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PTAB Mylan Decision Could Be Boon To Drug Innovators

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(November 12, 2020, 4:53 PM EST)

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The Leahy-Smith American Invents Act created the Patent Trial and Appeal Board and granted it the statutory discretion to deny institution of a trial when parallel litigation is underway in district court.[1]

Discretionary denials have emerged as a tool for the PTAB to further the policy goals of the AIA and ensure that instituted trials can be adequately resourced and decided in a timely manner.[2]

So too are discretionary denials a tool for innovator pharmaceutical companies holding new drug applications, or NDAs, to fend off PTAB review of patents challenged by generic drug manufacturers holding abbreviated new drug applications, or ANDAs, in parallel litigation under the Drug Price Competition and Patent Term Restoration, or Hatch-Waxman, Act.[3]

Numerous innovator pharmaceutical and biotechnology companies have raised concerns that AIA trials force patent validity battles on two fronts — in district court and at the PTAB.[4]

If generic drug manufacturers benefit from both the Hatch-Waxman framework and PTAB proceedings, they are afforded the opportunity for expedited generic drug market entry plus the expedited patent review and lower standards of proof at the PTAB.

Pharmaceutical innovators argue that this imbalance runs contrary to the congressional intent of the AIA to provide a faster alternative — not addition — to district court litigation.[5]

To date, a significant portion of the PTAB's discretionary denials of AIA trial petitions have occurred in the context of deferring to pending district court trials in quickly moving, so-called rocket docket jurisdictions. However, the subset of cases that involve PTAB review of pharmaceutical patents covering approved drug products that are listed in the U.S. Food and Drug Administration's Orange Book and at issue in copending Hatch-Waxman litigation presents unique considerations.

Upon the AIA's enactment, innovator pharmaceutical makers urged the PTAB to exercise discretion and deny inter partes review and post-grant review petitions relating to Orange Book patents involved in Hatch-Waxman litigation.[6] Fast forward to Mylan Laboratories Ltd. v. Janssen Pharmaceutica NV, in which the PTAB exercised its discretion and denied an IPR petition of an Orange Book patent at issue in copending litigation.[7]

Flying somewhat under the radar, the PTAB's Mylan IPR decision presents the first instance of a discretionary denial based on parallel Hatch-Waxman litigation. This important decision gives NDA holders the hook they have long sought to stave off PTAB petitions by ANDA applicants trying to supplant litigation. For generic drug manufacturers, the Mylan IPR decision does not foreclose PTAB review of patents at issue in Hatch-Waxman litigation, but rather signals the importance of timing for petitions filed by ANDA applicants to avoid discretionary denial.

The PTAB's Discretionary Denial of Mylan's IPR Petition

On Sept. 16, the PTAB exercised its discretion under Title 35 of the U.S. Code, Section 314(a), to deny institution of Mylan's IPR petition challenging Janssen's U.S. Patent No. 9,439,906. The timing of the PTAB's decision denying institution of Mylan's IPR meant that the statutory final written decision deadline would have been September 2021, well after the completion of two related Hatch-Waxman litigations involving the '906 patent: (1) Janssen Pharmaceuticals Inc. v. Teva Pharmaceuticals USA Inc. and (2) Janssen Pharmaceuticals v. Mylan Laboratories.[8]

At the time of the PTAB's institution decision, the Teva litigation was set for trial to begin two weeks later, on Sept. 28.[9] In the Mylan litigation, the tentative trial date was June 2021, with the 30-month stay of regulatory approval of Mylan's ANDA set to expire Jan. 2, 2022.[10]

The PTAB grounded its discretionary denial on two precedential decisions, Apple Inc. v. Fintiv Inc. and NHK Spring Co. v. Intri-Plex Technologies Inc.[11] In NHK, the board held that instituting an IPR petition on a patent challenged in district court that asserted the same prior art and arguments as the parallel district court litigation, "would not be consistent with 'an objective of the AIA ... to provide an effective and efficient alternative to district court litigation.'"[12]

The Fintiv holding does not expressly limit discretionary denials to cases in which trial was set before a final written decison, instead presenting six factors for the board to weigh when considering a denial based on a parallel district court:[13]

1. Whether a stay exists or is likely to be granted if a proceeding is instituted;

2. Proximity of the court's trial date to the board's projected statutory deadline;

3. Investment in the parallel proceeding by the court and the parties;

4. Overlap between issues raised in the petition and in the parallel proceeding;

5. Whether the petitioner and the defendant in the parallel proceedings are the same party; and

6. Other circumstances that impact the board's exercise of discretion, including the merits.

In Mylan, the PTAB found that Fintiv Factors 1-5 favored discretionary denial, while Factor 6 was neutral.

