promotes penile erection. In brief, the penis' smooth muscle, known as the *corpora cavernosa*, is in a contracted state when in normal resting state, and so restricts the arteries supplying blood to the penis. When an erection is triggered, the smooth muscle relaxes, no longer restricts the supply of arterial blood, which causes the penis to become tumescent. The smooth muscle relaxation results from a cascade of complex biochemical reactions within the body. Normally, sexual stimulation triggers the release of nitric oxide, which in turn leads to an increase in the production of a molecule called cyclic guanosine-3-5 monophosphate (cGMP). This cGMP molecule regulates the activity of other intracellular proteins and leads to the relaxation of the smooth muscle. Increasing cGMP promotes smooth muscle relaxation, which promotes penile erection. The intracellular breakdown of the cGMP is

regulated by a class of enzymes known as cyclic nucleotide PDE, and in the penis, the most prevalent is the PDE5 family. Inhibiting PDE5 results in a slower breakdown of cGMP, which then accumulates, promotes the relaxation of the smooth muscle and, in turn, penile erection.

[26] Tadalafil was first claimed in the British patent GB no 9401090.7 (which Canadian equivalent is the 2,181,377 Patent (the 377 Patent)), filed on January 21, 1994 by Laboratoires Glaxo. A number of other patents were also granted in relation to tadalafil, now owned by Lilly as the results of successive commercial transactions.

[27] The 684 Patent relates to unit dosages of tadalafil and a few undisputed scientific indications are useful to understand these reasons.

- The drug development process includes mainly the preclinical studies and three stages of clinical trials before approval of the drug by the regulators. When a compound candidate is discovered, it is first tested *in vitro* and *in vivo*, on animals, for an initial assessment of possible effectiveness (animal pharmacology) and safety and tolerability (toxicology), and further assessments are later performed if the profile of the compound is suitable. If it is safe and tolerable on animal models with a suitable profile, it could be selected for phase I tests that are performed on healthy human subjects in increasing doses to assess safety and tolerability. In phase II, dose response efficacy studies are performed on patients to ascertain the dosage and the efficacy of the compound. Finally, phase III large scale studies are generally performed on patients, before a drug is put to the market. Throughout the preclinicals, and each of the phases, new data, including pharmacokinetic and pharmacodynamics data, are gathered about the drug.
- Pharmacokinetics (PK) are a set of parameters used to describe the concentration of a drug over a period of time in the body (also known as the effect of the body on the drug).
- Pharmacodynamics (PD) are a set of parameters used to describe the effect of the drug at the site of action following its administration (also known as the effect of the drug on the body).
- IC_{50} (potency measure) is the concentration required to inhibit 50% of the target compound.
- EC_{50} is the effective concentration of a drug required for a half-maximal response.
- The half-life of a drug in a human body is the time required for the body to eliminate half of that drug or to reduce by half the drug concentration.

V. The statutory scheme under which the matter proceeds

[28] The parties agree that the law of patents is wholly statutory. The Supreme Court of Canada (SCC) has confirmed it again in 2008, in one of the landmark decision I will discuss later, *Apotex v Sanofi-Synthelabo Canada* 2008 CSC 61[*Sanofi*]. The SCC cited Justice Judson's words in *Commissionner of Patents v Farbwerke Hoechest Aktiengesellschaft Vormals Meister Lucius & Bruning*, [1964] SCR 49 at 57 that "There is no inherent common law right to a patent. An inventor gets his patent according to the terms of the Patent Act, no more and no less" (*Sanofi* para 12). The SCC also cited Lord Walker's words in *Synthon B.V. v SmithKline Beecham plc*, [2005] UKHL 59 at paras 57–58:

> 57. The law of patents is wholly statutory, and has a surprisingly long history… In the interpretation and application of patent statutes judge-made doctrine has over the years done much to clarify the abstract generalities of the statutes and to secure uniformity in their application.
>
> 58. Nevertheless it is salutary to be reminded, from time to time, that the general concepts which are the common currency of patent lawyers are founded on a statutory text, and cannot have any other firm foundation (*Sanofi* at para12).

[29] As the patent in suit was filed after October 1, 1989, the current provisions of the Patent Act apply. The relevant sections of the Patent Act are reproduced in Annex II for ease of reading.

VI. Decision on motion to update answers given on discovery

[30] On the morning of December 10, 2019, Lilly filed a motion seeking leave to update four answers given on discovery, raising Rule 245 of the *Federal Courts Rules*, SOR/98-106: They relate to items 421 Q 1030, 433 Q 1052, 441 Q 1107, and 722A Q 2969.

[31] The motion was argued on December 13, 2019 and on December 16, 2019, I requested additional submissions on the prejudice the Defendants alleged they would suffer in the event that the motion to update answers given on discovery was granted (transcript of December 16, 2019 at page 1). I granted Lilly's motion with short reasons to follow which I now give.

[32] I granted the motion on the basis that it would not be in the best interests of justice to deny the update because there was no compelling evidence suggesting that Lilly lacked diligence in answering discovery questions, and importantly, the Defendants had not established any prejudice (*Apotex v Astrazeneca*, 2012 FC 559 at paras 22–23, aff'd 2013 FCA 77). Despite having been granted the opportunity to do so, the Defendants did not state which witnesses they would need to re-examine for discovery, nor how their expert depositions would have been different, or how the trial would be impacted.

VII. Issue estoppel and judicial comity

A. *Introduction*

[33] As per the statement of issues, the Court must determine if Lilly are estopped against re litigating Justice de Montigny's findings in *Eli Lilly Canada Inc v Mylan Pharmaceuticals ULC*, 2015 FC 125 [the 684 Patent NOC decision] due to issue estoppel, collateral estoppel, comity and/or abuse of process. In their Closing Memorandum, the Defendants argue there is no legal justification to depart from the conclusions of Justice de Montigny based on the legal principles of issue estoppel and judicial comity.

B. *The 684 Patent NOC decision*

[34] The 684 Patent NOC decision followed Eli Lilly Canada's application for an order to prohibit the issuance of a NOC to Mylan for a generic version of tadalafil until the expiry of the 684 Patent (subsection 55.2(4) of the Patent Act and section 6 of the *Patented Medicines (Notice of Compliance) Regulations,* SOR 93-133).

[35] Mylan, the sole defendant, had then argued that if the 684 Patent were construed as a selection of the 784 Patent, the promised utility was neither demonstrated nor soundly predicted at the filing date, mainly because of the ongoing and serious problem of nitrate interaction. It added that, if the 684 Patent were not construed as a selection patent, it would fail for obviousness and anticipation, based on the 784 Patent, because the dose ranges of the 684 Patent fall entirely within those disclosed in the 784 Patent, and it would have been obvious to test lower doses.

[36] Justice de Montigny declined to issue the order sought by Eli Lilly Canada, and found the allegations of invalidity justified, in that the 684 Patent lacked utility, was anticipated by the 784 Patent and was obvious.

[37] In regards to the person skilled in the art (PSA), Justice de Montigny found the patent to be directed to a person or a drug development team having expertise in areas that are relevant to drug dosing, such as pharmacology and or pharmacokinetics, physiology, dose ranging and safety assessment of candidate therapeutics and with experience in the treatment of ED. This

team could include physicians, clinicians, research scientists, pharmacologists, toxicologists and statisticians, with at least a couple of years of experience working in a drug development environment in academia or in the pharmaceutical industry.

[38] Justice de Montigny analysed the patent's utility by reverting to the promise doctrine, since then abolished by the SCC in *AstraZeneca Canada Inc v Apotex Inc*, 2017 SCC 36 [*AstraZeneca SCC*]. He found the reduced side effect profile was not part of the claimed invention, but was merely a result of the invention (at para 148).

[39] Justice de Montigny acknowledged the fact that the only way for Eli Lilly Canada to avoid a finding of anticipation was to construe the 684 Patent as a selection, provided the improvement of tadalafil over sildenafil would be determined peculiar to the claimed dose range. He reviewed the three conditions set forth in *In re Farbenindustrie AG's Patents* (1930), 47 RPC 289 (ChD), [*IG Farbenindustrie*] adopted by the SCC in *Sanofi*, and found that the third condition was not satisfied (at paras 104–105). Justice de Montigny concluded that the 684 Patent could not be a selection of the 784 Patent as "there is nothing in the specification (let alone the claims themselves) to the effect that the promised advantage is peculiar to this particular dosage to the exclusion of any other unit dose", nor does it "assert that a larger number of unselected doses do not possess the same advantage", which is an essential characteristic of a selection patent.

[40] On the co-administration of tadalafil and nitrates, Justice de Montigny concluded that Eli Lilly Canada had not demonstrated that doses of 1mg to 20mg of tadalafil had any improvement

over sildenafil, that a sound prediction existed that a unit dose of 1mg to 20mg (at para 140) of tadalafil would provide an improvement in the nitrate interaction over sildenafil, nor that as of the time of the decision, there was such improvement.

[41] Justice de Montigny concluded that the 684 Patent was indeed anticipated by the 784 Patent. He cited section 28.2 of the Patent Act, and outlined that a patent is invalid if the essential elements of the claims were disclosed in such a manner that they became available to the public more than one year before the filing date, and were enabled to a skilled person (*Eli Lilly Canada v Novopharm Limited*, 2010 FCA 197 at paras 43–45 [*Novopharm FCA*]). Citing the SCC in *Sanofi* at paras 32 and 37 and Justice Hughes in *Abbott Laboratoties v Canada (Minister of health)*, 2008 FC 1359 at para 75, Justice de Montigny ultimately concluded that all of the essential elements of the 684 Patent were disclosed by the 784 Patent, and that the 784 Patent provided the skilled person with enough information to perform the invention claimed in the 684 Patent without undue burden.

[42] Justice de Montigny determined that a maximum daily dose of 20mg was not an essential element of the claims of the 684 Patent. He based his finding both on the reading of the claims and disclosure, and on the Canadian prosecution history (file wrapper) of the 684 Patent where, following an objection on the basis of non patentable subject-matter, the applicant removed the reference to a maximum daily dose in order to have its patent approved.

[43] Regarding obviousness, Justice de Montigny framed the issue as whether it would have been obvious for the PSA that unit dosage form of tadalafil between 2 and 20mg, or more

precisely between 2.5 and 5mg as asserted, would effectively treat ED. He found that it was more or less self evident that the lower and narrower doses of tadalafil in the 684 Patent would be effective in treating ED in humans and would result in a reduced side effect profile, and that the 684 Patent was obvious.

[44] Justice de Montigny also concluded that: (1) there is no question that sildenafil, as the only approved oral ED medication, would have guided the direction of research with regard to future ED medications acting through PDE5 inhibition; (2) it would be an overstatement to claim that there were an infinite number of predictable solutions, or that it was a long and arduous process involving the design and execution of complex clinical studies and the analysis of massive volumes of data resulting from those studies for a number of reasons he outlined; (3) a skilled person would likely have started the studies with doses of around 5mg and moved up to 50mg; and (4) the actual course of conduct did not establish otherwise.

C. *Decision on issue estoppel and judicial comity*

[45] The Defendants argue that issue estoppel applies to a number of discrete issues regarding which Lilly has failed to adduce "significant and important new evidence or argumentation" (*Apotex v Pfizer Ireland*, 2011 FCA 77 at para 25). They also argue that judicial comity applies to prevent this Court to decide the same legal issues, already decided by Justice de Montigny as there has been no demonstration that his legal determination were "manifestly wrong".

[46] Lilly submit they are not estopped from re litigating the findings of the 684 Patent NOC decision due to issue estoppel, collateral estoppel, comity and-or abuse of process. According to

Lilly, the Defendants' argument must fail because PM (NOC) applications are summary proceedings, not actions, and only seek to prohibit the Minister of Health from issuing a NOC, as opposed to an *in rem* finding of infringement or validity. Lilly submit that the test for issue estoppel is not met here, that infringement actions are not abuses of process even though applications were decided on those patents under the old NOC Regulations, and that comity does not apply between NOC proceedings and a subsequent action for infringement and impeachment.

[47] I note that the evidence adduced before Justice de Montigny and the one adduced before this Court is different, and that he heard no *viva voce* testimony (*Sanofi-Aventis Canada v Apotex Inc*, 2009 FC 676, aff'd 2011 FCA 300). I also note that, before Justice de Montigny, the asserted claims were slightly different, and that Mylan argued that the 684 Patent was a selection while Eli Lilly Canada took no position in this regard. In this Court, Lilly now assert that the 684 Patent is a selection, while the Defendants now argue it is not. Finally, two legal principles have changed since Justice de Montigny's decision, as the promise doctrine was abolished by the SCC and section 53.1 of the Patent Act was adopted.

[48] In regards to issue estoppel, I agree with Lilly's position that the Defendants' allegations of issue estoppel do not apply given the circumstances at hand. However, and in any event, I need not consider this issue further as I agree with Justice de Montigny's conclusions on the issues that are common to our cases. Also, given my agreement on his analysis of the relevant common questions of law, I need not consider the deference I might have accorded his analysis (*Biovail Corporation v Canada (Minister of National Health and Welfare*), 2006 FC 784 at para 8).

I. Burden of proof

[49] Lilly bear the burden to prove, on a balance of probabilities, infringement of the asserted Claims of the 684 Patent, while the Defendants bear the burden to prove, on a balance of probabilities, their invalidity.

II. Lilly's fact witnesses

A. *Dr. Karl Donn*

[50] Dr. Donn joined Glaxo in 1987. He is the former Product Development Leader, led a group that was responsible for development of all early human testing of compounds that came out of Glaxo US Discovery, and at the time of his retirement he was the Global Vice President of Project and Portfolio Management. He holds undergraduate degrees in chemistry and pharmacy and a Master and PhD in pharmacy.

[51] In 1991, Glaxo and ICOS signed a research agreement, and in 1995, Dr. Donn became involved in the tadalafil project until early 1997. The compound was known as GF 196960X at Glaxo, and as IC351 at ICOS. Dr. Donn led the team of cross-functional experts and was accountable to the committee that oversaw the development of all early stage compounds at Glaxo. His role was to integrate all the work that was being done on the project and to drive it forward as rapidly as possible.

[52] Dr. Donn testified essentially on the usual drug development process, the purpose for which the drug is being developed, the dosage, the preclinical studies and toxicity issues encountered, the healthy young and elderly male study, the termination of the Glaxo program, the guinea pigs test, and the knowledge the team had on sildenafil.

[53] Dr. Donn was overall a credible witness. However, there were slight discrepancies and gaps in his testimony, likely due to the passage of time.

[54] In particular, Dr. Donn failed to explain why, from early on in the tadalafil development process, the document GF 196960X Summary Exploratory Development Meeting of August 19, 1996 (Exhibit 22) indicated that "thus in man, 10mg, rather than 100mg, was found to exceed the estimated EC50 for 12h and 25 mg for 24h", and that "25mg, therefore, seemed to be the most likely therapeutic dose in man, at least for cardiovascular indications where a 24-hour cover would be required". This is a caveat in Lilly's invention story.

B. *Dr. Kenneth Ferguson*

[55] Dr. Ferguson joined ICOS in 1990. When ICOS signed a research agreement with Glaxo, he was called upon to lead the product development team at ICOS and act as the principal correspondent with Glaxo. Dr. Ferguson became the product development team leader for what became known as tadalafil and led the work on a PDE5 inhibitor. He holds a BSc, and a PhD in pharmacology, and completed a postdoctoral fellowship.

[56] He testified essentially on his experience prior to the development of tadalafil, on the dosage choices, on the termination of the research agreement between ICOS and Glaxo as of January 1997, on the investigative brochure submitted to the US Food and Drug Administration (FDA), on US Patent 2003/0144296, where the DSD04 and DSD06 studies were cited, and on the low 2mg doses. Dr. Ferguson wrote in Exhibit 44 as author of a journal article that the low 2mg doses as in the DSD06 study had no effect. Dr. Ferguson recalled that it was a team that selected the dose for the DSD04 and DSD06, studies, without giving any specifics.

[57] Dr. Ferguson was a credible witness.

C. *Dr. William Ernest Pullman*

[58] Dr. Pullman is a named inventor of the 684 Patent. He is a medical doctor specialised in Internal Medicine Gastroenterology, has a BSc in Medical Science, and undertook PhD training at the Australian National University and the London Imperial Cancer Research Institute.

[59] In 1995, he joined Lilly as a Regional Medical Doctor. Sometime in 1998, he was called upon to work on the due-diligence team of the development of tadalafil in a joint venture between Lilly and ICOS in Indianapolis. He was the Director of medical affairs at Lilly ICOS until June 2001.

[60] Dr. Pullman testified essentially on his past experiences, on dosages, on nitrates interactions, on flushing, on his involvement with sildenafil, on the halting of clinical trials by the FDA, on his contribution to DSD06 and DSD04 and on female sexual dysfunction.

> Although he was a credible witness, Dr. Pullman did not remember some of the details or did not have the details, especially on the dose selection of the DSD04 study. As a result, there still remained gaps in Lilly's invention story, similar as found by Justice de Montigny in the 684 Patent NOC decision at para 171.

III. Expert witnesses

A. *Defendants' expert witnesses*

(1) Dr. Sharon Baughman

[61] Dr. Baughman is an expert in the field of pre-clinical and clinical pharmacology including the pharmacokinetics and pharmacodynamics and metabolism of small molecule entities, the design, conduct, analysis and reporting of non-clinical and clinical studies and PK/PD modelling and dose selection. She received a PhD in Physical Organic Chemistry and BSc in Chemistry.

[62] Dr. Baughman was tendered as a expert witness in the field of preclinical and clinical pharmacology, including the pharmacokinetics, pharmacodynamics, and metabolism of protein and small molecule entities; the design, conduct, analysis, and reporting of nonclinical and clinical studies; and PK/PD modelling and dose selection. She submitted a report dated August 29, 2019 (Exhibit 69), in which she outlined how she would proceed onto the selection of doses with the tests and research results contained in Glaxo, ICOS, Lilly documents given by counsels.

[63] Lilly objected to the admissibility of her expert deposition on the basis that she had no experiences in small molecules drug development. I dismiss the objection as in any event,

Dr. Baughman confirmed she did have experience working with pharmaceutical proteins, and later, pharmaceutical small molecules.

[64] I have considered Lilly's comments that Dr. Baughman was not really blinded and I am satisfied she indicated accurately the circumstances of her opinion.

[65] I found Dr. Baughman to be direct, straightforward and engaging. She came across as independent, honest and thorough. I give her opinion much weight.

(2) Dr. Peter Ellis

[66] Dr. Ellis is a pharmacologist and expert with more than 35 years of drug development experience. He holds a BSc and a PhD in in pharmacology. He was part of the Pfizer Central Research team between 1981 and 2009 that discovered and developed the sildenafil molecule. Since 2009, he was Director of Pentropy Consulting Limited, providing drug development support to the pharmaceutical industry.

