UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD
EVERGREEN THERAGNOSTICS, INC.
Petitioner
– vs. –
ADVANCED ACCELERATOR APPLICATIONS SA
Patent Owner

DECLARATION OF STEPHAN MAUS
UNDER 37 C.F.R. § 1.68
IN SUPPORT OF PETITION FOR
POST GRANT REVIEW OF U.S. PATENT NO. 10,596,278
(ALL CLAIMS)

CASE NO. PGR2021-00001



Declaration of Stephan Maus Under 37 C.F.R. § 1.68 in Support of Petition for Post Grant Review of U.S. Patent No. 10,596,278

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	Statement (Ex. 1018), and De León-Rodríguez (Ex. 1014) or Other Prior Art Disclosing That it was Routine to Maintain pH With an Acetic Acid/Sodium Acetate Buffer During Complexation
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IX.

EXPERT DECLARATION OF STEPHAN MAUS

I, Stephan Maus, hereby declare that:

I. INTRODUCTION

- 1. I have been retained as an expert witness on behalf of Evergreen Theragnostics, Inc. ("Petitioner") relating to a petition for post grant review ("PGR") of U.S. Patent No. 10,596,278 (Ex. 1002, "the '278 patent"). I am being compensated at a rate of \$500/hour for the time I spend on this matter. My compensation is not affected by the outcome of this proceeding.
- 2. More specifically, I have been asked to provide my opinions regarding whether the claims of the '278 patent are unpatentable because they are anticipated by, and/or because they would have been obvious in view of, the prior art at the time of the alleged invention. It is my opinion, for the reasons set forth below, that the claims of the '278 patent are anticipated by or would have been obvious to a person of ordinary skill in the art ("POSA") at the time of the alleged invention in the '278 patent.
- 3. In forming the opinions expressed in this declaration, I relied upon my education and experience in the relevant field of art, and have considered the viewpoint of a POSA as of July 25, 2018. I have carefully read the '278 patent, along with substantive portions of its prosecution history. In forming my opinions, I have considered:



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- a) Ex. 1002, the '278 patent;
- b) Ex. 1004, the file history of the '278 patent;
- c) the documents and references cited in the analysis below, including:
 - Ex. 1011, J. Strosberg et al., Phase 3 Trial of 177Lu-Dotatate for Midgut Neuroendocrine Tumors, N. Engl. J. Med., 376(2):125–135, Jan. 12, 2017 ("Strosberg");
 - Ex. 1012, Protocol for: Strosberg J., El-Haddad G., Wolin E., et al. Phase 3 trial of ¹⁷⁷Lu-Dotatate for midgut neuroendocrine tumors, N. Engl. J. Med. 2017; 376:125-35 provided as supplemental material to Ex. 1011, Strosberg ("Protocol");
 - Ex. 1014, L. M. De León-Rodríguez et al., The Synthesis and
 Chelation Chemistry of DOTA-Peptide Conjugates,
 Bioconjugate Chem., 19(2):391-402, 2008 ("De León-Rodríguez");
 - Ex. 1028, A. Filice et al., Radiolabeled Somatostatin Analogues

 Therapy in Advanced Neuroendocrine Tumors: A Single Centre

 Experience, J. Oncology, 2012:1-10, Aug. 9, 2012 ("Filice");
 - Ex. 1016, S. Banerjee et al., Lutetium-177 Therapeutic

 Radiopharmaceuticals: Linking Chemistry, Radiochemistry,



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