

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MURRAY & POOLE ENTERPRISES LTD.,

Petitioner,

v.

INSTITUT DE CARDIOLOGIE DE MONTREAL,

Patent Owner.

Case IPR2023-01064

Patent 11,400,063

**PATENT OWNER'S OBJECTIONS
TO PETITIONER'S REPLY EVIDENCE**

Pursuant to 37 C.F.R. § 42.64(b)(1), the Patent Owner Institut de Cardiologie de Montréal (“MHI”) hereby makes the following objections to the Petitioner’s evidence provided with its Reply (Paper 34) filed July 12, 2024.

Exhibit 1051 (“CADTH Reimbursement Recommendation”)

1. MHI objects to Exhibit 1051 under Rules 401-403 of the Federal Rules of Evidence on relevance grounds. Exhibit 1051 was published after the priority date of the challenged patent yet Exhibit 1051 is relied upon to allege the disclosure of a claim limitation in the prior art. Paper 34 at 14. Thus, Exhibit 1051 fails to make any fact of consequence more or less probable in this proceeding. To the extent Exhibit 1051 might be considered relevant at all, its probative value is outweighed by countervailing considerations, including unfair prejudice, confusing the issues, misleading the Board, and wasting time.

Exhibit 1052 (“CADTH Stakeholder Feedback”)

2. MHI objects to Exhibit 1052 under Rules 401-403 of the Federal Rules of Evidence as irrelevant. Exhibit 1052 was published after the priority date of the challenged patent yet Exhibit 1052 is relied upon to allege the presence of a claim limitation in the prior art. Paper 34 at 14. Thus, Exhibit 1052 fails to make any fact of consequence more or less probable in this proceeding. To the extent Exhibit 1052 might be considered relevant at all, its probative value is outweighed by

countervailing considerations, including unfair prejudice, confusing the issues, misleading the Board, and wasting time.

Exhibit 1053 (“CADTH Reimbursement Review”)

3. MHI objects to Exhibit 1053 under Rules 401-403 of the Federal Rules of Evidence as irrelevant. Exhibit 1053 was published after the priority date of the challenged patent yet Exhibit 1053 is relied upon to allege the presence of a claim limitation in the prior art. Paper 34 at 14. Thus, Exhibit 1053 fails to make any fact of consequence more or less probable in this proceeding. To the extent Exhibit 1053 might be considered relevant at all, its probative value is outweighed by countervailing considerations, including unfair prejudice, confusing the issues, misleading the Board, and wasting time.

Exhibit 1054 (“Lipitor Label”)

4. MHI objects to Exhibit 1054 under Rules 401-403 of the Federal Rules of Evidence as irrelevant. Exhibit 1054 discloses prescribing information for a drug product unrelated and not recited or overlapping with any claims of the challenged patent. Yet, Exhibit 1054 is relied upon to create these comparisons. Paper 34 at 19. Thus, Exhibit 1054 fails to make any fact of consequence more or less probable in this proceeding. To the extent Exhibit 1054 might be considered relevant at all, its probative value is outweighed by countervailing considerations, including unfair prejudice, confusing the issues, misleading the Board, and wasting time.

Exhibit 1055 (“Rosuvastatin Label”)

5. MHI objects to Exhibit 1055 under Rules 401-403 of the Federal Rules of Evidence as irrelevant. Exhibit 1055 discloses prescribing information for a drug product unrelated and not recited or overlapping with any claims of the challenged patent. Yet, Exhibit 1055 is relied upon to create these comparisons. Paper 34 at 19. Moreover, Exhibit 1055 was published after the priority date of the challenged patent yet Exhibit 1055 is relied upon to support alleged knowledge in the prior art. *Id.* Thus, Exhibit 1055 fails to make any fact of consequence more or less probable in this proceeding. To the extent Exhibit 1055 might be considered relevant at all, its probative value is outweighed by countervailing considerations, including unfair prejudice, confusing the issues, misleading the Board, and wasting time.

Exhibit 1057 (“LoDoCo Label”)

6. MHI objects to Exhibit 1057 under Rules 401-403 of the Federal Rules of Evidence as irrelevant. Exhibit 1057 was published after the priority date of the challenged patent yet Exhibit 1057 is relied upon to support alleged knowledge in the prior art. Paper 34 at 19. Thus, Exhibit 1057 fails to make any fact of consequence more or less probable in this proceeding. To the extent Exhibit 1057 might be considered relevant at all, its probative value is outweighed by countervailing considerations, including unfair prejudice, confusing the issues, misleading the Board, and wasting time.

Exhibit 1060 (“2015 COLCOT Protocol”)

7. MHI objects to Exhibit 1060 under Rule 902 of the Federal Rules of Evidence because Exhibit 1060 is not self-authenticating and has not been authenticated. Therefore, under Rule 901 of the Federal Rules of Evidence, Exhibit 1060 is inadmissible.

