

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 OPPOSITION

TO PETITIONER'S MOTION TO EXCLUDE EVIDENCE

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Pursuant to 37 C.F.R. § 42.64 and the Scheduling Order (Paper 10), Patent Owner Institut de Cardiologie de Montreal (“MHI”) opposes Petitioner’s Motion to Exclude (Paper 41) because Petitioner fails to establish any basis to exclude the challenged exhibits and expert testimony.

I. INTRODUCTION

Petitioner’s motion to exclude disingenuously challenges the extensive credentials of MHI’s expert, Dr. Hossein Ardehali, whose medical and scientific experience undisputedly meets and exceeds both parties’ criteria for a Person of Ordinary Skill in the Art (“POSA”) and satisfies the requirements of Federal Rules of Evidence 702 and 703 for expert witnesses. Petitioner also improperly asks the Board to exclude the declarations of Dr. Tardif and Dr. Bouabdallaoui who were dragged into this matter and required to be deposed based on Petitioner’s unsupported speculation of incorrect inventorship. Finally, Petitioner improperly attempts to exclude several exhibits upon a misapplication of the authentication requirements and technicalities.

Accordingly, the Board should deny Petitioner’s motion to exclude.

II. ARGUMENT

A. There is no basis to exclude Dr. Ardehali’s Declarations.

Dr. Ardehali, a practicing physician, educator, and researcher specializing in cardiology, is eminently qualified to opine about the surprising and unexpected results of the methods of treatment claimed in U.S. Patent No. 11,400,063 (“the ’063

patent”). Petitioner’s only plausible basis for excluding Dr. Ardehali’s testimony is inapposite to expert witness requirements and based on an improper POSA definition—which Petitioner raises for the first time in its motion—requiring specific experience in the research of colchicine. *See Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1363 (Fed. Cir. 2008) (finding that an expert is not required to be a POSA); Paper 41 at 5. Moreover, even if Petitioner’s improper criticisms of Dr. Ardehali’s qualifications had any merit, they would go only to the weight of his testimony, not the admissibility. *See, e.g., Machinex Indus., Inc. v. JJG IP Holdings, LLC*, 2021 WL 4876262, at *42-43 (PTAB Oct. 4, 2021); *Hospira, Inc. v. Genentech, Inc.*, 2018 WL 5262656, at *25 (PTAB Oct. 3, 2018).

Additionally, Petitioner’s belief regarding certain flaws in Dr. Ardehali’s methods are not a basis to exclude a qualified expert. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 596 (1993) (explaining that cross-examination and presentation of contrary evidence rather than wholesale exclusion are appropriate safeguards); *Machinex Indus.*, 2021 WL 4876262, at *42-43 (finding criticisms of methods of analysis and facts goes to the weight of testimony, and the Board has the scientific ability and experience to evaluate expert testimony). Petitioner is simply trying to bias the Board against Dr. Ardehali through a baseless motion to exclude evidence.

1. Dr. Ardehali is a qualified expert and a POSA.

Although Dr. Ardehali need not be a POSA to be an expert, his experiences qualify as both an expert and POSA. Petitioner incorrectly alleges that the Board has adopted “M&P’s definition of a [POSA].” Paper 41 at 5. However, the Board only adopted Petitioner’s definition “[b]ased on the present record.” Paper 9 at 15. Regardless of Petitioner’s misrepresentation, Dr. Ardehali qualifies as a POSA even under Petitioner’s definition, which includes “aware[ness] of research relating to cardiovascular disease progression, including the role of inflammatory pathways in secondary cardiovascular events.” *Id.*¹

Contrary to Petitioner’s baseless accusations, Dr. Ardehali is familiar with “the basic research central to this case” and never testified to the contrary. Paper 41 at 5-6; *but see* EX2001, ¶3, 5-7; EX1076 17:9-21 (“So my research is mostly basic science... And we are specifically interested in the role of glucose metabolism, hexokinases in immune cells, *in inflammation, and how it relates to cardiovascular*

¹ Petitioner’s reliance on Dr. Ridker for the purported criticality of research in the role of inflammation is also misplaced. Paper 41 at 5 (citing EX1049, ¶¶ 34-42, 89). Dr. Ridker never makes such a statement in his explanation of the POSA, and Petitioner’s remaining citation is to Dr. Ridker’s discussion of the application of the CANTOS trial, which did not involve colchicine. EX1049, ¶¶ 34-42, 89.

