

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 No. 11,400,063

**SUR-REPLY IN SUPPORT OF PATENT OWNER'S
PRELIMINARY RESPONSE PURSUANT TO EXHIBIT 3001**

Petitioner's brief reverts to irrelevant pre-AIA law on antedating references and ignores facts in a last-ditch effort to classify Bouabdalloui (EX1005) as prior art. The issue is whether Bouabdalloui falls under the AIA 35 U.S.C. §102(b)(1)(A) or (B) exemptions from prior art, and the objective evidence demonstrates it does. Petitioner distorts Dr. Tardif's clear declaration that shows Bouabdallaoui is a disclosure within the one-year exception by him, the sole inventor of the '063 patent, or by others who received the information from him. In contrast, Petitioner merely speculates that pertinent disclosures originated from one of the other authors and doesn't identify any discovery it actually needs.

Petitioner's reply, like its petition, disregards that the examiner considered Bouabdallaoui during the '063 patent's prosecution and did not issue any rejections in view of it. The examiner would have appreciated Bouabdallaoui was published within the one-year exception period, that Dr. Tardif was the corresponding author, and therefore the reference falls within the prior-art exception. The Tardif declaration (EX2011) supports this most plausible interpretation by the examiner and provides additional independent supporting evidence.

Petitioner's arguments could have been made in its petition. It appears Petitioner deliberately held back to create a false sense of criticality that it needs discovery in the hopes the Board will institute review of the claims. But the objective facts corroborate that Bouabdallaoui falls within the statutory prior-art exception.

Petitioner Cites No Case Law Supporting The Relevant §102(b)(1) Issue

Petitioner attempts to re-frame the issue, stating on page 1: “Patent Owner has not shown that any claims are entitled to an earlier effective filing date.” First, the petition concedes that at least claims 27 and 29-39 are entitled to a filing date before Bouabdallaoui. Factual inaccuracies aside, Patent Owner’s position is that Bouabdallaoui falls within the statutory exception to prior art, not that it is entitled to an earlier filing date. Petitioner’s citations to *Dynamic Drinkware*, *Medtronic*, and *Pfizer* are all inapplicable as they involve antedating prior art. The single case Petitioner cites that does deal with §102(b)(1) exceptions—*Helsinn*—is about the on-sale bar and is also not relevant here. Thus, Petitioner fails to cite any relevant case law regarding publication disclosures by or from the inventor within one year.

Substantial Independent Evidence Corroborates Dr. Tardif

If antedating cases are relevant here, then Federal Circuit law shows that Bouabdallaoui falls within the prior art exception. The Federal Circuit held that the sufficiency of any independent documentary corroborating evidence provided by an inventor is evaluated under the “rule of reason.” *Medtronic, Inc. v. Teleflex Innovations S.À.R.L.*, 68 F.4th 1298, 1306 (Fed. Cir. 2023). Corroborating evidence may be circumstantial, and it “simply needs to be sufficient to support the credibility of the inventors’ story.” *Id.* (citing *E.I. du Pont de Nemours & Co. v. Unifrax I LLC*, 921 F.3d 1060, 1075 (Fed. Cir. 2019)). It is apparent from Bouabdallaoui itself that

the reference falls within the prior-art exception, but other independent evidence discussed in the Tardif declaration is consistent. The facts and evidence in the Tardif declaration are further corroborated by an independent expert.

First, the Bouabdallaoui reference itself makes apparent the prior-art exception applies. The publication date shows it was published less than one year before the US filing date of the '063 patent. As to whether the disclosure is by or from Dr. Tardif, MPEP §2153.01 states that “[a] disclosure is not prior art under AIA 35 U.S.C. §102(a)(1) if it is apparent from the disclosure itself that it is an inventor-originated disclosure.” While Petitioner falsely claims Bouabdallaoui is the “lead” author (as opposed to the first-named one), the article clearly lists Dr. Tardif as the corresponding author. Petitioner does not dispute it is well understood in the industry that a “corresponding author” is the individual that is responsible for the article, speaks on behalf of the other authors, and is responsible for edits, agreements, and publishing the article. (EX2011, ¶27.) This is corroborated by Dr. Ardehali. (EX2001, ¶¶30-31.) It is therefore clear from Bouabdallaoui itself that the article was published within one year and is an inventor-originated disclosure.

