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PTAB Newsletter

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Q&A with Arnold & Porter PTAB Practitioner Deborah Fishman

How would you describe your practice?

I have a life sciences litigation practice with a focus on patent contentious proceedings (PTAB, district court, and on appeal to the Federal Circuit). Since the beginning of my career, my cases have mainly involved biologics and biotech life sciences. In particular, I have litigated many recombinant protein, antibody, fusion protein, and medical device cases.

How long have you been practicing in front of the USPTO and in front of the PTAB?

I have been practicing in front of the USPTO since 1999. Early in my career, I counseled clients on patent claiming strategy to prepare for litigation. Before the creation of the PTAB, I was involved with *ex parte* and *inter parte* reexaminations, as well as interference proceedings in front of the BPAI. Since the early days of the PTAB, I have acted as lead counsel in many CBM and IPR proceedings, and more recently, in PGR proceedings. We even successfully appealed a CBM case to the Federal Circuit on an issue of first impression.

What's the biggest difference between practicing in front of the PTAB and a district court?

I find the contentious proceedings before the PTAB to be more akin to an inquisitorial process, where the APJs are there to ascertain their understanding of the truth, rather than the traditional adversarial process of district court litigation. The APJs are sophisticated technical fact finders and tend to bring their technical backgrounds into their fact finding process. Without the presence of a jury, rhetoric matters less. For example, during oral hearing, I would expect to move directly to the facts to address the APJs' questioning and to move them towards our truth.

What do you enjoy about practicing at Arnold & Porter?

Overall, I enjoy the culture at Arnold & Porter. I enjoy working with my colleagues, who are really bright, but who also bring a good sense of humor to the workplace. I also appreciate that I can count on my colleagues to do the right thing.

What do you like to do in your spare time?

I like to travel to foreign and new destinations to meet new people. I've started hiking more, and am preparing for a 9-day Inca Trail hike to Machu Picchu. But above all, I enjoy spending time with my dogs and my family.



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Q&A with Arnold & Porter PTAB Practitioner Alice Ho

How would you describe your practice?

My practice focuses on patent matters related to life sciences, including small molecules to biologics, medical devices, and other biotechnology. I spend most of my time on inter partes and ex parte matters before the Patent Trial and Appeal Board and patent prosecution. I also regularly counsel clients on matters related to patent eligible subject matter, obviousness-type double patenting, patent term extension, Orange Book listing, and other Hatch-Waxman and BPCIA issues.

How long have you been practicing in front of the USPTO and in front of the PTAB?

I've been practicing in front of the USPTO for more than five years, initially prosecuting patents for our clients. I was involved with interference proceedings during the AIA-transition. Since the AIA was passed, I have been involved with IPRs and PGRs through counselling clients on their post-grant strategies. I've started acting as backup counsel in these proceedings in the last couple years.

What's the biggest difference between contentious proceedings in front of the PTAB and patent prosecution?

Although there is an element of advocacy in patent prosecution, this aspect is greatly amplified in the IPR and PGR proceedings. These proceedings are like mini-trials and require me to especially hone in on my witness preparation and deposition skills.

Why were you interested in practicing before the PTAB, and how did you get involved in the practice?

Early on in my career, I witnessed other patent practitioners arguing before the PTAB, and I thought to myself, I want to do that too! I was encouraged to learn that my Ph.D. background in biomedical engineering from Johns Hopkins and my well-rounded patent law training made me a good fit to practice before the PTAB. I expressed my interest to different partners persistently and made myself available for legal analysis and research projects related to PTAB proceedings. These smaller projects led to larger, more substantive involvement in the same or different cases. I also made a point to attend conferences to learn more about the PTAB practice and participate in the PTAB Bar Association.

How would you like to grow your practice before the PTAB and USPTO?

I'd like to continue to expand my role in contentious proceedings before the PTAB and become a second chair or even lead counsel one day. For now, I am happy to jump on opportunities to help with various aspects of IPR and PGR proceedings to gain experience and absorb everything I can like a sponge. I am ready to participate in the LEAP program to argue for our clients when the right fit comes along (with client and partner support, of course)!

What do you enjoy about practicing at Arnold & Porter?

First and foremost, the ability to work with amazing colleagues who are supportive, knowledgeable, and creative. I also enjoy the opportunity to work through a range of challenging and intellectually stimulating legal issues in high impact cases from our clients.

What do you like to do in your spare time?

In my spare time, I enjoy brushing up on my Japanese and planning for my next hiking trip to Japan's "Machu Picchu" (Takeda Castle in the mountains of Hyogo Prefecture).



