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T-1623 (1624)-16
T-1627-16
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Citation: 2022 FC 1398

Ottawa, Ontario, December 20, 2022

PRESENT: 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

APOTEX INC.

Defendant
Plaintiff by Counterclaim

AND 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:

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:

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. ET LABORATOIRE RIVA INC.

Defendants
Plaintiffs by Counterclaim

PUBLIC JUDGMENT AND REASONS

(Confidential Judgment and Reasons issued October 17, 2022)

I. Introduction

[1] The Defendants Teva Canada Limited, Pharmascience Inc. and Laboratoire Riva Inc., Apotex Inc., and Mylan Pharmaceuticals ULC, have brought a motion for summary trial [the Motion].

[2] The Defendants' Motion was filed in the broader context of the Plaintiffs', Eli Lilly Canada Inc., Eli Lilly and Company, Lilly del Caribe Inc., Lilly, S.A., and ICOS Corporation [collectively referred to as Lilly], underlying actions against the Defendants for infringement of claims 2, 4, 10, 14, 18, 20, 22, and 23 [the Asserted Claims] of the Canadian Patent No. 2,226,784 [the 784 Patent]. Lilly based its action on the manufacturing, importing, and stockpiling in Canada prior to the July 11, 2016, expiry of the 784 Patent, as well as on springboarding damages purportedly flowing from that infringement. In their Defence and Counterclaim, the Defendants raised invalidity grounds and pleaded, namely, that physiologically acceptable salts of tadalafil cannot be made.

[3] In their Notice of Motion, the Defendants ask the Court for an order in their favour dismissing Lilly's actions for infringement on the grounds that the Asserted Claims of the 784 Patent are invalid for overbreadth, insufficiency and inutility. In brief, the Defendants assert that the physiologically acceptable salts of tadalafil referred to in each Asserted Claims cannot be

made and that as a result, the skilled person cannot make, construct, compound,or use a salt of tadalafil for the treatment of erectile dysfunction as required by each Asserted Claims.

[4] For the reasons that follow, I will grant the Defendants' Motion and dismiss Lilly's infringement actions. In brief, I agree with the parties and find it is appropriate to proceed by way of a motion for summary trial. I also find that the Defendants have met their burden and established that it is more probable than not that a physiologically acceptable salt of tadalafil cannot be made. The Defendants have established that the Asserted Claims are invalid on the grounds of overbreadth and of insufficiency. The Defendants have also established that there was not enough common general knowledge to support a sound prediction of utility of a physiologically acceptable salt. However, as it is not entirely clear to me that the case law on inoperable species applies, particularly in light of the Supreme Court's decision in *Teva Canada Limited v Pfizer Canada Inc*, 2012 SCC 60 [*Teva*, and given my conclusions on the two other invalidity allegations, I have not decided on the allegation of invalidity on the ground of inutility.

II. The Motion for Summary Trial

[5] I agree with the parties that it is appropriate to proceed by way of a motion for summary trial per Rules 213 to 219 of the *Federal Courts Rules*, DORS/98-106 [the Rules]. The Court has outlined the factors to be considered on a motion for summary trial and stated that summary trial is appropriate where the issues are well defined, the facts necessary to resolve the issues are already in evidence, credibility issues can be resolved, and the questions of law can be dealt with as they could be after a full trial (*ViiV Healthcare Company v Gilead Sciences Canada Inc*, 2020 FC 486 at paras 11-13; *Leo Ocean SA v Westshore Terminals Limited Partnership*, 2015 FCA

282 at para 37; *Canada (Ship-Source Oil Pollution Fund) v Dr. Jim Halvorson Medical Services Ltd*, 2019 FC 35 at paras 27-29; *Teva Canada Ltd v Wyeth LLC*, 2011 FC 1169).

[6] Subsection 43(2) of the *Patent Act*, RSC 1985, c P-4 provides that a patent is presumed to be valid in the absence of evidence to the contrary; this presumption is weak and the Defendants have rebutted it by adducing evidence supporting their allegations. The Defendants bear the onus to prove their allegations of invalidity on a balance of probabilities (*Georgetown Rail Equipment Company v Rail Radar Inc*, 2018 FC 70 at para 109 aff'd on this point in 2019 FCA 203 at para 57). In addition, the parties are required, on a motion for summary trial, to put their best foot forward (*United Yacht Transport LLC v Blue Horizon Corporation*, 2020 FC 1067 at para 20).

[7] I agree with Lilly that the issue on this Motion is limited to what the Defendants raised in their Notice of Motion. The Defendants limited the issue to the expression "physiologically acceptable salt" and they did not include the issue of whether this "physiologically acceptable salt" was *to treat erectile dysfunction* (ED). I particularly note paragraphs 28, 32 and 41 of the Defendants' Notice of Motion and, subscribing to the arguments Lilly presented, I conclude that the issue, i.e., *to treat erectile dysfunction*, cannot be included in these proceedings. I will thus decline the Defendants' invitation to include this added consideration, i.e., *to treat erectile dysfunction*, as part of their Motion.

[8] The Motion was heard by videoconference and the parties' expert witnesses were cross-examined.

III. Preliminary matter: Motion to Strike Hearsay

[9] Upon the start of the hearing, the Defendants filed a motion to strike for hearsay seeking an Order:

1. Striking the document labelled “CN 104086546”, which purports to be a Chinese patent “authorized” on August 17, 2016 [the Chinese Patent] and the document labelled “US 10,752,589”, which purports to be a United-States patent published on September 21, 2017 [the US Patent] from the evidentiary record in the summary trial;

2. Striking the affidavit of Stephen Murray affirmed January 8, 2021, including its exhibits;

3. Essentially striking opinions relating to the Chinese Patent and the US Patent from Dr. Stephen Byrn’s and Dr. Philip Jessop’s affidavits, and from the Plaintiffs’ Written Opening Submissions, and requiring them to file, respectively, amended affidavits and amended Written Opening Submissions; and

4. Awarding the Defendants’ costs of the motion in the amount of 5 000.00$.

[10] In brief, the Defendants submit that the issues to be determined on the Motion to strike for hearsay are: (i) whether the Chinese Patent and the US Patent should be struck from Lilly’s evidence on the basis that they constitute inadmissible hearsay and (ii) as a result, whether the references in the affidavits as well as in Lilly’s Written Opening Submissions should also be struck.

[11] The Defendants submit that hearsay evidence offered as proof of the truth of their content is inadmissible, although they add that some hearsay may be admissible if it falls under a “traditional exception” (*R v Bradshaw*, 2017 SCC 35) or exceptionally, if it meets the criteria of both necessity and reliability, on a balance of probabilities. The Defendants submit that the Chinese Patent and the US Patent are inadmissible hearsay that is neither necessary nor reliable enough to be admissible. The Defendants also submit that the Plaintiffs are in violation of Rule 232 of the Rules as they have never produced the Chinese Patent and the US Patent as part of

their Affidavit of Documents. Finally, the Defendants add that expert opinions that rely upon unproven facts and documents are inadmissible (*R v Lavallée*, [1990] 1 SCR 852 citing *R v Abbey*, [1982] 2 SCR 24). They outline particularly that before any weight can be given to an expert's opinion, the facts upon which the opinion is based must be found to exist. They stress that Dr. Byrn and Dr. Jessop's opinions are entirely based upon unproven facts and documents because the Chinese Patent and the US Patent are inadmissible hearsay. Said opinions thus ought to be ruled inadmissible and struck, or in the alternative, given "no weight".

[12] The Plaintiffs respond that the Motion to strike for hearsay should be dismissed due to delay and on the merits. I agree that the Motion should be dismissed due to delay. As the Plaintiffs outline, the Defendants allege, in their Written Representations, that Dr. Byrn and Dr. Jessop rely on the patents for the truth of their contents. The manner in which the patents were being used by the Plaintiffs' experts was thus evident from the affidavits themselves, which were available to the Defendants on February 12, 2021, hence eight (8) months before the hearing, and the Defendants' delay in bringing forward their objection is thus indefensible. The Plaintiffs are prejudiced due to the Defendants' delay in responding, having lost the opportunity to deal with the Court's order if steps were required.

[13] I will thus dismiss the Defendants' motion to strike for hearsay and will award the costs of said motion to strike to the Plaintiffs according to Rule 407 of the Rules.

IV. The 784 Patent

[14] The 784 Patent was filed in Canada on July 11, 1996, published on February 6, 1997, and issued on July 8, 2003. It claims a priority date of July 14, 1999.

[15] It is titled “Use of CGMP-Phosphodiesterase inhibitors to treat impotence”. The named inventor is Dr. Alain Claude-Marie Daugan and the initial owner was Glaxo France while its successor in title is now ICOS Corporation US.

[16] The disclosure indicates, in its first paragraph, that the invention relates to the use of tetracyclic derivatives which are potent and selective inhibitors of cyclic guanosine 3’,5’-monophosphate specific phosphodiesterase (cGMP specific PDE) in the treatment of impotence. The abstract states that:

> The use of compounds of formula (I) (6R, 12aR)-2,3,6,7,12,12a-hexahydro-2-methyl-6-(3,4-methylenedioxyphenyl)-pyrazino[2' ,1 ': 6, l]pyrido[3,4-b]indole-l,4-dione, (3S, 6R, 12aR)-2,3,6,7,12,12a-hexahydro-2,3-d.imethyl-6-(3,4-methylenedioxyphenyl)-pyrazino[2' ,1 ': 6, l]pyrido[3,4-b]indole-l ,4-dione, and physiologically acceptable salts and solvates thereof, in the treatment of impotence.

[17] The 784 Patent ends with 28 claims of which 8 are asserted, i.e., Claims 2, 4, 10, 14, 18, 20, 22 and 23. Each of the Asserted Claims is directed to a *physiologically acceptable salt* that is capable of being manufactured into a pharmaceutical composition with a pharmaceutically acceptable diluent or carrier, for the treatment of erectile dysfunction.

