MEALEY'S® LITIGATION REPORT
Intellectual Property

Arthrex's Aftermath

by
Jasper L. Tran
and
Chloe Jasper

Milbank LLP
Los Angeles, CA

A commentary article reprinted from the October 4, 2021 issue of Mealey's Litigation Report Intellectual Property

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Commentary

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[Editor's Note: Jasper L. Tran and Chloe Jasper are litigation associates at Milbank LLP. Any commentary or opinions do not reflect the opinions of Milbank LLP or LexisNexis®, Mealey Publications™. *Responses are welcome.]*

This article analyzes *United States v. Arthrex*, in which the Supreme Court found PTAB judges (sometimes dubbed as the "patent death squad") unconstitutionally appointed in violation of the Appointments Clause, along with its broader political and congressional impact ex ante. In particular, the article focuses on *Arthrex*'s actual and practical aftermath ex post in the three months since its issuance, including an analysis of the 120 pending appeals at the Federal Circuit with a similar Appointments Clause challenge and the Acting USPTO Director's 15 director review denials.

I. *United States v. Arthrex*

On June 21, 2021, the Supreme Court ruled in *Arthrex* that PTAB judges, who are appointed under the Appointments Clause as inferior Officers and have traditionally wielded "unreviewable authority" during IPR to cancel patents, have unconstitutionally acted as principal Officers. Pursuant to the AIA, PTAB judges are appointed by the Secretary of Commerce and not confirmed by the Senate, which has a constitutional defect in that appointment because they issue opinions on behalf of the government in cases involving patents potentially worth "[b]illions of dollars." The power to speak for the government, however, is reserved for principal Officers (such as Article III judges), who are nominated by the President and confirmed by the Senate. The Court fixed this constitutional defect by making PTAB judges' *unreviewable* authority *reviewable* by the USPTO Director.

Arthrex's facts are straightforward. In 2015, Arthrex, Inc., a medical device company, sued Smith & Nephew, Inc. for patent infringement in the Eastern District of Texas. A year later, Smith & Nephew filed an IPR to challenge the validity of Arthrex's patent, and in May 2018, the PTAB invalidated Arthrex's patent. Arthrex appealed, arguing that PTAB judges were unconstitutionally appointed. The Federal Circuit agreed, ruling that the proper remedy was to remove PTAB judges' tenure protections and remand for a new hearing at the PTAB—an outcome which "satisfied no one." Arthrex, Smith & Nephew, and the government asked the Supreme Court to weigh in. Arthrex argued for the overturn of the PTAB's invalidity decision. Both Smith & Nephew and the government argued that PTAB judges were constitutionally appointed but disagreed on the remedy if the court were to find an Appointments Clause defect.

Writing for the conservative majority, Chief Justice Roberts examined Supreme Court precedent explaining the distinctions among inferior-officer, principal-officer, and no-officer-at-all. In *Edmond v. United States*, the Court found that Coast Guard Court of Criminal Appeals judges, appointed by the Secretary of Transportation, were inferior officers because they had "no power to render a final decision on behalf of the United States unless permitted to do so by other Executive officers." Principal officers, in contrast,

have the power to issue decisions in the name of the government and are insulated from executive review.

Applying *Edmond* to the PTAB, five justices concluded that PTAB judges' *unreviewable* power to cancel patents conflicted with the Appointments Clause's aim of "preserv[ing] political accountability" to the public through a clear "chain of command" from the President down. To guarantee "accountability" for the appointees' actions, the Appointments Clause places the nomination power with the President so the "blame of a bad nomination would fall upon the president singly and absolutely." But neither the President himself nor those he directly controls can oversee the PTAB, rendering the "chain of command" constitutionally defective. Although the USPTO Director outranks the PTAB and "has various ways to *indirectly* influence the course" of IPR, the Director lacks the critical ability to override the PTAB's significant power to cancel issued patents. Moreover, because PTAB judges are only removable with good cause, the Court found that the Secretary of Commerce could not "meaningfully control [PTAB judges] through the threat of removal." In short, PTAB judges were insulated from the executive oversight constitutionally required for principal Officers.

