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Paper No. 10
Entered: March 20, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

HYBRIGENICS SA.
Petitioner,

v.

FORMA THERAPEUTICS, INC.
Patent Owner.

Case PGR2018-00098
Patent 9,840,491 B2

Before SHERIDAN K. SNEDDEN, ROBERT A. POLLOCK, and DAVID COTTA, *Administrative Patent Judges*.

COTTA, *Administrative Patent Judge*.

DECISION
Granting Institution of Post Grant Review
35 U.S.C. § 324(a)

I. INTRODUCTION

Hybrigenics SA ("Petitioner" or "Hybrigenics") filed a Petition requesting a post grant review of claims 1–17 of U.S. Patent No. 9,840,491 B2 (Ex. 1001, "the '491 patent").[1] Paper 4 ("Pet."). Forma Therapeutics, Inc. ("Patent Owner" or "Forma") filed a Preliminary Response to the Petition. Paper 9 (Prelim. Resp.).[2]

Institution of post grant review is authorized by statute only when "the information presented in the petition . . . demonstrate[s] that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable." 35 U.S.C. § 324; *see* 37 C.F.R. § 42.4. Upon considering the Petition, the Preliminary Response, and the cited evidence, we conclude that Petitioner has satisfied the burden under 35 U.S.C. § 324 to show that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable.

A. Related Proceedings

Petitioner represents that it is unaware of any other matters related to the '491 patent. Pet. 1. Patent Owner identifies several patent applications as related to the '491 patent, including Patent Cooperation Treaty Application No. PCT/US2016/016542, US Patent Application No. 62/112,487, and US Patent Application No. 15/837,393. Paper 6, 2.

B. The '491 Patent (Ex. 1001)

The '491 patent issued December 12, 2017, identifying Stephanos Ioannidis, Adam Charles Talbot, Bruce Follows, Alexandre Joseph Buckmelter, Minghua Wang, Ann-Marie Campbell, and David R. Lancia Jr.

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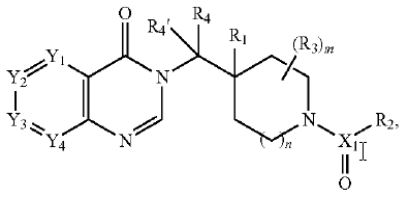
[1] Petitioner identifies Hybrigenics SA as the real party in interest. Pet. 1.
[2] Patent Owner identifies Forma Therapeutics, Inc. as the real party in interest. Paper 6, 2.

as joint inventors. Ex. 1001. The patent "relates to inhibitors of USP7 [ubiquitin-specific protease 7]." *Id.* at Abstract.

The '491 patent teaches that "USP7 deubiquitinates a variety of cellular targets involved in different processes related to cancer and metastasis, neurodegenerative diseases, immunological disorders, osteoporosis, arthritis inflammatory disorders, cardiovascular diseases, ischemic diseases, viral infections and diseases, and bacterial infections and diseases." Ex. 1001, 1:62–2:2. The '491 patent also teaches that "[i]nhibition of USP7 with small molecule inhibitors . . . has the potential to be a treatment for cancers and other disorders." *Id.* at 3:1–2.

The '491 patent discloses "compounds of Formula (I):



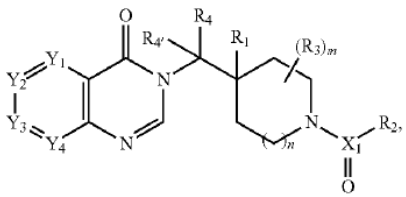
(I)

and pharmaceutically acceptable salts, hydrates, solvates, prodrugs, stereoisomers, and tautomers thereof." *Id.* at 3:7–23.

C. Challenged Claims

Petitioner challenges claims 1–17 of the '491 patent. Claims 1 and 16 are representative and are reproduced below.