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Patent Eligibility Updates: New USPTO Report, Supreme Court Cert. Denial, and Bill in Congress

USPTO Report: On June 24, 2022, Director Vidal, on behalf of the USPTO, delivered a report titled *Patent eligible subject matter: Public views on the current jurisprudence in the United States* to Senators Tillis, Coons, Hirono, and Cotton. The report confirmed split views on the current state of patent eligibility law from stakeholders from the life sciences and computer-related industries. Nonetheless, the report found that there is a general consensus among stakeholders that patent eligibility law "needs to be clear, predictable, and consistently applied."

Supreme Court Cert. Denial: Shortly after the USPTO report was published, on June 30, 2022, the Supreme Court denied the petition for certiorari in *American Axle & Mfg., Inc. v. Neapco Holdings LLC*, in which the Supreme Court was requested to consider the appropriate standard for determining patent eligibility and consider whether patent eligibility is a question of law or fact.

Bill Addressing Section 101: On August 2, 2022, Senator Tillis introduced a bill (S.4734) to reform patent eligibility law. The first draft of the bill proposes to amend 35 U.S.C. § 100 to codify that patent eligible subject matter "includes a use, application, or method of manufacture of a known or naturally-occurring process." The draft bill also proposes to amend 35 U.S.C. § 101 to codify four patent ineligible subject matter categories, including (A) a mathematical formula, (B) a process that is a non-technical economic, financial, business, social, cultural or artistic process, mental process, and natural process independent of human activity, (C) an unmodified human gene, and (D) an unmodified natural material. The draft bill further defines what is not considered as an "unmodified" human gene and natural material. In the current draft, the bill stresses that eligibility should be determined by considering the claimed invention as a whole. Finally, the bill provides some guidance on infringement action and related discovery.

Recent District Court Case Regarding IPR Estoppel: *Chemours Co. FC, LLC v. Daikin Indus., LTD*, C.A. No. 17-1612, 2022 WL 2643517 (D. Del. July 8, 2022)

In *Chemours Co. FC, LLC v. Daikin Indus., LTD*, C.A. No. 17-1612, 2022 WL 2643517 (D. Del. July 8, 2022), the court denied plaintiff's motion for summary judgment contending that IPR estoppel applied to prevent defendant from asserting prior art products in obviousness and anticipation invalidity counterclaims and defenses. Acknowledging that different district courts are divided on this issue, the court in *Chemours* reasoned that under 35 U.S.C. § 315(e)(2), because a prior art product cannot be used as a reference to challenge the validity of a patent claim in an IPR, "any invalidity theory relying upon that product as a prior art reference is not a 'ground' that reasonably could have been raised during the IPR." Since defendant could not have used prior art products to form the bases to challenge plaintiff's patented claims in an IPR, the district court found that estoppel did not apply in the subsequent litigation regardless of whether those products are cumulative of other printed publications previously asserted in the IPR proceedings.

Recent District Court Case Regarding the Scope of Collateral Estoppel: *IOENGINE, LLC v. PayPal Holdings, Inc.*, C.A. No. 18-826-WCB, 2022 WL 2800861 (D. Del. June 15, 2022)

In *IOENGINE, LLC v. PayPal Holdings, Inc.*, C.A. No. 18-826-WCB, 2022 WL 2800861 (D. Del. June 15, 2022), the court denied defendants' motion for summary judgment contending that collateral estoppel applied to prevent plaintiff from asserting dependent claims against defendants because the underlying independent claims had been held unpatentable in IPR. The court noted that collateral estoppel traditionally does not apply when the burden of proof was less stringent in the prior proceeding (preponderance of the evidence at

the PTAB) compared to the second proceeding (clear and convincing evidence in the district court) in which preclusion is sought. The court also distinguished this case from *XY, LLC v. Trans Ova Genetics, L.C.*, 890 F.3d 1282 (Fed. Cir. 2018), finding (1) the claims invalidated here in the IPR proceedings were not the same as the claims at issue in the district court case; (2) the parties in the prior case had advised the court that they assumed the affirmance of the Board's decision would result in an estoppel; and (3) the appeal of the PTAB's decision at the Federal Circuit was still pending.

