Paper No. __
Filed January 10, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC. and APOTEX CORP.

Petitioners

v.

ABRAXIS BIOSCIENCE, LLC

Patent Owner

U.S. Patent No. 7,820,788
Filed: October 26, 2006
Issued: October 26, 2010
Inventor: Neil P. Desai, et al.

TITLE: COMPOSITIONS AND METHODS OF DELIVERY OF PHARMACOLOGICAL AGENTS

Inter Partes Review No.: IPR2018-00152

REPLY TO PATENT OWNER'S OPPOSITION TO PETITIONER'S MOTION FOR JOINDER

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I. INTRODUCTION

Apotex has submitted a substantively identical petition and declaration as in the Actavis IPR, has agreed to an understudy role, and has made discovery and procedural concessions to minimize delay. The Board routinely grants joinder motions under such circumstances and should do so here. *See, e.g.*, *Samsung Elecs., Co., Ltd. v. Raytheon Co.*, IPR2016-00962, Paper 12 at 9 (PTAB Aug. 24, 2016). Facing these dispositive facts, Abraxis argues that joinder will cause undue delay and complexity in discovery, and asserts that all real-parties-in-interest have not been named. As explained in detail below, each of these arguments is without merit. Apotex has agreed to adhere to the procedural and discovery constraints in the Actavis IPR; to the extent there are any discovery delays, they are attributable solely to Abraxis. And while Abraxis contends that confidentiality issues will add to the complexity of the proceedings, this argument will be mooted by a two-tiered protective order in the Actavis IPR. As for its real-party-in-interest challenge, Abraxis' arguments fail, because Apotex named all the real-parties-in-interest. The Board should thus grant Apotex's joinder motion.

II. JOINDER WILL NOT DELAY THE ACTAVIS IPR

A. Abraxis Is the Only Party Seeking to Delay the Proceedings By Seeking Additional Discovery that Has No Valid Basis

Abraxis first argues that if joinder were ordered, it would require an extension of the discovery schedule in order for Abraxis to obtain discovery from Apotex

related to the loss of paclitaxel during commercial production of nanoparticles. Opp. Br. 6-7. This argument fails for several reasons. First, Abraxis will be unable to satisfy its burden of showing that such additional discovery is "necessary in the interest of justice." 25 U.S.C. § 316(a)(5). Despite extensive correspondence, Ex. 1027, Abraxis never explained, nor will it be able to explain, how the paclitaxel loss in Apotex's large-scale commercial process informs the amount of paclitaxel loss (if any) in the bench-scale Example 1 of WO 99/00133 ("Desai"), the lead prior art in the Actavis IPR.

Second, Abraxis over-reads the Board's Institution Decision with respect to what evidence Abraxis may seek concerning paclitaxel loss. The Board was clear that Abraxis could provide evidence concerning actual paclitaxel loss in Example 1 of Desai, as well as Abraxis' Capxol and Abraxane commercial production. Actavis IPR, Paper 7 at 17-18 & nn. 6-7 (PTAB Oct. 10, 2017). The Board's instruction follows from that the fact that this evidence is already under ***Abraxis'*** custody and control. The Board did ***not*** invite Abraxis to undertake a fishing expedition into Apotex's post-date processes for making albumin/paclitaxel nanoparticles. Such evidence is not relevant to the issue of paclitaxel loss in the prior art Desai reference.

Lastly, even if the Board were to allow for additional discovery, it would not impact the Actavis IPR schedule given that oral argument is not until July 11, 2018, and the scope of potential production would necessarily be limited pursuant to the

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