disease and cancer.”) (emphasis added). Moreover, the testimony Petitioner relies on was not an attempt to “free [Dr. Ardehali] of this requirement,” but was rather an explanation of his basis for disagreeing with the POSA definition offered by Dr. Ridker. Indeed, Dr. Ardehali testified that while knowledge *of all details* related to the role of inflammation in cardiovascular disease and secondary prevention would not be required, he also testified that it would be helpful to understand those details. *Id.* at 31:9-22.

Petitioner’s additional attempt to exclude Dr. Ardehali’s opinions because he has not done research on colchicine is inapposite. Neither Petitioner, MHI, nor the Board has ever included research experience with colchicine in a POSA definition until Petitioner’s contrived effort here. Indeed, even Petitioner’s expert, Dr. Ridker, would not be a POSA under Petitioner’s new requirement that a POSA have research experience with colchicine. EX2071 at 31:12-32:9 (testifying that colchicine research was not done until 2022).²

Finally, Petitioner’s last nitpicky accusation that Dr. Ardehali was not aware that the LoDoCo product received FDA approval in 2023 is irrelevant. There is no

² Additionally, Petitioner omits the fact that Dr. Ardehali testified that he was aware of studies on colchicine in cardiovascular disease “many years ago.” EX1076 at 22:5-16.

requirement that a medical doctor POSA (or an expert) be aware of each drug's FDA approval, particularly where, as here, LoDoCo had not been launched commercially as of Dr. Ardehali's declarations.³ Thus, contrary to Petitioner's "Hail Mary" argument, Dr. Ardehali more than satisfies either of the POSA definitions offered in this case, as a board certified cardiologist with over 20 years of clinical and research experience at a renowned research university. *See* EX1076 at Appx. A.

2. Dr. Ardehali's opinions will assist the trier of fact as to the validity of the patent-in-suit.

Dr. Ardehali has exceptional and eminent experience in the field of the relevant art and the opinions he provided in Paragraphs 16-59 of his First Declaration and Paragraphs 26-28 of his Supplemental Declaration will aid the Board in its findings of fact. *See* EX2001, ¶¶ 3-9; EX1076 at 14:6-19:8 (testifying regarding education and background, and opposing counsel's own admission that Dr. Ardehali "deserve[s] [to be called a polymath]. That's an impressive background."). Rather than provide any proper basis for excluding Dr. Ardehali's opinions, Petitioner falls back on its misplaced analysis that Dr. Ardehali is not a POSA. Paper 41 at 7.

³ The baselessness of Petitioner's attacks on Dr. Ardehali's knowledge are evident upon review of his extensive testimony of colchicine treatment and his use of colchicine in CV patients, and treatment of CV in general. EX1076 at 22:17-28:7.

Based upon his extensive experience and education in the relevant field for the '063 patent, Dr. Ardehali is more than qualified and his testimony on nonobviousness and related testimony should not be excluded.

Additionally, Petitioner's attempt to exclude Dr. Ardehali's opinions regarding EX1005, which is a paper on the post-hoc analysis of the COLCOT trial, should fail. Contrary to Petitioner's characterization, Dr. Ardehali testified that he has experience using statistics in his research "on a daily basis." EX1076 at 16:15. Dr. Ardehali's knowledge and experience in the statistical analysis of clinical studies is more than sufficient to analyze EX1005. Petitioner also incorrectly alleges that the statistical analysis in EX1005 has "significant flaws not apparent to the unskilled." Paper 41 at 8-9 (citing EX1078 at 72:8-73:10; 105:5-107:1). There is no evidence provided to support Petitioner's assertion. Indeed, the cited portions of Dr. Bouabdallaoui's deposition transcript make no such statement. Further, Dr. Ardehali does not hold himself out as an expert in statistics, and such expertise is not required for a cardiologist with over twenty years of experience in treating and researching treatments for cardiovascular disease to analyze a paper reporting post-hoc analyses of a clinical trial.

Accordingly, the Board should deny Petitioner's motion to exclude Dr. Ardehali's opinions regarding the nonobviousness of the '063 patent's claims, including EX1005.

