

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.

IPR2023-01064

Patent 11,400,063 B2

Before ULRIKE W. JENKS, SHERIDAN K. SNEDDEN, and
ZHENYU YANG, *Administrative Patent Judges*.

JENKS, *Administrative Patent Judge*.

ORDER

Denying in Part and Dismissing in Part Petitioner's Motions to Exclude
37 C.F.R. § 42.64(c)

A. INTRODUCTION

Petitioner has filed a Motion to Exclude Evidence (“Motion to Exclude” or “Mot. Exclude”). Paper 41. Patent Owner has filed an Opposition to the Motion to Exclude (“Opp.”; Paper 42) and Petitioner has filed a Reply (“Reply”; Paper 44).

Specifically, Petitioner seeks to exclude paragraphs 16–59 of Exhibit 2001 (“Ardehali First Decl.”) and paragraphs 26–28 of Exhibit 2072 (“Ardehali Suppl. Decl.”), paragraph 23 of Exhibit 2011 (“Tardif Decl.”), and paragraph 4 of Exhibit 2068 (“Bouabdallaoui Decl.”), and Exhibits 2002–10, 2012–16, 2054–66, 2069, 2070, 2073, and 2074. Paper 41, 1.

We consider the arguments in turn.

B. ANALYSIS

1. Exhibits 2001 and 2072

a. Petitioner’s argument

Petitioner contends that paragraphs 16–59 of Exhibit 2001 (Ardehali First Decl.) and paragraphs 26–28 of Exhibit 2072 (Ardehali Supplemental Decl.) should be excluded under Federal Rule of Evidence 702. Mot. Exclude 5. Petitioner asserts that Dr. Ardehali lacks the expertise to offer opinions regarding colchicine and his testimony is inadmissible under Federal Rules of Evidence (FRE) 702 and 703. *Id.* at 5. According to Petitioner, the definition of a person of ordinary skill in the art requires the person to be “aware of research relating to cardiovascular disease progression, including the role of inflammatory pathways in secondary cardiovascular events.” *Id.*; Reply 1. Specifically, Petitioner contends that

“that Dr. Ardehali was not aware of colchicine’s major milestone in 2023, approval by the FDA for treating cardiovascular disease.” *Id.* at 6. Petitioner contends that “because Dr. Ardehali lacks awareness of such basic developments related to colchicine as FDA approval . . . he is not ‘qualified in the pertinent art’ and his testimony about the state of the art involving colchicine research.” Mot. Exclude 7; Reply 2.

Petitioner also contends that because Dr. Ardehali admits he is not an expert in statistics and has limited training, Dr. Ardehali is, therefore, unqualified to offer expert testimony on the flawed statistical analysis in Bouabdallaoui. Mot. Exclude 8; Reply 3. Finally, Petitioner contends that Dr. Ardehali’s specific testimony about the authorship of Bouabdallaoui (Exhibit 1005) goes beyond just describing industry practices and should therefore be excluded. Reply 3; Mot. Exclude 11.

b. Patent Owner’s response

Patent Owner asserts that “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.” Opp. 2 (citing *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)). “Dr. Ardehali is familiar with ‘the basic research central to this case’ and never testified to the contrary.” *Id.* at 3. “Petitioner’s additional attempt to exclude Dr. Ardehali’s opinions because he has not done research on colchicine is inapposite.” *Id.* at 4. The

definition of a person of ordinary skill in the art as presented in the Petition did not include a requirement for colchicine research experience. *Id.*

Patent Owner contends that “Dr. Ardehali testified that he has experience using statistics in his research ‘on a daily basis.’ . . .

Dr. Ardehali’s knowledge and experience in the statistical analysis of clinical studies is more than sufficient to analyze EX1005.” Opp. 6.

