UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

Kowa Company, Ltd., et al.,

Plaintiffs,

v.

Amneal Pharmaceuticals, LLC

Defendant.

Civil Action No. 14-CV-2758 (PAC)

Kowa Company, Ltd., et al.,

Plaintiffs,

v.

Apotex, Inc., et al.,

Defendants.

Civil Action No. 14-CV-7934 (PAC)

FINDINGS OF FACT AND CONCLUSIONS OF LAW

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TABLE OF ABBREVIATIONS

'993 Patent	U.S. Patent No. 8,557,993
ANDA	Abbreviated New Drug Application
API	Active pharmaceutical ingredient
DMF	Drug master file
EPO	European Patent Office
EP '406	European Patent Application No. EP 0 520 406A1
FDA	U.S. Food and Drug Administration
IDS	Information Disclosure Statement
KCL	Kowa Company, Ltd.
KPA	Kowa Pharmaceuticals America, Inc.
MSN	MSN Laboratories Pvt. Ltd.
NCI	Nissan Chemical Industries, Ltd.
PTO	U.S. Patent and Trademark Office
TPO	Third Party Observation
USP	U.S. Pharmacopeia
XRPD or PXRD	X-ray powder diffraction

HONORABLE PAUL A. CROTTY, United States District Judge:

This is a Hatch-Waxman patent infringement litigation initiated by Plaintiffs Kowa Company, Ltd., Kowa Pharmaceuticals America, Inc., and Nissan Chemical Industries, Ltd. (collectively, "Plaintiffs"), manufacturers of the cholesterol-lowering drug Livalo®, against defendants Amneal Pharmaceuticals, LLC ("Amneal"), and Apotex, Inc. and Apotex Corp. ("Apotex"), generic drug manufacturers (together, "Defendants").[1] Plaintiffs allege that Defendants' proposed Abbreviated New Drug Application ("ANDA") products would infringe U.S. Patent No. 8,557,993 (the "'993 patent"). Both Amneal and Apotex contend that the '993 patent is invalid as (1) anticipated based on prior art, under 35 U.S.C. § 102(b); and/or (2) obvious in view of prior art, under 35 U.S.C. § 103. Only Apotex asserts non-infringement; Amneal concedes infringement.

The Court held a ten-day bench trial from January 17 through January 30, 2017, with closing arguments on February 3, 2017. Each of the parties submitted extensive post-trial briefing on the '993 patent's validity and infringement. After considering the documentary evidence and testimony, the Court makes the following findings of fact and conclusions of law pursuant to Fed. R. Civ. P. 52(a). As set forth below, the Court determines that the '993 patent is valid; and that Apotex's proposed ANDA product would infringe the '993 patent.

[1] Plaintiffs commenced this litigation against eight generic drug manufacturer defendants. Defendants asserted defenses of invalidity and non-infringement. Four defendants settled before commencement of the ten-day bench trial. The fifth defendant settled mid-trial; and the sixth settled post-trial. Only Amneal and Apotex remain. On April 11, 2017, the Court issued its Findings of Fact and Conclusions of Law regarding the other patent at issue at trial, U.S. Patent No. 5,856,336, finding it valid. (*Kowa Co., Ltd. v. Amneal Pharm., LLC.*, No. 14-CV-2758 (PAC) (S.D.N.Y. Apr. 11, 2017)).

INTRODUCTION AND LEGAL STANDARDS

I. The Hatch-Waxman Act and ANDA Filings[2]

1. The Hatch-Waxman Act, titled the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, permits pharmaceutical companies to seek United States Food and Drug Administration (FDA) approval for a generic drug based on an already-approved branded drug by filing an ANDA. (*See* 21 U.S.C. § 355(j)(2)(A), (8)(B)). In so doing, the generic manufacturer may rely on the branded drug's safety and efficacy data submitted to the FDA. (*See id.*).

2. If the branded drug manufacturer's patent has not yet expired, the generic manufacturer must file a "Paragraph IV" certification, establishing bioequivalence of the proposed generic version with the approved branded version of the drug. (*See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV); 21 C.F.R. § 314.94(a)(9)). The certification must also state and explain either that the generic product will not infringe the branded manufacturer's patent, or that the patent is invalid. (*See* 21 U.S.C. § 355(j)(2)(B)(iv)(II)).

3. "An ANDA-IV certification itself constitutes an act of infringement, triggering the branded manufacturer's right to sue." (*Ark. Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98, 101 (2d Cir. 2010), *cert. denied*, 131 S. Ct. 1606 (2011) (citing 35 U.S.C. § 271(e)(2)(A)). If litigation is initiated, the generic's entry to market is automatically stayed. (21 U.S.C. § 355(j)(5)(B)(iii)). "[T]his structure allows the parties to try the dueling issues of patent infringement and patent invalidity simultaneously." (*In re: OxyContin Antitrust Litig.*, No. 13-CV-3372 (SHS), 2015 WL 11217239, at *5 (S.D.N.Y. Apr. 8, 2015)).

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[2] For additional background on the policy goals of the Hatch-Waxman Act, see this Court's April 11, 2017 Findings of Fact and Conclusions of Law regarding the other patent at issue at trial, U.S. Patent No. 5,856,336. (*Kowa Co., Ltd. v. Amneal Pharm., LLC*, No. 14-CV-2758 (PAC) (S.D.N.Y. Apr. 11, 2017) at 9–10).

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