

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

**PETITIONER'S REPLY TO
PATENT OWNER'S OPPOSITION TO
MOTION TO EXCLUDE EVIDENCE**

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M&P hereby responds to MHI's opposition (Paper 42, herein "Opp'n") to M&P's motion to exclude (Paper 41).

I. DR. ARDEHALI'S TESTIMONY SHOULD BE EXCLUDED.

A. Dr. Ardehali's Technical Testimony

MHI questions whether it has disputed the definition of a POSA in this case. *See* Opp'n at 3. MHI has not. The institution decision adopted M&P's definition of a POSA, Inst. Dec'n at 14-15, and MHI did not contest that definition in its response (Paper 21). That definition has governed this trial to date and should be applied in the final written decision. That definition requires "aware[ness] of research relating to cardiovascular disease progression, including the role of inflammatory pathways in secondary cardiovascular events." Pet. (Paper 1) at 21; Inst. Dec'n (Paper 9) at 14–15. Dr. Ridker considers such awareness critical to understanding the state of the art related to colchicine. *See* EX1049 ¶¶ 34–42, 89. Dr. Ardehali has not established that he has such awareness. Dr. Ardehali's brief mention of "inflammation" when describing his research, Opp'n at 3-4 (citing EX1076 at 17:9-16), does not establish the requisite awareness. Rather, Dr. Ardehali argued such awareness is unnecessary. *See* EX1076 at 31:17–20. Indeed, Dr. Ardehali's research focuses on the role of iron in cardiovascular disease and glucose metabolism. *See* EX1076 at 17:9–21

MHI contends that "Dr. Ardehali need not be a POSA to be an expert." Opp'n at 3; *see also id.* at 2 (citing *Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d

1356, 1363 (Fed. Cir. 2008)). However, an expert must be “qualified in the pertinent art.” *Sundance* at 1364. Moreover, while it unnecessary to have “a perfect match between the expert’s experience and the relevant field,” Consol. Trial Practice Guide at 34 (Nov. 2019) (citing *SEB S.A. v. Montgomery Ward & Co.*, 594 F.3d 1360, 1373 (Fed. Cir. 2010)), the mismatch in this case is too great. “General experience in a related field may not suffice when experience and skill in specific product design are necessary to resolve patent disputes.” *Extreme Networks, Inc. v. Enterasys Networks, Inc.*, 395 Fed. App’x 709, 715 (Fed. Cir. 2010) (nonprecedential). Similarly, while Dr. Ardehali may be a fine cardiologist and may be doing good research in his niche, he is not qualified to opine as an expert in all areas of cardiology.

For example, Dr. Ardehali positioned himself as a potential champion for aggressively and immediately prescribing colchicine upon FDA approval. *See* EX1076 at 116:17–22, 117:1–11. Despite his posturing, Dr. Ardehali failed to provide patients with colchicine for at least a year because he only learned of colchicine’s game-changing FDA approval at his deposition. *Id.* at 158:1–3. Expecting awareness of FDA approval of the drug involved by a qualified expert in this case is hardly “nitpicky” as MHI asserts. Opp’n at 4. Rather, that lack of critical awareness reveals Dr. Ardehali lacks a focus related to inflammation, and therefore colchicine, and is not competent to opine on patentability of the ’063 Patent.

Allowing Dr. Ardehali to opine on patentability without the requisite knowledge of a POSA “would serve[] only to cause mischief and confuse the factfinder.” *Kyocera Senco Indus. Tools Inc. v. ITC*, 22 F.4th 1369, 1377 (Fed. Cir. 2022).

Additionally, in light of Dr. Ardehali’s admission that he is not an expert in statistics and has limited training, *see* EX1076 16:9–17:5, Dr. Ardehali is unqualified to offer expert testimony on the flawed statistical analysis in Bouabdallaoui (EX1005), and that testimony should be excluded. EX1076 at 16:9–17:5.

