v.

MYLAN PHARMACEUTICALS INC., et al.,

Defendants.

OPINION

Appearances

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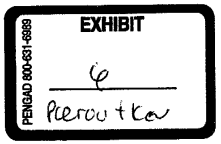

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BUMB, United States District Judge:

INTRODUCTION

This is an action for patent infringement brought by Plaintiff Endo Pharmaceuticals Inc. ("Endo" or "Plaintiff") against Defendants Mylan Pharmaceuticals Inc. and Mylan, Inc. (collectively, "Mylan" or "Defendants") pursuant to 35 U.S.C. § 271(e)(2)(A), and §§ 271(a), (b), and (c). Specifically, Endo alleges that Mylan has infringed and/or will infringe U.S. Patent Nos. 5,464,864 (filed Nov. 7, 1995) (the "'864 Patent"), 5,637,611 (filed June 10, 1997) (the "'611 Patent"), and 5,827,871 (filed Oct. 27, 1998) (the "'871 Patent") (collectively, the "King Patents") in connection with Mylan's submission of Abbreviated New Drug Application ("ANDA") number 202931 seeking the approval of the U.S. Food & Drug Administration ("FDA") to market its generic ANDA Product prior to the expiration of the King Patents.

Patents (the "Claim Construction Opinion"). (Dkt. Ent. 167.) Although Mylan disputes the claim construction adopted by the Court, it conceded prior to trial that, under the Court's claim construction, Mylan infringes or will infringe the asserted claims of the King Patents. (Notice of Concession of Infringement, Dkt. Ent. 182.) However, Mylan maintained that the King Patents are invalid under the doctrines of anticipation, obviousness, written description, and enablement. The Court held a bench trial from November 12 through November 21, 2013, after which it permitted the parties to submit proposed findings of fact and conclusions of law.[1]

After consideration of the evidence and the parties' post-trial submissions, and for the reasons set forth below, the Court finds that (1) Endo has waived and is now judicially estopped here from pursuing claims against Mylan related to the

[1] Mylan subsequently filed a letter requesting that the Court strike certain portions of Endo's opening brief and proposed findings of fact, which included inter alia certain irrelevant or confidential information. (See Dkt. Ent. 201.) Mylan's request is moot in light of the decision set forth herein and for the further reason that Endo's materials were filed under seal.

pursuant to Federal Rule of Civil Procedure 52(a).[2]

I. BACKGROUND

A. The Drug Approval Process

Under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., the FDA must approve all new drugs before they may be distributed in interstate commerce. 21 U.S.C. § 355(a). To secure approval for a new drug, an applicant may file a New Drug Application ("NDA") that includes, inter alia, the number and expiration date of any patents which claim the drug or a method of using the drug if a claim of patent infringement could reasonably be asserted. Id. § 355(b)(2). "The FDA publishes the names of approved drugs and their associated patent information in the Approved Drug Products with Therapeutic Equivalence Evaluations list, commonly referred to as the 'Orange Book.'" AstraZeneca LP v. Apotex, Inc., 633 F.3d 1042, 1045 (Fed. Cir. 2010). An applicant seeking approval to market a generic version

[2] Endo's oral motion made during trial, for judgment on partial findings pursuant to Rule 52(c), is DISMISSED as moot. Rule 52(c) permits such motions after "a party has been fully heard on an issue during a nonjury trial." As permitted under the rule, the Court exercised its discretion to reserve on the motion when it was made during trial. (Tr. 1176:11-12.)

(citing 21 U.S.C. § 355(b)(2), (j)).

"[F]or each patent listed in the Orange Book that claims either the listed drug or a use of the listed drug for which the applicant is requesting approval, an ANDA must include either one of four certifications or a 'section viii statement.'" AstraZeneca LP, 633 F.3d at 1046. If an applicant submits a certification, the applicant must certify "(I) that . . . patent information has not been filed, (II) that such patent has expired, (III) . . . the date on which such patent will expire, or (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug." 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV). The last of these is known as a "paragraph IV certification". If an ANDA applicant submits a paragraph IV certification and a patent infringement suit is commenced within 45 days, then the FDA may not approve the ANDA application until expiration of a 30-month statutory period. Id. § 355(c)(3)(C).

B. Frova

On November 8, 2001, the FDA approved NDA No. 21-006 for Frova (frovatriptan succinate) oral tablets. (Stipulated Facts

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