To impose such an oversight, seven justices voted to rewrite the statute, 35 U.S.C. § 6(c), and judicially convert these principal Officers to inferior Officers by giving the Director discretionary power to unilaterally and directly review the PTAB's IPR decisions, while effectively leaving the existing PTAB system in place and not vacating existing IPR decisions. The Director's review would follow the "almost-universal model of adjudication in the Executive Branch" and align the PTAB with the TTAB. "Because the source of the constitutional violation is the restraint on the review authority of the Director, rather than the appointment" of PTAB judges by the Secretary of Commerce, Arthrex and others similarly situated are not entitled to a hearing before a new PTAB panel. The majority expressly limited its narrow holding to only IPR and declined to address the Director's supervision over other types of PTAB adjudications, including the examination process for issuing patents.

II. *Arthrex*'s Impact Ex Ante

Arthrex has expanded the Director's power to review the PTAB's IPR cases and reach her own decisions. As Justice Gorsuch's dissent suggested, the new power creates risk that the Director, as a political appointee, may be politically motivated—*or perceived as politically motivated*—to cancel patents that carry with them significant financial or social consequences. This puts more pressure on the currently unfilled Director post in the Biden Administration. It is not difficult to imagine lobbying campaigns aimed to influence the future or Acting Director's decisions. Recent examples of patents at potential risk include those related to COVID vaccines. Not to put too fine a point on it, but patents have become less free of political influence than they might have been in the past.

Situating *Arthrex* in the context of the Supreme Court's patent jurisprudence in the last 20 years, this case sends a strong message that patent adjudication is not special in the administrative state and reaffirms the long-observed pattern of no patent exceptionalism in the justices' eyes. More broadly, *Arthrex* has provided a clear roadmap for Congress to rethink current regulatory regimes and design adjudicative regimes in the future: outside of patent law, *Arthrex*'s ruling may upend a handful of adjudicative agencies with internal administrative-law bodies that have final decision-making authority like the PTAB, such as the Department of Health and Human Services, the Department of Labor, and the Social Security Administration. Under *Arthrex*, those administrative law judges are, like PTAB judges, appointed as inferior Officers, but arguably may be unconstitutionally acting as principal Officers. These potential appointment defects may lead to future constitutional challenges based on the Appointments Clause (as well as the Vesting Clause), including those unresolved by *Arthrex* (e.g., the broader constitutional question of whether PTAB judges must be removable at will by the agency head—the Secretary of Commerce).

III. *Arthrex*'s Aftermath Ex Post

1. Federal Circuit Appeals

While *Arthrex* has resolved Arthrex's IPR appeal, confusion remains as to how *Arthrex* would affect other pending appeals at the Federal Circuit, each of which has a similar constitutional challenge but a different procedural posture. Two days after *Arthrex*'s issuance (June 23), the Federal Circuit stayed all deadlines in 120 pending appeals with an Appointments Clause challenge and ordered the appellants to explain, within 14 days, "how they believe their cases should

proceed" and other parties, including the USPTO, to respond.

The majority of the appellants want to move on to the merits. Most merits appellants explicitly waived their Appointments Clause challenge, while some were silent on the waiver issue. The appellees and the USPTO largely agreed and considered the Appointments Clause challenge waived. One appellant asked the Federal Circuit to reverse on the merits or alternatively sought remand to the Director for further review if it ends up affirming. The appellee and USPTO protested, arguing that constitutional challenges are not "backup plans." The Federal Circuit ordered this appellant to pick one of the two options.