MHI says M&P “*incorrectly* alleges that the statistical analysis in EX1005 has ‘significant flaws not apparent to the unskilled.’ . . . There is *no evidence provided* to support that assertion.” Opp’n at 6 (emphases added). Such evidence includes at least paragraphs 9 and 220-248 of Dr. Ridker’s declaration (EX1049) (citing, e.g., EX1012/1080, EX1067, EX1068). *See* Pet. at 56-61 (discussing same), Reply (Paper 34) at 22-27 (discussing same). MHI has never disputed that evidence.

B. Dr. Ardehali’s Authorship/Inventorship Testimony

Dr. Ardehali’s specific testimony about the authorship of Bouabdallaoui (EX1005) goes beyond just describing industry practices. He goes on to conclude – wrongly and without basis – that the work is Dr. Tardif’s alone. *See* Ardehali First Decl. ¶¶ 29–31; Ardehali Suppl. Decl. ¶¶ 26, 28. He has no firsthand knowledge to make that leap. His testimony on this point should therefore be excluded.

Moreover, his deposition testimony shows that he does not grasp the legal issue of inventorship. Specifically, he describes two instances of serving as a principal investigator (PI) and corresponding author, like Dr. Tardif, and as a co-inventor with a first author. *See* EX1076 at 57:22–62:10. Dr. Ardehali considers the PI to have autonomy to determine inventorship and authorship as the PI wishes. *Id.* According to him, some PIs dole those out as favors based on job performance while others are not generous. *Id.* His misunderstanding of the legal concept of inventorship demonstrates the danger of relying on his misguided inventorship testimony, which must be excluded as irrelevant under FRE 402 and 403.

II. DR. TARDIF’S INVENTORSHIP TESTIMONY LACKS RELEVANCE.

With the exception of paragraph 30’s final sentence – which lacks corroboration – all of Dr. Tardif’s declaration (EX2011) is irrelevant to the disputed inventorship issue: Who conceived of the 0-3 day TTI limitation? That conception occurred in brainstorming sessions *after* the COLCOT study was completed. *See* Reply (Paper 34) at 5-6. Dr. Tardif’s testimony about his role in the COLCOT study *per se* is therefore irrelevant and should be excluded. Likewise, authorship of Bouabdallaoui (EX1005) is irrelevant to the inventorship question. *See* Inst. Dec’n at 55; *Google LLC v. IPA Techs. Inc.*, 34 F.4th 1081, 1088 (Fed. Cir. 2022).

III. DR. BOUABDALLAOUI'S ATTEMPT TO DISAVOW INVENTORSHIP LACKS FOUNDATION AND RELEVANCE.

Dr. Bouabdallaoui states, “I do not consider myself an inventor.” EX2068 ¶ 4, but provides no foundation, facts, exhibits, or analysis. Nor does her declaration specifically address the disputed 0-3 day TTI limitation. Rather than substantiating that during her deposition, she instead revealed that that limitation was jointly conceived in a brainstorming session. *See* EX1078 at 64:9-22, 65:2-22, 71:10–72:16, 81:7–82:12. While that informative testimony is admissible, her statement of her subjective, lay belief that she is not an inventor lacks foundation and relevance and therefore should be excluded.

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

MHI presented these non-self-authenticating documents without any evidence to support a finding that they are authentic. After receiving objections, MHI still made no effort to authenticate these documents. For example, no one submitted a declaration saying he/she captured the webpage and the exhibit is an accurate and true printout. These exhibits are simply inadmissible on this record.

V. CONCLUSION

Accordingly, M&P requests that the Board exclude the indicated evidence.

Date: 2024 Oct. 7

By: /Kevin Laurence/
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CERTIFICATE OF SERVICE

I hereby certify that on October 7, 2024, copies of the foregoing PETITIONER'S REPLY TO PATEN OWNER'S OPPOSITION TO 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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