

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

HYBRIGENICS SA.
Petitioner,

v.

FORMA THERAPEUTICS, INC.
Patent Owner.

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
Final Written Decision
35 U.S.C. § 328

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 We determined, based on the information presented in the Petition and Preliminary Response, that there was a reasonable likelihood that Petitioner would prevail in showing that at least one of the challenged claims was unpatentable. Pursuant to 35 U.S.C. § 324, the Board instituted trial on March 20, 2019. Paper 10 (“Institution Decision” or “Inst. Dec.”).

Patent Owners filed a Response to the Petition (Paper 16, “PO Resp.”), Petitioner filed a Reply to Patent Owners’ Response (Paper 19, “Reply”), and Patent Owner filed a Sur-Reply (Paper 21, “Sur-Reply”). Neither party request an oral hearing.

We have jurisdiction under 35 U.S.C. § 6. We issue this Final Written Decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. Based on the record before us, we conclude that Petitioner has demonstrated by a preponderance of the evidence that claims 1–15 and 17 of the ’491 patent are unpatentable but has not demonstrated that claim 16 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

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.

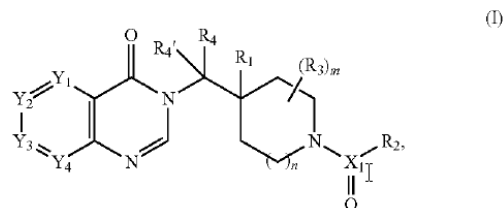
Application No. PCT/US2016/016542, US Patent Application No. 62/112,487, US Patent Application No. 15/837,393, US Patent Application 16/179,061, US Patent Application No. 16/179,071, US Patent Application No. 16/179,099, US Patent Application 16/179,111, US Patent Application 16/179,117, US Patent Application No. 16/179,125, and US Patent Application No. 16/694,500. Paper 6, 2; Paper 7; Paper 22.

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. as joint inventors. Ex. 1001 code (72). 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 3:1–3.

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

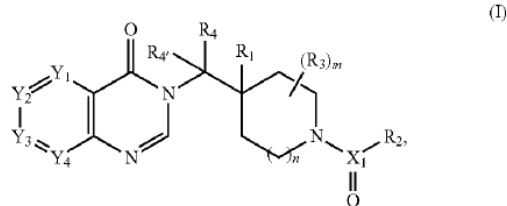


and pharmaceutically acceptable salts, hydrates, solvates, prodrugs, stereoisomers, and tautomers thereof.” *Id.* at 3:7–23.

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):



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 CR₅;

Y_3 is N or CR₆;

Y_4 is N or CR₇;

... R_2 is (C₁-C₆) alkyl, (C₆-C₁₄) aryl, 5- or 6- membered heteroaryl comprising 1 to 3 heteroatoms selected from O, N, and S, (C₅-C₈) cycloalkyl, 3- to 7-membered heterocycloalkyl comprising 1 to 3 heteroatoms selected from O, N, and S, or —NR₁₀R₁₁, wherein the alkyl, aryl, heteroaryl, cycloalkyl, and heterocycloalkyl are optionally substituted with one to three R₈;

... wherein R₅, R₆, and R₇ and not all simultaneously H;

... provided that when R₂ is optionally substituted alkyl, R₅ is H, and R₇ is H, then R₆ 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;

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.

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-((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

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

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