Recent Litigation Trends from an In-House Counsel Perspective

Patent Litigation in 2021

2021 has seen a marked increase in patent litigation, driven by many of the same trends that have driven record numbers of filings in 2020. It has been reported that non-practicing entity litigation is fueled by a flood of operating company divestments, and the continued rise of third-party funding. NCE-1 filing opportunities decreased sharply in 2020, and though these numbers are rebounding, it may be that the pandemic has put damper on ANDA filings. Uncertainty regarding so-called "skinny labels" may continue to impact how Hatch-Waxman and BPCIA cases are litigated.

Further Reading:

- *Intel Corp. v. Fortress Investment Group LLC*, 511 F.Supp.3d 1006 (N.D. Cal. 2021) (dismissing an antitrust claim against a non-practicing entity who partnered with an investment firm and acquired and asserted a number of patents)
- *GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc., No. 2018-1976 (Fed. Cir. Aug. 5, 2021)* (reinstating a jury's verdict of infringement and calling into question whether "skinny labels" are sufficient to avoid infringement)
- *Valeant Pharm. v. Mylan Pharm., Inc.,* 978 F.3d 1374 (Fed. Cir. 2020) (holding that infringement in Hatch-Waxman cases occurs for venue purposes only in districts where actions related to the submission of an ANDA occur)
- "Q1 in Review: Patent Litigation Surged as Third-Party Funding Further Unshackled NPEs," (April 13, 2021), available at https://www.rpxcorp.com/intelligence/blog/q1-in-review-patent-litigation-surged-as-third-party-funding-further-unshackled-npes/
- "Q3 in Review: The PTAB Reaches an Inflection Point as DOJ Touts New 'Balanced' SEP Policy," (October 12, 2021), available at https://www.rpxcorp.com/intelligence/blog/q3-in-review-the-ptab-reaches-an-inflection-point-as-doj-touts-new-balanced-sep-policy/
- Hatch-Waxman and BPCIA Cases and Trends to Watch in 2021, Blake Coblentz and Aaron Lukas, available at https://www.ipwatchdog.com/2021/01/25/hatch-waxman-bpcia-cases-trends-watch-2021/id=129305/

District Court v. PTAB

The AIA is 10 years old, and PTAB practice has become a significant player in patent disputes. 2021 has seen significant developments with regard to discretionary denials, and legislation to amend the AIA is now looming.

Further Reading:

- *United States v. Arthrex, Inc*., 141 S.Ct. 1970 (2021) (holding that APJs were unconstitutionally appointed, but remedied the issue by requiring director review of APJ decisions)

- *Apple Inc. v. Fintiv, Inc*., IPR2020-00019, Paper No. 11, March 20, 2020 (precedential) (setting forth factors for the Board to consider when the challenged patent is involved in co-pending litigation)
- Leahy-Cornyn Bill – Restoring the America Invents Act (proposing a number of amendments to the AIA, including vacating discretionary denials pursuant to Fintiv).
    - Text available at: https://patentlyo.com/media/2021/09/EHF21A231.pdf
    - Commentary: Restoring the America Invents Act, by Dennis Crouch https://patentlyo.com/patent/2021/09/restoring-america-invents.html

Venue Issues

Venue has continued to be a hot topic for litigation trend watchers, with the Western District of Texas and the District of Delaware far outpacing other jurisdictions when it comes to patent litigation. Recently, we've seen courts weigh in on venue issues.

Further Reading:

- *In re: Hulu, LLC*, No. 2021-142 (Fed. Cir. Aug. 2. 2021) (granting petition for writ of mandamus directing district court to transfer the case from E.D. Tex. to C.D. Cal)
- *In re: Juniper Networks, Inc.*, No. 2021-156 (Fed. Cir. October 4, 2021) (granting petition for writ of mandamus directing district court to transfer the case from W.D. Tex. to N.D. Cal
- *In re: Google LLC*, No. 2021-171 (Fed. Cir. Oct. 6, 2021) (granting petition for writ of mandamus directing district court to transfer the case from W.D. Tex. to N.D. Cal)
- "Federal Circuit's Wave of Judge Albright Transfer Reversals Keeps Rolling," available at https://insight.rpxcorp.com/news/68272-federal-circuit-s-wave-of-judge-albright-transfer-reversals-keeps-rolling
- "Extraordinary Writ or Ordinary Remedy? Mandamus at the Federal Circuit Part 3," Jason Rantanen, available at https://patentlyo.com/patent/2021/10/extraordinary-ordinary-mandamus-federal-circuit.html

Trends Providing Experience to Junior Attorneys

Courts and judges have realized that they can play a role in encouraging the development of junior attorneys. The PTAB and some district judges have established programs that provide perks to parties who allow more junior members of their teams to argue.

Further Reading

- PTAB's LEAP Program, information available at https://www.uspto.gov/sites/default/files/documents/PTABLEAPFlyer2021.pdf
- "Partners Step Aside. It's Time to Let Associates Shine in Court," Jenna Greene, available at https://www.reuters.com/legal/government/partners-step-aside-its-time-let-associates-shine-court-2021-08-03/

Substantive Developments

Substantive law is also continually evolving and will impact future cases. For example, developments in Section 112 and review of potential pay-for-delay settlements may affect litigation strategies going forward.

Further reading:

- *Amgen Inc. v. Sanofi, Aventisub LLC*, No. 2020-1074 (Fed. Cir. Feb. 11, 2021) (affirming district court's grant of JMOL of lack of enablement of claims directed to antibodies)
- *Impax Labs., Inc. v. FTC*, No. 19-60394 (5th Cir. April 13, 2021) (denying review of Commission conclusion that Impax violated antitrust law)
- "The Fifth Circuit Addresses Pay-For-Delay Areements: Money for Nothing (and Patent Settlements for Free)?" Sara W. Koblitz, available at https://www.thefdalawblog.com/2021/04/the-fifth-circuit-addresses-pay-for-delay-agreements-money-for-nothing-and-patent-settlements-for-free/
- "Takeda Settles Intuniv Pay-For-Delay Claims for $1.85 mln," Brendan Pierson, available at https://www.reuters.com/legal/litigation/takeda-settles-intuniv-pay-for-delay-claims-185-mln-2021-08-10/
- *AMG Capital Management, LLC v. FTC*, No. 19-508 (U.S. S. Ct. April 22, 2021) (holding that the FTC is not authorized to seek equitable money relief such as restitution or disgorgement)

IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE

INTEL CORPORATION, Plaintiff, v. FORTRESS INVESTMENT GROUP, LLC, VLSI TECHNOLOGY LLC, CF VLSI HOLDINGS LLC, FINJAN LLC, FINJAN SOFTWARE, INC., FINJAN HOLDINGS, INC., and CFIP GOLDFISH HOLDINGS LLC, Defendants.	)	C.A. No. 2021-0021-MTZ

MEMORANDUM OPINION

Date Submitted: June 10, 2021
Date Decided: September 30, 2021

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ZURN, Vice Chancellor

Several years ago, a technology company was sued by the same non-practicing entity ("NPE") for patent infringement in multiple jurisdictions.[1] Those actions proceeded apace, with some having reached a verdict. Last year, the technology company alerted the NPE of its belief that it has a license to the NPE's asserted patents via a contract with the NPE's affiliate. Rather than assert a license defense in each infringement action, the technology company has come to this Court seeking a sweeping declaratory judgment and an order of specific performance regarding all patents held by the NPE, its affiliates, and their parent company. The technology company also asserts claims for breach of contract and tortious interference.

The Court of Chancery is proudly a court of limited subject matter jurisdiction. This Court defends that limitation and has a duty to examine issues of subject matter jurisdiction *sua sponte*. Because the technology company has an adequate remedy at law in the form of a license defense in the infringement actions, this Court does not have subject matter jurisdiction over its requests for declaratory relief or specific performance. Those claims are therefore dismissed.

The technology company's breach of contract claims—that necessarily depend on the resolution of the license defense—are stayed. And even assuming the

[1] A non-practicing entity is a company that acquires and holds a patent portfolio and derives income from enforcing those patents, not by developing any marketable product or process.

existence of an underlying breach, the technology company has failed to plead the NPE and its parent company tortiously interfered with the affiliate's contract. Therefore, the tortious interference claims are dismissed.

I. BACKGROUND[2]

Plaintiff Intel Corporation ("Intel") is a Delaware corporation and a multinational technology company. Intel was sued for patent infringement by Finjan Software, Inc. ("Fijian Software"), a non-practicing entity. The litigation was resolved via a 2012 Confidential Settlement, Release and Patent License Agreement (the "Agreement") among Intel, its affiliate McAfee, Inc., Finjan Software, and Finjan, Inc. (together with Finjan Software, the "Finjan Signatories"). The Agreement established "a broad patent peace" between the signatories and their "Affiliates" for a ten-year "Capture Period."[3] "Affiliates" are defined as:

[2] I draw the following facts from the Verified Complaint, as well as the documents attached and integral to it. Docket Item ("D.I.") 1 [hereinafter "Compl."]. *See, e.g.*, *Himawan v. Cephalon, Inc.*, 2018 WL 6822708, at *2 (Del. Ch. Dec. 28, 2018); *In re Gardner Denver, Inc. S'holders Litig.*, 2014 WL 715705, at *2 (Del. Ch. Feb. 21, 2014).

[3] Compl. ¶¶ 24–28.

> [I]n relation to a specified Person (i) any Person that, now or hereafter, directly or indirectly through one or more entities, controls or is controlled by, or is under common control with, such specified Person, or (ii) any other Person, now or hereafter, that is deemed to be an affiliate of such specified Person under interpretations of the Exchange Act. As used in this Section 1.2, "controls", "control" and "controlled" means the possession, direct or indirect, of the power to direct the management and policies of a Person, whether through the ownership of any percentage of voting interests of such Person, through contract or otherwise.[4]

Under the Agreement, the applicable patents included "all Patent Rights" that the Finjan Signatories "owned or controlled at any time on or after November 6, 2012 by [the Finjan Signatories] or to which [they have] the right to grant licenses . . . without the requirement to pay consideration . . . for the grant of a license" and "that have a filing date or priority date" on or before the end of the Capture Period, November 20, 2022.[5] The Agreement granted Intel a "non-exclusive, perpetual, irrevocable license" to the applicable patents, a release from liability resulting from possible infringement, and a covenant not to bring an infringement action against Intel.[6]

Intel asserts this Agreement assured patent peace with not only the Finjan Signatories, but also any entity that was or became subject to the "common control"

[4] *Id.* Ex. A § 1.2. The parties dispute the meaning of "Affiliates" under the Agreement. This opinion does not resolve that issue.

[5] Compl. ¶¶ 29–30; *id.* Ex. A § 1.10.

[6] Compl. ¶ 31; *id.* Ex. A §§ 3.1, 4.1, 5.1.

of one or both Finjan Signatories, which was thereby bound not to sue Intel and its Affiliates for infringing defined patents during the Capture Period.[7]

On July 24, 2020, the Finjan Signatories' corporate parent, Finjan Holdings, Inc., was acquired by Defendant Fortress Investment Group, LLC ("Fortress"), a global investment manager (the "Acquisition").[8] Fortress acquired Finjan Holdings through an acquisition vehicle, Defendant CFIP Goldfish Holdings LLC ("Goldfish Holdings").

A. VLSI Sues Intel For Patent Infringement.

Fortress has another subsidiary, defendant CF VLSI Holdings LLC ("VLSI Holdings"). VLSI Holdings in turn owns defendant VLSI Technology LLC ("VLSI," and together with Fortress, VLSI Holdings, Goldfish Holdings, Finjan, Finjan Software, and Finjan Holdings, "Defendants"), a Delaware limited liability company and a non-practicing entity. A chart showing the relationships among the Defendants follows.[9]

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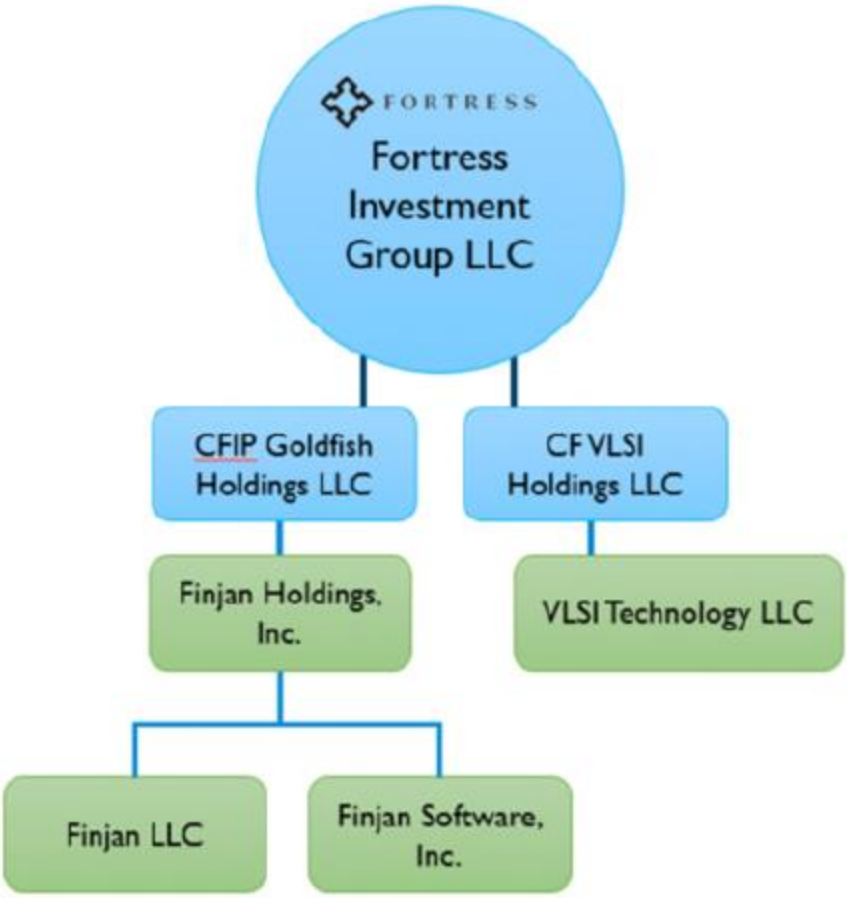
[7] *Id.* ¶ 27.

[8] Finjan Holdings, Inc. converted from a corporation to a limited liability company and changed its name to Finjan Holdings LLC. D.I. 28 n.1. Finjan Holdings LLC is a Delaware limited liability company, and a subsidiary of Goldfish Holdings. Compl. ¶¶ 7, 9. On July 31, 2020, Finjan, Inc. converted from a corporation to a limited liability company and changed its name to Finjan LLC. *Id.* n.1. Finjan LLC is a Delaware limited liability company and a subsidiary of Finjan Holdings. *Id.* ¶¶ 6, 9. Finjan Software is a Delaware corporation, which was dissolved in 2013. *Id.* ¶¶ 5, 9. D.I. 28 Ex. A.

[9] Compl. ¶ 9.



VLSI owns the patents identified in the Complaint in this action. VLSI filed at least seven patent infringement suits against Intel since 2017. The suit in the Northern District of California (the "California Action") was initiated on October 2, 2017[10] but stayed until September 1, 2021; the court ordered a status update from the parties by September 27, 2021.[11] On June 28, 2018, VLSI sued Intel in the

[10] *Id.* ¶¶ 60–63; *VLSI Tech. LLC v. Intel Corp.*, No. 5:17-CV-05671-BLF (N.D. Cal.). The California Action alleges past and current infringement of U.S. Patent Nos. 7,676,806, 7,706,207, 7,709,303, 8,004,922, 8,020,014, 8,268,672, and 8,566,836. Compl. ¶ 61.

[11] Order Modifying Case Schedule and Extending the Stay Until September 1, 2021, *VLSI Tech. LLC v. Intel Corp.*, No. 5:17-CV-05671-BLF (N.D. Cal. June 15, 2020), ECF No.

United States District Court for the District of Delaware for past and current infringement of U.S. Patent Nos. 7,246,027, 7,247,552, 7,523,331, and 8,081,026 (the "Delaware Action").[12] On July 6, 2021, the District Court of Delaware denied Intel's motion to stay but granted Intel leave to amend its answer and add an affirmative license defense.[13]

On April 11, 2019, VLSI filed three lawsuits against Intel in the United States District Court for the Western District of Texas alleging past and current infringement of U.S. Patent Nos. 8,156,357, 7,523,373, 7,725,759, 7,793,025, 7,606,983, 7,292,485, 6,633,187, and 6,366,522 (the "Texas Actions").[14] On February 25, 2021, the court granted Intel's motion for summary judgment of noninfringement on the '357 patent.[15] On March 2, 2021, a federal jury in Texas found for VLSI and awarded damages for infringement of the '373 and '759

290; Order Requesting Status Update by September 27, 2021, *VLSI Tech. LLC v. Intel Corp.*, No. 5:17-CV-05671-BLF (N.D. Cal. Sept. 13, 2021), ECF No. 309.

[12] Compl. ¶¶ 64–69; *VLSI Tech. LLC v. Intel Corp.*, No. 1:18-CV-00966-CFC (D. Del.). "[VLSI] previously also alleged that Intel was infringing U.S. Patent No. 6,212,633." Compl. ¶ 65. VLSI dropped claims related to this patent. *Id.* ¶ 67.

[13] D.I. 91; D.I. 92.

[14] Compl. ¶¶ 70–73. As a result of transfers and consolidations, the Texas Actions, all captioned *VLSI Technology LLC v. Intel Corporation*, have been filed under the following case numbers: No. 1:19-CV-0977-ADA; No. 6:19-CV-00254-ADA; No. 6:19-CV-00255-ADA; No. 6:19-CV-00256-ADA; No. 6:21-CV-00057-ADA; and No. 6:21-CV-00299-ADA.

[15] *VLSI Tech. LLC v. Intel Corp.*, 2021 WL 1432705, (W.D. Tex. Feb. 25, 2021).

patents.[16] On April 21, 2021, a federal jury in another of the Texas Actions found for Intel on the '187 and '522 patents.[17] On May 17, 2021, the court in the third Texas Action addressing the '025, '983, and '485 patents reset trial for December 16, 2021.[18]

On May 5, 2019, VLSI sued Intel in courts in Shanghai and Shenzhen, China, for past and current infringement of Chinese patents ZL201080025173.7 and ZL201410094015.9, respectively (collectively, the "China Actions" and together with the California Action, Delaware Action, and Texas Actions, the "Infringement Actions").[19] The Shenzhen court has not set dates for hearing or trial.[20] There is a post-trial stay in the Shanghai litigation.[21]

Several months after the Infringement Actions were initiated, and a month after the Acquisition, Intel sent a letter dated August 17, 2020 to the Defendants asserting, "As a result of Fortress's acquisition of Finjan, Intel holds a worldwide,

[16] D.I. 22 at 6; Jury Verdict, *VLSI Tech. LLC v. Intel Corp.*, No. 6:21-CV-00057-ADA (W.D. Tex. Mar. 2, 2021), ECF No. 564.

[17] Jury Verdict, *VLSI Tech. LLC v. Intel Corp.*, No. 6:21-CV-00299-ADA (W.D. Tex. Apr. 21, 2021), ECF No. 549.

[18] Order, Jury Selection and Trial Reset for 12/6/2021 09:00 AM before Judge Alan D. Albright, *VLSI Tech. LLC v. Intel Corp.*, No. 1:19-CV-00977-ADA (W.D. Tex. May 17, 2021), ECF No. 525.

[19] Compl. ¶¶ 74–81.

[20] D.I. 81 Ex. A ¶ 4.

[21] *Id.* ¶¶ 2–3.

fully paid-up, perpetual, irrevocable license to Fortress entities' patents, including all patents presently asserted by VLSI Technology LLC in California, Delaware, Texas, and China."[22] Intel requested that VLSI "dismiss all pending patent infringement litigation against Intel with prejudice."[23] Intel further invoked the Agreement's dispute resolution provision by providing "notice to Finjan and Fortress" regarding their alleged breaches of Sections 4, 5.1, and 8.3.[24] Alternatively, Intel indicated that it was "willing to agree to waive all Dispute Resolution requirements of Section 9.3 if Finjan/Fortress agree that Intel can proceed immediately to file a complaint in Delaware Chancery Court for adjudication of the dispute."[25] Intel's letter did not request VLSI's participation in the dispute resolution process.[26] While Finjan agreed to participate in dispute resolution, Fortress and VLSI did not.

B. Intel Files A Complaint In This Court.

On January 11, 2021, Intel filed a complaint here bringing five causes of action (the "Complaint"). The Complaint contends Intel has a license to all of the patents Defendants own or control under the Agreement because each of the

[22] Compl. Ex. E.

[23] *Id.*

[24] *Id.*

[25] *Id.*

[26] *Id.*

Defendants, as entities under Fortress's corporate umbrella, are Affiliates of Finjan as defined by the Agreement.[27] Intel seeks a declaratory judgment that the Agreement grants Intel "a worldwide, paid-up, non-exclusive, perpetual, irrevocable license under Finjan's Patents" extending to "all patents owned or controlled" by Defendants as Affiliates of the Finjan Signatories.[28] Intel seeks a second declaration that all of the patents asserted in the Infringement Actions (the "Asserted Patents") are subject to the Agreement's patent license. The proposed declaratory judgment would state, in effect, that Intel has a license to use the Asserted Patents and therefore, cannot be held liable for infringement. Intel alleges that this license is a defense to the Infringement Actions and that the Infringement Actions are a breach of the Agreement's covenant not to sue. Intel also asserts that Fortress and VLSI tortiously interfered with Finjan's Agreement.

[27] Compl. ¶¶ 56–57; *id.* Ex. A § 1.2. The Agreement defines Affiliate to include "any Person that, now or hereafter, directly or indirectly through one or more entities, controls or is controlled by, or is under common control with, such specified Person." *Id.* Intel contends that as a result of the Acquisition, each of the Defendants "controls or is controlled by, or is under common control with" the Finjan Signatories. Compl. ¶¶ 26, 49–50, 56–57. Any Affiliate who controls or is under "common control with" the Finjan Signatories is encompassed within the Agreement's definition of "Finjan;" following Intel's logic, "all patents owned or controlled" by Affiliates are included in the definition of "Finjan's Patents." *Id.* ¶¶ 29, 57. Intel also points to Finjan Holdings's description of the Acquisition as "'affiliates of Fortress Investment Group LLC (collectively "Fortress")' acquired Finjan Holdings." *Id.* ¶ 48 (quoting *id.* Ex. C at 5).

[28] Compl. Ex. A § 3.1(a); Compl. ¶¶ 58, 82–85, 95–102, 109.

On March 3, 2021, Defendants filed three motions to dismiss (the "Motions").[29] The Motions are fully briefed.[30] I heard argument on May 5 and *sua sponte* raised the issue of whether this Court has subject matter jurisdiction.[31] The parties submitted supplemental briefing regarding subject matter jurisdiction as of June 10.[32]

II. ANALYSIS

"The Court of Chancery is proudly a court of limited jurisdiction."[33] "Equitable jurisdiction is a predicate issue for every matter in this court of limited jurisdiction."[34] The Court has a duty to determine whether it has subject matter jurisdiction over a plaintiff's claims and can raise the jurisdictional issue *sua*

[29] D.I. 22 (VLSI's motion to dismiss); D.I. 23 (Fortress, Goldfish Holdings, and VLSI Holdings's motion to dismiss); D.I. 27 (Finjan, Finjan Holdings, and Finjan Software's motion to dismiss).

[30] D.I. 52; D.I. 62; D.I. 63; D.I. 67.

[31] D.I. 83 at 5, 53, 90 [hereinafter "Hr'g Tr"].

[32] D.I. 81; D.I. 85; D.I. 88.

[33] *Perlman v. Vox Media, Inc.*, 2019 WL 2647520, at *4 (Del. Ch. June 27, 2019); *see also Pike Creek Recreational Servs., LLC v. New Castle Cty.*, 238 A.3d 208, 212 (Del. Super. 2020) ("Delaware proudly guards the historic and important distinction between legal and equitable jurisdiction." (quoting *Weston Invs., Inc. v. Domtar Indus., Inc.*, 2002 WL 31011141, at *1 (Del. Super. Sept. 4, 2002)) (internal quotation marks omitted)).

[34] *Preston Hollow Cap., LLC v. Nuveen, LLC*, 2019 WL 3801471, at *4 (Del. Ch. Aug. 13, 2019) (citing *Athene Life & Annuity Co. v. Am. Gen. Life Ins. Co.*, 2019 WL 3451376 (Del. Ch. July 31, 2019)).

sponte.[35] "The Court of Chancery can exercise subject matter jurisdiction only when a case falls into one of three buckets."[36] Those buckets contain cases in which (i) "a plaintiff states an equitable claim," (ii) "a plaintiff requests equitable relief and there is no adequate remedy at law," and (iii) "jurisdiction exists by statute."[37] Intel seeks to invoke this Court's limited jurisdiction through the second bucket, requesting equitable relief in the form of declaratory judgments and specific performance. Defendants contend that Intel has an adequate remedy at law.[38]

A. This Court Does Not Have Subject Matter Jurisdiction Over Intel's License Defense.

Intel comes to this Court seeking a declaration absolving it of patent infringement liability *vis a vis* all the Defendants and all the patents they hold, buttressed by an order of specific performance. Intel's liability for infringing the

[35] *See, e.g.*, Ct. Ch. R. 12(h)(3) ("Whenever it appears by suggestion of the parties or otherwise that the Court lacks jurisdiction of the subject matter, the Court shall dismiss the action."); *Envo, Inc. v. Walters*, 2009 WL 5173807, at *4 n.10 (Del. Ch. Dec. 30, 2009) ("The issue of subject matter jurisdiction is so crucial that it may be raised at any time before final judgment and by the court *sua sponte*."), *aff'd*, 2013 WL 1283533 (Del. Mar. 28, 2013) (TABLE); *IBM Corp. v. Comdisco, Inc.*, 602 A.2d 74, 77 n.5 (Del. Ch. 1991) ("[U]nlike many jurisdictions, judges in the Delaware Court of Chancery are obligated to decide whether a matter comes within the equitable jurisdiction of this Court regardless of whether the issue has been raised by the parties." (citations omitted)).

[36] *Delawareans for Educ. Opportunity v. Carney*, 2018 WL 4849935, at *5 (Del. Ch. Oct. 5, 2018); *see also Candlewood Timber Grp., LLC v. Pan Am. Energy, LLC*, 859 A.2d 989, 997 (Del. 2004) (identifying the three ways the "Court of Chancery can acquire subject matter jurisdiction").

[37] *Delawareans for Educ. Opportunity*, 2018 WL 4849935, at *5.

[38] D.I. 85 at 7.

Asserted Patents is or was pending before several other jurisdictions, in which Intel has an adequate remedy at law in the form of a license defense. There is no controversy over the rest of Defendants' patents.

1. Intel Has An Adequate Remedy At Law That Prevents This Court From Exercising Jurisdiction.

In Count II, Intel seeks a declaration that it has a license for the Asserted Patents; Count IV seeks specific performance of the Agreement's reciprocal covenant not to sue. These counts present the question of whether each Defendant is a Finjan Affiliate under the Agreement, such that all patents owned or controlled by Finjan and all entities under the Fortress umbrella are licensed to Intel under the Agreement. In essence, Intel seeks a single declaration and injunction that would stand in for a license defense in the many fora in which Intel has been sued.

Intel argues that it needs a declaration and injunction from this Court because it lacks an adequate remedy at law in the many Infringement Actions against it.[39] This Court does not "have jurisdiction to determine any matter wherein sufficient remedy may be had by common law, or statute, before any other court or jurisdiction of this State."[40] "The question is whether the remedy available at law will afford the

[39] *Id.* at 9.

[40] 10 *Del. C.* § 342.

plaintiffs full, fair, and complete relief."[41] "In deciding whether or not equitable jurisdiction exists, the Court must look beyond the remedies nominally being sought, and focus upon the allegations of the complaint in light of what the plaintiff really seeks to gain by bringing his or her claim."[42] "[W]hen there exists an adequate and sufficient remedy at law, a claim cannot be converted to a cause in equity by the mere invocation of a formulaic prayer for traditional equitable relief."[43] In other words, this Court must "take a practical view of the complaint" to determine what a plaintiff really wants.[44] From there, "[a] practical analysis of the adequacy of any

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[41] *Delawareans for Educ. Opportunity*, 2018 WL 4849935, at *5 (quoting *Hughes Tool Co. v. Fawcett Publ'ns, Inc.*, 315 A.2d 577, 579 (Del. 1974)); Donald J. Wolfe, Jr. & Michael A. Pittenger, *Corporate and Commercial Practice in the Delaware Court of Chancery* § 2.03[b][2], at 2-33–34 (2021) [hereinafter Wolfe & Pittenger] ("As alluded to above, this is not to say that the mere existence of a potential remedy at law of any stripe will suffice to divest the Court of Chancery of subject matter jurisdiction. To preclude the exercise of concurrent equitable jurisdiction, the alternative legal remedy at a minimum must be available to the plaintiff as a matter of right and must offer full, fair, and complete relief, as prompt, practical, and efficient to the ends of justice as the requested equitable remedy." (footnotes omitted) (compiling cases)); *see also El Paso Nat. Gas Co. v. TransAmerican Nat. Gas Corp.*, 669 A.2d 36, 39 (Del. 1995); *Theis v. Board of Educ.*, 2000 WL 341061, at *1 (Del. Ch. Mar. 17, 2000); *In re Wife, K.*, 297 A.2d 424, 425–26 (Del. Ch. 1972))).

[42] *Candlewood*, 859 A.2d at 997.

[43] Wolfe & Pittenger, § 2.03[a], at 2-3; *id.* ("In the more plain-spoken words of Chancellor Chandler, 'one cannot parade a duck around and call it a swan.'" (quoting *Hillsboro Energy, LLC v. Secure Energy, Inc.*, 2008 WL 4561227, at *2 (Del. Ch. Oct. 3, 2008))).

[44] *United BioSource LLC v. Bracket Hldg. Corp.*, 2017 WL 2256618, at *2 (Del. Ch. May 23, 2017) (quoting *Int'l Bus. Machs. Corp. v. Comdisco, Inc.*, 602 A.2d 74, 78 (Del. Ch. 1991)).

legal remedy, then, must be the point of departure for each matter which comes before this Court."[45]

In general, "the ability of a party to obtain the equivalent of injunctive relief by raising its contentions as a defense in an action at law[] constitutes an adequate remedy that precludes injunctive relief in equity."[46] Put differently, "[w]here there is a defense cognizable at law the possessor of it has an adequate remedy at law and equity will not enjoin his adversary from suing."[47] Where a party can seek an

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[45] *Id.*

[46] *Takeda Pharms. U.S.A., Inc. v. Genentech, Inc.*, 2019 WL 1377221, at *5 (Del. Ch. Mar. 26, 2019) (quoting *Manor Healthcare Corp. v. Tolbert*, 1986 WL 5476, at *3 (Del. Ch. May 13, 1986)) (internal quotation marks omitted); *see also El Paso Nat. Gas Co. v. TransAmerican Nat. Gas Corp.*, 1994 WL 248195, at *3 (Del. Ch. May 31, 1994), *aff'd*, 669 A.2d 36 (Del. 1995) ("It would only have to litigate its forum-based defense and, if successful, El Paso could measure its damages by the costs of litigation."); *Buczik v. Wonchoba*, 1993 WL 93444, at *2 (Del. Ch. Mar. 24, 1993) (ruling plaintiff "clearly has an adequate remedy at law because she may raise the release as an affirmative defense" in another action); *E.I. duPont de Nemours & Co. v. HEM Rsch., Inc.*, 1989 WL 122053, at *4 (Del. Ch. Oct. 13, 1989) (granting motion to dismiss equitable rescission claim because "plaintiff would have an adequate legal defense to an action by defendant under the instrument"); *Barsky v. Flaherty*, 1987 WL 33981, at *11 n.1 (Del. Ch. Dec. 30, 1987) ("Moreover, it appears that Barsky would be entitled to raise defensively (or by a motion to stay) in the Ohio action, the same contentions that he raises in support of his injunction motion in this action. Barsky therefore has an adequate remedy at law." (citing *Manor Healthcare*, 1986 WL 5476)).

