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

REPLY TO PATENT OWNER'S PRELIMINARY RESPONSE PURSUANT TO EXHIBIT 3001

The '063 patent was filed November 13, 2020. EX1001, cover; Paper 1 ("Pet."), 19-20. It is undisputed that Bouabdallaoui (EX1005) was earlier published. EX1005, 1; Pet., 15; Paper 6 ("POPR"), 1. It is prior art under AIA § 102(a)(1) on its face and Patent Owner has not shown that any claims are entitled to an earlier effective filing date. *See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1380 (Fed. Cir. 2015); POPR, 4-5.

Patent Owner relies on a new and untested declaration from named inventor Dr. Tardif (EX2011) to argue that "the co-authors of Bouabdallaoui obtained the subject matter of the disclosure directly or indirectly from inventor Dr. Tardif" such that Bouabdallaoui "is a disclosure by Dr. Tardif himself within the one-year prior art exception under 35 U.S.C. §102(b)(1)(A), (B)." POPR,7-8. However, neither Patent Owner nor Dr. Tardif address the key Bouabdallaoui disclosures relied upon for anticipation and obviousness in Grounds 1 and 4. Patent Owner thus fails to establish any §102(b)(1) exception for Bouabdallaoui.

Any contentions that key relied-upon Bouabdallaoui disclosures were obtained from Dr. Tardif are contradicted by Bouabdallaoui itself, which identifies non-inventor Dr. Bouabdallaoui as the lead author and others as providing the relevant statistical analysis showing, e.g., cardiovascular risk reduction for treatment initiated within 3 days post-MI. At best, the Tardif Declaration creates a factual dispute for Grounds 1 and 4—though entirely irrelevant to Grounds 2

and 3—which can be disproven by Petitioner with proper notice and opportunity to be heard via cross-examination and rebuttal at trial. *Medtronic Inc. v. Teleflex Innovations SARL*, IPR2020-00134, Paper 20, at 16–17 (PTAB June 26, 2020); *Pfizer Inc. v. Genentech Inc.*, IPR2017-01488, Paper 27, at 13–15 (PTAB Dec. 1, 2017).

The Tardif Declaration Fails to Support a § 102(b)(1)(A), (B) Exception

Bouabdallaoui (EX1005) is relied upon for disclosing, *inter alia*, that 26.0% of the colchicine-treated patients initiated treatment 0-3 days of MI and that "primary endpoint event occurred in 4.3% of" of these patients, teaching at least claim elements 8[d] (initiating treatment "within about 3 days of the MI"), 8[e] ("wherein the patient is at a lower risk of a cardiovascular event, relative to a patient not being administered colchicine…"); Pet., 26-27 (quoting EX1005, 4, 5). Patent Owner fails to establish that these or any other relied-upon Bouabdallaoui disclosures are subject to the narrow §102(b)(1) exceptions as it fails to establish that they were either "made by" or previously "publicly disclosed by" "the inventor or joint inventor or by another who obtained the subject matter disclosed." *See Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, 855 F.3d 1356, 1360, n.1 (Fed. Cir. 2017) ("one-year grace period in the AIA is less protective than under pre-AIA § 102(b)"), *aff'd*, 139 S. Ct. 628 (2019).

As an initial matter, Patent Owner provides no evidence from any other co-

authors disclaiming contribution to the relevant subject matter. *See* MPEP § 2153 ("If, however, the application names fewer joint inventors than a publication… the publication would be treated as prior art under AIA 35 U.S.C. 102(a)(1) unless there is evidence of record that an exception under AIA 35 U.S.C. 102(b)(1) applies."). While Dr. Tardif contends he listed Dr. Bouabdallaoui as the first author to "acknowledge her assistance in conducting the trial as well as to provide a 'first author' publication for her CV," no supporting information from Dr. Bouabdallaoui is provided. EX2011, ¶29. Most notably, Dr. Tardif only contends that he was the "primary author" not the sole author. EX2011, ¶28. His conclusion that the disclosure was "by me with others who obtained the subject matter disclosed therein directly or indirectly from me" (EX2011, ¶30) is just a conclusion—unsupported by testimony much less corroborating evidence for the specific portions of Bouabdallaoui relied upon by the Petition.