B. Dr. Ardehali's opinions regarding authorship are relevant and admissible.

Petitioner's motion to exclude is fatally flawed in view of a critical misunderstanding of Dr. Ardehali's opinions regarding authorship of EX1005 and inventorship. Dr. Ardehali testified: (1) how a POSA would understand the authorship of EX1005 based on his own extensive experience in publishing his research work, as a peer-reviewer for scientific papers, and an editor of a journal; (2) that the '063 patent identifies Dr. Tardif as the sole inventor; and (3) that Dr. Ardehali's experiences with research papers are consistent with the statements in the declarations of Dr. Tardif and Dr. Bouabdallaoui. EX2001, ¶¶ 30-31; EX2072, ¶¶ 26-28.

Pursuant to Federal Rule of Evidence 602, Dr. Ardehali does in fact have personal knowledge from his review of the '063 patent that it lists Dr. Tardif as the sole inventor (EX1076 at 34:12-21; EX2001, Appx. B); the declarations of Dr. Tardif and Dr. Bouabdallaoui (EX2072, ¶¶ 6, 27); and of the manner in which a POSA interprets the list of authors on a scientific publication (EX2001, ¶¶ 30-31; EX2072, ¶¶ 27-28). Thus, contrary to Petitioner's assertions, Dr. Ardehali never provided any opinions on matters for which he does not have personal knowledge or experience. If Petitioner's view of personal knowledge was accepted, no independent expert would be able to provide opinions.

Moreover, Dr. Ardehali did not provide any opinion (legal or otherwise) as to who is the properly named inventor(s) of the '063 patent. Rather, Dr. Ardehali provided opinions that a POSA would regard the work of EX1005 as the work of Dr. Tardif, the named inventor of the '063 patent. EX2001, ¶¶ 30-31; EX2072, ¶¶ 26-28. As a physician with extensive experience in researching, publishing, reviewing, and editing scientific papers, Dr. Ardehali has the requisite experience to opine how a POSA as the time of the '063 patent would interpret the roles of the corresponding author and authors of EX1005.

Finally, Dr. Ardehali's opinions regarding authorship are highly relevant and do not confuse the issues or waste time, but rather are solely in response to Petitioner's spurious assertions that EX1005 is prior art, based in part on unsupported and incorrect speculations of authorship and inventorship. Indeed, MHI has consistently asserted that EX1005 and inventorship are irrelevant to the validity of the '063 patent, yet Petitioner continues down its unsupported path. In a last-ditch effort to maintain its baseless allegations of EX1005 as prior art and incorrect inventorship, Petitioner now tries to remove properly asserted rebuttal opinions from Dr. Ardehali on baseless grounds of relevance and unfair prejudice. Such maneuvers and reliance on technicalities are rather telling as to the strength of Petitioner's theories. Regardless, Dr. Ardehali's opinions regarding authorship are properly asserted, relevant, and not unfairly prejudicial as a result of Petitioner's own theories.

For the foregoing reasons, the Board should deny Petitioner's request to exclude ¶¶ 29-31 of EX2001 and ¶¶ 26-28 of EX2072.

C. Dr. Tardif's and Dr. Bouabdallaoui's statements regarding inventorship in EX2011 and EX2068 are highly relevant.

1. Dr. Tardif's declaration is relevant and should not be excluded.

After MHI's Patent Owner Preliminary Response provided several grounds to clearly demonstrate that EX1005 is not prior art (Paper 6 at II.A.), Petitioner continued down this rabbit hole of speculations of authorship and inventorship, based solely on the order of the authors listed in EX1005. *See* Paper 7; Paper 28; Paper 30; Paper 31; Paper 34 at 1-10. In response to Petitioner's improper assertion of EX1005 as prior art based on Dr. Bouabdallaoui's appearance as a first-named author, MHI submitted the declarations of Dr. Tardif and Dr. Bouabdallaoui to support Dr. Tardif's sole inventorship of the '063 patent. Dr. Tardif's declaration includes statements regarding the work he did to conceive, organize, and conduct the COLCOT trial, from which the results underwent a post-hoc analysis at his direction, which were disclosed in EX1005. *See* EX2011.