A minority of appellants want remand to the Director but split as to how the remand works. Roughly half of these remand appellants challenge Drew Hirshfeld's status as a Director or Acting Director because his appointment is also improper. Most of the others appear content with remand under the USPTO's post-*Arthrex* "interim Director review process," the details of which shall be covered in the next two paragraphs. Some want the Federal Circuit to vacate on the merits under *Arthrex*. In response, the USPTO and most of the appellees agreed that limited remand was appropriate, while some appellees argued waiver based on the timeliness of the appellant's raising of the Appointments Clause challenge. The USPTO demurred on the propriety of Hirshfeld's appointment. One appellee wants to avoid the remand cycle by noting that the USPTO has already been a party to the appeal and could simply brief its position about the remand.

2. USPTO Director Review Denials

Eight days after *Arthrex*'s issuance (June 29), the USPTO implemented an interim procedure for requesting post-*Arthrex* director review, stating that Hirshfeld, who is performing the Director's duties since President Biden has yet named anyone to the post, will be conducting the review. In particular, "such a review may be initiated *sua sponte* by the Director or requested by a party to a PTAB proceeding . . . by concurrently (1) entering a Request for Rehearing by the Director into PTAB E2E and (2) submitting a notification of the Request for Rehearing by the Director to the Office by email" within 30 days of the entry of a final written decision ("FWD") or a decision granting rehearing by a PTAB panel. To visualize how the interim procedure works, the USPTO provides two helpful flowcharts (Chart 1 and Chart 2).

Chart 1.

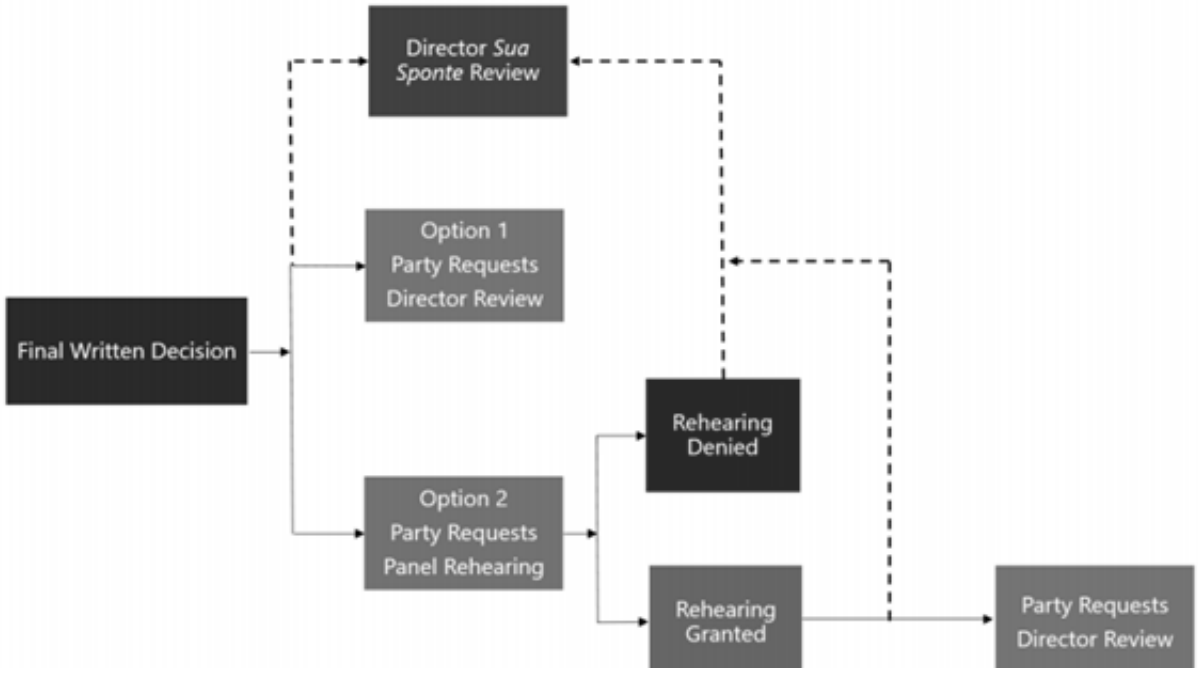
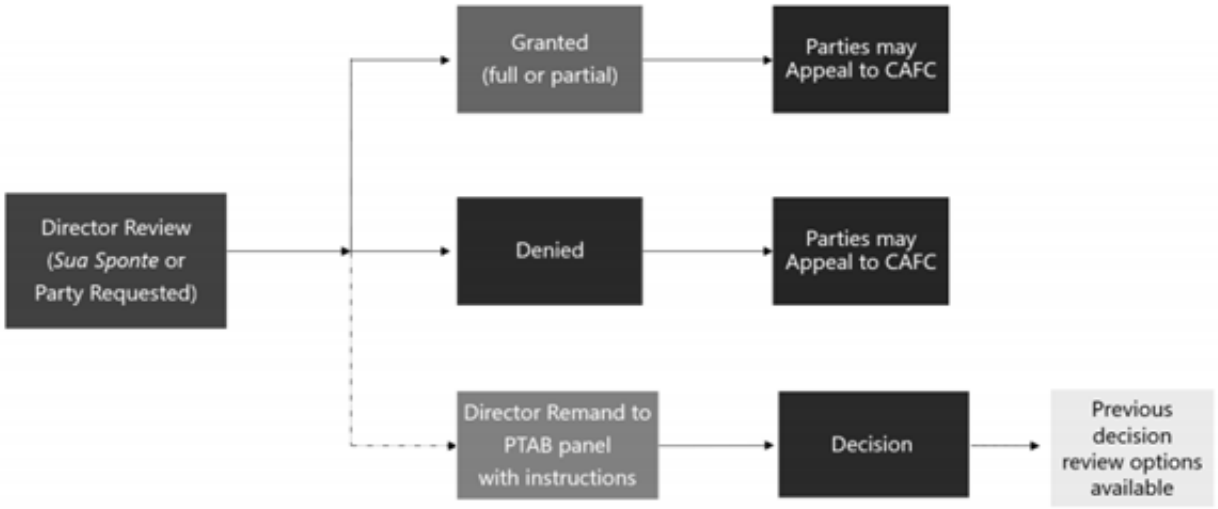


