

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MURRAY & POOLE ENTERPRISES LTD.,
Petitioner,

v.

INSTITUT DE CARDIOLOGIE DE MONTREAL, INC.,
Patent Owner.

Case No. IPR2023-01064
Patent 11,400,063

MURRAY & POOLE’S MOTION TO EXCLUDE EVIDENCE

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I. INTRODUCTION

Pursuant to 37 C.F.R. § 42.64(c) and the Federal Rules of Evidence (“FRE”), Petitioner Murray & Poole (“M&P”) respectfully moves to exclude certain evidence submitted by the Patent Owner (“MHI”), including ¶¶ 16–59 of Exhibit 2001 (“Ardehali First Decl.”), ¶¶ 26–28 of Exhibit 2072 (“Ardehali Suppl. Decl.”), ¶ 23 of Exhibit 2011 (“Tardif Decl.”), ¶ 4 of Exhibit 2068 (“Bouabdallaoui Decl.”), and Exhibits 2002–10, 2012–16, 2054–66, 2069, 2070, 2073, and 2074.

The indicated portions of the Ardehali declarations¹ should be excluded because his so-called expert testimony is unreliable and inadmissible under FRE 702

¹ Both Ardehali declarations omit a “truth” statement under 28 U.S.C. § 1746 and 37 C.F.R. § 1.68 and are thus unsworn testimony. *See* EX2001 at 28; EX2072 at 22. A truth statement must include an acknowledgement the declaration is made “under penalty of perjury that the foregoing is true and correct.” 28 U.S.C. § 1746. The Office also requires a truth statement to include an acknowledgment that false statements may jeopardize the validity of the patent. *See* 37 C.F.R. § 1.68. These statutory and regulatory requirements cannot be ignored. *See FedEx Corp. v. Katz Tech. Licensing, L.P.*, CBM2015-00053, Paper 9 at 7, 8 (June 29, 2015); *Bumble Bee Foods, LLC v. Kowalski*, IPR2014-00224, Paper 18 at 14, 15 (June 5, 2014).

and 703 because of his lack of qualifications. In particular, Dr. Ardehali's expertise does not extend to colchicine or its uses to treat cardiovascular disease. Thus, his testimony regarding the state of the art related to colchicine and obviousness is inadmissible. Relatedly, his technical testimony is premised on an incorrect definition of a person of ordinary skill in the art ("POSA"), a definition that Dr. Ardehali himself does not satisfy. In fact, Dr. Ardehali was unaware that colchicine had been approved by the FDA to treat cardiovascular disease. *See* EX1076 at 142:6–8, 200:19–203:10.

Additionally, Dr. Ardehali's testimony about authorship and inventorship are inadmissible as he lacks personal knowledge of the facts relevant to those issues in this case. Nor is he qualified to opine on the legal question of inventorship.

Dr. Bouabdallaoui's declaration² testimony about inventorship—a single sentence that she "do[es] not consider [her]self an inventor of . . . the '063 patent"

² The truth statements in the Tardif and Bouabdallaoui declarations omit content required by 37 C.F.R. § 1.68. *See* EX2011 at 11; EX2068 at 4 (both failing to acknowledge false statements jeopardize validity of patent). Also, because the declarations were made in Canada, they should have included an apostille from a Canadian official, as required by 37 C.F.R. § 1.66. *See Adobe Inc. v. RAH Color*

—should be excluded as lacking foundation and because her lay opinion on the legal question of inventorship is irrelevant.

Dr. Tardif’s declaration² testimony about inventorship should also be excluded as it is directed to irrelevant considerations.

Finally, MHI has failed to authenticate numerous documents, which should therefore be excluded.