Now, in an effort to unfairly create a one-sided record on an unsupported theory imagined by Petitioner, Petitioner seeks to exclude Dr. Tardif's own statements of fact as to the authorship of EX1005 and the ultimate inventorship of the '063 patent for which he is the sole-named inventor. After raising an invalidity theory based on inventorship, Petitioner cannot now ignore uncontested evidence

that are contrary to its contrived theory. Moreover, Petitioner was granted a full and fair opportunity to cross-examine Dr. Tardif, which they did. Striking the declaration unfairly prejudices Patent Owner and there is no bases to prevent the Board from evaluating all the relevant evidence.

Thus, Dr. Tardif's statements in his declaration and deposition are relevant to issues of authorship and inventorship, which are issues created by Petitioner in this case. Accordingly, the Board should deny Petitioner's unfairly prejudicial attempt to exclude the sole named inventor's own statements regarding the conception and reduction to practice of his invention and corresponding publications.

2. Dr. Bouabdallaoui's declaration is relevant and helpful in view of Petitioner's unsupported inventorship claims.

Dr. Bouabdallaoui's declaration was also submitted in response to Petitioner's unfounded theories of authorship and inventorship. Dr. Bouabdallaoui provided a short and straightforward declaration describing the facts surrounding the development, analysis, and publication of EX1005, as well as her opinion that she is not an inventor of the '063 patent. *See* EX2068.

Rather than accept Dr. Bouabdallaoui's disavowal of inventorship, Petitioner continues its unusual demand to find that she is in fact an inventor of the '063 patent. Petitioner went so far as arguing to the Board that a five-hour deposition of Dr. Bouabdallaoui would be critical to the issues of this case. *See* EX1050 at 19:8-10. Dr. Bouabdallaoui took time out of her busy schedule for the deposition and was

forthcoming and testified consistent with the statements in her declaration. *See, e.g.*, EX1078 at 14:12-16, 15:7-11, 16:17-17:8, 64:14-22, 72:8-16 (testifying that COLCOT work and any post-hoc analyses were done at the direction or under the supervision of Dr. Tardif).

Accordingly, the Board should deny Petitioner's motion to exclude Dr. Bouabdallaoui's statements and beliefs. To the extent the Board finds that Dr. Bouabdallaoui's statements include any improper legal opinions, which Patent Owner contends it does not, the Board may give such statements the appropriate weight rather than excluding the declaration entirely.

D. Petitioner's "truth" grounds are untimely.

Petitioner failed to timely object to the declarations of Dr. Ardehali, Dr. Tardif, and Dr. Bouabdallaoui on grounds pursuant to 37 C.F.R. § 1.68. "A party wishing to challenge the admissibility of evidence other than deposition evidence, must file any objections within five business days of service of evidence to which the objection is directed, or ten days after institution of trial." PTAB Trial & Prac. Guide at 78-79 (2019) (citing 37 C.F.R. §42.64(b)(1)). Accordingly, motions to exclude evidence must "identify where in the record the objection originally was made." *Id.* at 79. Here, Petitioner failed to assert 37 C.F.R. § 1.68 as grounds for objection to declarations submitted in support of MHI. *See* Paper 13; Paper 22. Additionally, here, unlike the cases cited by Petitioner, the declarants were each cross-examined

via deposition by Petitioner, under the penalty of perjury, and in each deposition Petitioner and the witnesses relied upon the respective declarations. *Compare* EX1076; EX1077; EX1078 *with Adobe Inc. v. RAH Color Tech. LLC*, IPR2019-00627, Paper 74 (Feb. 13, 2020); *FedEx Corp. v. Katz Tech. Licensing, L.P.*, CBM2015000053, Paper 9 (June 29, 2015); *Bumble Bee Foods, LLC v. Kowalski*, IPR2014-00224, Paper 18 (June 5, 2014).

Seemingly recognizing the fatal flaw, Petitioner does not even raise these bases of exclusion in the body of its motion, but rather only in footnotes. Paper 41 at n. 1, 2. Accordingly, the Board should deny Petitioner's motion on these grounds as untimely.

