Court File No. A-244-22
(T-1631(1639)-16 T-1623 (1624)-16 T-1627-16 T-1632-16)

FEDERAL COURT OF APPEAL

BETWEEN:

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

Appellants

- and -

APOTEX INC.

Respondents

AND BETWEEN:

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

Appellants

- and -

MYLAN PHARMACEUTICALS ULC

Respondents

AND BETWEEN:

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

Appellants

- and -

TEVA CANADA LIMITED

Respondents

AND BETWEEN:

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

Appellants

- and -

PHARMASCIENCE INC. ET LABORATOIRE RIVA INC.

Respondents

NOTICE OF APPEAL

TO THE RESPONDENTS:

A LEGAL PROCEEDING HAS BEEN COMMENCED AGAINST YOU by the Appellants. The relief claimed by the Appellants appears below.

THIS APPEAL will be heard by the Court at a time and place to be fixed by the Judicial Administrator. Unless the Court directs otherwise, the place of hearing will be as requested by the Appellants. The Appellants request that this appeal be heard at Toronto, Ontario or via video conference.

IF YOU WISH TO OPPOSE THIS APPEAL, to receive notice of any step in the appeal or to be served with any documents in the appeal, you or a solicitor acting for you must prepare a notice of appearance in Form 341A prescribed by the *Federal Courts Rules* and serve it on the Appellant's solicitor or, if the Appellant is self-represented, on the Appellant, WITHIN 10 DAYS after being served with this notice of appeal.

IF YOU INTEND TO SEEK A DIFFERENT DISPOSITION of the order appealed from, you must serve and file a notice of cross-appeal in Form 341B prescribed by the *Federal Courts Rules* instead of serving and filing a notice of appearance.

Copies of the *Federal Courts Rules*, information concerning the local offices of the Court and other necessary information may be obtained on request to the Administrator of this Court at Ottawa (telephone 613-992-4238) or at any local office.

IF YOU FAIL TO OPPOSE THIS APPEAL, JUDGMENT MAY BE GIVEN IN YOUR ABSENCE AND WITHOUT FURTHER NOTICE TO YOU.

November 16, 2022 Issued by: _____

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APPEAL

THE APPELLANTS, Eli Lilly Canada Inc., Eli Lilly and Company, Lilly Del Caribe, Inc., Lilly, S.A., and ICOS Corporation Inc. (collectively, "**Eli Lilly**"), **APPEAL** to the Federal Court of Appeal from the judgment of Justice St-Louis dated October 17, 2022 (the "**Summary Trial Judgment**") in Federal Court File Nos. T-1631(1639)-16, T-1623(1624)-16, T-1627-16, and T-1632-16.

THE APPELLANTS ASK that this Court issue an order:

1. Allowing this appeal;

2. Setting aside the Summary Trial Judgment;

3. Declaring that Canadian Patent No. 2,226,784 (the "**784 Patent**") is valid, as it pertains to the Respondents' allegations of insufficiency and overbreadth;

4. In the alternative, directing the Federal Court to assess the validity of the 784 Patent in accordance with the reasons provided;

5. In the further alternative, directing the Federal Court to conduct a new summary trial in respect of the issues, or a subset of the issues, previously addressed;

6. Referring the matter back to the Federal Court for the continuation of the action on issues that remain to be determined;

7. Granting Eli Lilly its costs of this appeal and the summary trial;

8. To the extent that Eli Lilly has paid any Respondent any money in respect of any order of costs made in respect of the Summary Trial Judgment, that said Respondent repay Eli Lilly said money, with interest, forthwith; and

9. Granting such further and other relief as counsel may request and/or this Honourable Court may permit.

THE GROUNDS OF APPEAL are as follows:

A. The 784 Patent

10. This appeal relates to a blockbuster drug called CIALIS® that is useful for the treatment of erectile impotence or dysfunction ("**ED**"), which affects a sizeable portion of the human male population in Canada. The prevalence of impotence is estimated to be between 2 and 7% of the male population, which increases with age, up to 50 years of age, and between 18 and 75% between the ages 55 and 80. Prior to the 784 Patent, different compounds were found to induce an erection; however, they were not approved to treat erectile dysfunction and were only effective after direct injection into the penis.