8. MHI objects to Exhibit 1060 under Rules 401-403 of the Federal Rules of Evidence as unfairly prejudicial, confusing issues, misleads the Board, and wastes time. Exhibit 1060 describes the protocol utilized in the COLCOT study, but is relied upon to refute later analysis of the results of that study, and the data resulting from the study. Paper 34 at 26. Thus, Exhibit 1060 fails to make any fact of consequence more or less probable in this proceeding.

Exhibit 1062 (“COLCOT Supplement”)

9. MHI objects to Exhibit 1062 under Rule 902 of the Federal Rules of Evidence because Exhibit 1062 is not self-authenticating and has not been authenticated. Therefore, under Rule 901 of the Federal Rules of Evidence, Exhibit 1062 is inadmissible.

10. MHI objects to Exhibit 1062 under Rules 401-403 of the Federal Rules of Evidence as unfairly prejudicial, confusing issues, misleads the Board, and wastes time. Exhibit 1062 describes certain sub-group analyses for the COLCOT study, yet is relied on to support the allegation that other sub-group analyses are incorrect.

Paper 34 at 24-25. Thus, Exhibit 1062 fails to make any fact of consequence more or less probable in this proceeding.

Exhibit 1066 (“EHJ 2021 Commentary”)

11. MHI objects to Exhibit 1066 under Rules 401-403 of the Federal Rules of Evidence as irrelevant, unfairly prejudicial, confusing issues, misleading the Board, and wasting time. Exhibit 1066 is a commentary in response to a reader of EX1005 seeking information for an additional analyses of the data from COLCOT, and yet Petitioner relies on this reference in support of allegations of the '063 patent being invented by person(s) other than Dr. Tardif. Paper 34 at 5. Thus, Exhibit 1066 fails to make any fact of consequence more or less probable in this proceeding.

Exhibit 1067 (“Sleight”)

12. MHI objects to Exhibit 1067 under Rule 902 of the Federal Rules of Evidence because Exhibit 1067 is not self-authenticating and has not been authenticated. Therefore, under Rule 901 of the Federal Rules of Evidence, Exhibit 1067 is inadmissible.

Exhibit 1068 (“Assmann”)

13. MHI objects to Exhibit 1068 under Rule 902 of the Federal Rules of Evidence because Exhibit 1068 is not self-authenticating and has not been authenticated. Therefore, under Rule 901 of the Federal Rules of Evidence, Exhibit 1068 is inadmissible.

Exhibit 1071 (“Bouabdallaoui STICH”)

14. MHI objects to Exhibit 1071 under Rules 401-403 of the Federal Rules of Evidence as irrelevant, unfairly prejudicial, confusing issues, misleading the Board, and wasting time. Exhibit 1071 describes analysis of a clinical trial unrelated to the claims of the '063 patent, the COLCOT study, or even colchicine, yet is relied upon to establish that Dr. Bouabdallaoui is an inventor of the '063 patent. Paper 34 at 6. Thus, Exhibit 1071 lacks any probative value and fails to make any fact of consequence more or less probable in this proceeding.

Exhibit 1072 (“Second Declaration of Mr. Cruitt”)

15. MHI objects to paragraphs 7-8 of Exhibit 1072 under Rule 602 of the Federal Rules of Evidence because the witness lack sufficient personal knowledge of the subject matter of that testimony. Specifically, Mr. Cruitt lacks personal knowledge regarding versions of protocols posted to clinicaltrials.gov for the COLCOT study, including which version of the protocol was purportedly posted accessible on March 8, 2017.

16. MHI objects to paragraphs 1-10 of Exhibit 1072 under Rule 702 of the Federal Rules of Evidence, at least because the testimony is not based on sufficient facts or data and the testimony is not the product of reliable principles and methods. Specifically, Mr. Cruitt’s methods fail to provide a version history or protocol availability as of March 8, 2017, despite use of the “wayback machine.” Moreover,

Mr. Cruitt's opinions are unreliable because he is employed by the firm that filed this Petition, and any opinions are the product of bias for that fiduciary.

Exhibit 1073 ("Mullins Declaration")

17. MHI objects to paragraphs 19-31 of Exhibit 1073 under Rules 401-403 of the Federal Rules of Evidence as irrelevant. Specifically, Dr. Mullins relies on Attachments A-1 through A-3 to support public availability of EX1006 in the prior art, however, A-1 is Dr. Mullins' own screenshot, and fails to address any of Patent Owner's previous arguments. A-2 and A-3 fail to show what the purported link represents. These documents lack any probative value on the public availability of EX1006. To the extent Exhibit 1073 might be considered relevant at all, its probative value is outweighed by countervailing considerations, including unfair prejudice, confusing the issues, misleading the Board, and wasting time.

18. MHI objects to paragraph 32 of Exhibit 1072 under Rule 602 of the Federal Rules of Evidence, because Dr. Mullins lacks personal knowledge as to Mr. Cruitt's motives.

