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23 Sep 2021 | **Analysis**

USPTO Faces Growing Pressure To Enter Battle Over Drug Pricing

by Brenda Sandburg

Members of Congress, companies and government agencies want the Patent Office to change policies that they say impede generic drug competition. The latest effort is focused on PTO's discretionary denial of inter partes review petitions, which is the subject of a bipartisan congressional letter and cert petition to the US Supreme Court.

The US Patent And Trademark Office has stayed on the sidelines in the fierce fight over the high cost of drugs. But in the past month calls for the agency to get involved in the dispute by changing its policies in issuing and reviewing patents has reached a crescendo. It is uncertain whether the outcry will result in significant changes but the lineup of forces facing off against the USPTO is giving renewed impetus to the drug pricing battle and has put a spotlight on one of the hottest topics in the patent bar right now.

Most recently, a bipartisan group of 11 members of Congress sent a letter to acting PTO director Andrew Hirshfeld objecting to the PTO's policies on its discretionary denials of inter partes review (IPR) petitions, which challenge an issued patent. They argue that there has been a decline in instituting inter partes review, which they say is one of the few tools "that can help address the root cause of high prescription drug prices and drive competition in the marketplace."

The signatories of the 16 September *letter* include Senators Patrick Leahy, D-Vt., chair of the Senate Judiciary Subcommittee on Intellectual Property, Ron Wyden, D-OR, and Elizabeth Warren, D-Mass., and Representatives Anna Eshoo, D-Calif, and Darrell Issa, R-Calif., chair and ranking member of the House Energy and Commerce Subcommittee on Health.

They cite the USPTO's Patent Trial and Appeal Board (PTAB)'s March 2020 precedential decision in Apple Inc. v. Fintiv Inc., in which the board said it would consider whether there is ongoing district court litigation involving the same patent in deciding whether to exercise its discretion to deny review of an IPR petition.

Since this decision "there has been a disturbing rise in discretionary denials of IPR petitions," the letter states. "By some accounts, following *Fintiv*, 19 percent of IPR petitions were denied in 2020 for reasons that had nothing to do with the merits, compared to only 5 percent in 2016."

"Without a sufficiently strong IPR system to serve as a check against questionable patents, brand manufacturers will continue to wield patent thickets that are nearly impossible to challenge and engage in product hopping, further burdening the American people with needlessly high drug prices," Leahy and his colleagues asserted.

Unpredictability For Petitioners

Attorneys specializing in IPR cases have differing views on whether the uptick in discretionary denials is a negative development.

"Amongst the patent bar and stakeholders this is a significant issue," Eldora Ellison, co-chair of Sterne Kessler Goldstein & Fox's patent office litigation practice, said. "For petitioners, there is concern as to what they'd say is the unpredictability" of whether a trial will be instituted on their petition.

She said the holding in *Fintiv* can be frustrating for petitioners. Under the America Invents Act of 2011, which established the inter partes review proceeding, if a party is served with a complaint it has one year to file an IPR petition. In reality, Ellison said, depending on where you are sued, if you wait 12 months minus a day to file a petition, the patent office may look at the schedule of parallel district court litigation and determine that that case will go to trial before it issues a final written decision and decide not to bother with the petition.

But Ellison questioned Leahy's thinking that limiting discretionary denials will have an impact on drug pricing. "The jury is out on how tight that connection is," she said. "There are many reasons drug prices are as they are. It's not all about the existence or non-existence of patents."

She also noted that it is not clear if the issue is having a real-world impact on the pharmaceutical space since the greatest volume of discretionary denials have been in industries where there is parallel litigation underway in Texas district courts. Pharma companies generally litigate in Delaware and New Jersey district courts.

Avoiding Duplicative Actions Against Patent Owners

Irena Royzman, the head of life sciences at Kramer Levin Naftalis & Frankel, said Leahy's letter

"misses the boat" in failing to recognize that the PTAB is treating IPR as an alternative to district court litigation and that petitioners are making a choice when they pursue parallel district court litigation.

"Discretionary denials are important. They avoid duplication of resources for PTAB and patent owners and they are an important anti-harassment measure," she said. "They don't deprive petitioners of IPRs. They force the petitioner to take into account what's going on and file earlier or make a choice" to go forward with an IPR petition instead of going to court.