[67] Dr. Ellis was tendered as an expert witness in the fields of the discovery and development of drugs. This includes drugs used in the treatment of urological conditions, such as PDE5 inhibitors used to treat male erectile dysfunction (MED), preclinical and clinical pharmacology and dose selection for drugs, including the development, design, conduct, analysis, and reporting of preclinical and clinical pharmacology and dosing studies.

[68] He produced a main Expert Report, a Responding Report, and a Reply Report, dated respectively August 28, 2019, October 30, 2019, and November 25, 2019 (Exhibits 71–73).

[69] Lilly attack Dr. Ellis' expert deposition on the basis that he was an argumentative witness on the stand, unable to answer simple questions without advocating for the Defendants. Lilly also argue that he placed the level of knowledge of the PSA at an excessively high level, and his evidence lacked credibility. As a whole, I found Dr. Ellis was a credible and nuanced witness.

(3) Dr. Wayne Hellstrom

[70] Dr. Hellstrom holds a BSc in physiology and has a doctor of medicine and master of surgery degree from McGill. He was a general surgery resident at the Montreal General Hospital and Royal Victoria Hospital before moving on to become a Resident and Chief Resident in Urology at the University of California San Francisco. He was also a fellow in andrology at the University of California Davis. He has been teaching at Tulane University since 1988 and he combines his academic duties with clinical practice, research and publication. He is board certified in urology.

[71] He was tendered as an expert in the field of urology and male sexual dysfunction disorders, including the physiology of the penis and mechanism of action of penile erection, with physiology, diagnosis and treatment of ED, and the design, conduct, analysis and reporting of clinical studies in the field of ED.

[72] He provided an Expert Report dated August 29, 2019 (Exhibit 75). Broadly summarized, he was retained to give his opinion on the efficacy and tolerability of tadalafil versus sildenafil and on the utility of the 684 Patent if the claims are construed as having a higher threshold of utility.

[73] I find that Dr. Hellstrom is a nuanced, detailed, and credible witness.

B. *Lilly's expert witnesses*

(1) Dr. Hartmut Derendorf

[74] Dr. Derendorf is an expert in the field of pharmacokinetics and drug dosing regimen development. Dr. Derendorf testified that he is presently a Distinguished Professor Emeretus in Pharmacology at the University of Florida. He was, in the past, the chair of pharmacology at that university. He holds a BSc in pharmacology and PhD in Pharmacochemistry. His work focused on pharmacokinetics and pharmacodynamics and taught these courses as well. He is member of various societies and is still involved in multiple publications including as an Associate Editor of the Journal of Clinical Pharmacology.

[75] He was tendered as an expert witness in preclinical and clinical pharmacokinetics and pharmacodynamics, as well as dose-regiment design.

[76] Dr. Derendorf submitted to the Court a Responding Report dated November 12, 2019 (Exhibit 86), where he responded to Drs. Ellis and Baughman.

[77] The Defendants attack the compellingness of various part of Dr. Derendorf's testimony and report. Dr. Derendorf's Responding Report contained references to the US patent and institutions.

[78] Dr. Derendorf acknowledged that he was not aware that the Canadian Patent Office required the removal of the dose per day because it encroached on the skills and judgment of a medical doctor (transcript of December 17, 2019 at page 193). Dr. Derendorf was also confronted with the similarities between his Canadian Responding Report and his US reports, which was on the US equivalent of the 684 Patent. The term "daily dosing" is included in the US patent, while it is not in the Canadian one, but Dr. Derendorf nonetheless largely kept the same passages in his Canadian report. Numerous typos and mistakes specific to the US patent wording were carried over to the Canadian report. Dr. Derendorf later again reiterated that PDE5 inhibitors should only be taken at the maximum dose of one tablet per day, not more.

[79] These circumstances cast a shadow on Dr. Derendorf's report and opinions in regards to the Canadian 684 Patent. I am not convinced he completely turned his mind to the issues and concept in play in this particular litigation, and I thus give his opinion less weight.

(2) Dr. Gerald Brock

[80] Dr. Gerald Brock is a medical doctor, urologist and professor at the Schulich School of Medicine & Dentistry of the University of Western Ontario. He is professor at the Department of Surgery, Division of Urology, and at the Department of Obstetrics and Gynaecology Urogynaecology. He submitted three reports to the Court: Infringement Report on September 30,

2019 (Exhibit 90), Responding Validity Report on November 20, 2019 (Exhibit 91), and a Reply Infringement Report on November 22, 2019 (Exhibit 92).

[81] He was tendered as an expert witness in sexual medicine, PDE5 physiology, diagnostic and therapeutic treatments for MED. He had further expertise in the use of animal models, and clinical development in the conduct of clinical trials across a wide range of different therapeutic agents in the field of urology with a special focus on ED and PDE5 inhibitors.

[82] The Defendants do not object to Dr. Brock's expert deposition, but they attack Dr. Brock's evidence on the basis that he was biased such that he would not be even able to fulfill his most basic duty to assist the Court by providing an impartial and independent expert deposition. They take the position that the evidence should be excluded or be given little to no weight. To support their assertion, they point to the fact that (1) Dr. Brock was himself involved in the development of tadalafil, including being present at the press conference of tadalafil's official launch organized by Lilly; (2) he published papers with the listed inventors of the 684 Patent, Drs. Pullman and Whitaker; (3) he was paid substantial sums for consulting, testifying, and training work for Lilly; (4) he also owned Lilly's stocks during the NOC proceedings while denying his ownership in these NOC proceedings; and (5) when Dr. Brock was confronted with glaring and irreconcilable contradictions between his current and past evidence, he simply disavowed his past evidence. The Defendants also attack the compellingness of Dr. Brock's opinions on multiple occasions.

[83] Lilly argue that it is normal Dr. Brock's opinion would differ in one case to the other because he was given different legal instructions, and counsel for the Defendants were jumping from one transcript to another without giving Dr. Brock sufficient context in cross-examination.

[84] Lilly also argue that Dr. Brock's opinion cannot be given little weight. They cite *Bombardier Recreational Products Inc v Arctic Cat Inc*, 2018 FCA 172 at paras 25–27 [*Bombardier Recreational Products*] for the proposition that experts can only testify on areas of their expertise, but Dr. Brock is the only urologist opining on construction, anticipation and obviousness. They add that an urologist, according to Dr. Hellstrom, is essential on the skilled team, without whom clinical results cannot be interpreted.

[85] In *White Burgess Langille Inman v Abbott and Haliburton Co*, 2015 SCC 23 [*White Burgess*], the SCC noted that the acid test for the impartiality and independence of an expert is "whether the expert's opinion would not change regardless of which party retained him or her" (at para 32). It further cited with approval UK decisions suggesting that exclusion is only warranted when "the expert is unwilling or unable to carry out his or her primary duty to the court" by providing an independent and impartial expert deposition (at para 42). However, the mere fact "of an interest or connection will not disqualify, but it nonetheless may do so in light of the nature and extent of the interest or connection in particular circumstances" (at para 42). It finally stated that "the lack of independence and impartiality goes to the admissibility of the evidence in addition to being considered in relation to the weight to be given to the evidence if admitted" (at para 45).

[86] I concur with Justice de Montigny, writing in the 684 Patent NOC decision that "most experts in the field are consulted and remunerated by the industry, and this does not in and of itself disqualify them as experts" (at para 46).

[87] However, in these proceedings, the partiality problem is different and extends further; it is troubling how Dr. Brock admittedly changed the opinions he held namely to support the sildenafil, the 377 and the 784 Patent litigations. His contradictions touched different subject-matters and significantly touched areas helpful to Lilly, essentially in relation with the general common knowledge of a skilled person regarding bio availability, selectivity, systemic safety and tolerability (*Boolell* paper of 1996), as well as the predictable effective dose of the sildenafil, moving from 15mg to 100mg, and female sexual dysfunction.

[88] The explanations he provided remain unconvincing, and I will thus give his opinion very little weight.

[89] The fact that he is the only urologist opining on the claim construction, anticipation and obviousness has no impact on my decision. It is settled law that the opinion of an expert is to assist the Court (*White Burgess* at para 2), and does not bind the Court; *Bombardier Recreational Products* did not hold otherwise. The error of the trial judge in that case was to retain the opinion of an expert who did not have the experiences to fall within the definition of the PSA as adopted by the trial judge (*Bombardier Recreational Products* at para 30). Before the Court, in this tadalafil case, all experts have significant experiences that make them fall within the definition of the skilled team as will be determined by the Court. Although urologists are important to the

skilled team because they understand the clinical manifestations of ED, are essential for the design of clinical trials with proper endpoints and know how to interpret clinical results, there is no gap in the scientific evidence by giving little weight to Dr. Brock's evidence because Dr. Hellstrom has opined extensively on these matters when discussing utility.

IV. The 684 Patent

A. *Overview*

[90] The 684 Patent relates to the dosage of tadalafil. It is titled "Compositions Comprising Phosphodiesterase Inhibitors for the Treatment of Sexual Dysfunction". It is owned by Lilly ICOS LLC US, and its named inventors are William Ernest Pullman and John Steven Whitaker.

[91] The Patent was filed on April 26, 2000, claiming priority from US Patent 60/132,036 filed on April 30, 1999. It was published in Canada on November 9, 2000, and was issued on October 23, 2007.

[92] The patent's specification starts with the disclosure and ends with the claims.

B. *The disclosure*

[93] The disclosure is divided in 5 main sections (1) Field of the invention; (2) Background of the invention; (3) Summary of the invention; (4) Detailed description; and (5) Preparations.

[94] The Field of the invention section indicates that the invention relates to a highly selective PDE enzyme inhibitor and to its use in a pharmaceutical unit dosage form and to a PDE5 useful for the treatment of sexual dysfunction. It also states that the unit dosage is characterized by selective PDE5 inhibition, with minimization or elimination of adverse side effects resulting from inhibition of other PDEs.

[95] The Background of the invention refers to *Taher et al*. (1993) in the *Journal of Urology*, and Murray (1993) in *DN&P* for the propositions that PDE5 is the major cGMP hydrolyzing enzyme in vascular smooth muscles and in penile *corpus cavernosum* and that PDE5 is an attractive target in the treatment of sexual dysfunction. It also refers to the sildenafil pharmaceutical product, available under the trademark Viagra, marketed in doses of 25, 50 and 100mg, and to its package insert. It states that the IC_{50} for sildenafil against PDE5 has been reported as 3nM in *Drugs of the future* in 1997 and as 3.9 nM in the *International Journal of Impotence* in 1997 by Boolell. Sildenafil is described as being highly selective for PDE5 versus for PDE1, PDE2, and PDE4, but its lack of selectivity for PDE5 versus PDE6 is theorised to be the basis for abnormalities related to color vision.

[96] The section outlines that sildenafil presents significant adverse side effects, including facial flushing at the rate of 10%, and that its use is limited for patients suffering from vision abnormalities, hypertension, and most significantly, by individuals who use organic nitrates, citing a paper by Welds et al. (1999) in the *American Journal of Cardiology*. It notes that the package label for sildenafil provides strict contraindications against its use in combination with

organic nitrates, citing a paper by C.R. Conti et al. (1999) in the *American Journal of Cardiology*.

[97] The Background of the Invention also refers to the Daugan US Patent 5,859, 006, (equivalent to the Canadian 377 Patent, which is not cited in the disclosure), which discloses certain tetracyclic derivatives that are potent inhibitors of cGMP-specific PDE, or PDE5. The IC_{50} disclosed in that US Patent is reported to be in the range of 1nM to 10μM, and the oral dosage for such compounds is reported to be 0.58mg daily for a 70kg adult. Thus, unit dosage forms are reported as 0.2 to 400mg of active compound. Significant adverse side effects for the subject compound of the invention were not disclosed in the Daugan Patent. The applicants continue and indicate having discovered that one such tetracyclic derivative that can be administered in a unit that provides an effective treatment without some of the side effects associated with the presently marketed sildenafil.

[98] The section outlines that the applicant's clinical studies revealed reduced tendency to cause flushing, and clinically insignificant side effects associated with the combined effects of a PDE5 inhibitor and an organic nitrate, such that the contraindication once believed necessary for a product containing a PDE5 inhibitor is unnecessary when tadalafil is administered as a unit dose of about 1 to about 20mg.

[99] The Summary of the invention section outlines namely that the invention provides a pharmaceutical dosage form for human pharmaceutical use, comprising about 1 to about 20mg of the compound in a unit dosage form suitable for oral administration. It adds that the invention

comprises administering to a patient in need thereof an oral dosage form containing about 1 to about 20mg of a selective PDE5 inhibitor, as needed, up to a total dose of 20mg per day, for the treatment of sexual dysfunction.

[100] The Detailed description section provides a definition for a number of terms among which vision abnormalities and flushing. It outlines a number of details pertaining to the package insert, that provides a description of how to administer a pharmaceutical product, and in this case, indicates that compound I is useful in the treatment of conditions wherein inhibition of PDE5 is desired. The package insert also provides instructions to administer one or more about 1 to about 20mg unit dosage forms as needed, up to a maximum total dose of 20mg per day. Preferably, the dose administered is about 5 to about 20mg/day, and more preferably about 5 to about 15mg/day. Most preferably, a 10mg dosage form is administered once per day.

[101] It outlines that the package insert preferably is free of contraindications associated with these conditions, and particularly the administration of the dosage form with an organic nitrate, and that (…) preferably, the package insert is free of any caution associated with retinal diseases, particularly *retinis pigmentosa*, and associated with individuals prone to vision abnormalities.

[102] The Detailed description outlines that the invention is based on detailed experiments and clinical trials, and that the unexpected observations that side effects previously believed to be indicative of PDE5 inhibition can be reduced to clinically insignificant levels by the selection of a compound and unit dose. These side effects include facial flushing, vision abnormalities and a significant decrease in blood pressure when compound 1 is administered alone or in combination

with an organic nitrate. It specifically compares itself with sildenafil in regards to administration in conjunction with organic nitrates.

[103] The Preparations section outlines four preparations, and IC_{50} determinations, *ie* potency, and proceeds to present seven examples to further illustrate the preparation of the claimed invention. It states that the scope of the invention is not to be construed as merely consisting of these seven examples.

[104] Examples 1 to 4 pertain to preparation of formulations, and examples 5, 6 and 7 relate to clinical studies.

[105] Example 5 discloses a randomized, double blind placebo controlled, two way crossover design clinical pharmacology drug interaction study (internally known as the LVAB study in Exhibit 35, conducted by ICOS in between January and February 1999, part of the phase 1 clinical trial) that evaluated the hemodynamic effects of concomitant administration of selective PDE5 inhibitor and short acting nitrates on healthy male volunteers. The subjects received either compound 1 at doses of 10mg or a placebo daily for seven days and, on the sixth or seventh day, received sublingual nitroglycerin while supine on a tilt table. In a preliminary analysis of this study, compound 1 was well tolerated and there were no serious adverse events.

[106] Example 6 includes two randomized double blinded placebo controlled studies (internally known as the DSD04 in Exhibit 31 and DSD06 in Exhibit 32, conducted by ICOS respectively from May 8 to October 7, 1998, and from September 4 to December 7, 1998 as part of phase 2

clinical trial), compound 1 was administered to patients in need, and doses from 5 to 20 mg were efficacious and demonstrated less than 1% flushing and no repots of vision abnormalities. The 10mg dose of Compound 1 was fully efficacious and demonstrated minimal side effects.

[107] Example 7 discloses a randomized double blind, placebo controlled study (internally known as the LVAC and DSD08 in Exhibit 34 by ICOS in April 22 to August 6, 1999) of compound 1 administered on demand to patients with male erectile dysfunction, 212 men at least 18 years of age. Compound 1 was administered in 2mg, 5mg, 10mg and 25mg on demand and not more than once every 24 hours. Co administration with nitrate was not allowed. Efficacy was evaluated based on the International Index of Erectile Function (IIEF), and overall, the study demonstrated that all four doses of compound 1 namely 2mg, 5mg, 10mg and 25mg taken on demand produced significant improvement. The most commonly reported adverse events were headache, dyspepsia, and back pain. The incidence of treatment emergent adverse events appeared related to dose.

[108] The disclosure ends with a section outlining the combined results from clinical studies, in two tables.

[109] The first table illustrates that the combined results from clinical studies showed that administration of compound (1), *ie* tadalafil, in doses from placebo to 100mg effectively treats MED. The table is titled *IIEF Erectile Function Domain (Change from Baseline)*.

[110] The second table illustrates that it was observed from the combined clinical studies that the percent of treatment-emergent adverse events increased with an increasing unit dose of Compound (1). The table is titled *Treatment-Emergent Adverse Events (%)*. It lists nine events on the vertical axe, and seven unit doses of compound (1) in mg on the horizontal axe, *i.e.* placebo, 2mg, 5mg, 10mg, 25mg, 50mg 100mg. It thus provides the percentage of adverse effects for each events, at each doses.

[111] In regards to flushing, the placebo, the 2mg and the 5mg each shows 0% of adverse flushing events; the 10mg shows fewer than 1%; the 25mg shows again 0%, the 50mg shows 3% and the 100mg shows 7% of adverse events.

[112] Below this second table, the patentee acknowledges that even though efficacy was observed at 25mg to 100mg, the adverse events observed from 25mg to 100mg doses must be considered.

[113] The penultimate paragraph of the disclosure states that “In accordance with the present invention, a unit dose of about 1 to about 20mg, preferably about 2 to about 20mg, more preferably about 5 to about 20mg, and most preferably about 5 to about 15mg of compound 1, administered up to a maximum of 20mg per 24 hour period both effectively treats ED and minimizes or eliminates the occurrence of adverse side effects. Importantly, no vision abnormalities were reported and flushing was essentially eliminated.”

[114] The last paragraph informs the reader that "Variations and changes may be made by those skilled in the art without departing from the spirit of the invention".

C. *The claims*

[115] The 684 Patent's specifications end with eighteen claims, and Lilly is asserting Claim 10 (as it depends on Claim 9, as it in turn depends on Claims 3–6), and Claims 13–16. The text of the claims is reproduced in Annex I.

V. Not a selection patent

[116] Lilly's position in asserting whether the 684 Patent is a selection of the 784 Patent seemed like a moving target even until their oral closing arguments. At trial, in their oral opening statement, Lilly confirmed their position that the 684 Patent (2 to 20mg asserted dose range) is a selection of the 784 Patent (0.2 to 400mg dose range). They asserted that the 684 Patent is a selection and that "(…) the essence of this invention is the disclosure talks about you have efficacy with minimal side effects. You have reduced side effects. You have better side effects than sildenafil (...) but the ones that are most important are facial flushing, the vision side effects, and side effects associated with the combined effects of the, of a PDE5 inhibitor and an organic nitrate" (transcript of December 5, 2019 at page 56 lines 2 to 10). They also asserted that the advantage was the surprising efficacy at low dose with the improved side effects profile that gets worse above 20mg (transcript of December 5, 2019 at page 86 lines 12–14 and 20–28).