[47] *Takeda*, 2019 WL 1377221, at *5 (quoting *Gray Co. v. Alemite Corp.*, 174 A. 136, 144 (Del. Ch. 1934)).

adequate legal remedy via a defense in a different forum, the Court of Chancery does not have subject matter jurisdiction to grant equitable relief.[48]

Here, Intel wants to escape the Infringement Actions without liability. To achieve this, it has nominally sought equitable relief in this Court in the form of declarations and specific performance. Intel has an adequate remedy at law in the form of a license defense in the Infringement Actions. This Court's decision in *Takeda Pharmaceuticals U.S.A., Inc. v. Genetech, Inc.* is analogous.[49] Like Intel, the plaintiff was an alleged infringer facing patent litigation in other fora.[50] The plaintiff argued it had a patent license defense to the infringement claims based on the definition of patents in an agreement to which it—but not the patentholder—was a party.[51] The alleged infringer filed a complaint against the licensor in the Court of Chancery "seek[ing] a declaratory judgment that [the alleged infringer] has a license

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[48] *El Paso*, 669 A.2 at 40 (affirming a Chancery plaintiff could raise its defense in a first-filed Texas action and therefore had an adequate remedy at law); *Buczik*, 1993 WL 93444, at *1–2 (holding the court did not have subject matter jurisdiction to grant specific performance enforcing a release where the plaintiff had "an adequate remedy at law because she may raise the release as an affirmative defense"); *see also Manor Healthcare*, 1986 WL 5476, at *3 ("In this case the grounds urged by Manor in support of its claim for injunctive relief in this Court could be asserted defensively by Manor in the Oklahoma action, either as an affirmative defense or in a motion to dismiss that action. In other factual settings, this Court has found that the ability of a party to obtain the equivalent of injunctive relief by raising its contentions as a defense in an action at law, constitutes an adequate remedy that precludes injunctive relief in equity." (collecting cases)).

[49] 2019 WL 1377221.

[50] *Id.* at *3.

[51] *Id.* at *1, *3.

and an anti-suit injunction against the [patentholder] and anyone acting in active concert or participation with it."[52] This Court held it did not have subject matter jurisdiction to grant the equitable relief the plaintiff sought because it had an adequate remedy at law in the form of its patent license defense.[53] The Court's "conclusion depend[ed] on Takeda's ability to assert a license defense in" the infringement action.[54]

Intel argues *Takeda* is inapplicable because in that case, unlike this one, the patentholder was not a party to the Chancery action and thus could not be bound by this Court's ruling.[55] In Intel's view, the patentholder's absence from the Chancery action meant the infringement action offered Takeda a superior legal remedy. Here, because all the Defendants are joined in the Chancery action, Intel asserts that "only injunctive relief in this Court would bind all parties and address all issues."[56]

But the Federal Circuit has found that a first-filed infringement action can, and should, resolve the scope of a license granted by a licensor that is not a party to the infringement dispute. *Futurewei Technologies, Inc. (Futurewei I) v. Acacia*

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[52] *Id.* at *1.

[53] *Id.* at *5–7.

[54] *Id.* at *7.

[55] D.I. 81 at 16 ("Takeda and its subsidiaries then filed suit against Roche's subsidiary in [the Court of] Chancery—without joining Roche.").

[56] *Id.* at 17.

Research Corp. addressed a patent infringement defendant's attempt to assert a license defense in a second-filed action.[57] Huawei had been sued for patent infringement in the Eastern District of Texas, and responded by suing the patentholder, as well as the parties to a license to which Huawei asserted it was a third party beneficiary, in a California District Court, seeking declaratory judgments for noninfringement and patent invalidity.[58] The California court dismissed Huawei's claims.[59] On appeal, the Federal Circuit affirmed that Huawei should assert its license defense as a third party beneficiary in the first-filed Texas infringement action.[60] "Separating the third-party-beneficiary issue [from the non-infringement and invalidity issues in the Texas case] cannot serve the objective of efficiency."[61] Under this authority, Intel can and should pursue its license defense in the Infringement Actions, even though not all Defendants are parties to those actions.

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[57] 2012 WL 12905300 (C.D. Cal. Oct. 22, 2012).

[58] *Id.* at *1.

[59] *Id.* at *7.

[60] *Futurewei Techs., Inc. (Futurewei II) v. Acacia Rsch. Corp.*, 737 F.3d 704, 707–08 (Fed. Cir. 2013); *id.* at 709 ("[T]here is no doubt that Huawei can argue for that status in the Texas case. And there is likewise no doubt that keeping the issue in the Texas case will serve key objectives in the first-to-file rule, including the minimization or avoidance of 'duplication of effort, waste of judicial resources, and risk of inconsistent rulings that would accompany parallel litigation.'" (citations omitted)).

[61] *Id.* at 709.

Intel also contends the number of Infringement Actions makes its license defenses inadequate. Intel argues it "will continue to be subjected to the burden of litigating multiple infringement actions" and the risk of inconsistent judgements.[62] Intel suggests the time and expense spent litigating in several fora constitutes irreparable harm.[63] But the adequacy of a legal remedy is not destroyed because of "the mere existence of a convenient or preferable equitable remedy."[64] "[E]quity will not interfere where the object is to obtain a consolidation of actions, or to save the expense of separate actions.'"[65] And even if this Court had jurisdiction, Intel would still face the risk of inconsistent analyses or outcomes, at least between this Court and the Delaware Action in which Intel is asserting a license defense.[66]

Along these same lines, Intel asserts that a successful license defense in a United States District Court action might not serve to collaterally estop a judgment

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[62] D.I. 81 at 13.

[63] *Id.* at 14.

[64] *N. Am. Philips Corp. v. Aetna Cas. & Sur. Co.*, 1988 WL 60376, at *3 (Del. Ch. June 9, 1988) (citing *Chateau Apartments Co. v. City of Wilm.*, 391 A.2d 205 (Del. Supr. 1978); and then citing *Dieman v. Sussex Cty.*, (Del. Ch. Aug. 25, 1982)).

[65] *N. Am. Philips Corp.*, 1988 WL 60376, at *3 (quoting *Murphy v. City of Wilm.*, 6 Houst. 108, 139 (Del. Ct. E. and A. 1880)); *Takeda*, 2019 WL 1377221, at ("[T]he Court's subject matter jurisdiction does not depend on convenience.").

[66] *See Takeda*, 2019 WL 1377221, at *7 ("I decline to decide these issues: I lack jurisdiction to do so, and addressing those issues in tandem with the German court may risk inconsistent analyses or outcomes."). Intel has also not addressed how a sweeping declaration in its favor would be consistent with the verdict against it in *VLSI Tech. LLC v. Intel Corp.*, No. 6:21-CV-00057-ADA (W.D. Tex.).

in a Chinese court, particularly in the absence of an injunction.[67] But Intel has not demonstrated that it has no adequate means of presenting its license defense, on a standalone basis or as buttressed by a federal judgment, to the Chinese courts.[68]

If Intel had come to this Court two years ago, on the heels of the Infringement Actions, the adequacy of its legal remedies and the boundary of this Court's subject matter jurisdiction would have been clear. Now, Intel suggests its remedy at law is not "presently available" because it is too late for Intel to assert a license defense, or take discovery in support of that defense, in many of the Infringement Actions.[69] Some of the cases have proceeded to a verdict; in others, the courts have not ruled on Intel's motions to amend its answers to include its license defense.[70]

The fact that Intel has not yet availed itself of a remedy at law in every Infringement Action does not render that remedy inadequate for purposes of invoking this Court's subject matter jurisdiction. As the maxim goes, "Equity aids

[67] D.I. 81 at 16.

[68] *Takeda*, 2019 WL 1377221, at *6 (finding Takeda did not offer evidence that the German court could not effectively resolve the disputes before it and therefore, Takeda had an adequate legal remedy in the German infringement proceedings).

[69] D.I. 81 at 12–13, 15–16; *see also id.* at 15 ("[T]he Shanghai court has evidenced a reluctance to adjudicate Intel's license defense as it did not review the issue during trial.") (citing *id.* Ex. A ¶¶ 2–3).

[70] *Id.* at 12–13.

the vigilant, not those who slumber on their rights."[71] Equity's reluctance to aid the slumbering classically manifests in denying an equitable claim based on laches. But I believe equity will also refuse to aid one who slumbered on its legal rights by expanding its jealously guarded subject matter jurisdiction to compensate for that failure.[72] By the time Intel filed its January 2021 Complaint, it had enjoyed an available legal remedy in the form of license defenses in the Infringement Actions for several months, since the July 2020 Acquisition.[73] Intel's choice not to promptly pursue those defenses in every Infringement Action does not change or blur the boundary of this Court's equitable jurisdiction.[74]

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[71] 2 *Pomeroy's Equity Jurisprudence* § 418 (5th ed. 1941) (explaining that the maxim "equity aids the vigilant, not those who slumber on their rights"—the equitable basis for the doctrine of laches—"may properly be regarded as a special form of the yet more general principle, He who seeks equity must do equity").

[72]

[73] Intel asserted its license defense in a letter to Defendants dated August 17, 2020, after each of the Infringement Actions had been initiated. *See* Compl. Ex. E. Intel raised a license defense in both of the China Actions and sought to raise a license defense in one of the Texas Actions before filing the January 11, 2021 Complaint. D.I. 81 at 4, 6. For reasons that are unclear, Intel did not raise its license defense in other actions until after filing its Complaint here. *See id.* at 4 (describing how Intel did not raise a license defense in two of the three Texas Actions until after Intel filed the Complaint in the Court of Chancery); *id.* at 5 (describing how Intel did not raise a license defense in the Delaware Action until after Intel filed the Complaint in the Court of Chancery); *id.* at 6 (stating Intel did not raise a license defense in the California Action).

[74] *Cf. Buczik*, 1993 WL 93444, at *2 (finding plaintiff's fear that "raising the release as an affirmative defense in the Superior Court action would not be an adequate remedy because the jury . . . might disregard the merits of the release" meritless); *Maplewood Indus., Inc. v. Dep't of Nat. Res. & Env't Control*, 1989 WL 155944, at *4 (Del. Ch. Dec. 7, 1989) (finding plaintiff had an adequate remedy at law via a damages action, notwithstanding

Finally, Intel suggests that it lacks an adequate remedy outside of the Court of Chancery because of the Agreement's forum selection clause. Section 11.4 provides "[a]ll disputes and litigation regarding this Agreement and matters connected with its performance shall be subject to the exclusive jurisdiction of the Court of Chancery of the State of Delaware . . . or the United States District Court for the State of Delaware."[75] Intel is the defendant in a patent infringement suit before the United States District Court for the State of Delaware.[76] Intel may present its license defense in that existing forum and comply with the Agreement's forum selection clause.[77]

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defendant's possible sovereign immunity defense to plaintiff's action, should plaintiff chose to move forward); *id.* ("Without deciding an issue which is not before me, moreover, it appears that an action at law is available to the plaintiffs if they are correct with respect to their constitutional claims.").

[75] Compl. Ex. A § 11.4; Compl. ¶ 37; D.I 81 at 9–10.

[76] *See VLSI Tech. LLC v. Intel Corp.*, No. 1:18-CV-00966-CFC (D. Del.).

[77] Alternatively, it appears Intel may present its license defense in the first-filed forum, the California Action. In *Futurewei I*, Huawei claimed it had to assert its rights under a license in the agreement's selected forum. 2012 WL 12905300, at *4–7. The Federal Circuit held it could and should assert those rights in the first-filed infringement action in a different forum. *Futurewei II*, 737 F.3d at 708 ("Here, Huawei has said that its status as a third-party beneficiary can matter for two purposes: to invoke the license agreement's section 2.1 to protect it against the allegations it is infringing the five patents; and to invoke the agreement's section 9.1, regarding forum selection. Those provisions of the license agreement are already at issue in the first-filed Texas action, or readily could be."); *id.* at 710 ("It makes no sense for this count to be adjudicated as a stand-alone claim in California while the relevant, substantive claims to which it directly relates are being litigated in Texas."); *see Comcast Corp. v. Rovi Corp.*, 2016 WL 4991625, at *3 (S.D.N.Y. Sept. 16, 2016) ("Litigants who believe that a forum selection clause governs an action brought in an alternative forum should first seek to resolve the venue issue in the first-filed forum, absent exceptional circumstances."); *see also Zix Corp. v. Echoworx Corp.*, 2016 WL 7042221, at *2–3 (E.D. Tex. June 9, 2016) (discussing the "continuum" of

For the foregoing reasons, it appears that the relief Intel seeks here is duplicative of an adequate remedy at law, and so this Court lacks subject matter jurisdiction.[78] Counts II and IV are dismissed without prejudice.[79]

2. Plaintiff's Breach Of Contract Claim Cannot Be Resolved Without Resolving Plaintiff's Claims Seeking Equitable Relief.

Building on its theory that the Agreement granted Intel a license to VLSI's Asserted Patents, Intel contends Fortress and VLSI breached their obligations under the Agreement by

> (i) refusing to follow the Dispute Resolution Process outlined in the [Agreement]; (ii) denying that Intel is licensed under all Asserted Patents, (iii) denying that Intel is released from all liability under them, and (iv) continuing to litigate (or causing a related entity to continue to litigate) the various patent infringement actions, currently ongoing across the U.S. and abroad, relating to the Asserted Patents against Intel.[80]

considerations for choosing a forum for license defenses, balancing the license agreement's contracted forum with the infringement plaintiff's first-filed forum). *But see Gen. Protecht Gp., Inc. v. Leviton Mfg. Co., Inc.*, 651 F.3d 1355 (Fed. Cir. 2011) (granting a preliminary injunction to enforce the parties' forum selection clause over the first-filed rule).

[78] *See El Paso*, 669 A.2 at 40 (citing *Gray*, 174 A. at 144).

[79] *See Takeda*, 2019 WL 1377221, at *7 & n.73 (granting dismissal without prejudice for lack of subject matter jurisdiction and collecting cases).

[80] Compl. ¶ 114.

Intel also argues Finjan breached its obligations by failing to cause its Affiliates, *e.g.* VLSI, to comply with the Agreement's license, release, and covenant not to sue.[81] Intel contends the breaches have caused it to "expend[] time and resources simultaneously defending itself against alleged infringement of the Asserted Patents, while seeking to vindicate its right to be free from such patent infringement actions under the [Agreement]."[82]

To successfully plead a breach of contract claim, a plaintiff must demonstrate: (1) the existence of the contract; (2) the breach of an obligation imposed by that contract; and (3) the resultant damage to the plaintiff.[83] While the parties do not dispute the existence of the Agreement, they do dispute which parties are bound by the Agreement and the duties owed.

Intel's breach claims present issues within the scope of Intel's license defenses, namely (i) the definition of Affiliates, (ii) whether Fortress and VLSI are bound by the Agreement, and (iii) whether Finjan's Patents encompass the Asserted Patents. I would need to resolve these issues in order to determine whether Finjan,

[81] *Id.* ¶ 113 (asserting Finjan breached the Agreement by: "(i) failing to cause its Affiliates to comply with the [Agreement], as required by § 8.3, including by failing to secure Intel's license to the Asserted Patents and release from all liability under them, and (ii) failing to ensure that Affiliates comply with the [Agreement]'s covenant not to sue.").

[82] *Id.* ¶ 115.

[83] *VLIW Tech., LLC v. Hewlett-Packard Co.*, 840 A.2d 606, 612 (Del. 2003) (citations omitted).

Fortress, or VLSI have breached the Agreement. But, for the reasons I have explained, these issues are properly decided in the first-filed Infringement Actions.[84]

Courts have "inherent power . . . to exercise [their] discretion to control the disposition of actions on [their] docket[s] in order to promote economies of time and effort for the court, litigants, and counsel."[85] Count III will be stayed until one of the Infringement Actions determines whether Fortress and VLSI are bound by the Agreement and whether VLSI's patents are licensed to Intel under the Agreement. I ask the parties to keep this Court informed of any material developments. If Intel chooses to ask one of the Courts presiding over an Infringement Action to hear not only its license defense, but also its breach claims building on that Court's interpretation of the Agreement, I ask Intel to inform this Court of that election.

B. Plaintiff Failed To Plead Fortress And VLSI Tortiously Interfered With The Agreement.

In the alternative to claiming Fortress and VLSI breached the Agreement, Intel also claims Fortress and VLSI "have intentionally caused Finjan to breach the [Agreement] by not allowing Finjan to secure Defendants' compliance with the

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[84] *See Futurewei II*, 737 F.3d at 709 ("The interest in the just and effective disposition of disputes likewise does not warrant an exception to the first-to-file rule. The Texas court can decide the issues presented by count 11, if necessary, including the relationship between the no-third-party-beneficiary rights provision of the license agreement and either (a) the enforcement-protection provision or (b) the [California] forum-selection provision").

[85] *Joseph v. Shell Oil Co.*, 498 A.2d 1117, 1123 (Del. Ch. 1985) (citing *Landis v. N. Am. Co.*, 299 U.S. 248 (1936)).

license and release provisions in the [Agreement]."[86] Like Intel's breach claims, its tortious interference claims require Intel's license defense to be adjudicated first. But unlike Intel's breach claims, they fail to pass muster under Court of Chancery Rule 12(b)(6). They are therefore dismissed.

The elements of tortious interference with a contract are: (1) a contract, (2) about which defendant knew, (3) an intentional act that is a significant factor in causing the breach of such contract, (4) without justification, (5) which causes injury.[87] Intel pleads "[o]n information and belief," Fortress directed VLSI to not dismiss the Infringement Actions knowing that this would cause Finjan to breach the Agreement.[88] Intel also alleges "[o]n information and belief, VLSI knew that by intentionally failing to dismiss the [Infringement Actions], it would cause Finjan to breach the terms of the [Agreement]."[89] Intel argues Fortress and VLSI "were not justified in their conduct because, just like they enjoyed the benefits of the Acquisition, they assumed Finjan's liabilities by virtue of the same Acquisition."[90]

Intel's theory of liability depends on VLSI owing Intel a license. If VLSI does

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[86] Compl. ¶ 126 (citing *id.* Ex. A §§ Preamble, 3.1, 5.1); Hr'g Tr. 75.

[87] *Bhole, Inc. v. Shore Invs., Inc.*, 67 A.3d 444, 453 (Del. 2013) (internal quotation marks omitted).

[88] Compl. ¶¶ 127–28.

[89] *Id.* ¶¶ 129.

[90] *Id.* ¶¶ 92, 130.

not owe Intel a license, Finjan did not breach the Agreement. In order for VLSI to owe Intel a license, it must be an Affiliate under the Agreement, contractually bound to give a license to Intel. If VLSI is an Affiliate, so is Fortress. As a matter of logic, Intel's claim against VLSI requires binding VLSI, and therefore Fortress, in contract. As a matter of law, those contractually bound entities may not be liable for tortious interference.[91] Intel's contractual theory of liability, which must hold true for Finjan to have committed a predicate breach, precludes a tortious interference claim against VLSI and Fortress.

And even if VLSI and Fortress could be liable in tort, Intel has failed to state a claim for tortious interference. As explained by cases Intel engaged with in briefing, nonsignatory parent and affiliate companies can tortiously interfere with their subsidiaries' contracts only as filtered through a "limited affiliate privilege."[92]

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[91] *Kuroda v. SPJS Hldgs., LLC*, 971 A.2d 872, 884 (Del. Ch. 2009) ("It is well settled that a party to a contract cannot be held liable for [both] breaching the contract and for tortiously interfering with that contract.").

[92] *Bandera Master Fund LP v. Boardwalk Pipeline P'rs, LP*, 2019 WL 4927053, at *26–28 (Del. Ch. Oct. 7, 2019); *id.* at *27 ("As with a corporate parent and its subsidiary, or wholly owned affiliates with a common parent, a general partner and its controllers 'share the commonality of economic interests which underlay the creation of an interference privilege.'" (quoting *Shearin v. E.F. Hutton Gp.*, 652 A.2d 578, 590 n.14 (Del. Ch. 1994))); *Shearin*, 652 A.2d at 590 n.14 (holding that for purposes of assessing justification, "the relationship among wholly owned affiliates with a common parent is no different . . . than that between a parent and a subsidiary"); *see also NAMA Hldgs., LLC v. Related WMC LLC*, 2014 WL 6436647, at *26 (Del. Ch. Nov. 17, 2014) ("Delaware law rejects the theory that 'a parent and its wholly owned subsidiaries constitute a single economic unit' such that 'a parent cannot be liable for interfering with the performance of a wholly owned

"When the defendant that a plaintiff has sued for tortious interference controls an entity that was a party to the contract, the weighing of factors becomes more complex because of the need to balance the important policies served by a claim for tortious interference with contract against the similarly important policies served by the corporate form."[93] The limited affiliate privilege protects a parent or other affiliated entity that "pursues lawful action in the good faith pursuit of the subsidiary's profit making activities" and "recognizes that the close economic relationship of related entities requires enhanced latitude in defining what improper interactions would be."[94] "In the parent-subsidiary context, the test for holding a parent corporation liable for tortious interference ha[s] to be high or every-day consultation or direction between parent corporations and subsidiaries about contractual implementation would lead parents to be always brought into breach of contract cases."[95]

To sufficiently plead that a corporate parent or affiliate acted without justification when interfering with a subsidiary's contract, the burden is on the

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subsidiary.'" (quoting *Shearin*, 652 A.2d at 590)); *id.* at *26 ("In other words, 'a parent corporation can be held liable for tortiously interfering with its subsidiaries' contracts when a plaintiff proves that the parent was not pursuing in good faith the legitimate profit seeking activities of the affiliated enterprises.'" (quoting *Allied Cap. Corp. v. GC–Sun Hldgs., L.P.*, 910 A.2d 1020, 1039 (Del. Ch. 2006))).

[93] *Bandera*, 2019 WL 4927053, at *26.

[94] *Id.* (internal quotation and alteration omitted) (quoting *Shearin*, 652 A.2d at 590).

[95] *Himawan v. Cephalon, Inc.*, 2018 WL 6822708, at *10 (Del. Ch. Dec. 28, 2018) (internal quotation marks omitted) (quoting *Allied Cap.*, 910 A.2d at 1039).

plaintiff to "plead and prove that the privilege among affiliates to discuss and recommend action is not applicable or, stated affirmatively, to allege facts that would make the 'interference' improper": the plaintiff must allege facts that support a reasonable inference that the "interfering party was not pursuing in good faith the legitimate profit seeking activities of the affiliated enterprises."[96] "Such a showing would, for example, be satisfied by allegations that the interference was motivated by some malicious or other bad faith purpose."[97]

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[96] *Shearin*, 652 A.2d at 590–91 (internal quotation marks omitted); *accord NAMA Hldgs*, 2014 WL 6436647, at *30 (noting a parent's intent for the subsidiary to breach the contract "will not support imposing liability for tortious interference if the breach is consistent with the good faith pursuit of the subsidiary's legitimate profit-making activities, such as through an efficient breach of contract"); *Bandera*, 2019 WL 4927053, at *27 (determining a "complaint must allege the facts that support a reasonable inference that the [affiliated entity's] interference was 'motivated by some malicious or other bad faith purpose' rather than 'to achieve permissible financial goals.'" (quoting *Shearin*, 652 A.2d at 591)); *Surf's Up Legacy P'rs, LLC v. Virgin Fest, LLC*, 2021 WL 117036, at *8 (Del. Super. Jan. 13, 2021) (explaining the complaint must "allege facts showing [the affiliate]'s interference was unjustified—a meddling motivated not by legitimate economic goals, but with bad faith to injure the [contractual counterparty]" (internal quotation marks and alterations omitted)).

Fortress sought dismissal on the grounds that Intel did not plead a lack of justification. D.I. 24 at 17. Specifically, Fortress contended Intel failed to allege that "any unpled intentional act was solely motivated by an intent to interfere." *Id.* (citing *WaveDivision Hldgs, LLC v. Highland Cap. Mgmt., LP*, 49 A.3d 1168, 1174 (Del. 2012)). *WaveDivision* explains that in considering the actor's predominant motive as one of many factors underlying a determination of lack of justification, the actor's motive will only support a finding of improper interference "[o]nly if the defendant's sole motive was to interfere with the contract." 49 A.3d at 1174. As Fortress recognized in its reply brief, its argument is even stronger through the lens of *Shearin*. D.I. 63 at 20.

[97] *Shearin*, 652 A.2d at 591; *see also, e.g.*, *Himawan*, 2018 WL 6822708, at *10–11 (rejecting as conclusory an allegation that pled the defendant "did not pursue the profit-seeking objectives of [subsidiary], but instead acted in bad faith to injure Plaintiffs," where

Assuming an underlying breach, Intel has not pled any facts to support a reasonable inference that VLSI or Fortress's alleged interference with the Agreement was motivated by a malicious or bad faith purpose, instead of financial reasons shared with Finjan. In fact, Intel's sole sentence about their justification does not mention malice or bad faith: it appears to plead they acted out of privileged economic alignment with Finjan affiliates, alleging they were not justified because they "assumed Finjan's liabilities by virtue of the same Acquisition."[98]

Intel has failed to plead that Fortress or VLSI tortiously interfered with the Agreement. Count V is dismissed.

C. There Is Not An Actual Controversy As To All Patents.

Intel also asks this Court for relief beyond the Asserted Patents, which cannot be remedied in the Infringement Actions. Count I seeks a declaratory judgment that the Agreement "Encompasses All Patents Owned or Controlled by Defendants."[99]

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the inference of bad faith was not supported); *NAMA Hldgs*, 2014 WL 6436647, at *30–31 (finding the parent interfered in bad faith by pursuing its own interest that the subsidiary did not share).

[98] Compl. ¶¶ 92, 130. In briefing, Intel asserts Fortress induced Finjan's breach to benefit VLSI, a separate affiliate, and so is not shielded by the limited affiliate privilege. D.I. 52 at 54. Intel argues it has pled that Fortress "acted maliciously and in bad faith by acquiring the Finjan Defendants, accepting the benefits of the Patent Licenses, and proceeding to cause the Finjan Defendants to breach their contractual obligations to Intel Corporation for reasons unrelated to efficient management of the Finjan Defendants." *Id.* at 55. Intel did not plead this motive, and Fortress's pursuit of enterprise profit does not constitute malice or bad faith toward Intel, as required under the limited affiliate privilege.

[99] Compl. ¶¶ 95–102; D.I. 81 at 10–11.

The parties dispute whether there is an actual controversy as to Count I beyond the Asserted Patents.[100]

"Delaware courts are statutorily authorized to entertain an action for a declaratory judgment, provided that an 'actual controversy' exists between the parties."[101] To show an "actual controversy," a party must show four factors:

> (1) It must be a controversy involving the rights or other legal relations of the party seeking declaratory relief; (2) it must be a controversy in which the claim of right or other legal interest is asserted against one who has an interest in contesting the claim; (3) the controversy must be between parties whose interests are real and adverse; (4) the issue involved in the controversy must be ripe for judicial determination.[102]

Here, the sticking point is whether the issue is ripe for judicial determination.[103] "Generally, a dispute will be deemed ripe if 'litigation sooner or later appears to be unavoidable and where the material facts are static.'"[104] Intel does not identify any litigation other than the Infringement Actions, or any other patents other than the Asserted Patents that are in dispute. Therefore, the scope of the Agreement beyond the Asserted Patents is not "ripe for judicial determination;" in the absence of

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[100] *Compare* D.I. 81 at 10–11, *with* D.I. 85 at 10; *see* Compl. ¶¶ 95–102.

[101] *XI Specialty Ins. Co. v. WMI Liquidating Tr.*, 93 A.3d 1208, 1216–17 (Del. 2014) (citing *Stroud v. Milliken Enters., Inc.*, 552 A.2d 476, 479 (Del. 1989)).

[102] *Id*. at 1217 (quoting *Stroud*, 552 A.2d at 479–80).

[103] D.I. 85 at 10 ("Intel's attempt to invoke a hypothetical, unpled dispute with respect to an untold number of alleged Fortress-owned entities or 'Fortress-controlled' patents cannot be the basis for subject matter jurisdiction in this Court." (footnotes omitted)).

[104] *XI Specialty Ins.*, 93 A.3d at 1217 (quoting *Julian v. Julian*, 2009 WL 2937121, at *3 (Del. Ch. Sept. 9, 2009)).

ripeness, there is not an actual controversy on which the Court can grant declaratory judgment. Count I is dismissed.

III. CONCLUSION

For the foregoing reasons, Defendants' Motions are **GRANTED** as to Counts I, II, IV, and V. Defendants' Motions as to Count III are **DENIED**. Count III is **STAYED**; the parties shall update the Court with any material developments.

United States Court of Appeals for the Federal Circuit

GLAXOSMITHKLINE LLC, SMITHKLINE BEECHAM (CORK) LIMITED,
Plaintiffs-Appellants

v.

TEVA PHARMACEUTICALS USA, INC.,
Defendant-Cross-Appellant

2018-1976, 2018-2023

Appeals from the United States District Court for the District of Delaware in No. 1:14-cv-00878-LPS-CJB, Judge Leonard P. Stark.

Decided: August 5, 2021

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Before MOORE, *Chief Judge*[*], NEWMAN and PROST[**], *Circuit Judges*.

Opinion for the court filed per curiam.

Dissenting opinion filed by *Circuit Judge* PROST.

PER CURIAM.

GlaxoSmithKline LLC and SmithKline Beecham (Cork) Ltd. (collectively, GSK) sued Teva Pharmaceuticals USA, Inc. in the United States District Court for the District of Delaware for infringement of claims of GSK's Reissue Patent No. RE40,000. After the jury's verdict of infringement and its award of damages, the district court granted Teva's renewed motion for judgment as a matter of law of noninfringement. *GlaxoSmithKline LLC v. Teva Pharm. USA, Inc.*, 313 F. Supp. 3d 582 (D. Del. 2018) (*Dist. Ct. Op.*). GSK appeals the JMOL, and Teva conditionally cross-appeals the jury's damages award. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

For the reasons below, we vacate the grant of JMOL, reinstate the jury's verdict and damages award, and remand for appropriate further proceedings.

BACKGROUND

GSK markets and sells the medicinal product carvedilol, a beta-blocker, under the brand name Coreg®. The Food and Drug Administration (FDA) has approved carvedilol for three indications of use. By 1997, the FDA had approved carvedilol for treatment of hypertension and congestive heart failure (CHF). Then, in 2003, the FDA approved carvedilol for a third use: to reduce cardiovascular

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[*] Chief Judge Kimberly A. Moore assumed the position of Chief Judge on May 22, 2021.

[**] Circuit Judge Sharon Prost vacated the position of Chief Judge on May 21, 2021.

mortality in patients suffering from left ventricular dysfunction following a myocardial infarction, i.e., the "post-MI LVD" indication.