II. DR. ARDEHALI’S TECHNICAL TESTIMONY SHOULD BE EXCLUDED UNDER FRE 702 AND 703.

A. Identification of Objections

Murray & Poole filed and served the following objections to the Ardehali First Declaration on January 30, 2024:

PETITIONER’S OBJECTIONS TO EX2001	
No foundation; improper expert testimony. Fed. R. Evid. (“FRE”) 702, 703; <i>Daubert v. Merrell Dow Pharms., Inc.</i> , 509 U.S. 579 (1993). Dr. Ardehali fails to identify that his field of research relates to colchicine or is related to colchicine’s known and useful functions on the cardiovascular system; fails to describe any scientific,	16– 59

Tech. LLC, IPR2019-00627, Paper 74 at 17, 8 (Feb. 13, 2020).

technical or other special knowledge or analysis he applied or conducted to reach his conclusions.	
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Paper 13 at 2.

Murray & Poole filed and served the following objections to the Ardehali Supplemental Declaration on April 16, 2024:

PETITIONER’S OBJECTIONS TO EX2072	¶¶
Because Exhibit 2072 incorporates all content of Exhibit 2001 filed on October 18, 2023, <i>see</i> EX2072 ¶ 2, Murray & Poole repeats and incorporates herein by reference all its objections to Exhibit 2001 made in Paper 13 on January 30, 2024. Those objections now apply to Exhibit 2072.	26

Paper 22 ¶¶ 26–28. MHI provided no supplemental evidence in response to these two sets of objections.

B. Paragraphs 16–59 of the Ardehali First Declaration and Paragraphs 26–28 of the Ardehali Supplemental Declaration Should be Excluded.

FRE 702 provides that expert testimony is admissible only if the witness is “qualified as an expert by knowledge, skill, experience, training, or education” and if “(a) the expert’s scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based upon sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles

and methods to the facts of the case.” Under , the Board has a gatekeeping role “to ensure that expert testimony admitted into evidence is both reliable and relevant.” *Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1360 (Fed. Cir. 2008). In essence, the individual must be “qualified in the pertinent art.” *Id.* In this case, Dr. Ardehali lacks the expertise to offer opinions regarding colchicine and his testimony is inadmissible under FRE 702.

MHI did not contest the Board’s adoption of M&P’s definition of a person of ordinary skill in the art (“POSA”). Pet. (Paper 1) at 21; Inst. Dec’n (Paper 9) at 14–15. That definition requires that the POSA is “aware of research relating to cardiovascular disease progression, including the role of inflammatory pathways in secondary cardiovascular events.” As explained by Dr. Ridker, a POSA’s awareness of research on the role of inflammation is critical to understanding the state of the art related to colchicine. EX1049, ¶¶ 34–42, 89.

In contrast, Dr. Ardehali indicated in his deposition, “I don’t think they need to know all the details related to the role of the inflammation in cardiovascular disease and secondary prevention.” EX1076, 31:17–20; *see also* Ardehali First Decl. ¶ 12; EX1076, 31:17–20 (attempting to free himself of this requirement). Without such awareness, however, Dr. Ardehali cannot competently characterize research related to these topics. His position is not surprising given his work as a cardiologist is unrelated to research related to colchicine.

Given his unfamiliarity with the basic research central to this case, it is not surprising that Dr. Ardehali was not aware of colchicine’s major milestone in 2023, approval by the FDA for treating cardiovascular disease, *see* EX1057 (FDA-approved label for low-dose colchicine (“LODOCO”) to reduce risk of cardiovascular disease events), until he was corrected at his deposition, one year after approval. In fact, Dr. Ardehali denied that colchicine had received such FDA approval at least six times as listed below:

EX1076	Transcript Text from Deposition of Dr. Ardehali
28:10–12	Q. Has the FDA approved colchicine for cardiovascular disease yet? A. No.
95:5–11	Q. So you’re comfortable concluding that 0 to 3 days has an efficacy established by the Bouabdallaoui paper. A. I would say that this paper shows that. And the data is convincing to a lot of physicians to practice that, and this may be sufficient for the FDA to approve this drug for that time period.
111:6–9	A. Well, what I would say is that first, I have to wait for the FDA approval, right? So if the FDA approves this drug, they’re probably gonna also provide some additional information.
116:17–22	A. And that’s the point I’m trying to emphasize here. That cardiologists, we have the data. Now we know. And that’s why I think this paper is a really big step forward in our practice if this drug gets approved by the FDA, that we need to be aggressive.

