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# J&J Case Raises Estoppel Issue For Successful IPR Litigants

By **Roshan Shrestha and Stephen Auten** (April 5, 2018, 1:05 PM EDT)

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In a case of first impression that may have significant, unforeseen consequences, a motion in limine is pending in front of U.S. District Judge Kevin McNulty in the District of New Jersey, where a patent owner is seeking to prevent the accused infringers from raising at trial the arguments that were successful in a final written decision issued by the Patent Trial and Appeal Board in an inter partes review proceeding involving the same parties and patent.

The plain language of the statute, namely 35 U.S.C. § 315(e)(2) and § 318(b) seemingly, at first blush, supports the patent owner's argument. However, when the legislative history and goals of the America Invents Act are properly considered, the court should deny the motion.

**Procedural History**

Janssen Oncology Inc., a division of Johnson & Johnson, launched Zytiga in 2011 with only about five years of term remaining on the patent covering the active ingredient, abiraterone acetate. Enter a new patent, U.S. Patent No. 8,822,438, which expires in 2027 and claims a method for treating prostate cancer.

In 2015, Janssen alleged patent infringement against a multitude of generic drug companies who had filed an abbreviated new drug application to market a generic version of Zytiga. The generic drug companies contested the validity of the '438 patent in the district court litigation, and many defendants also contested it in several parallel IPR proceedings.[1]

**AIA and IPR**

Congress created the IPR proceeding under the AIA umbrella, which went into effect in September 2012. IPR petitions gave the public a streamlined, less expensive alternative to district court litigation to challenge a patent. An IPR typically ends with a hearing at the PTAB (if elected) in front of a three-judge panel followed by the panel's final written decision on patentability.

Relevant here, there is an estoppel provision, which specifies that where an IPR "results in a final written decision" on a patent claim, the petitioner (and those in privity) may not assert a claim of invalidity in a

district court case or U.S. International Trade Commission proceeding against that patent claim "on any ground that the petitioner raised or reasonably could have raised" in the IPR.[2]

In the Janssen IPRs, the PTAB issued in January 2018 its final written decisions concerning the '438 patent, sustaining the challenges to the patentability of all the claims. Janssen subsequently moved the PTAB to reconsider while also moving the district court in limine to invoke the estoppel provision, both of which are presently pending. That is, Janssen argues that 35 U.S.C. § 315(e)(2) precludes the ANDA defendants from raising at trial the invalidity defenses that were successful in the IPR.

**Analysis**

On its face, the estoppel language of § 315(e)(2) is not limited to only unsuccessful IPR arguments:

The petitioner in an inter partes review of a claim in a patent under this chapter that results in a final written decision … may not assert either in a civil action … or in a proceeding before the International Trade Commission … that the claim is invalid on any ground that the petitioner raised or reasonably could have raised during that inter partes review.

Also, there is no stated time period as to when the estoppel attaches, which contrasts with 35 U.S.C. § 318(b) that delays a cancelation certificate for an unpatentable claim until the time for an appeal has expired or any appeal has terminated.

Janssen argues that the statute is unambiguous, leaving the court no license to allow at trial the prior-art defenses that were successful at the PTAB. Janssen further argues that such preclusion is consistent with the common law estoppel because Congress intended to eliminate duplicative litigation.[3]

The ANDA defendants expectedly argue that the estoppel provision should not punish a party that successfully defeated a patent in a final written decision.[4] Estoppel applies, they argue, "exclusively to unsuccessful parties to prevent them from re-litigating issues that they have already litigated and lost."[5]

The legislative intent and judicial interpretation of the estoppel effect of § 315(e)(2) appears to favor the ANDA defendants. When the clause "or reasonably could have raised" was added to § 315(e)(2), Senator Arlen Specter argued that if the scope of the estoppel is narrowly tailored, it could be abused as a delay tactic. He explained that a defendant with four prior art challenges might initiate an IPR proceeding using only two challenges while requesting a stay of the district court litigation. Specifically, "[o]nce those challenges are rejected, the defendant could then raise the two remaining prior-art challenges in the district court."[6] Congress thus seemingly intended for § 315(e)(2) to prevent selective election of defenses between an IPR and other proceedings to prevent serial challenges, rather than prevent an accused infringer from arguing at trial a defense that was successful in an IPR.

Specifically, Congress intended "to prevent petitioners from raising in a subsequent challenge the same patent issues that were raised or reasonably could have been raised in a prior challenge," with the result of "significantly reduc[ing] the ability to use post-grant procedures [including IPR] for abusive serial challenges to patents."[7] The estoppel provision was designed to protect "patent owners from harassment via successive petitions by the same or related parties, to prevent parties from having a 'second bite at the apple,' and to protect the integrity of both the USPTO and Federal Courts by assuring that all issues are promptly raised and vetted."[8]

With language such as “abusive serial challenges to patents” and “second bite at the apple,” Congress intended to protect the patent owners from harassment by curtailing the ability of unsuccessful petitioners from raising in a subsequent challenge the same patent issues that were raised or reasonably could have been raised in the IPR. At the time, Senator Tom Coburn noted that competitors routinely use opposition proceeding to tie up issued patents with multiple challenges, aiming to deplete the useful life of the patent.[9] This would suggest that Congress only intended to estop petitioners from repeatedly raising unsuccessful arguments, causing the patent owner to defend against these failed arguments. Congress could not have contemplated that once a patent is found unpatentable, the estoppel provision would be invoked to punish a successful IPR litigant.