[18] For example, Claim 2 reads:

> 2. A pharmaceutical composition for the curative or prophylactic treatment of erectile dysfunction in a male animal, comprising a compound selected from the group consisting of:

> (6R, 12aR) -2, 3, 6, 7, 12, 12a-hexahydro-2-methyl-6-(3, 4-methylenedioxyphenyl) - pyrazino [2', 1':6,1] pyrido [3,4-b] indole-1,4-dione or a physiologically acceptable salt or solvate thereof; and
>
> (3S, 6R, 12aR) -2,3,6,7,12,12a-hexahydro-2,3-dimethyl-6-(3, 4-methylenedioxyphenyl) - pyrazino [2', 1':6,1] pyrido [3,4-b] indole-1,4-dione or a physiologically acceptable salt or solvate thereof;
>
> together with a pharmaceutically acceptable diluent or carrier.

[19] All other Asserted Claims include the "physiologically acceptable salt […] thereof" claim limitation. At page 4, the 784 Patent outlines that:

> The pharmaceutically acceptable salts of the compound of formula (I), and in particular, compounds A and B which contain a basic centre are acid addition salts formed with pharmaceutically acceptable acids. Examples include the hydrochloride, hydrobromide, sulphate or bisulphate, phosphate or hydrogen phosphate, acetate, benzoate, succinate, fumarate, maleate, lactate, citrate, tartrate, gluconate, methanesulphonate, benzenesulphonate and p toluenesulphonate salts. Compounds of formula (1) and in particular compounds A and B can also provide pharmaceutically acceptable metal salts, in particular alkali metal salts, with bases. Examples include the sodium and potassium salts.

[20] At page 9, the 784 Patent outlines that:

> The pharmaceutically acceptable acid addition salts of a compound of formula (I), and in particular compound A and B which contain a basic centre may be prepared in a conventional manner. For example, a solution of the free base may be treated with a suitable acid, either neat or in a suitable solution and the resulting salt isolated either by filtration or by evaporation under vacuum of the reaction solvent. Pharmaceutically acceptable base addition salts may be obtained in an analogous manner by treating a solution of compound A or B with a suitable base. Both types of salt may be formed or interconverted using ion-exchange resin techniques.

[21] The 784 Patent was the subject of invalidity allegations in proceedings pursuant to the *Patented Medicines (Notice of Compliance) Regulations,* SOR/93-133 in *Eli Lilly Canada Inc v Apotex Inc*, 2015 FC 875, aff'd 2016 FCA 267 [*Eli Lilly*] and in *Eli Lilly v Mylan Pharmaceuticals Inc*, 2015 FC 17, aff'd 2016 FCA 119, whereby allegations of invalidity were dismissed as unjustified, and where the Court issued Orders of prohibition. I am satisfied that the issue raised in this Motion, centered around the expression "physiologically acceptable salt", has not specifically been addressed in those two (2) prior decisions.

[22] In this Motion, the parties agree that (1) the first compound described is tadalafil and the second compound is referred to as 3-methyl tadalafil or methyltadalafil; (2) the ability to form a salt is the same as between tadalafil and 3-methyl tadalafil, so it is not necessary to make a separate determination as between the two compounds, my references and conclusions in regards to tadalafil will thus include 3-methyl tadalafil; (3) each Asserted Claims include the term "physiologically acceptable salt"; and (4) the evidence shows that Glaxo France has not made a salt of tadalafil prior to filing the application that led to the 784 Patent.

[23] The Defendants have asserted that the parties also agree that all the Asserted Claims are invalid if physiologically acceptable salt were not invented, or enabled or useful, an assertion Lilly has not directly contested this assertion although its submissions do not entirely accord with it.

V. The Evidence

A. *Expert evidence-guidance*

[24] In *Rovu Guides Inc v Videotron Ltd*, 2022 FC 874, Justice Lafrenière referred to paragraph 64 of the *SNF Inc v Ciba Specialty Chemicals Water Treatments Limited*, 2015 FC 997 decision, where Justice Phelan sets out some of the factors to be considered in evaluating the credibility and weight of an expert's evidence. These include whether the witness:

- was intransigent, particularly during cross-examination and evaded questions that could expose any frailties in his theory and was intent on reiterating his views, when he deemed it necessary, irrespective of whether those views were responsive to the questions at hand (including by providing answers that went much beyond the question put to the witness);
- emphasized those areas favourable to the expert's interpretation and reluctant to respond to other questions;
- frequently would not concede something which seemed to be obvious or logical and when the concession came, did so reluctantly and grudgingly;
- was forthright, fair, thoughtful and reasonable in answering all questions asked of him/her during both direct and cross-examination;
- in testifying as to the teachings of the Prior Art and the patent in issue, varied their interpretation in order to reach the desired result.

[25] I keep these factors in mind when assessing the experts' credibility and the reliability of their evidence.

B. *The Defendants' evidence*

[26] The Defendants have adduced the affidavit of Dawn Trach, sworn September 17, 2020; the expert affidavit of Dr. André Beauchemin, sworn September 17, 2020; and the rebuttal affidavit of Dr. Beauchemin, sworn on April 15, 2021.

(1) Dawn Trach

[27] Ms. Trach introduced eight (8) exhibits. Exhibit F is Lilly's answers to undertakings dated September 19, 2019, where Lilly confirmed that prior to the filing of the 784 Patent, Dr. Daugan had not made a tadalafil salt and that no scientist at Les Ulis had made a salt of tadalafil.

[28] Exhibit G is a trial transcript dated December 6, 2019, whereby Dr. Karl Donn affirmed that the X in the compound name GF196960X designates that there was no salt. I agree with Lilly that the question of whether tadalafil could form a physiologically acceptable salt was not an issue in the portions of the trial where Dr. Donn testified and is of no help in these proceedings since Lilly has agreed that Glaxo France did not make a salt of tadalafil prior to filing.

[29] Exhibit H is a trial transcript dated December 17, 2019, whereby Dr. Harmut Derendorf, discussing solubility of tadalafil as compared to sildenafil, indicated that "[y]ou cannot make salt of tadalafil, so this is a compound that does not dissolve very well". Again, I agree with Lilly that whether tadalafil could form a physiologically acceptable salt or not was not an issue in that portion of the trial and cannot be relied upon in these proceedings without clarifications. Sadly, Dr. Derendorf passed away and no further evidence is available.

(2) Dr. André Beauchemin

[30] Dr. André Beauchemin was qualified as an expert in organic chemistry, including on the synthesis of bioactive molecules and their salts. He holds a BSc in Chemistry from Université

Laval and a Ph.D. in Chemistry from Université de Montréal. He was a NSERC Postdoctoral Fellow in the Department of Chemistry and Chem.Biol at Harvard University. He is a full professor in the Department of Chemistry and Biomolecular Sciences at the University of Ottawa. His mandate is confirmed at paragraph 10 of his affidavit.

[31] A summary of his opinions is outlined at paragraphs 12 to 15 of his affidavit. He essentially concludes the following: (1) a skilled chemist could look at a chemical structure of a small molecule drug and assess whether physiologically acceptable salt could be made; (2) physiologically acceptable salts of tadalafil cannot be made and tadalafil does not contain an ionisable group over the pH range conventionally used to make pharmaceutical salts; (3) public literature, including from the European Medicines Agency, strongly suggests that pharmaceutically acceptable salts of tadalafil cannot be made; and (4) contrary to statements in the 784 Patent, physiologically acceptable salts of tadalafil cannot be prepared. Dr. Beauchemin opines that, in any event, the 784 Patent does not teach the skilled chemist how to make physiologically acceptable salts of tadalafil.

[32] Dr. Beauchemin explains the Bronstead-Lowry theory of acids and bases. In regards to acids, he outlines that the transfer of protons between or within molecules makes up the modern theory of acids and that in the Bronstead-Lowry theory: an acid is a compound that when dissolved in water can release a proton according to a certain equation and a base, on the other hand, is a compound that can accept a proton according to a certain equation.

[33] Dr. Beauchemin defines salt as a neutral compound comprised of a negatively charged species, called an anion, that electrostatically interacts with a positively charge species called a cation. In his Rebuttal Affidavit, Dr. Beachemin confirms that the skilled person in 1997 would not have considered a cocrystal a salt.

[34] Dr. Beauchemin was not asked to construe the term *physiologically acceptable* and has not defined it particularly, in isolation. At paragraph 43 of his affidavit, he opines that physiologically acceptable salts are generally made by mixing the drug substance with an acid or a base to perform an acid-base reaction that provides a physiologically appropriate counterion. He outlines that unstable or degraded salt would not be physiologically acceptable (paragraphs 78, 79, 86, 88 and 89 of his affidavit). On cross-examination, Dr. Beauchemin confirmed that salts of tadalafil can be made, but not a physiologically acceptable salt, because of the degradation that would occur. Dr. Beauchemin confirmed it was important that a physiologically acceptable salt not be toxic as well.

[35] Dr. Beauchemin identifies the skilled chemist [the POSITA] as an organic or medicinal chemist either in an academic or industrial setting, with an advanced degree (MSC or Ph.D.) in chemistry and practical experience in a making physiologically acceptable salts of small molecule pharmaceuticals.

[36] Dr. Beauchemin opines that a skilled chemist, as of February 1997 up until today, looking simply at the structure of tadalafil would readily know that tadalafil does not contain any acidic or basic ionisable groups that are required to make physiologically acceptable salts by

conventional means. He adds that a skilled chemist, as of February 1997 up until today, looking simply at the structure of tadalafil would expect that salts of tadalafil would not form in reactions with either strong acid or base in water. He explains that in the presence of a strong base in water, one would expect that this strong base would almost exclusively react with water and not with the N-H bond of the indole subunit. He adds that, at the other extreme, tadalafil would need a strong acid to form a salt and that under either such strongly acid or basic conditions, a skilled chemist would expect degradation of tadalafil by reaction at or near the carbonyl group. He opines therefore that a skilled worker would not have considered such extreme conditions to be useful to produce a physiologically acceptable salt of tadalafil. Dr. Beauchemin indicates that most of the references he found confirmed that tadalafil does not have any ionisable groups at a physiologically acceptable pH range. Dr. Beauchemin adds that [redacted] and a copy of a journal article authored by *Rao et al*.

[37] Dr. Beauchemin opines that, while it may be theoretically possible to make base addition salts of indoles using superbases in non-aquaous solvents, such reagents are not conventionally employed to make physiologically acceptable salts of drug substances like tadalafil as they would almost certainly lead to the unwanted degradation of tadalafil (referring to *Rao et al*).