The AIA gives the director of the PTO the discretion to institute or deny an IPR. Royzman said the director may deny a petition if the patent office has already analyzed the same prior art and arguments cited in the petition and does not feel the IPR would be a good use of its resources. And it may decide not to go forward if there is a parallel IPR proceeding on the same patent or a district court case involving the same patent.

Royzman said petitioners can mitigate against discretionary denials by filing petitions prior to litigation. She noted that biosimilar makers typically do this, and may file before submitting an abbreviated biologics license application to the FDA. A petitioner could also stipulate that if the PTAB institutes the IPR it will not make the same prior art arguments asserted in the IPR in district court litigation. Roymzan commented that this is not much of a give since the AIA specifies that once the PTAB issues a final written decision one can't present the same argument in district court.

This stipulation was made by the petitioner in Sotera Wireless Inc. v. Masimo Corp. The PTAB issued a precedential decision in the case on 1 December 2020.

PTO Polls Stakeholders

The Leahy letter has cast a spotlight on the issue of discretionary denials. Ellison noted that it is a hot topic among patent law associations, with panels being held on the subject this week at meetings of the PTAB Bar Association and Intellectual Property Owners Association.

The PTO has also paid close attention to the issue. In October 2020 it issued a request for comments to obtain feedback from stakeholders on the PTAB's current case-specific approaches to exercising its discretion on whether to institute an IPR or other AIA post-grant proceeding.

In its January 2021 *executive summary* of public views on discretionary institution of AIA proceedings, the agency noted that it received 822 comments, including from three US Senators, 124 companies and 60 IP and trade organizations. The PTO said most commenters recognized that the discretion should continue to be exercised in order to help ensure that patent owners are not subjected to repeated, costly litigation on the same issue.

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Senators Christopher Coons, D-Del., and Mazie Hirono, D-Hawaii, submitted a joint letter and Senator Thom Tillis, R-N.C., submitted a separate letter. The PTO said they expressed the view that Congress intended the PTO director to use discretion to avoid repeated challenges and encouraged rulemaking to formalize the patent office's current approach to the exercise of discretion. Tillis, then chair and now ranking member of the Senate Judiciary Subcommittee on Intellectual Property, was not a signatory to Leahy's letter.

Tillis did co-sign a recent *letter with Leahy* requesting that the PTO take steps to reduce patent applicants' making conflicting statements in submissions to the PTO and other federal agencies, suggesting something about the scope of his patent concerns.

Tillis has advocated for patent policy favorable to brand manufacturers. Two years ago, as chair of the Senate IP subcommittee, he and Coons, then ranking member, drew up a draft framework for legislation to amend Section 101 of the Patent Act, which governs what subject matter is eligible to be patented, to make it less restrictive. The draft would have eliminated judicial exceptions that the US Supreme Court has held are categories of inventions that are not patent eligible, including "abstract ideas," "laws of nature," or "natural phenomenon." (Also see "*Battle Begins Over Legislation To Expand What Inventions May Be Patented*" - Pink Sheet, 3 Jun, 2019.)

The subcommittee held three hearings on the bill but it was never introduced. Last year, Tillis told the Intellectual Property Owners Association that given legitimate concerns expressed by some witnesses, as well as the difficulty of passing legislation without stakeholder consensus, he did not see a path forward for producing a bill and steering it to passage.

Pressure On USPTO

The Leahy letter used the IPR issue to once again denounce patent thickets, in which innovators amass a large portfolio of overlapping patents on a product, and product hopping, also referred to as evergreening, which occurs when a brand manufacturer seeks to switch consumers from an older version of a product to a new formulation as the original version is about to go off patent. These issues have been the subject of several congressional hearings over the last few years. (Also see "*US Patent Reform Legislation Threatened By Biden Support For Vaccine IP Waiver, Republicans Say*" - Pink Sheet, 18 May, 2021.) and (Also see "*Drug Product Hopping Bill Should Specify Anti-Competitive 'Window', Congress Advised*" - Pink Sheet, 19 Sep, 2019.)

