UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

BOEHRINGER INGELHEIM PHARMACEUTICALS INC., BOEHRINGER INGELHEIM INTERNATIONAL GMBH, BOEHRINGER INGELHEIM CORPORATION, and BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG,

Plaintiffs,

v.

HEC PHARM CO., LTD., HEC PHARM USA, MYLAN PHARMACEUTICALS INC., MYLAN INC., MYLAN LABORATORIES LIMITED, ACCORD HEALTHCARE, INC., AUROBINDO PHARMA LIMITED, AUROBINDO PHARMA USA, INC., DR. REDDY'S LABORATORIES, LTD., DR. REDDY'S LABORATORIES, INC., ZYDUS PHARMACEUTICALS USA, INC., CADILA HEALTHCARE LTD., MSN LABORATORIES PRIVATE LIMITED, MSN PHARMACEUTICALS, INC., PRINSTON PHARMACEUTICAL INC., INVAGEN PHARMACEUTICALS INC., SUN PHARMACEUTICAL INDUSTRIES LTD., SUN PHARMA GLOBAL FZE, and TEVA PHARMACEUTICALS USA, INC.,

Defendants.

Civil Action No:
15-cv-5982 (PGS)(TJB)

MEMORANDUM

SHERIDAN, U.S.D.J.

This is a consolidated a patent infringement action brought by Boehringer Ingelheim Pharmaceuticals Inc., Boehringer Ingelheim International GmbH, Boehringer Ingelheim Corporation, and Boehringer Ingelheim Pharma GmbH & Co. KG (collectively, "Boehringer" or "Plaintiffs") against Mylan Pharmaceuticals Inc., Mylan Inc., and Mylan Laboratories Limited

("Mylan") and Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. ("Aurobindo) (all defendants collectively, "Defendants")[1] for filing an Abbreviated New Drug Application ("ANDA") with the Food & Drug Administration ("FDA"), pursuant to 21 U.S.C. § 355(b)(2) (Hatch-Waxman Act), for approval to engage in the commercial manufacture, use or sale of a generic version of Tradjenta® and Jentadueto®. *See* 35 U.S.C. § 271 (Patent Act).

Tradjenta® (linagliptin) and Jentadueto® (linagliptin + metformin) are used to manage type 2 diabetes. Boehringer listed several patents for both Tradjenta® and Jentadueto® in the Orange Book. These included U.S. Patent Nos. 8,178,541 ("'541 patent"), 8,673,927 ("'927 patent) and 9,173,859 ("'859 patent"). These patents "generally describe methods to treat diabetes that involve the use of a compound known as linagliptin, alone or in combination with various other antidiabetic treatments [such as metformin]." (Tr. 480:20-24 (Accili)). While Aurobindo applied for an ANDA only with regards to Tradjenta®, Mylan applied for approval for both Tradjenta® and Jentadueto®. Defendants seek to start production of the generic products following expiration of Boehringer's U.S. Patent No. 7,407,955 ('955), U.S. Patent 8,119,648 ('648), and the '541 patent. Before the Court are claims 7, 9, 15, 17, 19, 25, and 26 of the '927 patent, and claims 1, 14, 15, 20, and 21 of the '859 patent, (all collectively, the "Asserted Claims" of the patents-in-suit). Claims 14 and 15 of the '859 patent are collectively referred to herein as the "tablet claims," as they deal with the formation of the drug; and the remaining Asserted Claims are referred to as the "method claims," as they deal with the administration of the drug.

Boehringer initiated this suit against Defendants alleging that Defendants' requests to market the generic version of Tradjenta® and Jentadueto® infringed upon Boehringer's rights granted under the '927 and '859 patents, because the proposed labels will induce physicians to

[1] Mylan and Aurobindo are the only remaining Defendants in this action.

administer linagliptin in combination with metformin in a specific dosage ("Combination Therapy[2]").

In response, Defendants argue that the asserted claims 7, 9, 15, 17, 19, 25, and 26 in the '927 patent and the asserted claims 1, 14, 15, 20, and 21 in the '859 patent are prima facie invalid for obviousness-type double patenting, because these claims are a recitation of the claims found in the '541 patent. Defendants further argue that the asserted claims are prima facie invalid as obvious, as the asserted claims had been previously disclosed by prior art. At trial, Defendants, bearing the burden to invalidate the asserted claims of the '927a nd '859 patents, presented expert evidence to show that the asserted claims are invalid as noted above. The experts were Joshua Cohen, M.D., Domenico Accili, M.D., George M. Grass, Ph.D., David Blackburn, Ph.D., and Christian Wolf, Ph.D.