11. The 784 Patent discloses and claims, for the first time, that tadalafil is useful for the treatment of ED. The Appellants either own, license, and/or are authorized to use the 784 Patent to provide CIALIS® to Canadians. The inventor describes the background leading to the invention as well as the work describing the invention in the 784 Patent. The examples describe the isolation of tadalafil and the preparation of pharmaceutical formulations of tadalafil. There is no dispute that formulations containing tadalafil are useful for the treatment of ED.

12. The 784 Patent ends with 28 claims that all relate 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. This appeal deals only with claims 2, 4, 10, 14, 18, 20, 22, and 23 (the "**Asserted Claims**"). Those claims relate generally to the use of tadalafil for the curative or prophylactic treatment of ED and include pharmaceutical compositions for that use, the preparation of medicaments for that use, and processes for preparing pharmaceutical compositions for that use. Importantly for this appeal, those claims also refer to "a physiologically acceptable salt or solvate" of tadalafil.

B. This Court's Prior History with the 784 Patent

13. Prior to the action giving rise to this appeal, the 784 Patent was listed on the Patent Register and was the subject of multiple generic challenges in the Federal Courts, all of which were unsuccessful. Those challenges came before the Federal Court by way of applications as those cases were brought pursuant to the *PM(NOC) Regulations*, as they read prior to its significant amendment on September 21, 2017.

14. In those applications, the generics (or, "second persons") did not pursue any allegation that the Asserted Claims would not be infringed were the generics to receive their Notices of Compliance and launch their drugs in Canada. The generics clearly intended to market their generic versions of tadalafil for the very use described and claimed in the 784 Patent. Instead, those applications dealt with whether the generics' allegations of invalidity were justified. The Federal Court invariably held that the generics' invalidity allegations were not justified:

(a) In Court File No. T-1598-13, Justice Gleason held that Apotex's allegations that the 784 Patent was invalid for insufficiency and double patenting was not justified. The Federal Court of Appeal dismissed Apotex's appeal (2016 FCA 267). Leave to appeal to the Supreme Court of Canada was denied.

(b) In Court File No. T-296-13, Justice de Montigny held that Mylan's allegations that the 784 Patent was invalid for lack of utility and for obviousness-type double patenting was not justified. The Federal Court of Appeal dismissed Mylan's appeal (2016 FCA 119). Leave to appeal to the Supreme Court of Canada was not sought.

15. The prohibition orders relating to the 784 Patent expired when the patent expired on July 11, 2016. The Respondents obtained their Notices of Compliance on July 12, 2016 and immediately launched.

C. The Underlying Actions

16. On or about September 28, 2016, Eli Lilly brought multiple actions for patent infringement in the Federal Court following generic launch of drugs containing tadalafil for the use claimed in the 784 Patent.[1] Given the generics' conduct, as pleaded, it was apparent that they had stockpiled their generic drugs for use in the curative or prophylactic treatment of ED in advance of patent expiry. The underlying actions allege, amongst other things, that all of the generics infringed the Asserted Claims of the 784 Patent by importing into Canada and stockpiling their drugs prior to the expiry of the 784 Patent.

D. The Summary Trial Judgment and Appeal

17. On September 17, 2019, the Respondents brought a motion for summary trial seeking summary judgment dismissing Eli Lilly's actions on the grounds that the 784 Patent was invalid for insufficiency, for containing claims broader than the invention made by the inventors, and for inutility. Two of those three general allegations (insufficiency and inutility) had been unsuccessfully advanced by the generics previously, though the generics asserted they were arguing these allegations in different ways.

18. The summary judgment motion was heard by Justice St-Louis on October 18-21, 2021. The Court below granted the Respondents' motion for summary trial on the basis that the Asserted Claims of the 784 Patent were invalid for overbreadth and insufficiency, and the Appellants' action for infringement against the Respondents' as it relates to the 784 Patent was dismissed.