[38] In his Rebuttal Affidavit, Dr. Beauchemin affirms that salts of tadalafil can only be made under harsh conditions that would destroy, including through epimerization in organic solvents, the structural integrity of the drug substance (citing the Shi paper). He added that any such salts made would not be considered to be physiologically acceptable.

[39] In regards to Dr. Byrn's opinion that rely on Chinese Patent suggesting that naphthalene-1,5-disulfonic acid likely formed an ionic salt with tadalafil, Dr. Beauchemin explains that the pH ranges from 2 to 3 with 2,5 preferable, at that range it is not clear if naphthalene -1,5-disulfonic acid would have formed a salt of tadalafil.

[40] On cross-examination, Dr. Beauchemin agreed that sodium hydrade is a pharmaceutically acceptable base, that a sodium salt of tadalafil formed as a transient (US Patent 589, example 5) (exhibit 18 of the Byrn affidavit), and that the salt could have been isolated, but he again expressed concerns about the purity and the degradation, which would make the salt not physiologically acceptable.

[41] Dr. Beauchemin testified very openly. He was forthright, fair, thoughtful and reasonable in answering all questions asked of him during both direct and cross-examination. I give his opinion great weight.

C. *Lilly's evidence*

[42] Lilly adduced the affidavits of Kerstin Roland sworn January 28, 2021; Linda Henson sworn February 11, 2021; Stephen Murray sworn January 8, 2021; and Kathy Paterson, sworn February 12, 2021, each introducing exhibits and translations.

[43] Lilly also adduced the expert affidavit of Dr. Philip G. Jessop, sworn on February 12, 2021, and of Dr. Stephen Byrn, sworn on February 12, 2021.

(1) Dr. Philip G. Jessop

[44] Dr. Jessop was qualified as an expert in organic and inorganic chemistry, including protonation, deprotonation reactions of organic molecules (the reactions of acids and bases and making salts). Dr. Jessop holds a B.Sc in Chemistry from the University of Waterloo and a Ph.D. in inorganic chemistry from the University of British Columbia. He spent more than a year in a postdoctoral appointment at the University of Toronto. He is Professor and Canada Research Chair of Green Chemistry at the Department of Chemistry, Queen's University, in Kingston, Ontario.

[45] His mandate and assumptions are outlined at paragraphs 6 to 18 of his affidavit and the summary of his opinion is found at paragraphs 19 to 21. He concludes that a POSITA would expect that a physiologically acceptable salt of tadalafil could be made, both now and in 1996 and 1997.

[46] Dr. Jessop describes the skilled person in the art as likely to be more than one person-a small team composed of the organic chemist, expected to have at least a Master's in organic chemistry or organic synthesis with industry experience making salts, the pharmacologist, and the biochemist.

[47] Dr. Jessop outlines that the main point of disagreement between Dr. Beauchemin and himself pertains to the interpretation of the expression *physiologically acceptable* and that

because Dr. Beauchemin and him interpret this expression differently, they come to different conclusions.

[48] Dr. Jessop opines that whether salts are physiologically acceptable is a function of whether they will harm the patient. At paragraph 64 of his affidavit, Dr. Jessop explains that the POSITA would understand the expression *physiologically acceptable* to mean that it causes no harm to the physiology of the patient or that the harm is small enough to be outweighed by the benefit that the pharmaceutical provides.

[49] In this regard, Dr. Jessop assumes that the pharmaceutically active molecule itself is not harmful and the chemist would only have to consider the acid or base component that was used to make the active molecule into a salt and points out that the question to be answered would be whether the acid or base used would be harmful to humans in its resulting form, concentration, pH, and location in the patient. Notably, he indicates that this aspect, essentially assessing whether a salt of tadalafil would not be harmful, hence physiologically acceptable, is outside of his area of expertise.

[50] He defines salt as a chemical that consists of electrically charged species, adding that some salts can be made by the reaction of an acid with a base. He restricts the discussion to Bronsted-Lowry acids and bases, which are proton donors and proton receptors. The capacity of bases and acids to accept or give a proton appears as an important consideration when reading Dr. Jessop's affidavit.

[51] At paragraph 43 of his affidavit, Dr. Jessop outlines that when a chemist looks at an organic structure, they see functional groups that are familiar to them and that through their training, and they learn the chemical properties of these various functional groups. He adds that this would include which ones are likely able to be protonated (basic) and which ones are likely to be able to give a proton (acidic). Dr. Jessop confirms that this tells the chemist which groups are likely to be able to form a salt.

[52] Dr. Jessop affirms having found an example of the preparation of the sodium salt of tadalafil in the US Patent described earlier (example 5, step 1, column 24). The reagent used to generate the sodium salt of tadalafil was the base sodium hydride (NaH) and the solvent was tetrahydrofuran (THF).

[53] Dr. Jessop outlines that the Chinese Patent describes the preparation of a salt of tadalafil by reaction with the strong acid napthalenedisulfonic acid, using an organic solvent, tetrahydrofuran in the absence of water. Dr. Jessop also indicates that they also tested the stability of other tadalafil salts, including the hydrochloride and found that the amount of degradation of the tadalafil molecule in salt over 30 days was about 0.1% and that according to the results in the Chinese Patent, the conversion of tadalafil to a salt makes tadalafil more stable. Finally, Dr. Jessop outlines that the Chinese Patent also describes the preparation of what he considers cocrystals rather than salts.

[54] At paragraph 21 of his affidavit, Dr. Jessop opines that salts of tadalafil can be made, which, he asserts, is confirmed by both the US Patent and the Chinese Patent. He goes on to

indicate that whether those salts are physiologically acceptable is a function of whether they will harm the patient, not whether they are stable in water or whether they were prepared in the pH range of 0-14. For example, the sodium and chloride salts of tadalafil can be made and are physiologically acceptable.

[55] Also and despite having indicated it was outside his expertise, Dr. Jessop goes on to evaluate if the tadalafil salts would cause harm to the patient at paragraph 87 of his affidavit, i.e., if they are physiologically acceptable salts. Dr. Jessop concludes that the hydrochloride salt of tadalafil and the sodium salt of tadalafil would cause no harm to the patient and would thus be physiologically acceptable (sodium chloride and hydrogen chloride). He confirms that whether the other salts would cause harm to the patients is beyond his expertise, but goes on to outline that if they cause no harm, or so little harm that the benefit outweighs the harm, then they too would be physiologically acceptable.

[56] In essence, Dr. Jessop thus opines that two (2) physiologically acceptable salts of tadalafil, salts that will not cause harm, can be made: the hydrochloride salt of tadalafil and the sodium salt of tadalafil. Relying on the US and Chinese Patents, he opines that they were in fact made.

[57] Dr. Jessop came across as a reliable expert witness. He was open, candid and willing to help the Court understand. I note he was thoughtful and reasonable in answering all questions asked of him during both direct and cross-examination. I find him very reliable, and it is for

different reasons, as detailed below, that I do not retain his construction of the expression "physiologically acceptable".

(2) Dr. Stephen Byrn

[58] Dr. Byrn was qualified as an expert in organic and physical chemistry with particular expertise in complex pharmaceutical formulation and direct development, including salt formation. He holds a BA in Chemistry from DePauw University and a Ph.D. in Organic and physical Chemistry from the University of Illinois. He completed Postdoctoral training in Physical Chemistry at the University of California. Dr. Byrn has over 40 years of experience in the pharmaceutical area and is currently the Charles B. Jordon Professor of Medicinal Chemistry in the School of Pharmacy and Pharmaceutical Sciences and the Co-Director of the Center for Biotechnology Innovation and Regulatory Science at Purdue University where he has taught since 1972.

[59] Dr. Byrn outlines his mandate at paragraphs 15 to 19 of his affidavit and provides a summary of opinion at paragraphs 20 to 22. He opines that the POSITA of the 784 Patent as it relates to his area of expertise would be a medicinal chemist, a chemist or a pharmaceutical scientist with a master's degree with several years of experience or a Ph.D. with fewer years of experience. This person would have experience in drug synthesis, salt formation, and crystallization among other things.

[60] Dr. Burn opines that the term physiologically acceptable means non-toxic. He adds that salt would be understood by the skilled person in 1997 to be the result of a reaction of an acid

and a base. Dr. Byrn opines that cocrystals would have fallen within the definition of salt for a person skilled in the art in 1997. He explains that a skilled person would not have known to consider whether a cocrystal may have formed and adds that there was no easy way to make the distinction between cocrystals and ionic salts, even if he or she had considered it.

[61] Dr. Byrn opines that a skilled person would be able to make a physiologically acceptable salt of tadalafil now and in 1996/1997 and that a physiologically acceptable salt could be made using the common general knowledge and the 784 Patent. He adds that there are references that show salts have been made and he disagrees with Dr. Beauchemin that they cannot be made.

[62] Dr. Byrn explains that hydrochloric acid is by far the most frequently used acid to make drug salts, in part because hydrochloric acid naturally occurs in the stomach. At paragraphs 70 and 71 of his affidavit, Dr. Byrn outlines two references that support his opinion that compound containing the diketopiperazine group found in the tadalafil would form salts, such as hydrochlorine salts in non-aquaous solvents. At paragraph 74 of his affidavit, Dr. Byrn opines that a skilled person would have known in 1997, and knows now, that an acid addition salt could be formed at two (2) sites of the tadalafil molecule with hydrochloride, hydrobromic and sulfuric acid, at least.

[63] Dr. Byrn also opines that a skilled person, both now and in 1997, would also consider it likely that he or she would be able to successfully form a base addition salt at the indole group with a strong base such a sodium hydride or sodium methoxide in an aprotic solvent.

[64] Starting at paragraph 110 of his affidavit, Dr. Byrn outlines that there is evidence of cocrystals formation that fits within the definition of salt in 1997. He indicates that his literature search on cocrystals and tadalafil revealed papers that provide evidence that cocrystal of tadalafil can be formed. Dr. Byrn affirms that he found the reference to the Chinese Patent and opines that the claims of this patent relate to tadalafil salicyclate, tadalafil mandelate and tadalafil napthalenedisaulfonate calling these compounds “salts”. Dr. Byrn adds that the disclosure of the Chinese Patent also provides stability and dissolution studies for several salts disclosed but not claimed, namely the tadalafil hydrochloride and tadalafil sulfate. He opines that both must have been formed, showing that these salts have sufficient stability to be useful as pharmaceuticals, noting that these two (2) salts are also listed in the 784 Patent (page 4, line 10).