Rather than establish any contribution by Dr. Tardif to the specific Bouabdallaoui disclosures relied upon in the Petition, the Tardif Declaration focuses on irrelevant background, the COLCOT study generally, and data ownership and publication rights. EX2011, ¶¶13-21. For example, it is irrelevant if he "conceived of and designed the COLCOT study and its protocol." *Id.*, ¶17. At best, this is the subject matter of the still-earlier-in-time COLCOT trial protocol (EX1006) and/or the original COLCOT publication (EX1022). Likewise, data

ownership, publication rights, and funding agreement from approximately 2013-2015 are irrelevant to any specific Bouabdallaoui disclosures.

The few statements potentially related to the Bouabdallaoui reference itself are generic at best and fail to assert much less establish that the relied-upon subject matter was "by the inventor or joint inventor or by another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor," as required under the § 102(b)(1) exceptions. *E.g.,* EX2011, ¶¶28 ("primary author"), 30 ("subject matter disclosed therein directly or indirectly from me"). Moreover, at least for material elements of the claims taught by Bouabdallaoui, such as "a reduction of 48% in the risk of the primary endpoint" that is relevant to, *inter alia*, elements 8[e] and cardiovascular event recited in claims 6-7, 9-11, 28, and 50 (*see* Pet., 27-28), the Tardif Declaration is inconsistent with those disclosures having been by or from Dr. Tardif.

First, the Tardif Declaration characterizes these results as "surprising," meaning that they had not been predicted or expected from the earlier COLCOT Protocol. EX2011, ¶21. His testimony regarding having designed or been the principled investigator of the COLCOT study to treat "patients who had experienced a recent myocardial infarction (within 30 days)" (EX2011, ¶¶16-18), thus fails to establish Dr. Tardif as the source of the relied-upon "surprising" reduction in the primary endpoint for patients treated *within 3 days* disclosed in

Bouabdallaoui.

Second, inconsistent with Dr. Tardif having originated this "surprising" subject matter, Bouabdallaoui expressly attributes the analysis to "an independent academic biostatistics centre at the Montreal Health Innovations Coordinating Center." EX1005, 3, 7 (acknowledging others for "for assistance with biostatistics"). The Tardif Declaration further admits that "Marie-Claude Guertin, a statistician employed by MHICC… perform[ed] a data analysis." EX2011, ¶20. That the statisticians' analyses were purportedly conducted "at [his] direction and to report the results to [him]" (*id.*) is irrelevant as "posing the problem" or requesting analysis does not establish that the specific subject matter was by or from Dr. Tardif. *See Morgan v. Hirsch*, 728 F.2d 1449, 1452 (Fed. Cir. 1984) ("[A]sking someone to produce something without saying just what it is to be or how to do it is not what the patent law recognizes as inventing.").

Finally, any inference that the relied-upon subject matter of Bouabdallaoui was obtained from Dr. Tardif should be further explored during trial. EX2011, ¶¶29-30; *see* 78 Fed. Reg. 11,080 (Feb. 14, 2013); *Ex parte Kroger*, 219 U.S.P.Q. 370 (Bd. App. 1982) (rejecting declaration attesting to inventorship in view of contrary evidence). At the very best, the Tardif Declaration raises issues of fact that would "benefit from development during trial." *MerchSource,LLC v. Dodocase VR, Inc.*, IPR2018-00494, Paper 12, at 20 (PTAB Aug. 22, 2018).

Respectfully submitted,

Dated: December 6, 2023

By: /Mark J Feldstein/
Mark J. Feldstein, Reg. No. 46,693
FINNEGAN, HENDERSON,
FARABOW, GARRETT &
DUNNER, LLP

Counsel for Petitioner

CERTIFICATE OF SERVICE

The undersigned certifies that a copy of the foregoing **Reply To Patent Owner's Preliminary Response Pursuant to Exhibit 3001** was served electronically via email on December 6, 2023, in its entirety on the following:

Sailesh K. Patel
Imron T. Aly
ArentFox Schiff LLP
233 S. Wacker Dr.
Suite 7100
Chicago, Illinois 60606
Sailesh.patel@afslaw.com
Imron.aly@afslaw.com

Patent Owner has consented to service by electronic mail.

Dated: December 6, 2023

/William Esper/
William Esper
Case Manager and PTAB Coordinator
Finnegan, Henderson, Farabow,
Garrett & Dunner LLP