

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PAR PHARMACEUTICAL, INC., WOCKHARDT BIO AG, and
AMNEAL PHARMACEUTICALS LLC,
Petitioners,

v.

JAZZ PHARMACEUTICALS, INC.,
Patent Owner.

Case IPR2015-00554¹
Patent 7,668,730 B2

**PETITIONERS PAR PHARMACEUTICAL, INC.’S
AND AMNEAL PHARMACEUTICALS LLC’S RESPONSE
TO PATENT OWNER’S NOTICE REGARDING NEW
ARGUMENTS AND EVIDENCE IN PETITIONERS’ REPLY**

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

¹ Case IPR2015-01818 has been joined with this proceeding.

Petitioners' Response to Patent Owner's March 10, 2016 Notice

Pursuant to the Board's March 3, 2016 e-mail, Petitioners Par Pharmaceutical, Inc. and Amneal Pharmaceuticals LLC identify the following portions of Patent Owner's Response (Paper No. 39) to which the arguments and evidence that Patent Owner Jazz Pharmaceuticals, Inc. identified in its March 10, 2016 Notice (Paper No. 50) respond:

1. The arguments and evidence Jazz identified in Paragraph 1 of its Notice respond to the arguments in Patent Owner's Response starting on page 9, after subheading (c), through page 12, line 2; including Jazz's argument that: "the redactions in Ex. 1004 do not evidence public accessibility before the critical date" (page 10); and "Petitioners ignore that the Briefing Booklet is addressed to a limited Advisory Committee panel that was responsible for reviewing the Xyrem drug application for FDA approval." (page 11).

2. The arguments and evidence Jazz identified in Paragraph 2 of its notice respond to arguments in Patent Owner's response starting on page 11, line 1, through page 12, line 2; including Jazz's argument that: "Petitioners ignore that the Briefing Booklet is addressed to a limited Advisory Committee panel that was responsible for reviewing the Xyrem drug application for FDA approval." (page 11). Further, the evidence to which Jazz refers was provided with the Petition. *See* Paper No. 2.

IPR2015-00554
Patent No. 7,668,730
Petitioners' Response to Patent Owner's March 10, 2016 Notice

3. The arguments and evidence Jazz identified in Paragraph 3 of its notice respond to arguments in Patent Owner's response starting on page 5, line 7 (under subheading (a)) through line 17; including Jazz's argument that: "[t]he dates on the documents do not establish public accessibility before the critical date" (page 5). Further, the evidence Jazz refers to was provided with the Petition. *See* Paper No. 1 at 15; *see also* Paper No. 2.

Date: March 17, 2016

Respectfully Submitted,



Janine A. Carlan
Registration No. 42,387
ARENT FOX LLP
1717 K Street, NW
Washington, DC 20006
202.857.6000
Attorney for Petitioners Par Pharmaceutical,
Inc. and Amneal Pharmaceuticals LLC

CERTIFICATION OF SERVICE (37 C.F.R. §§ 42.6(e), 42.105(a))

The undersigned hereby certifies that the above-captioned “Petitioners Par Pharmaceutical, Inc.’s and Amneal Pharmaceuticals LLC’s Response to Patent Owner’s Notice Regarding New Arguments and Evidence in Petitioners’ Reply,” was served in its entirety on March 17, 2016, upon the following parties via e-mail:

F. Dominic Cerrito
nickcerrito@quinnemanuel.com
Eric C. Stops
ericstops@quinnemanuel.com
Evangeline Shih
evangelineshah@quinnemanuel.com
Frank Calvosa
frankcalvosa@quinnemanuel.com

QUINN EMANUEL URQUHART &
SULLIVAN LLP
51 Madison Avenue
22nd Floor
New York, NY 10010

Counsel for Patent Owner Jazz Pharmaceuticals, Inc.

Patrick C. Gallagher
PCGallagher@duanemorris.com
DUANE MORRIS LLP
190 South LaSalle Street, Suite 3700
Chicago, IL 60603-3433

Counsel for Petitioner Wockhardt Bio AG

John V. Biernacki
jvbiernacki@jonesday.com
JONES DAY
North Point
901 Lakeside Avenue
Cleveland, OH 44114

Jordana Garallek
JGarallek@duanemorris.com
DUANE MORRIS LLP
1540 Broadway
New York, NY 10036-4086

IPR2015-00554
Patent No. 7,668,730
Certificate of Service

Respectfully Submitted,



Bradford C. Frese
Registration No. 69,772
Attorney for Petitioner Par Pharmaceutical,
Inc.

Date: March 17, 2016
ARENT FOX LLP
1717 K Street, NW
Washington, DC 20006
202.857.6000