

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS, LLC and
PAR PHARMACEUTICAL, INC
Petitioners

v.

JAZZ PHARMACEUTICALS, INC.
Patent Owner

Case IPR2015-00554
Patent 7,668,730

DECLARATION OF BARRY GILMAN

Mail Stop "PATENT BOARD"
Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

IPR2015-00554 (Patent 7,668,730)
Declaration of Barry Gilman (Exhibit 1040)

I, Barry Gilman, declare as follows:

1. I am the Deputy General Counsel for Par Pharmaceutical, Inc. (“Par Inc.”). I am also the Secretary for Par Inc.

2. Par Inc. is a wholly-owned subsidiary of Par Pharmaceutical Companies, Inc. (“Par Co.”). Par Co. is the sole wholly-owned subsidiary of Sky Growth Intermediate Holdings II, Inc. (“SGIH II”), which is the sole wholly-owned subsidiary of Sky Growth Intermediate Holdings I, Inc. (“SGIH I”). SGIH I is the sole wholly-owned subsidiary of Par Pharmaceutical Holdings, Inc. (“Par Holdings”). For ease of reference, I will refer to Par Co., SGIH I, SGIH II, and Par Holdings collectively as the “Par Parents.”

3. Par Inc. is a corporation engaged in the business of, *inter alia*, manufacturing, distributing, and selling drugs, including generic drugs. As part of its business, Par Inc. prepares and files Abbreviated New Drug Applications (“ANDAs”) directed to generic drug products. As Par Inc. is engaged in this business, Par Inc. holds various Federal and state licenses to engage in the business of manufacturing, distributing, and selling drugs, including licenses with the United States Drug Enforcement Agency, the New York State Board of Pharmacy, and the United States Food and Drug Administration.

4. The Par Parents, by contrast, do not engage in any operations. The Par Parents do not manufacture, distribute, or sell generic pharmaceuticals. None

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of the Par Parents hold any licenses with the United States Drug Enforcement Agency, any state Pharmacy Board, or the United States Food and Drug Administration.

5. Par Inc. solely prepared and filed ANDA No. 205403, which is directed to a 500 mg/mL sodium oxybate solution that is a generic version of Jazz Pharmaceuticals, Inc.'s ("Jazz") XYREM drug product ("the ANDA Product"). Par Inc. is the owner of all right and title to ANDA No. 205403. Par Inc. paid all fees associated with filing ANDA No. 205403. The individuals who prepared and filed ANDA No. 205403 are employed on behalf of Par Inc. Michelle Bonomi-Huvala, an employee of Par Inc., signed the notice letter to Jazz stating that Par Inc. had filed an ANDA that included a Paragraph IV certification to Jazz's patents.

6. Jazz has sued Par Inc.—but none of the Par Parents—for infringement of U.S. Patent Nos. 7,668,730; 7,765,106; 7,765,107; 7,895,059; 8,457,988; and 8,589,182 ("the Petition Patents") as a result of Par Inc. filing ANDA No. 205403. Par Inc. is the sole party directing, controlling, and funding that litigation.

7. Par Inc. was also the sole Par entity responsible for directing, controlling, and funding the preparation and filing of the petitions for *inter partes* review of the Petition Patents (the "instant Petitions"). Par Inc. was the only Par entity that paid any filing or legal fees associated with the preparation of the instant

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Petitions. None of the Par Parents participated in the decision to file the instant Petitions, nor did they co-author the instant Petitions, nor exercise any control over the filing or content of the instant Petitions, nor provide funding or other compensation for the preparation and filing of the instant Petitions. At no point was the filing, content, or funding of the instant Petitions discussed at any meeting of the Board for any of the Par Parents. The individuals primarily responsible for the decision to file and the content of the instant Petitions, David Silverstein and Lawrence Brown, are employed on behalf of Par Inc. David Silverstein and Lawrence Brown are not employed by any of the Par Parents.

8. None of the Par Parents have any reason for or interest in seeking review of the Petition Patents. As stated above, each of the Par Parents is a holding company that merely holds ownership of its subsidiaries, and conducts no independent operations. Not one of the Par Parents has ever been accused of infringing the Petition Patents, nor have any of the Par Parents moved to intervene in the ongoing litigation, or sought a declaratory judgment of invalidity of any of the Petition Patents in Federal district court.

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9. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Respectfully Submitted,



Barry Gilman

Deputy General Counsel,
Par Pharmaceutical, Inc.

Secretary,
Par Pharmaceutical, Inc.

Date: May 26, 2015