Dr. Tardif provided additional corroborating evidence as an inventor is permitted to do. *See* MPEP §2155.03. The COLCOT protocol lists Dr. Tardif as the sole principal investigator. As the principal investigator, Dr. Tardif was responsible for conducting the study and its results that underly Bouabdallaoui. Despite

Petitioner attempting to dismiss the relevance of the protocol, *Petitioner itself relied on the protocol in its petition*. And without Dr. Tardif creating the protocol, there would have been no COLCOT study and without the study, no Bouabdallaoui article. Petitioner's suggestions otherwise strain credulity. The most logical conclusion that can be drawn is that the disclosure is by him or by others from him.

The final piece of Dr. Tardif's corroborating evidence is the most damning to Petitioner's argument, which is why Petitioner ignored it completely. Dr. Tardif provided agreements with the clinics that obtained the data on his behalf as a part of his COLCOT study. Petitioner does not dispute that it is impractical for a medical doctor to individually compile all the data necessary to demonstrate a drug will be useful for a clinical indication, and therefore will involve other clinics to provide relevant data pursuant to a clinical study, like the COLCOT study. (EX2011, ¶19.) The clinic agreements make clear that MHI and Dr. Tardif are responsible for the overall conduct of the study and compiling the data, and own the data and associated IP and control any publication rights. (*Id.*, EX2012-2015.) The other authors and clinicians participating in the study all worked under the direction of Dr. Tardif. This is strong independent evidence that the data in Bouabdallaoui was controlled by Dr. Tardif and came from him at least indirectly if not directly.

The independent corroborating evidence supports Dr. Tardif's declaration statements and demonstrates that Bouabdalloui was a result of information provided

by Dr. Tardif. It therefore falls under the prior art exception of §102(b)(1).

Petitioner's Allusion to Other Inventors Has No Legal or Factual Support

Dr. Tardif conceived of the COLCOT study to demonstrate the benefits of colchicine in a certain patient population. That he used the services of a statistician to perform statistical analyses that yielded surprising results does not make the statistician an inventor. Petitioner's argument is contrary to law and is merely an effort to get the Board to keep certain claims alive and unnecessarily increase costs.

An individual must "contribute to the *conception* of the invention" to be considered an inventor. *Fiers v. Revel*, 984 F.2d 1164, 1168 (Fed. Cir. 1993) (emphasis added). One that is following directions is merely a technician, not an inventor. *See Mattor v. Coolegem*, 530 F.2d 1391, 1395 (CCPA 1976). The statistician who assisted Dr. Tardif in performing a statistical analysis, while providing technical skill, was simply acting at Dr. Tardif's direction. It is immaterial that Dr. Tardif did not personally conduct the statistical analysis because "those steps does not require the exercise of inventive skill." *Fritsch v. Lin*, 21 USPQ2d 1737, 1739 (Bd. Pat. App. & Inter. 1991); *see also In re DeBaun*, 687 F.2d 459, 463, 214 USPQ 933, 936 (CCPA 1982) (holding "there is no requirement that the inventor be the one to reduce the invention to practice so long as the reduction to practice was done on his behalf"). If Petitioner's argument were to be accepted, every testing facility, contract manufacturer, and consultant would be an inventor.

Respectfully submitted,

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By: /Sailesh K. Patel/

Sailesh K. Patel (Reg. No. 46,982)

Imron T. Aly (Reg. No. 48,706)

ArentFox Schiff LLP

233 S. Wacker Dr.

Suite 7100

Chicago, Illinois 60606

Sailesh.patel@afslaw.com

Imron.aly@afslaw.com

Counsel for Patent Owner

CERTIFICATE OF SERVICE

The undersigned certifies that a copy of the foregoing Sur-Reply In
Support of Patent Owner's Preliminary Response Pursuant to Exhibit 3001
was served electronically via email on December 13, 2023, in its entirety on the
following:

IPR2023-01064@finnegan.com

Mark J. Feldstein (mark.feldstein@finnegan.com)

Yieyie Yang (yieyie.yang@finnegan.com)

Petitioner has consented to service by electronic mail.

Dated: December 13, 2023

By: /Sailesh K. Patel/

Sailesh K. Patel

ARENTFOX SCHIFF LLP