Recent PTAB Case Regarding *Fintiv* Denial-PTAB Denies Institution of PGR Based On *Fintiv*, Institutes on Rehearing, Then Once Again Denies Based On *Fintiv*: *Daiichi Sankyo, Inc. and AztraZeneca Pharmaceuticals, LP v. SeaGen Inc*, PGR2021-00030

On July 15, 2022, the PTAB granted rehearing of a decision to institute post-grant review of a patent directed to an antibody based anticancer treatment in *Daiichi Sankyo, Inc. and AztraZeneca Pharmaceuticals, LP v. SeaGen Inc*, PGR2021-00030. The Board initially exercised its discretion to deny institution under Fintiv even though it initially indicated Petitioners' enablement challenges had merit. Petitioners filed both a Request for Rehearing before the Board panel and a Request for Precedential Opinion Panel (POP) Review. Although POP review was denied, the Board panel granted rehearing and instituted review, reversing its initial denial based on *Fintiv*. The Board attributed its rehearing decision to, in part, "the strong merits of Petitioner's [sic] argument that the claims lack enablement" and to its decision to institute on a related post-grant proceeding wherein it would effectively consider the same issues. Patent Owner then requested rehearing on that rehearing decision pointing out that, among other things, the day after the Board's decision to institute, the jury in the parallel district court litigation found that defendants (PGR petitioners) had willfully infringed and that defendant's defenses of invalidity based on Sections 102 and 112 failed. The Board granted Patent Owner's request for rehearing and again exercised its discretion to deny institution based on *Fintiv*. Notably, in referring to Director Vidal's *Fintiv* Guidance Memorandum, the Board panel commented that, "we have been instructed not to exercise discretion to deny a petition when 'the information presented at the institution stage presents a compelling unpatentability challenge.'" The Board explained that due to changed circumstances, including a jury not finding invalidity of the challenged claims based on Section 112, Petitioner's identical grounds in its PGR were no longer compelling given the risks of duplicative efforts and creating conflicting outcomes.

Recent Changes in the Assignment of Patent Cases in W.D. Texas

On July 25, Judge Orlando Garcia, Chief United States District Judge for the Western District of Texas, signed an order directing all cases involving patents filed in the Waco Division on or after July 25 to be randomly assigned to one of twelve District Judges in the Western District, including to the judges seated in the district courts of Austin, El Paso, and San Antonio. The order was in response to the volume of new patent cases being assigned to the Waco Division and intended to more equitably distribute those cases. The sole District Judge in the Waco Division is Judge Albright and an overwhelming majority of new cases filed in the Western District have been filed in Judge Albright's court. Judge Garcia's order will restrict plaintiff's ability to selectively choose Judge Albright's court.

PTAB Boardside Chat Webinar: Request for Comments on Director Review, Precedential Opinion Panel Review, and Internal Circulation and Review of PTAB Decisions-August 11, 2022

On August 11, 2022, the PTAB held a Boardside Chat webinar to discuss proposed formalization of processes to "promote the accuracy, consistency, and integrity of PTAB decision-making" in AIA proceedings. The USPTO seeks input on:

- the Director review process that allows a party to request Director review of a PTAB final written decision in IPR or PGR proceedings;
- the Director's option to sua sponte initiate the review of any PTAB decisions (at the Director's discretion), including institution decisions and decisions on rehearing;
- the Precedential Opinion Panel (POP) process; and
- the current interim process for PTAB decision circulation and internal PTAB review.

The comment period ends on September 19, 2022.

USPTO-FDA Interagency Collaboration and Disclosure Guidance

On July 6, 2022, Director Vidal, on behalf of the USPTO, responded to a letter from the Food and Drug Administration (FDA) in September 2021, in which FDA sought increased exchange and collaboration between the two agencies relating to grants of patent rights to pharmaceutical innovations pursuant to President Biden's Executive Order 14036 (EO). In the response letter, Director Vidal responded favorably to FDA's invitation and shared the Patent Office's current thoughts on the collaboration, including engaging FDA in AIA proceedings and revisiting patent term extension practices.

On July 29, 2022, the USPTO published a Notice on "Duties of Disclosure and Reasonable Inquiry During Examination, Reexamination, and Reissue, and for Proceedings Before the Patent Trial and Appeal Board" (87 Fed. Reg. 145). The Notice clarified that the duty of disclosure covers material information including, but not limited to, statements "received from or submitted to the FDA and other government agencies." The notice emphasized "inconsistent statements submitted to the [FDA] … [that] can [] be directly contradicted by statements made to the [USPTO] to secure a patent on the product … should be cause of rejecting the application, and when made knowingly and with bad intent, *potentially other sanctions*." The Notice also stressed that the duty to disclose also extends to parties and individuals involved in a proceeding before the PTAB.

On August 2, 2022, an amendment to the "Interagency Patent Coordination and Improvement Act of 2022" (S.4430) was reported to the Judiciary Committee. The amended text includes a new provision notifying the drug or biological product sponsor of the agency's intent to share confidential information, and provides a 30-day period of consultation with the agency.

Questions/Comments?

Contact a member of our Editorial Committee



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