[117] In their written Closing Memorandum, Lilly outlined the principles of selection without detailing how the 684 Patent actually qualifies as a selection of the 784 Patent. However, under their novelty argument, they asserted that "Tadalafil is a subset of the compounds disclosed in the 784 Patent and the doses and dose ranges claimed in the asserted claims of the 684 Patent are subsets of the dosage ranges set out in the 784 Patent. Therefore the subject-matter of the asserted claims are a subset of what is disclosed in the 784 Patent. This means that the 684 Patent is a selection patent" (Lilly Closing Memorandum at para 120). Lilly presented the special advantages of the 684 Patent as "the surprising efficacy at low doses with an improved side effects profile, including clear data showing flushing to be reduced in the claimed dosages ranges, as described in the 684 Patent" (Lilly Closing Memorandum at para 122). In the inventiveness section of their Closing Memorandum, Lilly outlined the link between the advantages of the selection and the inventiveness inquiry (see for example at paras 147, 154). They described the inventive concept of the claims of the 684 Patent as the surprising efficacy "with a minimization of side effects as compared to VIAGRA sildenafil" (Lilly Closing Memorandum at para 168). They also indicated that, with respect to 2.5mg and 5mg doses, there was an additional advantage over the 784 Patent, namely that these dosages permit daily dosing (Lilly Closing Memorandum at para 170, Dr. Brock Validity Report at paras 156–157).

[118] Ultimately, Lilly attempted to confirm their final position during their oral closing arguments. They argued that the unexpected advantage of the subset over the genus is "what the patent said, essentially eliminating the flushing" (transcript of February 4, 2020 at page 61 lines 27–28). They also indicated that "In our case, it is the surprising efficacy that it worked so well at the low doses was surprising, in combination with essentially eliminating flushing" (transcript

of February 4, 2020 at page 62 lines 15–17). In essence, in their oral closing argument, Lilly thus eliminated the side effects comparison with sildenafil, and limited the better side effects profile to that of flushing.

[119] However, there remain some uncertainly. When discussing the inventive concept, Lilly cited their experts for the proposition that the inventive concept of the 684 Patent dosage subset was that, surprisingly, low doses of tadalafil as claimed are effective in treating ED with a minimizing of side effects *as compared to Viagra sildenafil*, and narrowed the side effects to one, the flushing (transcript of February 4, 2020 at page 115 lines 17–27).

[120] So, in order to avoid any misunderstanding, I will examine each of the two subsets last presented by Lilly in support of their allegation that the 684 Patent is a selection. The first is the better flushing profile of the 684 Patent subset against the wider range of the 784 Patent as compared with sildenafil, and the second is the better flushing profile of the 684 Patent against only the wider range of the 784 Patent.

[121] Regarding a selection patent's disclosing requirement, Lilly acknowledge that one must be able to identify the genus in the alleged selection patent. Lilly submit that the 784 Patent is properly disclosed as the genus in the 684 Patent, although it is not named, because the 684 talks about the ranges. Lilly submit that it was not possible for the patentee to refer to the 784 Patent as the genus in the 684 Patent, as the 784 Patent had not yet been issued. They assert that, in any event, the ranges of the 784 Patent were disclosed in the 684 Patent although it carried a typographical error in one instance (transcript of February 4, 2020 at page 72).

[122] The Defendants argue that the 684 Patent is not a selection of the 784 Patent under either of Lilly's arguments. First, the better than sildenafil flushing side effect of the 684 Patent is not a substantial advantage of the peculiar doses over the 784 Patent, as even at 100mg, tadalafil is still better than sildenafil. They argue that this argument fails on each of the three conditions of the test because (1) it does not disclose a species of dosage ranges that offer substantial advantages; (2) it does not lay claim to a range of dosages wherein all of the independent dosages deliver a substantial advantage; and (3) there is no statement in the 684 Patent that members outside of the class of claimed dosages would not deliver the same benefits as do the dosages within the range (Defendants Closing Memorandum at page 3). On the second subset, the flushing compared to other doses of tadalafil, the Defendants assert that it is simply not what the 684 Patent is about.

[123] The Defendants cite para 114 of the SCC's decision in *Sanofi*, and stress that it is necessary for the specification to define in clear terms the nature of the characteristics which the patentee alleges to be possessed by the selection for which he claims a monopoly. The Defendants add that failure to disclose the genus from which the selection is made, coupled with advantages or the avoidance of disadvantages amounts to a violation of the sufficiency requirements. They stress that the 684 Patent refers to the 377 Patent, but does not refer at all to the 784 Application, which was published in 1997, more than 2 years before the 684 Application was filed.

[124] As Lilly point out, a selection patent is, by definition, measured against a previous genius patent. In general terms, a selection patent is one whose subject-matter is a fraction of a larger known class which was the subject-matter of a prior patent (*Sanofi* at para 1). A selection patent

claims a subset of a genus patent that has an unexpected advantage over the genus patent. A selection patent can be claimed for a selection from a class of thousands or for a selection of one out of two.

[125] Simply stated, the originating (or genus) patent typically refers, in general terms, to a group of products or processes from all of which a particular result (or results) may be obtained or predicted. If a property, quality or use in relation to one or more members of the genus is subsequently discovered, that discovery may be an invention giving rise to a valid selection patent. As explained in *Pfizer Canada Inc v Canada (Minister of Health)*, 2006 FCA 214 and *Sanofi*, selection patents exist to encourage researchers to further use their inventive skills so as to discover new advantages for compounds within the known class (*Novopharm FCA* at para 20). In the case of a selection patent, the inventor "selects only a bit of the subject-matter of the original genus patent because that bit does something better from what was claimed in the genus patent" (*Novopharm FCA* at para 66).

[126] Being an improper selection patent by itself is not a ground for invalidity, but the determination of whether or not a patent is a selection will inform the analysis into each of the grounds of alleged invalidity. The notion of selection permeates the entire analysis in relation to each of the grounds of alleged invalidity (*Novopharm FCA* at para 32).

[127] In *Sanofi* , Justice Rothstein found *I. G. Farbenindustrie* to be a useful starting point for the analysis as to whether a patent is a selection (*Sanofi* at para 11). In undertaking an analysis of

novelty, obviousness, sufficiency and utility, one should know the nature of the beast with which one is dealing (*Novopharm FCA* at para 28).

[128] As the Defendants point out, the determination that a patent is not a selection patent has consequences, as the purported advantages relied upon by the patentee, if not in the claims, may not be considered in the assessment of novelty and inventiveness, as examined later on.

[129] The conditions to identify a selection patent are outlined in *Sanofi* at para 10, referring to the ones set in *IG Farbenindustrie* at 322–323:

> 1. There must be a substantial advantage to be secured or disadvantage to be avoided by the use of the selected members.
>
> 2. The whole of the selected members (subject to "a few exceptions here and there") possess the advantage in question.
>
> 3. The selection must be in respect of a quality of a special character peculiar to the selected group. If further research revealed a small number of unselected compounds possessing the same advantage, that would not invalidate the selection patent. However, if research showed that a larger number of unselected compounds possessed the same advantage, the quality of the compound claimed in the selection patent would not be of a special character.

[130] As Lilly also points out, the Court in *IG Farbeindustrie* offered clarification of the third factor (Lilly Closing Memorandum at para 104):

> The third proposition requires a little explanation. If there are five thousand possible members of the group, and a hundred have been selected as possessing some new and definite advantage, it is not intended to assert that such a selection patent would be bad if it were shown as the result of further research that there existed another hundred members possessing the same advantage. If, on

> the other hand, it were to be established that there were a thousand unselected members which possessed the same advantage, I doubt very much whether the patent could be sustained. The quality must be of a special character. It must not be one which those skilled in the art will expect to find in a large number of the members. It would be rash to attempt a closer definition; for the question is ultimately one of appreciation. Returning to the same old fashioned metaphor I would say that the citadel must be defended, and that there is no reward if the gates have been opened at the first blast of the trumpet.

[131] Based on the law governing the determination of a selection patent, Lilly has not convinced me that the 684 Patent meets the conditions and can be considered a selection patent. I note first that the 684 Patent, filed in 2000, makes no mention of the 784 Application, published in 1997.

[132] More importantly, in regards to Lilly's argument that the substantial advantage of the 684 Patent lies in the better than sildenafil flushing side effect at 2 to 20mg, I conclude that there is nothing in the specification, or the claims themselves, to the effect that the advantage is peculiar to this particular dosage to the exclusion of any other unit dose, nor does it assert that a larger number of unselected doses do not possess the same advantage, which is an essential characteristic of a selection patent. My conclusion is similar to that of Justice de Montigny in the 684 Patent NOC decision.

[133] The Table in the 684 Patent shows a percentage of treated people experiencing flushing, up to 100mg dose. At the 100mg dose, tadalafil's percentage is still lower than sildenafil's recognised 10% rate. Lilly has not adduced evidence of the facial flushing rates for doses over 100mg. There is no indication regarding the number, or ranges, of doses of the 784 Patent that do

not present the facial flushing advantage. I am cognizant of the clarification set by *IG Farbenindustrie* and cited by Lilly in regards to the third factor. However, no evidence was adduced to demonstrate that there exists only but a small number (in *IG Farbenindustrie*, the judge refers to "another hundred out of five thousand") of the possible doses of the 784 Patent that possess the same advantage as the dosage claimed by the 684 Patent. At the minimum, we know that the dose range starting over 20mg, and going up to 100mg still present the flushing advantage. This is already a bigger proportion that the one proposed by the judge in *IG Farbenindustrie*.

[134] Based on the evidence adduced before me, I reach the same conclusion as Justice de Montigny that the third condition in *IG Farbenindustrie* has not been met.

[135] In regards to Lilly's argument that the substantial advantage of the 684 Patent lies in the better or elimination of the flushing side effect at 2 to 20mg, I agree with the Defendants that this is not what the patent is about, nor claimed as the invention, nor specifically described as being the invention in the disclosure of the 684 Patent. The comparison to sildenafil is part of the 684 Patent, and even Lilly's experts described the inventiveness of the 684 Patent as its efficacy at low doses with a better side effect profile than sildenafil (Dr. Brock Responding Validity Report at para 228). In any event, there is no evidence that this advantage is peculiar to the 2 to 20mg range.

[136] In conclusion, I find Lilly has not fulfilled its burden to establish the 684 Patent as a selection of the 784 Patent. The allegations of invalidity will consequently be considered on the basis that the 684 Patent is not a selection.

VI. Claim construction

A. *Relevant date for claim construction*

[137] The relevant date for claim construction of the 684 Patent is the date of publication, which is November 9, 2000.

B. *Law of claim construction*

(1) Introduction

[138] The content of a patent specification is regulated by subsection 27(3) of the Patent Act. The first part is the disclosure, where the patentee must "fully describe the invention and its operation or use as contemplated by the inventor", "set out clearly the various steps in a process, […] 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 it", and in the case of a process, "explain the necessary sequence, if any, of the various steps, so as to distinguish the invention from other invention". As stated in *Whirlpool Corp. v Camco Inc.* 2000 SCC 67 at para 42 [*Whirlpool*], the disclosure is the *quid* part of the bargain, provided to the inventor in exchange for the *quo* of a, now 20 year, monopoly on the exploitation of the invention.

[139] The monopoly is enforceable, and it is thus important for the public to know what is prohibited, and where they may safely go, while the patent is still in existence. The public notice function is performed by the claims at the end of the specification which must "distinctly and in explicit terms define the subject-matter of the invention for which an exclusive privilege or property is claimed" (Patent Act, subsection 27(4)).

[140] An inventor is not obliged to claim a monopoly on everything new, ingenious and useful disclosed in the specification. The usual rule is that what is not claimed is considered disclaimed (*Whirlpool* at para 42; *Monsanto Canada Inc v Schmeiser*, 2004 SCC 34 at paras 122–123). If the inventor has misspoken, or otherwise created an unnecessary or troublesome limitation in the claims, it is a self-inflicted wound (*Free World Trust* at para 51).

[141] Claims are not to be construed with extrinsic evidence with the exception of the common general knowledge that the skilled addressee already possesses. In December 2018, another exception was introduced, as section 53.1 was added to the Patent Act. It provides a limited exception to admit as evidence parts of communications between the patentee and the Patent Office during the prosecution of the patent, but only to rebut a representation by the patentee in an action (*Canmar Foods Ltd v TA Foods Ltd*, 2019 FC 1233 at para 68 [*Canmar*]).

(2) One construction for all purposes

[142] The first step in a patent suit is to construe the claims. This construction is antecedent to consideration of both validity and infringement issues and is the same for all purposes (*Free World Trust* at paras. 33-50; *Whirlpool* at paras. 42-43; *AstraZeneca SCC* at para 31).

[143] This was made clear in *Whirlpool*, where the appellants had argued that the two inquiries – validity and infringement – were distinct, and that if the principles of "purposive construction" derived from *Catnic Components Ltd v Hill & Smith Ltd*, [1982] RPC 183 (UKHL) [*Catnic*] were to be adopted, they should properly be confined to infringement issues only. The principle of "purposive construction", they argued, had no role to play in the determination of validity. The SCC rejected this argument, as accepting it could result in a different claim construction for the purpose of validity than for the purpose of infringement, contrary to the fundamental rule of claim construction that the claims receive one and the same interpretation for all purposes (*Whirlpool* at para 49).

[144] A claim cannot be construed with an eye on the allegedly infringing device in respect of infringement or with an eye to the prior art in respect of validity to avoid its effect (*Dableh v Ontario Hydro*, [1996] 3 FC 751 (FCA)).

[145] Claim construction is a matter of law for the judge. The role of the expert is not to interpret the patent claims, but to put the trial judge in the position of being able to do so in a knowledgeable way; expert evidence regarding the construction of a patent claim is permissive, but not obligatory (*Whirlpool* at para 61; *Purdue Pharma v Canada (Attorney General)* 2011 FCA 132 at para 16). Claims should be construed by the PSA, as of the date of the publication, based on his or her common general knowledge.

[146] Finally, the canons of the law of claim construction have been set by the SCC in *Consolboard Inc v MacMillan Bloedel (Saskatchewan) Ltd*, [1981] 1 SCR 504 at 520–525, *Free*

World Trust, and *Whirlpool*. Although these decisions pertained to patents governed by a previous version of the Patent Act, they do apply (see for example *Cobalt Pharmaceuticals Company v Bayer Inc*, 2015 FCA 116 [*Cobalt*]).

(3) Purposive construction: essential and non essential elements

[147] In both *Whirlpool* and *Free World Trust*, the SCC retained the purposive construction approach. By doing so, the SCC rejected the so-called "two-step" approach to patent construction, whereby courts first considered whether on a literal construction the allegedly infringing device embodied the patented invention and, if not, whether that device embodied the "pith and marrow" or "substance" of the invention (*Canamould Extrusions ltd v Driangle inc* 2004 FCA 63 para 20 [*Canamould Extrusions*]).

[148] The single-step, or purposive, approach was preferred because "the greater the level of discretion left to courts to peer below the language of the claims in search for 'the spirit of the invention', the less the claims can perform their public notice function, and the greater the resulting level of unwelcome uncertainty and unpredictability" (*Free World Trust* at para 50). That approach, as enunciated by Lord Diplock in *Catnic*, calls for a "purposive construction" of a patent. It was applied by the FCA in *Eli Lilly & Co v O'Hara Manufacturing Ltd* (1989), 26 CPR (3d) 1 (FCA).

[149] In *Whirlpool*, the SCC stated that purposive construction properly directs itself to the words of the claims interpreted knowledgeably and in the context of the specification as a whole, and advances the objective of an interpretation of the patent claims that is reasonable and fair to

both patentee and public. The SCC specified that the key to purposive construction is the identification, by the court, with the assistance of the skilled reader, of the particular words or phrases in the claims that describe what the inventor considered to be “essential” elements of his invention (at paras 49, 45).

[150] In fact, claim elements are presumed to be essential, and a party alleging otherwise bears the onus of establishing non-essentiality (*Mediatube Corp v Bell Canada*, 2017 FC 6 at para 33 [*Mediatube*]).

[151] In *Free World Trust*, the SCC provided additional guidance on how to determine essential and non-essential elements of the claims. I note that the SCC’s guidance in this regard was provided mainly while it was addressing the infringement issues, and only after it had, at paras 20–23, construed the claims. Understandably, the SCC thus provides guidance both on how to distinguish the essential from the non-essential elements as it pertains to claim construction, and on how this determination affects the infringement analysis. Those two aspects appear intertwined, and, at para 55, the SCC confirms that the elements of the invention are identified as either essential elements (where substitution of another element or omission takes the device outside the monopoly), or non-essential elements (where substitution or omission is not necessarily fatal to an allegation of infringement). Hence, if an element is construed as being essential, its substitution will take the defendant outside the realm of the monopoly, and there will be no infringement.

[152] Since the Court must construe the claim without regard to the infringement or validity issues, I will, thus for now, identify the elements of the *Free World Trust* decision that guides claim construction. Importantly, the claims language will, on a purposive construction, show that some elements of the claimed invention are essential while others are non-essential. As per paragraph 31 of *Free World Trust*, the identification of elements as essential or non-essential is to be made:

i. on the basis of the common knowledge of the worker skilled in the art to which the patent relates;

ii. as of the date the patent is published;

iii. having regard to whether or not it was obvious to the skilled reader at the time the patent was published that a variant of a particular element would *not* make a difference to the way in which the invention works; or

iv. according to the intent of the inventor, expressed or inferred from the claims, that a particular element is essential irrespective of its practical effect;

v. without, however, resort to extrinsic evidence of the inventor's intention.

[153] The SCC examined each of those five points at paragraphs 51 to 67 of the decision.

[154] As part of the exam of components iii and iv, the SCC confirmed that for an element to be considered non-essential, it must be shown either (i) that on a purposive construction of the words of the claim, it was clearly *not* intended to be essential, or (ii) that at the date of publication of the patent, the skilled addressees would have appreciated that a particular element could be substituted without affecting the working of the invention, *ie*, had the skilled worker at that time been told of both the element, specified in the claim, and the variant and “asked

whether the variant would obviously work in the same way", the answer would be yes (*Free World Trust* at para 55).

[155] The SCC referred to the decision of *Improver Corp v Remington Consumer Products Ltd*, [1990] FSR 181 (Pat Ct), and cited Justice Hoffmann, himself citing *Catnic*, and his three questions, now referred to as the *Improver* questions:

> i. Does the variant have a material effect upon the way the invention works? If yes, the variant is outside the claim. If no: –
>
> ii. Would this (i.e.: that the variant had no material effect) have been obvious at the date of publication of the patent to a reader skilled in the art? If no, the variant is outside the claim. If yes: –
>
> iii. Would the reader skilled in the art nevertheless have understood from the language of the claim that the patentee intended that strict compliance with the primary meaning was an essential requirement of the invention? If yes, the variant is outside the claim.