[65] As the Defendants outline, Dr. Byrn confirmed under cross-examination that salt forming is unpredictable and must be found empirically. He also confirmed that the search for salt requires a lot of experimental work and requires a skilled person to exercise some degree of inventiveness.

[66] I have very strong reservations relying on Dr. Byrn’s testimony for the reasons expressed by the Defendants in their Written Closing Submissions. Dr. Byrn’s insistence on contextualising prior statements that were presented as objective scientific notions, as well as his contradictory statements, particularly in regards to the definition of a salt, are very troubling. Equally troubling is his characterization of the evidence he adduced with his affidavit purportedly to support his opinion that cocrystals where, in 1996/1997, included in the definition of salts.

[67] I cannot conclude that Dr. Byrn was willing to carry out his primary duty to the Court and provide fair, non-partisan and objective assistance. In the words of Justice Phelan, Dr. Byrn frequently would not concede something that seemed to be obvious or logical, and when he did concede, he did so reluctantly and grudgingly.

[68] Dr. Byrn's opinion will consequently be given very little weight.

VI. The Person of Ordinary Skill in the Art (the POSITA)

[69] I am satisfied that the evidence demonstrates that the POSITA in relation to the 784 Patent, in the context of these proceedings, is an organic or medicinal chemist with a Master's degree and several years of experience or a Ph.D. with fewer experience and experience in drug synthesis, salt formation, physiologically acceptable salt, and crystallisation among other things.

[70] I note in this regard that the expert evidence must not come from a person who has the POSITA requisite skills. It is sufficient if the witness is in a position to give evidence about what the appropriately skilled person would have known and understood at the relevant time. The fact that an expert is not himself a person skilled in the relevant art does not make his evidence on that point inadmissible (*Crila Plastic v Ninety-Eight* (1987), 18 CPR (3d) 1 (FCA); *Halford v Seed Hawk*, 2006 FCA 275).

VII. Claim Construction

A. *Overview*

[71] The first step in a patent suit is to construe the claims according to the applicable principles (*Tearlab Corporation v I-Med Pharma Inc*, 2019 FCA 179 at paras 30-34). This construction is antecedent to consideration of both validity and infringement issues and is the same for all purposes (*AstraZeneca Canada Inc v Apotex Inc*, 2017 SCC 36 at para 31 [*AstraZeneca*]).

[72] In brief, 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 (*Whirlpool Corp v Camco Inc*, 2000 SCC 67 at paras 61, 76 [*Whirlpool*]; *Purdue Pharma v Canada (Attorney General)*, 2011 FCA 132 at para 16 [*Purdue*]). Expert evidence regarding the construction of a patent claim is permissive, but not obligatory (*Purdue* at para 16; *Abbott Laboratories Ltd v Canada (Attorney General)*, 2008 FCA 354 at para 42). Claims should be construed through the eyes and with the common knowledge of the POSITA to which the patent relates, as of the date of the publication, i.e., here February 6, 1997.

[73] Given the issue raised on the Motion, I must construe the expression *physiologically acceptable salt*. The parties have in fact divided the expression in two parts, hence first the expression *physiologically acceptable* and second, the word *salt*.

[74] It is necessary to address two preliminary issues raised by the parties before construing the terms.

[75] First, as mentioned earlier, I agree with Lilly that the issue of construction of the expression *physiologically acceptable salt* has not been determined in a previous decision and I thus agree with paragraphs 17 to 21 of Lilly's Written Closing Submissions in this regard.

[76] Second, in its Written Closing Submissions, Lilly relies on paragraph 150 of Dr. Byrn's affidavit to assert that a POSITA reading the claims of the 784 Patent would realize that the conjunction "or" means "either-or" and that the phrase "or a physiologically acceptable salt or solvate" means it could or could not be present. Based on this premise, Lilly asserts that the inability to predict making the salt, or inability to make the salt, has no consequence on the validity of the Asserted Claims of the 784 Patent. Lilly adds that it is also open to the Court to construe a physiologically acceptable salt to be inessential element. In its closing arguments, Lilly also raised the fact that all experts agree that the salt will revert to tadalafil in a neutral form in the body when administered.

[77] The Defendants outline that this "or" argument is a new one, set out in many parts of Lilly's Written Closing Submissions: paragraphs 7 to 21, 37(g), 118, 140, 142. The Defendants submit that this argument presents the three following fundamental problems: (1) Lilly failed to provide notice of this argument when it was required to do so, hence in opening argument at the latest; (2) the relevant legal question has already been decided by Justice Gleason in *Eli Lilly*;

and (3) there is no credible debate that Lilly has failed to meet its burden to prove that *physiologically acceptable salts* are inessential elements of the Asserted Claims.

[78] I have not seen that the relevant legal question, i.e., on the meaning of "or" physiologically acceptable salt "or" solvates, was put to or decided by Justice Gleason in *Eli Lilly*. However, I agree with the Defendants that Lilly failed to provide notice of its argument when it was being required to do so.

[79] I accept that the issue of whether or not the physiologically acceptable salt is an essential element of the Asserted Claims was mentioned by both Dr. Beauchemin (paragraph 75 where he refers to "necessary") and Dr. Byrn (paragraph 150) in their respective affidavit. However, Lilly did not raise, argue or submit that physiologically acceptable salt could be an inessential element until its Written Closing Submissions, hence only after the evidence portion of the trial had concluded. None of the experts have been cross-examined in regards to this issue.

[80] In any event, even assuming that Lilly's argument is properly before the Court, I find Lilly has not met its burden to demonstrate that the element is non-essential. Claim elements are presumed to be essential and a party alleging otherwise bears the onus of establishing non-essentiality (*Free World Trust v Électro Santé Inc*, 2000 SCC 66; *Mediatube Corp v Bell Canada*, 2017 FC 6 at para 33). Also, and given my conclusion on Dr. Byrn's credibility and reliability, the opinion he stated at paragraph 150 of his affidavit alone is insufficient to convince me that the formulation "or a physiologically acceptable salt" means such a salt could or could not be present, and that this element is non-essential. Conversely, Dr. Beauchemin has found it to

be necessary. Since Lilly has not met its burden to establish it is non-essential, I find the "physiologically acceptable salt" to be an essential element of the Asserted Claims.

B. *Physiologically acceptable*

[81] The parties recognized that the expression *physiologically acceptable* used in the Asserted Claims is not defined in the disclosure of the 784 Patent. In fact, the expression *physiologically acceptable* is used in the Abstract and it is used twice at page 3 of the disclosure.

[82] The patentee uses the expression *pharmaceutically acceptable* in the disclosure and in fact even within Claim 2 itself. The term *pharmaceutically acceptable* or *pharmaceutical* is likewise not defined.

[83] I would not have readily considered that the words physiologically and pharmaceutically could be regarded as synonyms. I would have assumed, as I will do with the term non-toxic below, that the use of different words would be indicative of the patentee's intention to convey to each word a different meaning. I note that the patentee alternatively uses the expression pharmaceutically acceptable salt and physiologically acceptable salt to designate the same element and I also note that the parties' and the experts' agree that in the context of the 784 Patent, the patentee uses the words physiologically and pharmaceutically as synonyms. I therefore accept that the two words are considered as synonyms in the context of the 784 Patent.

[84] The Defendants do not contest that their expert, Dr. Beauchemin, did not specifically dedicate a section of his affidavit to construe the term physiologically or pharmaceutically, nor

that he was not instructed to do so. They assert that Dr. Beauchemin's affidavit provided nonetheless a functional definition of "physiologically acceptable" that focused on the important points of evidence, i.e., the extreme conditions required to make a salt of tadalafil would degrade tadalafil, which would be unstable and thus physiologically unacceptable. They add that Dr. Beauchemin provided the opinion that a mixture of degradants and tadalafil would not be considered to be a physiologically acceptable salt and that both Dr. Byrn and Dr. Jessop explicitly addressed Dr. Beauchemin's evidence on degradation.

[85] Dr. Jessop opines that the POSITA would understand the expression *physiologically acceptable* to mean that it causes no harm to the physiology of the patient or that the harm is small enough to be outweighed by the benefit that the pharmaceutical benefit provided. He adds that it did not have to be regulatory approved. Dr. Jessop bases his interpretation, not in the terms of the 784 Patent, but on the words themselves, as physiologically refers to physiology and acceptable means not detrimental. Dr. Jessop does not examine the meaning of the term pharmaceutically, nor how its interchangeable use with physiologically acceptable could possibly influence the construction. Pointing to page 4 of the 784 Patent, Dr. Jessop asserts that it tells the reader, for the case of the acid addition salts, that a pharmaceutically acceptable salt would be the ones made with the pharmaceutically acceptable acid.

[86] Dr. Jessop indicates that his main disagreement with Dr. Beauchemin in regards to the meaning of the term is that Dr. Beauchemin seems to require that a physiologically acceptable salt be synthesized within the pH range of 0-14, in water and that it be stable in water. Dr. Jessop opines that the POSITA would understand that the 784 Patent contains no such limitations. He

adds that it was common for a skilled chemist, prior to 1997, to make salts in solvents other than water, and at pHs other than 0-14 and that it still is common now. In Dr. Jessop's opinion, a POSITA would not rule out non-aqueous chemistry to make a physiologically acceptable tadalafil salt, just the opposite. Likewise, a POSITA looking to make a physiologically acceptable tadalafil salt would not rule out a salt that would react with water in the patient's body to – re-form an active pharmaceutical.

[87] On cross-examination, Dr. Jessop stated that if one made a salt of tadalafil and it contained degradants, one would need to determine if the degradants caused more harm than the benefit of the drug by designing or implementing studies, which aligns with his construction of the term physiologically acceptable. At paragraph 87 of his affidavit, Dr. Jessop opines that two salts would cause no harm, and acknowledges that whether the other salts would cause no harm is beyond his expertise.