Exhibit 1074 ("RMS Final Assessment")

19. MHI objects to Exhibit 1074 under Rules 401-403 of the Federal Rules of Evidence as irrelevant. Exhibit 1074 was published after the priority date of the challenged patent yet Exhibit 1074 is relied upon to allege the presence of a claim limitation in the prior art. Paper 34 at 14. Thus, Exhibit 1074 fails to make any fact

of consequence more or less probable in this proceeding. To the extent Exhibit 1074 might be considered relevant at all, its probative value is outweighed by countervailing considerations, including unfair prejudice, confusing the issues, misleading the Board, and wasting time.

Exhibit 1075 (“Second Ridker Declaration”)

20. MHI objects to paragraphs 7-46 of Exhibit 1075 under Rule 702 of the Federal Rules of Evidence for providing legal opinions and conclusions. Dr. Ridker is not a legal expert, yet testifies extensively as to his purported, and newly asserted, claim construction of the '063 patent's claims requiring patient stability.

21. MHI objects to paragraphs 7-46 of Exhibit 1075 under Rules 401-403 of the Federal Rules of Evidence as irrelevant. Dr. Ridker's testimony in each of paragraphs 7-46 requires legal conclusions related to an alleged additional claim limitation, thus paragraphs 7-46 fail to make any fact of consequence more or less probable in this proceeding. To the extent paragraphs 7-46 might be considered relevant at all, their probative value is outweighed by countervailing considerations, including unfair prejudice, confusing the issues, misleading the Board, and wasting time.

Exhibit 1076 (“Ardehali Deposition Transcript”)

22. MHI objects to Exhibit 1076 under the Federal Rules of Evidence including Rule 902 because Exhibit 1076 is not a final transcript that has been

reviewed and signed by Dr. Ardehali. Neither Dr. Ardehali nor MHI was afforded an opportunity to review Exhibit 1076 and correct its errors. Therefore, Exhibit 1076 is inadmissible.

Exhibit 1077 (“Tardif Deposition Transcript”)

23. MHI objects to Exhibit 1077 under the Federal Rules of Evidence including Rule 902 because Exhibit 1077 is not a final transcript that has been reviewed and signed by Dr. Tardif. Neither Dr. Tardif nor MHI was afforded an opportunity to review Exhibit 1077 and correct its errors. Therefore, Exhibit 1077 is inadmissible.

Exhibit 1078 (“Bouabdallaoui Deposition Transcript”)

24. MHI objects to Exhibit 1078 under the Federal Rules of Evidence including Rule 902 because Exhibit 1078 is not a final transcript that has been reviewed and signed by Dr. Bouabdallaoui. Neither Dr. Bouabdallaoui nor MHI was afforded an opportunity to review exhibit 1078 and correct its errors. Therefore, Exhibit 1078 is inadmissible.

Exhibit 1079 (“Marquis-Gravel”)

25. MHI objects to Exhibit 1079 under Rule 902 of the Federal Rules of Evidence because Exhibit 1079 is not self-authenticating and has not been authenticated. Therefore, under Rule 901 of the Federal Rules of Evidence, Exhibit 1079 is inadmissible.

26. MHI objects to Exhibit 1079 under Rules 401-403 of the Federal Rules of Evidence as irrelevant. Specifically, Exhibit 1079 was published after the priority date of the challenged patent, and yet Petitioner relies on Exhibit 1079 to establish the reasonable expectations of a POSA in the prior art. Paper 34 at 20. Thus, Exhibit 1079 fails to make any fact of consequence more or less probable in this proceeding. To the extent paragraphs Exhibit 1079 might be considered relevant at all, its probative value is outweighed by countervailing considerations, including unfair prejudice, confusing the issues, misleading the Board, and wasting time.

Respectfully submitted,

Date: July 19, 2024

By: /s/ Sailesh Patel

Sailesh Patel
Reg. No. 46,982
Lead Counsel for Patent Owner

CERTIFICATE OF SERVICE

I hereby certify that on July 19, 2024, copies of the foregoing Patent Owner's Objections to Petitioner's Reply Evidence and all documents filed with it were served via electronic mail, as agreed to by counsel, upon the following counsel for the Petitioner:

Joanna Brougher (jbrougher@biopharmalaw.com)

Thomas Siepmann (tsiepmann@biopharmalaw.com)

Kevin Laurence (klaurence@lpiplaw.com)

Matthew Phillips (mphillips@lpiplaw.com)

Derek Meeker (dmeeker@lpiplaw.com)

Joe Hawkins (jhawkins@lpiplaw.com)

Petitioner has agreed to electronic service.

Date: July 19, 2024

By: /s/ Sailesh Patel

Sailesh Patel
ArentFox Schiff LLP
Lead Counsel for Patent Owner

SHDOCS:221144769.1