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Paper 32
Entered: January 20, 2022

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SLAYBACK PHARMA LLC,
Petitioner,

v.

SUMITOMO DAINIPPON PHARMA CO., LTD.,
Patent Owner.

IPR2020-01053
Patent 9,815,827 B2

Before SUSAN L. C. MITCHELL, ZHENYU YANG, and KRISTI L. R. SAWERT, *Administrative Patent Judges.*

YANG, *Administrative Patent Judge*.

JUDGMENT

Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)

Granting Patent Owner's Motion to Seal
37 C.F.R. § 42.55

Dismissing Petitioner's Motion to Seal
37 C.F.R. § 42.55

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I. INTRODUCTION

Slayback Pharma LLC ("Petitioner") filed a Petition (Paper 2 ("Pet.")), seeking an *inter partes* review of claims 1–75 of U.S. Patent No. 9,815,827 B2 (Ex. 1001, "the '827 patent"). We instituted trial to review the challenged claims. Paper 7 ("Dec." or "Decision to Institute"). Thereafter, Sumitomo Dainippon Pharma Co., Ltd. ("Patent Owner") filed a Response to the Petition (Paper 14, "PO Resp."), Petitioner filed a Reply (Paper 21), and Patent Owner filed a Sur-reply (Paper 25). An oral hearing for this proceeding was held on August 11, 2021, and the transcript of that hearing is of record. *See* Paper 28 ("Tr.").

The Board has jurisdiction under 35 U.S.C. § 6 and issues this final written decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons provided below, we conclude Petitioner has established by a preponderance of the evidence that claims 1–75 of the '827 patent are unpatentable.

A. Related Matters

According to the parties, the '827 patent is the subject of the following district-court litigations: 2:18-cv-02065 (NJD); 1:18-cv-00256 (DED); 2:18-cv-02620 (NJD); 1:18-cv-02107 (NYSD); 1:18-cv-01444 (NYED); 1:18-cv-00185 (NCMD); 1:18-cv-00369 (DED); 2:18-cv-13478 (NJD); 2:18-cv-13833 (NJD); 2:18-cv-14787 (NJD). Pet. 64; Paper 5, 2. Petitioner is not a party to any of those cases. Pet. 19. Patent Owner represents that "[n]one of the litigations is pending." Paper 5, 2.

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B. The '827 Patent and Related Background

The '827 patent is titled "[a]gent for treatment of schizophrenia." Ex. 1001, Code (54). It relates to "a method for improving schizophrenia without being accompanied by extrapyramidal symptoms by orally administering a prescribed dose of a specific bicycloheptane dicarboximide derivative once a day, and a therapeutic agent used in said method." *Id.* at 1:15–20.

There are 75 claims in the '827 patent. Petitioner divides them into two groups: (1) claims comprising treating manic depressive psychosis[1] ("manic depressive claims"), including claims 8–18, 25–28, 30, 31, 33–44, 46, 48–60, 62, 64, 66, 67, 69, 71, 73, and 75; and (2) claims limited to treating schizophrenia ("schizophrenia claims"), including claims 1–7, 19–24, 29, 32, 45, 47, 61, 63, 65, 68, 70, 72, and 74. Pet. 13. Patent Owner adopts these groupings. *See* PO Resp. 27 (discussing "manic depressive claims"). For consistency, we do the same.

Patent Owner explains that schizophrenia and manic depressive psychosis, both chronic and severe mental disorders, "can have symptoms in common." PO Resp. 3–4, 29. According to the '827 patent, schizophrenia is mainly treated with medication, and the treatment should be continued for a long time. Ex. 1001, 1:37–39. Thus, "any side effects of medication may always be serious problems, and based on this perspective, it has been

[1] The parties agree that "manic depressive psychosis" is now known as "bipolar disorder." Pet. 21; PO Resp. 3. We use the two terms interchangeably in this Decision.

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desired to develop a medicine being suitable for prolonged medication." *Id.* at 1:42–45.

The '827 patent explains that antipsychotics have been used to treat schizophrenia. *Id.* at 1:46–56. According to Patent Owner, "antipsychotics were known to treat schizophrenia and manic depressive psychosis by targeting the dopamine D_2 receptor." PO Resp. 29. The antipsychotics, however, have various drawbacks: the first generation, or "typical" antipsychotics are linked to severe side effects, such as extrapyramidal symptoms; whereas the second generation, or "atypical" antipsychotics are associated with substantial weight gain. PO Resp. 4–6. The '827 patent states "it has been desired to develop a safe medicament which exhibits an excellent effect on various schizophrenia as an antipsychotic without causing side effects." Ex. 1001, 2:1–4.

The '827 patent states that prior art teaches a genus of imide derivatives that "may be useful as an antipsychotic (c.f., neuroleptic agent, antia[n]xiety, etc.), especially as an agent for treatment of schizophrenia, senile insanity, manic depressive psychoses, and nervous breakdown." *Id.* at 2:5–39 (citing Ex. 1009[2]).

According to the '827 patent, its inventors found that a compound in this genus, (1R,2S,3R,4S)-N-[(1R,2R)-2-[4-(1,2-benzoisothiazol-3-yl)-1-piperazinylmethyl]-1-cyclohexylmethyl]-2,3-bicyclo[2.2.1]heptane-dicarboximide or a pharmaceutically acceptable salt thereof, "is effective for

[2] U.S. Patent No. 5,532,372, issued July 2, 1996 (Ex. 1009, "Saji"). Saji is one of the prior-art references asserted in this proceeding.

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relieving the wide-ranging symptoms of schizophrenia, and may treat schizophrenia quite safely without being accompanied by extrapyramidal symptoms by orally administering a prescribed dose thereof once a day." *Id.* at 2:50–3:6. The parties agree this compound is lurasidone.

The '827 patent contains results from a Phase II clinical trial where patients with schizophrenia were treated with SM-13496, i.e., lurasidone hydrochloride. Ex. 1001, 4:47–10:25.

C. Illustrative Claims

Claim 1 is illustrative of the schizophrenia claims, and is reproduced below:

> 1. A method for treating schizophrenia in a patient without a clinically significant weight gain, comprising:
>
> administering orally to the patient (1R,2S,3R,4S)-N-[(1R,2R)-2-[4-(1,2-benzoisothiazol-3-yl)-1-piperazinylmethyl]-1-cyclohexylmethyl]-2,3-bicyclo[2.2.1]heptanedicarboximide or a pharmaceutically acceptable salt thereof at a dose of from 20 to 120 mg/day such that the patient does not experience a clinically significant weight gain.

Ex. 1001, 10:51–59.

Claim 8 is illustrative of the manic depressive claims, and is reproduced below:

> 8. A method for treating manic depressive psychosis in a patient without a clinically significant weight gain, comprising:
>
> administering orally to the patient (1R,2S,3R,4S)-N-[(1R,2R)-2-[4-(1,2-benzoisothiazol-3-yl)-1-piperazinylmethyl]-1-cyclohexylmethyl]-2,3-bicyclo[2.2.1]heptanedicarboximide or a pharmaceutically acceptable salt thereof at a dose of from 20 to

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