In response, Boehringer defended the patents by arguing the '541 claims are patentably distinct. Further, Boehringer argues that the asserted claims are not invalid for obviousness as Defendants have failed to show that a person of ordinary skill in the art ("POSA") would have been directed to prior art, that a POSA would have been motivated to select specific dosages of linagliptin, and that a POSA would have been motivated to combine linagliptin and metformin. Additionally, Boehringer argues that secondary considerations support a non-obvious finding. In order to advance these positions, Boehringer relied on the following witnesses and experts: Michael G. Mark, Ph.D., M. James Lenhard, M.D., Y.W. Francis Lam, Ph.D., William L. Jorgensen, Ph.D., and Steven Schwartz, Ph.D.

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[2] Dr. Accili, Defendant's expert, explained that "combination therapy is when you mix more than one drug for the purpose of treating diabetes." (Tr. 496:14-19) (Accili)).

At the end of the trial, the parties submitted proposed findings of fact and conclusions of law, followed by reply papers.

I

A. The Parties

Plaintiff Boehringer is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business in Ridgefield, Connecticut. (Stip. of Facts, ECF No. 539-1 at ¶ 1). Plaintiff Boehringer Ingelheim International GmbH ("BII") is a private limited liability company organized and existing under the laws of Germany, having a principal place of business in Ingelheim, Germany. (*Id.*) Plaintiff Boehringer Ingelheim Pharma GmbH & Co. KG ("BIPKG") is a limited liability partnership organized and existing under the laws of Germany, having a principal place of business in Ingelheim, Germany. (*Id.*) Plaintiff Boehringer Ingelheim Corporation ("BIC") is a corporation organized and existing under the laws of Nevada, having a principal place of business in Ridgefield, Connecticut. (*Id.*) BIPI, BII, BIPKG and BIC are collectively referred to as "Plaintiffs" or "Boehringer."

Defendant Mylan Pharmaceuticals Inc. ("Mylan Pharms") is a corporation organized and existing under the laws of the State of West Virginia, having a principal place of business in Morgantown, West Virginia. (*Id.*) Defendant Mylan Inc. is a corporation organized and existing under the laws of the State of Pennsylvania, having a principal place of business in Canonsburg, Pennsylvania. (*Id.*) Defendant Mylan Laboratories Limited ("Mylan Labs") is a corporation organized and existing under the laws of India and has a principal place of business in Hyderabad, India. (*Id.*) Mylan Pharms, Mylan Inc., and Mylan Labs are collectively referred to hereinafter as "Mylan."

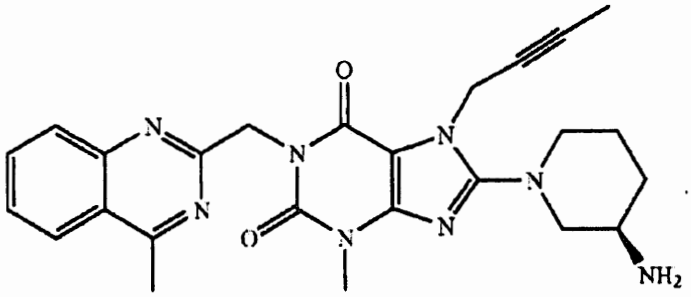
Defendant Aurobindo Pharma Limited ("Aurobindo Ltd.") is a corporation organized and

existing under the laws of India, with a registered place of business in Andhra Pradesh, India. (*Id.*) Defendant Aurobindo Pharma USA, Inc. ("Aurobindo USA") is a corporation organized and existing under the laws of the State of Delaware and has a principal place of business in Dayton, New Jersey. (*Id.*) Aurobindo Ltd. and Aurobindo USA are collectively referred to as "Aurobindo."

B. The Drugs

1. Tradjenta ®

Boehringer holds an approved New Drug Application (No. 201280) ("NDA") for linagliptin, for oral use in 5mg dosages, which is marketed and sold under the trade name Tradjenta®. (Stip. Facts, ECF No. 539-1, at ¶ 35.) Tradjenta® was first approved by the FDA in 2011, and contains 5mg of linagliptin as its active ingredient. (*Id.* at ¶¶ 36-37). Linagliptin is a Dipeptidyl peptidase-4 (DPP-IV) inhibitor, and is used to treat type 2 diabetes mellitus (hereinafter "type 2 diabetes"). (*Id.* at ¶ 46). Linagliptin has the following chemical structure:



Among others, Boehringer listed U.S. Patent Nos. '541, '927, and '859 in the FDA's Orange Book for Tradjenta ®. (*Id.* at ¶ 57).

2. Jentadueto ®

Boehringer holds an approved NDA (No. 201281) for linagliptin and metformin hydrochloride tablets, for oral use in 2.5mg/500 mg, 2.5mg/850 mg, and 2.5/1000 mg dosages, which is marketed and sold under the trade name Jentadueto ®. (*Id.* at ¶ 47). Jentadueto® was

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