[88] I accept, as Dr. Byrn opines and all the experts agree that a POSITA in 1997 would have understood that a physiologically acceptable salt was certainly a non-toxic one. However, I do not accept that the POSITA would have understood that a salt is physiologically or pharmaceutically acceptable by the mere fact of being non-toxic or causing no harm. This is too low a threshold; surely, pharmaceutically acceptable products are held to a higher standard.

[89] The disclosure of the 784 Patent itself provides an indicia that non-toxic does not correspond to pharmaceutically or physiologically acceptable. The patentee does use the term "non-toxic" at page 5 of the disclosure in the context of veterinary use, but nowhere else. There

is here no indication that the patentee considered the word non-toxic to be a synonym of the term physiologically acceptable, as it was the case between physiologically and pharmaceutically. The patentee knows the term non-toxic but has used it only in relation with a salt destined to veterinary use. We can thus infer that the patentee, had he intended to limit the meaning of physiologically or pharmaceutically acceptable to non-toxic, would have signaled so.

[90] In addition, the amalgamated use of the terms physiologically with pharmaceutically acceptable obviously elevates the threshold beyond what is merely not toxic or not harmful for the body. I can easily follow Dr. Beauchemin's guidance and conclude that a physiologically or pharmaceutically acceptable salt also must be stable and pure, not degraded.

[91] Lilly's experts do not suggest that a tadalafil salt with degradants caused by the reaction to produce the salts would be understood to be a physiologically acceptable salt. All experts agree that avoiding degradation is critical. Dr. Byrn agreed that knowledge of the stability of the formulation is critical because chemical degradation of a drug can lead to the formation of toxic degradation products.

[92] I thus find that POSITA, armed with the common general knowledge of 1997, would have understood a "physiologically acceptable" salt certainly required the salt be non-toxic and to not cause harm. However, I find the POSITA would also have understood that the salt needed to be stable and pure, not degraded.

C. *Salt*

[93] The 784 Patent provides some information about salts at page 4 (lines 7-13 and 13-16) and at page 9 (lines 3-8, but does not define the term salt).

[94] At paragraph 37 of his affidavit, Dr. Beauchemin defines a “salt” as a neutral compound comprised of a negatively charged species, called an anion that electronically interacts with a positively charged species, called a cation.

[95] At paragraph 23 of his affidavit, Dr. Jessop defines salt as a chemical that consists of electrically charged species. He adds that some salts can be made by the reaction of an acid with a base, while other salts can be made by reactions that are not related to Bronsted-Lowry acids and bases. Dr. Jessop clearly distinguishes salt and cocrystals at paragraph 107 of his affidavit.

[96] At paragraphs 21 and 49 of his affidavit, Dr. Byrn defines salts generally as the reaction product of an acid and a base, and he includes cocrystals in the definition of salts. At paragraph 29 of his affidavit, Dr. Byrn indicates that the constituents of the resulting salts molecule are ionically bonded, which refers to the fact that they are held together solely by their opposite charges, i.e., opposite attracts. At paragraph 54 of his affidavit, Dr. Byrn opines that a skilled person in 1997 would have understood the definition of salt to include cocrystals. He affirms that in the mid-2000s, in the pharmaceutical industry, there started to be a recognition that in some “salts” there was incomplete proton transfer and instead these should be characterized as cocrystals. He goes on to affirm that in 1997, salts were simply regarded as the reaction products

of acids and bases and a skilled person would not have known to consider whether a cocrystal may have formed and there was no easy way to make the distinction between cocrystals and ionic salts even if he or she had considered it.

[97] However, Dr. Byrn was confronted with a prior inconsistent statement in which, for purposes of science as between 1986 and 2004, he opined that a "[…] salt is formed by a reaction of an acid with a base in which the hydrogen (ie the proton) of the acid is replaced by a positive ion of the base". This definition would not include a cocrystal. Ultimately, Dr. Byrn did admit that the distinction between a salt and a cocrystal can be made based on whether a proton transfer has occurred from an acid to a base.

[98] I note that the exhibits Dr. Byrn attached to his affidavit do not readily support his and Lilly's proposition that it was not until the mid-2000 that differentiation between cocrystals and salts began to emerge in the pharmaceutical field, nor that the pharmaceutical industry did not know, in 1996/97, the distinction between salts and cocrystals or that they were unable to distinguish the two. I did not find any confirmation that in 1997 the distinction was not made between salts and cocrystals. On the contrary, some of the evidence adduced by Dr. Byrn confirms that cocrystals were known as far back as the 1850s.

[99] Although I am not bound by their opinion on claim construction, I rely on Dr. Beauchemin and Dr. Jessop's evidence to help me construe how the POSITA, armed with the common general knowledge, would have understood the term salt in 1996.

[100] It is clear that in 1997, the POSITA would have understood a salt to involve a transfer of proton. Salt consisted of a negatively charged species, called and anion that electronically interacts with a positively charged species, called a cation. In 1997, the POSITA would not have included cocrystals in the definition of salt.

VIII. Are the Asserted Claims invalid?

A. *Overbreadth*

(1) The parties' position

[101] The Defendants' submissions on overbreadth are contained at paragraphs 94 to 119 of their Written Closing Submissions. The Defendants submit that the Asserted Claims are broader than the invention made by the inventor as they claim a physiologically acceptable salt when none, they say, can be made.

[102] The Defendants outline that the question in this case is, as a fact, did the name inventor invent physiologically acceptable salts of tadalafil (i.e., a tadalafil salt that was not mixed with unwanted impurities) that would treat ED.

[103] The Defendants argue that Lilly has not tendered any evidence from the inventor or business records to show that the inventor invented physiologically acceptable salts for treating ED. The Defendants do not point to any direct evidence. They take issue with Lilly having not tendered any evidence from the named inventor to show he invented physiologically acceptable salt for treating ED. The Defendants cite the Federal Court of Appeal's decision in *Teva Canada*

Ltd v Pfizer Canada Inc, 2016 FCA 161, citing *R v Munoz* (2006) 86 OR (3d) 134 [*Munoz*], to point to a series of primary facts and they ask the Court to draw reasonable inferences. These primary facts include:

- tadalafil has a low water solubility;
- converting compounds into salts was and is a proven way of increasing their solubility;
- the POSITA would have tried to improve tadalafil's low solubility;
- neither the inventor, Dr. Daugan, nor Glaxo France made salt of tadalafil prior to the filing;
- internal Lilly records state that tadalafil does not possess ionisable functional groups;
- without an ionisable functional group, a physiologically acceptable salt of tadalafil cannot be made;
- tadalafil was known to undergo degradation or epimerization under acid and basic conditions;
- tadalafil epimerizes in the presence of a strong base even in an organic solvent.

[104] The Defendants submit that it is reasonable to infer as a fact, based on the direct facts set out above, that the named inventor, who was an employee of Glaxo, working on poorly soluble compounds, did not invent physiologically acceptable salts of tadalafil. The Defendants also take issue with the fact that Lilly did not serve responding evidence on facts asserted from the evidence from the prior trial, and they raise Rule 216(4) of the Rules to ask the Court to draw an adverse inference from Lilly's failure to file responding or rebuttal evidence.

[105] Lilly responds that the Defendants have limited their overbreadth allegations to one aspect of the doctrine, i.e., that the claims must not exceed the invention which the inventor has made. Lilly adds that the Defendants were required to put forth evidence of claim construction showing that what is claimed is broader than what is invented and they failed to do so.

[106] Lilly agrees that a salt does not appear to have been made prior to filing of the 784 Patent and stresses that it is not necessary in law to do so.

[107] Lilly also submits it is clear law that a valid claim may exceed what the inventor has personally physically made, so long as the specification provides a description sufficient to allow a skilled person to make it and it is new useful and non-obvious across its scopes. Essentially, Lilly submits that the Defendants' overbreadth allegation must fail because the ability to make a physiologically acceptable salt is soundly predicted. It refers the Court to the utility section of their submissions. Lilly asserts there can thus be no overbreadth of the claims (*Apotex v Merck &Co*, 2010 FC 1265; *MIPS AB v Bauer Hockey LTD*, 2018 FC 485 at paras 246-247).

[108] In addition, Lilly responds that the Defendants have not established that salts were never contemplated. Lilly stresses that the Defendants have not met their burden on the facts as they have not submitted evidence to support the contention that it is inconceivable that the named inventor conceived of his invention as including the salts of tadalafil, let alone physiologically acceptable salts of tadalafil. Ultimately, Lilly argues that the Defendants have not established that the claimed invention is a physiologically acceptable salt, and that it was not soundly predicted.

(2) Discussion

[109] There are two (2) ways that a patent claim can fail for overbreadth (or overclaiming): it can be broader than the invention disclosed in the specification, or it can be broader than the invention made by the inventor (*Pfizer Canada Inc v Canada (Health)*, 2007 FCA 209 at para 115; see also *Western Oilfield v M-1 LLC*, 2021 FCA 24 at para 128 [*Western Oilfield*]; *Seedlings Life Science Ventures LLC v Pfizer Canada ULC*, 2021 FCA 154 at para 50 [*Seedlings Life*]).

[110] The concept of claim invalidity for overbreadth (or overclaiming) arises from the combination of the requirements that a patent specification (i) correctly and fully describe the invention (see subsection 27(3) of the Patent Act), and (ii) include "claims defining distinctly and in explicit terms the subject-matter of the invention for which an exclusive privilege or property is claimed" (see subsection 27(4)) (*Western Oilfields* at para 129).

[111] It can be considered an extension of the bargain theory in patent law, ensuring an inventor does not claim more than what they invented in good faith and disclosed (*Seedlings Life* at paras 50-51, 60, citing *Western Oilfield* at paras 128-130). It is common ground that "[n]o inventor is entitled to a monopoly on more, or even a little more, than he invents" (*Radio Corporation of America v Hazeltine Corporation* (1981), 56 CPR (2d) 170 at 188). As stated by the Supreme Court of Canada in *Burton Parsons Chemicals v Hewlett-Packard*, [1976] 1 SCR 555 at paragraph 16:

> It is stressed in many cases that an inventor is free to make his claims as narrow as he sees fit in order to protect himself from the

> invalidity which will ensue if he makes them too broad. From a practical point of view, this freedom is really quite limited because if, in order to guard against possible invalidity, some area is left open between what is the invention as disclosed and what is covered by the claims, the patent may be just as worthless as if it was invalid.