E. Detailed Grounds of Appeal

19. Justice St-Louis erred in her assessment of the evidence, construction of the Asserted Claims, construction of the invention relating to the 784 Patent, articulation

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[1] In respect of the 784 Patent, these Court File Nos. are T-1631(1639)-16, T-1623(1624)-16, T-1627-16, and T-1632-16.

of legal principles, application of legal principles and application of the evidence to the law. To the extent that any of these errors involved issues of fact, Justice St-Louis made palpable and overriding errors.

20. In particular, and without limitation, Justice St-Louis made the following errors of law that each led to her erroneous order:

(a) **First**, Justice St-Louis erred in law by construing the term "physiologically acceptable salt" in the Asserted Claims to mean a salt that is non-toxic and to not cause harm, as well as a salt that is stable and pure, not degraded. Justice St-Louis held that the term "physiologically acceptable salt" was not explicitly defined in the 784 Patent. There is nothing in the disclosure, or the claims, to suggest that a "physiologically acceptable salt" required all of stability, purity, lack of degradation, non-toxicity, and a lack of harm. Justice St-Louis applied that erroneous claim construction to her assessment of the Respondents' invalidity allegations. The effect of that erroneous construction was to heighten the requirements that Eli Lilly had to meet to respond to the Respondents' allegations that the 784 Patent was insufficient and overbroad. In particular, Justice St-Louis held that:

(i) the person skilled in the art could not produce a physiologically acceptable salt, on her construction, using only the instructions contained in the disclosure. Rather, she held that the person skilled in the art would need to complete a minor research project to try and find a physiologically acceptable salt of tadalafil that was stable, pure, did not degrade, was non-toxic, and did not cause harm. Consequently, she held that the Asserted Claims were invalid for insufficiency.

(ii) it was more probable than not that a physiologically acceptable salt, again on her construction, cannot be made, and that such a

salt was not invented. Consequently, she held that the Asserted Claims were broader than what was invented.

(b) **Second**, Justice St-Louis erred in law by construing the term "physiologically acceptable salt" in the Asserted Claims to be an essential element, stating: "Lilly [had] 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".[2] Given her finding that it was an essential element, Justice St-Louis applied her construction of the term "physiologically acceptable salt" to her validity analysis.

(c) **Third**, Justice St-Louis erred in law by failing to apply section 27(5) of the *Patent Act* and hold that each alternative of the Asserted Claims is a separate claim (i.e. "tadalafil **or** a physiologically acceptable salt or solvate thereof"). Regardless of Justice St-Louis' errors with respect to her construction of the "salt" alternative of the Asserted Claims, and its status as an essential element, the claims to the use of tadalafil for the curative or prophylactic treatment of ED are separate and should have been treated as such for the purposes of assessing the Respondents' invalidity allegations. Accordingly, Justice St-Louis' was wrong to invalidate the Asserted Claims in whole, and not in part, on the reasons she articulated.

(d) **Fourth**, Justice St-Louis erred in law by failing to construe the "invention" for the purposes of assessing insufficiency or overbreadth. Moreover, Justice St-Louis expressly declined from construing the subject matter of the invention as claimed for the purpose of her utility assessment. Despite this, Justice St-Louis states that, "[t]he invention for the purpose of this Motion is a physiologically acceptable salt of

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[2] Summary Trial Decision, para 80.

tadalafil."[3] To the extent that purports to be a construction of the "invention" for the purposes of insufficiency and overbreadth, it is incorrect. The "invention" cannot exclude the use of tadalafil for the curative or prophylactic treatment of ED; to the contrary, that is the crux of the invention. To the extent Justice St-Louis made any factual findings in arriving at that purported construction, such factual findings misapprehend the evidence and constitute palpable and overriding errors.