For Fintiv Factors 1 and 2, the PTAB found that the Teva litigation was scheduled for trial imminently, indeed, a matter of days after the institution decision date, so a stay was highly unlikely. In the Mylan litigation, no stay had been requested nor did the parties express any intent to request a stay, and the June 2021 date for the Mylan litigation trial was months before the projected September 2021 final written decision date.[14]

The PTAB found that Fintiv Factor 3 favored denial, describing the Teva litigation as trial-ready and noted that in the Mylan litigation, validity contentions had been exchanged, fact discovery was ongoing, there were no claim construction issued to be resolved.[15]

For Fintiv Factor 4, nearly all of the asserted references in the petition were the same as those before the district court in both litigations, and validity was the principal issue at trial, as is usually the case for Hatch-Waxman litigations.[16] For Fintiv Factor 5, Mylan's role as a defendant in one of the cases and the issues being the same — validity being central to both litigations — also supported discretionary denial.[17]

Having found five of the six factors favored a discretionary denial, the PTAB did not delve deeply into the merits of the petition but deemed the final factor neutral and denied institution.

PTAB's Mylan Decision Paves the Way for Discretionary Denials of PTAB Petitions With Parallel Hatch-Waxman Litigation

The PTAB's Mylan decision presents a well-reasoned framework to deny duplicative validity challenges of Orange Book patents mounted by ANDA applicants involved in Hatch-Waxman litigation. It is important for ANDA applicant petitioners and for NDA holders crafting patent owner preliminary responses to petitions of Orange Book patents alike.

While all of the Fintiv factors but for the last factor tipped heavily toward discretionary denial in Mylan, there are some themes that will resonate in Hatch-Waxman litigations where the factors are not as clear. For example, NDA holders will nearly always have a strong argument for Fintiv Factor 1. The 30-month stay of ANDA approval means that stays of district court litigation are less likely than in other litigations not bound by such statutory framework.

District courts are motivated to issue a decision on the merits before the 30-month stay of approval expires, and courts may not be particularly willing to toll the 30-month clock to exercise discretion to stay hotly contested first-to-file ANDA actions.[18]

Few Hatch-Waxman litigations have been stayed pending PTAB review, and most petitions on Orange Book patents are filed after Hatch-Waxman litigation has begun.[19] Because PTAB proceedings last 18 months from filing, an ANDA applicant waiting until the one-year statutory bar date to file an IPR petition will almost surely face a district court trial date before a final written decision.

In sum, ANDA applicants who want to get to market, particularly first filers seeking to capture their 180-day exclusivity period, may be disincentivized from filing IPRs if the Hatch-Waxman action is filed in a fast jurisdiction where the action is not stayed.

ANDA applicants face a risk if they assert their best invalidity defenses in an IPR, and the NDA holder prevails in the Hatch-Waxman action, the district court would be obliged to enter an order under Title 35 of the U.S. Code, Section 271(e)(4)(A), delaying approval of the ANDA until the infringed patent expires. In that case, the ANDA applicant would be held off the market even with a favorable PTAB final written decision, until it was affirmed on appeal and the district court order was vacated, which would likely be after expiration of the 30-month stay.

Delays by an ANDA applicant in filing a PTAB petition give the NDA holder fodder for Fintiv Factors 2 and 3. Although Mylan filed its petition months before the statutory bar, this fact was not persuasive to favor institution, because Mylan filed its petition long after it served its invalidity contentions — in fact, on the day Janssen's responses to the invalidity contentions were due — indicating that the parties and district court had already expended considerable resources.[20]

What is more, Mylan could not justify its own delay in filing its IPR petition, when it had already prepared and presented the same patent invalidity arguments in its contentions in the district court action.

