

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: IPR2015-00547 (7,765,107)

**PETITIONERS' REPLY REGARDING THE IDENTIFICATION OF REAL
PARTIES IN INTEREST**

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I. INTRODUCTION

Pursuant to the Board’s Order on May 12, 2015 (Paper 11), Petitioner Par Pharmaceutical, Inc. (“Par Inc.”) hereby responds to Jazz Pharmaceuticals, Inc.’s (“Jazz”) assertion that the above-captioned petition for *inter partes* review failed to name Par Inc.’s direct and indirect parent holding companies as “real parties-in-interest” (“RPI”). The Board should reject Jazz’s arguments as they fail to establish that Par Inc.’s parent holding companies have an interest in or control over this proceeding sufficient to render them RPIs.

II. LEGAL STANDARD

The patent owner challenging a Petitioner’s RPI disclosure must provide sufficient evidence to show the disclosure is inadequate. *Intellectual Ventures Mgmt, LLC v. Xilinx, Inc.*, IPR2012-00018, Paper 12, at 3 (P.T.A.B. Jan. 24, 2013). The RPI is “the party that desires review of the patent”—that is, the party “at whose behest the petition has been filed.” Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,759 (Aug. 14, 2012) (to be codified at 37 C.F.R. Pt. 42). The RPI requirement exists to ensure that a non-party is not “litigating through a proxy.” *See Aruze Gaming Macau, Ltd. v. MGT Gaming, Inc.*, IPR2014-01288, Paper 13, at 12 (P.T.A.B. Feb. 20, 2015). Moreover, the RPI analysis is a narrowly tailored inquiry into the “relationship between a party and a *proceeding*,” not “the relationship between *parties*.” *Id.* at 11.

The mere existence of a parent-subsidary relationship “does not establish a relationship sufficient to make the parent a real party in interest.” *TRW Automotive U.S. LLC v. Magna Elec. Inc.*, IPR2014-01499, Paper 7 at 11 (P.T.A.B. Mar. 19, 2015). Instead, Patent Owner must sufficiently demonstrate with evidence that the parent controls a subsidiary’s participation in the *inter partes* review. *Compass Bank v. Intellectual Ventures II*, IPR2014-00719, Paper 11 at 8 (P.T.A.B. Oct. 24, 2014).

III. FACTUAL BACKGROUND

Par Inc. is the wholly-owned subsidiary of a series of holding companies, including Par Pharmaceutical Companies, Inc. (“Par Co.”); Sky Growth Intermediate Holdings II, Inc. (“SGIH II”); Sky Growth Intermediate Holdings I, Inc. (“SGIH I”); and Par Pharmaceutical Holdings, Inc. (“Par Holdings”) (collectively, the “Par Parents”). (AMN1039, ¶2.) Par Inc. is engaged in the business of making, selling and distributing pharmaceuticals; the Par Parents, however, do not conduct any such operations. (*Id.*, ¶¶2–4.)

Par Inc. prepared and filed ANDA No. 205403 (“Par’s ANDA”) with the United States Food and Drug Administration, directed to a 500 mg/ml solution of sodium oxybate (“Par’s ANDA Product”), and holds all right and title to that ANDA (*Id.*, ¶5). Par’s ANDA includes “Paragraph IV” certifications that U.S. Patent Nos. 7,668,730; 7,765,106; 7,765,107; 7,895,059; 8,457,988; and 8,589,182

(collectively, “the Petition Patents”) are invalid or would not be infringed by Par’s ANDA Product. Based on that ANDA filing, Jazz sued Par Inc.—and, after nearly eighteen months of litigation, has yet to sue any of the Par Parents—for infringement of the Petition Patents, among others and seeking a declaration that Par’s ANDA Product would infringe them upon FDA approval of Par’s ANDA (See AMN1038 at 16–23).

IV. THE PETITIONS CORRECTLY IDENTIFY PAR INC. AS THE REAL PARTY IN INTEREST.

Far from being a “nominal plaintiff” with “no substantial interest,” Par Inc. is the *only* Par entity with a cognizable interest in these Petitions, and is the only Par entity that has maintained any control over their preparation and filing.¹ Jazz has failed to offer credible evidence that Par Inc. is acting as a proxy for the Par Parents, or that the Par Parents control these Petitions so as to render them RPIs.²

¹ Amneal Pharmaceuticals LLC, of course, is also an RPI with respect to IPR2015-00545, -00546, -00547, and -00554.

² Notably, Jazz named Jazz Pharmaceuticals, Inc. as the sole RPI in its Mandatory Notices, (*see* Paper 8 at 1) despite Jazz being a wholly-owned subsidiary of Jazz Pharmaceuticals PLC, which could presumably control or direct its behavior in these proceedings as well for the same reasons. (*See* AMN1037 at 29 and Exhibit 21.1.) In other words, even Jazz apparently does not believe that a parent-

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