[156] It appears these questions have been formulated first and foremost to assist the Court identify the essential and the non-essential elements of the claims. In *Canamould Extrusions*, the FCA noted the perspective Justice Hoffmann added at page 190 of his *Improver* decision where he indicated, essentially, that the first two questions do not primarily involve construction, they provide factual background, their answers are not conclusive, and that it is the third question, related to the patentee's intention, which raises the question of construction.

[157] Justice Scott in *Hollick Solar Systems Ltd v Matrix Energy Inc*, 2011 FC 1213 at paras 54-82 and Justice Locke in *Mediatube* at paras 33–34, 52 both applied *Improver* as part of their claim construction in order to identify the essential and non essential elements.

[158] In regards to the intention of the inventor, the SCC indicated that "The courts recognize the pitfalls of language and will do what they can to give the inventor 'protection for that which he has actually in good faith invented' (*Western Electric*, supra, at p. 574), but there are limits". Citing the FCA, the SCC added that a court must interpret the claim and cannot redraft them. When an inventor stated in the claim that he considered a requirement as essential to his invention, a court cannot decide otherwise for the sole reason that he was mistaken (*Free World Trust* at paras 58–59).

(4) Purposive construction: the patentee's words

[159] Words chosen by the inventor must be read in the sense the inventor is presumed to have intended and in a way that is sympathetic to accomplishment of the inventor's purpose expressed or implicit in the text of the claims. Again, claims are to be read in an informed and purposive way with a mind willing to understand, viewed through the eyes of the person skilled in the art as of the date of publication having regard to the common general knowledge.

[160] Courts have traditionally protected a patentee from the effects of excessive literalism. It is unsafe in many instances to conclude that a term is plain and unambiguous without a careful review of the specification (*Whirlpool* at para 52). When applying a purposive construction of claims, the court must look at the specification of the patent for the meaning of a word before looking in dictionaries. A patentee is entitled to be his, her or its own lexicographer (*Kramer v Lawn Furniture Inc* (1974), 13 CPR (2d) 231 at 237 (FCTD); *Pfizer Canada v Canada (Minister of Health)*, 2005 FC 1725 at para 19; *Minerals Separation North American Corp v Noranda Mines Ltd* (1952), 15 CPR (1st) 133 at 144–145 (Priv Coun)).

[161] The patent specification "is not addressed to grammarians, etymologists or to the public generally, but to skilled individuals sufficiently versed in the art to which the patent relates to enable them, on a technical level, to appreciate the nature and description of the invention" (H. G. Fox, The Canadian Law and Practice Relating to Letters Patent for Inventions, 4th ed, (Toronto: Carswell, 1969) at 185). As per the words of Dr. Fox, The Court must place itself "in the position of some person acquainted with the surrounding circumstances as to the state of the art, and the manufacture at the time, and making itself acquainted with the technical meaning in that art or manufacture that any particular word or words may have" (*Whirlpool* at para 53). The FCA has recently cited this passage from *Whirlpool* in *AFD Petroleum Ltd v Frac Shack Inc*, 2018 FCA 140 at para 60.

[162] However, "the purposive approach is not an invitation to the Court to ignore the ordinary rules of grammar and syntax" (*ABB Technology AG v Hyundai Heavy Industries Co, Ltd*, 2015 FCA 181 at para 45, aff'g 2013 FC 947).

[163] While *Free World Trust* adopts the purposive construction approach, it also confirms that the Patent Act, as it then read, promotes adherence to the language of the claims.

[164] In a more recent decision, the FCA in *Tearlab v I-MED Pharma Inc*, 2019 FCA 179 at para 47 [*Tearlab FCA*] approved the trial judge's construction and his adherence to the words of the claims. The trial judge refused to add limitations that were not expressly included and focused on the claims without redrafting them. The FCA also reiterated that, although consideration can be given to the patent specifications to understand what was meant by the

words in the claims, one must be wary not to use these so as “to enlarge or contract the scope of the claim as written and understood” (at paras 32–34).

[165] In *Hospira Healthcare Corporation v Kennedy Trust for Rheumatology Research*, 2020 FCA 30, [*Hospira FCA*] the FCA also saw no error in the Federal Court judge’s decision to interpret the words of the claims to have their plain meaning and to look at the disclosure for assistance in their construction given the arguments raised by the appellants. In that particular case, the appellants, which were the ones sued for infringement, sought to limit ambits of the claims although the claims contained no explicit limitation, and the disclosure confirmed that there were no such limitations.

(5) Claim differentiation

[166] The concept of claim differentiation presumes that patent claims are drafted as not to be redundant and that each different claims have different scopes (Donald Cameron, *Canadian Patent Law Benchbook*, 3rd Ed, (Toronto: Thomson Reuters, 2019); *Halford v Seed Hawk Inc*, 2004 FC 88, aff'd 2006 FCA 275). The rebuttable presumption that claims are not redundant was first applied between a claim and its dependant claims (*Apotex Inc v Lundbeck Canada Inc*, 2010 FCA 320 at para 110; *Bridgeview Manufacturing Inc v 931409 Alberta Ltd (Central Alberta Hay Centre)*, 2010 FCA 188; *ViiV Healthcare Company v Gilead Sciences Canada, Inc*, 2020 FC 486 at para 56). It is now also applied in claim differentiation between independent claims (*Camso Inc v Soucy International Inc*, 2019 FC 255 at paras 103, 186–190).

[167] Claim differentiation is useful to determine whether a claim element is essential. Hence, where one claim differs from another in only a single feature, it is difficult to argue that the different feature has not been made essential to the claim (*Whirlpool* at para 79). It would be peculiar that the inventor intended for two claims to be redundant.

[168] If an essential feature of a claim is defined in a specific way and a different more expansive term is also introduced that can include the specific term, one would not generally interpret the two terms as denoting the same thing. The usual purpose of using different words is to distinguish one feature from another and not to express synonyms (*ABB Technology AG v Hyundai Heavy Industries Co Ltd*, 2013 FC 947 at para 29, aff'd 2015 FCA 181).

C. *Person skilled in the Art (PSA)*

[169] A patent is to be construed through the eyes of a person of ordinary skills in the art (PSA), who is not an inventor (*Beloit Canada Ltd v Valmet OY* (1986), 8 CPR (3d) 289 (FCA) at 294 [*Beloit*]. Multiple decisions suggested that the PSA is neither first nor last in her class but somewhere in the middle (*Merck-Frosst-Schering Pharma GP v Canada (Health)*, 2010 FC 933 at para 69; *Amgen Canada Inc* v *Apotex Inc*, 2015 FC 1261 at para 45). However, Justice Locke recently qualified the statement that the PSA is neither first nor last in her class because "the quality of inventiveness is not tied to class rank" but is concerned with "the ability to look at a problem in a way that would not be obvious to others in their field" (*Hospira* at para 80). Justice Locke added that "An inventive person may be at the bottom of the class, and a person at the top of the class may not be inventive. The same may be said of experts. Highly specialized practitioners may be leaders in their field, but may not be inventive. Conversely, inventiveness may manifest in persons with limited expertise" (*Hospira FCA* at para 80).

[170] There is very little dispute as between the parties as to the PSA in this case. Lilly emphasizes the importance of the urologist over other members of the teams, whereas the Defendants want the Court to adopt the characterization of the PSA by Justice de Montigny in the 684 Patent NOC decision.

[171] There is no reason to believe that the urologist is more important than the pharmacologist or other members on the team, as the team would not function without these other members. Therefore, the PSA is a drug development team, with expertise in pharmacology,

pharmacokinetics, physiology, dose ranging and safety assessment of candidate therapeutics, and with experience in the treatment of ED. The team could include physicians, clinicians, research scientists, pharmacologists, toxicologists and statisticians.

D. *Prior art*

[172] Prior art is "the collection of learning in the field of the patent at issue" and "comprises any publically available teaching, however obscure or not generally accepted" (*Mylan Pharmaceuticals ULC v Eli Lilly Canada Inc*, 2016 FCA 119 at para 23 [*Mylan Pharmaceuticals FCA*]).

[173] *Ciba Specialty Chemicals Water Treatments Limited's v SNF Inc*., 2017 FCA 225 at para 56 [*Ciba FCA*] confirms that state-of-the-art is simply another term for prior art. I may thus refer to either terms in these reasons. The FCA recently held that no public piece of art should be excluded from the prior art solely because it could not be located following a reasonable diligent search (*Hospira FCA* at para 86).

[174] In this case, the Defendants point to the 784 Application as the element of prior art for the allegation of invalidity on the ground of anticipation, and to the sildenafil, the tadalafil of the 377 Patent, and the 784 Application as the elements of prior art for the allegation of invalidity on the ground of obviousness.

(1) Sildenafil

[175] Sildenafil is a first in class PDE5 inhibitor drug. The Defendants rely on it for their allegation of obviousness.

[176] Upon its approval by regulators, it rapidly became the standard of care for the treatment of erectile dysfunction. It was ground-breaking because previous treatment involved injections or other forms of invasive treatment. A doctor in Canada, upon the approval of sildenafil, would receive multiple calls per day from patients requesting prescriptions and ought to have been aware of this piece of prior art. A blueprint of the testing conducted with sildenafil was widely distributed by Pfizer, revealing the whole slate of studies (preclinical and clinical studies), the doses actually tested, the potency of 3.0–3.9nM, the poor selectivity for PDE5 relative to PDE6 leading to transient vision abnormalities, the efficacy in low doses of 5 and 10mg, and the efficacy plateau in the 50–100mg range. Dr. Ellis cite some of the information from the Viagra Label (1998), and from a number of journal articles such as Boolell (1996A) & (1996B), Christiansen (1996), Gingell (1996), Olsson (1996), Terrett (1996), (Virag 1996), Bailey 1997, Dean (1997), Eardley (1998), Lue 1997, Goldstein (1997) & (1998), Ballard (1998), De Mey (1998), Goldenberg 1998, Morales (1998) that noted additional information or commented on Pfizer information. It is uncontested that these form part of the prior art, but as discussed earlier, Lilly objected that these data form part of the common general knowledge.

(2) The 377 Patent

[177] The 377 Patent is titled “Tetracyclic Derivatives, Process Of Preparation and Use”. The name inventor of the Patent is Dr. Alain Claude-Marie Daugan. The application was filed on January 19, 1995, claiming priority from UK Patent 9401090.7 filed on January 21, 1994. In Canada, it was published on July 27, 1995, and was issued in May 28, 2002.

[178] The Defendants rely upon it for their obviousness allegation. They point to the disclosure and the claims of the 377 Patent, suggesting that they are binding admissions made by Lilly. Arguing that the 377 Patent only claims tadalafil in claim 10, the Defendants indicate that this is an indication that this was the lead compound. Additionally, the Defendants emphasize that the 377 Patent discloses that the compounds are “potent and selective inhibitor of [PDE5]” and are of interest for “use in therapy, specifically for the treatment of a variety of conditions where inhibition of is thought to be beneficial” (the 377 Patent at page 6). The 377 Patent also indicate that oral dosages in tablet form for an average adult patient (70kg) should range from 0.2–400mg of active compound (the 377 Patent at page 8). The IC_{50} of tadalafil for PDE5 was measured to be 2nM and the EC_{50} was 0.2 µM in Example 95 of Table 1 (the 377 Patent at pages 74–76). The effect (blood pressure decrease) on spontaneous hypertensive rats was also observed to be 135mmHg h (Area under the curve for hours 0–5) (the 377 Patent at pages 76), which for Dr. Brock indicated in the past it means for the PSA that the compound tadalafil is bioavailable (transcript of December 19, 2019 at page 105).

[179] Lilly argue that the 377 Patent does not disclose the specific doses, and that the PSA reading the 377 Patent would expect hypotensive effects.

(3) The 784 Application

[180] The 784 Application is titled "Use of cGMP-Phosphodiesterase Inhibitors to Treat Impotence". The named inventor is Alain Claude-Marie Daugan. The 784 Application was filed on July 11, 1996, claiming priority from UK Patent 9514464.8 filed on July 14, 1995. In Canada, it was first published in February 6, 1997 and the patent issued in July 8, 2003. It is a use patent of a potent and selective inhibitor of cGMP specific PDE, which is in this case tadalafil, for the treatment of impotence.

[181] The 784 Application relates to the use of tadalafil to treat ED. The Defendants assert it both for the purposes of anticipation and obviousness, and suggest that this piece of prior art contains binding admissions on the fact that the disclosed tetracyclic derivatives are "potent and selective inhibitors" of PDE5 (the 784 Application at page 1), by elevating the cGMP levels which in turn can mediate relaxation of the *corpus cavernosum* (the 784 Application at page 4), and are useful in the treatment of erectile dysfunction in a male animal through oral administration (the 784 Application at page 4). The Defendants also point to the fact that the 784 Patent discloses methods to make tablets and tests regarding IC_{50} value for PDE5 inhibition as well as the $EC_{50.}$ It also discloses a dose range of 0.2 to 400mg for each unit dose, or 0.5 to 800mg daily for 70kg adults.

[182] Lilly respond that it does not teach the specific doses in the 684 Patent and actually teaches away from low dosage since the only dose exemplified in the 784 Application is the 50mg.

E. *Common general knowledge*

[183] Common general knowledge does not amount to all information in the public domain. Rather, common general knowledge is the knowledge generally known at the relevant time by the person skilled in the field of art or science to which the patent relates (*Bell Helicopter Textron Canada Limitée v Eurocopter, société par actions simplifiée*, 2013 FCA 219 at paras 63–65 [*Bell Helicopter Textron*]).

[184] The assessment of common general knowledge is governed by the principles found in *Eli Lilly & Co v Apotex Inc*, 2009 FC 991 at para 97 [*Eli Lilly 2009*], aff'd 2010 FCA 240, citing *General Tire & Rubber Co v Firestone Tyre & Rubber Co*, [1972] RPC 457 (UKHL) at 482–483:

> 1) Common general knowledge is distinct from what in patent law is regarded as public knowledge. Public knowledge is theoretical and includes each and every patent specification published, however unlikely to be looked at and in whatever language it is written. Common general knowledge, in contrast, is derived from a common sense approach to the question of what would be known, in fact, to an appropriately skilled person that could be found in real life, who is good at his or her job.
>
> 2) Individual patent specifications and their contents do not normally form part of the relevant common general knowledge, although there may be specifications which are so well known that they do form part of the common general knowledge, particularly in certain industries.

> 3) Common general knowledge does not necessarily include scientific papers, no matter how wide the circulation of the relevant journal or how widely read the paper. A disclosure in a scientific paper only becomes common general knowledge when it is generally known and accepted without question by the bulk of those engaged in the particular art.
>
> 4) Common general knowledge does not include what has only been written about and never, in fact, been used in a particular art.

[185] In other words, as stated in *Mylan Pharmaceuticals FCA*, "common general knowledge […] is the knowledge generally known by persons skilled in the relevant art [skilled persons] at the relevant time […]" (at para 24). Unlike the prior art, which is a broad category encompassing all previously disclosed information in the field, a piece of information only migrates into the common general knowledge if a skilled person would become aware of it and accept it as "a good basis for further action."

[186] A PSA's common general knowledge cannot be assumed; rather, it must be proven with fact evidence on a balance of probabilities. (*Eli Lilly 2009* at para 109)

[187] The relevant date for assessing common general knowledge for the purpose of claim construction is the publication date, hence November 9, 2000. However, the relevant date for assessing common general knowledge for the purpose of the obviousness and anticipation analysis is the claim date, which is April 30, 1999, and parties made their submissions as of that date.

[188] Lilly refer to section V of Dr. Derendorf's Validity Report and to sections 5 and 6 of the Dr. Brock's Validity Report for the common general knowledge of the PSA.

[189] Dr. Derendorf summarized the drug development process, including the preclinical and clinical studies, in section V of his Expert Report. He emphasized that the failure rate for chemical entities at the preclinical stage to reach the market is extremely high because notably of poor drug physicochemical activity, high toxicity, and interspecies differences in pharmacokinetic parameters. He added that even if a drug is safe, effective and tolerable in the short term in animals, it may not be so in humans for a longer term. Consequently, he indicated that no one could have reasonably predicted the dosing regimens of the drug that would be safe, tolerable and effective at the preclinical and early clinical stages. He also indicated that a wide range of pharmacokinetic parameters must be gathered through the process and criticised Dr. Ellis' opinion for overly emphasizing drug potency in dosing.

[190] Dr. Brock in sections 5 and 6 of his Validity Report discussed the background on erectile dysfunction and on the development of a pharmaceutical drug. Dr. Brock indicated that the means to measuring efficacy of an erectile dysfunction treatment must be considered before any dose determination step can begin. He mentioned that the measure of penis rigidity (Rigiscan), the global assessment question (GAQ), the erectile dysfunction inventory of treatment satisfaction questionnaire (EDITS), and sexual encounter profile diaries, as well as the IIEF questionnaire used by Pfizer for the development of sildenafil, were some of the measurements used. Before reading Rosen (2011), he opined that clinicians would not know how to properly use the IIEF questionnaire and interpret the results. Dr. Brock then also responded to Dr. Hellstrom, opining that the inhibition of PDE5 may also indirectly inhibit PDE3 through an increase of cAMP level. He also responded that the vision abnormalities side effect of sildenafil led to pilot and air traffic controller professional associations to restrict its use and that the

flushing side effect of sildenafil may be an embarrassment for the patient. Finally, regarding drug development, Dr. Brock indicated that "there is no one way to proceed in bringing a drug to market, although the ultimate information that must be provided is similar" (Dr. Brock Validity Report at para 55), and the "aim of drug development is to maximize the therapeutic benefit while minimizing the side effects and potential safety issues" (at para 108). For dose selection, he indicated that the potency, the selectivity, the absorption, the distribution, the metabolism, the elimination, and sildenafil must all be considered. He also disagreed about the determination of the minimum and maximum effective dose for every drug, considering that although it was in various guidelines, it was not mandatory. He added that Rosen (2011), which clarified some of the questions in the IIEF, was not published until 2011, and that the clinicians in different studies would set different clinical endpoints, which would lead to different dosing regimens. He also opined that the success rate in bringing a compound to market is low, and that there is no assurance that tadalafil, the second in-class drug, would bind and work the same way as the sildenafil because they are chemically different. He also indicated that on-demand dosing was used for sildenafil and was the clear approach for tadalafil, until Lilly preferred a daily dosing regimen.

[191] At trial, Dr. Brock also testified that although the IIEF questions form part of the common general knowledge, the specific questions do not. Although some journal articles form part of the common general knowledge, as well as sildenafil data, he sought to carve out the pharmacokinetics data from these documents.