The federal courts have not directly addressed this precise estoppel issue. However, the decisions to date suggest that Section 315(e)(2) estoppel was meant to only prevent the use of unsuccessful arguments addressed in a final written decision.

In Depomed Inc. v. Purdue Pharma LP, the court explained that “where all of the asserted claims are found invalid as a result of the IPR proceedings, the ‘litigation would be simplified because it would be concluded.’”[10] The court explained that the PTAB’s final written decision would provide insight on the PTAB’s review process, including when “some or all of the claims are found not invalid,” the litigation would be “simplified due to the estoppel effect” of § 315(e)(2). Here, the court is interpreting § 315(e)(2) to bar only unsuccessful arguments from being relitigated in the district court. The Depomed court is not alone in reaching that conclusion.[11]

In sum, Janssen asks the trial court for extraordinary relief, which could have a sweeping effect on successful IPR litigants. If an ANDA sponsor could not assert at trial a defense that rendered the asserted claims unpatentable, then ANDA sponsors would be deterred to avail themselves of the IPR process. That would inevitably lead to increased litigation costs, the very effect Congress sought to curtail.

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[1] Wockhardt Bio AG v. Janssen Oncology, Inc., IPR2016-01582 (PTAB); Amerigen Pharmaceuticals, Ltd. v. Janssen Oncology, Inc., IPR2016-00286 (PTAB); Argentum Pharmaceuticals LLC v. Janssen Oncology, Inc., IPR2016-01317 (PTAB); Mylan Pharmaceuticals Inc. v. Janssen Oncology, Inc., IPR2016-01332 (PTAB); Actavis Laboratories FL, Inc. v. Janssen Oncology, Inc., IPR2017-00853 (PTAB).

[2] 35 U.S.C. § 315(e)(2).

[3] BTG Int’l Ltd., et al., v. Actavis Labs. FL, Inc. et al., Janssen’s Op. Br., Dkt. No. 454 at 1 (redacted) (D.N.J.); see also, Janssen’s Rep. Br., Dkt. No. 428 at 1.

[4] Id. Defs. Opp’n Br. Dkt. No. 418 at passim.

[5] Id. at 13-14 citing Parklane Hosiery Co. v. Shore, 439 U.S. 322, 329 (1979) ("In both the offensive and defensive use situations, the party against whom estoppel is asserted has litigated and lost in an earlier action."); see also, B&B Hardware, Inc. v. Hargis Indus., 135 S. Ct. 1293, 1298-99 (2015) ("[a]llowing the same issue to be decided more than once wastes litigants' resources and adjudicators' time, and it encourages parties who lose before one tribunal to shop around for another.").

[6] See S. Rep. No. 110-259, at 67 (Additional Views of Senator Specter Joined with Minority Views of Senators Kyl, Grassley, Coburn, and Brownback).

[7] 157 Cong. Rec. S952 (daily ed. Feb. 28, 2011) (statement of Sen. Grassley).

[8] Federal Register / Vol. 77, No. 157 / Tuesday, August 14, 2012 / Rules and Regulations 48759.

[9] See S. Rep. No. 110-259, at 72 (Minority views on Post Grant Review by Senators Coburn, Grassley, Kyl and Brownback). S. Rep. No. 110-259, at 72 (Minority views on Post Grant Review by Senators Coburn, Grassley, Kyl and Brownback).

[10] Depomed Inc. v. Purdue Pharma L.P., No. CIV. A. 13-571 JAP, 2014 WL 3729349, at *5 (D.N.J. July 25, 2014) (internal citations omitted).

[11] Milwaukee Elec. Tool Corp. v. Snap-On Inc., 271 F. Supp. 3d 990, 1027 (E.D. Wis. 2017); Evolutionary Intelligence, LLC v. Sprint Nextel Corp., No. C-13-4513-RMW, 2014 WL 819277, at *5 (N.D. Cal. Feb. 28, 2014); Intellectual Ventures II LLC v. SunTrust Banks, Inc., No. 1:13-cv-02454-WSD, 2014 WL 5019911, at *1 (N.D. Ga. Oct. 7, 2014); Wonderland Nursery Goods Co. v. Baby Trend, Inc., No. EDCV 14-01153-VAP (SPx), 2015 WL 1809309, at *3 (C.D. Cal. Apr. 20, 2015); Emed Techs. Corp. v. Repro-med Sys., Inc., No. 2:15-cv-1167-JRG-RSP, 2016 WL 2758112, at *2 (E.D. Tex. May 12, 2016); Rovi Guides, Inc. v. Comcast Corp., No. 16-CV-9278 (JPO), 2017 WL 4876305, at *3 (S.D.N.Y. Oct. 27, 2017); Douglas Dynamics, LLC v. Meyer Prods. LLC, No. 14-cv-886-JDP, 2017 WL 1382556, at *4 (W.D. Wis. Apr. 18, 2017); FastVDO LLC v. AT&T Mobility LLC, No. 3:16-CV-00385-H-WVG, 2017 WL 2323003, at *4 (S.D. Cal. Jan. 23, 2017).