“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.” *Id.*

Patent Owner contends that Dr. Ardehali would understand the authorship of a journal publication (Exhibit 1005) “based on his own extensive experience in publishing his research work, as a peer-reviewer for scientific papers, and an editor of a journal.” Opp. 7. In addition,

“Dr. Ardehali’s experiences with research papers are consistent with the statements in the declarations of Dr. Tardif and Dr. Bouabdallaoui.” *Id.*

“Dr. Ardehali’s opinions regarding authorship are properly asserted, relevant, and not unfairly prejudicial as a result of Petitioner’s own theories.” *Id.* at 8.

c. Analysis

Dr. Ardehali testifies that he holds a medical degree (MD) and a doctor of philosophy (Ph.D.) in molecular physiology and biophysics. Ex. 2001 ¶ 4. Dr. Ardehali is presently the Director of the Center for Molecular Cardiology in the Feinberg Cardiovascular and Renal Research Institute at Northwestern University Medical Center. *Id.* ¶ 3. Dr. Ardehali

attests that he is a Board-certified cardiologist and has been practicing in the field at least since 2004. *Id.*

Dr. Ardehali testifies that he maintains awareness of the developments in cardiovascular care and treatment, including as serving on editorial boards for journals. *Id.* ¶ 5. Dr. Ardehali not only treats patients in the clinic but also teaches future cardiologists. *Id.* ¶ 6. Dr. Ardehali also maintains a robust research practice and has been the recipient of at least 35 grants since 2004. *Id.* Dr. Ardehali states that he has published at least 112 articles and 7 book chapters, in addition he has been an invited lecturer on numerous occasions. *Id.* ¶ 7.

Petitioner's definition of a person of ordinary skill in the art, which we adopted in our Final Written Decision, is:

- An M.D. degree and be board-certified with a subspecialty in the treatment of cardiovascular disease.
- At least 3-5 years of experience, following board certification, in cardiology and cardiovascular disease treatment and sufficient clinical experience to understand standard good medical practice in patient management.
- Been familiar with acute coronary syndromes, stable coronary diseases, cardiovascular diseases, and their standard treatments, including the acute management and long-term secondary preventions of myocardial infarction.
- Been aware of research relating to cardiovascular disease progression, including the role of inflammatory pathways in secondary cardiovascular events.

See Paper 49.

By this definition, Dr. Ardehali is at least a person of ordinary skill in the art. He possesses a medical degree and is Board-certified in cardiology, and has sufficient clinical and research experience in the diagnosis and

methods of treatment of treating patients with cardiac issues. Dr. Ardehali is therefore qualified to testify at least as to the knowledge of a skilled artisan. *Kyocera Senco Indus. Tools Inc. v. Int’l Trade Comm’n*, 22 F.4th 1369, 1376–77 (Fed. Cir. 2022). Furthermore, given his past research and clinical experience, his current position as a director at a major research university, and his extensive record of publication, we find Dr. Ardehali qualified to opine as an expert in the nature of treating patients with cardiovascular disease, including their standard treatments, as well as for acute management and long-term secondary preventions. Based on his editorial board role and serving as a reviewer to various periodicals, we find that Dr. Ardehali would be aware of research relating to cardiovascular disease progression, including the role of inflammatory pathways in secondary cardiovascular events. Ex. 2001 ¶ 5.

To the extent “that Dr. Ardehali was not aware of colchicine’s major milestone in 2023, approval by the FDA for treating cardiovascular disease,” that he admitted to not “know[ing] all the details related to the role of the inflammation in cardiovascular disease and secondary prevention,” or that he admitted to only having limited training in statistics (*see* Ex. 1076, 6:9–17:5, 28:10–12, 31:17–20, 119:16–19), we will weigh his testimony regarding those matters accordingly. However, for the reasons explained above, Petitioner’s Motion to Exclude Dr. Ardehali’s opinions in paragraphs 16–59 of Exhibit 2001 and paragraphs 26–28 of Exhibit 2072 is denied.

2. *Exhibits 2002, 2069*

Petitioner contends that Exhibits 2002 and 2069 are not properly authenticated under FRE 902 and that Ex. 2002 lacks relevance under FRE 401–402. Mot. Exclude 14.

Patent Owner responds that Exhibit 2002 is an official publication by a government entity. Opp. 12. Exhibit 2002 is the electronically stored and maintained publication of the LoDoCo trial registration with the Australia and New Zealand Clinical Trials Registry (“ANZCTR”). *Id.* at 13. Patent Owner contends that “Petitioner’s own expert, Dr. Ridker, testified that he understands ANZCTR to be the Australian counterpart to clinicaltrials.gov.” *Id.* (citing Ex. 2071, 187:12-188:1). Patent Owner contends that Exhibit 2069 “is also self-authenticating as a record history of the COLCOT trial from clinicaltrials.gov, an official publication pursuant to FRE 902(5).” *Id.* at 14.