117:1–11	A: So what I will probably do if this drug get approved by the FDA is I'm gonna tell my residents, as soon as they are – you know, the patient goes to the cath lab and they come back, I would say this patient should be on statins, . . . , they should also be on colchicine while they are in the hospital. So that's how this is gonna change our practice.
119:16–19	Q. So when do you think the FDA will approve colchicine for cardiovascular disease? A. When will they approve it? I have no idea.

However, colchicine received FDA approval on June 20, 2023 “to reduce the risk of myocardial infarction (MI), stroke, coronary revascularization, and cardiovascular death.” EX1057 at 1; EX1076, 158:1–3.

Further, because Dr. Ardehali lacks awareness of such basic developments related to colchicine as FDA approval and considers it unimportant to a POSA to be aware of research on the role of inflammation, he is not “qualified in the pertinent art” and his testimony about the state of the art involving colchicine research (Ardehali First Decl. ¶¶ 16–28) is inadmissible. For example, he is not competent to support MHI’s assertion that “the LoDoCo trial results were of limited value because that study was not placebo controlled.” Response at 35 (with vague citation to one of the Ardehali declarations, sans pinpoint). For the same reasons, Dr. Ardehali is also unqualified under FRE 702 to offer expert testimony on obviousness

and his related testimony (Ardehali First Decl. ¶¶ 33–59) is inadmissible. For example, his testimony cannot support whether it would not have been obvious to treat without a pre-loading dose as asserted by MHI. *See* Response at 35, 36, 40 (citing EX2001 at 23, 25, 36–42); Prelim. Response (Paper 6) at 28–30, 33 (citing EX2001 at ¶ 38, 41, 42, 44).

Dr. Ardehali is also unqualified to opine about the statistical issues, such as alleged unexpected results, implicated by Bouabdallaoui (EX1005)³. He admitted that his only training in statistics was a single undergraduate course and that he is not an expert in statistics. EX1076 at 16:9–17:5. With such a limited background, Dr. Ardehali is unqualified to analyze EX1005, whose statistical analysis has highly

³ Although M&P does not move to exclude EX1005, its statistical analysis is so unreliable that it is inadmissible as evidence of unexpected results. A court, especially in a jury trial, would certainly exclude EX1005 in the court’s gatekeeper role to prevent the jury from being influenced by the article’s misleading statistical claims. *See* EX1068 (warning against subgroup analyses in general), EX1069 (same), EX1080 (criticizing EX1005 for those reasons), EX1049 ¶¶ 220–248 (same). Nonetheless, M&P believes the Board can evaluate the statistical claims in EX1005 correctly if it remains in the record.

significant flaws not apparent to the unskilled. *See* EX1078 at 72:8–73:10; 105:5–107:10. Interpretation of those statistics is central to the alleged unexpected results in this case. *See* Paper 1 at 56–63, EX1049 ¶¶ 220–248, Paper 34 at 22–27.

Yet, despite his lack of expertise, Dr. Ardehali testified about the Bouabdallaoui reference. *See* Ardehali First Decl. ¶¶ 29–32; Ardehali Suppl. Decl. ¶¶ 18–25. In light of Dr. Ardehali’s admission that he is not an expert in statistics and has limited training, Dr. Ardehali is unqualified under FRE 702 to offer expert testimony on the Bouabdallaoui reference, and that testimony should be excluded.