1. A compound of Formula (I):



(I)

or a pharmaceutically acceptable salt, stereoisomer, and tautomer thereof,
wherein:
X_1 is C, S, or S(O);

Y_1 is N or CH;
Y_2 is N or CR_5;
Y_3 is N or CR_6;
Y_4 is N or CR_7;

. . . R_2 is (C_1-C_6) alkyl, (C_6-C_{14}) aryl, 5- or 6- membered heteroaryl comprising 1 to 3 heteroatoms selected from O, N, and S, (C_5-C_8) cycloalkyl, 3- to 7-membered heterocycloalkyl comprising 1 to 3 heteroatoms selected from O, N, and S, or —$NR_{10}R_{11}$, wherein the alkyl, aryl, heteroaryl, cycloalkyl, and heterocycloalkyl are optionally substituted with one to three R_8;

. . . wherein R_5, R_6, and R_7 and not all simultaneously H;

. . . provided that when R_2 is optionally substituted alkyl, R_5 is H, and R_7 is H, then R_6 is not chloro.[3]

16. A compound selected from:
3-((4-hydroxy-1-(3-phenylbutanoyl)piperidin-4-yl) methyl)-7-methoxyquinazolin-4(3H)-one;
3-((4-hydroxy-1-(3-phenylbutanoyl)piperidin-4-yl) methyl)-8-methylquinazolin-4(3H)-one;
7-amino-3-((4-hydroxy-1-(3-phenylbutanoyl)piperidin-4–yl)methyl)quinazolin-4(3H)-one;
N-(3-((4-hydroxy-1-(3-phenylbutanoyl)piperidin-4-yl)methyl)-4-oxo-3,4-dihydroquinazolin-7-yl)acetamide;
(R)-3-((4-hydroxy-1-(3-phenylbutanoyl)piperidin-4-yl)methyl)-7-methoxyquinazolin-4(3H)-one;
(R)-3-((4-hydroxy-1-(3-phenylbutanoyl)piperidin-4-yl)methyl)-8-methylquinazolin-4(3H)-one;
3-((1-(1-benzylindoline-5-carbonyl)-4-hydroxypiperidin-4-yl)methyl)-7- methylquinazolin-4(3H)-one;
3-((1-benzoyl-4-hydroxypiperidin-4-yl)methyl)-7-phenylquinazolin-4(3H)-one;
3-((1-benzoyl-4-hydroxypiperidin-4-yl)methyl)-8-phenylquinazolin-4(3H)-one;

[3] Claim 1 also includes limitations further limiting R substituents, and further limiting m, n, and q, but those limitations are not relevant to the dispositive issues in this Petition and so are not reproduced herein.

3-((1-(4-fluorobenzoyl)-4-hydroxypiperidin-4-yl)methyl)-8-(4-fluorophenoxy)quinazolin-4(3H)-one;
3-((4-hydroxy-1-(3-phenylbutanoyl)piperidin-4-yl)methyl) pyrido[2,3-d]pyrimidin-4(3H)-one;
3-((4-hydroxy-1-(3-phenylbutanoyl)piperidin-4-yl)methyl) pyrido[3,4-d]pyrimidin-4(3H)-one; or
3-((4-hydroxy-1-(3-phenylbutanoyl)piperidin-4-yl)methyl) pyrido[3,2-d]pyrimidin-4(3H)-one.

D. The Prosecution History

We discuss the prosecution history of the '491 patent for context because one of the prior art references asserted in this proceeding, the '150 patent,[4] was cited by the Examiner during prosecution and because Petitioner challenges material added by amendment as lacking written description support.

The application that issued as the '491 patent (Application No. 15/015,571), was filed on February 4, 2016. Ex. 1001. In an Office Action dated September 29, 2016, the Examiner rejected claims corresponding to the claims at issue under 35 U.S.C. § 112(a) as indefinite because the claims "defined variables (where applicable) as heterocycle, heteroaryl, heterocyclic, and or aryl" but the "specification does not define the ring size, heteroatom, number and nature of substituents, and the exact point of contact with the atom(s) for the substituents." Ex. 1002, 186. The Examiner also rejected these claims under 35 U.S.C. § 112(a) for failure to comply with the enablement requirement. *Id.* at 187. The pending claims were drawn to compounds of Formula I "or a pharmaceutically acceptable salt, hydrate, solvate, prodrug, stereoisomer, and tautomer thereof." *Id.* at

[4] Colland et al., US Patent No. 9,546,150 B2, issued Jan. 17, 2017 (Ex. 1003, "the '150 patent").

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