The PTO has not been at the center of these debates, however, as remedies have primarily focused on actions other agencies, such as US Federal Trade Commission, could take to rein in anticompetitive practices.

But FDA Acting Commissioner Janet Woodcock has also pressed the PTO to address these topics. In a 10 September letter to Hirshfeld, she asked if the patent office is considering means of limiting these practices and offering training of FDA public information and databases to help

the PTO determine whether particular documents constitute prior art. (Also see "*US FDA's Patent 'Concerns' Include Thickets, Product Hopping, And Evergreening*" - Pink Sheet, 10 Sep, 2021.)

The letter was a striking departure for the FDA, which has often said it has no role in drug pricing.

"I was surprised to see the FDA taking an outward facing role on that," Chad Landmon, the chair of Axinn, Veltrop & Harkrider's IP and FDA practice groups, said. He also said he could not recall anyone in the administration ever contacting the PTO about the role it could play on drug pricing.

Regarding Woodcock's offer to assist the PTO, he noted that the patent office has a lot of good scientists and that the letter may have been part of a broader effort by the administration to see if the patent office could rely on some of the FDA's resources.

As for Leahy's letter, he noted that a lot of the discretionary denials of IPR petitions involve technology patents being litigated in Texas jurisdictions. So even if the PTO agreed not to invoke these denials, he said he is not sure it would have a big impact on the pharmaceutical industry.

Seeking Supreme Court Review

However, the issue has impacted at least one drug company, which has requested the Supreme Court to weigh in on the matter. Last month, *Mylan Pharmaceuticals Inc.* filed a *petition for certiorari* asking the court to determine whether the law categorically precludes appeal of all decisions not to institute inter partes review.

Mylan also asks the court to consider whether the rule established in *Fintiv* and an earlier 2018 PTAB decision (NHK Spring Co. v. Intri-Plex Technologies Inc.) to determine whether to institute IPR review in light of parallel infringement litigation pending in district court is substantively and procedurally unlawful.

The NHK-Fintiv rule has resulted in chaos, Mylan says. "Numerous timely filed IPR petitions have been denied due to little more than an aggressive (and oftentimes unrealistic) district-court scheduling order. Worse, the rule has encouraged plaintiffs to seek out courts that boast break-neck trial schedules in patent cases, hoping that filing in these jurisdictions will minimize the chance of facing IPR," the petition states.

The cert petition, Mylan Laboratories Ltd. v. *Janssen Pharmaceutica NV*, involves an IPR petition Mylan filed against Janssen. Janssen filed an infringement suit against Mylan after Mylan submitted an abbreviated new drug application for paliperidone palmitate. Mylan petitioned for IPR in February 2020, less than six months after Janssen filed suit. The Patent Trial and Appeal Board denied the petition, concluding that it would be inefficient to grant the petition given co-

pending district court litigation on the same patent.

Mylan appealed to the US Court of Appeals for the Federal Circuit, which dismissed the appeal, concluding that it lacked jurisdiction since the statute bars review of non-institution decisions.

The Association for Accessible Medicines filed an amicus brief in support of Mylan. It said facets of pharmaceutical IPRs and litigation mean that the PTO's rule will frequently bar IPR petitions by generic and biosimilar manufacturers. The association cited the practice of brand manufacturers obtaining patent estates that make it difficult for a generic or biosimilar manufacturer to file an IPR until the branded manufacturer has sued for infringement and identified the patents and claims it intends to assert.

The Supreme Court may decide to take up the case given the prominence of the issue and its interest in the America Invents Act. The court has considered seven cases challenging the application of the inter partes review process. Most recently, in June it ruled in United States v. Arthrex Inc. that PTAB judges were unconstitutionally appointed and that to overcome this problem the PTO director has the discretion to review the board's final decisions in IPR proceedings. (Also see "*US Supreme Court Gives PTO Director Chance To Impact Outcome Of Patent Disputes*" - Pink Sheet, 21 Jun, 2021.)

Apple Inc. has also filed a cert petition, Apple v. Optis Cellular Technology LLC, asking the court to determine if the Federal Circuit may review a PTO decision denying a petition for inter partes review of a patent.