

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PAR PHARMACEUTICAL, INC. and AMNEAL PHARMACEUTICAL, LLC,
Petitioners,

v.

JAZZ PHARMACEUTICAL, INC.,
Patent Owner.

Case IPR2015-00548
Patent 7,895,059 B2

PATENT OWNER NOTICE OF APPEAL

NOTICE OF APPEAL

Notice is hereby given, pursuant to 35 U.S.C. § 141 and 37 C.F.R. § 90.2, that Patent Owner Jazz Pharmaceuticals, Inc. (“Jazz”) hereby appeals to the United States Court of Appeals for the Federal Circuit from the Patent Trial and Appeal Board’s (the “Board”) Final Written Decision entered on July 27, 2016 (Paper 69), the Decision Denying Patent Owner’s Request for Rehearing entered on December 22, 2016 (Paper 73), and from all orders, decisions, rulings, and opinions underlying those decisions regarding Jazz’s U.S. Patent No. 7,895,059 (the “’059 patent”) set forth in *inter partes* review IPR2015-00548.

In accordance with 37 C.F.R. § 90.2(a)(3)(ii), Patent Owner anticipates that the issues on appeal may include, but are not limited to, the following, as well as any underlying findings, determinations, rulings, decisions, opinions, claim interpretations, or other related issues:

- Whether the Board erred in finding that Petitioners met their burden in proving that the FDA Advisory Committee Transcript and Slides (Ex. 1003), FDA Preliminary Clinical Safety Review (Ex. 1004), Briefing Booklet (Ex. 1005), and Xyrem Video and Transcript (Ex. 1006) (collectively “the ACA Materials”) qualify as prior art;
- Whether the Board erred in its constructions of the following claim terms: “generating with the computer processor periodic reports via

the exclusive computer database to evaluate potential diversion patterns”; “the prescription requests [for GHB] containing information identifying patients”; and “the prescription requests [for GHB] containing information identifying . . . various credentials of the any and all [medical doctors/authorized prescribers]”;

- Whether the Board improperly relied upon new evidence and argument submitted for the first time in Petitioners’ reply and, therefore, failed to provide Jazz of the adequate notice and opportunity to respond to that evidence and argument; and
- Whether the Board erred in finding that Petitioners met their burden of proving that claims 1-16 of the ’059 patent are unpatentable under 35 U.S.C. § 103(a) as obvious over the ACA Materials.

In accordance with 35 U.S.C. § 142 and 37 C.F.R. §§ 90.2 and 90.3, copies of this Notice of Appeal are being timely filed simultaneously with the Director of the United States Patent and Trademark Office and the Patent Trial and Appeal Board. In addition, a copy of this Notice of Appeal, along with the required docketing fees, are being filed with the Clerk’s Office for the United States Court of Appeals for the Federal Circuit via CM/ECF. A copy of this Notice of Appeal is also being served on Petitioners.

Date: February 22, 2017

Respectfully submitted,

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Attorneys for Jazz Pharmaceuticals, Inc.

CERTIFICATE OF FILING

I hereby certify that, in addition to being filed electronically through the Patent Trial and Appeal Board's Patent Review Processing System (PRPS), the original version of the foregoing Patent Owner's Notice of Appeal was filed by Express Mail (Express Mail Label No. EL 332418397 US) on this 22nd day of February 2017, with the Director of the United States Patent and Trademark Office, at the following address:

Director of the United States Patent and Trademark Office
c/o Office of the General Counsel
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, Virginia 22313-1450

CERTIFICATE OF FILING

I hereby certify that a true and correct copy of the foregoing Patent Owner's Notice of Appeal was filed with the Clerk's Office of the United States Court of Appeals for the Federal through the federal courts' Case Management and Electronic Case Files (CM/EFC) system on this 22nd day of February 2017.

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e) and 90.2(a), the undersigned hereby certifies that PATENT OWNER NOTICE OF APPEAL was served on February 22, 2017 by filing this document through the Patent Review Processing System, as well as e-mailing a copy to janine.carlan@arentfox.com, bradford.frese@arentfox.com, richard.berman@arentfox.com, and XYREM@arentfox.com.

Date: February 22, 2017

Respectfully submitted,

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