When GSK began investigating carvedilol's use for treating CHF, beta-blockers were contraindicated for that use. This was because beta-blockers slow the heart rate and reduce the heart's ability to pump blood, a potentially deadly combination for patients with heart failure. Very few doctors or companies, therefore, saw the potential for investigating beta-blockers for treating CHF. Despite this skepticism, GSK spent years investigating, and conducting trials of, carvedilol for the treatment of heart failure. And at the time, the only known treatment for improving mortality rates in CHF patients was with angiotensin-converting enzyme (ACE) inhibitors. Still, even with ACE inhibitors, patients continued to die from heart failure at high rates. It was not until the FDA approved GSK's Coreg® that using a beta-blocker to treat CHF became the standard of care for reducing mortality in heart failure patients.

The carvedilol compound was patented in 1985. *See* U.S. Patent No. 4,503,067, expiration date March 5, 2007. In 1998, U.S. Patent No. 5,760,069 issued, which claimed a method of administering a combination of carvedilol and one or more of an ACE inhibitor, a diuretic, and digoxin to decrease mortality caused by CHF in a patient.

In March 2002, Teva filed an Abbreviated New Drug Application (ANDA) for FDA approval of its generic carvedilol for all three indications. It certified, under Paragraph III of the Hatch-Waxman Act,[1] that it would not launch its product until the '067 patent on the carvedilol compound expired in March 2007. *See* 21 U.S.C.

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[1] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. 98–417, 98 Stat. 1585 (1984).

§ 355(j)(2)(A)(vii)(III). Teva also certified, under Paragraph IV, that the '069 patent was "invalid, unenforceable, or not infringed." *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV). On May 24, 2002, Teva sent GSK a Paragraph IV notice stating that the claims of the '069 patent are anticipated or would have been obvious. GSK did not sue Teva upon receipt of the notice, and on November 25, 2003, GSK applied for reissue of the '069 patent under 35 U.S.C. § 251. Teva received FDA "tentative approval" for its ANDA in 2004, "for treatment of heart failure and hypertension." J.A. 7437. The approval was to become effective when the '067 patent expired in 2007.

On January 8, 2008, the PTO issued Reissue Patent No. RE40,000, and GSK notified the FDA on February 6, 2008. *See* J.A. 6880–82. The '000 patent, asserted in this case, claims a method of decreasing mortality caused by CHF by administering carvedilol with at least one other therapeutic agent. *See, e.g.*, '000 patent, col. 1, ll. 17–25. Claim 1 recites:

> 1. A method of decreasing mortality caused by congestive heart failure in a patient in need thereof which comprises[:]
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> administering a therapeutically acceptable amount of carvedilol in conjunction with one or more other therapeutic agents, said agents being selected from the group consisting of an angiotensin converting enzyme inhibitor (ACE), a diuretic, and digoxin,
>
> *wherein the administering comprises administering to said patient daily maintenance dosages for a maintenance period to decrease a risk of mortality caused by congestive heart failure, and said maintenance period is greater than six months.*

(emphasis in original). The '000 patent is listed in the FDA's publication "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the

Orange Book, as a patent claiming a method of using Coreg®.

Just before Teva launched its generic carvedilol in 2007, it certified to the FDA that its label "will not include the indication defined in use code U-233" until the expiration of the '069 patent. J.A. 6176; *see* 21 U.S.C. § 355(j)(2)(A)(viii) (section viii). Patent use code U-233 corresponded to "decreasing mortality caused by congestive heart failure." J.A. 7833. Teva's label dated "8/2007" thus included only two indications: the post-MI LVD indication and the hypertension indication. J.A. 5506, 5508. Teva's press releases and marketing materials, however, touted its generic carvedilol as "indicated for treatment of heart failure and hypertension," as the "Generic version of [GSK's] cardiovascular agent Coreg®," and as an "AB-rated generic equivalent of [GSK's] Coreg® Tablets."[2] J.A. 6347, 6353.

In 2011, following GSK's delisting of certain patents from the Orange Book, including the '069 patent and U.S. Patent No. 5,902,821, the FDA instructed Teva to "revise [its] labeling to include the information associated with patent '821 (delisted) and the associated Use Code (U-313)." J.A. 5557. It told Teva to submit labeling "that is identical in content to the approved [GSK Coreg®] labeling (including the package insert and any patient package insert

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[2] The FDA assigns an "AB rating" for a drug that is considered therapeutically equivalent to another drug. FDA, Orange Book Preface § 1.7 (41st ed. current as of Jan. 21, 2021), https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface. A therapeutically equivalent drug is one that "can be expected to have the same clinical effect and safety profile when administered to patients under the conditions *specified in the labeling*." *Id.* § 1.2 (emphasis added); *see also* 21 C.F.R. § 314.3(b) (same).

and/or Medication Guide that may be required)." J.A. 5557. The FDA also requested Teva "provide information regarding [its] position on [the '000 patent]." *Id.*

Teva amended its label to include the indication for treating patients with chronic heart failure by administering carvedilol to increase survival and to reduce the risk of hospitalization. J.A. 5532. In addition, the post-MI LVD and hypertension indications remained on the label. In response to the FDA's request for information regarding its position on the '000 patent, Teva told the FDA it believed it need not "provide certification to [the '000 patent]" because it received final approval of its ANDA before the '000 patent issued. J.A. 5554.

On July 3, 2014, GSK sued Teva and Glenmark Pharmaceuticals USA, the two largest suppliers of generic carvedilol, in the District of Delaware, alleging that each had induced infringement of the '000 patent. The action against Glenmark was severed and stayed.

During a seven-day jury trial, Teva argued the asserted claims of the '000 patent were invalid and not infringed. Teva argued it could not have induced infringement, at least prior to 2011, because it had "carved out" the indication and prescribing information for treatment of congestive heart failure in its 2007 label under section viii. Teva also argued that it could not be liable for inducement for any time period because it did not cause others to infringe the method claimed in the '000 patent.

The district court instructed the jury to assess whether Teva induced infringement during two distinct time periods: the "partial label" period and the "full label" period. J.A. 171. The partial label period was from January 8, 2008, through April 30, 2011, when Teva's label had the post-MI LVD and hypertension indications but not the chronic heart failure indication. *Id.* The full label period was from May 1, 2011, through June 7, 2015, when Teva's

label had all three indications, including the chronic heart failure indication. *Id.*

The jury found the '000 patent was not invalid, that Teva induced infringement of claims 1–3 during the partial label period, and that Teva induced infringement of claims 1–3 and 6–9 during the full label period. The jury assessed damages based on a combination of lost profits and a reasonable royalty and found Teva's infringement willful.

The district court granted Teva's renewed motion for JMOL, stating that substantial evidence did not support the verdict of induced infringement because GSK failed to prove that Teva's alleged inducement, as opposed to other factors, actually caused physicians to directly infringe by prescribing generic carvedilol for the treatment of mild to severe CHF. *Dist. Ct. Op.* at 591. The district court explained that "[w]ithout proof of causation, which is an essential element of GSK's action, a finding of inducement cannot stand." *Id.*

The district court also determined no reasonable juror could have found induced infringement based on the post-MI LVD indication in Teva's partial label, which GSK had argued instructed practice of the claimed method. *Id.* at 592 n.9. Although the district court acknowledged there is some overlap with CHF patients and post-MI LVD patients, it reasoned "the two indications are distinct and require different clinical testing and different FDA approvals to treat." *Id.* It further reasoned infringement required carvedilol be "prescribed to treat the risk of mortality ***caused by CHF***." *Id.* (emphasis in original). The district court concluded a reasonable juror could not have found Teva's post-MI LVD indication "caused or even encouraged direct infringement" of this claimed use. *Id.*

GSK appealed, arguing that substantial evidence supported the jury's finding of induced infringement and that its verdict should be reinstated. We agreed. Teva petitioned for *en banc* rehearing, which we construed as also

requesting panel rehearing. Teva argued our October 2, 2020 decision could be broadly read to impose liability on ANDA filers that carve out patented uses under section viii when seeking approval to market generic drug products, in direct contravention of the Hatch-Waxman Act. *Amici curiae* raised concerns about lack of clarity of our decision when the patented uses are carved out of the FDA-approved label. On February 9, 2021, we granted the petition for panel rehearing, vacated the October 2, 2020 judgment, and withdrew the October 2, 2020 opinions.

Amici were concerned that our prior decision could be read to upset the careful balance struck with section viii carve-outs. The Novartis Brief explained, "Generics *could* be held liable for actively inducing infringement if they marketed a drug with a label describing a patented therapeutic use or if they took active steps to encourage doctors or patients to use the drug in an infringing manner. But generics could *not* be held liable for merely marketing and selling under a 'skinny' label omitting all patented indications, or for merely noting (without mentioning any infringing uses) that FDA had rated a product as therapeutically equivalent to a brand-name drug." Novartis Br. at 1–2. We agree that Novartis accurately stated the law, and we agreed to rehear this case to make clear how the facts of this case place it clearly outside the boundaries of the concerns expressed by *amici*. As this record reflects, in both time periods, substantial evidence supports that Teva actively induced by marketing a drug with a label *encouraging a patented therapeutic use*. They did not "omit[] all patented indications" or "merely note[] (without mentioning any infringing uses) that FDA had rated a product as therapeutically equivalent to a brand-name drug." Novartis Br. at 1–2. This is a case in which substantial evidence supports a jury finding that the patented use was on the generic label at all relevant times and that, therefore, Teva failed to carve out all patented indications. This narrow, case-specific review of substantial evidence does not upset

the careful balance struck by the Hatch-Waxman Act regarding section viii carve-outs.

DISCUSSION

We apply regional circuit law for review of a district court's grant of JMOL. *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1309 (Fed. Cir. 2009). The Third Circuit reviews those grants *de novo*. *Curley v. Klem*, 499 F.3d 199, 205–06 (3d Cir. 2007). Following a jury trial, a district court should grant JMOL "sparingly" and "only if, viewing the evidence in the light most favorable to the nonmovant and giving it the advantage of every fair and reasonable inference, there is insufficient evidence from which a jury reasonably could find liability." *Marra v. Phila. Hous. Auth.*, 497 F.3d 286, 300 (3d Cir. 2007). "To prevail on a renewed motion for JMOL following a jury trial, a party must show that the jury's findings, presumed or express, are not supported by substantial evidence or, if they were, that the legal conclusion(s) implied by the jury's verdict cannot in law be supported by those findings." *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 843 F.3d 1315, 1326 (Fed. Cir. 2016).

I

INDUCED INFRINGEMENT

"Whoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). "Infringement is a question of fact, reviewed for substantial evidence when tried to a jury." *Lucent*, 580 F.3d at 1309. A finding of inducement requires establishing "that the defendant possessed specific intent to encourage another's infringement." *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006) (*en banc* in relevant part) (internal quotation marks omitted). This requires a plaintiff to show "that the alleged infringer's actions induced infringing acts and that he knew or should have known his actions would induce actual infringements." *Id.* (internal quotation

marks omitted). "While proof of intent is necessary, direct evidence is not required; rather, circumstantial evidence may suffice." *Id.* (internal quotation marks omitted). When a plaintiff relies on a drug's label accompanying the marketing of a drug to prove intent, "[t]he label must encourage, recommend, or promote infringement." *Takeda Pharm. USA, Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 631 (Fed. Cir. 2015) (citations omitted).

GSK argues that substantial evidence supports the jury's verdict of induced infringement. Throughout the trial and on appeal, GSK argued there are two indications on the labels that instruct doctors to prescribe carvedilol for uses that directly infringe the '000 patent claims: the post-MI LVD indication and the congestive heart failure indication. Thus, GSK argues both the partial label and the full label encourage infringement. We first address the partial label period and then turn to the full label period.

THE PARTIAL LABEL PERIOD

A generic producer may exclude a patented use from its label, by way of a "section viii carveout" as provided by 21 U.S.C § 355(j)(2)(A)(viii):

> (2)(A) An abbreviated application for a new drug shall contain—
>
> > (i) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (7) (hereinafter in this subsection referred to as a "listed drug");
> >
> > * * *
> >
> > (viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) for a method of

> use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

The applicant must also submit its proposed label to the FDA omitting or carving out all methods of use claimed in a patent. 21 C.F.R. § 314.94(a)(8)(iv). "FDA acceptance of the carve-out label allows the generic company to place its drug on the market (assuming the ANDA meets other requirements), but only for a subset of approved uses—*i.e.*, those not covered by the brand's patents." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 406 (2012).

GSK argues that, despite Teva's section viii certification purporting to carve out one heart failure indication and its deletion of the indication from its partial label, substantial evidence supports the jury's finding that Teva induced doctors to infringe the method of use claimed in the '000 patent. GSK argues that substantial evidence supports the jury's verdict that Teva's partial label encouraged an infringing use (via the post-MI LVD indication) and that Teva's marketing materials encouraged prescribing carvedilol in a manner that would cause infringement of the '000 patent. We agree.

A

The parties dispute whether Teva effected a section viii carve-out of GSK's patented methods of use, making Teva's label a so-called "skinny label." Since the jury found infringement, we must assume it decided that question in GSK's favor. *Williamson v. Consol. Rail Corp.*, 926 F.2d 1344, 1348 (3d Cir. 1991) ("When reviewing the jury's finding . . . , we give [plaintiff], as verdict winner, the benefit of all logical inferences that could be drawn from the evidence presented, resolve all conflicts in the evidence in his favor and, in general, view the record in the light most favorable to him."). And as a quintessential fact question, we must

uphold the jury's verdict on that point so long as substantial evidence supports it. GSK provided substantial evidence that Teva's partial label instructed the method of use claimed in the '000 patent and thus was not a skinny label.

At the outset, GSK's cardiology expert, Dr. McCullough, explained that doctors, the alleged direct infringers, receive information about generic drug products from a variety of sources, including the drug labels. J.A. 10612:1–9. He then walked through each element of claim 1 of the '000 patent and compared it to Teva's partial label. He relied on the post-MI LVD indication in Teva's partial label, which stated:

> Carvedilol is indicated to reduce cardiovascular mortality in clinically stable patients who have survived the acute phase of a myocardial infarction and have a left ventricular ejection fraction of ≤ 40% (with or without symptomatic heart failure) (*see CLINICAL STUDIES [14.1]*).

J.A. 5508 (emphasis and brackets in original). Dr. McCullough testified this description satisfied the "decreasing mortality caused by congestive heart failure in a patient" limitation. *See* J.A. 10623:6–17; *see also* J.A. 10629:19–10630:6, 10630:16–20. He also explained that post-MI LVD "is intertwined with heart failure." J.A. 10673:23–10674:1. Teva's cardiology expert, Dr. Zusman, agreed that a patient who has a left ventricular ejection fraction of less than or equal to 40% with symptomatic heart failure (as recited on Teva's partial label) would be diagnosed as suffering from congestive heart failure under the district court's construction. J.A. 11226:14–19.

GSK presented evidence that Teva's partial label also satisfied the remaining claim limitations. Dr. McCullough testified that the Dosage and Administration section of the partial label disclosed administering particular dosages that satisfied the "administering a therapeutically acceptable amount of carvedilol" and administering "daily

maintenance dosages" limitations. *See* J.A. 10624:12–18, 10624:24–10625:3, 10626:9–19, 10626:23–10627:1. The post-MI LVD indication, the portion of the label Dr. McCullough testified satisfied the CHF limitation, explicitly directs the reader to Clinical Studies § 14.1 of Teva's label. J.A. 5508. The Clinical Studies § 14.1 showed that patients taking carvedilol in the study had background treatment of ACE inhibitors and diuretics. Dr. McCullough explained this satisfied the claim limitation of administering carvedilol in conjunction with one or more other therapeutic agents selected from the group consisting of ACE inhibitors, a diuretic, and digoxin. J.A. 10625:4–19, 10625:24–10626:8; *see also* J.A. 5523 (CAPRICORN study in which 47% of patients receiving carvedilol had symptoms of heart failure, 97% also had background treatment of ACE inhibitors or angiotensin receptor blockers, and 34% had background treatment of diuretics); *Sanofi v. Watson Labs. Inc.*, 875 F.3d 636, 645 (Fed. Cir. 2017) (Indication section referencing clinical study section "expressly direct[ed] the reader to that section for elaboration of the class of patients for whom the drug is indicated to achieve the stated objective"). Finally, Dr. McCullough testified that Figure 1 in Clinical Studies § 14.1 showed treatment for longer than six months, which satisfied the "maintenance period is greater than six months" limitation. J.A. 10627:9–21, 10629:15–18, 10630:21–10631:6, 10631:12–15; *see also* J.A. 5524 (Fig. 1).

Teva characterizes GSK's argument as a "cobbl[ing] together" of disparate portions of the partial label. Teva Principal and Resp. Br. at 48, 50. The dissent appears to adopt Teva's characterization, arguing that a jury would have to "piece[] together" the partial label to arrive at the infringing use. Dis. at 18–20; *see also id.* at 33. All of the claim limitations were contained in the Indication section (which amounted to a single sentence), the Clinical Study section (to which doctors were directly referred by the Indication section), and the Dosage and Administration

section (which immediately follows the Indication section and which says how much and how often to give the carvedilol). The jury was entitled to credit expert testimony regarding the label's instructions on who should take what drug, when, why, and how, and to reject the argument that certain portions of the label were disjointed from others.

Teva relies on our decision in *Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316 (Fed. Cir. 2012). In *Bayer Schering*, the patented method of use required achieving three simultaneous effects in the body. *Id.* at 1320. The defendant's drug product label contained an indication for only one of those effects, with no discussion of safety or efficacy for the other two claimed effects. *Id.* at 1322. Thus, we held the label failed to recommend or suggest achieving the claimed combination of effects. *Id.* at 1324. Here, however, as discussed above, Dr. McCullough marched through Teva's label explaining how it met the limitations of claim 1. Unlike the absence of information in the label of *Bayer Schering*, Dr. McCullough provided testimony that Teva's partial label instructed the claimed treatment and use.

Teva never genuinely challenged Dr. McCullough's testimony regarding the contents of Teva's partial label. Teva cites portions of Dr. Zusman's testimony as purporting to contradict that the post-MI LVD indication means treating heart failure. Teva relies on Dr. Zusman's testimony that treating patients to help them survive heart attack is not treating heart failure. Teva Principal and Resp. Br. at 53 (citing J.A. 11183). But Dr. Zusman also agreed the post-MI LVD patients with symptomatic heart failure would be diagnosed as suffering from congestive heart failure under the district court's construction of that term (which has not been appealed). J.A. 11226:14–19. It was within the province of the jury to weigh the testimony presented by both sides and make its finding. *See Dardovitch v. Haltzman*, 190 F.3d 125, 140 (3d Cir. 1999) ("Credibility determinations are the unique province of a fact finder, be it a jury, or a judge sitting without a jury."); *MobileMedia Ideas LLC*

v. Apple Inc., 780 F.3d 1159, 1168 (Fed. Cir. 2015) ("[W]hen there is conflicting testimony at trial, and the evidence overall does not make only one finding on the point reasonable, the jury is permitted to make credibility determinations and believe the witness it considers more trustworthy.").

We also do not agree with Teva's argument that its partial label's recitation of treating patients "with or without symptomatic heart failure" precludes inducement since this may encourage both infringing and noninfringing uses. Teva relies on *HZNP Medicines LLC v. Actavis Laboratories UT, Inc.*, 940 F.3d 680 (Fed. Cir. 2019), and *Grunenthal GmbH v. Alkem Laboratories Ltd.*, 919 F.3d 1333 (Fed. Cir. 2019). According to Teva, when its generic carvedilol is used to treat patients without symptomatic heart failure, there is no infringement, and thus, the label's recommended use on both types of patients somehow obviates infringement. We do not find this argument persuasive, and neither of the cases cited by Teva is analogous to these facts.

In *HZNP*, the claimed method of use required three steps: applying a topical medication, waiting for the treated area to dry, and then applying a second topical product. 940 F.3d at 702. Actavis' generic label, however, only required the first applying step. The district court examined the label and held, at summary judgment, it did not induce the claimed use. *Id.* We agreed given the lack of evidence that the label encouraged, recommended, or promoted users to perform two of the three claimed steps. *Id.* In contrast, substantial evidence in this case supports the jury's determination that Teva's partial label contained information encouraging each claimed step and the preamble. Dr. McCullough's testimony that the partial label met each claim limitation and represented to doctors that the treatment decreased mortality caused by CHF supports the jury's finding. *See* J.A. 10623:6–17, 10629:19–10630:6, 10630:16–20.

In *Grunenthal*, the claimed method of use was treating polyneuropathic pain. 919 F.3d at 1336. The defendants filed section viii statements carving out treatment of diabetic peripheral neuropathy (DPN), a type of polyneuropathic pain. *Id.* at 1339. The generic labels nonetheless maintained an indication to broadly treat severe pain requiring around-the-clock treatment. Yet evidence supported that this severe pain would not necessarily be polyneuropathic, but could also be mononeuropathic or nociceptive. *Id.* In that case, the district court made a factual determination that this label did not instruct the claimed method. We found no *clear error* in the district court's finding of no inducement because the generic labels did not "implicitly or explicitly encourage or instruct users to take action that would inevitably lead to . . . treatment of polyneuropathic pain." *Id.* at 1340.[3] Here, a jury found inducement. The combination of Teva's partial label, Dr. McCullough's element-by-element testimony that the partial label explicitly instructs administering carvedilol for the claimed use of decreasing mortality caused by CHF, and Dr. Zusman's admission that the post-MI LVD indication falls within the definition of congestive heart failure is substantial evidence that supports the jury's finding.

Critically, the district court erred by treating this fact question—whether the post-MI LVD indication instructs a physician to prescribe carvedilol for a claimed use—as though it were a legal one for it to decide *de novo*. In a footnote of the district court's JMOL decision, it decided the post-MI LVD portion of Teva's label was insufficient to find that the label instructed an infringing use. *Dist. Ct. Op.* at 592 n.9. The district court erred at JMOL by making a fact

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[3] Moreover, in contrast to this case, we recognized in *Grunenthal* that the partial label was the only evidence of inducement and that we could not conclude on those facts that the district court clearly erred.

finding, namely, "[w]hile there may be some overlap between populations of patients suffering from CHF – the treatment of which is within the scope of the '000 patent's claims – and those suffering from post-MI LVD – whose treatment is outside the scope of the claims – the two indications are distinct and require different clinical testing and different FDA approvals to treat." *Id.* Whether treating post-MI LVD patients with symptomatic heart failure with carvedilol was within the scope of the claims was a fact question. It was for the jury, not this court or the district court, to resolve. "In determining whether the evidence is sufficient to sustain [the jury's finding of] liability, the court may not weigh the evidence, determine the credibility of witnesses, or substitute its version of the facts for the jury's version." *Lightning Lube, Inc. v. Witco Corp.*, 4 F.3d 1153, 1166 (3d Cir. 1993). The district court erred in reweighing the evidence and finding against GSK following the jury's verdict in its favor.

B

To be sure, the record was not devoid of contrary or equivocal evidence. Teva argues that GSK's submissions to the FDA for Orange Book listing associated with the '000 patent is such evidence. If a new drug application (NDA) has already been approved when the applicant obtains a patent, the applicant must notify the FDA of such patent within 30 days of it issuing. 21 C.F.R. § 314.53(c)(2)(ii). Under penalty of perjury, GSK submitted information for the '000 patent, which issued after carvedilol was FDA-approved, declaring it claimed a method of use for carvedilol. J.A. 6880–87 (Form FDA 3542). GSK was required in part 4.2a of its declaration to "identify the use with specific reference to the approved labeling for the drug product." J.A. 6881. It listed: "treatment of mild-to-severe heart failure of ischemic or cardiomyopathic origin, usually in addition to diuretics, ACE inhibitor, and digitalis, to increase survival." *Id.* GSK did not mention the post-MI LVD indication in this submission to the FDA. This,

however, does not appear to be the information listed in the Orange Book.

The FDA further required, in part 4.2b of the Form, that GSK "[s]ubmit the description of the approved indication or method of use that [it] propose[d] FDA include as the '*Use Code*' in the Orange Book." J.A. 6882. GSK answered: "Decreasing Mortality Caused By Congestive Heart Failure." *Id.* The FDA accepted that representation and listed the corresponding use code in the Orange Book as describing what is covered by the '000 patent.

There are two ways in which GSK's failure to identify the post-MI LVD use in its part 4.2a statement could be relevant to inducement in this case. First, that failure is relevant to whether the post-MI LVD use infringes. Second, at least for the partial label period, that failure is relevant to intent to induce infringement.[4] On both points, the jury decided against Teva.

As Teva acknowledged, GSK's submissions to the FDA are "not absolutely dispositive of infringement." *See GlaxoSmithKline LLC v. Teva Pharm. USA, Inc.*, No. 18-1976 (Feb. 23, 2021), Oral Arg. at 55:49–57:07, available at http://oralarguments.cafc.uscourts.gov/default.aspx?fl=18-1976_02232021.mp3. As we have observed, "the FDA is not the arbiter of patent infringement issues." *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1061 (Fed. Cir. 2010). In fact, the FDA has made clear that use codes in the Orange Book "are not meant to substitute for the [ANDA] applicant's review of the patent and the approved labeling."

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[4] It is hard to imagine how GSK's failure to identify that the '000 patent claims the post-MI LVD use has any bearing on the full label period, as during the full label period, Teva's listed all three indications without regard for GSK's assertions in the Orange Book or its FDA declaration.

Applications for FDA Approval to Market a New Drug, 68 Fed. Reg. 36,676, 36,683 (June 18, 2003) (to be codified at 21 C.F.R. pt. 314). The FDA further concluded that it has no expertise in patent law and that a court is the appropriate forum for determining the scope of patent rights. *Id.*; *see also* Trial Tr. at 525:12–526:15 (GSK's regulatory expert, Prof. Lietzan, discussing the FDA's statements). Teva's FDA expert, Mr. Karst, agreed that a generic may not rely upon the Orange Book use codes provided by the brand for patent infringement purposes and that ANDA applicants have a separate obligation to analyze the scope of the patents themselves:[5]

> Q. And FDA has also stated that [use codes listed in the Orange Book provided by the patentee] are not meant to substitute for the applicant's review of the patent and the approved labeling. Correct?
>
> A. That is what FDA said, correct.
>
> Q. And that is something that you understand in your line of work; is that correct?
>
> A. Yes, I do.
>
> [. . .]
>
> Q. You believe there's a separate obligation by ANDA applicants to analyze the scope of patents listed in the Orange Book to determine how to prepare their Section viii carve-out label; is that correct?

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[5] In fact, an ANDA filer can omit from its label "an indication or other aspect of labeling protected by patent," whether that patent is contained in the Orange Book or not. *See* 21 C.F.R. § 314.94(a)(8)(iv).

> A. It's correct that FDA said the statement you just had up there. I guess it's gone now, where FDA provides a statement to that effect. That is correct.

Trial Tr. at 1057:13–1058:10. Both FDA experts agreed that the FDA plays no role in determining patent infringement. The jury heard this evidence and the evidence discussed above as to GSK's claim that the post-MI LVD indication infringed the '000 patent. Thus, substantial evidence supports the jury's finding that the post-MI LVD indication infringed the '000 patent.

At oral argument on rehearing, Teva suggested that GSK's FDA submission for the Orange Book listing for the '000 patent, which according to Teva is at odds with GSK's infringement allegations, creates equitable estoppel. *See* Oral Arg. at 53:56–55:28. There are serious consequences for filing false or incomplete information to the FDA. *See id.* at 55:28–56:04 (Teva explaining the consequences including rejection of the NDA); *see also* 18 U.S.C. § 1001 (it is a criminal act to file a false declaration under penalty of perjury). Teva argues one such consequence ought to be equitable estoppel, which should preclude GSK's assertion of the '000 patent against Teva at least as to the post-MI LVD use. GSK's representations regarding the Orange Book listing of the '000 patent, Teva's reliance, and fairness go directly to an equitable estoppel defense, which has not yet been tried to the district court. The district court acknowledged that Teva raised this defense, but decided that it was "reserved to be tried to the Court at a later date." J.A. 29.

There are factual disputes regarding the estoppel issue that the district court has not yet had an opportunity to decide. For example, GSK argued on appeal that the use code that was listed in the Orange Book—"decreasing mortality caused by congestive heart failure"—covers all heart failure patients including post-MI LVD patients and that Teva's assertion that the use code covers only the CHF

indication is wrong. GSK Resp. and Reply Br. at 30. GSK further argues that "the use code is not tied to any particular indication, and the FDA tells generics that the use code 'is not meant to substitute for the applicant's review of the patent and the approved labeling.'" *Id.* (quoting 68 Fed. Reg. at 36,683). And Dr. McCullough testified that the post-MI LVD indication satisfied the first claim limitation, i.e., decreasing mortality caused by congestive heart failure. J.A. 10623:6–10623:23. It is also not clear from this record whether Teva had access to GSK's declaration (which was marked confidential and is not included in the Orange Book). Teva responds that it modified the label exactly as the FDA instructed it to in accordance with the GSK-provided use code. *See* J.A. 6908–10 (FDA mark-up of Teva label). As acknowledged above, Teva's own FDA expert, Mr. Karst, explained that an ANDA filer must perform its own analysis for patent infringement purposes. Trial Tr. at 1057:13–1058:10 (testimony of Mr. Karst). Issues of fact remain as to GSK's representations and Teva's reliance on those representations that have been "reserved to be tried" by the district court. J.A. 29.

The dissent proposes that this court leapfrog that normal process and resolve these questions of law, equity, and fact on appeal without any trial. We decline to do so. The dissent claims it is not focused on estoppel, but rather on whether "the law" permits an inference of intent from a label in light of GSK's representations to the FDA. *See* Dis. at 19. The dissent would hold that GSK's representations to the FDA in its declaration bar a finding of intent by the jury *as a matter of law* regardless of the remainder of the record. But intent is itself a question of fact, and this record contained substantial evidence from which the jury could find Teva intended to infringe despite GSK's representation to the FDA. This rule of law the dissent seeks is exactly the estoppel case made by Teva, which the district court has yet to try.

The issues before us are the issues that were tried to the jury and decided in the district court. We conclude substantial evidence supports the finding that Teva's partial label was evidence Teva instructed physicians to use its carvedilol in an infringing way. Dr. McCullough explained where Teva's partial label met each claim limitation and discussed other materials that would lead physicians to the partial label, culminating with his conclusion that Teva took action that it "intended would encourage or assist actions by another, i.e., the physician." J.A. 10644:15–19. Dr. McCullough did not testify that Teva's actions merely describe infringement; he testified that Teva's actions encouraged infringement.

The dissent's suggestion that there were only three pieces of evidence (the partial label plus the two press releases) on which the jury could have relied to find intent is equally inaccurate. The jury received Teva's partial label, extensive expert testimony, Teva's product catalogs, Teva's advertising and promotional activities, Teva's Monthly Prescribing References for doctors, and testimony from Teva's own company witnesses, all of which the jury could have relied on to find Teva intended to encourage, recommend, or promote infringement.

As the Supreme Court explained in *Grokster*:

> Evidence of active steps taken to encourage direct infringement such as advertising an infringing use or instructing how to engage in an infringing use, show an affirmative intent that the product be used to infringe, and a showing that infringement was encouraged overcomes the law's reluctance to find liability when a defendant merely sells a commercial product suitable for some lawful use.

Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd., 545 U.S. 913, 936 (2005) (citation and alterations omitted). In this case, we must presume the jury found that Teva sold carvedilol with a label that instructed physicians to use it

in an infringing manner. Our precedent has consistently held that, when a product is sold with an infringing label or an infringing instruction manual, such a label is evidence of intent to induce infringement. *See Vanda Pharm. Inc. v. West-Ward Pharm. Int'l Ltd.*, 887 F.3d 1117, 1130–31 (Fed. Cir. 2018) (no clear error in the district court's finding that the label instructions constituted a recommendation to infringe the claimed use); *Sanofi v. Watson Labs. Inc.*, 875 F.3d 636, 646 (Fed. Cir. 2017) ("The content of the label in this case permits the inference of specific intent to encourage the infringing use."); *Eli Lilly and Co. v. Teva Parenteral Med., Inc.*, 845 F.3d 1357, 1368 (Fed. Cir. 2017) ("When the alleged inducement relies on a drug label's instructions, '[t]he question is not just whether [those] instructions describ[e] the infringing mode, . . . but whether the instructions teach an infringing use *such that* we are willing to infer from those instructions an affirmative intent to infringe the patent. The label must encourage, recommend, or promote infringement.'") (citation omitted) (quoting *Takeda*, 785 F.3d at 631); *AstraZeneca*, 633 F.3d at 1060 ("The pertinent question is whether the proposed label instructs users to perform the patented method. If so, the proposed label may provide evidence of . . . affirmative intent to induce infringement."); *Arthrocare Corp. v. Smith & Nephew, Inc.*, 406 F.3d 1365, 1377 (Fed. Cir. 2005) (affirming jury's induced infringement determination when defendant distributed marketing material and manuals that instructed how to use the product in an infringing manner).[6]

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[6] Consistent with all of these cases, when a label instructs or teaches an infringing use, it can be considered evidence of intent to encourage that use. The jury was entitled to credit expert testimony regarding the label's instructions on who should take what drug, when, why, and

We assume, as we must, that the jury found the post-MI LVD use infringes the '000 patent, and that Teva's label contained instructions encouraging prescribing carvedilol in a manner that infringes the '000 patent. Throughout, the dissent claims that there was not substantial evidence upon which the jury could conclude that Teva's label would encourage doctors to prescribe Teva's carvedilol for the labeled uses. That is because, according to Teva (and the dissent), there is no evidence that doctors read labels or prescribe according to those labels. But the jury was presented expert testimony from Dr. McCullough (GSK's expert), from Dr. Zusman (Teva's expert), and from Teva's own documents to the contrary. First, Dr. McCullough testified that doctors do read labels. *See* J.A. 10612:7–9 ("Q. Two, that doctors don't read labels? Do you agree that that is the case? A. No, I disagree with that."). Second, Teva's own Monthly Prescribing References, which were "intended solely for use by the medical professional," explained that "[t]he clinician must be familiar with the full product labeling provided by the manufacturer or distributor of the drug, of every product he or she prescribes, as well as the relevant medical literature." J.A. 6196 (Teva's 2012 Monthly Prescribing Reference); *see also* J.A. 10611:19–25 (Dr. McCullough); Trial Tr. at 1253:15–23, 1254:23–1255:9 (Dr. Zusman agreeing that Teva's MPR indicates that the MPR "has been produced to provide an easily accessible reminder of basic information useful to review when prescribing medications" and that physicians should verify any questions against the labelling). In other words, the literature Teva provided to doctors told them to read labels and to prescribe according to them. While Teva's Monthly Prescribing References were published during the full label period, they powerfully refute Teva's claim that doctors do not and need not read labels in

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how, and to reject the dissent's claim that the label describes rather than instructs as to an infringing use.

conjunction with their prescribing practices. Teva's own Monthly Prescribing References merely confirm the quite logical proposition that doctors read labels and that the labels are intended to affect prescribing decisions. We cannot conclude that it would be unreasonable for the jury to think that, in 2007 or 2011, Teva believed doctors did not and need not read labels and only then wisened to the idea in 2012. In fact, Teva's own Director of National Accounts, Mr. Rekenthaler, testified to his belief that doctors would prescribe carvedilol according to the package insert (the label). Trial Tr. at 590:15–17 ("I guess my expectation is, like any drug, that it would be used as detailed in the package insert."); *id.* at 592:5–8 ("I mean my assumption would be, unless something specific was brought up, that it would be used, that the physicians would use it as they should use it, again which is detailed in our insert.").

This is record evidence that Teva intended its label to affect physician's prescribing practices, and the jury was entitled, as our caselaw has repeatedly held, to rely upon that to determine Teva's intent. But it is not the only evidence.

GSK also presented extensive expert testimony along with Teva's marketing efforts, catalogs, press releases, and testimony from Teva's own witnesses, showing that Teva encouraged carvedilol sales for CHF despite its attempted carve-out. This is evidence supporting the jury's finding that Teva induced infringement.

The jury was presented with evidence of Teva's marketing materials. Teva's Spring 2008 and Spring 2009 Product Catalogs described Teva's carvedilol as an AB rated therapeutic equivalent to Coreg®. J.A. 6221, 6270. Teva and *amici* agree that an AB rating means the generic product is therapeutically equivalent to the brand product under the conditions specified in the generic's label. As explained above, substantial evidence supports the jury's presumed conclusion that the partial label's

indication for post-MI LVD did not effectively carve out the use claimed in the '000 patent. Thus, Teva's AB rated representations under these limited circumstances, when substantial evidence supports the jury's presumed determination regarding the label's contents, are further affirmative evidence supporting the jury's inducement finding.[7]

GSK also presented evidence that, prior to the '000 patent's issuance, Teva issued two relevant press releases: one in 2004 and another in 2007. In its 2004 press release, Teva announced that the FDA granted it "tentative approval" for its carvedilol tablets, with final approval "anticipated upon expiry of patent protection for the brand product on March 5, 2007." J.A. 6347. It noted its "Carvedilol Tablets are the AB rated generic equivalent of GlaxoSmithKline's Coreg® Tablets and are indicated for *treatment of heart failure* and hypertension." *Id.* (emphasis added). The dissent suggests that Teva's "reference to heart failure" is not evidence that supports the jury's finding that Teva intended to encourage infringement of GSK's claimed method. The entire purpose of this press release is to announce its approval as a substitute for GSK's Coreg® Tablets, and it expressly says that the Teva generic "tablets are the AB-rated generic equivalent of GlaxoSmithKline's Coreg® Tablets and are indicated for treatment of heart failure and hypertension." J.A. 6347. The press release's use of "heart failure" does not parse between congestive heart failure or post-MI LVD. This is not an

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[7] We do not hold that an AB rating in a true section viii carve-out (one in which a label was produced that had no infringing indications) would be evidence of inducement. In this case, Teva's representation of AB rating would point physicians to its partial label, which, for the reasons above, the jury was free to credit as evidence of induced infringement.

errant reference to "heart failure"; it is Teva in a press release telling the world that its generic is a substitute for GSK's Coreg® tablets to treat congestive heart failure in the same manner as Coreg® (which is a method that infringed the '000 patent). The dissent criticizes our analysis, claiming that we have weakened intentional encouragement because "simply calling a product a 'generic version' or 'generic equivalent'—is now enough." Dis. at 34–35. That is not our holding or the facts.

Though the dissent seems to think the press release is not evidence of encouragement, it seems self-evident that a jury could conclude that Teva's intent in issuing a press release telling the world it could use Teva's tablets as a substitute for GSK's Coreg® tablets to treat congestive heart failure was to encourage that use. Moreover, Dr. McCullough testified that he saw the 2004 press release and that it indicates physicians should prescribe generic carvedilol for heart failure. J.A. 11656:1–10; J.A. 11657:6–10 (testifying that Teva's press release informed doctors that "it certainly *should* be" prescribed for the treatment of heart failure); J.A. 11659:11–19 (Teva's press release indicates that doctors *should* be able to prescribe generic carvedilol for heart failure). Dr. McCullough also testified that doctors consider press releases so they "know when drugs are going generic." J.A. 11655:9–24.

Teva issued a second press release in 2007 in which it stated that it had received final approval "to market its Generic version of GlaxoSmithKline's cardiovascular agent Coreg® (Carvedilol) Tablets." J.A. 6353. Dr. McCullough testified that the 2007 press release's use of "cardiovascular agent" indicated to doctors they could use Teva's carvedilol "for all indications," including heart failure. J.A. 11660:3–13. Dr. McCullough also testified that he believed that this press release would encourage doctors to prescribe Teva's generic carvedilol for the infringing indications. J.A. 10644:15–19 ("Q. And so this element that Teva took action and failed to take action, what Teva intended

would *encourage* or assist actions by another party, i.e., the physician. In your expert opinion, has that requirement been met? A. Yes." (emphasis added)) (Dr. McCullough discussing the impact of the press releases on doctors). On appeal, we review the jury's verdict for substantial evidence based upon the record; we cannot hunt outside the record to find evidence to try to contradict the verdict. The dissent claims there is no intentional encouragement because the word cardiovascular is "[a] well-understood adjective" that means "relating to the heart," and as such Teva's press release could simply be read to encourage use for non-patented heart related conditions. Dis. at 23. First, the dissent goes outside the record to make up this definition, something the district court explicitly told the jury it could not do. *See* Trial Tr. at 264 ("During the course of the trial, you must not conduct any independent research about the case . . . . In other words, you should not consult dictionaries or reference materials."). Second, there was actual testimony in the record about how the word cardiovascular in this press release would be understood by skilled artisans. *See* J.A. 11660:3–13 (McCullough testifying that a skilled artisan would understand the word cardiovascular in this press release to indicate that the generic could be used for all indications including heart failure). Third, Teva did not merely say its drug is a cardiovascular agent, leaving the world to wonder about its uses. It said its product is a generic equivalent of GSK's cardiovascular agent Coreg®. It was reasonable for the jury to conclude, especially in light of the prior press release that expressly mentioned heart failure, that Teva was again encouraging the substitution of its product for all of Coreg's® cardiovascular indications, including as claimed in the '000 patent.

We have acknowledged that, as a matter of law, affirmative acts taken before a patent issues cannot violate § 271(b). *Nat'l Presto Indus., Inc. v. W. Bend Co.*, 76 F.3d 1185, 1196 (Fed. Cir. 1996). Consistent with this rule, the

jury was instructed GSK needed to prove by a preponderance of the evidence:

> that Teva took some affirmative action, or that Teva continued to take an action that began before the '000 patent issued, after the '000 patent was issued on January 8, 2008, intending to cause the physicians to directly infringe by administering Teva's carvedilol product[.]

J.A. 168. In this case, the jury was presented with evidence from which it could infer that Teva's press releases remained on Teva's website until at least 2015. J.A. 6353 (2007 press release date stamped "4/14/2015"). Teva's Director of Marketing testified that Teva added carvedilol product information to the Teva website as part of its 2007 launch. J.A. 10991:13–22 (Suzanne Collier, Teva's Director of Marketing Communications and Trade Dress). The 2007 press release given to the jury contains a directory path showing it was stored on the Teva website as follows: "Home page>Media>Latest News." And GSK demonstrated the 2007 Teva press release was available on the Teva website as late as 2015. The press releases were extensively and repeatedly presented before the jury, with at least five witnesses discussing them. *See* J.A. 10643:2–10644:14, 11656:4–11657:5, 11659:11–11660:17 (discussed with Dr. McCullough); J.A. 11238:10–11241:14, Trial Tr. at 1241:15–1243:5 (discussed with Dr. Zusman); J.A. 10533:16–23, 10542:1–25 (discussed with Prof. Lietzan); Trial Tr. at 445:9–447:10, J.A. 10973:15–10974:23, Trial Tr. at 974:24–975:4 (discussed with Teva's Senior Director of Regulatory Affairs, Jill Pastore); Trial Tr. at 1619:9–18 (discussed with Teva's damages expert, Dr. Sumanth Addanki). Teva neither provided contrary evidence nor argued to the jury that the press releases, at least one of which could be found on the Teva website even at the time of trial, were not available on Teva's website throughout the alleged infringement period. Under these circumstances, the jury could infer, from Teva's placement of

information on its website and from its press releases, that Teva intended its website to be a source of information for prescribing doctors and that its website promoted the infringing use throughout the period of infringement.[8] Teva had encouraged in its labels, press releases, product catalogs, and marketing materials. Substantial evidence supports the jury's verdict that Teva induced infringement.

C

GSK presented evidence that Teva's partial label did not successfully carve out the patented use, and thus, Teva was selling its generic with a label which infringed the method claim. GSK presented evidence that doctors read and consider labels, that Teva's marketing materials guided doctors to the label and to its website promoting the patented use, that Teva issued press releases encouraging doctors to prescribe carvedilol for the patented use, that Teva's own employees expected doctors to prescribe carvedilol during the partial label period for the patented uses, and expert testimony that Teva's actions encouraged doctors to do so. This is substantial evidence from which a reasonable jury could conclude that Teva intentionally encouraged the practice of the claimed method. Accordingly,

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[8] The jury was even presented evidence that Teva encouraged doctors to visit its website for information about its generic drugs when prescribing them. Trial Tr. at 1245:16–19 (Teva's expert, Dr. Zusman, acknowledging that Teva advised doctors to "visit its website" to obtain product information); Trial Tr. at 1249:12–15 (same); Trial Tr. at 1251:8–11 (same); Trial Tr. at 1258:12–20 (same). Though the evidence comes from Teva's 2012 and 2013 Monthly Prescribing References for doctors (during the full label period), it was reasonable for the jury to conclude that Teva intended for doctors to visit its website for prescribing information about the Teva's products.

substantial evidence supports the jury's finding of induced infringement for the partial label period.

THE FULL LABEL PERIOD

Beginning on May 1, 2011, Teva's carvedilol label contained all three indications present in the Coreg® label. That is, in addition to the post-MI LVD and hypertension indications, Teva's label contained the "Heart Failure" indication. Specifically, it added the following indication:

> 1.1 Heart Failure. Carvedilol tablets are indicated for the treatment of mild-to-severe chronic heart failure of ischemic or cardiomyopathic origin, usually in addition to diuretics, ACE inhibitors, and digitalis, to increase survival and, also, to reduce the risk of hospitalization [see Drug Interactions (7.4) and Clinical Studies (14.1)].

J.A. 5532 (brackets in original, italics omitted). Dr. McCullough testified that the addition of the heart failure indication also met all the claim limitations of the '000 patent. J.A. 10623:24–10625:3, 10625:20–10626:11, 10626:20–10627:8, 10628:15–10629:20, 10630:7–23, 10631:7–21. Substantial evidence supports the jury's presumed finding that Teva's full label contains all of the claim limitations, which Teva does not dispute.

In addition to the information Teva placed in its press releases and on its websites, Teva sent marketing materials and catalogs to healthcare providers during the full label period. For example, Teva's 2012 Monthly Prescribing Reference, which explained a "clinician must be familiar with the full product labeling . . . of every product he or she prescribes, as well as the relevant medical literature," contained a listing for carvedilol with the heart failure indication. J.A. 6196, 6200. Dr. McCullough testified that the 2012 MPR was intended for prescribing doctors and that he and doctors across the country receive the MPR "on a regular basis." J.A. 10607:9–10608:1, 10609:19–22. He

also testified that the 2012 MPR was telling doctors to "verify any questions against the labeling or contact the company marketing the drug," that the label "provides the base information that flows to doctors," and that Teva is "clearly telling doctors they should read the labels." J.A. 10610:3–21.

Teva's 2013 MPR contained the same information, same instructions to doctors, and same carvedilol listing with the heart failure indication. J.A. 6205, 6208. Dr. Zusman agreed that one could interpret the 2013 MPR as being a part of the educational materials Teva provided to doctors and that Teva wanted the MPR to be a part of a treating doctor's toolbox. Trial Tr. at 1250:18–23, 1252:5–1253:9. He also agreed that the 2013 MPR was instructing doctors to verify the information in the MPR by referring to the product labeling or contacting the company marketing the drug, here Teva. Trial Tr. at 1254:24–1255:9, 1256:1–10. He also acknowledged that the 2013 MPR instructed doctors to visit Teva's website for more information. Trial Tr. at 1258:8–20.

Substantial evidence supports the finding that Teva encouraged physicians to use its carvedilol for an infringing purpose during the full label period. The jury was entitled to credit the full label itself containing the infringing use, Dr. McCullough's testimony that the full label contained each claim limitation, and Teva's marketing materials as demonstrating Teva specifically intended to encourage, recommend, or promote the use of carvedilol in an infringing manner. The dissent confronts none of this evidence. To be clear, the dissent would overturn a jury verdict, finding Teva's full label encouraged doctors to prescribe an infringing manner, as not supported by substantial evidence where the label undisputedly encourages an infringing uses (CHF) and when Teva tells doctors to read its label for prescribing information. To do so would be a major change in our precedent.

CAUSATION

To establish inducement, a patent owner must show that the accused inducer's actions actually induced the infringing acts of another and knew or should have known that its actions would induce actual infringement. *DSU Med.*, 471 F.3d at 1304. The jury was instructed "GSK must prove that Teva's alleged inducement, as opposed to other factors, actually caused physicians to directly infringe the '000 patent." J.A. 173. Teva could only be found liable for induced infringement if GSK showed "Teva successfully communicated with and induced a third-party direct infringer and that the communication was the cause of the direct infringement by the third-party infringer." *Id.* The jury was also instructed "GSK must prove that Teva's actions led physicians to directly infringe a claim of the '000 patent, but GSK may do so with circumstantial – as opposed to direct – evidence." *Id.*

Teva argues that it did not cause doctors to actually prescribe generic carvedilol. Teva argues that, at all relevant times, doctors were prescribing carvedilol for CHF based on information they had received for GSK's Coreg®. Teva points to guidelines from the American College of Cardiology (ACC), the American Heart Association (AHA), medical textbooks, and treatises to argue doctors already knew to treat CHF using carvedilol long before Teva launched its generic. Teva argues that this information, not its actions, made physicians aware of all the benefits of carvedilol for heart failure patients. The district court accepted Teva's argument as sufficient to overcome the jury's verdict in GSK's favor. *Dist. Ct. Op.* at 594. We do not agree.

The jury had before it Teva's partial label, full label, various marketing materials, and press releases. It heard from the expert witnesses that doctors read labels and that Teva's labels satisfied all of the claim limitations. *See* J.A. 10612:7–9 (testimony of Dr. McCullough: "Q. Two, that

doctors don't read labels? Do you agree that that is the case? A. No, I disagree with that."). It also heard that doctors received marketing materials from Teva, that these materials directed doctors to prescribe according to the labels, and that these materials told doctors to visit Teva's website for more information regarding its products. Teva tried to convince the jury that doctors do not read labels even after its own marketing material, which was sent directly to doctors, explicitly instructed them to read the labels.

Despite all of this evidence, Teva asks us to supplant the role of the jury and reweigh evidence in its favor. But it was for the jury to decide—not us, the district court, or the dissent—whether Teva's efforts actually induced infringement. It was fair for the jury to infer that when Teva distributed and marketed a product with labels encouraging an infringing use, it actually induced doctors to infringe.[9] "Indeed, we have affirmed induced infringement verdicts based on circumstantial evidence of inducement (e.g., advertisements, user manuals) directed to a class of direct infringers (e.g., customers, end users) without requiring hard proof that any individual third-party direct infringer was actually persuaded to infringe by that material." *Power Integrations*, 843 F.3d at 1335; *see also Arthrocare*, 406 F.3d at 1377 ("There was also strong circumstantial evidence that Smith & Nephew's probes were used in an infringing manner, and that Smith &

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[9] The dissent acknowledges that an example of when a jury might reasonably infer causation is when a product's user manual encourages an infringing use. Dis. at 32–33 (collecting cases). But the dissent would hold, nonetheless, that a jury cannot infer causation from the full label, which undisputedly contains all of the claim limitations, despite the evidence showing the full label instructs doctors to infringe, just as a user manual.

Nephew induced users to employ the probes in that way."). Given Teva distributed other materials in addition to its labels, we do not have to decide in this case whether the labels alone are enough to establish causation. The dissent criticizes the presence of circumstantial evidence, but as the jury was correctly instructed, "[i]t is your job to decide how much weight to give the direct and circumstantial evidence. The law makes no distinction between the weight that you should give to either one, nor does it say that one is any better evidence than the other." J.A. 147 (Jury Instruction 1.4). The jury had sufficient circumstantial evidence, in the form of labels, marketing materials, catalogs, press releases, and expert testimony, for it to conclude that Teva succeeded in influencing doctors to prescribe carvedilol for the infringing use. We thus vacate the district court's grant of JMOL of no induced infringement and reinstate the jury verdict, which was supported by substantial evidence.

II

DAMAGES

The Patent Act provides: "the court shall award [the patent owner] damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use of the invention by the infringer." 35 U.S.C. § 284. To recover lost profit damages, "the patent owner must show 'causation in fact,' establishing that 'but for' the infringement, he would have made additional profits." *Grain Processing Corp. v. Am. Maize-Prod. Co.*, 185 F.3d 1341, 1349 (Fed. Cir. 1999).

GSK's damages expert testified that 17.1% of Teva's generic carvedilol sales during the period of infringement were for the method claimed in the '000 patent. Teva does not dispute this calculation. The jury assessed damages of $234,110,000 based on lost profits, plus a reasonable royalty payment of $1,400,000. The verdict amount is about half of that presented by GSK's damages expert. Teva

argues that, if the jury had been properly instructed, it would have assessed no damages or at most only a reasonable royalty.

Teva argues the jury should have been instructed that GSK must prove that, for every infringing sale Teva made, the direct infringer would have purchased Coreg® rather than another generic producer's carvedilol. The district court declined to present that instruction, explaining:

> The undisputed evidence is that [Teva's] generic carvedilol is interchangeable with the generic carvedilol of the non-party manufacturers; therefore, the generic carvedilol of these non-party manufacturers is an ***infringing alternative*** – and ***not*** a non-infringing alternative. These non-parties' products, thus, would not exist in the but-for world, which must be constructed to include "likely outcomes with ***infringement factored out of the economic picture.***" *Grain Processing Corp. v. Am. Maize-Prods. Co.*, 185 F.3d 1341, 1350 (Fed. Cir. 1999) (emphasis added).

J.A. 222 (Memorandum Order (June 9, 2017) (emphasis in original)). The district court recognized that "[i]t is undisputed that, at all times relevant to the lost profits analysis, there were generic carvedilol tablets available from at least eight different generic manufacturers," J.A. 222 n.3, and stated that "[i]t doesn't matter whether the ***sales*** by other generic suppliers would be non-infringing, because the ultimate ***use*** of those products by doctors ***would*** be infringing and thus not a permissible consideration." J.A. 223 (emphasis in original).

Teva argues that it was incorrect to instruct the jury that "[t]he use of the acceptable substitutes also must not infringe the patent because they did not include all the features required by the patent. For example, the use of generic carvedilol supplied by companies other than Teva was not an acceptable non-infringing substitute." J.A. 195

(Jury Instruction 6.3.3). Teva argues that this instruction ignores the reality of the marketplace because other carvedilol producers who had not been sued for infringement would have made the sales Teva made, in part because pharmacies would automatically substitute generic carvedilol for Coreg® prescriptions. Teva's argument is in conflict with long-standing precedent that the presence of noninfringing alternatives precludes an award of lost profits, but the presence of other infringers does not.

The district court correctly instructed the jury that the availability of carvedilol from other generic producers is not a "non-infringing substitute." GSK's expert's analysis accounted for Teva's sales for the infringing use, amounting to 17.1% of Teva's total carvedilol sales. Had another generic producer made those sales, those uses too would have been infringing. The other generic carvedilol producers were, therefore, not noninfringing alternatives. *See Grain Processing*, 185 F.3d at 1350 ("The 'but for' inquiry therefore requires a reconstruction of the market, as it would have developed absent the infringing product, to determine what the patentee would have made.") (internal quotations and alterations omitted); *Micro Motion, Inc. v. Kane Steel Co., Inc.*, 894 F.2d 1318, 1322 (Fed. Cir. 1990) ("There is precedent for finding causation despite an alternative source of supply if that source is an infringer."). Accordingly, the damages verdict, which is not otherwise challenged, is sustained.

CONCLUSION

Because substantial evidence supports the jury's verdict of induced infringement, we vacate the district court's grant of JMOL. Because the district court did not err in its jury instructions on damages, we affirm on the cross-appeal. We remand for appropriate further proceedings.

VACATED-IN-PART, AFFIRMED-IN-PART, AND REMANDED

COSTS

Costs are awarded to GSK.

United States Court of Appeals for the Federal Circuit

GLAXOSMITHKLINE LLC, SMITHKLINE BEECHAM (CORK) LIMITED,
Plaintiffs-Appellants

v.

TEVA PHARMACEUTICALS USA, INC.,
Defendant-Cross-Appellant

2018-1976, 2018-2023

Appeals from the United States District Court for the District of Delaware in No. 1:14-cv-00878-LPS-CJB, Judge Leonard P. Stark.

PROST, *Circuit Judge*, dissenting.

GSK's patent on carvedilol expired in 2007. At the time, however, it still had a patent on one of carvedilol's three FDA-approved uses. Because the FDA cannot authorize a generic version of a drug that would infringe a patent, this one remaining patented use could have prevented a less-expensive, generic carvedilol from coming to market altogether—even though the drug *itself* and other uses of it were unpatented. Congress saw this problem coming. It wanted to make sure that one patented use wouldn't prevent public access to a generic version of a drug that also has unpatented uses. *See Caraco Pharm.*

Labs. Ltd. v. Novo Nordisk A/S, 566 U.S. 399, 415 (2012). So it created rules for just this situation.

These rules, embodied in the so-called skinny-label provisions of the Hatch-Waxman Act, are straightforward. If a brand drug company (here, GSK) has a patent on one of a drug's uses, it tells the FDA which use is patented. In fact, it tells the FDA exactly what language from its label is covered by its patents. The FDA will then permit a generic version of that drug to come to market if the manufacturer "carves out" such use from its drug label by omitting the language that the brand drug company identified. That's what happened here. GSK's sworn FDA filings identified just one use as patented. So Teva carved out that use and came to market with its "skinny" label. It played by the rules, exactly as Congress intended. It sold its generic for years without controversy.

And then, in the seventh year, GSK finally sued. It alleged that, even though Teva's skinny label carved out the very use—indeed, the *only* use—that GSK said was patented, the label showed that Teva intended to encourage an infringing use. GSK also supported its inducement case by pointing to two cursory, pre-patent press releases that announced Teva's drug's approval (or "tentative" approval) and called it the generic equivalent of GSK's brand drug Coreg. The evidence of inducement—i.e., that Teva had culpable intent to encourage infringement and that its skinny label or press releases caused doctors' prescribing practices—was thin to nonexistent. But a jury found Teva liable all the same. This sometimes happens. And when it does, there is a remedy: a court will reverse a jury's verdict if there is insufficient evidence to support it. The experienced trial judge sensibly did just that.

The majority, now on its second try, again reinstates the verdict nonetheless. Its first try prompted widespread criticism concerning the troubling implications for skinny labels. This effort is no better. With reasoning sometimes

labored, sometimes opaque, the majority strains to prop up a jury verdict that is unsupportable. For example, based on language that remained on the skinny label after Teva's carve-out, the majority finds it reasonable to infer that Teva *intentionally encouraged* infringement. It finds this reasonable even though Teva, by carving out everything that GSK said would infringe, was trying to *avoid* having its label encourage infringement. The majority then indulges the inference that doctors, as a class, *relied* on Teva's skinny label to infringe, even though every expert cardiologist at trial said he *didn't even read* the label to make prescribing decisions. And, most troubling, the majority is willing to see culpable intent behind a generic's describing its product as the "equivalent" of a brand drug—in a system that *requires* generic drugs to be equivalent, and in which everyone understands that generic drugs are equivalent.

I write in this case because far from being a disagreement among reasonable minds about the individual facts, this case signals that our law on this issue has gone awry. I am particularly concerned with three aspects of the majority's analysis. First, even setting aside the majority's willingness to glean intentional encouragement from a label specifically designed to avoid encouragement, the majority further weakens the intentional-encouragement prong of inducement by effectively eliminating the demarcation between describing an infringing use and encouraging that use in a label. Second, the majority defies basic tort law by eviscerating the causation prong of inducement. The upshot of these two moves is that a plaintiff now has to show very little for a jury to speculate as to the rest. Third, the majority creates confusion for generics, leaving them in the dark about what might expose them to liability. These missteps throw a wrench into Congress's design for enabling quick public access to generic versions of unpatented drugs with unpatented uses.

I. BACKGROUND

A. *Hatch-Waxman: Congress's Compromise*

With the Hatch-Waxman Act, Congress contemplated this case. Indeed, Congressman Waxman himself agrees.[1] When Congress passed the Act, it enacted a complex statutory framework to balance generic and brand interests. *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585.[2] One effect was to bolster patent terms for brand companies. *Eli Lilly & Co. v. Medtronic Inc.*, 496 U.S. 661, 669 (1990). Another was to "speed the introduction of low-cost generic drugs to the market," *Caraco*, 566 U.S. at 405, in part by permitting immediate market entry for drugs with at least one unpatented FDA-approved use.[3]

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[1] *See* Brief of Amicus Curiae Former Congressman Henry A. Waxman in Support of Petition for Rehearing En Banc 3–8, ECF No. 170 ("Waxman Br.").

[2] *See generally* Brief of Amici Curiae Fifty-Seven Law, Economics, Business, Health, and Medicine Professors in Support of Cross-Appellant's Petition for Rehearing En Banc, ECF No. 171 ("57 Law Professors Br."); Waxman Br.; Brief of Amicus Curiae Association for Accessible Medicines in Support of Defendant-Cross-Appellant in Support of Affirmance 1–9, ECF No. 69; Brief for the Association for Accessible Medicines as Amicus Curiae in Support of Rehearing En Banc 5–7, ECF No. 164.

[3] *See also Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1358 (Fed. Cir. 2003); H.R. Rep. No. 98–857, pt. 1, at 14–15 (1984) ("The purpose . . . is to make available more low cost generic drugs by establishing a generic drug approval procedure . . . ."); *id.* at 22 (explaining that a "listed drug may be approved for two indications. If the [generic] applicant is seeking approval only for Indication No. 1, and not Indication No. 2 because it is protected

Under Congress's design, the FDA regulates the manufacture, sale, and labeling of prescription drugs. *See Caraco*, 566 U.S. at 404–05. The process begins when a brand manufacturer submits a new drug application ("NDA"). The NDA must include a proposed label describing the specific uses—called indications—for the drug. *Id.* at 404; *see* 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.50(a)(1), (e)(2)(ii). *See generally* 21 C.F.R. pt. 201.

Once the FDA has approved a brand drug, another company may seek permission to market a generic version by filing an abbreviated new drug application ("ANDA"). Because the Act is designed to minimize the barriers to entry for generic drugs, the generic doesn't have to rehash the brand's safety-and-efficacy trials. It must, however, show that what it manufactures is bioequivalent to the brand drug. 21 U.S.C. § 355(j)(2)(A)(iv), (j)(4)(F); 21 C.F.R. § 314.94(a)(7)(i).[4] And the generic's proposed labeling must essentially copy the brand drug's label. *See* 21 U.S.C. § 355(j)(2)(A)(i), (v), (j)(4)(G); *Caraco*, 566 U.S. at 406. Thus, by congressional design, generic approval is a comparison of equivalence between the generic and a specific brand drug.

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by a use patent, then the applicant must make the appropriate certification and a statement explaining that it is not seeking approval for Indication No. 2").

[4] "Bioequivalence is the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed [bioequivalence] study." 21 C.F.R. § 314.3(b). That is, two drugs are "bioequivalent" if they would be expected for all practical purposes to be the same.

Often a generic wants to launch while patents remain on a drug or its uses. Anticipating this, Congress provided two pathways for generics to show that a proposed label will not infringe.