Chart 2.



Director "review may address any issue, including issues of fact and issues of law, and will be *de novo*." Upon receiving a director review request, an advisory committee established by the Director uses a non-exclusive list of criteria ("USPTO's Criteria") to evaluate whether the request warrants director review: if the PTAB decision at issue "include[s], for example, material errors of fact or law, matters that the [PTAB] misapprehended or overlooked, novel issues of law or policy, issues on which [PTAB] panel decisions are split, issues of particular importance to the Office or patent community, or inconsistencies with Office procedures, guidance, or decisions." For the *sua sponte* director review, "[t]he PTAB has an internal management review team that ensures all PTAB final written decisions are reviewed using many of the same criteria noted above. The internal management review team will alert the Director to decisions that may warrant Director review." Requests for director review have begun rolling in.

The USPTO received the first two director review requests on July 6 and 7. First, Google's request in *Google v. Hammond* advanced arguments of issue preclusion, obviousness combination that the FWD failed to address, and arguments that the FWD overlooked. Second, Solas's request in *Samsung v. Solas* contended that the PTAB misinterpreted claim construction. On August 2, Hirshfeld denied both review requests. And on August 27, Hirshfeld denied a wave of thirteen director review requests: two in *Samsung v. Cellect* and eleven in *Medtronic v. Teleflex*. Cellect's two requests were based on arguments of improper application of the obviousness standard and the PTAB's failure to view references from a POSITA's perspective. In *Medtronic v. Teleflex*, Medtronic submitted two sets of requests: three requests simply contended that the PTAB erred in its analysis of secondary considerations, whereas the other eight requests argued that the PTAB's corroboration and diligence findings set dangerous precedents contrary to established law. Needless to say, none of these arguments was effective.