The PTAB's emphasis on the investment of resources in Mylan suggests that this should be a point of emphasis in a NDA holder's arguments against institution based on the PTAB's discretionary denial. Mylan left some room for ANDA applicants to avoid such denial, stating that:

> if the evidence shows that the petitioner filed the petition expeditiously, such as promptly after becoming aware of the claims being asserted, this fact has weighed against exercising the authority to deny institution under NHK.[21]

Again, this timing scenario presents risks for ANDA applicants that file PTAB petitions once Hatch-Waxman litigation has begun.

Second-wave ANDA filers can also expect PTAB scrutiny when filing petitions projected to reach final written decisions after a trial for the first-to-file ANDA applicant, particularly if the grounds raised in the PTAB petition overlap with the grounds in an earlier-scheduled Hatch-Waxman trial.

Mylan suggests that even a later litigation trial date may not have saved Mylan's IPR petition. The Teva litigation's imminent trial and the significant overlap of the grounds raised against the '906 patent, combined with the exchange of contentions in the Mylan litigation, may have been enough to warrant discretionary denial in the eyes of the PTAB.

Post-Mylan Discretionary Denials May Curtail PTAB Challenges of Orange Book Patents

From the NDA holders' perspective, Mylan signals that discretionary denials may finally relieve the imbalance created by permitting the institution of one or more AIA trials to interfere with district court ANDA actions and the associated 30-month stay of approval.

By filing an ANDA, the generic drug applicant is afforded various advantages, such as being able to rely on the drug innovator's safety and efficacy studies to obtain FDA approval. In exchange, any ANDA applicant wishing to challenge an Orange Book patent must make a Paragraph IV certification, which allows the NDA holder to sue for infringement in district court.[22] Through this process, the ANDA applicant controls the timing and can begin work on the ANDA — and associated patent validity theories — long before Hatch-Waxman litigation begins.

When an ANDA applicant files a PTAB petition on an Orange Book patent, it also drives the timing the corresponding AIA trial. The ANDA applicant's unilateral control over these patent challenges arguably runs contra to Congress' intent for AIA trials to provide an efficient and expeditious alternative to district court litigation.

Indeed, in other contexts, the AIA recognized and corrected the potential unfairness of having one party being able to control the timing of mounting duplicative patent challenges across forums.[23] Mylan implicitly recognizes this inequity and provides a reasoned basis to discretionarily deny institution of an AIA trial.[24]

State of Play of the PTAB's Use of Discretionary Denials

Since the AIA's inception, NDA holders have voiced concerns about the burdens of having to engage in parallel district court and PTAB proceedings. They argue AIA proceedings have upset the balance created by the Hatch-Waxman Act and the Biologics Price Competition and Innovation Act, which is tightly coupled with the FDA's drug regulatory approval process — including the safe harbor that shields generic and biosimilar drug development from patent infringement actions prior to FDA approval — which is not the case for any other types of patentable technology.[25]

NDA holders have expressed concerns that while a district court action can be stayed pending AIA review, the 30-month stay is not suspended.[26] Further, patent challengers have certain strategic advantages, for example, the NDA holder is disproportionately burdened by parallel district court litigation, often against several defendants, and AIA proceedings, later ANDA filers can use earlier-filed Hatch-Waxman litigation to inform IPR strategy, and parallel proceedings risk different outcomes.[27]

Other thorny issues arise when PTAB proceedings occur alongside Hatch-Waxman litigation. For example, in BTG International Ltd. v Amneal Pharmaceuticals LLC, the U.S. Court of Appeals for the Federal Circuit considered the potential for a Hatch-Waxman action that had been denied a stay to overtake copending IPRs.[28]

The BTG court also considered whether Section 315 overall reflected Congress' attempt to codify a choice of venue provision in each of its subsections to avoid duplicative litigation forums between courts and the PTAB.

While the Federal Circuit ultimately did not rule on the statutory interpretation issue, it entertained the argument that a contrary reading could "bring the Hatch-Waxman statute to its knees" and debated whether a solution would be for parties to file their IPRs a bit earlier in an effort to obtain a result contemporaneously with Hatch-Waxman litigation and before expiration of a 30-month stay.[29]

In 2019, proposed legislation advanced the pick a lane argument that ANDA plaintiffs should not be subject to the AIA post-grant procedures, but has failed to advance.[30] Discretionary denial, however, presents an immediate opportunity to lessen the burden of having to fight both Hatch-Waxman actions and PTAB proceedings on Orange Book patents in parallel.