We reject Petitioner’s argument that Exhibits 2002 and 2069 are not properly authenticated. Exhibits 2002 and 2069 are documents provided by a public authority and is self-authenticating under FRE 902(5). Rule 902 states, in relevant part, that: “The following items of evidence are self-authenticating; they require no extrinsic evidence of authenticity in order to be admitted: ... (5) Official Publications. A book, pamphlet, or other publication purporting to be issued by a public authority.” Fed. R. Evid. 902(5).

We agree with Patent Owner that Exhibit 2002 should not be excluded because it is a document provided by a public authority at <https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=>.

Ex. 2002, 1. The ANCTR is the Australia and New Zealand Clinical Trials Registry. Opp. 13.

We agree with Patent Owner that Exhibit 2069 should also not be excluded because it is a record history of the COLCOT trial from clinicaltrials.gov, an official publication pursuant to FRE 902(5). Opp. 14.

In addition, the Exhibit 2002 is directed to a clinical trial to determine the effect of adding colchicine 0.5mg per day to usual medical therapy in patients with proven coronary disease or the risk of future coronary events and stroke. Ex. 2002, 4. Here, Exhibit 2002 is directed to the same subject matter as the claims at issue in the present IPR and, therefore, is relevant evidence under FRE 401–402.

Because we conclude that Petitioner has not established a sufficient basis to exclude Exhibits 2002 and 2069, we deny Petitioner’s Motion to Exclude the Exhibits.

3. Exhibits 2005–2010, 2054–2056, 2061, 2064, 2065

Petitioner contends that Exhibits 2005–2010 are not properly authenticated under FRE 902 and they lack relevance under FRE 401–402. Mot. Exclude 14. Petitioner contends that Exhibits 2054–2056, 2061, 2064, and 2065 are not self-authenticating under FRE 902 and lack authentication under FRE 901. Mot. Exclude 14–15.

Patent Owner contends that Petitioner does not include any factual allegations in support of the position that Exhibits 2005–2010 should be excluded. Opp. 12–13. “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.” *Id.* at 13. Exhibits 2005–2010 were cited in Dr. Ardehali’s declaration. *Id.* Patent Owner further contends that Exhibits 2054–2056, 2061, 2064, and 2065 are scientific publications, which on their face are printed in periodicals and thus self-authenticating pursuant to FRE 902(6). *Id.* at 14.

We reject Petitioner’s argument that Exhibits 2005–2010, 2054–2056, 2061, 2064, and 2065 are not properly authenticated.

Exhibit 2005 is an article printed in *Circulation*, a publication of the American Heart Association. The article looks at the effect of colchicine on the treatment and prevention of recurrent pericarditis. Ex. 2005, Abstract.

Exhibit 2006 is an article printed in *Archives of Internal Medicine*, a publication of the American Heart Association. The article looks at the effect of colchicine for treating recurrent pericarditis. Ex. 2006, Abstract.

Exhibit 2007 is an article printed in *Annals of Internal Medicine*. The article looks at the effect of colchicine for treating recurrent pericarditis. Ex. 2007, Abstract.

Exhibit 2008 is an article printed in *RMD Open* a periodical covering topics of rheumatic and musculoskeletal diseases. The article looks at the use of colchicine as adjunct therapy for treating patients with COVID-19. Ex. 2008, 1.

Exhibit 2009 is an article printed in the *Journal of the American College of Cardiology (JACC)*. The article is titled “Ineffectiveness of Colchicine for the Prevention of Restenosis After Coronary Angioplasty.” Ex. 2009, 1.

Exhibit 2010 is an article printed in Arthritis and Rheumatism, a publication of the American College of Rheumatology. The article is directed to dosing of oral colchicine in early acute gout flares. Ex. 2010, 1.

Exhibit 2054 is an article printed in the Journal Thrombolysis, a publication of Springer Science + Business Media. The article is directed to studying the effect of colchicine in patients with acute coronary syndrome or acute stroke. Ex. 2054, 1.

Exhibit 2055 is an article printed in Archives of Cardiovascular Disease, a publication of Elsevier Masson SAS. The article is directed to the use of colchicine in the treatment of patients with acute myocardial infarction and inflammatory response. Ex. 2055, 1.