[192] The Defendants submit that per ICH (known at the claim date of the 684 Patent as the International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use) guidelines, both the minimum and maximum effective doses must be identified. They refer to Dr. Ellis' Expert Report at para 36, as well as Dr. Brock who admitted at trial in T-169-13, that "[the ICH guidelines document] describes how designing studies to investigate the dose response is necessary" (transcript of December 19, 2019 at page 160). Regarding generally about dose selection, the Defendants refer to Dr. Ellis indicating that adverse events and efficacy tend to increase with dose, with at some point a therapeutic (efficacy) plateau (transcript of December 12, 2019 at page 119).

[193] The Defendants essentially agree with Lilly that the drug development process with the preclinical and three phases of clinical form part of the common general knowledge.

[194] The Defendants also ask the Court to recognize the use of PDE5 inhibitors and mechanism of action to be part of the common general knowledge (Dr. Ellis' Expert Report at para 59), as well as the IIEF questions, especially questions 3 and 4 (see also the 684 Patent at page 29). Emphasizing that the sildenafil launch was well known due to the revolutionary nature of the drug which can treat ED in a non invasive manner, the Defendants put forward the sildenafil drug development history as forming part of the common general knowledge (IC_{50} potency to fall in between 3.0–3.9nM, efficacy of sildenafil at a low 5mg dose, efficacy plateau of sildenafil at 100mg, sildenafil being offered at doses of 25, 50, 100mg, 50mg dose to be safe and effective for all men, sildenafil being well tolerated with mild and transient side effects but contraindicated against co-administration with nitrates).

[195] The parties disagree mainly on two points, hence is it common general knowledge that the PSA would seek to ascertain the minimum effective dose, and do the pharmacokinetic data and information in the journal articles and from sildenafil, as well as the specific IIEF questions form part of the common general knowledge?

[196] Having found Dr. Ellis more reliable and more compelling than Dr. Brock, I find that on general common knowledge, the skilled team would seek to identify the minimum effective dose despite the uncertainty on what is minimally effective by making a judgment call with what the team knows, and the pharmacokinetic data and the information in the journal articles and from sildenafil as well as the specific IIEF questions formed part of the common general knowledge at the relevant dates, which is the claim date, April 30, 1999, for the assessment of anticipation and obviousness, and the publication date, November 9, 2000, for claim construction.

F. *Claims needing construction*

(1) Introduction

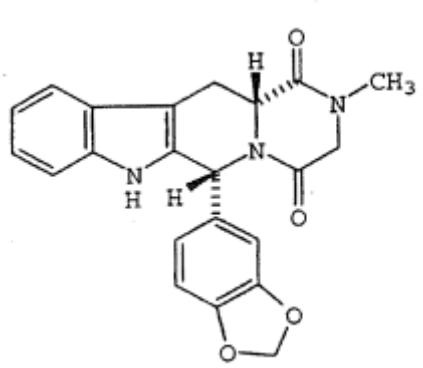
[197] As mentioned earlier, the claims needing constructions are Claim 10 (as it depends on Claim 9, as it in turn depends on Claims 3–6), and Claims 13–16. More specifically, the construction will be focused on “where the shoes pinches” (*Cobalt Pharmaceuticals Company v Bayer Inc*, 2015 FCA 116 at para 83).

(2) Construction of Claim 10 (as it depends on Claim 9, as it in turn depends on Claims 3–6)

[198] Claim 10 reads: “The dosage form of claim 9 wherein the sexual dysfunction is male erectile dysfunction.”

[199] Claim 9 reads: “The dosage form of any one of claims 1 through 6 for use in treating sexual dysfunction in a patient where inhibition of PDE5 provides a benefit.”

[200] Claims 1, 3–6 read:

> 1. A pharmaceutical unit dosage form comprising about 1 to about 20 mg of a compound having the structural formula:
>
> 
>
>
> said unit dosage form being suitable for oral administration.
>
> 3. The dosage form of claim 1 comprising about 5 to about 20 mg of the compound in unit dosage form.
>
> 4. The dosage form of claim 2 comprising about 2.5 mg of the compound in unit dosage form.
>
> 5. The dosage form of claim 3 comprising about 5 mg of the compound in unit dosage form.
>
> 6. The dosage form of claim 3 comprising about 10 mg of the compound in unit dosage form.

[201] The construction of Claim 10 is for the most part not controversial and the parties' disagreement is on whether or not a maximum daily dose or a maximum of one dose per day should be read in the claim.

[202] The parties agree that there are no words in the claims expressively limiting it to a maximum daily dose. However, Lilly's position is that Claim 10 should be read to include such a maximum of one dose per day. Since the highest dose is 20mg, Lilly argue it is limited to 20mg. Only Dr. Derendorf supports this position. Dr. Brock on the other hand, construed the claims in the prior NOC case relating to this 684 Patent to include this limitation, but was instructed not do so in this case.

[203] Dr. Derendorf relies on the common general knowledge to read in the claim a limit of one dose per day, whatever the unit dose, for the treatment of ED because of the very nature of such treatment, and he also relies on the patent itself for teaching this. Since the highest dose claimed in the patent is 20mg, Lilly argue that the PSA would implicitly understand that this is effectively the same as having a maximum of 20mg per day. Lilly also point out that this maximum daily dose is provided in the 684 Patent's disclosure at pages 5 and 32. Therefore, on a purposive construction of the patent, they argue the one dose per day maximum originating from the common general knowledge, which is the same as a 20mg per day maximum, should be included. Lilly argues that the law is clear that limitations to restrict a claim can be read into the claim if the PSA would do so.

[204] The Defendants argue that the expert evidence regarding whether a maximum daily dose is an essential element of the asserted Claims is consistent with Justice de Montigny's decision and they outline Drs. Ellis and Brock's opinions. Dr. Ellis opined that the claims contain no explicit restriction to a maximum daily dose and that nothing in the claims' language could be interpreted to provide such a maximum. The Defendants stress the fact that Dr. Derendorf, the only expert to read a daily dose limitation in the claim, based his Responding Report on the report he prepared for the litigation of the US equivalent of the 684 Patent, which included an express maximum daily dose limitation.

[205] The Defendants raise subsection 27(4) of the Patent Act that requires claims to define the subject-matter of the invention in explicit terms. They also raise section 53.1 of the Patent Act to submit that Lilly's position in these proceedings is inconsistent with their position during the prosecution of the application for the 684 Patent when Lilly had to redraft initial claims and remove a maximum daily dose from the claim language to overcome the Patent Examiner's objections. The Patent Examiner found that such initial claims were invalid for claiming a method of medical treatment (*Pollard Banknote v BABN Technology*, 2016 FC 883 [*Pollard*]). Finally, the Defendants outline that the 684 Patent was listed against Lilly's ADCIRCA product on the Patent Register, although ADCIRCA requires 40mg a day.

[206] The Canadian prosecution history reveals that on November 30, 2005, the Patent Examiner informed Lilly ICOS LLC's patent agents of defects in the 684 Application. Among other things, the Patent Examiner signaled that Claims 13–17, outlining a maximum total dose of 20 mg a day, were directed to a method of medical treatment (…). On May 2, 2006, Lilly ICOS

LLC, through their patent agents, wrote to the Commissioner of Patents and confirmed that the claims had been amended, whereby Claims 13–17 are rewritten as “use” claims, without the maximum daily dose.

[207] Lilly argue that the file wrapper estoppel does not apply because (1) Dr. Derendorf did not read into the claims a maximum daily dose but only a one dose per day regimen based on the common general knowledge; and (2) the Patent Office did not object to the maximum daily dose but only to the wording of “method of treating” in the initial Claims 13–17 although the removal of a maximum daily dose was made at the same time as the change in wording.

[208] In his decision in *Canmar*, Justice Manson confirmed that “With the introduction of section 53.1, purposive construction of patent claims in Canada now includes three prongs; (1) the claims themselves; (2) the disclosure; and (3) the prosecution history in Canada, when used to rebut a representation made by the patentee as to the construction of a claim in the patent” (at para 68).

[209] Considering the text of the claims, the canons of claim construction, subsection 27(4) and section 53.1 of the Patent Act, and considering I give more weight to Dr. Ellis’s expert opinion, I find Claim 10, as well as Claims 13–16, do not include a maximum daily dose, or one dose per day. The plain meaning and plain reading of the claims reveal no ambiguity and include no such limitations (*Hospira FCA* at paras 16–18).

[210] This finding is confirmed by the 684 Patent's Canadian prosecution history where Lilly redrafted the claims to take away the initial reference to the maximum daily dose. To permit Lilly to read-in a limitation of a maximum daily dose or one dose per day to the asserted Claims would be perverse (*Pollard*).

[211] The essential elements of Claim 10 (as it depends on Claim 9, as it in turn depends on Claims 3 to 6) are:

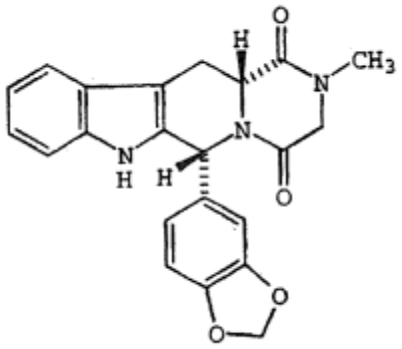
- A pharmaceutical unit dosage form (for example, a pill or tablet);
- Suitable for oral administration;
- Containing tadalafil;
- At certain doses, hence Claim 3: 5–20mg, Claim 4: 2.5mg, Claim 5: 5mg, and Claim 6: 10mg;
- For use in treating male erectile dysfunction, where inhibition of PDE5 provides a benefit;

[212] No maximum daily dose or one dose per day are read in Claim 10.

(3) Construction of Claims 13–16

[213] Claims 13-16 are use claims as they relate to the use of a unit dose. They refer to independent Claim 12. They read:

> 12. Use of a unit dose containing about 1 to about 20 mg of a compound having the structure



for treating sexual dysfunction in a patient.

13. The use of claim 12 wherein the unit dose contains about 2 to about 20 mg of the compound.

14. The use of claim 12 wherein the unit dose contains about 5 mg of the compound.

15. The use of claim 12 wherein the unit dose contains about 10 mg of the compound.

16. The use of claim 12, wherein the unit dose contains about 20 mg of the compound.

[214] There is disagreement as to whether "sexual dysfunction" means MED, and/or female sexual dysfunctional (FSD), namely female arousal disorder (FAD). The Defendants argue that these claims are not limited to any particular type of sexual dysfunction. The Defendants also highlight the fact that these claims make no reference to side effects or lack of contraindications, limit to a maximum daily dose of 20mg, or limit to a single dose per day. Lilly argue that the distinction between MED or FSD is only relevant to utility and argue that utility is fulfilled because tadalafil can treat MED. Lilly also argue that the PSA would understand a one dose per day maximum, and because 20mg is the maximum unit dose, the maximum daily dose is 20mg (Dr. Derendorf Responding Report at para 123). This is where the shoe pinches.

[215] Having already addressed the one dose per day or maximum daily dose, I will only address sexual dysfunction. There is general agreement that sexual dysfunction, in its plain meaning, at the time the 684 Patent was published, should be construed to include male and female sexual dysfunction (see Dr. Derendorf's Responding Report at para 117). As Dr. Pullman explained, it was believed at that time that PDE5 inhibitors could be used to treat both male and female sexual dysfunction.

[216] Claim 9 also refers to use in treating sexual dysfunction, but also mention "where inhibition of PDE5 provides a benefit". Claims 10 and 11 explicitly limit the sexual dysfunction to MED and FAD respectively.

[217] Claims 13–16, referring to Claim 12, do not specify "where inhibition of PDE5 provides a benefit", as is the case in Claim 9, nor does it limit the sexual dysfunction to either MED or FSD. According to claim differentiation principles, a limitation should not be read in if it is not expressly written. A different wording leads the Court to conclude that the patentee intended to give Claims 12, 13–16 a broader meaning than Claim 10, and that the plain meaning of the words "sexual dysfunction" relates to both male and female sexual dysfunction.

[218] I find the essential elements of Claims 13–16 are:

- Use of a unit dose;
- Containing tadalafil (Claim 13: 2–20mg; Claim 14: about 5mg; Claim 15: about 10mg; and Claim 16: about 20mg);
- For treating sexual dysfunction (including both MED and FSD) in a patient.

[219] Again, no maximum daily dose or one dose per day are read in.

VII. The Defendants' counterclaims of invalidity

A. *Introduction*

[220] As outlined in subsection 43(2) of the Patent Act, a patent is presumed to be valid. It is the Defendants' burden to prove invalidity on the balance of probabilities.

[221] The Defendants raised eight grounds of invalidity. However, as mentioned at paras 19-20 of these reasons, some of these grounds depends on the claim construction and/or have not been asserted in closing arguments.

[222] The Defendants indicated during the opening arguments that their allegations of invalidity on the grounds of overbreadth, lack of sound prediction or demonstration and inutility/inoperability are asserted only in the event the asserted Claims are construed to include the better side effect advantages. I have determined the 684 Patent not to be a selection of the 784 Patent. I have not been asked to construe the better side effects profile or the better flushing side effect profile in the asserted Claims, nor have I included the said side effect profile in construing the asserted Claims. In any event, these allegations of invalidity have not been argued at closing, which is also the case for the allegations on grounds of double patenting and insufficiency. As I did not received fulsome representations and the Defendants have not fulfill their burden on these grounds, I will thus not consider those allegations.

[223] The Defendants' allegations of non patentable subject-matter remain asserted only in the event the claims were construed as including a maximum daily dose. As I did not construe it in the asserted Claims, I will not examine this allegation.

[224] The Defendants have only fully argued invalidity on the grounds of anticipation and obviousness.

[225] In brief, and for the reasons exposed hereinafter, I find the Defendants have established anticipation and obviousness of the asserted Claims.

B. *Anticipation*

(1) The anticipation allegations

[226] The Defendants claim that the 684 Patent is anticipated by the 784 Application as the essential elements of the asserted Claims of the 684 Patent were all previously disclosed and enabled by the 784 Application. The Defendants outline that the essential elements of the 684 Patent are a pharmaceutical unit dosage form suitable for oral use containing tadalafil at specified dosage ranges or amounts used for the treatment of sexual dysfunction, or for Claim 10, MED, which do not include a maximum daily dose. They argue that the 684 Patent is necessarily anticipated and invalid unless it is a selection patent.

[227] As part of the two steps anticipation analysis outlined in *Sanofi* and in regards to disclosure, the Defendants stress that it is stated specifically in section 28.2 of the Patent Act,

and that it is therefore neither derived from the common law nor added implicitly to the language of the statute.

[228] They argue that the 784 Application discloses each and every essential elements of the 684 Patent or asserted Claims. In fact, they stress that every single doses of tadalafil claimed in the 684 Patent are entirely within the dosage range of the 784 Application. In response to Lilly' s argument regarding the proper test for disclosure, the Defendants stress that the words of the statute clearly indicate that the inquiry starts with the subject-matter defined by a claim, and then proceeds as to whether this subject-matter was disclosed in the prior art, not the other way around. They submit metaphorically that there is anticipation when the 784 Application discloses A and B and the 684 Patent discloses only B.

[229] They also cite decisions, namely that of Justice Hughes in *Merck & Co, Inc v Pharmascience Inc*, 2010 FC 510 [*Merck*], for the proposition that a dosage range out of a broader disclosure is anticipation, unless the patent qualifies as a selection.

[230] Regarding enablement, the Defendants cite Dr. Ellis' opinion that the 784 Application taught how to make tadalafil and how to make tablets containing it in the claimed range using standard techniques known to the skilled person. They also outlined Dr. Derendorf's testimony on cross-examination whereby he accepted that using the teachings of the 784 Application and altering the ratio of the exemplified tablet would allow the PSA to make smaller dose or larger dose tablets (transcript of December 17, 2019 at page 141).

[231] Lilly respond that the Defendants have not established the 784 Application anticipates the 684 Patent. Lilly does not dispute that the 784 Application is prior art, and they agree with the Defendants on the two-step test on anticipation, as established by *Sanofi*, although they disagree on the application of the disclosure part of the test.

[232] In their written Closing Memorandum, Lilly argue that the 784 Application discloses tadalafil for the treatment of ED, but that, with respect to dosage, it discloses only one specific example, the 50mg. They acknowledge that the 784 Application discloses a possible range for single oral tablets or capsules of 0.2–400mg and a daily dose range of 0.5–800mg, and further describes these ranges as exemplary of the average case but allows for individual instances that are higher or lower than the stated ranges.

[233] Lilly assert that the 784 Application clearly does not disclose any of the claims of the 684 Patent, as (1) the broad range or genus of 0.2–400mg does not inevitably result in any of the claim ranges or dosages of the 684 Patent and as, moreover (2) the 50mg mentioned in the 784 Application clearly is not any of the doses or dosage strengths of the 684 Patent. In their written Closing Memorandum, Lilly cite the SCC for various elements of the disclosure test (at para 114). They rely, namely, on paragraph 21 of the *Sanofi* decision, although the SCC confirmed the application judge had overstated the stringency of the test for anticipation that the “exact invention” has already been made and publicly disclosed (*Sanofi* at para 23).

[234] In their oral argument in closing, Lilly argue that two steps test for anticipation, disclosure and enablement, is not expressly statutorily mandated, although there is a statutory basis.

[235] They also argue that the qualification of a patent as a selection does not impact the disclosure analysis, as it comes into play only in the enablement analysis (transcript of February 4, 2020 at page 127). They thus confirmed that the principles they set forth as guiding the disclosure analysis apply to all patents, selection and non-selection alike.

[236] In regards to disclosure, Lilly argue that the analysis must start with the prior art, hence the 784 Application, and that there will be anticipation only if, every time you practice the 784 Application and follow the instructions, you come within the claims of the 684 Patent. Lilly thus conclude that the disclosure test is not met here as there are a number of dosages in the 784 Application that are not found in the 684 Patent. They point to, for example, all the doses over 20mg that are in the 784 Application, but are not in the 684 Patent. In fact, Lilly confirmed that the patent in suit should always be "larger" than the one cited as prior art for disclosure to be found (transcript of February 4, 2010 at pages 125–126).

[237] Hence, as per Lilly's argument, the 784 Application does not give directions that inevitably result in the selected subject-matter of the 684 Patent (*Pfizer Canada Inc v Canada (Minister of Health)*, 2008 FCA 108 at para 83).

[238] Lilly add that, in the event the 684 Patent is construed as a selection, the 784 Application does not disclose its special advantage.

[239] Lilly, therefore, take the position that enablement need not be analysed as there is no disclosure. In the alternative, if there were disclosure, Lilly argue that it is clear upon considering the nature of the invention and the fact that the work done to identify the claimed doses was in no way routine, the PSA would need a plethora of further information to come up with the claimed doses.

(2) The anticipation framework

(a) *Section 28.2 of the Patent Act and the Sanofi test*

[240] The anticipation allegations are governed by section 28.2 of the Patent Act. Under the heading "Subject-matter of claim must not be previously disclosed", section 28.2 states that the subject-matter defined by a claim in an application for a patent in Canada (the "pending application") must not have been disclosed. It appears clear that the disclosure step of the anticipation test in embedded in the words of the statute.