Thus far—as of mid-September—Hirshfeld has issued a total of 15 director review denials. For each case, Hirschfeld's denial order is brief—just four sentences—and provides no reasoning as to why he decided to deny the director review request. Each order states essentially in full: "The Office has received a request for Director review of the Final Written Decision in this case. The request was referred to Mr. Hirshfeld, Commissioner for Patents, Performing the Functions and Duties of the Under Secretary of Commerce for Intellectual Property and Director of the [USPTO]. It is ORDERED that the request for director review is denied; and FURTHER ORDERED that the [PTAB's FWD] is the final decision of the agency."

Nevertheless, to read between the lines, these denial orders imply that the submitted requests failed to meet any of the USPTO's Criteria or raise issues that warrant granting director review. Conversely, for a director review request to be (potentially) successful, a party should follow the USPTO's Criteria to a tee and make arguments that address, to the extent they are applicable, material errors of fact or law; matters

that the PTAB misapprehended or overlooked; new caselaw or statute; split issues depending on a certain PTAB panel; important patent issues; and inconsistencies with the USPTO procedures, guidance, or decisions. It could also be the case that early failures came from a weak sample to test the water for later requests to learn from and build on. It may be too early to tell what would warrant granting director review until we see and analyze some exemplary successful requests.

With all that being said, the Director post is still unfilled and the USPTO's Criteria merely serves as an *interim* procedure for parties to follow. When a new Director is appointed by the President and confirmed by the Senate, that individual may very well change how to conduct director review. And the USPTO's interim procedure "may change based on input from the public and experience with conducting Director reviews." It remains to be seen how the director review process works in the long run, but until then, the USPTO's Criteria remains the gold standard for requesting a director review.

As hindsight is 20/20, Shakespeare could have summed up *Arthrex*'s aftermath in a few words: much ado about nothing—at least for now.

Endnotes

1. U.S. v. Arthrex, 141 S. Ct. 1970, 1985 (2021).

2. *See, e.g.*, Peter J. Pitts, '*Patent Death Squads' vs. Innovation,* WALL ST. J. (June 10, 2015, 7:23 PM), https://www.wsj.com/articles/patent-death-squads-vs-innovation-1433978591 (noting that former Chief Judge Randall Rader of the Federal Circuit and other patent experts "have referred to the 300-odd administrative judges, attorneys and legal aids on the board as 'patent death squads.'").

3. U.S. Const. art. II, § 2, cl. 2 (The President "shall nominate, and by and with the Advice and Consent of the Senate, shall appoint . . . all other Officers of the United States, whose Appointments are not herein otherwise provided for, and which shall be established by Law: but the Congress may by Law vest the Appointment of such inferior Officers, as they think proper, in the President alone, in the Courts of Law, or in the Heads of Departments."). That is, the Appointments Clause distinguishes between "principal Officers," who must be appointed by the President with Senate confirmation, and "inferior Officers," who may be appointed by the President alone, Courts of Law, or Heads of Departments if Congress permits by statute.

4. *Arthrex*, 141 S. Ct. at 1985.

5. Leahy-Smith America Invents Act of 2011, Pub. L. No. 112-29, 125 Stat. 284, 293 (2011) (codified in various sections of Title 35 of the U.S. Code).

6. *Arthrex,* 141 S. Ct. at 1976.

7. Arthrex Inc. v. Smith & Nephew, Inc., No. 15-cv-1756, ECF No. 1 (E.D. Tex. Nov. 10, 2015).

8. Smith & Nephew, Inc. v. Arthrex Inc., No. IPR2017-00275, Paper 1 (P.T.A.B. Nov. 15, 2016).

9. *Id.*, Paper 36, 2018 Pat. App. LEXIS 7285, 2018 WL 2084866 (P.T.A.B. May 2, 2018).