The first pathway is to file a certification explaining why the generic label will not infringe any patent that a brand has identified to the FDA as covering the drug. The commonly used "paragraph IV" certification states that a generic label will not infringe because the patent "is invalid or will not be infringed by the manufacture, use, or sale of the [generic] drug." 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Paragraph IV often prompts litigation. If a generic, armed with a good-faith paragraph IV argument, files an ANDA with a brand's full label, the Hatch-Waxman Act allows the brand to sue and entitles it to an automatic 30-month stay of final FDA approval of the generic drug while the underlying patent issues are worked out in court. *See* 35 U.S.C. § 271(e)(2)(A); 21 U.S.C. § 355(j)(5)(B)(iii); *Eli Lilly*, 496 U.S. at 670–71, 676. This first pathway, then, has parties sort things out up front if infringement or validity are in legitimate dispute.

The second pathway—and the one relevant here—is available if at least one brand-labeled use is unpatented. If that's so, the generic can just "carve out" the patented uses from its label. *See* 21 U.S.C. § 355(j)(2)(A)(viii) ("section viii"); 21 C.F.R. § 314.94(a)(8)(iv); *Caraco*, 566 U.S. at 404–07; *Takeda*, 785 F.3d at 630 ("Congress intended that a single drug could have more than one indication and yet that an ANDA applicant could seek approval for less than all of those indications." (cleaned up)). The result, an exception to "the usual rule that a generic drug must bear the same label" as the brand, *Caraco*, 566 U.S. at 406, is commonly called a "skinny" or "partial" or "carve-out" label.

Because the skinny-label pathway's availability depends on at least one brand-labeled use being unpatented, the FDA needs to know whether any labeled uses are

unpatented—and which. More pragmatically, because the FDA "cannot authorize a generic drug that would infringe a patent," *Caraco*, 566 U.S. at 405, it needs assurance that a generic's skinny label has carved out the patented brand-labeled uses, leaving behind only unpatented ones. But because the FDA is not an arbiter of patent issues,[5] how can it know whether the skinny-label pathway is available and whether it can approve a given label?

The solution that worked—before today, at least—was for the FDA and generics to rely on what brands say their patents cover. *See Caraco*, 566 U.S. at 407 ("[W]hether section viii is available to a generic manufacturer depends on how the brand describes its patent."); *see also* 21 U.S.C. § 355(b), (c) (requiring submission of patent information with NDA). In particular, a brand submits under penalty of perjury a declaration identifying "each pending method of use or related indication and related patent claim" and "the specific section of the proposed labeling for the drug product that corresponds to the method of use claimed by the patent submitted." 21 C.F.R. § 314.53(c)(2)(O) (2008).[6] This declaration also contains a brand-crafted, 240-character "use code."[7] 68 Fed. Reg. at 36,683, 36,686, 36,697; *see*

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[5] Indeed, it routinely disclaims expertise on that front. *See, e.g.*, 68 Fed. Reg. 36,676, 36,683 (2003) ("[W]e have long observed that we lack expertise in patent matters."); *Caraco*, 566 U.S. at 406–07.

[6] Subsequent amendments to the FDA's regulations now require even *more* detail, underscoring the critical public-notice function of patent declarations. *See, e.g.*, 21 C.F.R. § 314.53(c)(2)(O) (2020).

[7] The majority quotes a portion of the Federal Register saying that use codes "are not meant to substitute for the [ANDA] applicant's review of the patent and the approved labeling" and relies on testimony concerning the same. Maj. 20–21 (alteration in original) (quoting 68 Fed.

also 21 C.F.R. § 314.53(c). This "use code" appears in the Orange Book,[8] a reference in which brands list the patents on their drugs and the covered uses to provide notice to generics and the FDA. The FDA relies on what the brand says: "In determining whether an ANDA applicant can 'carve out' the method of use, . . . we will rely on the description of the approved use provided by the NDA holder or patent owner in the patent declaration and listed in the Orange Book." 68 Fed. Reg. at 36,682; *see also Caraco*, 566 U.S. at 406 (in assessing a proposed skinny label, the FDA looks to what the brand says, takes it "as a given," and approves the label only if there is no perceived overlap).

Reg. at 36,683); *see also id.* at 21–23. It bears emphasizing that this statement refers specifically to the 240-character use code (given its length limitations and particular notice role), as distinct from other parts of the declaration (e.g., part 4.2a) identifying the label language corresponding to the claimed method. The full context of the passage makes this clear:

> Use codes are intended to alert ANDA applicants to the existence of a patent that claims an approved use. They are not meant to substitute for the applicant's review of the patent and the approved labeling. We understand that in some cases 240 characters may not fully describe the use as claimed in the patent. The declaration, which includes the complete description of the method-of-use claim and the corresponding language in the labeling of the approved drug, will be publicly available after NDA approval.

68 Fed. Reg. at 36,683.

[8] U.S. Food & Drug Admin., *Approved Drug Products with Therapeutic Equivalence Evaluations* (40th ed. 2020).

The point is clarity. Hatch-Waxman is designed to resolve patent disputes as early as possible.[9] And to know whether there *is* a dispute, the FDA and generic manufacturers rely on a brand's representations of which labeled indications are patented. *See, e.g.*, 68 Fed. Reg. at 36,682.

B. *Carvedilol*

Carvedilol, the drug here, is well studied and well understood. By 2007, the compound itself was no longer patented, nor were most uses of it.

Carvedilol is a beta blocker, a class of drugs used since the 1960s to treat heart conditions. Carvedilol in particular was developed in the 1980s and was covered by U.S. Patent No. 4,503,067, which issued in 1985 and claimed the compound itself.

By the early 1990s, research from various groups revealed that beta blockers could be useful for treating a condition called congestive heart failure ("CHF"), which prevents the heart from being able to deliver enough oxygenated blood to the body. By 1995, GSK had already received approval for an NDA under the brand name Coreg for hypertension. A supplement to that NDA added the CHF indication to the label in 1997. After the approval of the CHF labeling, GSK received U.S. Patent No. 5,760,069, relating to a particular manner of using carvedilol with other drugs to treat CHF. GSK listed the '069 and

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[9] *See* Brief of Amici Curiae Novartis Pharmaceuticals Corporation and Sandoz Inc. in Support of Rehearing En Banc 7, ECF No. 168 ("Novartis & Sandoz Br.") ("Both branded and generic pharmaceutical companies require stable, predictable legal environments to operate effectively. Patent litigation inherently entails some uncertainty, but the governing legal framework should be as predictable as possible and consistent with Congress's intent.").

'067 patents in the Orange Book. Eventually, and well before any generic launched, carvedilol became the standard of care for CHF. This standard was incorporated into the official guidelines of the American College of Cardiology and American Heart Association (as well as numerous medical textbooks and journals) and taught to medical students around the country.

As the 2007 expiration of GSK's carvedilol compound patent approached, interest grew among generics. Upon this expiration, generics would be able to market carvedilol in one of two ways: either with an all-indications label (by challenging GSK's method patent under a paragraph IV certification) or by simply omitting any patented uses from the label (with a section viii statement). Teva first chose the former, reasoning—correctly, as it turned out—that GSK's '069 method patent was invalid. And so in mid-2002 Teva filed its ANDA with a proposed full label directed to hypertension and CHF, certifying that it would wait for GSK's compound patent to expire but that GSK's '069 method patent was invalid. J.A. 3003–19, 5463. GSK did not sue or seek to block Teva's approval. Instead it sought reissue of its '069 patent, admitting invalidity of the original and adding narrowing limitations to overcome validity challenges.

In 2003, GSK got approval to add another indication to its label: post-MI LVD.[10] This entailed a discrete new set of label text, with new underlying clinical studies and new instructions. Teva likewise updated the label accompanying its pending ANDA to include all three indications. In 2004, the FDA determined that Teva had shown its product

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[10] This condition concerns patients who have recently suffered a heart attack (a "myocardial infarction," or "MI") and whose hearts have trouble pumping blood ("left ventricular dysfunction," or "LVD").

to be bioequivalent to GSK's and granted it tentative approval pending resolution of any exclusivity issues.

But by 2007—the year GSK's compound patent was set to expire—it was apparent that other generic manufacturers had opted for skinny labels instead. So Teva did too, informing the FDA that it now intended to carve out from GSK's label the uses GSK said were patented.

Again, GSK's label contained three sets of instructions for three distinct indications: CHF, post-MI LVD, and hypertension:

INDICATIONS AND USAGE

Congestive Heart Failure: COREG is indicated for the treatment of mild to severe heart failure of ischemic or cardiomyopathic origin, usually in addition to diuretics, ACE inhibitor, and digitalis, to increase survival and, also, to reduce the risk of hospitalization (see CLINICAL TRIALS).

Left Ventricular Dysfunction Following Myocardial Infarction: COREG is indicated to reduce cardiovascular mortality in clinically stable patients who have survived the acute phase of a myocardial infarction and have a left ventricular ejection fraction of ≤40% (with or without symptomatic heart failure) (see CLINICAL TRIALS).

Hypertension: COREG is also indicated for the management of essential hypertension. It can be used alone or in combination with other antihypertensive agents, especially thiazide-type diuretics (see PRECAUTIONS, Drug Interactions).

J.A. 7992. And according to GSK's sworn declaration to the FDA (which appropriately tracked the label's language), only one of these three was patented—CHF:

4.2a If the answer to 4.2 is "Yes," identify with specificity the use with reference to the proposed labeling for the drug product.	Use: *(Submit indication or method of use information as identified specifically in the approved labeling.)* Treatment Of Mild-To-Severe Heart Failure Of Ischemic Or Cardiomyopathic Origin, Usually In Addition To Diuretics, ACE Inhibitor, And Digitalis, To Increase Survival

J.A. 6895. Faithful to GSK's declaration, the FDA forwarded Teva a redlined label for use that omitted everything GSK had said the '069 method patent covered:

1 INDICATIONS AND USAGE

~~**1.1 Heart Failure**~~

~~COREG is indicated for the treatment of mild-to-severe heart failure of ischemic or cardiomyopathic origin, usually in addition to diuretics, ACE inhibitors, and digitalis, to increase survival and, also, to reduce the risk of hospitalization *(see CLINICAL STUDIES [14.1]).*~~

1.1 Left Ventricular Dysfunction following Myocardial Infarction

Carvedilol is indicated to reduce cardiovascular mortality in clinically stable patients who have survived the acute phase of a myocardial infarction and have a left ventricular ejection fraction of =40% (with or without symptomatic heart failure) *(see CLINICAL STUDIES [14.1]).*

1.2 Hypertension

Carvedilol is indicated for the management of essential hypertension. It can be used alone or in combination with other antihypertensive agents, especially thiazide-type diuretics *(see DRUG INTERACTIONS [7.2]).*

J.A. 6913. It instructed Teva to use that label, which Teva did—with the same carve-out as the other seven generic manufacturers that launched at that time.

After the generics launched, GSK's '069 method patent reissued as U.S. Patent No. RE40,000, the patent relevant here. GSK added several narrowing limitations to the '000 patent to save it from invalidity. With the reissue process now completed, GSK delisted its '069 method patent from the Orange Book and listed the '000 patent in its stead—again submitting a sworn declaration identifying *only* the CHF indication as covered. J.A. 6880–87. Consistent with this representation, GSK did not sue the generics, whose skinny labels included everything but CHF.

Years later in 2011, the FDA directed Teva to revise its label to include the CHF indication. Teva complied. The skinny-label period thus ended and the full-label period began. Teva did not issue a press release or otherwise notify doctors of the change to its label. Indeed, Teva did not change anything about how it marketed its generic

carvedilol; it continued to sell its product in the same manner since approved. And, to little surprise, nothing changed in the market: Teva and GSK maintained their respective market shares, and no doctor's prescribing habits changed.

C. *This Litigation*

GSK did not sue in 2004 when Teva made its full-label paragraph IV certification. Nor in 2007 when Teva launched its skinny-label generic. Nor in 2008 when GSK's '000 patent emerged from reissue. Nor even in 2011 when Teva transitioned to the full label. It sued instead in 2014, just before the '000 patent expired.

The lawsuit ultimately led to a seven-day jury trial in 2018. The jury was asked to determine whether Teva induced infringement of the '000 patent based on the skinny-label period and the full-label period separately. It found that Teva induced infringement of the '000 patent based on both labels. It also found that GSK was entitled to $234.1 million in lost profits and $1.4 million in reasonable-royalty damages.

After the verdict, Teva filed a renewed motion for JMOL, arguing that GSK had not presented legally sufficient evidence to support a finding of inducement. The district court agreed and granted Teva's motion. *See GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 313 F. Supp. 3d 582 (D. Del. 2018). GSK appealed, and Teva cross-appealed as to damages.

The case was argued to us in September 2019. In October 2020, the majority issued a first opinion reversing the district court's JMOL. That opinion prompted widespread consternation and confusion, as described in Teva's petition for rehearing and the eight amicus briefs in support. Among these amici: both generics *and* brands, fifty-seven law professors, and Congressman Waxman. *See* Novartis & Sandoz Br.; 57 Law Professors Br.; Waxman Br.

Following these submissions, the majority vacated its first opinion and ordered another round of oral argument. Order, ECF No. 181. The majority now issues a second opinion reaching the same result as before, but with new reasoning. In particular, it now declares that this is not a "true" skinny-label case. *E.g.*, Maj. 10–11, 28 n.7. But this remains a skinny-label case, the record remains the record, and inducement liability remains unsupportable.

II. DISCUSSION

Although the JMOL standard is well settled, two points bear emphasizing. First, while we give the verdict winner the benefit of "every favorable and reasonable inference," *Dun & Bradstreet Software Servs., Inc. v. Grace Consulting, Inc.*, 307 F.3d 197, 205 (3d Cir. 2002), the operative word here is "reasonable." Indeed, "only all *reasonable*" inferences need be drawn in GSK's favor, not "*all* possible inferences." *See Villiarimo v. Aloha Island Air, Inc.*, 281 F.3d 1054, 1065 n.10 (9th Cir. 2002). Second, if too many inferences must be strung together to support the verdict, the verdict is likely unsupportable. *See Roebuck v. Drexel Univ.*, 852 F.2d 715, 736 (3d Cir. 1988) ("Although we believe that each of the inferences that we have discussed [is] individually logically sound, we recognize that at some point too many inferences become[s] mere speculation . . . ."); *cf. United States v. Weber*, 923 F.2d 1338, 1345 (9th Cir. 1990) ("Each of these inferences standing alone may be reasonable. But with each succeeding inference, the last reached is less and less likely to be true.").

As to induced infringement under 35 U.S.C. § 271(b), GSK bore the burden at trial to prove two things relevant here. First, GSK had to prove that, more likely than not, Teva engaged in "culpable conduct, directed to encouraging another's infringement." *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006) (en banc in relevant part); *see Metro-Goldwyn-Mayer Studios Inc. v. Grokster*, 545 U.S. 913, 937 (2005) ("The inducement rule . . .

premises liability on purposeful, culpable expression and conduct . . . ."). In other words, not only must Teva have "possessed specific intent to encourage another's infringement," *DSU*, 471 F.3d at 1306, it must have taken "affirmative steps to bring about [that] desired result," *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 760 (2011).

Second, GSK had to prove that, more likely than not, Teva's affirmative steps actually *caused* the infringement it wanted to bring about. *DSU*, 471 F.3d at 1304 (plaintiff must show that "the alleged infringer's actions induced infringing acts"); *see Grokster*, 545 U.S. at 936–37 (when defendant takes "affirmative steps" to "foster infringement, [it] is liable for the *resulting* acts of infringement by third parties" (emphasis added)); *Sanofi v. Watson Labs. Inc.*, 875 F.3d 636, 644 (Fed. Cir. 2017) (noting the "purposeful-causation connotation" of the Supreme Court's characterization of inducement).

The discussion that follows has three parts. Part A addresses the lack of inducement during the skinny-label period, as well as the flaws in the majority's analysis. Part B does the same for the full-label period. Part C addresses more broadly why the majority's analysis has troubling implications for skinny labels and inducement law generally.

A. *The Skinny-Label Period*

For the skinny-label period—that is, from Teva's skinny-label launch in 2007 to its full-label amendment in 2011—the majority relies on three key pieces of evidence to conclude that substantial evidence supports the verdict: the skinny label itself (in particular, the post-MI LVD indication on that label) and two press releases distributed before the '000 patent issued—one from 2007, another from 2004. I discuss each in turn, followed by the majority's supposedly substantial other evidence of intent. From them, alone or combined, no reasonable jury could have found (1) culpable intent to encourage infringement or (2) causation, much less both.

1. The Skinny Label Itself

Before discussing what the skinny label said, recall what it didn't say—and why. The label omitted the CHF indication (and only the CHF indication) because GSK's sworn FDA filings asserted patent coverage of the CHF indication (and only the CHF indication). Analogizing to a typical patent case, it's as though Teva had drafted a potentially infringing user manual and then, abiding by the patentee's clear guidance, deleted all the pages that might be viewed as encouraging infringement of a patented method. Ironically, everything about this process signals that, far from intending to encourage infringement, Teva very much intended *not* to encourage infringement with its skinny label.

Of course, this will likely be true of most generics that get approved via the Hatch-Waxman section viii skinny-label pathway. Indeed, inferring intentional encouragement to infringe a method—from a label that has intentionally omitted everything that the brand said covers that method—is a lot to ask of a reasonable factfinder. Only once has this court upheld an inducement finding involving a putative skinny label, and that case had a crucial, additional fact: the generic knew it had an infringement problem. *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1060 (Fed. Cir. 2010); *see Grunenthal GmbH v. Alkem Labs. Ltd.*, 919 F.3d 1333, 1340 (Fed. Cir. 2019) ("[*AstraZeneca*] held that specific intent could be inferred because the defendant proceeded with a plan to distribute the generic drug knowing that its label posed infringement problems."). By contrast, GSK put on no similar evidence here. Indeed, the facts surrounding Teva's skinny label are simple and undisputed.

The majority nonetheless manufactures a factual dispute, all on its own. It surmises that: maybe, just maybe, GSK's declarations were confidential, hidden from Teva's view—the implication being that Teva *couldn't* have relied

on them.[11] Maj. 23. Of course, GSK itself has never made this argument, despite having every incentive to do so (given how Teva featured the declarations and their significance to the jury, the district court, and this court). It's easy to guess why: the FDA confirms that the declarations are available to the public. 68 Fed. Reg. at 36,683.

At any rate, the majority's confidentiality conjecture is a red herring. Even if it were true that Teva never laid eyes on GSK's exact documents, it wouldn't matter. As no one disputes, Teva asked to carve out GSK's patented uses, and the FDA in return used GSK's representations to provide Teva with a carved-out label. The FDA itself took no non-infringement position; GSK did. And so by accepting the FDA-provided skinny label, which hewed to GSK's patent declarations, Teva relied on GSK's representations of patent scope.[12] *See, e.g.*, Cross-Appellant's Br. 12–13, 51–52; J.A. 12475 (Teva's JMOL motion).

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[11] The suggestion appears to be based on the word "confidential" at the bottom of the declarations' pages in our appendix. *See* Maj. 23. The majority's reliance on this branding seems misplaced. Among documents similarly branded "confidential": (1) the American College of Cardiology/American Heart Association Guidelines, published in the Journal of American College of Cardiology, J.A. 3245; and (2) Teva's 2012 Monthly Prescribing Reference, J.A. 6192, a circulation that the majority says doctors received "on a regular basis," Maj. 33 (quoting J.A. 10607–08).

[12] To that end, the declarations also belie GSK's insistence that the 240-character use code was "not tied to any particular indication." *See* Appellant's Reply Br. 30. GSK submitted a patent declaration identifying only one indication. *E.g.*, J.A. 6895. From that declaration came the use code. GSK's use-code argument is therefore wrong as a matter of law here. And regardless, GSK's problem

Everything that follows must be assessed against the carve-out backdrop. With that in mind, I turn to what remained of the label *after* it was carved out. For a drug label to induce, it must "encourage, recommend, or promote infringement." *Takeda*, 785 F.3d at 631. "Merely describing an infringing use" in a label "will not suffice." *HZNP Meds. LLC v. Actavis Labs. UT, Inc.*, 940 F.3d 680, 702 (Fed. Cir. 2019); *Takeda*, 785 F.3d at 631.

The majority supports the verdict with GSK's expert testimony concerning the post-MI LVD indication. Again, this indication remained on the label because GSK's sworn declarations never said it was patented. Dr. McCullough did walk through claim 1 of the '000 patent and compare each limitation to somewhere on the skinny label. Maj. 14–16 (citing testimony at J.A. 10623–31). But he never testified that the skinny label encouraged, recommended, or promoted practicing the claimed method.[13]

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remains part 4.2a of the declarations, which required GSK to "[s]ubmit indication or method of use information *as identified specifically in the approved labeling*." *E.g.*, J.A. 6895 (emphasis added).

[13] The majority suggests otherwise, via a misleading cite to a snippet of testimony. *See* Maj. 24 (citing J.A. 10644). While Dr. McCullough did testify that Teva "took action" intended to encourage, none of the evidence he was referencing included the skinny label itself. His earlier skinny-label testimony concerned underlying direct infringement. *E.g.*, J.A. 10631. But after moving to the *intent* element of inducement, where the majority finds this testimony, the label did not come up again—neither directly nor indirectly. J.A. 10634–44. This may explain why GSK never cited this testimony to show that the skinny label encouraged. Had GSK done so, Teva would have had an opportunity to contest the characterization the majority now adopts.

Rather, in response to a series of questions about whether certain portions of the label "met" the claim limitations, he testified that some limitations were met (or "mentioned") in the Indications and Usage section, others in the Dosage and Administration section, and still others in the Clinical Studies section. J.A. 10623–31. At most, a reasonable jury could have found that the skinny label *described* the infringing use (if pieced together just right), in the context of post-MI LVD patients. Describing is not enough.

This failure of proof alone should end the intentional-encouragement inquiry as to the skinny label here. But when we also consider the backdrop as to how the skinny label arose—i.e., that Teva took out the only indication GSK said was patented—the lack of inducement based on this label is beyond dispute. *See Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1329 n.2 (Fed. Cir. 2009) ("[The question] is whether [defendant's] instructions teach an infringing use . . . *such that we are willing to infer* from those instructions an affirmative intent to infringe the patent." (emphasis added)); *see also Grokster*, 545 U.S. at 937 ("The classic instance of inducement is by advertisement . . . that broadcasts a message *designed to* stimulate others to commit violations." (emphasis added)). The law simply does not permit an inference of culpable, intentional encouragement from the label on this record.[14]

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[14] Despite the majority's characterization, this is not a contention that estoppel arose from GSK's FDA filings. Maj. 23. Rather, the issue concerns what *intent* could be reasonably gleaned from the skinny label, given the way that label came about and the absence of other evidence of intent. Intent is a required element of inducement—and, as the majority itself acknowledges, GSK's failure to list the post-MI LVD indication in its FDA filings "is relevant to intent to induce infringement." *Id.* at 20. Estoppel is a separate issue based on a different legal standard that the

All of that is just the intentional-encouragement prong though; GSK also had to show causation. At a minimum, it had to prove that doctors would have read the skinny label, then pieced together the disparate portions just like Dr. McCullough did at trial, then viewed that pieced-together description as an encouragement to prescribe carvedilol for CHF according to the specific limitations of the claimed method, and *then relied* on that pieced-together message to make that prescribing decision.

Dr. McCullough certainly didn't connect these dots. Indeed, he would have been a poor choice for that task. A question arose at trial as to whether he had even *read* the label before making his prescribing decisions. To survive a pre-verdict JMOL motion on causation, GSK's counsel promised the trial judge that if given another chance, Dr. McCullough would "absolutely" testify that he did so. J.A. 10959; *see also* J.A. 10959 (counsel insisting that "obviously, he always reads the label"). But when given the chance, he testified that no, he *didn't* read the label before making his prescribing decisions. J.A. 11662–63. Not that Dr. McCullough was alone in this regard; the other two expert cardiologists at trial testified that they didn't do so either. J.A. 11151 (Dr. Zusman); J.A. 11296–97 (Dr. Rosendorff).

Nothing else connected these dots. In fact, evidence from both sides showed that doctors relied primarily on

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district court may resolve in the first instance. The majority's charge that I seek to "leapfrog" and resolve estoppel here on appeal is therefore disturbingly off-base. *Id.* at 23. I am instead addressing what a reasonable jury could find Teva's intent to be. I do not understand the majority to be suggesting that the potential availability of a different type of relief (i.e., estoppel) forecloses the court from considering the main issue in this appeal (i.e., inducement) if resolution of the two issues might involve some of the same facts.

medical guidelines, experience, education, and journals when making their prescribing decisions. *E.g.*, J.A. 10668, 10676–77 (Dr. McCullough), 11151–52, 11164–68 (Dr. Zusman), 11296–97 (Dr. Rosendorff). Evidence from both sides also showed that pharmacies substituted generics for the brand version automatically, as all fifty states allow or even require. *See, e.g.*, J.A. 10678–79 (Dr. McCullough), 10750–51 (Dr. Reisetter), 11038 (Mr. Karst), 11076–77 (Ms. Kinsey). The majority, however, disregards this uncontroverted, direct evidence of causation in favor of letting unsupported inferences bridge GSK's evidentiary gap. It starts with the label's contents and that they were perhaps "read"—then ends up at causation. Maj. 35–36. I disagree with the majority that this inferential leap is "fair," *id.* at 36, particularly here, where direct evidence across the board points to medical texts and expertise as being the main influence. In my view, "fair" would be ensuring that causation means something. *See infra* Part II.C.2.

Before turning to the press releases, one last, critical point bears mentioning. The majority confines its reliance on the skinny label to the post-MI LVD indication. In particular, its skinny-label inducement path starts with "encouragement" from the post-MI LVD indication, and ends in direct infringement when a doctor prescribes carvedilol for any post-MI LVD patient who *also* happens to have CHF (assuming that the rest of the claim limitations are met when so prescribing). *See* Maj. 13–16, 18–19. Notably, however, as both sides acknowledge, the damages award in this case was *not* confined to just the appropriate subset of infringing prescriptions to post-MI LVD patients who also had CHF—it encompassed CHF patients more broadly. Cross-Appellant's Br. 54; *see* Appellant's Reply Br. 31–32. GSK's damages testimony was not predicated on, nor did it quantify, the subset of uses that would infringe under the majority's skinny-label-based inducement theory.

Recognizing the problem, GSK leans on the press releases to save the full damages award; it says they

"encouraged the infringing use for all . . . symptomatic heart failure patients." Appellant's Reply Br. 31. But, as I explain below, that's far too much weight for these press releases to bear. Accordingly, even if the majority's upholding the verdict on the basis of the skinny label were appropriate, we would have to remand this case for a proper damages calculation. But Teva's argument on this important issue goes unacknowledged in the majority's opinion.

2. The 2007 Press Release

Beyond the skinny label itself, the majority also supports the verdict with a 2007 Teva press release that announced final FDA approval for Teva to market its "[g]eneric version of [GSK's] cardiovascular agent Coreg® (Carvedilol) Tablets." Maj. 29 (citing J.A. 6353). From this press release—which was distributed before the '000 patent issued but apparently appeared on Teva's website during the patent's term—the majority permits inferences of intentional encouragement and causation. Neither is reasonable.

As to intentional encouragement, the majority interprets Teva's 2007 press release as saying that its product is a "generic equivalent of GSK's cardiovascular agent Coreg®," *id.* at 30—and, from this, permits the inference that Teva intended to encourage substitution of its product for *all* of Coreg's indications, including CHF, *id.* at 29–30. In other words, the majority holds that a generic can be deemed liable for inducement for saying that its product is a "generic version" or "generic equivalent" of a brand drug. This is a drastic holding. And it makes little sense. Essentially *all* ANDA generics are the "generic version" or "generic equivalent" of a brand drug; the law *requires* them to be. To come to market, such a generic must demonstrate that its product is bioequivalent to a brand drug. 21 U.S.C. § 355(j)(2)(A)(iv), (j)(4)(F); 21 C.F.R. § 314.94(a)(7)(i); *see also* 21 C.F.R. § 314.92(a) (noting that, with limited

exceptions not relevant here, ANDAs are suitable only for "[d]rug products that are the same as a listed drug," and that "the same as" includes drugs with label modifications made for patent carve-outs). *See generally supra* Part I.A. The system is inherently comparative. I therefore find it highly unlikely that Congress intended to make generics liable for simply stating what the law requires.

The majority also sees culpable intent in Teva's describing its product as a "cardiovascular" agent. *See* Maj. 29–30. A well-understood adjective, "cardiovascular" means relating to the heart. Carvedilol is a heart-related drug; it's used to treat CHF, post-MI LVD, and hypertension—all heart-related conditions. I cannot see how using the word "cardiovascular" to describe a heart-related drug could *reasonably* be viewed as evidencing culpable intent to encourage practicing the specific claimed CHF method in particular here—or how this adjective does anything beyond what "generic version" or "generic equivalent" do in terms of intent.

And still there remains causation. The majority never explains how a reasonable jury could have found that this press release (as it later appeared on Teva's website) affected doctors' prescribing practices so as to cause their infringement. Indeed, outside of testimony that doctors "get" press releases, J.A. 11655, and that it's "possible" doctors read them, J.A. 11239, GSK supplied no evidence that any doctor read *this* one before the litigation—much less accessed it from Teva's website, and was then so moved by it that it caused him or her to prescribe carvedilol in an infringing manner, trumping every medical text along the way.

We simply have a press release that describes a generic version of a cardiovascular brand drug as a "*generic version*" of a "*cardiovascular*" brand drug. From that alone, the majority permits inferences of culpable intent to

encourage and causation. I fail to see how those inferences are reasonable.

3. The 2004 Press Release

The majority's final key piece of evidence is the 2004 press release, which announced Teva's "tentative [FDA] approval" to market its product, described as "the AB-rated generic equivalent of [GSK's] Coreg® . . . indicated for treatment of heart failure and hypertension." J.A. 6347.

Before turning to whether these statements could show intentional encouragement to infringe, some undisputed facts must be acknowledged. First, this press release was distributed several years before the '000 patent issued, at a time when Teva was pursuing a different pathway to regulatory approval. At that time, Teva's product *was* indicated for treatment of CHF. But Teva ultimately pursued the section viii pathway. Second, the press release announced the product's "*tentative* approval," which has a specific, legal meaning—namely, that a patent or regulatory exclusivity stands in the way of final approval. 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd)(A); 21 C.F.R. § 314.3(b); *see* J.A. 10533. In other words, this "approval" had conditions.

With that in mind, the question remains: what is there in this press release to suggest intent to encourage infringement of the (future-issued) '000 patent? Like the 2007 press release, the majority sees culpable intent in Teva's describing its product as the "AB-rated generic equivalent" of Coreg. Maj. 28. But, for the reasons described above, this cannot plausibly support liability within Congress's framework in this area. And although the press release does reference "heart failure," given the circumstances here—i.e., that the press release was distributed years before the patent issued (under materially different regulatory circumstances) and announced "tentative" approval—inferring culpable intent from this press release exceeds the bounds of reasonableness.

And again: causation. To prove it, GSK first had to show that Teva made this years-old press release available on its website during the patent's term. This should have been a crucial showing—after all, this press release is one of the three key pieces of evidence the majority relies on. Once again, though, direct evidence is missing. And once again, the majority is untroubled. It simply calls up some inferences to bridge the gap. In particular, the majority suggests the inference that, because the 2007 press release was on Teva's website, and because Teva had a website with some information about carvedilol, the 2004 press release must have been there too. Maj. 30–31. GSK, for its part, never argued any of these inferences to the jury. And while the majority faults Teva for not showing that the 2004 press release was *not* there, *id.* at 31, this is GSK's case and its burden—and besides, it's hard to blame Teva for not rebutting a fact that GSK never even tried establishing.