21. Justice St-Louis invalidated the Asserted Claims despite her acknowledgement that the experts agreed that salts of tadalafil could in fact be made.[4] The Asserted Claims were invalidated only because Justice St-Louis held the inventor to a higher standard that required the inventor to support a special character of salts (stable, pure, not degraded, non-toxic, and does not cause harm) that Justice St-Louis held could not be made and were more than what the inventor made.

22. Had Justice St-Louis not made these errors, she would have dismissed the Respondents' invalidity allegations:

(a) **First**, had Justice St-Louis correctly construed the term "physiologically acceptable salt" in the Asserted Claims, she would have found that the skilled person could make physiologically acceptable salts using routine skill, and that such salts were no broader than the invention made. Furthermore, Justice St-Louis erred in not considering whether the skilled person would have soundly predicted the full scope of the Asserted Claims, which was a full answer to the Respondents' allegation that salts of tadalafil were not made as of the relevant time.

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[3] *Ibid*, para. 143.
[4] *Ibid*, para. 113.

(b) **Second**, had Justice St-Louis correctly found that the "physiologically acceptable salt" element of the Asserted Claims was not essential, she would have dismissed the Respondents' allegations that the Asserted Claims were insufficient and overly broad. Justice St-Louis would have held that the full scope of the Asserted Claims, properly construed, was sufficient and not overly broad.

(c) **Third**, had Justice St-Louis properly applied section 27(5) of the *Patent Act*, she would have held that the Asserted Claims relating to the use of tadalafil were valid and untarnished by the Respondents' allegations, which were entirely directed to an alternative in the Asserted Claims (physiologically acceptable salts).

(d) **Fourth**, had Justice St-Louis construed the "invention" for the purposes of sufficiency and overbreadth, she would have held that the invention related to the use of tadalafil for the curative or prophylactic treatment of ED. The invention was not the "physiologically acceptable salts" as construed by Justice St-Louis. The 784 Patent is the Canadian patent that disclosed, and claimed, the meritorious invention that tadalafil is useful for the curative or prophylactic treatment of ED. It should have been assessed as such and Justice St-Louis erred in law in not considering that invention when addressing the Respondents' allegations of invalidity.

23. Though Justice St-Louis did not invalidate the Asserted Claims for inutility, she nevertheless made palpable and overriding errors in her appreciation of the evidence and an error of law in her articulation of or application of the legal test for inutility:

(a) Justice St-Louis made a palpable and overriding error when she found that "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."[5] She erred because a patent is not required to disclose how to solve routine problems that the skilled person knows as part of their common general knowledge. Furthermore, since, on a proper construction, the 784 Patent did not claim salts of tadalafil that did not degrade, it was incorrect for Justice St-Louis to look to the disclosure to solve this issue which only arose on her construction.

(b) Justice St-Louis further erred in law when she found "the Defendants [had] 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."[6] In particular, she erred in law when she failed to perform the analysis from the perspective of the person skilled in the art.

24. In her reasons, and in making the above findings, Justice St-Louis variously made palpable and overriding errors in her appreciation and/or application of the evidence of Kerstin Roland, Linda Henson, Stephen Murray, Kathy Paterson, Dr. Philip G. Jessop and Dr. Stephen Byrn.[7]

25. Eli Lilly further pleads and relies on:

(a) The pleadings, evidence and proceedings in the summary trial and the motion record;

(b) The *Patent Act*, as amended;

(c) The *Federal Courts Act,* R.S.C., 1985, c. F-7, as amended;

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[5] *Ibid*, para. 170.
[6] *Ibid*, para. 171.
[7] Without limitation, these errors are found at paragraphs 4, 89, 90, 92, 99, 100, 113, 116-120, 143, 145, 148 and 170-171.

(d) The *Federal Courts Rules*, S.O.R./98-106, as amended; and

(e) Such further and other grounds as Eli Lilly may advise and this Honourable Court may permit.

November 16, 2022

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I HEREBY CERTIFY that the above document is a true copy of the original issued out of / filed in the Court on the NOV 16 2022 day of _____ A.D. 20___

Dated this ___ day of NOV 16 2022 20___

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