III. DR. ARDEHALI’S AUTHORSHIP AND INVENTORSHIP TESTIMONY SHOULD BE EXCLUDED FOR LACKING PERSONAL KNOWLEDGE.

A. Identification of Objections

Murray & Poole filed and served the following objections to the Ardehali First Declaration and the Ardehali Supplemental Declaration on January 30, 2024 and April 16, 2024, respectively:

PETITIONER’S OBJECTIONS TO EX2001	¶¶
Lacks personal knowledge; no foundation. FRE 602, 702.	29–33

PETITIONER’S OBJECTIONS TO EX2072	¶
Because Exhibit 2072 incorporates all content of Exhibit 2001 filed on October 18, 2023, <i>see</i> EX2072 ¶ 2, Murray &	2

Poole repeats and incorporates herein by reference all its objections to Exhibit 2001 made in Paper 13 on January 30, 2024. Those objections now apply to Exhibit 2072.	
Murray & Poole objects to paragraphs 26–28 of Exhibit 2072 under Rule 602 of the Federal Rules of Evidence because the witness lacks sufficient personal knowledge of the subject matter of that testimony. Specifically, Dr. Ardehali lacks personal knowledge regarding Dr. Bouabdallaoui’s (or anyone else’s) role in the COLCOT study or in conceiving the subject matter claimed in the ‘063 Patent.	26-28
Murray & Poole objects to paragraphs 26–28 of Exhibit 2072 under Rules 402 and 403 of the Federal Rules of Evidence because the statements and opinions therein are irrelevant to the issues of who contributed what to the content of the Bouabdallaoui reference (EX1005) and the probative value of those statements and opinions is substantially outweighed by the danger of confusing the issues and wasting time in this compressed IPR proceeding. To the extent those statements and opinions might be considered relevant at all, their probative value is outweighed by countervailing considerations, such as unfair prejudice, confusing the issues, misleading the Board, undue delay, wasting time, and cumulativeness.	26-28

Paper 13 at 2; Paper 22 ¶¶ 26–28. MHI provided no supplemental evidence in response to these two sets of objections.

B. Argument for Exclusion

FRE 602 requires that a witness “may testify to a matter only if . . . the witness has personal knowledge of the matter.” In this case, Dr. Ardehali lacks personal knowledge to assert that Bouabdallaoui is not an inventor. Thus, his testimony regarding inventorship is inadmissible under both FRE 602 and 702.

MHI relies on Dr. Ardehali’s testimony that Bouabdallaoui is not an inventor. *See* Response (Paper 21) at 18 (citing Ardehali First Decl. ¶¶ 30–31). However, what Dr. Ardehali wrote about inventorship was not based on personal knowledge but instead on his general experience. *See* Ardehali Suppl. Decl. ¶¶ 26–28.

Dr. Ardehali testified that he lacks any firsthand knowledge of inventorship of Patent No. 11,400,063 and authorship of the Bouabdallaoui article. EX1076 at 62:11–69:15. Dr. Ardehali’s basis for his opinion regarding inventorship is based on reading the declarations of Dr. Tardif and Dr. Bouabdallaoui and his views of common practice. *See id.* at 65:19–69:15. As such, Dr. Ardehali is not competent to testify pursuant to FRE 602 regarding authorship or inventorship, and his testimony to that effect is inadmissible.

Additionally, even if he had firsthand personal knowledge of who conceived what in the '063 Patent claims, Dr. Ardehali is not qualified to opine on the legal question of inventorship. *In re VerHoef*, 888 F.3d 1362, 1365 (Fed. Cir. 2018) (“Conception and inventorship are ultimately questions of law . . .”) (finding unnamed person was an inventor). In other words, he is not an expert on inventorship.

Moreover, his opinions on authorship are irrelevant under FRE 402 and 403 because authorship of the Bouabdallaoui reference is irrelevant to the inventorship issue, and the probative value of his opinions on that topic is substantially outweighed by the danger of confusing the issues and wasting time.

Accordingly, ¶¶ 29–31 of Ardehali First Decl. and ¶¶ 26–28 of Ardehali Second Decl. should be excluded.

IV. DR. TARDIF’S AND DR. BOUABDALLAOUI’S STATEMENTS ABOUT INVENTORSHIP IN EXHIBITS 2011 AND 2068 SHOULD BE EXCLUDED AS LACKING RELEVANCE.

