

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

SECOND DECLARATION OF RAYMOND CRUITT, M.S.

I. INTRODUCTION

1. I prepared a declaration (“First Declaration”), which is dated June 16, 2023 and was filed in IPR2023-01064 as Exhibit 1038. I reaffirm and incorporate into this, my Second Declaration, the content of my First Declaration.

2. In my First Declaration, I addressed the public accessibility of several documents submitted in IPR2023-01064 including Exhibit 1006. I submit this Second Declaration to address assertions made by the Patent Owner regarding Exhibit 1006 in its Response (Paper 021).

3. I stated in my First Declaration that: (1) Exhibit 1006 is “a true and accurate copy of the Internet Archive HTML file record for the ClinicalTrials.gov webpage archived on October 20, 2017” from the publicly accessible “Wayback Machine” website, and (2) the page “shows that the date of ‘Last Update Posted’ was March 8, 2017.” Ex. 1038 ¶ 23.

4. I understand from Petitioner’s counsel that the Patent Owner relies on Exhibit 2069 to assert that “the FDA clinical trials website record history data does not comport with Mr. Cruitt’s opinions” regarding the public accessibility of Exhibit 1006 because “the public availability of the COLCOT protocol is listed as July 16, 2020.”

5. While Exhibit 2069 does refer to “2020-07-16” as *an* upload date for the COLCOT study protocol, pages 1-2 of Exhibit 2069 list ten version of the COLCOT study record submitted from September 15, 2015 through September 23, 2020. As I explained in detail in my First Declaration, a version of the COLCOT Protocol was submitted on March 6, 2017 and publicly accessible by March 8, 2017:

24. Appendix B is the current version of the COLCOT trial protocol that I accessed on June 13, 2023, from the publicly accessible ClinicalTrials.gov webpage <https://clinicaltrials.gov/ct2/show/NCT02551094>, which shows that the protocol was last updated on October 19, 2020. When I clicked on the “History of Changes” on this webpage, it shows various “Study Record Versions,” including the version of the COLCOT trial protocol that was submitted on March 6, 2017, which I am attaching here as Appendix C. The webpage also states that the changes of this version compared to the earlier versions are addition of “Contacts/Locations, Study Status and Study Identification.” Appendix C, 1. That the content of the COLCOT trial protocol in Appendix C is identical to that of EX1006 further confirms that COLCOT Protocol (EX1006) was submitted to ClinicalTrials.gov on March 6, 2017, and posted on the publicly accessible website on March 8, 2017. *Compare Appendix A with Appendix C.*

First Declaration (Ex. 1038) ¶ 24.

6. Based on the foregoing, I concluded that Exhibit 1006 “would have been publicly available online by March 8, 2017 (its online posting date) and accessed

publicly no later than October 20, 2017 (its Wayback Machine archiving date).” *Id.*

¶ 25.

7. My conclusion is confirmed by the Patent Owner’s Exhibit 2069, which refers to the “2017-03-06” submission in the table on page 2 as “Version . . . 3” of the study record.

8. I also understand from Petitioner’s counsel that the Patent Owner further asserts that “the linked version of the study protocol . . . is internally dated November 15, 2018, more than eighteen months *after* Mr. Cruitt alleges the protocol was publicly available.” To the extent Patent Owner is referring to the “linked version” obtained by clicking on the “Prot_001.pdf” link on page 13 of Exhibit 2069, as explained above, that is only one version of the COLCOT Protocol. While it is true that *that* version of the protocol bears “November 15th, 2018” on its title page, earlier versions of the protocol were publicly accessible, including the one that is Exhibit 1006 in this case, which was publicly accessible by March 8, 2017.

9. Finally, I understand from Petitioner’s counsel that the Patent Owner asserts that because I am employed by Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, which is the firm that filed the Petition on behalf of the Petitioner, that my First Declaration is “not reliable due to bias as a result of fiduciary duty owed to his employer—Petitioner’s law firm.” And I understand that the Patent Owner further

asserts that “Mr. Cruitt is not an objective expert witness, and his biased opinion should be stricken and afforded no weight.”

10. Those aspersions on my integrity are completely unfounded. My First Declaration, like this Second Declaration, concludes with several statements including my recognition that “willful false statements and the like are punishable by fine or imprisonment” and my expression of willingness to “appear for cross-examination.”

II. RIGHT TO SUPPLEMENT

11. I reserve the right to supplement my opinions in the future to respond to any arguments that the Patent Owner raises and to take into account new information as it becomes available to me.

III. CERTIFICATION

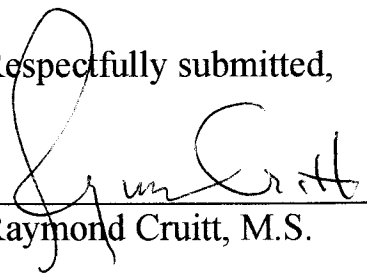
12. In signing this declaration, I recognize that this declaration will be filed in support of the Petitioner in case number IPR2023-01064 at the U.S. Patent and Trademark Office.

13. I acknowledge that, as part of this IPR, I may be subject to cross-examination in the United States regarding the content of this declaration. If cross-examination is required of me, I will make myself reasonably available for cross-examination within the United States during the time allotted for cross-examination.

14. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and, further, that these statements were made with the knowledge that willful false statements and the like are punishable by fine, imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dated: July 8, 2024

Respectfully submitted,



Raymond Cruitt, M.S.