[241] The parties agree that the anticipation test is laid out in *Sanofi* and that, in order to determine if a subject-matter is anticipated, a two steps analysis must be performed. The first step is a requirement of prior disclosure and means that the prior art, as of the claim date, must disclose subject-matter, which if performed, would necessarily result in an infringement of the patent (*Sanofi* at para 25). If yes, the second step is to look at enablement and ask whether a PSA

would have been able to perform the invention (*Sanofi* at para 26). The enablement must come from a disclosed single prior art reference (*Beloit* at 297) such that the PSA can "perform or make the invention of the second patent without undue burden" (*Sanofi* at para 33). The PSA may apply common general knowledge in the assessment of enablement (*Sanofi* at para 37). If trials and experiments are generally carried out, the threshold for undue burden will tend to be higher than in circumstances in which less effort is normal. Furthermore, routine trials should not be considered as being undue burden (*Sanofi* at para 37).

[242] The anticipation analysis must be made as of the claim date, which is April 30, 1999 as confirmed by the parties.

(b) *The disclosure requirement*

[243] In the component of the trial that pertains to the 540 Patent, Lilly did not dispute that the disclosure is concerned with the essential elements of the asserted Claims, and that the disclosure analysis consists in examining if each of those essential elements have been disclosed in the prior art, claim by claim. This is in fact how Lilly conducted the disclosure analysis in the trial pertaining to the 540 Patent.

[244] Oddly, in this component of the trial, Lilly argue that the disclosure analysis must start with the prior art, and consists in examining if each element of the prior art, if performed, would infringed the claims of the patent in suit. Lilly confirmed this applies to every patent, selection and non-selection alike.

[245] Contrary to Lilly's contention in this component of the trial, it appears clear that the disclosure analysis must start with the essential elements of the asserted Claims of the 684 Patent. It must proceed to examine if the essential elements have been disclosed in the piece of prior art identified by the Defendants. The element identified as disclosure in the prior art must, if performed, result in an infringement of the essential elements of the claim of the patent in suit (*SmithKline Beecham Pharma Inc, v Apotex* 2002 FCA 216; *Lundbeck Canada Inc. v Ratiopharm* 2009 FC 1102).

[246] I already found the asserted Claims do not include a one daily dose or maximum daily dose. I also already found that Lilly have not demonstrated the 684 Patent to be a selection of the 784 Patent with the consequence that the better side effect profile in regards to flushing, compared to sildenafil or not, does not factor into the anticipation analysis. This conforms to Justice de Montigny's reasons that "when a second patent is not interpreted as a selection patent, its advantages do not factor into the inquiry of anticipation and need not be disclosed in a previous patent to be anticipated" (the 684 Patent NOC decision at para 148). This also aligns with the decision in *Sanofi* whereby the disclosure requirement for anticipation was not satisfied because the prior art did not disclose the special advantages of the selection patent (at paras 31–32, 38–41).

[247] In light of my construction of the asserted Claims, I am satisfied that the essential elements of the asserted Claims of the 684 Patent are disclosed in the 784 Application.

[248] I have confirmed the essential elements of Claim 10, as it depends on Claim 9, as it in turn depends on Claims 3 to 6 to be:

- A pharmaceutical unit dosage form (for example, a pill or tablet);
- Suitable for oral administration;
- Containing tadalafil;
- At certain doses, hence Claim 3: 5–20mg, Claim 4: 2.5mg, Claim 5: 5mg, and Claim 6: 10mg;
- For use in treating male erectile dysfunction, where inhibition of PDE5 provides a benefit;

[249] These essential elements are all disclosed within the 784 Application. At pages 3, the 784 Application indicates that "the specific compounds of the invention are [Compound A and Compound B]." The 784 Application continues at pages 3–4 and indicates that "compounds A and B are useful in the treatment of erectile dysfunction", and that "furthermore the compounds may be administered orally, thereby obviating the disadvantages associated with i.c. administration." Tadalafil, although not specifically indicated, is compound A.

[250] The 784 Application also indicates at the same page that "compounds of the present invention are potent and selective inhibitors of cGMP specific PDE", and clarifies three lines later that they inhibit PDE5 selectively. The 784 Application at page 4 then adds that "the compounds of the invention are envisaged primarily for the treatment of erectile dysfunction or male sexual dysfunction", but that "they may also be useful for the treatment of female sexual dysfunction". At pages 12–16, the 784 Application exemplifies pharmaceutical formulations of both compounds in tablets, wet granulations, film coated tablets, and capsules. Finally, at page 5,

the 784 Application indicates that for the typical adult patient, individual tablets contain 0.2–400mg of active compound can be used in single or multiple doses, once or several times per day. According to the 784 Application, the dose should generally range in between 0.5–500mg daily for a 70kg adult patient, except for individual instances. This range is wider than the 2.5–20mg dose range in the asserted Claims.

[251] I have confirmed the essential elements of Claims 13–16 are :

- Use of a unit dose;
- Containing tadalafil (Claim 13: 2–20mg; Claim 14: about 5mg; Claim 15: about 10mg; and Claim 16: about 20mg);
- For treating sexual dysfunction (including both MED and FAD) in a patient.

[252] For the same reason as above for Claim 10, all essential elements of Claims 13–16, are disclosed. As noted earlier, the 784 Application at page 3 indicates that two compounds, one of which is tadalafil, is useful in the treatment of erectile dysfunction. The range of doses in the use claims are from 2–20mg, but again, they fall within the range of 0.2–400mg.

[253] The Defendants have established that the 794 Application discloses elements that, if performed, would infringed the asserted Claims of the 684 Patent. All the essential elements of the asserted Claims of the 684 Patent are disclosed by the 784 Application.

(c) *The enablement requirement*

[254] For purposes of enablement, the question is no longer what the PSA would think the disclosure of the prior patent meant, but whether he or she would be able to work the invention (*Sanofi* at para 27). The skilled team and reader must still be able to practice the invention and go from the 0.2–400mg unit dose range to the 2–20mg.

[255] Dose selection is a routine pharmaceutical work performed without undue burden, and forming part of Phase II clinical studies at the end of which, typically, a dose response curve is drawn for the final selection of doses for large scale studies. The skilled team, in Phase II, has to ascertain the minimum effective dose as well as the maximum. Although the determination of endpoints in studies involve a judgment call by the urologist, he or she will have no problem identifying what would be minimally effective in treating male ED. The efficacy plateau is identified in Phase II, and using a host of factors from previous work in preclinicals and Phase I, including, for example, what experts have summarized as absorption, distribution, metabolism, and excretion (ADME), as well as the side effect profile, the final doses, which offer the best balance between safety-tolerability and effectiveness, are selected for large scale Phase III studies. Even if the skilled team fails to draw up a dose response curve following a single Phase II trial because the doses studied are too high and all are effective, or because the doses studied are too low and none is effective, a second Phase II trial can be performed (transcript of December 18, 2019 at page 44). Nothing inventive is required for the routine trials.

[256] Furthermore, the molar mass of tadalafil versus sildenafil and the IC_{50} and EC_{50} of both molecules, which form part of the common general knowledge of the skilled team, will be an aid to ascertain the doses for the first dose ranging study as indicated by Dr. Baughman (Dr. Baughman Expert Report at paras 68–75). The specific subset of doses of the 784 Application that properly balance efficacy, and safety and tolerability, are thus identified from the study. The PSA would thus be enabled to perform the invention in the asserted Claims of the 684 Patent.

[257] Dosage patents, such as the 684 Patent, have been the subject of some prior decisions. In general, dosing a drug itself does not bring anything novel, subject to exceptional circumstances, which means that a dosage patent will almost always be anticipated. Justice Hughes expressed the view in *Merck* at para 167 that in general "it would be within the expected skill of a person skilled in the art, as the '457 Patent itself acknowledges, to determine an appropriate dosage for a given person". Justice Hughes continued and wrote the following at para 176:

> [176] I find, given the state of the law in Canada as set out in Sanofi, in particular, that the use of finasteride in an oral composition to treat male baldness has been disclosed, and that the selection of a dosage range was within the skill of an ordinary person skilled in the art. Claim 5 of the '457 Patent does nothing more than confirm that it works at a dosage of 1 mg/day. No new technical feature has been disclosed or claimed. To the extent that Harris and Thigpen suggest that finasteride may not work, there is no clear teaching that it will not work. In the absence of Harris and Thigpen, claim 5 has no novelty. With Harris and Thigpen, the '457 Patent, including claim 5, is merely confirmatory, without undue experimentation, as to what was already known.

[258] In a similar vein as Justice Hughes, I am concluding that the 684 Patent is merely confirming that tadalafil works at a dosage of 2–20mg. The dosing of tadalafil, by involving a

straightforward dosing regimen, is distinguishable from *Janssen Inc v Teva Canada Ltd*, 2020 FC 593, which involved a wholly different dosing regime: loading doses and maintenance doses.

(3) Conclusion on anticipation

[259] The Defendants have established the 784 Application discloses and enables the essential elements of the asserted Claims of the 684 Patent. The asserted Claims are invalid for anticipation.

C. *Obviousness*

(1) The obviousness allegations

[260] The Defendants allege that the whole of the 684 Patent is obvious to the PSA because no degree of invention would have been required by this PSA to confirm that 2–20mg doses of tadalafil are effective. They submit that the 684 Patent is, therefore, invalid.

[261] The Defendants add that most of the actual course of conduct of the inventors, if not all, is irrelevant to the 684 Patent, and that the relevant aspects demonstrate that the inventors conducted routine studies well within the knowledge and abilities of the skilled person to arrive at the invention.

[262] The Defendants submit that the *subject-matter defined by a claim* stated in section 28.3 of the Patent Act lies in the essential elements of the claims. Hence, they submit that the fact that

tadalafil can be used and administered orally at specific doses to treat MED, where inhibition of PDE5 provides a benefit, has been taught by the 377 Patent, the 784 Application and sildenafil.

[263] Lilly respond that the 684 Patent is not obvious. They accept that the subject-matter defined by a claim is indeed in the language of the statute. However, they argue that the inventive concept is not the subject-matter defined by a claim, by being a concept different from the claims as construed. Arguing that the 684 Patent is a selection, they stress that the inventive concept includes, in this case, the surprising minimization of side effects or only of flushing as compared to Viagra sildenafil, when the maximum daily dose is set at 20mg. Even if it were not construed as a selection, they add that inventive concept should nevertheless include the minimization of side effects compared to Viagra sildenafil. They thus propose the inventive concept to be understood as "the discovery that surprising low doses of tadalafil as claimed in each of the asserted Claims with a maximum daily dose of 20mg is effective in treating ED with a minimization of side effects as compared to Viagra sildenafil" (Lilly Closing Memorandum at para 168).

[264] Given the parties' contradictory positions, I must determine how the SCC and the FCA have directed this Court to conduct the obviousness enquiry.

(2) The obviousness framework

(a) *Section 28.3 of the Patent Act*

[265] The obviousness assessment is governed by section 28.3 of the Patent Act, which states that *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.

[266] In this case, the 684 Patent must not be obvious for the PSA on April 30, 1999.

(b) *The Sanofi test on obviousness*

[267] In 2008, the SCC issued its decision in *Sanofi*, recognised since as the seminal decision on the obviousness inquiry. *Sanofi* pertained to a selection patent, and, as it was not governed by section 28.3 of the Patent Act, it was not discussed.

[268] In *Sanofi*, finding the test of obviousness in *Beloit* too rigid, the SCC indicated it would be useful to follow the four-step approach first outlined in *Windsurfing International Inc v Tabur Marine (Great Britain) Ltd*, [1985] RPC 59 (EWCA) [*Windsurfing*] and updated in *Pozzoli SPA*

v BDMO SA [2007] EWCA Civ 588 [*Pozzoli*]. The SCC restated the *Windsurfing* questions, at para 67, as:

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

[269] In regards to the inventive concept, the SCC found it was not readily discernable from the claims themselves, and thus referred to the rest of the specification to identify it: "A bare chemical formula in a patent claim may not be sufficient to determine its inventiveness. In such cases, I think it must be acceptable to read the specification in the patent to determine the inventive concept of the claims" (*Sanofi* at para 77). The SCC found the inventive concept of the claims of the selection patent in suit to reside in its advantages over the other compounds of its genus patent and in the methods for obtaining that compound (at para 78).

[270] I will examine each step.

(c) *First step: identify the notional PSA and the relevant common general knowledge of that person*

[271] The PSA has already been identified by the Court at paras 170-172, and the common general knowledge has been identified at paras 184-197.

(d) *Second step: identify the inventive concept of the claim in question or if that cannot readily be done, construe it*

(i) Issues

[272] Following *Sanofi*, much debate have ensued to determine if, by introducing the term "inventive concept" in the obviousness test and by referring to the disclosure to construe it, the SCC in fact changed the jurisprudence that prevailed, set by the FCA in *Beloit*. Questions arose as to the meaning of "inventive concept", whether it is different from the claim construction, whether the test set by the SCC under former provisions of the Patent Act applied to patents governed by section 28.3 of the Patent Act, or whether it is permitted to ascertain the inventive concept from outside the claims in the context of selection, or non-selection patents, if it is, or not, readily discernible from the claims. As the parties disagree on how to answer these questions, I will briefly expose the jurisprudence and the legislative amendment chronologically, situate *Sanofi* in that chronology, and outline the answers the FCA provided up to now to direct my analysis.

(ii) 1986: the *Beloit* framework

[273] Prior to 1993, the Patent Act contained no specific provision on obviousness, or its antithesis: inventive ingenuity and inventiveness. Inventiveness, as a requirement for patentability, was ingrained within the definition of the word invention of section 2 of the Patent Act.

[274] Until 2008, the leading case on obviousness was the FCA's decision in *Beloit*, where in fact, both parties had obtained a patent for the same invention. The patent related to a press mechanism installed on one of the four sections of a paper machine, and it was not a selection patent.

[275] Justice Hugessen, for the FCA, indicated that what was claimed as novel and inventive was the combination of previously known elements in the design of a high-speed press section, and outlined a simplification and vulgarisation of the patent's claim and the actual text of the claim, which did not mention the speed of the machine.

[276] Justice Hugessen confirmed the proper test for obviousness. He first stated that the test was not to ask what competent inventors would have done, as inventors are by definition inventive. He added that the "classical touchstone for obviousness is the technician skilled in the art but having no scintilla of inventiveness or imagination; a paragon of deduction and dexterity, wholly devoid of intuition; a triumph of the left hemisphere over the right" and that the question to be asked was "whether this mythical creature [the man in the Clapham omnibus of patent law]

would in light of the state of the art, and of common general knowledge as at the claimed date of invention, have come directly and without difficulty to the solution taught by the patent. It is a very difficult test to satisfy" (*Beloit* at 294, my emphasis).

[277] Justice Hugessen thus referred to "the solution taught by the patent" as the element that must be compared to the prior art, *ie* as the second point, but he did not define it. As we will see below, *the solution taught by the patent* was later interpreted to mean *the claim or claims as construed by the Court.*

[278] Justice Hugessen identified a series of ascertainable facts as to which there was no dispute, and found that their cumulative effect showed inventiveness: (1) the defendant in that case had claimed and continued to claim inventiveness for the same apparatus; (2) the speed of the machine increased; (3) it was difficult in getting the new machine accepted because convention wisdom pointed away from the invention; and (4) the machine was an outstanding commercial success after its acceptance.

(iii) Section 28.3 of the Patent Act

[279] In 1993, the Patent Act was modified, and section 28.3 was introduced, applying to patent applications filed on or after October 1, 1989. It identified the second point, *ie* the element that must be compared against the prior art, as *the subject-matter defined by a claim.* As we examined earlier, it is the same term as the one used in section 28.2, governing the anticipation analysis.

[280] In *Janssen-Ortho Inc v Novopharm Ltd*, 2006 FC 1234, although the patent in suit was not governed by section 28.3 of the Patent Act, Justice Hughes noted the legislative change and the fact that a definition of obviousness had been introduced. Justice Hughes stated that the definition "is not different from the law as it was generally understood previously" (at para 109). He questioned whether the solution taught by the patent, *ie* the invention taught, was different from the claim as properly construed. He confirmed the test for obviousness was that of *Beloit*, and confirmed that what was at issue is *the claim* or are *the claims as construed by the Court*: the "invention as generally expressed in the patent or by the inventors is not the issue, it is the claim as properly construed" (at para 113). He discussed a list of factors and noted primary and secondary ones. He determined the invention as claimed to be the claim as he construed, which did not include the compound's properties or uses (at para 114). The FCA upheld Justice Hughes's decision in 2007 FCA 217 (*Janssen FCA*), and confirmed the test set by *Beloit* in that "what it in issue is the patent claim as construed by the Court" (at para 25).

[281] From *Janssen FCA*, it appears clear that *the solution taught by the patent,* as the second point set out by *Beloit*, was understood to be equivalent *to the claims as construed by the Court.*

(iv) *Sanofi* in 2008

[282] As mentioned earlier, in 2008, the SCC examined the obviousness framework in the context of a selection patent, not governed by section 28.3 of the Patent Act. The SCC introduced the term "inventive concept" to designate the "second point", *ie*, the element that must be compared to the prior art, and what the FCA in *Beloit* referred to as the "solution taught by the patent". Noting that the inventive concept was not discernable from the claims, the SCC

referred to the disclosure to identify it as "a compound useful in inhibiting platelet aggregation which has greater therapeutic effect and less toxicity than the other compounds of the 875 patent and the methods for obtaining that compound" (*Sanofi* at paras 77–78).

(v) Post-*Sanofi*

[283] Shortly after *Sanofi*, the FCA issued its decision in *Apotex Inc v ADIR*, 2009 FCA 222 [*ADIR FCA*]. The FCA then reviewed a decision rendered by the FC before *Sanofi* was issued, in which Justice Snider had applied the framework set out in *Janssen FCA*. The patent in suit was not a selection and was not governed by section 28.3 of the Patent Act.

[284] Before the FCA, Apotex argued that the trial judge had erred by directing the obviousness inquiry to the claims of the patent and rejecting what the disclosure taught about inventiveness. The FCA found the framework in *Janssen FCA* was not inconsistent with what was described in *Sanofi*. It rejected Apotex's proposition by endorsing and adopting the reference from Conor MedSystems Inc v. Angiotech Pharmaceuticals Inc. [2008] UKHL 49 [*Conor MedSystems*] at para 19: "the invention is the product specified in a claim and the patentee is entitled to have the question of obviousness determined by reference to his claim and not to some vague paraphrase based upon the extent of his disclosure in the description". The FCA cited *Janssen FCA* for the proposition that "what is in issue is the patent claim as construed by the Court" and reconciled its statement with *Sanofi*, noting that Justice Rothstein had stated the second step to be the need to identify the inventive concept of the claim in question or if that cannot readily be done construe it" (*ADIR FCA* at para 69).

