Trials@uspto.gov
571-272-7822

Paper 7
Entered: December 9, 2020

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 RICHARD J. SMITH, *Administrative Patent Judges.*

YANG, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

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"). Sumitomo Dainippon Pharma Co., Ltd. ("Patent Owner") filed a Preliminary Response (Paper 6 ("Prelim. Resp.")).

We have authority under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). On April 24, 2018, the Supreme Court held that a decision under § 314 may not institute review on fewer than all claims challenged in the petition. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1355–56 (2018). In addition, the Federal Circuit has interpreted the statute to require "a simple yes-or-no institution choice respecting a petition, embracing all challenges included in the petition." *PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018).

For the reasons provided below, we determine Petitioner has satisfied the threshold requirement set forth in 35 U.S.C. § 314(a). Thus, based on the information presented, we institute an *inter partes* review of claims 1–75 of the '827 patent on all grounds.

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.

B. The '827 Patent

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.

According to the '827 patent, schizophrenia is mainly treated with medication, and the treatment should be continued for a long time. *Id.* at 1:37–39. Thus, "any side effects of medication may always be serious problems, and based on this perspective, it has been 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, but the conventional antipsychotics have various drawbacks. *Id.* at 1:46–67. As a result, "it has been desired to develop a safe medicament which exhibits an excellent effect on various schizophrenia as an antipsychotic without causing side effects such as extrapyramidal symptoms." *Id.* at 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, antiaxiety, 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[1]).

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 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 that this compound is lurasidone. Pet. 15; Prelim. Resp. 1.

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. Prosecution History

The '827 patent issued from Application No. 14/471,919 ("the '919 application"), filed on August 28, 2014. Ex. 1001, codes (21), (22). The '919 application is a continuation of application No. 10/525,021 ("the '021 application"), filed on August 20, 2003, now U.S. Patent No. 9,174,975 B2. *Id.*, code (63). The '827 patent also claims priority to provisional application No. 60/404,927, filed on August 22, 2002. *Id.*, code (60). The parties agree

[1] 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.

that the specifications of all three applications "are identical in all relevant respects." *See* Prelim. Resp. 8–9.

On August 28, 2014, the filing date of the '919 application, the applicant filed an amendment, canceling the originally filed claims 1–19 and adding claims 20–27. Ex. 1020, 3–4.[2] Both the canceled claims and the newly added claims were limited to a method of treating schizophrenia. *Id.* The newly added claim 20, the sole independent claim, reads as follows:

> 20. A method for treating schizophrenia in a patient, without causing a clinically significant weight gain in the patient, the method comprising administering to the patient a dose of 5 mg to 120 mg of the active compound: (1R,2S,3R,4S)—[*sic*]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.

Id. at 3.

On October 5, 2015, the applicant amended pending claim 20 to recite a "method for treating schizophrenia or manic depressive psychoses." Ex. 1006, 2. The applicant also added dependent claim 28, reciting "wherein the method is for treating manic depressive psychoses." *Id.* at 3. For written-description support, the applicant relied on the following language in the '919 application:

> On the other hand, it has been known that the imide derivative of the following formula, which was found by the co-workers of the present inventors, may be useful as an antipsychotic (c.f., neuroleptic agent, antiaxiety, etc.), especially as an agent for

[2] Unless otherwise noted, we use the pagination provided by the parties for the exhibits.

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