But, for argument's sake, let's assume the jury could have reasonably found that GSK carried its burden on this point. A further question remains: what is there to suggest that any doctor saw it—years later on the website—then relied on *that* as the basis for his or her infringing prescribing decisions? The answer: nothing. At least, that's the answer the majority gives. *See id.* at 35–37. Nothing in the record suggested that doctors were in the habit of searching a generic's website for old press releases to help them make life-or-death prescribing decisions. The most we have is that Dr. McCullough saw the 2004 press release (timing unspecified) and that it said what it said. The rest is left to sheer possibility.

And indeed, it's possible that things panned out this way. Maybe a doctor *did* search Teva's website for old press releases, found this one (assuming it was there), and then relied on that press release to make his or her prescribing decision (at least three years after the date of this press release), trumping every medical text along the way.

Maybe every relevant doctor did. Many things are possible. But "'[m]ere speculation' is not substantial evidence." *OSI Pharms., LLC v. Apotex Inc.*, 939 F.3d 1375, 1382 (Fed. Cir. 2019) (quoting *Intell. Ventures I LLC v. Motorola Mobility LLC*, 870 F.3d 1320, 1331 (Fed. Cir. 2017)).

In sum, the 2004 press release's description of Teva's product as the "AB-rated generic equivalent" of Coreg, along with its reference to "heart failure," would be a slender enough reed upon which to rest culpable intent, given that this communique was distributed years before the patent issued (under materially different regulatory circumstances) and announced an approval that was only "tentative." But it's the causation that truly vexes me. It's the notion that, instead of the various medical texts (and experience, and education), all along it was really the 2004 press release, found years later on the website, that caused doctors' CHF prescribing decisions. In the face of uncontroverted evidence of the former, *some* evidence of the latter should be necessary. But there's none.

4. The Supposedly Substantial Other Evidence of Intent

The majority calls it "inaccurate" to observe that it relies on only three key pieces of evidence as to culpable intent during the skinny-label period. Maj. 24. It says there's additional evidence too.[15] But while the majority discusses the three pieces above in some detail, it only gestures to the rest without much meaningful discussion. Such references can hardly be enough to sustain a verdict, and they return us to the uncertainty concerns plaguing the first, vacated version of the majority's opinion. At

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[15] Much of this evidence comes in the form of trial testimony that was not included in the record on appeal—which means it's testimony that GSK didn't rely on, and to which Teva therefore had no occasion to respond. Anything the majority cites as "Trial Tr." references such testimony.

bottom, however, this other evidence just relates back to the three key pieces.

There was "extensive expert testimony," the majority first insists without elaboration. Maj. 24. As best I can tell, the majority is referring to Dr. McCullough and Dr. Zusman, *see id.* at 26—Dr. McCullough saying that doctors read labels, and Dr. Zusman agreeing that Teva's circulations suggested reading labels if doctors have questions. So, we're back to the skinny label—the first of the three key pieces of evidence. And if the skinny label doesn't show intent, then neither does suggesting that doctors should read it.[16]

Teva's "Monthly Prescribing References" get some attention elsewhere. *See id.* at 26–27. But, like the "extensive" expert testimony discussed above, that's just for the proposition that Teva intended doctors to read its labels. Again, back to the skinny label.

The majority adds to the list Teva's "product catalogs" and "advertising and promotional activities." *Id.* at 24. I presume it means Teva's catalogs discussed shortly afterward. But the only thing for which *that* evidence was relied on was to show that Teva described its drug as the "AB rated" equivalent to Coreg. *See id.* at 27 (discussing 2008 and 2009 catalogs at J.A. 6221 and J.A. 6270). Statements of equivalence were discussed with respect to the two press releases—the other two key pieces of evidence. So it's unclear what this adds to the intent calculus. And as before, if this is evidence of intent, we should be disturbed.

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[16] Of course, because causation is an element, what matters in the end is whether doctors *did* in fact not only read but also *rely* on this label. *See supra* pp. 20–21. Recall too that every relevant witness testified that he *hadn't* read this label before prescribing.

Finally, the majority notes "testimony from Teva's own company witnesses." *Id.* at 24. Maybe this means Teva's marketing director (who the majority says "added carvedilol product information to the Teva website" in 2007) and regulatory-affairs director (who the majority says "discussed" the press releases with the jury). *See id.* at 31. Whatever the case, this discussion just concerns the press releases—well-trodden ground. Or maybe instead the majority means Mr. Rekenthaler, who it quotes as having "expected" or "assum[ed]" that doctors would use drugs as labeled. *Id.* at 27. But this just brings us back to the skinny label.

The bottom line is that, to the extent that this evidence is relevant, its relevance depends on finding culpability from the three key pieces of evidence—i.e., the skinny label or the two press releases, particularly their statements of equivalence.

B. *The Full-Label Period*

As with the skinny-label period, JMOL of no inducement was necessary for the full-label period. The reason is simple: nothing about doctors' prescribing practices changed when Teva amended its label to the full version. Both GSK and its experts confirmed as much. Appellant's Br. 21 ("Doctors continued to administer Teva's accused product for infringing use during [the full-label] period (*without change from the partial label period*) . . . ." (emphasis added)); J.A. 12204–05 (GSK's counsel conceding that any market impact as a result of the amendment was "minimal"); J.A. 10699 (Dr. McCullough agreeing that, in his practice, there was "no difference in [his] prescribing habits from when Teva had its skinny label to after Teva amended to have its full label"); J.A. 10754 (different GSK expert testifying that his survey of 200 doctors indicated no change in prescription patterns from pre- to post-amendment).

The majority, for its part, identifies nothing about doctors' prescribing practices that changed after Teva amended its label. Maj. 33–37. If nothing about this changed, then nothing Teva did during the full-label period could have caused anything beyond whatever caused direct infringement during the skinny-label period. And because the record lacks evidence that Teva caused direct infringement during the skinny-label period, Teva cannot have caused direct infringement during the full-label period—and therefore cannot have induced.

C. *Why the Majority's Flawed Analysis Matters*

In reinstating the jury's unsupportable verdict, the majority commits several errors—some legal, some practical, and all spelling trouble for skinny labels specifically and inducement law generally. Below are three main concerns with the majority's approach.

1. The Majority Weakens the Intentional-Encouragement Requirement as to Labels

Direct infringement is strict liability; induced infringement is not. And when it comes to inducement's intentional-encouragement requirement, the law draws a line between encouraging, recommending, or promoting an infringing use and merely describing that use. *E.g.*, *Takeda*, 785 F.3d at 631. This line is important because while the former provides evidence of intent, the latter does not. *See id.* (collecting cases); *HZNP*, 940 F.3d at 702 ("Merely describing an infringing use . . . will not suffice . . . ."). The majority blurs this line beyond recognition.[17]

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[17] GSK would have us ignore this line entirely. Appellant's Reply Br. 28 ("It is doubtful whether such a distinction actually exists . . . ."); *see id.* at 16 ("Teva's partial label encouraged doctors to infringe GSK's patent because it described every limitation of the claimed method.").

Take the skinny label here. GSK's expert Dr. McCullough, despite having *never read* the label himself before making prescribing decisions, walked through it and found piecemeal language that he could say "met" or "mentioned" each claim limitation in isolation. *Supra* pp. 18–19. That was the extent of it. There was no testimony or other evidence that this label language encouraged practicing the patented method, or that it even came with a wink or nudge. At most, then, a reasonable jury could have found that the skinny label *described* the infringing use.

The majority somehow ends up at encouragement but fails to justify how it got there. In particular, it never meaningfully engages with the legal distinction between encouraging, recommending, or promoting an infringing use and describing it. Nor does it explain how a reasonable jury could have found the former from the latter on this record. If a jury can simply infer culpable intent to encourage from a mere description, the legal distinction is meaningless. Description would *always* suffice to infer inducement.

That's a problem. "[S]howing that infringement was encouraged" is necessary to "overcome[] the law's reluctance to find liability when a defendant merely sells" a product with legitimate non-infringing uses, like carvedilol. *Grokster*, 545 U.S. at 936; *see id.* at 937 (acknowledging "the need to keep from trenching on regular commerce or discouraging the development of technologies with lawful and unlawful potential"). "This requirement of inducing acts is particularly important in the Hatch-Waxman Act context because the statute was designed to enable the sale of drugs for non-patented uses even though this would result in some off-label infringing uses." *Takeda*, 785 F.3d at 631 (citing *Caraco*, 566 U.S. at 414–15).

On that note, I emphasize that this criticism is all about how the majority treats what was left of the skinny

label *after* the carve-out. That Teva first carved out exactly what GSK said would infringe should settle the question of what intent could be reasonably inferred from the label itself on these facts. It's also a circumstance that distinguishes every case the majority relies on to support its holding.

2. The Majority Eviscerates the Causation Requirement

Patent infringement is a tort. *E.g.*, *Wordtech Sys., Inc. v. Integrated Networks Sols., Inc.*, 609 F.3d 1308, 1313 (Fed. Cir. 2010); *see Carbice Corp. of Am. v. Am. Pats. Dev. Corp.*, 283 U.S. 27, 33 (1931). Accordingly, liability attaches only to one who causes the injury—here, practice of the patented method. Legal cause, not simply but-for cause, is required. Restatement (Second) of Torts § 9 cmt. a.

Traditional tort principles inform how a plaintiff proves, or fails to prove, causation:

> As on other issues in civil cases, the plaintiff is required to produce evidence that the conduct of the defendant has been a *substantial factor* in bringing about the harm he has suffered, and to sustain his burden of proof by a preponderance of the evidence. . . . *A mere possibility of such causation is not enough; and when the matter remains one of pure speculation and conjecture, or the probabilities are at best evenly balanced, it becomes the duty of the court to direct a verdict for the defendant*.

Id. § 433B cmt. a (emphasis added); *see also id.* § 876 cmt. d (noting that if "encouragement or assistance is a substantial factor in causing [a] resulting tort, the one giving it is himself a tortfeasor"). Therefore, to prove causation, GSK had to show that Teva's conduct (apart from simply being on the market) was a substantial factor in causing doctors to prescribe its carvedilol in an infringing way. A mere

possibility wouldn't do; rather, a reasonable jury must have been able to find that it was more likely than not. Here it could not.

To start, the majority identifies no direct evidence of causation by Teva. And it casts aside the direct evidence from both sides pointing to the same things—things other than Teva—as the cause. *Supra* pp. 20–21, 23–26. Instead, it says that it was "fair" for the jury to "infer" causation from the existence of the skinny label itself and the two press releases. Maj. 36. This conclusion relies on a passing observation in one case saying: "[W]e have affirmed induced infringement verdicts based on circumstantial evidence of inducement (e.g., advertisements, user manuals) directed to a class of direct infringers (e.g., customers, end users) without requiring hard proof that any individual third-party direct infringer was actually persuaded to infringe by that material." *Id.* (quoting *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 843 F.3d 1315, 1335 (Fed. Cir. 2016)). But this observation is not a license to substitute speculation for proof. The evidence-to-conclusion link must always make sense.

In some inducement cases, a jury might reasonably infer causation based solely on circumstantial evidence. One example might be where a product's user manual encourages an infringing use, and where the user had no familiarity with the product *other than* the manual. A reasonable jury might infer that the manual caused the user, otherwise unfamiliar with the product's intricacies, to use the product that way, and we have upheld inducement verdicts on this basis. *E.g.*, *Golden Blount, Inc. v. Robert H. Peterson Co.*, 438 F.3d 1354, 1362–63 (Fed. Cir. 2006) (causation evidence included an instruction sheet teaching infringement and packaged with each product); *ArthroCare Corp. v. Smith & Nephew, Inc.*, 406 F.3d 1365, 1377 (Fed. Cir. 2005) (causation evidence included "sales literature accompanying one of the accused devices" and other instruction manuals recommending an infringing use); *Moleculon*

Rsch. Corp. v. CBS, Inc., 793 F.2d 1261, 1272 (Fed. Cir. 1986) (causation evidence included "dissemination of an instruction sheet teaching" the infringing method). Although purely circumstantial, the inferential hops are few and short. In those cases, what else but the user manual might have caused the user to use the product in an infringing way? *Cf. Golden Blount*, 438 F.3d at 1363 ("[N]othing in the record suggests that either [defendant] or any end-user ignored the instructions . . . .").

In other inducement cases, inferential leaps are too many and too great, and evidence of a different cause too strong, for the circumstantial evidence that is offered to carry the day. Take this case. To accept that Teva's skinny label was a substantial factor in causing doctors to infringe, one would have to infer doctors read it to make prescribing decisions (even though all three testifying expert cardiologists said they didn't); infer those doctors pieced together the portions of the label to uncover a description of the infringing use (maybe); infer those doctors interpreted that description as an encouragement (no evidence); and then infer those doctors relied on that description to make their prescribing decisions (no evidence). *Supra* pp. 20–21. As to the press releases, one would have to infer Teva made them available during the relevant time period (maybe); infer doctors read them during that time (no evidence); and then infer doctors relied on some inducing message therein to make prescribing decisions affecting their patients' health (no evidence).[18] *Supra* pp. 23–26.

Unlike the prototypical user-manual case, in which we might permit the inference that a user relied on the manual without requiring testimony to that effect, the

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[18] This is to say nothing of the causal implications of pharmacies' ubiquitous automatic-substitution practices—where, for example, a doctor might write "Coreg," but a generic is dispensed nonetheless. *See* J.A. 10750–51.

inference might not hold up as well in this context—with highly educated users and well-studied products. And whatever strength the inference has in a context such as this, it crumbles when, as here, we *have* users who testified, and they either (1) failed to say they relied or (2) affirmatively said they *didn't* rely on the allegedly inducing materials.

Moreover, unlike the prototypical user-manual case, it's not as though the record here was wanting for another cause. Both sides' expert cardiologists said under oath and without contradiction that medical texts, education, and experience caused their prescribing decisions. *Supra* pp. 20–21. Under these circumstances, would accepting the Teva-caused version of events amount to anything more than speculation, given the chain of inferences required—not all of them reasonably grounded in the record evidence?

The most troubling part of all this is that the majority never explains how a reasonable jury could have come out this way on this record. Given the size of the infringing doctor class here, it should have been easy to present testimony of causation if that theory had a basis in fact. *Cf. TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2212 (2021) (pointing to evidence that could have been sought and citing *Interstate Circuit, Inc. v. United States*, 306 U.S. 208, 226 (1939), for the proposition that "[t]he production of weak evidence when strong is available can lead only to the conclusion that the strong would have been adverse"). But not a single doctor testified as to causation by Teva, and in fact, the most on-point testimony shows the *absence* of causation.

As a doctrinal matter, the majority's opinion suggests that there is no independent causation element for inducement; intentional encouragement might always suffice to infer causation too. Add that to the majority's weakening of intentional encouragement (where describing an

infringing use piecemeal—or simply calling a product a "generic version" or "generic equivalent"—is now enough), and finding inducement becomes possible based largely on speculation. The law requires more from a plaintiff.

3. The Majority Creates Confusion About Skinny Labels

The majority's opinion will create confusion for everyone. Under its analysis, the difference is indiscernible between this case and one in which the generic is safe. Indeed, it's unclear what Teva even did wrong—or, put another way, what another generic in its shoes should do differently.

Initially, the majority suggests that this is not a skinny-label case. Nothing to see here, the majority reassures concerned amici: the Act remains intact. *See* Maj. 10–11. But it's hard to see how. As a matter of law, this is a skinny-label case about the skinny-label provisions. The Act's text makes that much clear: section viii by its own terms references the brand-submitted patent "information" (i.e., patent declaration). 21 U.S.C. § 355(j)(2)(A)(viii); *see* 21 C.F.R. § 314.53(c)(2)(O) (patent "information" includes portions of label covered by method patent). This patent information dictates whether a generic label is a section viii label. If a generic omits the uses the brand has said are patented, the label is skinny. The FDA understands that. *See supra* Part I.A (discussing brand-dependent regulatory framework). So does the Supreme Court. *Caraco*, 566 U.S. at 404–07. So should we.

What's more, the background facts here will seemingly persist in most skinny-label cases. Under the Act, "[g]eneric copies" are essentially "the same as the original drug." *See* H.R. Rep. No. 98–857, pt. 1, at 14–15; *accord* 21 U.S.C. § 355(j)(2)(iv); 21 C.F.R. § 314.92(a)(1). Thus, bioequivalence; comparison to a brand drug; duplication of a brand's label (at least in part); reliance on a brand's clinical-trial data; references to a drug's therapeutic class;

cursory press releases announcing a generic's regulatory approval; doctors' assumptions about what going generic means; pharmacies' generic substitution; a generic's knowledge that some sales may occur from off-label, infringing uses—all of that will generally be there whether there is inducement or not. *See, e.g.*, *AstraZeneca Pharms. LP v. Apotex Corp.*, 669 F.3d 1370, 1380 (Fed. Cir. 2012) (discussing "market realities" of substitution that do not implicate infringement). Those facts cannot sort inducement from non-inducement.

So where did Teva go wrong in this case? Should it not have followed the brand's sworn representations as to what was patented? The majority offers no principled division between this and what it suggests would be a true skinny label. For decades, everyone has assumed they could rely on what brands said about what their patents covered. The FDA's skinny-label approval pathway and regulations are expressly predicated on that. As far as adherence to Congress's framework, this was about as faithful as it gets.

Or is the takeaway, instead, that Congress meant to expose ANDA generics to liability for simply describing themselves as the "generic version" or "generic equivalent" of a brand drug? Given that the Hatch-Waxman Act's framework requires ANDA generics to be the same as a brand drug, and that doctors understand what being a generic means, this seems a dubious proposition.

One of amici's key criticisms of the first version of the majority's opinion was that it was unclear what among the muddled mass of evidence actually formed the basis of liability. So too here. It's unclear whether the skinny label was enough—or whether the press releases were, or some of the other ancillary evidence in the record, "all of which" the majority suggests the jury "could have relied on." Maj. 24.

The lack of clarity extends to the majority's characterization of its holding as "case-specific." *See id.* at 10–11.

For example, the majority's new opinion relies on the post-MI LVD indication remaining on the skinny label as a potentially "case-specific" circumstance. *See id.* Not only is this reliance problematic (for the reasons described above), it's a mirage. If the majority were truly relying on this circumstance to distinguish this case, it would accept Teva's argument that the damages should be confined to the appropriate subset of infringing prescriptions to post-MI LVD patients who also had CHF. *See supra* pp. 21–22. But, given that this argument goes unacknowledged in the majority's opinion, the implication is that the press releases alone—with their references to "generic version" or "generic equivalent"—suffice to support the *entire* verdict, encompassing CHF patients more broadly. And if that's so, then it's unclear why the majority's analysis of the skinny label itself is relevant. Under the majority's holding, a brand can just rely on statements of equivalence to capture even that portion of the market that was specifically carved out.

The only clear thing now is that no generic can know until hit with the bill whether it's staying within the confines of the law. Being unable to predictably rely on use codes and patent declarations "throws a wrench" into Congress's skinny-label design. *See Caraco*, 566 U.S. at 419.

III. CONCLUSION

Before today, there was an equilibrium to the skinny-label system—one that allowed companies to make informed, responsible decisions in this area. If a generic wanted to avoid patented uses, it had the simple expedient of omitting from its label the uses the brand identified. And if a brand wanted to block a skinny label containing a use it thought was patented, it had the simple expedient of including that use in its FDA patent declaration. That equilibrium is no more.

So, what's next? We are now on the majority's second opinion in this case. The first was vacated in light of Teva's

petition for rehearing and the eight amicus briefs in support. This new opinion does little to assuage, and even exacerbates, concerns raised by the original.

I respectfully dissent.

United States Court of Appeals for the Federal Circuit

VALEANT PHARMACEUTICALS NORTH AMERICA LLC, VALEANT PHARMACEUTICALS IRELAND LTD., DOW PHARMACEUTICAL SCIENCES, INC., KAKEN PHARMACEUTICAL CO., LTD.,
Plaintiffs-Appellants

v.

MYLAN PHARMACEUTICALS INC., MYLAN LABORATORIES LTD., MYLAN INC.,
Defendants-Appellees

2019-2402

Appeal from the United States District Court for the District of New Jersey in No. 3:18-cv-14305-PGS-LHG, Senior Judge Peter G. Sheridan.

Decided: November 5, 2020

THOMAS P. STEINDLER, McDermott, Will & Emery LLP, Washington, DC, argued for all plaintiffs-appellants. Plaintiffs-appellants Valeant Pharmaceuticals North America LLC, Valeant Pharmaceuticals Ireland Ltd., Dow Pharmaceutical Sciences, Inc. also represented by IAN BARNETT BROOKS, CHRISTOPHER MICHAEL BRUNO, PAUL MICHAEL SCHOENHARD; CHARLES H. CHEVALIER, Gibbons P.C., Newark, NJ.

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STEFFEN NATHANAEL JOHNSON, Wilson Sonsini Goodrich & Rosati, Washington, DC, argued for defendants-appellees. Also represented by ADAM WILLIAM BURROWBRIDGE; WENDY L. DEVINE, KRISTINA M. HANSON, TUNG ON KONG, San Francisco, CA.

Before NEWMAN, O'MALLEY, and TARANTO, *Circuit Judges*.

O'MALLEY, *Circuit Judge*.

In 2017, the Supreme Court dramatically changed the venue landscape in patent cases. *See TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S. Ct. 1514 (2017). It held that the general venue provision in 28 U.S.C. § 1391—which provides that a corporation is deemed to "reside" in any judicial district in which it is subject to personal jurisdiction—does not modify the term "resides" in 28 U.S.C. § 1400, the more specific venue statute applicable to patent cases. Specifically, it held that "resides" in § 1400(b) refers only to a corporation's state of incorporation. That means that a corporation may be sued for patent infringement in only two categories of judicial districts: those in the state in which it is incorporated and those in which it has a regular and established place of business and an act of infringement has occurred. *TC Heartland* raised more questions than it answered; we and district courts around the country have been working through those questions since 2017. Today we tackle one more.

Today we answer the question of where "acts of infringement" under § 1400(b) occur with respect to

infringement claims brought pursuant to the Hatch-Waxman Act.[1] We conclude that, in cases brought under 35 U.S.C. § 271(e)(2)(A), infringement occurs for venue purposes only in districts where actions related to the submission of an Abbreviated New Drug Application ("ANDA") occur, not in all locations where future distribution of the generic products specified in the ANDA is contemplated.

Given this conclusion, we affirm the district court's order dismissing the claims against the two U.S.-based defendants pursuant to Rule 12(b)(3) of the Federal Rules of Civil Procedure for improper venue. *See Valeant Pharms. N. Am. LLC v. Zydus Pharms. (USA) Inc.*, No. 18-cv-13635-PGS-LHG, 2019 WL 4179832 (D.N.J. Aug. 14, 2019). For the reasons explained below, however, we vacate and remand the portion of the court's order dismissing the action against the foreign defendant—as to which venue was unquestionably proper—pursuant to Rule 12(b)(6), because the court failed to address the substance of that motion.

I. BACKGROUND

Because this appeal is primarily a venue dispute, the locations of the parties' places of incorporation are important. Less significantly, Valeant Pharmaceuticals North America LLC, Valeant Pharmaceuticals Ireland Ltd., Dow Pharmaceutical Sciences, Inc. ("Dow"), and Kaken Pharmaceuticals Co., Ltd. (collectively "Valeant" or "plaintiffs") reside in a range of locations, including Japan, Ireland, and Delaware. On the defendants' side, Mylan Pharmaceuticals Inc. ("MPI") is a West Virginia corporation with a principal place of business in Morgantown, West Virginia; Mylan Inc. is a Pennsylvania corporation with a principal place of business in Canonsburg,

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[1] The Hatch-Waxman Act is the common name for the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98–417, 98 Stat. 1585.

Pennsylvania; and Mylan Laboratories Ltd. ("MLL") is an Indian corporation with a principal place of business in Hyderabad, India.

The parties are all players in the pharmaceutical industry. Dow holds New Drug Application No. 203567 for the brand name drug Jublia®, approved by the United States Food and Drug Administration ("FDA") on June 6, 2014. Jublia® is a medication used to treat fungal infections (onychomycosis) of toenails. The active ingredient in Jublia® is efinaconazole. There are nine patents listed in the Orange Book for Jublia®.

In June 2018, MPI, a generic drug company, executed an ANDA seeking approval to market a generic version of Jublia®. MPI sent the ANDA from its West Virginia corporate office to the FDA, located in White Oak, Maryland. The ANDA included a Paragraph IV certification that the Orange-Book-listed patents for Jublia® are invalid, unenforceable, or would not be infringed by the ANDA product. MPI notified Valeant of the ANDA submission in August 2018.

On September 26, 2018, Valeant filed suit against Mylan[2] in the District of New Jersey, alleging infringement of Dow's Orange Book patents pursuant to the Hatch-Waxman Act and requesting declaratory judgment of validity of the Orange Book patents.[3] The complaint contained several allegations about Mylan's connection to New Jersey:

- Each Mylan defendant "directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this

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[2] We refer to appellees collectively as "Mylan."

[3] Valeant also filed complaints in the District of New Jersey against eighteen other ANDA filers. None of those filers challenged venue and the cases have been consolidated with trial scheduled for June 2, 2021.

judicial district, and this judicial district is a likely destination for Mylan's generic efinaconazole topical solution." J.A. 147, ¶ 10 (MPI), 148, ¶ 12 (MLL), 149, ¶ 13 (Mylan Inc.).

- Each Mylan defendant does business in New Jersey and is registered to do so. J.A. 147, ¶ 10 (MPI), 148 ¶ 12 (MLL), 149, ¶ 13 (Mylan Inc.).
- Each defendant has previously submitted to the jurisdiction of the court and has a place of business in New Jersey. J.A. 147–48, ¶ 10 (MPI), 148–49 ¶ 12 (MLL), 149, ¶ 13 (Mylan Inc.).
- MPI applied for FDA approval of its generic drug, which will be "purposefully directed at, upon information and belief, New Jersey and elsewhere. [MPI's] ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs." And MPI plans to market and sell its generic drug into New Jersey upon FDA approval. J.A. 148 ¶ 11.

The next day, Valeant filed an essentially identical protective suit against Mylan in the Northern District of West Virginia. *See* Complaint, *Valeant Pharms. N. Am. LLC v. Mylan Pharms. Inc.*, No. 18-cv-00184-IMK, D.I. 1 (N.D. W. Va. Sept. 27, 2018). That suit is ongoing.

In January 2019, Mylan moved to dismiss Valeant's New Jersey District Court complaint against MPI and Mylan Inc. for improper venue pursuant to Federal Rule of Civil Procedure 12(b)(3). Mylan further moved to dismiss MLL and Mylan Inc. for failure to state a claim pursuant to Rule 12(b)(6). As to venue, Mylan did not deny the majority of the venue allegations in Valeant's complaint. Instead, it argued that venue was improper under § 1400(b) because no Mylan defendant resides in New Jersey, the only alleged act of infringement—submission of the ANDA—did not occur in New Jersey, and the Mylan

defendants do not have regular and established places of business in New Jersey.

In response, Valeant argued that it is unduly narrow to limit "an act of infringement" under § 1400(b) to the act of submitting the ANDA. Valeant contended that "the Court must consider Mylan's planned, future acts." J.A. 760. It maintained that, in the Hatch-Waxman context, the language of § 1400(b) must be deemed to contemplate such planned future conduct. In making this argument, Mylan relied heavily on *Bristol-Myers Squibb Co. v. Mylan Pharmaceuticals Inc.*, No. 17-cv-379-LPS, 2017 WL 3980155 (D. Del. Sept. 11, 2017) (holding that venue was appropriate in ANDA cases, even after *TC Heartland*, wherever planned future acts likely would occur).

As to the Rule 12(b)(6) motion, Mylan argued that the complaint alleged that MPI alone submitted the ANDA and MPI was thus the only entity against which a case could be brought under the Hatch-Waxman Act. Valeant answered that liability for submitting an ANDA is not limited to the entity that sends the final ANDA to the FDA. J.A. 404 (citing *In re Rosuvastatin Calcium Patent Litig.*, 703 F.3d 511, 527–28 (Fed. Cir. 2012) (holding that a "submitter" can include those who participate in the preparation of the ANDA and intend to directly benefit from marketing of the product identified in it)).

In August 2019, the district court granted Mylan's motion to dismiss the complaint against all defendants based on improper venue. The court found that the ANDA was submitted from West Virginia, rendering venue proper there. The court then discussed the parties' arguments about the relevance of planned future acts to the venue analysis under § 1400(b). Citing *In re Cray Inc.*, 871 F.3d 1355, 1361 (Fed. Cir. 2017), and *In re ZTE (USA) Inc.*, 890 F.3d 1008, 1014 (Fed. Cir. 2018), for the proposition that the requirements of the venue statute are specific, unambiguous, and not amenable to liberal construction based on

policy concerns, the court concluded that the discussion of venue in *Bristol-Myers Squibb* "does not follow from a plain reading of the statute, which is clear: only where a defendant has committed an act of infringement may a party bring a patent suit." *Valeant Pharms.*, 2019 WL 4179832, at *3. Accordingly, the court concluded that the two places where an act of infringement might have occurred before the filing of the action were West Virginia and Maryland, not New Jersey. The court therefore dismissed the infringement claims.

The district court did not separately address Mylan's Rule 12(b)(6) motion to dismiss as to MLL and Mylan Inc. or explain its rationale for dismissing MLL. It did, however, insert a footnote acknowledging the argument that MLL, a foreign entity, was properly subject to venue in every judicial district. The court stated it would not consider MLL in the venue analysis, but noted that venue would be proper for MLL in West Virginia. *Id.* at *3 n.2.[4]

Valeant timely filed a notice of appeal on September 10, 2019. We have jurisdiction to review the final decision of the district court pursuant to 28 U.S.C. § 1295(a)(1).

II. ANALYSIS

This appeal presents two issues. First, as noted, we have been asked to answer a question of first impression relating to proper venue in Hatch-Waxman cases after *TC Heartland*. Second, we apply well-established law to the question of proper venue for patent cases brought against foreign entities. We affirm the district court's determination that venue was not proper in New Jersey as to the

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[4] The court also dismissed Valeant's declaratory judgment actions. *Valeant Pharms.*, 2019 WL 4179832, at *4. That decision is not contested on appeal.

domestic defendants. We reverse and remand, however, as to foreign defendant MLL.

A. Venue in Hatch-Waxman Cases

For purposes of determining whether venue is proper in a district other than one in a state in which a defendant is incorporated, a court must determine, among other things, "where the defendant has committed acts of infringement." 28 U.S.C. § 1400(b).[5] Under the Hatch-Waxman Act, it is "an act of infringement to submit [an ANDA] for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval . . . to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent." 35 U.S.C. § 271(e)(2). Once the act of infringement occurs, the patent holder may then commence an action under 35 U.S.C. § 271 for infringement.[6] The litigation then proceeds to address the question of whether any future distribution of the identified generic would infringe a valid patent claim. If so, the court shall enter an order barring the FDA from approving that distribution

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[5] To find that venue is proper, a court must also determine that a defendant "has a regular and established place of business" in the district. 28 U.S.C. § 1400(b). The district court did not reach the question of whether Mylan has a regular and established place of business in New Jersey. As such, we do not address that issue on appeal.

[6] If the patent holder files its action within forty-five days of the ANDA submission the FDA's authority to approve manufacture and distribution of the generic identified in the ANDA is stayed for thirty months so that the litigation may proceed before such activities occur. 21 U.S.C. § 355(j)(5)(B)(iii).

prior to expiration of the infringed patent. 35 U.S.C. § 271(e)(4)(A).