[112] Under the claims broader than invention made, it is a question of fact as to what the inventor actually invented. If the evidence establishes that the inventor did not invent what is claimed, or the claims are broader than what was invented, the claims are invalid (as opposed to the entire patent) (*Canadian Patent Law Benchbook*, third edition, Donald M Cameron, Bereskin and Parr LLP, 580ff).

[113] The experts all agreed that a salt of tadalafil can be made, but they did not agree as to whether such a salt would be physiologically acceptable.

[114] Dr. Beauchemin, whose opinion I found to be reliable, states that a skilled chemist would understand that a physiologically acceptable salt of tadalafil cannot be made. In brief, as mentioned earlier, Dr. Beauchemin's evidence is that the extremes of pH required to make salts of tadalafil would result in the degradation of tadalafil and the salts would therefore not be physiologically acceptable, as they would not be pure and stable. He opined that the degradation of tadalafil would occur in acidic and basis conditions in water as well as in organic solvents.

[115] Dr. Jessop opined that two physiologically acceptable salts of tadalafil could be made, based on his construction that the salt cause no harm, although he indicated himself determining if the salt would be harmful or not was outside his expertise. In any event, I construed the term

physiologically acceptable differently than Dr. Jessop and his opinion as to whether physiologically acceptable salts can be made is unhelpful. In addition, his reliance on the Chinese and US Patents (tadalafil hydrochloride and tadalafil sulfate) is problematic for the reasons exposed at paragraphs 23 to 27 of the Defendants' Written Submissions in Closing.

[116] I am not convinced that the degradation Dr. Beauchemin confirmed will occur could be dealt with by a skilled chemist with known conventional techniques in 1996/1997 as Lilly asserts relying on Dr. Byrn's opinion.

[117] Dr. Byrn limited his construction of physiologically acceptable to non-toxic, which I considered insufficient. He has not convinced me that Napthalenedisulfonate, tadalafil hydrochloride and tadalafil sulfate are physiologically acceptable.

[118] Based on the evidence I found most reliable, which is Dr. Beauchemin's, on my construction of the expression "physiologically acceptable" and of the term "salt", I find it is more probable than not that a physiologically acceptable salt of tadalafil cannot be made.

[119] The Defendants take issue with the evidence that Lilly could have but failed to provide and ask me to draw inference from primary facts. I note that it is not disputed that tadalafil has low solubility in water and that converting a compound into salt was and is a proven way of increasing their solubility. Yet despite this motivation to try and develop a soluble salt form of tadalafil, neither the inventor nor anyone else at Glaxo France has made a salt of tadalafil prior to

the filing of the 784 Patent. Although it is not required that it be made prior to filing, this further tilts the scale in favour of the Defendants' position.

[120] As I conclude that it is more probable than not that physiologically acceptable salts of tadalafil cannot be made I conclude, as the Defendants argue, that such a salt was not invented. The Asserted Claims therefore claim broader than what was invented and are thus invalid for overbreadth.

B. *Insufficiency*

(1) The parties' position

[121] The Defendants submit that the 784 Patent does not enable the POSITA to make physiologically acceptable salts of tadalafil and that the specification of the 784 Patent is insufficient. The Defendants cite subsection 27(3) of the *Patent Act* and the principles outlined by the Supreme Court of Canada in regards to allegations of insufficiency (*Teva*).

[122] The Defendants assert that subsection 27(3) of the *Patent Act* has long required the specification to disclose everything necessary for the invention to function properly (*Teva*) and that it is not enough for the disclosure to teach how to make the preferred embodiment, the skilled person must be able to make them all (*Seedlings Life* at paras 68, 70).

[123] In response to Lilly's argument, the Defendants assert that what the Court is dealing with here is not the invention at large; it is the invention claimed in the Asserted Claims, which all

include a physiologically acceptable salt of tadalafil. The Defendants refer to the decision in *Eli Lilly*, where Justice Gleason looked only at solvates to see if it was invented, sufficiently enabled and soundly predicted. The Defendants stress that the invention for the purpose of this Motion is the physiologically acceptable salt of tadalafil. They link Lilly's argument in relation to the nature of the invention to Lilly's "or" argument and to Lilly's argument that physiologically acceptable salt is nonessential (see pages 48 and 49 of transcript – Defendants' Closing Submissions).

[124] The Defendants add that the experts agree the 784 Patent does not disclose the actual preparation of any salt of tadalafil, physiologically acceptable or otherwise. They submit that the 784 Patent simply asserts, at page 9, that acid addition and base addition salts of tadalafil may be prepared in a "conventional manner" and that it provides a list of exemplary acid and base addition salts of tadalafil and methyltadalafil, many of which cannot be made.

[125] The Defendants submit that the 784 Patent does not disclose any physiologically acceptable salt has been made. They add that the POSITA would need to try to make salts and test them to see if they are physiologically acceptable and useful to treat ED. The Defendants stress that the 784 Patent must enable the POSITA to make physiological acceptable salts of tadalafil without undue burden. They add that the amount and nature of the efforts to attempt to find a physiologically acceptable salt is troublesome for Lilly; requiring a POSITA to undertake a minor research project to find the compound that works renders a claim invalid for insufficiency. The Defendants highlight that Dr. Byrn confirmed that finding a salt is not predictable and that it must be done empirically. They also stress that he stated the hydrochloride

salt of tadalafil could be easily made while admitting, on cross-examination, that a skilled person‘s judgment, experience and knowledge would include an understanding that if you add hydrochloric acid to a base, “all kinds of things could happen, including decomposition”.

[126] The Defendants submit that the 784 Patent is insufficient because it gives the skilled reader a research project rather than enabling the POSITA to make and use it.

[127] Lilly asserts first that the allegation of insufficiency is not available to the Defendants because they have adduced no evidence on the nature of the invention of the 784 Patent. They stress that it is the invention that must be enabled, nothing more, and that the nature of the invention of the 784 Patent is not a physiologically acceptable salt (citing *Teva* at para 71).

[128] Second, Lilly outlines that all the experts agree that a physiologically acceptable salt will revert to tadalafil upon exposure to a patient, and that the salt is thus not in the relevant range and need not be enabled (*Regeneron Pharmaceuticals Inc v Kymab Ltd*, [2020] UKSC 27; *Apotex v Shire*, 2018 FC 637 aff’d 2021 FCA 52).

[129] Third, and if the Court finds the allegation of insufficiency is available to the Defendants, Lilly responds that the 784 Patent is sufficient, as it relates to a physiologically acceptable salt. Lilly asserts that the evidence sets out what a POSITA would do, with the patent in hand, and it would not be considered a “minor research project”. Lilly refers to page 4 of the 784 Patent as the list of acid addition salts include hydrochloride, hydrobromide, bisulphate, methanesulphonate, benzenesulphonate, and p-toluenesulphonate, all of which the POSITA

would expect to form salts with tadalafil, It adds that the first acid on the list, hydrochloride, is a good choice and that a POSITA would know how to do an evaporation to make a salt, and that arduous experimentation would not be needed in the case of the 784 Patent.

[130] Lilly relies on the affidavit of Dr. Byrn at paragraphs 59, 44, 142-143 (relying on the Chinese Patent) and 75, on the affidavit of Dr. Jessop at paragraphs 92, 44 and 54, and on Dr. Byrn and Dr. Jessop's testimonies. Lilly adds that three cases relied upon by the Defendants do not apply in the present circumstances as the facts are different and they were not about sound prediction (*Seedlings, Consolboard, and Teva*).

[131] Lilly closes this argument by stressing that it is based on Dr. Byrn's construction, that the physiologically acceptable salt is not essential and so does not need to be enabled. But, if it does need to be enabled, then the skilled person would be able to make a physiologically acceptable salt without arduous experimentation, routine trial based on the common general knowledge.

(2) Discussion

[132] In light of the parties' arguments, I must first determine if the allegation of insufficiency is available to the Defendants. If it is available to them, then I must determine if they have established it.

[133] A patent specification must provide enough information to enable the POSITA to practice the invention: subsection 27(3) of the *Patent Act* and *Teva* at para 51, citing *Pioneer Hi-Bred Ltd*

v Canada (Commissioner of Patents), [1989] 1 SCR 1623 at 1637. Therefore, adequate disclosure in the specification is a precondition for the granting of a patent (*Teva* at para 34).

[134] The disclosure must be sufficient as of the filing date of the patent, here July 11, 1996 (*Teva* at para 90).

[135] In *Teva*, the Supreme Court stated that it had previously correctly analysed the disclosure requirements in *Consolboard Inc v MacMillan Bloedel (Sask) Ltd*, [1981] 1 SCR 504 [*Consolboard*] and in *Pioneer Hi-Bred Ltd. v Canada (Commissioner of Patents)*, [1989] 1 SCR 1623 [*Pioneer Hi-Bred*]. In *Teva*, the Supreme Court added that the reasoning in *Consolboard* and in *Pioneer Hi-Bred* should be reaffirmed and applied (*Teva* at para 52). The Supreme Court cited this passage of *Pioneer Hi-Bred*:

> In summary, the *Patent Act* requires that the applicant file a specification including disclosure and claims (*Consolboard Inc.*, *supra*, at p. 520). Canadian courts have stated in a number of cases the test to be applied in determining whether disclosure is complete. The applicant must disclose everything that is essential for the invention to function properly. To be complete, it must meet two conditions: it must describe the invention and define the way it is produced or built … The applicant must define the nature of the invention and describe how it is put into operation**.** A failure to meet the first condition would invalidate the application for ambiguity, while a failure to meet the second invalidates it for insufficiency**.** The description must be such as to enable a person skilled in the art or the field of the invention to produce it using only the instructions contained in the disclosure … and once the monopoly period is over, to use the invention as successfully as the inventor could at the time of his application (*Minerals Separation, supra*, at p. 316). [Emphasis added; citations omitted; pp 1637-38]

[136] In *Teva*, the Supreme Court of Canada goes on to set out a two-step analysis to determine whether the disclosure requirements have been met. It is not clear how the invalidity for "ambiguity" referred to in the passage from *Pionner Hi-Bred* fits into the two-step test described at paragraph 53 onwards of *Teva*. In any event, the Supreme Court does confirm that the first step of the sufficiency analysis is to define the nature of the invention in the patent (*Teva* at para 53) and outlines that the specification as a whole must be considered in making this determination, not just a particular claim, as a patent is issued for one invention (*Teva* at paras 55-60). The second step is to determine whether the disclosure is sufficient to enable the skilled person to practice the invention, i.e., to produce the invention using only the instructions contained in the disclosure (*Teva* at paras 70-71).