A recent letter to the U.S. House and Senate Judiciary Committees supports rulemaking that would codify the PTAB's use of discretionary denials in regulations.[31]

Discretionary denial faces opposition by major technology companies that have filed suit arguing that

the PTAB's practice applying NHK and Fintiv factors is arbitrary and capricious.[32] The complaint argues that the PTAB's use of discretionary denials to date have been inconsistent and unpredictable, and asserts that formal notice-and-comment rulemaking at the very least is required.

For its part, the U.S. Patent and Trademark Office is presently seeking public comment through mid-November on possible regulations concerning the PTAB's discretion to grant or deny institution of AIA trials.[33] Amid all of these moving pieces, for now, Mylan provides NDA holders with what they have long been asking for — a tool to cut down on having to face PTAB challenges alongside Hatch-Waxman litigation.

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[1] 35 U.S.C. §§314(a) and 325(d).

[2] Britain Eakin, PTAB Institution Rate Drops, Petitions Stay Steady In FY 2020, Law360 (October 26, 2020, 9:49 PM EDT), https://www.law360.com/articles/1322844/ptab-institution-rate-drops-petitions-stay-steady-in-fy-2020 (noting that while the PTAB's institution rate is declining, the number of petitions filed has remained relatively stable, while "the [PTAB's] exercise of discretionary denial hovered around 5% in fiscal year 2016. It then ballooned to 12% in fiscal year 2019 and jumped to more than 17% this fiscal year.").

[3] Pub. L. No. 98-417, 98 Stat. 1585 (1984).

[4] See, e.g., Letter from a coalition of numerous pharmaceutical and biotechnology companies, universities, the Pharmaceutical Research Manufacturers of America (PhRMA), the Biotechnology Innovation Organization and 235 individual inventors to The Committee on the Judiciary (October 26, 2020), https://usinventor.org/letter-to-the-committee-on-the-judiciary/.

[5] Id.; see also, Scott Graham, Pharma Comes Out Swinging For More PTO Discretion Over AIA Trials, National Law Journal (Oct. 26, 2020, 06:53 PM), https://www.law.com/nationallawjournal/2020/10/26/pharma-comes-out-swinging-for-more-pto-discretion-over-aia-trials/.

[6] See PhRMA, Comments on Trial Proceedings Under the America Invents Act Before the Patent Trial and Appeal Board at 12 (Oct. 16, 2014), https://www.uspto.gov/sites/default/files/ip/boards/bpai/phrma_20141016.pdf (citing 35 U.S.C. § 314(a)) ("[I]n many cases, fairness and efficiency concerns would suggest that a review not be instituted. The AIA provides the Director with the discretion to decide not to institute an IPR or PGR.").

[7] Mylan Labs. Ltd. v. Janssen Pharmaceutica NV, IPR2020-00440 (P.T.A.B. Sep. 16, 2020) (Paper 17) ("Mylan") (Discretionary denial under 35 U.S.C. § 314(a)).

[8] Id. at 9. Janssen Pharmaceuticals Inc. et al v. Teva Pharmaceuticals USA, Inc. et al., 2-18-cv-00734 (D.N.J.); Janssen Pharmaceuticals, Inc. et al. v. Mylan Laboratories Ltd., 2-19-cv-16484 (D.N.J.).

[9] Id. at 10-11.

[10] Id. at 11 (Fact discovery was to be completed by November 13, 2020 and expert discovery was to be completed by February 19, 2021).

[11] NHK Spring Co. v. Intri-Plex Techs., Inc., IPR2018-00752 (P.T.A.B. Sep. 12, 2018) (Paper 8) (designated precedential) ("NHK"); Apple Inc. v. Fintiv, Inc., IPR2020-00019 (P.T.A.B. May 13, 2020) (Paper 15) (designated informative) ("Fintiv"); see also Apple Inc. v. Fintiv, Inc., IPR2020-00019 (P.T.A.B. Mar. 20, 2020) (Paper 11) (designated precedential).

[12] NHK at 20 (quoting General Plastic Ind. Co., Ltd. v. Canon Kabushiki Kaisha, IPR2016-01357, Paper 19 at 16–17 (PTAB Sept. 6, 2017).

[13] Fintiv at 7-8.

[14] Mylan at 13-15.

[15] Id. at 15-19.

[16] Id. at 19-21.

[17] Id. at 22-23.