A. Identification of Objections

M&P filed and served objections to ¶¶ 18, 21–24, and 26 of the Tardif Declaration as lacking relevance under FRE 401–403 on January 30, 2024. *See* Paper 13 at 4. M&P filed and served the following objections to the Bouabdallaoui Declaration on April 16, 2024:

18. Murray & Poole objects to paragraph 4 of Exhibit 2068 under the Federal Rules of Evidence as lacking foundation.

19. Murray & Poole objects to paragraph 4 of Exhibit 2068 under Rules 402 and 403 of the Federal Rules of Evidence because whether or not Dr. Bouabdallaobui [sic] considers herself an inventor of the '063 Patent is irrelevant . . .

Paper 22 ¶¶ 18, 19. MHI did not provide any supplemental evidence in response to these two sets of objections.

B. Paragraph 23 of the Tardif Declaration Should be Excluded.

Dr. Tardif provides no acknowledgment of the legal standard for inventorship, no details of his alleged conception of the claimed invention, and no related documents to corroborate his assertions. Instead, Dr. Tardif mostly testifies about irrelevant activities he undertook while conceiving, organizing, and conducting the COLCOT trial. All of that testimony is irrelevant to the question of who conceived the time-to-treatment initiation (TTI) limitations, which were conceived in group brainstorming meetings *after* completion of the COLCOT trial, as explained below.

C. Paragraph 4 of the Bouabdallaoui Declaration Should be Excluded as Lacking Foundation and Under FRE 402 and 403.

A single sentence in the Bouabdallaoui Declaration relates to inventorship: “I do not consider myself an inventor of U.S. Patent No. 11,400,063.” EX2068 ¶ 4.

Dr. Bouabdallaoui provided no foundation for that conclusion. For example, she does not establish that she has an understanding of legal principles related to inventorship. Nor does she discuss conception or the circumstances concerning her alleged non-involvement in the relevant conception.

Dr. Bouabdallaoui's deposition was much more enlightening, revealing that the TTI limitations were conceived (by whom she cannot remember) in brainstorming sessions that she attended with Dr. Tardif and others including statisticians. *See* EX1078 at 14:12–17:10, 64:9–65:22, 71:10–72:16, 78:15–80:11, 107:4–10.

Finally, Dr. Bouabdallaoui's lay, uninformed, unexplained conclusion about inventorship is irrelevant under FRE 402 and 403. What matters, instead, is who conceived the claimed invention.

V. EXHIBITS 2002–10, 2012–16, 2054–66, 2069, 2070, 2073, AND 2074 SHOULD BE EXCLUDED FOR LACK OF AUTHENTICATION.

M&P filed and served objections to Exhibits 2002–10 and 2012–16 for improper authentication under FRE 902 and as lacking relevance under FRE 401–402 for not being cited in the Preliminary Response. Paper 13 at 2–4. M&P also objected to Exhibit 2016 as hearsay and for lacking a translation. *Id.* at 4. M&P also filed and served objections to Exhibits 2054–66, 2069, 2070, 2073, and 2074 as not self-authenticating under FRE 902 and thus lacking authentication under FRE

901. Paper 22 at 2–7, 9, 11. MHI did not provide any supplemental evidence in response to either set of objections.

Because Exhibits 2002–10 and 2012–16, 2054–66, 2069, 2070, 2073, and 2074 are not properly authenticated, these exhibits are inadmissible and should be excluded under FRE 902.

VI. CONCLUSION

For at least the foregoing reasons, M&P respectfully requests that the Board exclude the indicated evidence and not consider the excluded evidence in this case.

Date: 2024 Sept. 24

Respectfully submitted,

By: / Kevin Laurence /

Kevin Laurence

Registration No. 38,219

CERTIFICATE OF SERVICE

I hereby certify that on September 24, 2024, copies of the foregoing MURRAY & POOLE'S MOTION TO EXCLUDE EVIDENCE and all documents filed with it were served via electronic mail, as agreed to by counsel, upon the following counsel for the patent owner:

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