[285] In *Novopharm FCA*, Justice Layden-Stevenson endorsed the framework set out in *Sanofi* to assess the obviousness allegations in regards to a selection patent, governed by section 28.3 of the Patent Act.

[286] Justice Layden-Stevenson, before addressing the obviousness analysis, stated there was no authority where the analysis of the conditions for a valid selection patent, without more, rendered a patent invalid. She confirmed that a selection patent is the same as any other patent and its validity is vulnerable to attack on any of the grounds set out in the Patent Act. However, she added that the conditions for a valid selection patent serve to characterize the patent and accordingly inform the analysis for the grounds of validity set out in the act (at para 27). In regards to obviousness, Justice Layden-Stevenson confirmed that "in the context of a selection patent, the obviousness analysis considers the special properties of the compound, along with its alleged advantages, as described in the selection patent disclosure, for it is there that the inventiveness of the selection lies" (my emphasis). Justice Layden-Stevenson did not indicate or discuss how the obviousness inquiry of a patent that is not a selection should be informed. There is thus no indication that she displaced the teaching of the FCA in *ADIR FCA* for patents that are not selections.

[287] However, other decisions adopted a different position, such as *Allergan Inc v Canada (Health)*, 2011 FC 1316 at paras 53–54 [*Allergan*]; *Apotex Inc v Allergan Inc* 2012 FCA 308; *Bell Helicopter Textron*, creating somewhat of a confusion.

[288] The parties have particularly outlined five recent decisions of the FCA shedding light on the interpretation and the application of the *Sanofi* obviousness test, and I will thus examine them briefly to identify the interpretation the FCA directs me to adopt. These decisions pertain to patents that are not selections, and are governed by section 28.3 of the Patent Act.

[289] In *Zero Spill Systems (Int'l) Inc v Heide*, 2015 FCA 115 [*Zero Spill FCA*], Justice Stratas confirmed that sections 28.2 and 28.3 of the Patent Act both begin with the same terms, and that both require a reviewing court to focus on the subject-matter "defined by a claim" (at para 81). Justice Stratas noted sections 28.2 and 28.3 established a standard, and certain conditions for their application, but they did not prescribed a test. He confirmed that the leading authority on anticipation and obviousness was the *Sanofi* decision (although it was decided under the former version of the Patent Act) which "affirmed two common law tests, each of which confirms that invalidity for anticipation or obviousness must be established claim by claim" (at para 85). I have not found in Justice Stratas' reasons a clear definition of *Sanofi's* "inventive concept", nor reference that the inventive concept of Sanofi derives from a common law test.

[290] In *Bristol-Myers Squibb Canada Co v Teva Canada Limited*, 2017 FCA 76 [*BMS FCA*], Justice Pelletier examined the obviousness framework. Commenting on the *Sanofi* decision, he wrote that its innovative feature, in relation to obviousness, was its adoption of the "obvious to try" test linked to UK jurisprudence of Windsurfing/Pozzoli and the three *Lundbeck* "obvious to try" factors (*H. Lundbeck A/S* v *Generics (UK) Ltd*, [2008] EWCA Civ. 311).

[291] In regards to the inventive concept, Justice Pelletier, in *BMS FCA*, outlined the fact that the SCC had not discussed its reasons for adopting the Windsurfing/Pozzoli framework. He also noted that the SCC had not referred to the cautionary note struck in *Pozzoli* regarding the inventive concept to the effect that "in the end what matters is-are the difference(s) between what is claimed and the prior art" (at para 63). Justice Pelletier added that, until *Sanofi*, the jurisprudence followed *Beloit* and referred to "the solution taught by the patent", and that, since *Sanofi*, varying interpretations of the inventive concept had been applied. He also remarked that the SCC in *Sanofi* modified the test for obviousness by modifying the manner in which the gap between the prior art and the solution taught by the patent can be bridged, but did not, without saying so, change the definition of obviousness (*BMS FCA* at paras 67–68). He determined that the SCC's use of the term "inventive concept" had not changed what the prior art must be compared against, and ultimately found the Federal Court erred by implicitly adopting a definition of the inventive concept which focused on the properties of the compounds (at para 74). The inventive concept amounts to what is claimed in the patent.

[292] In *Ciba FCA*, Justice Pelletier again examined the obviousness test, and the meaning of the term inventive concept as found in *Sanofi*. He cited *Unilever v Chefaro*, [1994] RPC 567 (Pt Ct) and *Conor MedSystems* for the proposition that the "patentee is entitled to have the question of obviousness determined by reference to his claim and not to some vague paraphrase based upon the extent of his disclosure in the description". He held that this focus on the claims is consistent with section 28.3, which stipulates that it is the *subject-matter defined by a claim*, which must not be obvious. He stressed that the term inventive concept remained undefined, which brought considerable confusion, and suggested we avoid it altogether until the SCC is able

to develop a workable definition. Justice Pelletier then proceeded to compare the prior art with the elements of the claims as construed.

[293] In *Tearlab FCA*, the discussion of the inventive concept in regards to the obviousness inquiry starts at para 75 of the decision. Justice de Montigny cited *Sanofi* and commented that the SCC has hinted claim construction and inventive concept are not identical concepts, although it offered no description or explanation as to what inventive concept actually is, leaving many to wonder if they are, in practice, different. Justice de Montigny cited *BMS FCA* for the proposition that references in the jurisprudence to "the inventive concept", "the solution taught by the patent", or simply "the invention", are merely attempts to define the second point, and are treated as synonymous with "what is claimed" in the patent (at para 77).

[294] Justice de Montigny then referred to recent decisions of the FCA (*Ciba FCA* and *ADIR FCA*) that have downplayed the importance of the "inventive concept" as an analytical tool in the context of an obviousness analysis, and focused the analysis on the claims themselves, in line with the principle expressed by Lord Hoffmann in *Conor MedSystems* at para 19 (*Tearlab FCA* at para 78).

[295] In *Hospira FCA*, Justice Locke confirmed the reference to section 28.3 as the statutory basis for a requirement of inventiveness as well as the four step approach to obviousness analysis as set out in para 67 of *Sanofi*. Justice Locke also focused on the claims in ascertaining the inventive concept by reiterating the principle that "the claimed invention for any given claim in

issue is defined by the essential elements thereof, which do not contemplate any particular experiments or results" (at para 94).

[296] In addition, I wish to point out that in 2017, the SCC issued its decision in *AstraZeneca SCC*, abolishing the promise doctrine. Non-obviousness was not in issue and the SCC did not address it, save the mention at para 31 that Generally, an analysis regarding issues of validity, such as novelty or non-obviousness, focuses on the claims alone, and only considers the disclosure where there is ambiguity in the claims (*Sanofi-Synthelabo*). This is in accordance with this Court's direction that claims construction precedes all considerations of validity: *Free World Trust v. Électro Santé Inc.*, 2000 SCC 66, [2000] 2 S.C.R. 1024, at paras. 33-50; *Whirlpool Corp. v. Camco Inc.*, 2000 SCC 67, [2000] 2 S.C.R. 1067, at paras. 42-43."

[297] Obviousness was, however, an issue in the Federal Court's decision (*AstraZeneca Canada Inc v Apotex Inc*, 2014 FC 638 [*AstraZeneca FC*]), in which Justice Rennie acknowledged that the meaning of the "inventive concept" of a patent's claims was the subject of controversy, and that the parties before him, as they do before me, adopted conflicting interpretations of the inventive concept. He noted that "the parties had conflicting views on the legal principles underpinning the inventive concept as well. AstraZeneca, in its closing, argued that the inventive concept, promise of the patent, and claims construction, are 'just one construction for all purposes.' By contrast, Apotex argued that all three exercises are distinct inquiries. Such a stark contrast in the basic legal framework underlying key doctrines in patent law, between two highly sophisticated litigants, is alarming to say the least" (at para 266). Justice Rennie determined that, similar to claim construction, the identification of the inventive concept

begins with the claims, and the remainder of the patent may be consulted only if necessary (at para 266). Justice Rennie, ultimately, found there was no need to look to the disclosure for improved properties within the inventive concept of the 653 patent because a viable inventive concept was present in the claims alone. The FCA confirmed the FC directed itself to the correct legal test and the SCC did not address the issue.

[298] Justice Rennie's interpretation of *Sanofi*'s inventive concept, like that of the FCA decision, centered on the patent's claims, and the SCC did not displace this interpretation.

(vi) The meaning of the term *inventive concept*

[299] The element that must be compared with the prior art in the obviousness analysis has been named "the solution taught by the patent" in *Beloit,* the "inventive concept" in *Sanofi,* and is named the "subject-matter defined by a claim" in the Patent Act.

[300] It appears clear from the afore-mentioned decisions of the FCA, that these terms all mean the same thing and that they relate to the essential elements of the claims, identified by claim construction.

[301] The Courts have acknowledged that recourse to elements of the disclosure may be permitted when there is ambiguity in the claims or when the inventive concept is not discernable from the claims. For example, in the context of a selection patent, the inventiveness has been found to lie in the advantages the selection presented over the genus (*Astrazeneca SCC* at para 31; *Sanofi* at para 77; *Novopharm FCA*). The FCA and the Court confirmed that a distinction

must be made between the invention and what are alternatively called properties of the invention, benefits of the invention, or results of the invention (*BMS FCA* at para 74; *Apotex v Pfizer* 2019 FCA 16 para 37–45; *Hospira FCA* at para 94; the 684 Patent NOC decision at para 164). There is no need to look to the disclosure for improved properties, if a viable inventive concept is present in the claims alone (*AstraZeneca FC* at para 272).

[302] Focusing on the essential elements of the claims when conducting the obviousness analysis accords with overarching principles. As the Defendants point out, the statute refers to the subject-matter defined by a *claim*, not by a patent. The patent law is wholly statutory, and the statute itself directs us to focus on the claims.

[303] Furthermore, sections 28.2 and 28.3 of the Patent Act both refer to the *subject-matter defined by a claim* to identify the element that must be assessed against the prior art. As per the general rules of interpretation, the same term in both sections should mean the same thing, and the same element should thus be used as the point of comparison against the appropriate prior art in both the anticipation and the obviousness enquiries. “Giving the same words the same meaning throughout a statute is a basic principle of statutory interpretation (Elmer Driedger, *Construction of Statutes* (2nd ed. 1983), at p. 93)” (*R v Zeolkowski* 1989 1 SCR 1378; Ruth Sullivan, *Sullivan on the Construction of statutes* (Markham: LexisNexis, 2014) at §8.34; *Aux Sable Liquid Products LP v JL Energy Transportation Inc* 2019 FC 581; *Zero Spill FCA*).

[304] The subject-matter defined by a claim of the anticipation analysis resides in the essential elements of the claims. Hence, given the general rules of interpretation, the subject-matter defined by a claim of the obviousness analysis should reside in the same essential elements.

[305] Finally, the SCC taught us that claim construction is antecedent to the validity and infringement analyses, that it serves all purposes, and that the key to purposive construction is the identification of the essential elements of the claims. As the infringement analysis is concerned with the essential elements of the claims, the validity analysis, which include the obviousness analysis, should also be concerned with the essential elements of the claims.

(vii) The *subject-matter defined by a claim* of the 684 Patent

[306] The Defendants argue that for a patent that does not qualify as a selection, any purported advantages set out in the disclosure, but not claimed, ought to be irrelevant to the obviousness inquiry. Their inventive concept, or subject-matter defined by a claim, thus corresponds to the essential elements of the asserted Claims and, here, lies in the fact that the claimed dosages provide efficacy to treat male ED. The Defendants point out that Dr. Brock previously opined, in the 684 Patent NOC decision, the better side effect profile was a result of the invention rather than being a part of the inventive concept, and also pointed out that Dr. Brock only seemed to have changed his opinion in his examination-in-chief because he indicated at para 18 of his Validity Report that the reduced side effects is a benefit of the invention.

[307] Lilly assert that the inventive concept is different from the claims as construed. They assert that the language used by the SCC in Sanofi directs the parties, at the third step of the test,

to construe “it”, meaning to construe the inventive concept. Following Lilly’s argument, as the claim construction would have been completed already from the onset, there was no need for the SCC to direct courts to construe the claims again as part of the obviousness inquiry. For Lilly, the inventive concept is thus an additional and distinct concept, which, in some cases, will actually amount to the same thing as the claims as construed, but not necessarily.

[308] Lilly confirm both in their written argument (Lilly Closing Memorandum at para 168) and in their oral closing arguments (transcript of February 4, 2020 at page 115), that the inventive concept is as outlined by both Drs. Derendorf and Brock. It lies in “the discovery that a surprisingly low dose of tadalafil as claimed in each of the asserted Claims with a maximum daily dose of 20 mg is effective in treating ED with a minimization of side effects as compared to VIAGRA sildenafil”. Lilly narrowed the side effect down to the flushing during closing oral arguments, and did not eliminate the sildenafil side effect comparison from their inventive concept submissions.

[309] As outlined earlier, the FCA confirmed the inventive concept, ie, the subject-matter defined by a claim, resides in the essential elements of the claims.

[310] I thus agree with the Defendants’ formulation of the subject-matter defined by a claim and confirm that it lies here in that the claimed dosages of tadalafil, orally administered, provide efficacy to treat male ED. The advantages raised by Lilly are not included because they are not essential elements of the claims, the 684 Patent is not a selection, and a viable subject-matter is discernable from the claims.

(e) *Third step: identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim or the claim as construed*

[311] The Defendants argue that there are no differences between the prior art and the inventive concept of the claims, but that if there any difference, it would lie in confirming that tablets containing 2–20mg of tadalafil could be orally-administered to treat ED in humans (which is already taught by the 784 Application). The Defendants also cite a number of statements made in the 377 and the 784 Patents, as well as the sildenafil label and articles on sildenafil.

[312] Lilly vaguely argue that the differences between the prior art and the inventive concept are numerous and significant. Dr. Brock, in his Validity Report, wrote that the state of the art did not disclose the specific maximum daily dose range of 2–20mg or the unexpected level of efficacy in the treatment of ED for that range, the minimization of flushing and vision abnormalities that would be expected from a PDE5 inhibitor, and the advantage the 2–20mg doses have over the other doses within the 0.5–800mg range.

[313] As per the evidence, and given my prior conclusion, I find the sole difference between the prior art (the 377 Patent, the 784 Application, and sildenafil) and the subject-matter defined by a claim of the 684 Patent to be the lower and narrower subset of dose range in the 684 Patent.

[314] The prior art already disclosed that oral administration of tadalafil can be effective at treating ED with a unit dose between 0.2–400mg.

(f) *Fourth step: Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?*

[315] The Defendants argue that there are no steps. Alternatively, they submit that routine testing is sufficient to arrive at the proper unit dosage, without undue burden.

[316] Recounting Drs. Baughman's and Ellis' evidence, the Defendants explain that (1) given tadalafil's relative greater potency and sildenafil's known efficacy at doses as low as 5mg, the PSA would expect doses of 1–2mg of tadalafil to be efficacious; (2) the expectation would be confirmed through Phase 1 dose-escalation studies and Phase 2 dose-ranging studies; (3) dose ranging studies are routine and are required by regulatory authorities; and (4) the IC_{50} potency of tadalafil is essential for predicting the lower doses.

[317] The Defendants also criticise Lilly's approach in that the 377 and 784 Patents and Applications are treated as speculative documents with no basis for their teachings. The Defendants point out that Dr. Donn testified that no one at Glaxo would believe that taladafil was safe for humans shortly before the filing of the 784 Application, which would put into question whether the 784 Patent was soundly predicted, and the disclosure sufficient. The 784 Patent was upheld to be valid on two occasions by the FCA.

[318] The Defendants further add that Lilly incorrectly relied upon the entirety of the tadalafil development process before the filing of the 784 Application. At the time of filing of the 784 Application, pre-clinical testing in rats and dogs to support Phase 1 studies in humans for

doses from 1–500mg were performed, as well as that first Phase 1 study that provided to Glaxo a significant amount of single-dose pharmacokinetic, safety and tolerability information. The Defendants submit that Lilly attempt to improperly rely on the entirety of the tadalafil program although work prior to the 784 Patent have already been subject to patents. The Defendants also adds that the work after DSD06 is entirely irrelevant for the purpose of this analysis, as doses chosen to pursue in Phase 3 and for regulatory approval and commercial sale are entirely irrelevant (*Apotex Inc. v Wellcome Foundation Ltd*., 2002 SCC 77 at para 77).

[319] Regarding the actual course of conduct, the Defendants submit that Lilly in their development of tadalafil did precisely what was required by standard industry practice, including the identification of a minimum effective dose. The Defendants argue that the dog toxicology issue was overblown, arguing that the evidence suggest the termination of the program at Glaxo was really because of a terrible commercial agreement with ICOS. ICOS, after taking over the development program, simply requested an opinion that the dog issue was beagle dog specific. It also continued human clinical studies unimpeded in Europe, despite being temporarily subject to a clinical hold in the US.

[320] Finally, although a UK decision is not binding, the Defendants cite *Actavis Group v ICOS Corporation*, [2019] UKSC 15 in which the UK Supreme Court invalidated the UK equivalent of the 684 Patent on the basis of obviousness under a very similar test.

[321] Lilly argue that the differences constitute non obvious steps because (1) the broad range taught by the 784 Application is meaninglessly broad; (2) the broad range in the 784 Patent could

include unsafe doses; (3) there is no teaching about how to develop a dosing regimen in the 784 Application; (4) there is no teaching about the significant reduction in side effects, especially of flushing which can cause embarrassment and which was thought to be inherent in PDE5 inhibitors; (5) there is no motivation for the PSA to focus on the low end of the range of the 784 Patent in order to compete with the sildenafil's efficacy; (6) there is no daily maximum in the 784 in contrast to the 684; (7) there are no reason to single tadalafil out from the literature; (8) Glaxo terminated the development of tadalafil due to dog toxicological issues; (9) the FDA placed a clinical hold on the development in response to the dog toxicological issues; and (8) knowledge about sildenafil is of no assistance because (a) sildenafil is structurally different from tadalafil, (b) predicting dosages using IC_{50} and the molar mass is unsound in the absence of precise IC_{50} measurements and tadalafil pharmacokinetics data, (c) Drs. Baughman and Ellis admitted that IC_{50} values are variable and dependant on experimental conditions before admitting that IC_{50} of tadalafil and sildenafil are within the same magnitude, (d) safety concerns exist in the absence of bioavailability, metabolism, protein binding and half-life data, and (e) multiple potent PDE5 inhibitors never made their ways to the market.

[322] Lilly also attack Dr. Baughman's opinion on the basis that (1) she was an expert in proteins and not pharmaceutical small molecules, (2) she was clearly not blinded, (3) she did not approach her task on the point of view from the PSA, (4) she did not read the 784 Application including the 50mg example, and (5) IC_{50} values are variable and depend on experimental conditions.