The question we must answer in this appeal, therefore, is whether the act of infringement identified in § 1400(b) occurs only when and where an ANDA-filer submits its ANDA to the FDA or occurs wherever future distribution of the generic is contemplated. We address this question in two parts. We first recount some of our pre-*TC Heartland* case law discussing infringement actions under the Hatch-Waxman Act. We then address the specific arguments made by Valeant and Mylan as to the propriety of venue in New Jersey for this case, and how those arguments fare in light of the two statutory schemes at issue.

1. Statutory and Legal Backdrop

Prior to 2017, defendants hoping to transfer Hatch-Waxman cases to a different district generally objected to a plaintiff's chosen venue on personal jurisdiction grounds. We definitively resolved those arguments in *Acorda Therapeutics Inc. v. Mylan Pharmaceuticals Inc.*, 817 F.3d 755 (Fed. Cir. 2016), where we held that planned future acts were sufficient to justify the exercise of specific personal jurisdiction over a defendant in ANDA cases. In *Acorda*, we held that planned future interactions with the state in the form of marketing activities met the constitutional minimum requirements for personal jurisdiction. *Id.* at 760. While we did not address any statutory venue questions and specifically disclaimed having done so, this holding was important to the then-extant venue analysis because, at that point in time, our case law effectively had equated personal jurisdiction with venue by incorporating the definition of "reside" in the general venue statute, 28 U.S.C. § 1391(c)(2), into § 1400(b). *See VE Holding Corp. v. Johnson Gas Appliance Co.*, 917 F.2d 1574, 1584 (Fed. Cir. 1990) (holding that changes to the general venue statute meant that, in patent cases, corporations reside in every venue where personal jurisdiction is proper). Thus,

if personal jurisdiction over an ANDA filer could be obtained in any district where that filer intended to market the generic product described in the ANDA, then venue under § 1400(b) would be proper in the same district because the ANDA filer would be deemed to "reside" there for venue purposes as well.

The practical significance of *Acorda* was markedly contracted when the Supreme Court changed the venue landscape for patent cases in *TC Heartland*. That decision not only overturned *VE Holding* and its progeny, it reopened the effectively resolved question of where Hatch-Waxman cases could be venued.

When faced with other questions growing out of *TC Heartland*, we have narrowly construed the requirements of venue in patent cases. In *Cray*, for example, we narrowly construed § 1400(b)'s requirement of a "regular and established place of business." 871 F.3d at 1361 ("[T]he requirement of venue is specific and unambiguous; it is not one of those vague principles which, in the interests of some overriding policy, is to be given a liberal construction." (quoting *Schnell v. Peter Eckrich & Sons, Inc.*, 365 U.S. 260, 264 (1961))). We held that (1) there must be "a physical, geographical location in the district from which the business of the defendant is carried out"; (2) the defendant's presence "must for a meaningful time period be stable, established"; and (3) "it must be a place *of the defendant*." *Id.* at 1362–63 (emphasis in original). In *In re Google LLC*, we further reinforced the narrowness of the venue inquiry by clarifying that the venue statute excludes "agents' activities, such as maintenance, that are merely connected to, but do not themselves constitute, the defendant's conduct of business . . . ." 949 F.3d 1338, 1347 (Fed. Cir. 2020); *see also id.* at 1346 ("[T]he Supreme Court has cautioned against a broad reading of the venue statute."). Consistently, we have warned that "[c]ourts should be mindful of [the specific and unambiguous nature of venue] in applying the statute and be careful not to conflate showings that

may be sufficient for other purposes, *e.g.*, personal jurisdiction or the general venue statute, with the necessary showing to establish proper venue in patent cases." *Cray*, 871 F.3d at 1361.

We have had no chance since *TC Heartland* to address the question of where infringement occurs in an ANDA case, however.[7] District courts have struggled with the question and two competing views have emerged. The first significant case to address the question was *Bristol-Myers Squibb*, 2017 WL 3980155. There, the district court identified what it called "an almost impenetrable problem" of reconciling the venue statute's use of the present perfect tense ("where the defendant *has* committed acts of

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[7] The question of where infringement occurs in the Hatch-Waxman context is unique in its lack of pre-*TC Heartland* guidance. We answered the "where" question with respect to traditional acts of infringement years ago in extraterritorial infringement cases. *See, e.g.*, *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Contractors USA, Inc.*, 617 F.3d 1296, 1309 (Fed. Cir. 2010) (stating that the analysis for determining the location of an offer for sale should focus on "the location of the future sale that would occur pursuant to the offer"); *Litecubes, LLC v. N. Light Prods., Inc.*, 523 F.3d 1353, 1369–70 (Fed. Cir. 2008) (holding that an infringing sale may occur in more than one location as a sale has both a physical and a conceptual dimension to it); *NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282, 1317 (Fed. Cir. 2005) ("The use of a claimed system under section 271(a) is the place at which the system as a whole is put into service, *i.e.*, the place where control of the system is exercised and beneficial use of the system obtained."); *id.* at 1318 ("[A] process cannot be used 'within' the United States as required by section 271(a) unless each of the steps is performed within this country.").

infringement" (emphasis added)) with the Hatch-Waxman scheme, which focuses on potential future acts. *Id.* at *6–7. Ultimately, the court reasoned that, because the actual substance of ANDA litigation is not about the documents filed with the FDA but about whether potential future conduct would infringe a valid patent, it must be those future acts that are relevant to the venue analysis. *Id.* at *8. The court concluded that "[t]he submission of an ANDA is a stand-in that serves to move forward in time the infringement and invalidity challenges that otherwise would come later in time, such as after approval or marketing of the ANDA drug." *Id.* And, though acknowledging that it was not controlling of the issue presented, the court noted that our *Acorda* decision supported the result reached. *Id.* at *8–10.

When faced with the same question a few months later, one district court in the District of New Jersey adopted the reasoning in *Bristol-Myers Squibb*. *See Celgene Corp. v. Hetero Labs Ltd.*, No. 17-cv-3387-ES-MAH, 2018 WL 1135334, at *3 (D.N.J. Mar. 2, 2018). On that basis, it denied a motion to dismiss for improper venue filed by some of the generic defendants in that case.

A district court in the Northern District of Texas respectfully disagreed with the Delaware court's reasoning. *Galderma Labs., L.P. v. Teva Pharms. USA, Inc.*, 290 F. Supp. 3d 599, 606–09 (N.D. Tex. 2017). The court concluded both that § 1400(b) requires a *past* infringement and that the plain language of the Hatch-Waxman Act does not identify any act of infringement other than the ANDA submission. *Id.* at 607–08. The court reasoned that, because the potential future acts that the Hatch-Waxman act anticipates are speculative—many actions never happen precisely because of the litigation—they cannot control the venue of the action. *Id.* at 608. Noting that *Cray* warned away from conflating the personal jurisdiction and venue analyses, the court held that only the locations where the

ANDA materials were prepared and from which it was submitted are relevant to the venue analysis. *Id.* at 608–09.

The district court's opinion in this case took a position akin to that taken by the district court in the Northern District of Texas. We agree with the district court that venue is improper in New Jersey as to MPI and Mylan Inc. For the reasons discussed below, we hold that venue in Hatch-Waxman cases must be predicated on past acts of infringement—*i.e.*, acts that occurred before the action alleging infringement was filed. And we hold those acts occur only in districts where actions related to the ANDA submission occur.

2. Venue Was Not Available in New Jersey for MPI and Mylan Inc.

We review whether venue is proper under § 1400(b) de novo. *Westech Aerosol Corp. v. 3M Co.*, 927 F.3d 1378, 1381 (Fed. Cir. 2019). This is an issue unique to patent law and is therefore governed by Federal Circuit precedent. *ZTE*, 890 F.3d at 1012.

We begin our analysis with the plain language of the statutes. At least by the time briefing was complete in this appeal, both parties agreed that § 1400(b) requires a past act of infringement. *See* Appellees' Br. 14–21; Appellants' Reply Br. 5. Specifically, "has committed acts of infringement," a present perfect phrase, counsels that the acts accused of infringement must have already occurred. This understanding is supported by Congress's choice of words for the rest of the provision. Congress included two phrases that are plainly in the present tense ("where the defendant resides" and "where the defendant . . . has a regular and established place of business"), indicating that its choice to place the infringement in the past was intentional. The heart of the dispute, therefore, is the nature and scope of the act of infringement defined by 35 U.S.C. § 271(e)(2).

As noted, the Hatch-Waxman Act makes it "an act of infringement to submit [an ANDA] for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent." 35 U.S.C. § 271(e)(2). A plain language reading of this provision directs us to the conclusion that it is the submission of the ANDA, and only the submission, that constitutes an act of infringement in this context. Valeant makes several arguments as to why we should understand § 271(e)(2) as encompassing more. None persuade us to reach a different conclusion.

Valeant first argues that the Hatch-Waxman act of infringement is "artificial" and, therefore, requires us to look to planned future conduct to define what is really infringing. Appellants' Br. 21–25. The Supreme Court, our court, and district courts have referred to the ANDA submission as an "artificial act of infringement." *See, e.g.*, *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990); *Acorda*, 817 F.3d at 760; *Belcher Pharms., LLC v. Int'l Medication Sys., Ltd.*, 379 F. Supp. 3d 326, 330 (D. Del. 2019). The Hatch-Waxman Act itself never says the act that constitutes infringement is artificial, however. It speaks in real terms—submission of the ANDA *is* the infringing act. It does so, moreover, after declaring other acts, which otherwise may have been infringing, to be non-infringing when undertaken solely for purposes of requesting regulatory approval to market a drug—*i.e.*, solely for purposes of submitting the ANDA. 35 U.S.C. § 271(e)(1). Thus, the statute "artificially" declares certain very real acts of infringement to be non-infringing acts and other acts that would not otherwise constitute infringement to be acts of infringement. But, in both instances the result is real; the statute delineates which acts may or may not give rise to a cause of action under the Hatch-Waxman Act. The language used by

courts to characterize Hatch-Waxman cases does not change that an ANDA submission is a real, albeit statutorily created, act of infringement. *See Eli Lilly*, 496 U.S. at 678 (The Hatch-Waxman Act creates "a highly artificial act of infringement that *consists of submitting an ANDA*." (emphasis added)).

Valeant next focuses on the nature and substance of Hatch-Waxman litigation and argues that the act of infringement must encompass more than just submission of the ANDA. Appellants' Br. 24–25. As noted, it is true that the judicial inquiry on the merits once an action has been commenced considers the ANDA defendant's potential future conduct—*i.e.*, whether the conduct in which that defendant would like to engage would infringe a valid patent. The content of the litigation does not, however, turn potential future acts into past infringement. Under the plain language of the statute, the only past infringing act is the ANDA submission, which creates the right to bring suit in the first instance. The result of virtually all Hatch-Waxman litigation is, moreover, that no post-submission infringement happens. Sales and offers for sale of the ANDA product are either non-infringing as determined through the litigation, or such acts typically never occur. In that ordinary circumstance (where there is no at-risk market entry of the generic), the only concrete locations that will ever be touched by a non-hypothetical past act of infringement are those connected to the submission of the ANDA itself.

Valeant also argues that congressional intent supports its interpretation. Appellants' Br. 34–39. Valeant argues that Congress *must* have meant to allow venue in all the places that might have been available had a generic entered the market at-risk. The statute does not say that, however. Importantly, the Supreme Court told us several things in *TC Heartland*. First, that its own decision in *Fourco Glass Co. v. Transmirra Products Corp.*, 353 U.S. 222 (1957), made clear that Congress enacted § 1400(b) in

1948 to be a standalone venue statute for patent cases. *TC Heartland*, 137 S. Ct. at 1519. Second, that the term "resides" in the first clause of § 1400(b) was meant to have the same meaning in 1948 as the term "inhabits" had in the earlier version of that statute—*i.e.*, that corporations were only subject to suit in patent cases under the first clause of § 1400(b) in their state of incorporation. *Id.* Third, that Congress expressed no intention to alter either clause of § 1400 in 1988 when it enacted amendments to the general venue statute and made that intention even clearer when it enacted the current version of the general venue statute in 2011. *Id.* at 1521. Given this guidance, we similarly must assume that, when Congress enacted the Hatch-Waxman Act in 1984, it did so with a clear understanding of where § 1400(b) allowed patent actions to be commenced at that time. And, we must assume that, when it excepted Hatch-Waxman cases from the new joinder provisions for patent cases enacted in 2011, Congress understood that it was not *sub silentio* also excepting Hatch-Waxman cases from 1400(b). As the Court noted in *TC Heartland*, when Congress intends to effect a change as sweeping as a revision to § 1400(b), "it ordinarily provides a relatively clear indication of its intent in the text" of the statute. *Id.* at 1520 (citing *United States v. Madigan*, 300 U.S. 500, 506 (1937)). We can glean no such clear guidance from the text of the Hatch-Waxman Act.

Valeant further contends that the second clause of the patent venue statute, allowing venue where an act of infringement occurs if the accused infringer has a regular and established place of business, is rendered superfluous by a plain-language reading of the statute. Appellants' Br. 25–26. Surely, a statute should be interpreted to give all of its provisions meaning. *Corley v. United States*, 556 U.S. 303, 314 (2009). But Valeant's argument fails to recognize that the second clause retains meaning in every other type of patent infringement case and will be operative in every

Hatch-Waxman case where the ANDA is submitted from a venue different than the submitter's place of incorporation.

Next, Valeant argues that we should hold that an ANDA submission is a nationwide act of infringement based on a "conceptual" aspect beyond the literal act defined in the statute. Appellants' Br. 28; Appellants' Reply Br. 16–21. It cites *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Contractors USA, Inc.*, 617 F.3d 1296, 1309–11 (Fed. Cir. 2010), where we considered which locations can logically be said to be the locations of sales and offers for sale in patent cases. We held that those acts can occur in more than one location. The analysis looks to both the location of the parties at the time of contracting and to the location of anticipated performance. Valeant argues for a similar, but markedly more expansive, analysis in this case. Valeant would have us hold that the literal act of infringement—submission of the ANDA—encompasses a vast "conceptual" element of nationwide infringement in every judicial district. While we have held that sales and offers for sale have both physical and conceptual elements, *see Litecubes, LLC v. N. Light Prods., Inc.*, 523 F.3d 1353, 1369–70 (Fed. Cir. 2008), the conceptual elements in those cases were connected to common law understandings of "sales" and "offers for sale." There is no analogous common law here that would compel a conclusion that submitting an ANDA has a purely conceptual effect of causing infringement *everywhere* in the United States. To reach such a broad interpretation of the infringing act, without any textual hook in the statute, would be a bridge too far.

Valeant does have strong policy reasons for adopting its reading of the statutes. For example, a generic company may "game" the system to avoid venue in certain jurisdictions. Appellants' Reply Br. 20. And brand name drug companies may "be required to file and maintain largely identical suits in multiple districts" causing an increase in time and expense to resolve the cases and "result[ing] in inconsistent judgments." *Bristol-Myers Squibb*, 2017 WL

3980155, at *12 n.17. While intuitively persuasive, these policy arguments cannot trump the plain language of § 271(e)(2) and the requirements of § 1400(b). We are, as we must be, guided in our analysis by controlling precedent stating that venue is not amenable to such policy concerns. *See Cray*, 871 F.3d at 1361 (quoting *Schnell*, 365 U.S. at 264). Congress can revise the two statutes to the extent it finds these, or other, policy concerns compelling; all we can do is give the statutes their current plain meaning.

Finally, Valeant looks to *Acorda*. Appellants' Br. 29–33. *Acorda* did not, however, address proper venue—a question of statutory interpretation. It was focused on the narrow constitutional question of whether minimum contacts were present for purposes of personal jurisdiction based on the ANDA submission. We held that submission with an intent to distribute the generic product in a given state was sufficient for personal jurisdiction purposes. *Acorda*, 817 F.3d at 762. *Acorda* said nothing about whether an act of infringement had already occurred in any such state or venue. While our then-current venue law meant *Acorda* had a big impact on the venue analysis in Hatch-Waxman cases, we did not address venue in the case. And, though our venue law has changed, we cannot stretch *Acorda* to reach that issue now. As we indicated then, we would be remiss to treat venue and personal jurisdiction as the same inquiry. *See id.* at 763.

Accordingly, we hold that, in Hatch-Waxman cases, venue is not proper in all judicial districts where a generic product specified in an ANDA is likely to be distributed. It is proper only in those districts that are sufficiently related to the ANDA submission—in those districts where acts occurred that would suffice to categorize those taking them as a "submitter" under § 271(e). We find ourselves bound by the plain language of the statutes and a directive from the Supreme Court that venue "is not one of those vague principles which, in the interest of some overriding policy,

is to be given a liberal construction." *Schnell*, 365 U.S. at 264 (internal quotation marks omitted).

The district court found that no act involved in the submitting of the ANDA occurred in New Jersey. Valeant does not challenge that finding on appeal. We therefore affirm the district court's dismissal of MPI and Mylan Inc. for improper venue.[8]

B. Venue Is Proper for MLL in New Jersey

The district court decision clearly articulates, and it is undisputed, that MLL is properly subject to venue in any judicial district, including the District of New Jersey. *See Valeant Pharms.*, 2019 WL 4179832, at *3 n.2; *see also In re HTC Corp.*, 889 F.3d 1349, 1358 (Fed. Cir. 2018). The court's conclusion dismissing the complaint as to all defendants after only evaluating Mylan's venue argument is, therefore, incongruous. Mylan invites us to affirm on an alternative basis by holding, in the first instance, that Valeant failed to state a claim against MLL and that the district court likely understood that fact. Appellees' Br. 44–46. Whether MLL can be held answerable to claims of

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[8] The district court's suggestion that an act of infringement for purposes of this case may have occurred in the District of Maryland where the FDA received the ANDA is not challenged in this appeal. While it may well be that the District of Maryland satisfies the test for venue that we have laid out here, we do not resolve that question. We also do not define what all relevant acts involved in the preparation and submission of an ANDA might be, leaving those questions for other cases where the precise contours are presented and briefed. We do agree with the Delaware district court, however, that acts protected by the safe harbor provisions in § 271(e) are non-infringing for all purposes, including venue. *See Bristol-Myers Squibb*, 2017 WL 3980155, at *7, 11.

infringement in this case turns on whether MLL's involvement in the submission of the ANDA is sufficient for it to be considered a "submitter," and thus, amenable to suit. *See Rosuvastatin*, 703 F.3d at 527–29. For purposes of a Rule 12(b)(6) motion, the court must decide whether Valeant plausibly alleged sufficient involvement on the part of MLL. *See*, *e.g.*, *Galderma*, 290 F. Supp. 3d at 615–18; *Cephalon, Inc. v. Watson Pharms., Inc.*, 629 F. Supp. 2d 338, 349 (D. Del. 2009). Mylan points to paragraph 29 of the complaint and says Valeant unambiguously asserted that only MPI was involved in submitting the ANDA. Appellees' Br. 44 (citing J.A. 153, ¶ 29). But, as Valeant notes, there are eight other paragraphs in the complaint asserting that "Mylan"—defined to encompass all three entities—"submitted" the ANDA and materials related to it. J.A. 154–64, ¶¶ 35, 46, 57, 68, 79, 90, 101, 112. The district court may well find that these paragraphs are sufficient to state a claim against MLL, despite the phrasing in paragraph 29, or that leave to amend to clarify any apparent confusion would be appropriate. We thus reverse the district court's venue-based dismissal of MLL and remand for further consideration.[9]

III. CONCLUSION

While, as noted, we are sympathetic to the policy concerns associated with limited venue for Hatch-Waxman cases, especially those relating to lost judicial efficiencies in the handling of these mostly multi-defendant cases, we are compelled to our conclusion by the plain language of

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[9] The district court also did not answer whether a claim under § 271(e) has been stated against Mylan Inc. Because we affirm the dismissal of Mylan Inc. under Rule 12(b)(3), we do not address the district court's failure to consider the motion as to that entity under Rule 12(b)(6).

the two statutes at issue.[10] We therefore affirm the district court's dismissal of Valeant's complaint as to MPI and Mylan Inc. for improper venue. As to MLL, because venue is proper in New Jersey for any foreign defendant, we reverse the district court's dismissal and remand.

AFFIRMED-IN-PART, REVERSED-IN-PART, AND REMANDED

COSTS

No costs.

[10] While cumbersome for these types of cases, 28 U.S.C. § 1407 is at least a viable path for consolidation of these cases for pretrial purposes.

Syllabus

NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States* v. *Detroit Timber & Lumber Co.,* 200 U. S. 321, 337.

SUPREME COURT OF THE UNITED STATES

Syllabus

UNITED STATES *v.* ARTHREX, INC. ET AL.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

No. 19–1434. Argued March 1, 2021—Decided June 21, 2021*

The question in these cases is whether the authority of Administrative Patent Judges (APJs) to issue decisions on behalf of the Executive Branch is consistent with the Appointments Clause of the Constitution. APJs conduct adversarial proceedings for challenging the validity of an existing patent before the Patent Trial and Appeal Board (PTAB). During such proceedings, the PTAB sits in panels of at least three of its members, who are predominantly APJs. 35 U. S. C. §§6(a), (c). The Secretary of Commerce appoints all members of the PTAB—including 200-plus APJs—except for the Director, who is nominated by the President and confirmed by the Senate. §§3(b)(1), (b)(2)(A), 6(a). After Smith & Nephew, Inc., and ArthroCare Corp. (collectively, Smith & Nephew) petitioned for inter partes review of a patent secured by Arthrex, Inc., three APJs concluded that the patent was invalid. On appeal to the Federal Circuit, Arthrex claimed that the structure of the PTAB violated the Appointments Clause, which specifies how the President may appoint officers to assist in carrying out his responsibilities. Art. II, §2, cl. 2. Arthrex argued that the APJs were principal officers who must be appointed by the President with the advice and consent of the Senate, and that their appointment by the Secretary of Commerce was therefore unconstitutional. The Federal Circuit held that the APJs were principal officers whose appointments were unconstitutional because neither the Secretary nor Director can review their decisions or remove them at will. To remedy this constitutional violation, the Federal Circuit invalidated the APJs' tenure protections,

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*Together with No. 19–1452, *Smith & Nephew, Inc., et al.* v. *Arthrex, Inc., et al.* and No. 19–1458, *Arthrex, Inc.* v. *Smith & Nephew, Inc., et al.*, also on certiorari to the same court.

Syllabus

making them removable at will by the Secretary.

Held: The judgment is vacated, and the case is remanded.

941 F. 3d 1320, vacated and remanded.

THE CHIEF JUSTICE delivered the opinion of the Court with respect to Parts I and II, concluding that the unreviewable authority wielded by APJs during inter partes review is incompatible with their appointment by the Secretary of Commerce to an inferior office. Pp. 6–19.

(a) The Appointments Clause provides that only the President, with the advice and consent of the Senate, can appoint principal officers. With respect to inferior officers, the Clause permits Congress to vest appointment power "in the President alone, in the Courts of Law, or in the Heads of Departments." Pp. 6–8.

(b) In *Edmond* v. *United States,* 520 U. S. 651, this Court explained that an inferior officer must be "directed and supervised at some level by others who were appointed by Presidential nomination with the advice and consent of the Senate." *Id.*, at 663. Applying that test to Coast Guard Court of Criminal Appeals judges appointed by the Secretary of Transportation, the Court held that the judges were inferior officers because they were effectively supervised by a combination of Presidentially nominated and Senate confirmed officers in the Executive Branch. *Id.*, at 664–665. What the Court in *Edmond* found "significant" was that those judges had "no power to render a final decision on behalf of the United States unless permitted to do so by other Executive officers." *Id.*, at 665.

Such review by a superior executive officer is absent here. While the Director has tools of administrative oversight, neither he nor any other superior executive officer can directly review decisions by APJs. Only the PTAB itself "may grant rehearings." §6(c). This restriction on review relieves the Director of responsibility for the final decisions rendered by APJs under his charge. Their decision—the final word within the Executive Branch—compels the Director to "issue and publish a certificate" canceling or confirming patent claims he had previously allowed. §318(b).

The Government and Smith & Nephew contend that the Director has various ways to indirectly influence the course of inter partes review. The Director, for example, could designate APJs predisposed to decide a case in his preferred manner. But such machinations blur the lines of accountability demanded by the Appointments Clause and leave the parties with neither an impartial decision by a panel of experts nor a transparent decision for which a politically accountable officer must take responsibility.

Even if the Director can refuse to designate APJs on *future* PTAB panels, he has no means of countermanding the final decision already on the books. Nor can the Secretary meaningfully control APJs

through the threat of removal from federal service entirely because she can fire them only "for such cause as will promote the efficiency of the service." 5 U. S. C. §7513(a); see *Seila Law LLC* v. *Consumer Financial Protection Bureau*, 591 U. S. ___, ___. And the possibility of an appeal to the Federal Circuit does not provide the necessary supervision. APJs exercise executive power, and the President must be ultimately responsible for their actions. See *Arlington* v. *FCC*, 569 U. S. 290, 305, n. 4.

Given the insulation of PTAB decisions from any executive review, the President can neither oversee the PTAB himself nor "attribute the Board's failings to those whom he *can* oversee." *Free Enterprise Fund* v. *Public Company Accounting Oversight Bd.,* 561 U. S. 477, 496. APJs accordingly exercise power that conflicts with the design of the Appointments Clause "to preserve political accountability." *Edmond*, 520 U. S., at 663. Pp. 8–14.

(c) History reinforces the conclusion that the unreviewable executive power exercised by APJs is incompatible with their status as inferior officers. Founding-era congressional statutes and early decisions from this Court indicate that adequate supervision entails review of decisions issued by inferior officers. See, *e.g.*, 1 Stat. 66–67; *Barnard* v. *Ashley*, 18 How. 43, 45. Congress carried that model of principal officer review into the modern administrative state. See, *e.g.*, 5 U. S. C. §557(b).

According to the Government and Smith & Nephew, heads of department appoint a handful of contemporary officers who purportedly exercise final decisionmaking authority. Several of their examples, however, involve inferior officers whose decisions a superior executive officer can review or implement a system for reviewing. See, *e.g.*, *Freytag* v. *Commissioner*, 501 U. S. 868. Nor does the structure of the PTAB draw support from the predecessor Board of Appeals, which determined the patentability of inventions in panels composed of examiners-in-chief without an appeal to the Commissioner. 44 Stat. 1335–1336. Those Board decisions could be reviewed by the Court of Customs and Patent Appeals—an executive tribunal—and may also have been subject to the unilateral control of the agency head. Pp. 14–18.

(d) The Court does not attempt to "set forth an exclusive criterion for distinguishing between principal and inferior officers for Appointments Clause purposes." *Edmond*, 520 U. S., at 661. Many decisions by inferior officers do not bind the Executive Branch to exercise executive power in a particular manner, and the Court does not address supervision outside the context of adjudication. Here, however, Congress has assigned APJs "significant authority" in adjudicating the public rights of private parties, while also insulating their decisions from review and their offices from removal. *Buckley* v. *Valeo,* 424 U. S.

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1, 126. Pp. 18–19.

THE CHIEF JUSTICE, joined by JUSTICE ALITO, JUSTICE KAVANAUGH, and JUSTICE BARRETT, concluded in Part III that §6(c) cannot constitutionally be enforced to the extent that its requirements prevent the Director from reviewing final decisions rendered by APJs. The Director accordingly may review final PTAB decisions and, upon review, may issue decisions himself on behalf of the Board. Section 6(c) otherwise remains operative as to the other members of the PTAB. When reviewing such a decision by the Director, a court must decide the case "conformably to the constitution, disregarding the law" placing restrictions on his review authority in violation of Article II. *Marbury* v. *Madison*, 1 Cranch 137, 178.

The appropriate remedy is a remand to the Acting Director to decide whether to rehear the petition filed by Smith & Nephew. A limited remand provides an adequate opportunity for review by a principal officer. Because the source of the constitutional violation is the restraint on the review authority of the Director, rather than the appointment of APJs by the Secretary, Arthrex is not entitled to a hearing before a new panel of APJs. Pp. 19–23.

ROBERTS, C. J., delivered the opinion of the Court with respect to Parts I and II, in which ALITO, GORSUCH, KAVANAUGH, and BARRETT, JJ., joined, and an opinion with respect to Part III, in which ALITO, KAVANAUGH, and BARRETT, JJ., joined. GORSUCH, J., filed an opinion concurring in part and dissenting in part. BREYER, J., filed an opinion concurring in the judgment in part and dissenting in part, in which SOTOMAYOR and KAGAN, JJ., joined. THOMAS, J., filed a dissenting opinion, in which BREYER, SOTOMAYOR, and KAGAN, JJ., joined as to Parts I and II.

SUPREME COURT OF THE UNITED STATES

Nos. 19–1434, 19–1452 and 19–1458

UNITED STATES, PETITIONER
19–1434 *v.*
ARTHREX, INC., ET AL.

SMITH & NEPHEW, INC., ET AL., PETITIONERS
19–1452 *v.*
ARTHREX, INC., ET AL.

ARTHREX, INC., PETITIONER
19–1458 *v.*
SMITH & NEPHEW, INC., ET AL.

ON WRITS OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

[June 21, 2021]

CHIEF JUSTICE ROBERTS delivered the opinion of the Court with respect to Parts I and II.

The validity of a patent previously issued by the Patent and Trademark Office can be challenged before the Patent Trial and Appeal Board, an executive tribunal within the PTO. The Board, composed largely of Administrative Patent Judges appointed by the Secretary of Commerce, has the final word within the Executive Branch on the validity of a challenged patent. Billions of dollars can turn on a Board decision.

Under the Constitution, "[t]he executive Power" is vested in the President, who has the responsibility to "take Care

that the Laws be faithfully executed." Art. II, §1, cl. 1; §3. The Appointments Clause provides that he may be assisted in carrying out that responsibility by officers nominated by him and confirmed by the Senate, as well as by other officers not appointed in that manner but whose work, we have held, must be directed and supervised by an officer who has been. §2, cl. 2. The question presented is whether the authority of the Board to issue decisions on behalf of the Executive Branch is consistent with these constitutional provisions.

I

A

The creation of a workable patent system was a congressional priority from the start. The First Congress established the Patent Board—consisting impressively of Secretary of State Thomas Jefferson, Secretary of War Henry Knox, and Attorney General Edmund Randolph—to issue patents for inventions they deemed "sufficiently useful and important." §1, 1 Stat. 109–110. Jefferson, a renowned inventor in his own right, "was charged with most of the responsibility" to administer the new patent system. Federico, Operation of the Patent Act of 1790, 18 J. Pat. Off. Soc. 237, 238–239 (1936). The Patent Board was a short-lived experiment because its members had much else to do. Jefferson candidly admitted that he had "been obliged to give undue & uninformed opinions on rights often valuable" without the "great deal of time" necessary to "understand & do justice by" patent applicants. Letter from T. Jefferson to H. Williamson (Apr. 1, 1792), in 6 Works of Thomas Jefferson 459 (P. Ford ed. 1904).

In 1793, Congress shifted to a registration system administered by the Secretary of State. See 1 Stat. 319–321. The Secretary no longer reviewed the substance of patent applications but instead issued patents through a routine process "as a ministerial officer." *Grant* v. *Raymond*, 6 Pet.