10. Arthrex, Inc. v. Smith & Nephew, Inc., 941 F.3d 1320, 1340 (Fed. Cir. 2019).

11. *Arthrex*, 141 S. Ct. at 1978.

12. *Id*. at 1980 (quoting *Edmond* v. United States, 520 U.S. 651, 665 (1997)).

13. *Id*. at 1982 (quoting Edmond, 520 U.S. at 663).

14. *Id*. at 1979 (quoting THE FEDERALIST No. 77 (Alexander Hamilton) at 517 (J. Cooke ed. 1961)).

15. *Id*. (quoting Free Enter. Fund v. Pub. Co. Acct. Oversight Bd., 561 U.S. 477, 496 (2010)). Justice Thomas' dissent (joined by Justices Breyer, Sotomayor, and Kagan) noted that the majority held, "[f]or the very first time, . . . that Congress violated the Constitution by vesting the appointment of a federal officer in the head of a department." Id. at 1997–98 (Thomas, J., dissenting).

16. *Id*. at 1972 (emphasis added).

17. *Id*.

18. *Id*. at 1987. Relatedly, the Federal Circuit found that TTAB judges were not unconstitutionally appointed in violation of the Appointments Clause

because the USPTO Director has "had the authority to regulate not only the procedures employed by the TTAB, but also the substance of the TTAB's decision-making process." Piano Factory Grp., Inc. v. Schiedmayer Celesta GmbH, No. 2020-1196, __ F.4th __, 2021 U.S. App. LEXIS 26344, 2021 WL 3889834, at *6–7 (Fed. Cir. Sept. 1, 2021).

19. *Arthrex*, 141 S. Ct. at 1988. Both Justices Gorsuch and Thomas dissented on this point, as they would have vacated the existing PTAB decisions. Additionally, Justice Gorsuch would then leave the problem to Congress to fix.

20. *See id*. at 1993 (Gorsuch, J., concurring in part and dissenting in part).

21. *See id*. (warning about the influence of "lobbyists" (quoting Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC, 138 S. Ct. 1365, 1381 (2018) (Gorsuch, J., dissenting))).

22. That is, the expanded power of the Director is another avenue to cancel challenged patents related to COVID vaccines, in addition to President Biden's patent waiver on COVID vaccines. *See, e.g., A Patent Waiver on COVID Vaccines Is Right and Fair,* 593 NATURE 478 (May 25, 2021).

23. *See id*. at 1996 (Breyer, J., concurring-in-judgment, dissenting-in-part) ("The nature of the PTAB . . . calls for greater, not less, independence from those potentially influenced by political factors.").

24. *See* Timothy R. Holbrook, *Explaining the Supreme Court's Interest in Patent Law,* 3 IP THEORY 62, 71–72 (2013).

25. *See* Jimmy Hoover, *In Arthrex, Justices Deal New Blow to Agency Independence*, LAW360 (June 22, 2021, 9:11 PM) (noting "that the Department of Health and Human Services, the Department of Labor, and the Social Security Administration, to name a few, all have internal administrative law bodies with final decision-making authority" that may be at risk after *Arthrex*).

26. *See Arthrex*, 141 S. Ct. at 2005 (Thomas, J., dissenting) (noting that "[a]lthough the parties raise only an Appointments Clause challenge . . . the [majority] appears to suggest that the *real* issue is that this [PTAB] scheme violates the Vesting Clause." (citing U.S. Const. art. II, § 1, cl. 1) (emphasis in original)).

27. John Evans et al., *Most Arthrex Challengers Say "No Thanks" to Director Remand*, PTAB Litig. Blog (July 19, 2021), https://www.ptablitigationblog.com/most-arthrex-challengers-say-no-thanks-to-director-remand/. For a detailed analysis of these 120 Federal Circuit appeals, see generally John Evans et al., *Review of Post-*Arthrex *Handling of Pending Federal Circuit Appeals with Appointments Clause Challenges*, 20 CHI.-KENT J. INTELL. PROP. __ (forthcoming 2022) (PTAB Bar Association issue).