[323] The obvious to try test is an appropriate test to apply in this case because the patent at issue is in an area of endeavour where advances are often won by experimentation (see *Sanofi* at para 78). When applying the obvious to try test, *Sanofi* at para 69 directs the Court to consider the following factors:

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

[324] While I recognize that the factors suggested in *Sanofi* are not exhaustive, I am satisfied upon review of the above factors that the difference between the prior art and the subject-matter as defined by the asserted Claims would have been obvious to the PSA on April 30, 1999.

[325] As outlined by the experts, drug dosing is typically done during Phase II clinical trials. It is routine work, and there are even expert pharmacologists such as Dr. Baughman who are specialised in dose selection (or dosing) of drugs. The skilled team, in attempting to dose tadalafil, would use available information from the 784 Application and the 377 Patent, including information on tadalafil bioavailability, potency and selectivity for PDE5, as well as information from sildenafil. As Dr. Baughman wrote in her Expert Report at paras 68–75, the relative molecular weight of tadalafil versus that of sildenafil, and the relative potency of tadalafil versus that of sildenafil will allow the skilled team to make a rough prediction of the dose, within the range disclosed in the 784 Application. Working from there, and using all available information in the prior art, the skilled team can design a Phase II dose ranging study, graph the dose response curve from data gathered during the study, identify the side effects, and

select the dose range that provides the best balance between efficacy, and safety and tolerability (Dr. Baughman Expert Report at paras 50, 96). If the initial dose ranging study does not allow the drawing of a full drug response curve because the minimum effective dose was not identified or because the maximum effective dose was not identified, a second Phase II study may be performed with different doses to properly identify them (transcript of December 18, 2019 at page 44). The skilled team, using known and routine trial design techniques, shall be able to design trials to appropriately select the doses for tadalafil and proceed to Phase III large scale studies.

[326] While obtaining regulatory approval to conduct the Phase II dose ranging study, and later to market the drug, may be a costly endeavour, the purpose of patent law is not to reward work done for the purpose of obtaining regulatory approval (see *Apotex Inc v Wellcome Foundation Ltd*, 2002 SCC 77 at para 77; *Apotex Inc v Sanofi-Aventis*, 2011 FC 52 at paras 28, 71) but, rather, for work that brings something new, useful, and inventive (see Patent Act, s 2).

[327] As per the expert evidence, the number of predictable solutions is not infinite, but rather well defined with a final outcome with minor possible variations. The ultimate aim is to select a dose range that offers the best balance between efficacy, and safety and tolerability. There is only really one method to identify the dose range: trials have to be performed in order to graph the efficacy of the drug in relation to the dose, and to identify the side effect occurrences in relation to the dose (Dr. Ellis Expert Report at paras 37–39).

[328] Additionally, despite the effort required to obtain regulatory approval, the steps to take are really only routine. Having already identified a viable compound for the PDE5 inhibition and the treatment of ED, the skilled team would certainly be motivated to identify the doses that offer the best balance between efficacy, and safety and tolerability to push the compound one-step closer to the market.

[329] My conclusion is similar to the holding in *Actavis Group PTC EHF v ICOS Corporation*, [2019] UKSC 15, which held the UK equivalent of the 684 Patent to be obvious. The UK Supreme Court cited, at para 76, Lord Justice Jacob in *Actavis UK Ltd v Merck & Co Inc*, [2009] 1 WLR 1186 (EWCA) at para 32. Lord Justice Jacob wrote that a new dosage regime in a Swiss-form claim is nearly always obvious because "it is standard practice to investigate appropriate dosage regimes."

(3) Conclusion on obviousness

[330] The Defendants have demonstrated that the asserted Claims are obvious and are thus invalid.

D. *Conclusion on the counterclaims of invalidity*

[331] The asserted Claims are invalid for both anticipation and obviousness.

VIII. Lilly's infringement claim

A. *Principles*

[332] Under section 42 of the Patent Act, the patentee and their legal representatives have the exclusive right, privilege and liberty of making, constructing, and using the invention and selling it to others. Subsection 55(1) of the Patent Act provides that a person who infringes a patent is liable for all damages sustained by the patentee by reason of the infringement.

[333] The burden of proving infringement is on the party that alleges it (*Monsanto Canada Inc v Schmeiser*, 2004 SCC 34 at para 29).

[334] Lilly submit that the issue of infringement is a mixed question of fact and law, as claim construction is a matter of law while the determination of infringement is a question of fact. After the claims are construed purposively, the alleged infringing device is compared as against the essential and non-essential elements of the claims. If the Defendants' product comprises all of the essential elements of the claim as construed there is infringement, but there is no infringement if an essential element is different or omitted. There may still be infringement, however, if non-essential elements are substituted or omitted (*Free World Trust*; *Canamould Extrusions*).

[335] Lilly also submit that a party who induces another person to infringe a patent is guilty of infringement of the patent. They outline that inducement is assessed on a three-prong test: (1) the act of infringement must have been completed by the direct infringer; (2) the completion of the

acts of infringement must be influence by the acts of the alleged inducer to the point that, without the influence, direct infringement would not take place; (3) the influence must knowingly be exercised by the inducer, that is, the inducer knows that this influence will result in the completion of the act of infringement.

[336] Lilly argue that, in addition to direct infringement of Claim 10 as it depends on Claim 9 which depends on Claims 3–6, the inducement to infringement of Claims 13–16 is also present: (1) doctors and pharmacists prescribe patients infringing tablet; (2) if the Defendants did not make these unit doses available by way of sale to doctors, pharmacists and patients, the unit doses would not be used to treat ED; (3) if the Product Monograph prescribes a particular indication for a drug, the inducer knows will result in the completion of the act of infringement.

[337] The Defendants have raised the *Gillette* defence in their opening statement but have made no mention of it in closing. In fact, the Defendants presented no defence in their closing submissions in the event that the asserted Claims of the 684 Patent were valid.

[338] There is no dispute among the parties that the infringement analysis is concerned with the essential elements of the asserted Claims.

B. *Conclusion on the infringement claim*

[339] The evidence shows that, on or around July 12, 2016, Apotex, Mylan, Teva/Actavis, Pharmascience, and Riva each received a NOC for their respective tadalafil with CIALIS as reference product, and they all either marketed, used, induced, manufactured, sold or imported

the infringing tablets (2.5mg, 5mg, 10mg and 20mg tablets, except for Riva who has offered for sale and sold 5mg and 20mg tablets in Canada).

[340] If I am wrong on the validity assessment, and if the asserted Claims are valid, Lilly has met their burden to establish their infringement.

IX. Election between damages and accounting of profits

[341] In the event that the asserted Claims are valid and the Defendants infringed them, Lilly demand the entitlement to elect between damages and an accounting of profits. The Defendants argued in their pleadings that they are entitled to make the election between damages or an accounting of profits in favour of Lilly.

[342] It is generally the rule that the trial judge has complete discretion in deciding whether or not to grant this equitable remedy (*Merck & Co v Apotex Inc*, 2006 FCA 323), and the right to elect has been denied for a variety of reasons such as the delay in bringing forward an action for infringement, misconduct on the part of the patentee and good faith of an infringer (*Eli Lilly & Co v Apotex Inc*, 2009 FC 991 at paras 647–648).

[343] In this case, there is no reason to deny Lilly the entitlement to make the election if there were infringement of valid claims.

X. Declaratory relief

[344] In their Closing Memorandum, Lilly do not seek the delivery up, nor the destruction of the wares. Lilly also do not seek an injunction. The Court has discretion to issue declarations in the event there were infringement (Patent Act, s 57). Lilly seek a declaration that the Defendants infringed and/or induced the infringement of the asserted Claims, that the 684 Patent is valid, that the Plaintiffs may elect between damages and an accounting of profits.

[345] If there were infringement, Lilly would be entitled to the declarations sought.

XI. Sealing order

[346] The parties will have fifteen days from the release of these confidential reasons to suggest redactions, before a public version is released.

XII. Costs

[347] The parties made scarce representations as to costs, they have no asked for the Court to reserve nor for the opportunity to file submissions on this issue. Lilly asked for "costs of this action on a scale to be determined by this Court, including all applicable taxes and disbursements" while the Defendants asked "that this action, as it relates to the 684 Patent, be dismissed with costs payable to the Defendants."

[348] As Lilly's action relating to the 684 Patent is dismissed and the Defendants' counterclaims are granted, costs will be payable to the Defendants.

PUBLIC JUDGMENT in T-1627-16

THIS COURT'S JUDGMENT is that:

1. Claim 10 (as it depends on Claim 9, as it in turn depends on Claims 3–6), and Claims 13–16 of Canadian Patent No. 2,371,684 are invalid for anticipation and obviousness.

2. The infringement action against the Defendant relating to Canadian Patent No. 2,371,684 is dismissed.

3. Costs are awarded in favour of the Defendant.

4. The parties have fifteen days from the release of these confidential reasons to make submissions on redactions before a public version is released.

5. A copy of these confidential reasons shall be filed in each of the following files T- 1631-16 (T-1639-16), T-1623-16 (T-1624-16) and T-1632-16.

"Martine St-Louis"
Judge

Annex I

Claim 3

The dosage form of claim 1 comprising about 5 to about 20mg of the compound in unit dosage form.

Claim 4

The dosage form of claim 2 comprising about 2.5mg of the compound in unit dosage form.

Claim 5

The dosage form of claim 3 comprising about 5mg of the compound in unit dosage form.

Claim 6

The dosage form of claim 3 comprising about 10mg of the compound in unit dosage form.

…

Claim 9

The dosage form of any one of claims 1 through 6 for use in treating sexual dysfunction in a patient where inhibition of PDE5 provides a benefit.

Claim 10

The dosage form of claim 9 wherein the sexual dysfunction is male erectile dysfunction.

…

Claim 13

The use of claim 12 wherein the unit dose contains about 2 to about 20mg of the compound.

Claim 14

The use of claim 12 wherein the unit dose contains about 5mg of the compound.

Claim 15

The use of claim 12 wherein the unit dose contains about 10mg of the compound.

Claim 16

The use of claim 12, wherein the unit dose contains about 20mg of the compound.

Annex II

As the patents in suit were issued after October 1, 1989, the provisions of the current *Patent Act* apply. The relevant sections of the *Patent Act* provide as follows:

Definitions	**Definitions**
2 In this Act, except as otherwise provided,	2 Sauf disposition contraire, les définitions qui suivent s'appliquent à la présente loi.
invention means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter; (*invention*)	invention Toute réalisation, tout procédé, toute machine, fabrication ou composition de matières, ainsi que tout perfectionnement de l'un d'eux, présentant le caractère de la nouveauté et de l'utilité. (*invention*)
Specification	**Mémoire descriptif Specification**
27 (3) The specification of an invention must	27 (3) Le mémoire descriptif doit :
(a) correctly and fully describe the invention and its operation or use as contemplated by the inventor;	a) décrire d'une façon exacte et complète l'invention et son application ou exploitation, telles que les a conçues son inventeur;
(b) set out clearly the various steps in a process, or the method of constructing, making, compounding or using a machine, manufacture or composition of matter, in such full, clear, concise and exact terms as to enable any person skilled in the art or science to which it pertains, or with which it is most closely connected, to make, construct, 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	d) s'il s'agit d'un procédé, expliquer la suite nécessaire, le cas échéant, des diverses phases du procédé, de façon à distinguer

other inventions.

Claims

(4) The specification must end with a claim or claims defining distinctly and in explicit terms the subject-matter of the invention for which an exclusive privilege or property is claimed.

Subject-matter of claim must not be previously disclosed

28.2 (1) The subject-matter defined by a claim in an application for a patent in Canada (the "pending application") must not have been disclosed

(a) before the one-year period immediately preceding the filing date or, if the claim date is before that period, before the claim date by the applicant, or by a person who obtained knowledge, directly or indirectly, from the applicant, in such a manner that the subject-matter became available to the public in Canada or elsewhere;

(b) before the claim date by a person not mentioned in paragraph (a) in such a manner that the subject-matter became available to the public in Canada or elsewhere;

(c) in an application for a patent that is filed in Canada by a person other than the applicant, and has a filing date that is before the claim date; or

(d) in an application (the "co-pending application") for a patent that is filed in Canada by a person other than the applicant and has a filing date that is on or after the claim date if

l'invention en cause d'autres inventions.

Revendications

(4) Le mémoire descriptif se termine par une ou plusieurs revendications définissant distinctement et en des termes explicites l'objet de l'invention dont le demandeur revendique la propriété ou le privilège exclusif.

Objet non divulgué

28.2 (1) L'objet que définit la revendication d'une demande de brevet ne doit pas :

a) soit plus d'un an avant la date de dépôt de celle-ci, soit, si la date de la revendication est antérieure au début de cet an, avant la date de la revendication, avoir fait, de la part du demandeur ou d'un tiers ayant obtenu de lui l'information à cet égard de façon directe ou autrement, l'objet d'une communication qui l'a rendu accessible au public au Canada ou ailleurs;

b) avant la date de la revendication, avoir fait, de la part d'une autre personne, l'objet d'une communication qui l'a rendu accessible au public au Canada ou ailleurs;

c) avoir été divulgué dans une demande de brevet qui a été déposée au Canada par une personne autre que le demandeur et dont la date de dépôt est antérieure à la date de la revendication de la demande visée à l'alinéa (1)a);

d) avoir été divulgué dans une demande de brevet qui a été déposée au Canada par une personne autre que le demandeur et dont la date de dépôt correspond ou est postérieure à la date de la revendication de la demande visée à l'alinéa (1)a) si :

(i) the co-pending application is filed by

(A) a person who has, or whose agent, legal representative or predecessor in title has, previously regularly filed in or for Canada an application for a patent disclosing the subject-matter defined by the claim, or

(B) a person who is entitled to protection under the terms of any treaty or convention relating to patents to which Canada is a party and who has, or whose agent, legal representative or predecessor in title has, previously regularly filed in or for any other country that by treaty, convention or law affords similar protection to citizens of Canada an application for a patent disclosing the subject-matter defined by the claim,

(ii) the filing date of the previously regularly filed application is before the claim date of the pending application,

(iii) the filing date of the co-pending application is within twelve months after the filing date of the previously regularly filed application, and

(iv) the applicant has, in respect of the co-pending application, made a request for priority on the basis of the previously regularly filed application.

Invention must not be obvious

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

(a) information disclosed before the one-year period immediately preceding the filing date

(i) cette personne, son agent, son représentant légal ou son prédécesseur en droit, selon le cas :

(A) a antérieurement déposé de façon régulière, au Canada ou pour le Canada, une demande de brevet divulguant l'objet que définit la revendication de la demande visée à l'alinéa (1)a),

(B) a antérieurement déposé de façon régulière, dans un autre pays ou pour un autre pays, une demande de brevet divulguant l'objet que définit la revendication de la demande visée à l'alinéa (1)a), dans le cas où ce pays protège les droits de cette personne par traité ou convention, relatif aux brevets, auquel le Canada est partie, et accorde par traité, convention ou loi une protection similaire aux citoyens du Canada,

(ii) la date de dépôt de la demande déposée antérieurement est antérieure à la date de la revendication de la demande visée à l'alinéa a),

(iii) à la date de dépôt de la demande, il s'est écoulé, depuis la date de dépôt de la demande déposée antérieurement, au plus douze mois,

(iv) cette personne a présenté, à l'égard de sa demande, une demande de priorité fondée sur la demande déposée antérieurement.

Objet non évident

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) qui a été faite, soit plus d'un an avant la date de dépôt de la demande, soit, si la date

or, if the claim date is before that period, before the claim 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

(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

de la revendication est antérieure au début de cet an, avant la date de la revendication, 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) 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.

Form and duration of patents

43 (1) Subject to section 46, every patent granted under this Act shall be issued under the seal of the Patent Office, and shall bear on its face the filing date of the application for the patent, the date on which the application became open to public inspection under section 10, the date on which the patent is granted and issued and any prescribed information.

Délivrance

43 (1) Sous réserve de l'article 46, le brevet accordé sous le régime de la présente loi est délivré sous le sceau du Bureau des brevets. Il mentionne la date de dépôt de la demande, celle à laquelle elle est devenue accessible au public sous le régime de l'article 10, celle à laquelle il a été accordé et délivré ainsi que tout renseignement réglementaire.

Validity of patent

(2) After the patent is issued, it shall, in the absence of any evidence to the contrary, be valid and avail the patentee and the legal representatives of the patentee for the term mentioned in section 44 or 45, whichever is applicable.

Validité

(2) Une fois délivré, le brevet est, sauf preuve contraire, valide et acquis au breveté ou à ses représentants légaux pour la période mentionnée aux articles 44 ou 45.

Term of patents based on applications filed on or after October 1, 1989

44 Subject to section 46, where an application for a patent is filed under this Act on or after October 1, 1989, the term limited for the duration of the patent is twenty years from the filing date

Durée du brevet

44 Sous réserve de l'article 46, la durée du brevet délivré sur une demande déposée le 1er octobre 1989 ou par la suite est limitée à vingt ans à compter de la date de dépôt de cette demande.

Admissible in evidence

53.1 (1) In any action or proceeding respecting a patent, a written communication,

Admissibilité en preuve

53.1 (1) Dans toute action ou procédure relative à un brevet, toute communication

or any part of such a communication, may be admitted into evidence to rebut any representation made by the patentee in the action or proceeding as to the construction of a claim in the patent if

écrite ou partie de celle-ci peut être admise en preuve pour réfuter une déclaration faite, dans le cadre de l'action ou de la procédure, par le titulaire du brevet relativement à l'interprétation des revendications se rapportant au brevet si les conditions suivantes sont réunies :

(a) it is prepared in respect of

(i) the prosecution of the application for the patent,

(ii) a disclaimer made in respect of the patent, or

(iii) a request for re-examination, or a re-examination proceeding, in respect of the patent; and

a) elle est produite dans le cadre de la poursuite de la demande du brevet ou, à l'égard de ce brevet, d'une renonciation ou d'une demande ou procédure de réexamen;

(b) it is between

(i) the applicant for the patent or the patentee; and

(ii) the Commissioner, an officer or employee of the Patent Office or a member of a re-examination board.

b) elle est faite entre, d'une part, le demandeur ou le titulaire du brevet, et d'autre part, le commissaire, un membre du personnel du Bureau des brevets ou un conseiller du conseil de réexamen.

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	**T-1627-16**
STYLE OF CAUSE:	**ELI LILLY CANADA INC., ELI LILLY AND COMPANY, LILLY DELCARIBE, INC., LILLY, S.A. and ICOS CORPORATION INC. and MYLAN PHARMACEUTICALS ULC ET ALS.**
PLACE OF HEARING:	**OTTAWA, ONTARIO**
DATE OF HEARING:	**DECEMBER 5, 2019**
PUBLIC JUDGMENT AND REASONS:	**ST-LOUIS, J.**
DATED:	**SEPTEMBER 10, 2020**

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