[137] In *Amgen Inc v Pfizer Canada ULC*, 2020 FC 522, Justice Southcott outlined the principles applicable to the insufficiency allegation (paragraphs 450-463) and stated the two-step test set out by the Supreme Court in *Teva.*

[138] Justice Fothergill also outlined the principles applicable to sufficiency in *Apotex v Shire*, 2018 FC 637 [*Apotex*]. Notably, Justice Fothergill indicated that the analysis of insufficiency requires answers to the three (3) following questions: "(i) What is the invention? (ii) How does it work? and (iii) Having only the specification, can a [Person of Ordinary Skill in the Art] successfully produce the invention using only the instructions contained in the disclosure?" (*Apotex* at para 151 citing *Uponor AB v Heatlink Group Inc*, 2016 FC 320 at para 172, citing *Teva* at paras 50-51). The Court must thus look at the specification as a whole to determine whether the patent meets the disclosure requirements (*Apotex* at para 151).

[139] To support its argument that the insufficiency allegation is not available to the Defendants, Lilly faults them for failing to establish the nature of the invention, which it says, is not the physiologically acceptable salt. Lilly here thus faults the Defendants for failing to meet the first prong of the test set out in *Teva*.

[140] It is clear that the Defendants have not, to cite the Supreme Court of Canada in *Teva*, "defined the nature of the invention in the patent", i.e., the patent's one invention. The Defendants have not argued that the physiologically acceptable salt of tadalafil is, on its own, the 784 Patent's one invention. However, they assert that it can and should be considered as the invention for the purpose of this Motion.

[141] The Supreme Court in *Teva* confirmed, as the Defendants argued, that the applicant must disclose everything that is essential for the invention to function properly. I have earlier decided that the physiologically acceptable salt is an essential element. It must thus be enabled.

[142] I also note that in *Eli Lilly* and in *Apotex Inc v Eli Lilly Canada Inc*, 2016 FCA 267, the Courts examined Apotex's allegations of invalidity of insufficiency as it related to a solvate (hydrate) of tadalafil. Although both the Federal Court and the Federal Court of Appeal referred to the Supreme Court's decision in *Teva*, I have found nothing in those decisions indicating that the Courts took issue with, determined or discussed the 784 Patent's one invention in their sufficiency analysis or that the insufficiency allegation was not available to *Apotex*. Conversely, both Courts discussed the insufficiency allegation as it related only to a solvate (hydrate) and its enablement. I have found nothing in those decisions doubting the proposition that the solvate had

to be sufficiently disclosed. The nature of the invention as it related to the first-prong of the test set out in *Teva* was thus, for the purpose of those proceedings, limited to the solvate.

[143] Guided by the Courts' application of the disclosure requirements in those decisions, I am thus satisfied that the insufficiency allegation is available to the Defendants in this Motion. The invention for the purpose of this Motion is a physiologically acceptable salt of tadalafil.

[144] The second step of the test set out in *Teva* is to determine whether the disclosure is sufficient to enable the skilled person to practice the invention, i.e., to produce the invention using only the instructions contained in the disclosure (*Teva* at paras 70-71). One must bear in mind that the disclosure will be insufficient if the POSITA can only find the invention after they have conducted a minor research project.

[145] As the Defendants assert, the experts agree that the 784 Patent does not disclose the actual preparation of any salt, physiologically acceptable or otherwise, of tadalafil (paragraph 128 of the Defendants' Written Closing Submissions, Beauchemin and Byrn affidavits). The 784 Patent simply asserts that acid addition and base addition salts of tadalafil may be prepared in a "conventional manner" (784 Patent, page 9) and it provides a list of exemplary acid and base addition salts (784 Patent, page 4). Although Lilly argues that the POSITA would know how to make a salt, it says nothing on how the POSITA would know how to make a physiologically acceptable one, hence one that is pure and not degraded. Furthermore, I agree that there is no disclosure in the 784 Patent that any physiologically acceptable salt had been made and the

POSITA would therefore be required to try and make salts and determine if they are physiologically acceptable.

[146] Furthermore, and as the Defendants detail at paragraphs 133 to 142 of their Written Closing Submissions, Lilly's expert, Dr. Byrn, outlined that finding a salt is unpredictable. The POSITA reading the 784 Patent would therefore in fact need to complete a research project to find a physiologically acceptable salt.

[147] Dr. Jessop's opinion is of limited help given that he confirmed it was outside his expertise to assess whether a salt would be physiologically acceptable, i.e., at least not harmful save for the two salts at paragraph 87 of his affidavit and given that I construed the expression differently.

[148] Given the evidence adduced, I find the Defendants have met their burden and established that, having only the specification, the POSITA could not produce the invention using only the instructions contained in the disclosure. The POSITA would need to complete a minor research project to try and find a physiologically acceptable salt of tadalafil.

[149] The Asserted Claims are thus invalid for insufficiency of disclosure.

C. *Utility*

(1) The parties' position

[150] The Defendants cite the Supreme Court decision in *AstraZeneca*. They also review applicable principles and assert that utility must be established by either demonstration or sound prediction as of the filing date (*Wellcome Foundation*). They outline the three following requirements to establish a sound prediction: (1) factual basis for the prediction; (2) an articulate and sound line of reasoning from which the desired result can be inferred from the factual basis; and (3) proper disclosure. They stress that the focus of the utility analysis is always on the claims (*Western Oilfields* at para 139).

[151] The Defendants add that the utility requirement found in section 2 of the *Patent Act* ensures that the subject matter of the invention as claimed does not include speculative or inoperable inventions. They add that a claim must fail if, in addition to claiming something that is useful, it also claims something that is useless.

[152] As a salt of tadalafil was not made before the application or the 784 Patent was filed, the Defendants assert that this case is therefore one of predicted utility.

[153] The Defendants argue that it was not soundly predicted as (1) the inventors did not have a factual basis to predict that they could make physiologically acceptable especially since it was believed that tadalafil had no ionisable groups and was unstable at both high and low pH and since Glaxo knew per the uncontested records attached to Dr. Beauchemin's affidavit; (2) there

is no disclosure of a factual basis or a sound and articulable line of reasoning as (a) all the experts agree that the 784 Patent does not teach that any particular salt will be physiologically acceptable, (b) the 784 Patent points to physiologically acceptable salts of tadalafil that the evidence established cannot in fact be made, (c) there is no factual basis disclosed in the 784 Patent to support a prediction that a salt can be sued to treat ED, and (d) the Defendants stress that even Dr. Byrn said that the lists of salts in the 784 Patent are just options that could be considered and ultimately revealed that the formation of salts is unpredictable; and (3) the 784 Patent does not disclose, let alone provide guidance on a solution to the fragility of tadalafil in strong acids and bases.

[154] Ultimately, the Defendants assert that given that forming a salt is not predictable, and must be determined empirically, the failure of the 784 Patent to indicate which of the many possible salts can be made as a physiologically acceptable salt of tadalafil renders the Asserted Claims invalid for a lack of soundly predicted utility.

[155] The Defendants highlight Dr. Byrn's fundamental contradiction on predicted utility. They stress that Dr. Byrn relied on publications involving other compounds (i.e., not tadalafil) for his opinion that the POSITA would know that pharmaceutically acceptable salts of tadalafil can be made (dihydrochloride salt; referencing Exhibits 11, 12, 13, 14, 16, 17 of his affidavit) while admitting to (1) the fact that a salt formed with one compound does not tell you whether the same salt can be formed with a different compound; and (2) confirming that all salt chemistry is case by case, compound by compound.

[156] The Defendants also outline that neutral tadalafil was not soundly predicted to treat ED. They first outline that the physiologically acceptable salts of tadalafil contemplated by the Asserted Claims must be capable of going into a pharmaceutical composition, which in turn must be capable of treating ED in a man. They then outline that Dr. Byrn and Dr. Jessop initially suggested that every salt that could be made, when included in a pharmaceutical composition and administered to a man, would be predicted to and would in fact convert to neutral tadalafil which, when inside the body would be pharmaceutically active and treat ED. However, the Defendants highlight that on cross-examination, the fundamental premise underlying the opinions of Dr. Byrn and Dr. Jessop was exposed to be incorrect as both experts agreed that because tadalafil's extremely low solubility, it would in fact not be absorbed by the body and not treat ED. I have already decided that whether the physiologically acceptable would treat ED is not part of this Motion.

[157] Lilly responds that the Defendants have not met their burden to prove that a physiologically acceptable salt of tadalafil cannot be made as the experts agree that salts of tadalafil can be made. Lilly adds that those salts are physiologically acceptable.

[158] Lilly argues that (i) the Defendants have not met their burden to establish that the 784 Patent is not useful; (ii) Lilly's witnesses provided the evidence necessary to show that the ability to make physiologically acceptable salts of tadalafil is soundly predicted in the 784 Patent; (iii) there is no requirement to be able to make a salt with every acid and base listed in the Patent.

[159] Again, Lilly asserts that the Defendants have not met their burden to establish that a physiologically acceptable salt of tadalafil cannot be made or that it was not soundly predicted. Lilly asserts on the contrary that such a salt can be made.

[160] They stress that there is no evidence that the 784 Patent is a useless patent or that monopoly rights were granted in exchange of misinformation. Lilly particularly notes that (a) the court must first identify the subject-matter of the invention claimed in the patent but as Dr. Beauchemin has not construed the patent, there is no evidence to support the Defendants' allegation of a lack of sound prediction that physiologically acceptable salts can be made; (b) statements in internal *Glaxo* and *Lilly* documents do not demonstrate on balance of probabilities that no physiologically acceptable salts of tadalafil can be formed; (c) there is no requirement for inventors to make every compound claimed, and there is no need for the inventors to have made any salts.