E. Exhibits 2002-2010, 2012-2016, 2054-2066, 2069, 2070, 2073, and 2074 are properly authenticated.

Petitioner alleges that Exhibits 2002-10 and 2012-16 should be excluded for improper authentication under FRE 902 and lacking relevance under FRE 401-402 for not being cited in the Preliminary Response. Petitioner's conclusory grounds are incorrect. As an initial matter, Petitioner tellingly does not include any factual allegations in support of its exclusion of these exhibits. Paper 41 at 14. Regardless of Petitioner's shortfall, each document is properly authenticated under either FRE 901 or 902.

Exhibits 2002-2004 are each documents of official publications by government entities. Specifically, EX2002 is the electronically stored and

maintained publication of the LoDoCo trial registration with the Australia and New Zealand Clinical Trials Registry (“ANZCTR”). Indeed, Petitioner’s own expert, Dr. Ridker, testified that he understands ANZCTR to be the Australian counterpart to clinicaltrials.gov. EX2071 at 187:12-188:1. Similarly, EX2003 and EX2004 are each clinical trial registrations stored and maintained on clinicaltrials.gov, which is a Food and Drug Administration (“FDA”) maintained publication and record. Moreover, EX2003 is the clinical trial registration for the CANTOS trial, the same trial relied on extensively by Petitioner and for which its expert, Dr. Ridker was the principal investigator. Similarly, EX2004 is the clinical trial registration for the COLCOT study as available on October 4, 2023, rather than the wayback machine version relied upon by Petitioner. Petitioner relies on an outdated version of the COLCOT trial protocol for two of its grounds of invalidity. Accordingly, each of these exhibits is self-authenticated under FRE 902(5) and are highly relevant to the issues in this case.

Exhibits 2005-2010 are each publications in scientific journals regarding research on colchicine and/or cardiovascular disease relevant to the issues in this case. Pursuant to FRE 902(6) each material is from a periodical and is thus self-authenticating. Because each reference directly corresponds the field of the relevant art of the ’063 patent they are also highly relevant to this case. To the extent any of EX2002-2010 is not cited in MHI’s Preliminary Response directly, these materials

were cited by Dr. Ardehali's declaration, and such portions were cited in MHI's Preliminary Response, as well as disclosed in MHI's Exhibit List.

Exhibits 2012-2016 are each foreign public documents executed and maintained by Canadian government agencies or Canadian government subdivision agencies and other entities, including a government subdivision of Scotland. Each document details the relationship between inventor Dr. Tardif, patent owner MHI, and contracted COLCOT study locations relating to Dr. Tardif's inventions claimed in the '063 patent. Additionally, all parties have been given a reasonable opportunity to investigate the documents' authenticity, including specifically as the deposition of Dr. Tardif. Thus, each document is self-authenticating under FRE 902(3)(A). Moreover, each exhibit is relevant, because it was either cited explicitly in MHI's Preliminary Response or indirectly through the citations and reliance on the declaration of Dr. Tardif.

Similar to EX2005-10, EX2054-66, 2070, 2073, and 2074, each are scientific publications, which on their face are printed in periodicals and thus self-authenticating pursuant to FRE 902(6). Finally, EX2069 is also self-authenticating as a record history of the COLCOT trial from clinicaltrials.gov, an official publication pursuant to FRE 902(5).

Moreover, Dr. Ardehali authenticated multiple of the documents Petitioner now seeks to exclude, including EX2009, EX2010, EX2054, EX2055, and EX2056.

See EX1076. Similarly, Dr. Ridker, Petitioner's expert, also authenticated several of the now allegedly unauthenticated documents, including EX2056, EX2069, and EX2070. *See* EX2071.

Accordingly, Petitioner fails to show that any of Exhibits 2002-10, 2012-16, 2054-66, 2069, 2070, 2073, and 2074 are not authenticated or inadmissible. Thus, the Board should deny Petitioner's motion to exclude these exhibits.

III. CONCLUSION

For at least the foregoing reasons, MHI respectfully requests that the Board deny Petitioner's motion to exclude the indicated evidence and to give full weight and consideration to MHI's properly submitted and admissible evidence in this case.

Respectfully submitted,

Date: October 1, 2024

By: /s/ Sailesh Patel
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CERTIFICATE OF SERVICE

I hereby certify that on October 1, 2024, copies of the foregoing Patent Owner's Opposition to Petitioner'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 Petitioner:

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