Trials@uspto.gov
571.272.7822

Paper 10
Date: April 27, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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PROGENICS PHARMACEUTICALS, INC.,
Petitioner,

v.

MAX-PLANCK-GESELLSCHAFT ZUR FOERDERUNG DER WISSENSCHAFTEN E.V.
AND
UNIVERSITAT ZU KOLN,
Patent Owners.

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PGR2019-00052
Patent 10,112,974 B2

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Before GEORGIANNA W. BRADEN, J. JOHN LEE, and MICHAEL A. VALEK, *Administrative Patent Judges*.

VALEK, *Administrative Patent Judge*.

# JUDGMENT
Final Written Decision
Determining No Challenged Claims Unpatentable
*35 U.S.C. § 328(a)*

# I. INTRODUCTION

This Final Written Decision is issued pursuant to 35 U.S.C. § 328(a) and 37 C.F.R. § 42.73. Progenics Pharmaceuticals, Inc., ("Petitioner") bears the burden of providing the unpatentability of the challenged claims by a preponderance of the evidence. 35 U.S.C. § 326(e) (2018). For the reasons explained below, we determine Petitioner has failed to establish by a preponderance of the evidence that claims 6, 8, and 10–12 of U.S. Patent No. 10,112,974 B2 (Ex. 1001, "the '974 patent") are unpatentable. Max-Planck-Gesellschaft zur Foerderung der Wissenschaften e.V. and Universitat zu Koln (collectively "Patent Owner") have disclaimed all of the other claims of the '974 patent previously at issue in this proceeding.

## *A. Procedural Background*

Petitioner filed a Petition seeking post-grant review of claims 1–15 and 31 of the '974 patent. Paper 2 ("Pet."). Patent Owner did not file a preliminary response. Upon consideration of the information presented in the Petition, we determined Petitioner had shown it was more likely than not that claims 1–5, 7, 9, 13, 15, and 31 were unpatentable for one or more of the asserted grounds. Paper 7, 35 ("Institution Decision"). We also explained why we were not persuaded that Petitioner had met its burden with respect to the other challenged claims. *Id.* Nevertheless, following *SAS Institute Inc. v. Iancu*, 138 S. Ct. 1348 (2018) and USPTO guidance, we instituted review of all claims challenged under all grounds in the Petition. *Id.*

After institution, Patent Owner notified the Board that it intended to file a statutory disclaimer of claims 1–5, 7, 9, 13, 15, and 31 and was waiving its opportunity to file a response and motion to amend. Paper 9, 2. Patent Owner further indicated that it would "not request adverse judgment

as to Petitioner's grounds for claims 6, 8, 10–12, and 14." *Id.* Thus, we ordered that "the post grant review will continue as instituted, albeit without a response or other papers from Patent Owner." *Id.*

On March 13, 2020, Patent Owner filed a statutory disclaimer disclaiming claims 1–5, 7, 9, 13–15, and 31. Ex. 2001. Claims 1–5, 7, 9, 13–15, and 31 are, therefore, no longer at issue in this proceeding. *See* 35 U.S.C. § 253 (2018) (disclaimer of claims considered effective as if part of original patent); 37 C.F.R. § 42.207(e) ("No post-grant review will be instituted on disclaimed claims."). Claims 6, 8, and 10–12 remain at issue.

Both Petitioner and Patent Owner subsequently confirmed that they would not request oral argument and did not intend to file any other paper prior to entry of our Final Written Decision on the remaining claims. As such, the record is complete and consists of the Petition and accompanying exhibits Ex. 1001–1033, as well as Patent Owner's statutory disclaimer (Ex. 2001).

### *B. The '974 Patent*

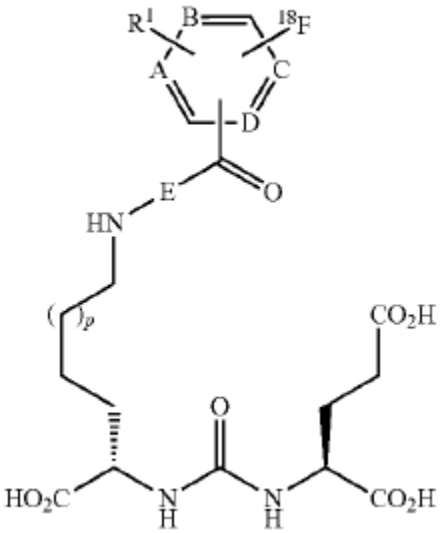
The '974 patent describes methods and chemical precursors for making "$^{18}$F-labelled active esters via nucleophilic substitution of the corresponding onium precursors with $^{18}F^-$. . . ." Ex. 1001, Abstr. The Specification indicates that such compounds are "useful for positron emission tomography (PET) imaging, especially imaging prostate tumor." *Id.* at 1:14–18. According to the Specification,

> In recent years imaging of prostate carcinoma (PCa) with PET isotope labelled PSMA ligands has become of considerable importance in clinical diagnosis. This can mainly be attributed to the high expression of the extracellular localized prostate specific membrane antigen (PSMA) in PCa. Ligands bearing the syL-C(O)-Glu-binding motif exhibit high binding affinity to PSMA.

*Id.* at 5:60–66.

The $^{18}F$-labelled compounds taught in the Specification exhibit a "syL-C(O)-Glu" or glutamate-urea-lysine ("GUL") motif and correspond to general formula (I), which is reproduced below.

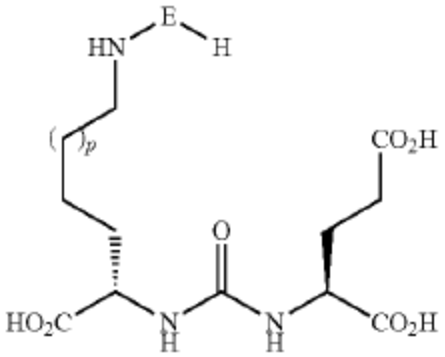
(I)



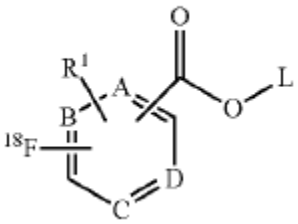

*Id.* at 7:40–55.[1] The compounds in formula (II) and formula (III), shown below, are described in the Specification as precursors used to make compounds of formula (I) according to the methods therein.

[1] The Specification's descriptions for the variables depicted in formulas (I), (II), and (III) are not reproduced here for sake of brevity.

(II)

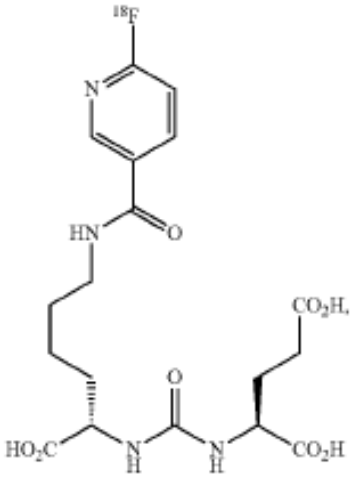


(III)



The Specification provides numerous examples of compounds corresponding to general formula (I) that may be made with the disclosed methods. *See generally id.* at 26:11–28:10; 45:45–59:60 (listing compounds). One of these examples, "[$^{18}$F]DCFPyL" or compound 1-10 in the Specification, is shown below.

1-10



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