[161] Lilly asserts that the factual basis for the prediction of whether pharmaceutically acceptable salts could be made is found in the 784 Patent and in the common general knowledge. At paragraphs 170 and 171, Lilly enumerates five (5) elements of information contained in the 784 Patent that may be relevant to pharmaceutically acceptable tadalafil salt formation, which include the structure of tadalafil. Regarding the common general knowledge, Lilly enumerates ten (10) elements of information that the POSITA would have known and that may be relevant to pharmaceutically acceptable tadalafil salt formation. Lilly relies heavily on Dr. Byrn's affidavit and on his definition of salt that includes cocrystals.

[162] Lilly adds that Dr. Byrn's testimony establishes that the patent demonstrates a sound line of reasoning for making salts both for acid addition and for base addition salts. Lilly outlines that Dr. Byrn stated that a physiologically acceptable salt of tadalafil could be made using the common general knowledge and the 784 Patent: a skilled person would identify that a salt could form either at the diketopiperazine group and/or at the indole group.

[163] Lilly responds that where the sound prediction is based on knowledge forming part of the common general knowledge and on a line of reasoning that would be apparent to the POSITA, the requirements of disclosure may readily be met by simply describing the invention in sufficient detail such that it can be practiced. Those elements of the doctrine of sound prediction that would be self-evident to the POSITA need not be explicitly disclosed in the patent (*Eurocopter c Bell Helicopter Textron Canada*, 2013 FCA 219). Lilly adds that the Court is concerned with the sufficiency of the disclosure not the sufficiency of the data underlying the invention (*Apotex Inc v Merck & Co*, 2010 FC 1265). Lilly argues that here the POSITA would be able to make a pharmaceutically acceptable salt of tadalafil using the information in the patent and the POSITA's common general knowledge.

[164] Finally, Lilly asserts that there is no requirement to be able to make salt with every acid and base listed in the patent. The Defendants are attempting to revive the promise doctrine by alleging that every acid and base listed in the patent has to form a salt with tadalafil.

(2) Discussion

[165] Section 2 of the *Patent Act* defines an invention as "any new and useful art, process, machine or composition of matter or any new and useful improvement" therein. Unquestionably, a patent is invalid if it lacks utility (*AstraZeneca* at para 2). "If it is not useful, it is not an invention within the meaning of the Act" (*Wellcome Foundation* at para 51). In order for a patent to be valid, the invention it purports to protect must be useful (*Teva* at para 37; *AstraZeneca* at para 26).

[166] At paragraphs 54 to 57 of its decision in *AstraZeneca*, the Supreme Court also states that:

> To determine whether a patent discloses an invention with sufficient utility under s. 2, courts should undertake the following analysis. First, courts must identify the subject-matter of the invention as claimed in the patent. Second, courts must ask whether that subject-matter is useful — is it capable of a practical purpose (i.e. an actual result).
>
> The Act does not prescribe the degree or quantum of usefulness required, or that every potential use be realized — a scintilla of utility will do. A single use related to the nature of the subject-matter is sufficient, and the utility must be established by either demonstration or sound prediction as of the filing date (*AZT*, at para. 56).
>
> The utility requirement serves a clear purpose. To avoid granting patents prematurely, and thereby limiting potentially useful research and development by others, the case law has imposed a requirement that an invention's usefulness be demonstrated or soundly predicted at the time of application, rather than at some later point. This ensures patents are not granted where the use of the invention is speculative. What matters is that an invention "be useful, in the sense that it carries out some useful known objective" and is not merely a "laboratory curiosity whose only possible claim to utility is as a starting material for further research" (*Re Application of Abitibi Co.* (1982), 62 C.P.R. (2d) 81 (Patent Appeal Board and Commissioner of Patents), at p. 91)

> The application of the utility requirement in s. 2, therefore, is to be interpreted in line with its purpose — to prevent the patenting of fanciful, speculative or inoperable inventions.

[167] Utility must either be demonstrated or be a sound prediction based on the information and expertise then available. As of the filing date, the utility of the invention had not been demonstrated and accordingly, Lilly had to meet the requirements for a sound prediction of utility.

[168] As both parties stated, the doctrine of sound prediction has three components. First, there must be a factual basis for the prediction. Second, the inventor must outline an articulable and "sound" line of reasoning from which the desired result can be inferred from the factual basis. Third, there must be proper disclosure of the factual basis and line of reasoning, unless the factual basis and line of reasoning would be self-evident to a POSITA (*Bell Helicopter Textron v Eurocopter*, 2013 FCA 219 at paras 151-155).

[169] I have construed physiologically acceptable and salt by following the opinion of Dr. Beauchemin. Again, Dr. Beauchemin opined that a skilled chemist, reading the patent, would know that physiologically acceptable salts of tadalafil cannot be made at all because of the extreme acid conditions required to make acid addition salts of tadalafil would cause the tadalafil to degrade. It was also believed that tadalafil had no ionazable groups even after the filing date of the 784 Patent.

[170] I note that Lilly relies heavily on Dr. Byrn's opinion in its response to the sound prediction argument. Dr. Byrn's assertion that the skilled person would know how to eliminate

the undesired reactions, for the salt to be physiologically acceptable, is unconvincing and the 784 Patent itself does not even disclose or address any possible degradation issues. The common general knowledge would thus not support a sound prediction and the disclosure does not supplement or explain how to resolve the issues of degradation.

[171] Hence, based on this evidence, the Defendants have established that the inventor did not have a factual basis to predict that he could make a physiologically acceptable salt, i.e., a non-toxic, pure and stable, non-degraded salt, or an articulable and sound line of reasoning and that he disclosed neither.

[172] This being said, I must now determine if the Asserted Claims can be found invalid on the ground of inutility based on the inutility of the physiologically acceptable salt. I am mindful of the Supreme Court's teaching in *AstraZeneca* outlining that courts must first identify the subject-matter of the invention as claimed in the patent and that courts must then ask whether that subject-matter is useful — is it capable of a practical purpose (i.e., an actual result). This raises questions as to whether a physiologically acceptable salt can be considered as the subject-matter of the invention for the purpose of this Motion's utility assessment.

[173] The Defendants argue that a claim must fail if, in addition to claiming something that is useful, it also claims something that is useless. Hence, per this argument, the Defendants present the physiologically acceptable salt as a species, and once it is established that it cannot be made or that it was not soundly predicted, the Defendants assert that the Asserted Claims are invalid.

[174] The Defendants rely on the decisions of *Abbott Laboratories v Canada (Health)*, 2005 FC 1332 [*Abbott*]; *Aventis Pharma Inc v Apotex Inc* 2005 FC 1283 aff'd 2006 FCA 64; *Société des Usines Chimique Rhône Poulenc v Jules Gilbert Ltd*, [1968] SCR 950) in support of their argument.

[175] In *Abbott*, under the inutility assessment, Justice Phelan did state clearly that: "It has been well settled law that a patent claim which includes inoperable species results in the entirety of the claim being invalid; see *Mineral Separation North America Corp v Noranda Mines Ltd* (1952), 15 CPR (Sec II) 133; also see *Société des Usines Chimiques Rhone-Poulenc and CIBA, SA v Jules R Gilbert Limited et al*, [1968] SCR 950" (*Abbott* at para 100).

[176] However, the decisions cited by the Defendants predate the Supreme Court's decision in *AstraZeneca* where, in addition to the passages I already cited, it is stated at paragraphs 48 to 50 that:

> Section 2 of the Act requires a "useful" subject-matter; a single use makes a subject-matter useful.
>
> The subject-matter of an invention can be multi-faceted, such that a single subject-matter can be described in many ways. As explained by David Vaver:
>
> […] Yet, ultimately, every invention pertains to a single subject-matter, and any single use of that subject-matter that is demonstrated or soundly predicted by the filing date is sufficient to make an invention useful for the purposes of s. 2.
>
> To require all multiple uses be met for the patent's validity to be upheld, has the potential for unfair consequences. The Promise Doctrine risks, as was the case here, for an otherwise useful invention to be deprived of patent protection because not every promised use was sufficiently demonstrated or soundly predicted by the filing date.

[177] In *Apotex v Shire LLC*, 2021 FCA 521, the Federal Court of Appeal also indicated that the assessment of a patent's subject-matter or utility requires a more holistic appreciation of the patents and its claim.

[178] Hence, assuming that a physiologically acceptable salt is a species, does *AstraZeneca* confirm the proposition that its inutility renders the entire claim invalid (*Abbott*)? Or, does *AstraZeneca* stand on the contrary for the proposition that the Asserted Claims could be useful despite the physiologically acceptable salt having no utility – as "The Act does not prescribe (..) that every potential use be realized" and as "a single use related to the nature of the subject-matter is sufficient". In the absence of a full debate on this issue, and as I have already found the Asserted Claims invalid on the two other grounds alleged, I prefer to refrain from determining whether the principle outlined by the Defendants and the case law supporting it has been modified by the Supreme Court in *AstraZeneca.*

IX. Costs

[179] The Defendants proposed that costs be dealt with following release of the decision while the Plaintiffs asked for costs at an elevated level.

[180] The issue of costs is thus reserved and the parties are asked to provide short submissions of no more than 15 pages in this regard.

JUDGMENT IN T-1631-16 & ALS.

THIS COURT'S JUDGMENT is that :

1. The Defendants' Motion to strike hearsay evidence is denied.

2. The costs on the Motion to strike hearsay evidence is awarded to the Plaintiffs in accordance with Rule 407.

3. The Defendants' Motion for summary trial is granted.

4. The Asserted Claims are invalid for overbreadth and insufficiency.

5. The Plaintiffs' action in infringement against each Defendant as it relates to the 784 Patent is dismissed.

6. The issue of costs is reserved.

7. Within 45 days of the issuance of this judgment, the Defendants must serve and file their submissions regarding costs, not to exceed 15 pages in length.

8. Within 30 days of the receipt of the Defendant's submissions, the Plaintiffs must serve and file their submissions in response regarding costs, not to exceed 15 pages in length.

"Martine St-Louis"

Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-1631 (1639)-16, T-1623 (1624)-16, T-1627, T-1632-16
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