28. John Evans et al., *Post-Arthrex PTAB Appeals Mostly Moving on from Constitutional Kerfuffle*, PTAB Litig. Blog (Aug. 11, 2021), https://www.ptablitigationblog.com/post-arthrex-ptab-appeals-mostly-moving-on-from-constitutional-kerfuffle/.

29. *USPTO Implementation of an Interim Director Review Process Following Arthrex*, USPTO (June 29, 2021), https://www.uspto.gov/patents/patent-trial-and-appeal-board/procedures/uspto-implementation-interim-director-review.

30. *Id*.

31. *Id*.

32. *Arthrex Q&As*, USPTO, https://www.uspto.gov/patents/patent-trial-and-appeal-board/procedures/arthrex-qas (last updated July 20, 2021) (citing 37 C.F.R. § 42.71(d)).

33. Drew Hirshfeld et al., *Patent Trial and Appeal Board Boardside Chat*: Arthrex *and the Interim Procedure for Director Review*, USPTO (July 1, 2021), https://www.uspto.gov/sites/default/files/documents/20210701-PTAB-BoardsideChat-Arthrexfinal.pdf at 15 & 16 (showing the flowcharts in color).

34. *Arthrex Q&As, supra* note 32.

35. *Id*.

36. *Id*.

37. Google LLC v. Hammond Development Int'l Inc., No. IPR2020-00081, Paper 38 (P.T.A.B. July 6, 2021).

38. Samsung Display Co., Ltd. v. Solas OLED Ltd., No. IPR2020-00320, Paper 37 (P.T.A.B. July 7, 2021).

39. *Id.*, Paper 38, 2021 WL 335543 (P.T.A.B. Aug. 2, 2021); Google, Paper 39, 2021 WL 335539 (P.T.A.B. Aug. 2, 2021).

40. Samsung Elecs. v. Cellect LLC, Nos. IPR2020-00476 & -00477, Paper 35 (P.T.A.B. Aug. 27, 2021).

41. Medtronic v. Teleflex Innovations S.À.R.L, Nos. IPR2020-00127, -00130, -00136, Paper 109, Nos. IPR2020-00126, -00128, -00132, -00134, -00135, -00137, Paper 132 (P.T.A.B. Aug. 27, 2021).

42. *Cellect*, Nos. IPR2020-00476 & -00477, Paper 34 (P.T.A.B. July 30 & Aug. 16, 2021).

43. *Medtronic*, No. IPR2020-00127, Paper 108, No. IPR2020-00130, Paper 106, No. IPR2020-00136, Paper 107 (P.T.A.B. July 21, 2021).

44. *Id.*, Nos. IPR2020-00126 & -00128, Paper 130, No. IPR2020-00132, Paper 128, No. IPR2020-00134, Paper 125, No. IPR2020-00135, Paper 129, No. IPR2020-00137, Paper 131 (P.T.A.B. July 21, 2021).

45. *E.g., Google*, 2021 WL 335539 at *1 (citation omitted).

46. *Arthrex Q&As, supra* note 32.

47. *See* WILLIAM SHAKESPEARE, MUCH ADO ABOUT NOTHING (1600). ■

MEALEY'S LITIGATION REPORT: INTELLECTUAL PROPERTY
edited by Melissa Ritti
The Report is produced twice monthly by

1600 John F. Kennedy Blvd., Suite 1655, Philadelphia, PA 19103, USA
Telephone: (215)564-1788 1-800-MEALEYS (1-800-632-5397)
Email: mealeyinfo@lexisnexis.com
Web site: http://www.lexisnexis.com/mealeys
ISSN 1065-9390