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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC., APOTEX CORP., APOTEX PHARMACEUTICALS HOLDINGS INC., AND APOTEX HOLDINGS, INC.,
Petitioner,

v.

OSI PHARMACEUTICALS LLC,
Patent Owner.

Case IPR2016-01284
Patent 6,900,221 B1

Before LORA M. GREEN, RAMA G. ELLURU, and ZHENYU YANG, *Administrative Patent Judges*.

GREEN, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
Determining That Claims 44–46 and 53 Are Shown to Be Unpatentable
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. INTRODUCTION

Apotex Inc., Apotex Corp., Apotex Pharmaceuticals Holdings Inc., and Apotex Holdings, Inc., ("Apotex" or "Petitioner") filed a Petition requesting an *inter partes* review of claims 44–47 and 53 of U.S. Patent No. 6,900,221 B1 (Ex. 1001, "the '221 patent"). Paper 3 ("Pet."). OSI Pharmaceuticals LLC[1] ("OSI" or "Patent Owner") filed a Preliminary Response to the Petition.[2] Paper 7 ("Prelim. Resp."). We determined that the information presented in the Petition and the Preliminary Response demonstrated that there was a reasonable likelihood that Petitioner would prevail in challenging claims 44–47 and 53 as unpatentable under 35 U.S.C. § 103(a). Pursuant to 35 U.S.C. § 314, we instituted trial on January 9, 2017, as to all of the challenged claims of the '221 patent. Paper 8 ("Institution Decision" or "Dec. Inst.").

On February 8, 2017, the parties filed a Joint Motion to Limit Petition Under 37 C.F.R. § 42.71, seeking to remove claim 47 from trial. Paper 12. We *granted* that Motion. Paper 19. Thus, trial is limited to claims 44–46 and 53.

Patent Owner filed a Response (Paper 20, "PO Resp.") and Petitioner filed a Reply (Paper 33, "Reply"). Patent Owner also filed a Motion to Exclude Evidence (Paper 37, "Mot. Exclude"), to which Petitioner filed an Opposition (Paper 40, "Opp. Mot. Exclude"), and Patent Owner filed a

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[1] Patent Owner underwent a name change from OSI Pharmaceuticals Inc. to OSI Pharmaceuticals LLC, which change was recorded at the United States Patent and Trademark Office. Reply 1 n.2.

[2] OSI further identifies Astellas US LLC, Astellas US Holding, Inc., Astellas Pharma Inc., and Genentech, Inc., as real parties-in-interest. Paper 5, 1.

Reply (Paper 43). Oral hearing was held on October 3, 2017, and a transcript of that hearing has been entered into the record. Paper 48 ("Tr.").

We have jurisdiction under 35 U.S.C. § 6. Petitioner bears the burden of proving unpatentability of the challenged claims, and the burden of persuasion never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). To prevail, Petitioner must establish facts supporting its challenge by a preponderance of the evidence. *See* 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d). This Final Written Decision is issued 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 44–46 and 53 of the '221 patent are unpatentable. We also *deny* Patent Owner's Motion to Exclude in part, and *dismiss* it in part.

A. Related Proceedings

According to Patent Owner, the '221 Patent is presently at issue "in *OSI Pharms. LLC. et al. v. Apotex Inc. et al.*, Case No. 1:15-cv-00772-SLR (D. Del. Sept. 2, 2015) and *OSI Pharms. LLC. et al. v. Breckenridge Pharms. Inc. et al.*, Case No. 1:15-cv-01063-SLR (D. Del. Nov. 17, 2015), which are consolidated in lead Case No. 1:15-00772-SLR." Paper 5, 3–4. Patent Owner further identifies a number of closed matters involving the '221 patent, including *OSI Pharms, Inc. v. Mylan Pharms Inc.*, Case No. 1:09-cv-00185-SLR (D. Del. Mar. 19, 2009). *Id.*

B. The '221 Patent (Ex. 1001)

The '221 patent is generally directed to the B polymorph of N-(3-ethynylphenyl)-6, 7-bis(2-methoxyethoxy)-4-quinazolinamine hydrochloride. Ex. 1001, Abstract. The '221 patent further discloses that

"N-(3-ethynylphenyl)-6, 7-bis(2-methoxyethoxy)-4-quinazolinamine, in either its hydrochloride or mesylate forms, or in an anhydrous and hydrous form, is useful in the treatment of hyperproliferative disorders, such as cancers, in mammals." *Id.* at 1:21–25. The '221 patent references U.S. Patent No. 5,747,498 (Ex. 1009, "Schnur"), and incorporates it by reference in its entirety. *Id.* at 1:27–29. In addition, the '221 patent notes that Example 20 of Schnur refers

> to [6,7-bis(2-methoxyethoxy)-quinazolin-4-yl]-(3-ethynylphenyl)amine hydrochloride [i.e., the hydrochloride salt of erlotinib], which, the patent discloses, is an inhibitor of the erbB family of oncogenic and protooncogenic protein tyrosine kinases, such as epidermal growth factor receptor (EGFR), and is therefore useful for the treatment of proliferative disorders, such as cancers, in humans.

Id. at 1:28–35.

According to the '221 patent, the method of treating cancer using the disclosed compound

> may be for the treatment of a cancer selected from brain, squamous cell, bladder, gastric, pancreatic, breast, head, neck, oesophageal, prostate, colorectal, lung, renal, kidney, ovarian, gynecological and thyroid cancer.
>
> The method may also be for the treatment of a cancer selected from non-small cell lung cancer (NSCLC), refractory ovarian cancer, head and neck cancer, colorectal cancer and renal cancer.

Id. at 4:23–30.

C. Illustrative Claim

As discussed above, the claims challenged in this proceeding are 44–46 and 53 of the '221 patent. Claim 44, representative of the challenged subject matter, is the only independent challenged claim and is reproduced below:

> 44. A method for the treatment of NSCLC (non small cell lung cancer), pediatric malignancies, cervical and other tumors caused or promoted by human papilloma virus (HFV), Barrett's esophagus (pre-malignant syndrome), or neoplastic cutaneous diseases in a mammal comprising administering to said mammal a therapeutically effective amount of a pharmaceutical composition comprised of at least one of N-(3-ethynylphenyl)-6,7-bis(2-methoxyethoxy)-4-quinazolinamine, or pharmaceutically acceptable salts thereof in anhydrous or hydrate forms, and a carrier.

Ex. 1001, 35:26–36. Challenged claim 53 limits the cancer to be treated to non-small cell lung cancer. *Id.* at 35:64–65.

D. Instituted Challenge

We instituted trial on the challenged claims based on the following ground of unpatentability (Dec. Inst. 29):

References	Basis	Claims Challenged
Schnur[3] and OSI's 10K[4] or Gibbs[5]	§ 103	44–46 and 53

Petitioner relies also on the Declaration of Giuseppe Giaccone, M.D., Ph.D. (Ex. 1002), the Declaration of Laurence S. Lese, Esq. (Ex. 1012), as well as the Reply Declaration of Dr. Giaccone (Ex. 1053) and Kristopher A. Boushie (Ex. 1054).

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[3] Schnur et al., U.S. Patent No. 5,747,498, issued May 5, 1998 (Ex. 1009) ("Schnur").

[4] Annual Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the Fiscal Year Ended September 30, 1998, Commission File Number 0-15190, OSI Pharmaceuticals, Inc. (Ex. 1011) ("OSI's 10K").

[5] J.B. Gibbs, "*Anticancer Drug Targets: Growth Factors and Growth Factor Signaling*," 105 J. CLIN. INV. 9–13 (2000) (Ex. 1010) ("Gibbs").

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