[18] See, e.g., Allergan Inc. v. Deva Holding A.S., No. 16-CV-01447-RWS (E.D. Tex. July 28, 2017) ("[B]ecause this is an ANDA lawsuit, a stay could postpone district court proceedings until after the expiration of the 30-month regulatory stay. While this is not necessarily unduly prejudicial to Allergan in light of the nature and purpose of the 30-month stay, postponing the district court action could require costly preliminary injunction proceedings, wasting both the Court's and the parties' resources"); AstraZeneca AB v. Aurobindo Pharma Ltd., No. 14-cv-664-GMS, slip op. at 2, n.3 (D. Del. Aug. 23, 2016) (Denying a stay pending an IPR, in part, because "the 30-month stay of FDA approval will expire for most defendants' ANDAs before [the FWD statutory deadline]."); see also BTG Int'l Ltd. v. Amneal Pharms. LLC, 352 F.Supp.3d 352, 373 n.13 (D.N.J. 2018) (Declining to delay deciding a Hatch-Waxman litigation pending a parallel reconsideration of an IPR FWD and appeal.).

[19] See Jonathan J. Darrow et al., Will Inter Partes Review Speed US Generic Drug Entry?, 35 Nature Biotech. 1139, 1140 (2017) ("At least two-thirds of inter partes reviews addressing pharmaceutical patents have been initiated after the generics firm has been sued for infringement….").

[20] Id. at 17-18.

[21] Id. at 16

[22] 21 U.S.C. § 355(b)(2)(A)(iv).

[23] For example, in a declaratory judgment, the alleged infringer controls when litigation commences, but is then barred from filing a PTAB petition. 35 U.S.C. § 315(a)(1). A potential PTAB petitioner is

expressly permitted, however, to assert invalidity grounds in a counterclaim without foregoing the opportunity to file an IPR. 35 U.S.C. § 315(a)(3).

[24] Mylan has appealed the PTAB's decision denying institution, in Mylan v. Janssen, Case No. 21-1071 (Fed. Cir. Oct 20, 2020). The Federal Circuit has dismissed similar appeals and denied writs of mandamus to review such PTAB discretionary denials based on a lack of jurisdiction under 28 U.S.C. § 1295(a)(4)(A) to review whether PTAB proceedings should have been instituted. See, e.g., In re Cisco Sys., Case Nos. 2020-148,-2047, -2049 (Fed. Cir. Oct. 30, 2020).

[25] Carlos A. Garcia & Jonathan Stroud, Ships in the Night: Resolving Administrative Conflict Between FDA- and Patent-Related Legislation, 68 American University Law Review 1111, 1144-45 (2019) (For example, "35 U.S.C. § [271(e)(1)] provides protection from patent infringement for a significant period prior to FDA approval to allow for the development of generics and biosimilars").

[26] Id.

[27] Id.

[28] On oral argument, the Federal Circuit considered problems that could arise when, e.g., a court could be required to enter a preliminary injunction against infringement based on patents already found invalid by IPR decisions not yet deemed "final" for purposes of section 315(e). Oral Argument for BTG Int'l Ltd. v Amneal Pharms. LLC, 923 F.3d 1063 (Fed. Cir. 2019) (No. 2019-1147), http://oralarguments.cafc.uscourts.gov/Audiomp3/2019-1147.mp3.

[29] Id. Interestingly, the BTG panel noted on oral argument that a district court would have discretion to extend if needed and would be mandamus-worthy if denied.

[30] Hatch-Waxman Integrity Act of 2019, H.R. 990, 116th Cong. §§ 2-3 (2019). The summary of the bill reasons that Congress never intended for the IPR process to upset standard litigation procedures, and this legislation would close the loophole created by the IPR process.

[31] See supra, endnote 4.

[32] Complaint for Declaratory and Injunctive Relief, Apple Inc. v. Iancu, No. 20-cv-06128-EJD (N.D. Cal. Aug. 31, 2020).

[33] See Fed. Reg. Notice, 37 C.F.R. Part 42, Docket No. PTO-C-2020-0055, Request for Comments on Discretion to Institute Trials before the Patent Trial and Appeal Board (Oct. 20, 2020), https://www.federalregister.gov/documents/2020/10/20/2020-22946/request-for-comments-on-discretion-to-institute-trials-before-the-patent-trial-and-appeal-board.