Exhibit 2056 is an article printed in Circulation, a publication of the American Heart Association. The article is directed to the study of colchicine in patients with acute coronary syndrome. Ex. 2056, 1.

Exhibit 2061 is an article printed in European Heart Journal, a publication of the European Society of Cardiology. The article is directed to the role of studying C-reactive protein in cardiovascular disease. Ex. 2061, 1.

Exhibit 2064 is an article printed in Journal of the American College of Cardiology, a publication of the American College of Cardiology Foundation. The article is directed to colchicine treatment for the prevention of stent restenosis. Ex. 2064, 1.

Exhibit 2065 is an article printed in The New England Journal of Medicine. The article is directed to the study of colchicine in patients with chronic coronary disease. Ex. 2065, 1.

Contrary to Petitioner’s arguments, Exhibits 2005–2010, 2054–2056, 2061, 2064, and 2065 are articles published in peer-reviewed professional publications, and are self-authenticating under Federal Rule of Evidence 902(6). Rule 902 states, in relevant part, that: “The following items of evidence are self-authenticating; they require no extrinsic evidence of authenticity in order to be admitted: ... (6) Newspapers and Periodicals. Printed material purporting to be a newspaper or periodical.” Fed. R. Evid. 902(6). The Exhibits provide specific publication numbers, printing dates and publisher information, all of which are indicia understood, at least under Rule 902(6), as characteristics of self-authenticating documents. As such, we conclude that the references are self-authenticating. *See Microsoft Corp. v. FG SRC LLC*, IPR2018-01599, Paper 78, at 12–13 (PTAB Apr. 30, 2020); *Weatherford Int’l, LLC v. Packers Plus Energy Srvcs., Inc.*, IPR2016-01514, Paper 65, at 11 (PTAB Apr. 3, 2018); *Funai Elec. Co., Ltd. v. Gold Charm Ltd.*, IPR2015-01468, Paper 40, at 52 (PTAB Dec. 27, 2016).

Furthermore, Exhibits 2005–2010 are each directed to the use of colchicine in treating patients. The exhibits are directed to subject matter that is similar to the claims at issue in the present IPR and, therefore, are relevant evidence under FRE 401–402.

Because we conclude that Petitioner has not established a sufficient basis to exclude Exhibit 2005–2010, 2054–2056, 2061, 2064, and 2065 we deny Petitioner’s Motion to Exclude the Exhibit.

4. *Exhibit 2003, 2004, 2011–2016, 2057–2060, 2062, 2063, 2066, 2068*

Petitioner filed a Motion to Exclude paragraph 23 of Exhibit 2011 and paragraph 4 of Exhibit 2068. Mot. Exclude 13–14. Petitioner also filed a

IPR2023-01064
Patent 11,400,063 B2

Motion to Exclude Exhibits 2003, 2004, 2012–2016, 2057–2060, 2062, 2063, and 2066. Mot. Exclude 14–15.

We do not rely on Patent Owner’s Exhibits 2003, 2004, 2011–2016, 2057–2060, 2062, 2063, 2066, and 2068 to resolve the dispute in our Final Written Decision. Paper 49. Therefore, Petitioner’s Motion to Exclude Exhibits 2003, 2004, 2011–2016, 2057–2060, 2062, 2063, 2066 and 2068 is dismissed as moot.

C. ORDER

Accordingly, it is:

ORDERED that Petitioner’s Motion to Exclude Exhibits 2001, 2002, 2005–2010, 2054–2056, 2061, 2064, 2065, 2069, and 2072 is *denied*,

FURTHER ORDERED that Petitioner’s Motion to Exclude Exhibits 2003, 2004, 2011–2016, 2057–2060, 2062, 2063, 2066, and 2068 is *dismissed as moot*.

IPR2023-01064
Patent 11,400,063 B2

PETITIONER:

Joanna Brougher
jbrougher@biopharmalaw.com

Kevin Laurence
Matthew Phillips
Derek Meeker
klaurence@lpiplaw.com
mphillips@lpiplaw.com
dmeeker@lpiplaw.com

PATENT OWNER:

Sailesh Patel
Imron Aly
sailesh.patel@afslaw.com
ialy@schiffhardin.com