

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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EVERGREEN THERAGNOSTICS, INC.

Petitioner

– vs. –

ADVANCED ACCELERATOR APPLICATIONS SA

Patent Owner

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CASE NO. PGR2021-00003

**DECLARATION OF PAUL E. DIETZE, Ph.D., ESQ.  
IN SUPPORT OF REPLY TO PATENT OWNER'S PRELIMINARY  
RESPONSE**

**DECLARATION OF PAUL E. DIETZE**

I, Paul E. Dietze, hereby declare that:

1. I am an attorney at Parker, Poe, Adams, and Bernstein LLP.
2. I provide this declaration in connection with Petitioner Evergreen Theragnostics, Inc.'s Reply to Patent Owner Advanced Accelerator Applications SA's Preliminary Response in the above-captioned PGR2021-00003.
3. I was involved with gathering information and preparing documents for filing the Petition for Post Grant Review in PGR2021-00001 and PGR2021-00003.
4. One of my tasks was to establish the date that various prior art references were publicly available. In particular, I undertook an effort to establish the date that Protocol (Ex. 1012) was publicly available. Protocol (Ex. 1012) is supplemental material, available on-line, that is associated with *J. Strosberg et al., Phase 3 Trial of <sup>177</sup>Lu-Dotatate for Midgut Neuroendocrine Tumors*, N. Engl. J. Med., 376(2):125–135, Jan. 12, 2017 ("Strosberg," Ex. 1011). Protocol (Exhibit 1012) provided the protocol used in the clinical study reported in Strosberg (Ex. 1011).
5. This declaration provides a summary of my efforts to establish the date that Protocol (Ex. 1012) was publicly available.
6. I obtained Protocol (Ex. 1012) from the link at the end of the on-line version of Strosberg (Ex. 1011). Strosberg (Exhibit 1011) stated that "The protocol and statistical analysis plan are available with the full text of this article at NEJM.org" (Strosberg (Ex. 1011) at p. 127, col. 2) indicating that Protocol (Ex. 1012) was publicly available at the same time Strosberg (Ex. 1011) was publicly available.
7. To further establish that Protocol (Ex. 1012) was publicly available contemporaneously with Strosberg (Exhibit 1011), I contacted the New England Journal of Medicine ("NEJM"), the publisher of Strosberg (Ex. 1011). Specifically, at my direction, our firm's librarian, Ms. Lisa Williams, contacted NEJM to see if they could provide us with information on when supplemental material associated with a published article has to be

submitted. On April 13, 2020, Ms. Williams received a response from Pam Miller of the NEJM editorial department. Ms. Miller stated: “*normally the supplementary material is posted at the same time as the main article.*” The only exception would be if the main article is moving so quickly that the supplementary material is not ready yet (see Covid-19).” (Emphasis added). The e-mail chain between Ms. Williams and myself is attached hereto as Exhibit A.

8. In an effort to establish that this procedure was followed with the publication of Strosberg (Exhibit 1011), Ms. Williams, at my direction, again reached out to the Editorial Department at NEJM asking them if they could verify that Protocol (Exhibit 1012) was published at the same time that Strosberg (Ex. 1011) was published. Ms. Williams received a response from Ms. Vivian L. Vu, Editorial Assistant, New England Journal of Medicine, stating that “Any post-publication changes are noted at the end of the article. As this is not the case for the article in question, *it is safe to say that the supplemental material was posted at the same time as the supporting content.*” (Emphasis added). The e-mail chain between Ms. Williams and Ms. Vu is attached hereto as Exhibit B.

9. I then personally contacted Ms. Vu via e-mail to see if we could arrange for a telephone conversation so that we could “be sure that we properly understand the process that is followed by the NEJM regarding availability of supplemental material.” In response, I received an e-mail from Mr. Patrick Hannon, indicating that he was Ms. Vu’s supervisor, and confirming “that what [Ms. Vu] said is accurate – *the supplemental material was posted at the same time as the article.*” (Emphasis added).

10. Mr. Hannon also indicated that if there were further questions about NEJM procedures, it would be best to direct them to its legal counsel, Mr. Joseph Appel, Senior Counsel, Massachusetts Medical Society, NEJM Group.

11. Thus, I reached out to Mr. Appel by e-mail to see if we could arrange for a short telephone call to discuss what we could do to establish with certainty that Protocol (Exhibit 1012) was publicly available at the same time that Strosberg (Ex. 1011) was publicly available. Mr. Appel, in his response, indicated that he was not sure he could provide additional information and noted that, before disclosing internal business information that’s not available

publicly, NEJM generally requires service with a valid subpoena, but that he would be happy to talk with us.


12. The e-mail chain of my correspondence with Ms. Vu, Mr. Hannon and Mr. Appel is attached hereto as Exhibit C.

13. I arranged for a June 10, 2020 teleconference with Mr. Appel. In the teleconference my colleague, Mr. Musgrove, and I explained to Mr. Appel that we were trying to establish the date that Protocol (Ex. 1012) was publicly available so that we could show that it is prior art that can be used in a Post Grant Review proceeding before the U.S. Patent and Trademark Office (“USPTO”) and that we would like to get an affidavit or declaration, executed by a knowledgeable person at NEJM, stating definitively the date that Protocol (Exhibit 1012) was publicly available, before requesting that the USPTO institute a PGR proceeding. Mr. Appel reiterated that generally a subpoena is required before NEJM will disclose internal business information that is not publicly available, but that he would “run it up the ladder” to see if there was anything he could do to assist us.

14. On July 10, 2020, I again spoke with Mr. Appel on the telephone and he informed me that he had “run things up the ladder” but, without a subpoena, he could not provide us with additional information because it is the policy of NEJM to only respond to a subpoena. He indicated, however, that if they were served with a subpoena they would cooperate.

15. I hereby declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct, and that all statements made 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 so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Date: 2-19-2021

Executed:   
Paul E. Dietze, Ph.D., Esq.

# EXHIBIT A

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