218, 241 (1832). The courts would make the initial determination of patent validity in a subsequent judicial proceeding, such as an infringement suit. See 1 Stat. 322. This scheme unsurprisingly resulted in the Executive Branch issuing many invalid patents and the Judicial Branch having to decide many infringement cases. See S. Doc. No. 338, 24th Cong., 1st Sess., 3 (1836). Judge William Van Ness—who before taking the bench had served as second to Aaron Burr in his duel with Alexander Hamilton—lamented that Congress had left the door "open and unguarded" for imposters to secure patents, with the consequences of "litigation and endless trouble, if not total ruin, to the true inventor." *Thompson* v. *Haight*, 23 F. Cas. 1040, 1041–1042 (No. 13,957) (CC SDNY 1826). Congress heeded such concerns by returning the initial determination of patentability to the Executive Branch, see 5 Stat. 117–118, where it remains today.

The present system is administered by the Patent and Trademark Office (PTO), an executive agency within the Department of Commerce "responsible for the granting and issuing of patents" in the name of the United States. 35 U. S. C. §§1(a), 2(a)(1). Congress has vested the "powers and duties" of the PTO in a sole Director appointed by the President with the advice and consent of the Senate. §3(a)(1). As agency head, the Director "provid[es] policy direction and management supervision" for PTO officers and employees. §3(a)(2)(A).

This suit centers on the Patent Trial and Appeal Board (PTAB), an executive adjudicatory body within the PTO established by the Leahy-Smith America Invents Act of 2011. 125 Stat. 313. The PTAB sits in panels of at least three members drawn from the Director, the Deputy Director, the Commissioner for Patents, the Commissioner for Trademarks, and more than 200 Administrative Patent Judges (APJs). 35 U. S. C. §§6(a), (c). The Secretary of Commerce appoints the members of the PTAB (except for the Director),

including the APJs at issue in this dispute. §§3(b)(1), (b)(2)(A), 6(a). Like the 1790 Patent Board, the modern Board decides whether an invention satisfies the standards for patentability on review of decisions by primary examiners. §§6(b)(1), 134(a).

Through a variety of procedures, the PTAB can also take a second look at patents previously issued by the PTO. §§6(b)(2)–(4). One such procedure is inter partes review. Established in 2011, inter partes review is an adversarial process by which members of the PTAB reconsider whether existing patents satisfy the novelty and nonobviousness requirements for inventions. See §6(a) of the America Invents Act, 125 Stat. 299. Any person—other than the patent owner himself—can file a petition to institute inter partes review of a patent. 35 U. S. C. §311(a). The Director can institute review only if, among other requirements, he determines that the petitioner is reasonably likely to prevail on at least one challenged patent claim. §314(a). Congress has committed the decision to institute inter partes review to the Director's unreviewable discretion. See *Thryv, Inc.* v. *Click-To-Call Technologies, LP*, 590 U. S. ___, ___ (2020) (slip op., at 6). By regulation, the Director has delegated this authority to the PTAB itself. 37 CFR §42.4(a) (2020).

The Director designates at least three members of the PTAB (typically three APJs) to conduct an inter partes proceeding. 35 U. S. C. §6(c). The PTAB then assumes control of the process, which resembles civil litigation in many respects. §316(c). The PTAB must issue a final written decision on all of the challenged patent claims within 12 to 18 months of institution. §316(a)(11); see *SAS Institute Inc.* v. *Iancu*, 584 U. S. ___, ___ (2018) (slip op., at 5). A party who disagrees with a decision may request rehearing by the PTAB. 35 U. S. C. §6(c); 37 CFR §42.71(d).

The PTAB is the last stop for review within the Executive Branch. A party dissatisfied with the final decision may seek judicial review in the Court of Appeals for the Federal

Circuit. 35 U. S. C. §319. At this stage, the Director can intervene before the court to defend or disavow the Board's decision. §143. The Federal Circuit reviews the PTAB's application of patentability standards *de novo* and its underlying factual determinations for substantial evidence. See *Oil States Energy Services, LLC* v. *Greene's Energy Group, LLC*, 584 U. S. ___, ___ (2018) (slip op., at 4). Upon expiration of the time to appeal or termination of any appeal, "the Director shall issue and publish a certificate canceling any claim of the patent finally determined to be unpatentable, confirming any claim of the patent determined to be patentable, and incorporating in the patent by operation of the certificate any new or amended claim determined to be patentable." §318(b).

B

Arthrex, Inc. develops medical devices and procedures for orthopedic surgery. In 2015, it secured a patent on a surgical device for reattaching soft tissue to bone without tying a knot, U. S. Patent No. 9,179,907 ('907 patent). Arthrex soon claimed that Smith & Nephew, Inc. and ArthroCare Corp. (collectively, Smith & Nephew) had infringed the '907 patent, and the dispute eventually made its way to inter partes review in the PTO. Three APJs formed the PTAB panel that conducted the proceeding and ultimately concluded that a prior patent application "anticipated" the invention claimed by the '907 patent, so that Arthrex's patent was invalid. See App. to Pet. for Cert. in No. 19–1434, p. 128a.

On appeal to the Federal Circuit, Arthrex raised for the first time an argument premised on the Appointments Clause of the Constitution. That Clause specifies how the President may appoint officers who assist him in carrying out his responsibilities. *Principal* officers must be appointed by the President with the advice and consent of the Senate, while *inferior* officers may be appointed by the

President alone, the head of an executive department, or a court. Art. II, §2, cl. 2. Arthrex argued that the APJs were principal officers and therefore that their appointment by the Secretary of Commerce was unconstitutional. The Government intervened to defend the appointment procedure.

The Federal Circuit agreed with Arthrex that APJs were principal officers. 941 F. 3d 1320, 1335 (2019). Neither the Secretary nor Director had the authority to review their decisions or to remove them at will. The Federal Circuit held that these restrictions meant that APJs were themselves principal officers, not inferior officers under the direction of the Secretary or Director.

To fix this constitutional violation, the Federal Circuit invalidated the tenure protections for APJs. Making APJs removable at will by the Secretary, the panel held, prospectively "renders them inferior rather than principal officers." *Id.*, at 1338. The Federal Circuit vacated the PTAB's decision and remanded for a fresh hearing before a new panel of APJs, who would no longer enjoy protection against removal. *Id.*, at 1338–1340.

This satisfied no one. The Government, Smith & Nephew, and Arthrex each requested rehearing en banc, which the Court of Appeals denied. 953 F. 3d 760, 761 (2020) (*per curiam*). The parties then requested review of different aspects of the panel's decision in three petitions for certiorari.

We granted those petitions to consider whether the PTAB's structure is consistent with the Appointments Clause, and the appropriate remedy if it is not. 592 U. S. ___ (2020).

II

A

The President is "'responsible for the actions of the Executive Branch'" and "'cannot delegate [that] ultimate responsibility or the active obligation to supervise that goes

with it.'" *Free Enterprise Fund* v. *Public Company Accounting Oversight Bd.*, 561 U. S. 477, 496–497 (2010) (quoting *Clinton* v. *Jones*, 520 U. S. 681, 712–713 (1997) (BREYER, J., concurring in judgment)). The Framers recognized, of course, that "no single person could fulfill that responsibility alone, [and] expected that the President would rely on subordinate officers for assistance." *Seila Law LLC* v. *Consumer Financial Protection Bureau*, 591 U. S. ___, ___ (2020) (plurality opinion) (slip op., at 2).

Today, thousands of officers wield executive power on behalf of the President in the name of the United States. That power acquires its legitimacy and accountability to the public through "a clear and effective chain of command" down from the President, on whom all the people vote. *Free Enterprise Fund*, 561 U. S., at 498. James Madison extolled this "great principle of unity and responsibility in the Executive department," which ensures that "the chain of dependence [will] be preserved; the lowest officers, the middle grade, and the highest, will depend, as they ought, on the President, and the President on the community." 1 Annals of Cong. 499 (1789).

The Appointments Clause provides:

> "[The President] shall nominate, and by and with the Advice and Consent of the Senate, shall appoint Ambassadors, other public Ministers and Consuls, Judges of the supreme Court, and all other Officers of the United States, whose Appointments are not herein otherwise provided for, and which shall be established by Law: but 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." Art. II, §2, cl. 2.

Assigning the nomination power to the President guarantees accountability for the appointees' actions because the "blame of a bad nomination would fall upon the president

singly and absolutely." The Federalist No. 77, p. 517 (J. Cooke ed. 1961) (A. Hamilton). As Hamilton wrote, the "sole and undivided responsibility of one man will naturally beget a livelier sense of duty and a more exact regard to reputation." *Id.*, No. 76, at 510–511. The Appointments Clause adds a degree of accountability in the Senate, which shares in the public blame "for both the making of a bad appointment and the rejection of a good one." *Edmond* v. *United States*, 520 U. S. 651, 660 (1997).

Only the President, with the advice and consent of the Senate, can appoint noninferior officers, called "principal" officers as shorthand in our cases. See *id.*, at 659. The "default manner of appointment" for inferior officers is also nomination by the President and confirmation by the Senate. *Id.*, at 660. But the Framers foresaw that "when offices became numerous, and sudden removals necessary, this mode might be inconvenient." *United States* v. *Germaine*, 99 U. S. 508, 510 (1879). Reflecting this concern for "administrative convenience," the Appointments Clause permits Congress to dispense with joint appointment, but only for inferior officers. *Edmond*, 520 U. S., at 660. Congress may vest the appointment of such officers "in the President alone, in the Courts of Law, or in the Heads of Departments."

B

Congress provided that APJs would be appointed as inferior officers, by the Secretary of Commerce as head of a department. The question presented is whether the nature of their responsibilities is consistent with their method of appointment. As an initial matter, no party disputes that APJs are officers—not "lesser functionaries" such as employees or contractors—because they "exercis[e] significant authority pursuant to the laws of the United States." *Buckley* v. *Valeo*, 424 U. S. 1, 126, and n. 162 (1976) (*per curiam*); see *Lucia* v. *SEC*, 585 U. S. ___, ___–___ (2018) (slip op., at

8–9). APJs do so when reconsidering an issued patent, a power that (the Court has held) involves the adjudication of public rights that Congress may appropriately assign to executive officers rather than to the Judiciary. See *Oil States*, 584 U. S., at ___–___ (slip op., at 8–9).

The starting point for each party's analysis is our opinion in *Edmond*. There we explained that "[w]hether one is an 'inferior' officer depends on whether he has a superior" other than the President. 520 U. S., at 662. An inferior officer must be "directed and supervised at some level by others who were appointed by Presidential nomination with the advice and consent of the Senate." *Id.*, at 663.

In *Edmond*, we applied this test to adjudicative officials within the Executive Branch—specifically, Coast Guard Court of Criminal Appeals judges appointed by the Secretary of Transportation. See *id.*, at 658. We held that the judges were inferior officers because they were effectively supervised by a combination of Presidentially nominated and Senate confirmed officers in the Executive Branch: first, the Judge Advocate General, who "exercise[d] administrative oversight over the Court of Criminal Appeals" by prescribing rules of procedure and formulating policies for court-martial cases, and could also "remove a Court of Criminal Appeals judge from his judicial assignment without cause"; and second, the Court of Appeals for the Armed Forces, an executive tribunal that could review the judges' decisions under a *de novo* standard for legal issues and a deferential standard for factual issues. *Id.*, at 664–665. "What is significant," we concluded, "is that the judges of the Court of Criminal Appeals have no power to render a final decision on behalf of the United States unless permitted to do so by other Executive officers." *Id.*, at 665.

Congress structured the PTAB differently, providing only half of the "divided" supervision to which judges of the Court of Criminal Appeals were subject. *Id.*, at 664. Like the Judge Advocate General, the PTO Director possesses

powers of "administrative oversight." *Ibid.* The Director fixes the rate of pay for APJs, controls the decision whether to institute inter partes review, and selects the APJs to reconsider the validity of the patent. 35 U. S. C. §§3(b)(6), 6(c), 314(a). The Director also promulgates regulations governing inter partes review, issues prospective guidance on patentability issues, and designates past PTAB decisions as "precedential" for future panels. §§3(a)(2)(A), 316(a)(4); Brief for United States 6. He is the boss, except when it comes to the one thing that makes the APJs officers exercising "significant authority" in the first place—their power to issue decisions on patentability. *Buckley*, 424 U. S., at 126. In contrast to the scheme approved by *Edmond*, no principal officer at any level within the Executive Branch "direct[s] and supervise[s]" the work of APJs in that regard. 520 U. S., at 663.

Edmond goes a long way toward resolving this dispute. What was "significant" to the outcome there—review by a superior executive officer—is absent here: APJs have the "power to render a final decision on behalf of the United States" without any such review by their nominal superior or any other principal officer in the Executive Branch. *Id.*, at 665. The only possibility of review is a petition for rehearing, but Congress unambiguously specified that "[o]nly the Patent and Trial Appeal Board may grant rehearings." §6(c). Such review simply repeats the arrangement challenged as unconstitutional in this suit.

This "diffusion of power carries with it a diffusion of accountability." *Free Enterprise Fund*, 561 U. S., at 497. The restrictions on review relieve the Director of responsibility for the final decisions rendered by APJs purportedly under his charge. The principal dissent's observation that "the Director alone has the power to take final action to cancel a patent claim or confirm it," *post*, at 7 (opinion of THOMAS, J.), simply ignores the undisputed fact that the Director's

"power" in that regard is limited to carrying out the ministerial duty that he "shall issue and publish a certificate" canceling or confirming patent claims he had previously allowed, as dictated by the APJs' final decision. §318(b); see §§131, 153. The chain of command runs not from the Director to his subordinates, but from the APJs to the Director.

The Government and Smith & Nephew assemble a catalog of steps the Director might take to affect the decisionmaking process of the PTAB, despite his lack of any statutory authority to review its decisions. See Brief for United States 30–32; Brief for Smith & Nephew, Inc., et al. 25–27. The Government reminds us that it is the Director who decides whether to initiate inter partes review. §314(a). The Director can also designate the APJs who will decide a particular case and can pick ones predisposed to his views. §6(c). And the Director, the Government asserts, can even vacate his institution decision if he catches wind of an unfavorable ruling on the way. The "proceeding will have no legal consequences" so long as the Director jumps in before the Board issues its final decision. Brief for United States 31.

If all else fails, the Government says, the Director can intervene in the rehearing process to reverse Board decisions. The Government acknowledges that only the PTAB can grant rehearing under §6(c). But the Director, according to the Government, could manipulate the composition of the PTAB panel that acts on the rehearing petition. For one thing, he could "stack" the original panel to rehear the case with additional APJs assumed to be more amenable to his preferences. See *Oil States*, 584 U. S., at ___ (GORSUCH, J., dissenting) (slip op., at 3). For another, he could assemble an entirely new panel consisting of himself and two other officers appointed by the Secretary—in practice, the Commissioner for Patents and the APJ presently designated as Chief Judge—to decide whether to overturn a decision and reach a different outcome binding on future panels. See

Brief for United States 6–7, 31–32. The Government insists that the Director, by handpicking (and, if necessary, repicking) Board members, can indirectly influence the course of inter partes review.

That is not the solution. It is the problem. The Government proposes (and the dissents embrace) a roadmap for the Director to evade a statutory prohibition on review without having him take responsibility for the ultimate decision. See *post*, at 2–3 (BREYER, J., concurring in judgment in part and dissenting in part); *post*, at 8–10 (opinion of THOMAS, J.). Even if the Director succeeds in procuring his preferred outcome, such machinations blur the lines of accountability demanded by the Appointments Clause. The parties are left with neither an impartial decision by a panel of experts nor a transparent decision for which a politically accountable officer must take responsibility. And the public can only wonder "on whom the blame or the punishment of a pernicious measure, or series of pernicious measures ought really to fall." The Federalist No. 70, at 476 (A. Hamilton).

The Government contends that the Director may respond after the fact by removing an APJ "from his judicial assignment without cause" and refusing to designate that APJ on *future* PTAB panels. *Edmond*, 520 U. S., at 664. Even assuming that is true, reassigning an APJ to a different task going forward gives the Director no means of countermanding the final decision already on the books. Nor are APJs "meaningfully controlled" by the threat of removal from federal service entirely, *Seila Law*, 591 U. S., at ___ (slip op., at 23), because the Secretary can fire them after a decision only "for such cause as will promote the efficiency of the service," 5 U. S. C. §7513(a). In all the ways that matter to the parties who appear before the PTAB, the buck stops with the APJs, not with the Secretary or Director.

Review outside Article II—here, an appeal to the Federal Circuit—cannot provide the necessary supervision. While

the duties of APJs "partake of a Judiciary quality as well as Executive," APJs are still exercising executive power and must remain "dependent upon the President." 1 Annals of Cong., at 611–612 (J. Madison); see *Oil States*, 584 U. S., at ___ (slip op., at 8). The activities of executive officers may "take 'legislative' and 'judicial' forms, but they are exercises of—indeed, under our constitutional structure they *must be* exercises of—the 'executive Power,'" for which the President is ultimately responsible. *Arlington* v. *FCC*, 569 U. S. 290, 305, n. 4 (2013) (quoting Art. II, §1, cl. 1).

Given the insulation of PTAB decisions from any executive review, the President can neither oversee the PTAB himself nor "attribute the Board's failings to those whom he *can* oversee." *Free Enterprise Fund*, 561 U. S., at 496. APJs accordingly exercise power that conflicts with the design of the Appointments Clause "to preserve political accountability." *Edmond*, 520 U. S., at 663.

The principal dissent dutifully undertakes to apply the governing test from *Edmond*, see *post*, at 5–10 (opinion of THOMAS, J.), but its heart is plainly not in it. For example, the dissent rejects any distinction between "inferior-officer power" and "principal-officer power," *post*, at 12, but *Edmond* calls for exactly that: an appraisal of how much power an officer exercises free from control by a superior. The dissent pigeonholes this consideration as the sole province of the Vesting Clause, *post*, at 14–15, but *Edmond* recognized the Appointments Clause as a "significant structural safeguard[ ]" that "preserve[s] political accountability" through direction and supervision of subordinates—in other words, through a chain of command. 520 U. S., at 659, 663. The dissent would have the Court focus on the location of an officer in the agency "organizational chart," *post*, at 1, but as we explained in *Edmond*, "[i]t is not enough that other officers may be identified who formally maintain a higher rank, or possess responsibilities of a greater magnitude," 520 U. S., at 662–663. The dissent stresses that "at least

two levels of authority" separate the President from PTAB decisions, *post*, at 1, but the unchecked exercise of executive power by an officer buried many layers beneath the President poses more, not less, of a constitutional problem. Conspicuously absent from the dissent is any concern for the President's ability to "discharge his own constitutional duty of seeing that the laws be faithfully executed." *Myers* v. *United States*, 272 U. S. 52, 135 (1926).

The other dissent charges that the Court's opinion has "no foundation" in past decisions. *Post*, at 5 (opinion of BREYER, J.). Of course, we have a different view on the proper application of *Edmond* in this dispute. As for other past decisions, it is the dissent that expressly grounds its analysis in dissenting opinions from *Free Enterprise Fund* and *Seila Law*, while frankly acknowledging that the *Court's* opinions in those cases support the principles that guide us here. *Post*, at 5–7.

C

History reinforces the conclusion that the unreviewable executive power exercised by APJs is incompatible with their status as inferior officers. Since the founding, principal officers have directed the decisions of inferior officers on matters of law as well as policy. Hamilton articulated the principle of constitutional accountability underlying such supervision in a 1792 Treasury circular. Writing as Secretary of the Treasury to the customs officials under his charge, he warned that any deviations from his instructions "would be subversive of uniformity in the execution of the laws." 3 Works of Alexander Hamilton 557 (J. Hamilton ed. 1850). "The power to superintend," he explained, "must imply a right to judge and direct," thereby ensuring that "the responsibility for a wrong construction rests with the head of the department, when it proceeds from him." *Id.*, at 559.

Early congressional statutes expressly empowered department heads to supervise the work of their subordinates,

sometimes by providing for an appeal in adjudicatory proceedings to a Presidentially nominated and Senate confirmed officer. See, *e.g.*, 1 Stat. 66–67 (authorizing appeal of auditor decisions to Comptroller); §4, 1 Stat. 378 (permitting supervisors of the revenue to issue liquor licenses "subject to the superintendence, control and direction of the department of the treasury"). For the most part, Congress left the structure of administrative adjudication up to agency heads, who prescribed internal procedures (and thus exercised direction and control) as they saw fit. See J. Mashaw, Creating the Administrative Constitution 254 (2012).

This Court likewise indicated in early decisions that adequate supervision entails review of decisions issued by inferior officers. For example, we held that the Commissioner of the General Land Office—the erstwhile agency that adjudicated private claims to public lands and granted land patents—could review decisions of his subordinates despite congressional silence on the matter. Our explanation, almost "too manifest to require comment," was that the authority to review flowed from the "necessity of 'supervision and control,' vested in the commissioner, acting under the direction of the President." *Barnard* v. *Ashley*, 18 How. 43, 45 (1856). "Of necessity," we later elaborated, the Commissioner "must have power to adjudge the question of accuracy preliminary to the issue of a [land] patent." *Magwire* v. *Tyler*, 1 Black 195, 202 (1862).

Congress has carried the model of principal officer review into the modern administrative state. As the Government forthrightly acknowledged at oral argument, it "certainly is the norm" for principal officers to have the capacity to review decisions made by inferior adjudicative officers. Tr. of Oral Arg. 23. The Administrative Procedure Act, from its inception, authorized agency heads to review such decisions. 5 U. S. C. §557(b). And "higher-level agency reconsideration" by the agency head is the standard way to maintain political accountability and effective oversight for

adjudication that takes place outside the confines of §557(b). Walker & Wasserman, The New World of Agency Adjudication, 107 Cal. L. Rev. 141, 157 (2019). To take one example recently discussed by this Court in *Free Enterprise Fund*, the Public Company Accounting Oversight Board can issue sanctions in disciplinary proceedings, but such sanctions are reviewable by its superior, the Securities and Exchange Commission. 15 U. S. C. §§7215(c)(4), 7217(c).

The Government and Smith & Nephew point to a handful of contemporary officers who are appointed by heads of departments but who nevertheless purportedly exercise final decisionmaking authority. Several examples, however, involve inferior officers whose decisions a superior executive officer can review or implement a system for reviewing. For instance, the special trial judges in *Freytag* v. *Commissioner*, 501 U. S. 868 (1991), may enter a decision on behalf of the Tax Court—whose members are nominated by the President and confirmed by the Senate, 26 U. S. C. §7443(b)—but only "subject to such conditions and review as the court may provide." §7443A(c); see also 8 CFR §1003.0(a) (2020) (establishing Executive Office for Immigration Review under control of Attorney General). And while the Board of Veteran Affairs does make the final decision within the Department of Veteran Affairs, 38 U. S. C. §§7101, 7104(a), its decisions are reviewed by the Court of Appeals for Veterans Claims, an Executive Branch entity, §§7251, 7252(a). See *Henderson* v. *Shinseki*, 562 U. S. 428, 431–432 (2011). Other examples are potentially distinguishable, such as the Benefits Review Board members who appear to serve at the pleasure of the appointing department head. See 33 U. S. C. §921(c); *Kalaris* v. *Donovan*, 697 F. 2d 376, 396–397 (CADC 1983).

Perhaps the Civilian and Postal Boards of Contract Appeals are most similar to the PTAB. The Administrator of General Services and the Postmaster General appoint the

members of the respective Boards, whose decisions are appealable to the Federal Circuit. See 41 U. S. C. §§7105(b), (d), (e), 7107(a). Congress established both entities in 2006 and gave them jurisdiction over disputes involving public contractors. 119 Stat. 3391–3394. Whatever distinct issues that scheme might present, the Boards of Contract Appeals—both young entrants to the regulatory landscape—provide the PTAB no "foothold in history or tradition" across the Executive Branch. *Seila Law*, 591 U. S., at ___ (slip op., at 21).

When it comes to the patent system in particular, adjudication has followed the traditional rule that a principal officer, if not the President himself, makes the final decision on how to exercise executive power. Recall that officers in President Washington's Cabinet formed the first Patent Board in 1790. 1 Stat. 109–110. The initial determination of patentability was then relegated to the courts in 1793, but when the Executive Branch reassumed authority in 1836, it was the Commissioner of Patents—appointed by the President with the advice and consent of the Senate—who exercised control over the issuance of a patent. 5 Stat. 117, 119. The patent system, for nearly the next hundred years, remained accountable to the President through the Commissioner, who directed the work of his subordinates by, for example, hearing appeals from decisions by examiners-in-chief, the forebears of today's APJs. 12 Stat. 246–247.

The Government and Smith & Nephew find support for the structure of the PTAB in the predecessor Board of Appeals established in 1927. 44 Stat. 1335–1336. Simplified somewhat, the Board of Appeals decided the patentability of inventions in panels composed of examiners-in-chief without an appeal to the Commissioner. But decisions by examiners-in-chief could be reviewed by the Court of Customs and Patent Appeals (CCPA), an entity within the Ex-

ecutive Branch until 1958. 45 Stat. 1476; see *Ex parte Bakelite Corp.*, 279 U. S. 438, 460 (1929); see also 72 Stat. 848. The President appointed CCPA judges with the advice and consent of the Senate. 36 Stat. 105. Even after 1958, the Commissioner appears to have retained "the ultimate authority regarding the granting of patents" through the examination and interference processes, notwithstanding the lack of a formal appeal from the Board's decision. *In re Alappat*, 33 F. 3d 1526, 1535 (CA Fed. 1994) (en banc) (plurality opinion). The history of the Board of Appeals, though more winding and varied than recounted here, has little to say about the present provision expressly ordering the Director to undo his prior patentability determination when a PTAB panel of unaccountable APJs later disagrees with it. See 35 U. S. C. §318(b).

The Government and Smith & Nephew also note that early Patent Acts authorized the Secretary of State to appoint two types of officials who made final decisions on questions of patent law. See 1 Stat. 322–323 (panel of arbitrators in interference proceedings); 5 Stat. 120–121 (board of examiners to hear appeal from patentability or priority decision of Commissioner). Neither example, however, serves as historical precedent for modern APJs. Both the arbitrators and the examiners assembled to resolve a single issue—indeed, these ad hoc positions may not have even constituted offices. See *Auffmordt* v. *Hedden*, 137 U. S. 310, 327 (1890). If they were officers, they exercised their limited power under "special and temporary conditions." *United States* v. *Eaton*, 169 U. S. 331, 343 (1898) (holding that an inferior officer can perform functions of principal office on acting basis). APJs, by contrast, occupy a permanent office unless removed by the Secretary for cause.

* * *

We hold that the unreviewable authority wielded by APJs

during inter partes review is incompatible with their appointment by the Secretary to an inferior office. The principal dissent repeatedly charges that we never say whether APJs are principal officers who were not appointed in the manner required by the Appointments Clause, or instead inferior officers exceeding the permissible scope of their duties under that Clause. See *post*, at 3, 11, 16 (opinion of THOMAS, J.). But both formulations describe the same constitutional violation: Only an officer properly appointed to a principal office may issue a final decision binding the Executive Branch in the proceeding before us.

In reaching this conclusion, we do not attempt to "set forth an exclusive criterion for distinguishing between principal and inferior officers for Appointments Clause purposes." *Edmond*, 520 U. S., at 661. Many decisions by inferior officers do not bind the Executive Branch to exercise executive power in a particular manner, and we do not address supervision outside the context of adjudication. Cf. *post*, at 13–14 (opinion of THOMAS, J.). Here, however, Congress has assigned APJs "significant authority" in adjudicating the public rights of private parties, while also insulating their decisions from review and their offices from removal. *Buckley*, 424 U. S., at 126.

III

We turn now to the appropriate way to resolve this dispute given this violation of the Appointments Clause. In general, "when confronting a constitutional flaw in a statute, we try to limit the solution to the problem" by disregarding the "problematic portions while leaving the remainder intact." *Ayotte* v. *Planned Parenthood of Northern New Eng.*, 546 U. S. 320, 328–329 (2006). This approach derives from the Judiciary's "negative power to disregard an unconstitutional enactment" in resolving a legal dispute. *Massachusetts* v. *Mellon*, 262 U. S. 447, 488 (1923). In a case that presents a conflict between the Constitution and

a statute, we give "full effect" to the Constitution and to whatever portions of the statute are "not repugnant" to the Constitution, effectively severing the unconstitutional portion of the statute. *Bank of Hamilton* v. *Lessee of Dudley*, 2 Pet. 492, 526 (1829) (Marshall, C. J.). This principle explains our "normal rule that partial, rather than facial, invalidation is the required course." *Brockett* v. *Spokane Arcades, Inc.*, 472 U. S. 491, 504 (1985).

Arthrex asks us to hold the entire regime of inter partes review unconstitutional. In its view, any more tailored declaration of unconstitutionality would necessitate a policy decision best left to Congress in the first instance. Because the good cannot be separated from the bad, Arthrex continues, the appropriate remedy is to order outright dismissal of the proceeding below. The partial dissent, similarly forswearing the need to do anything beyond "identifying the constitutional violation," would grant full relief to Arthrex. *Post*, at 5–6 (GORSUCH, J., concurring in part and dissenting in part).

In our view, however, the structure of the PTO and the governing constitutional principles chart a clear course: Decisions by APJs must be subject to review by the Director. Congress vested the Director with the "powers and duties" of the PTO, 35 U. S. C. §3(a)(1), tasked him with supervising APJs, §3(a)(2)(A), and placed the PTAB "in" the PTO, §6(a). A single officer has superintended the activities of the PTO since the Commissioner of Patents assumed the role of "chief officer" of the Patent Office in 1836. §1, 5 Stat. 117–118. The Commissioner long oversaw examiners-in-chief, see 12 Stat. 246–247, just as the Director today has the responsibility to oversee APJs. While shielding the ultimate decisions of the 200-plus APJs from review, Congress also provided the Director means of control over the institution and conduct of inter partes review. 35 U. S. C. §§314(a), 316(a). In every respect save the insulation of their decisions from review within the Executive Branch,

APJs appear to be inferior officers—an understanding consistent with their appointment in a manner permissible for inferior but not principal officers.

The America Invents Act insulates APJs from supervision through two mechanisms. The statute provides that "each . . . inter partes review shall be heard by at least 3 members of the [PTAB]" and that "only the [PTAB] may grant rehearings." §6(c). The upshot is that the Director cannot rehear and reverse a final decision issued by APJs. If the Director were to have the "authority to take control" of a PTAB proceeding, APJs would properly function as inferior officers. *Go-Bart Importing Co.* v. *United States*, 282 U. S. 344, 354 (1931).

We conclude that a tailored approach is the appropriate one: Section 6(c) cannot constitutionally be enforced to the extent that its requirements prevent the Director from reviewing final decisions rendered by APJs. Because Congress has vested the Director with the "power and duties" of the PTO, §3(a)(1), the Director has the authority to provide for a means of reviewing PTAB decisions. See also §§3(a)(2)(A), 316(a)(4). The Director accordingly may review final PTAB decisions and, upon review, may issue decisions himself on behalf of the Board. Section 6(c) otherwise remains operative as to the other members of the PTAB.

This does not result in an incomplete or unworkable statutory scheme. Cf. *United States* v. *Treasury Employees*, 513 U. S. 454, 479 (1995). To the contrary, review by the Director would follow the almost-universal model of adjudication in the Executive Branch, see *supra*, at 15–16, and aligns the PTAB with the *other* adjudicative body in the PTO, the Trademark Trial and Appeal Board, see §228 of the Trademark Modernization Act of 2020, 134 Stat. 2209.

The Government defends the different approach adopted by the Federal Circuit. The Court of Appeals held unenforceable APJs' protection against removal except "for such

cause as will promote the efficiency of the service," 5 U. S. C. §7513(a), which applies through 35 U. S. C. §3(c). See 941 F. 3d, at 1337, 1340. If the for-cause provision were unenforceable, the Secretary could remove APJs at will. See *Ex parte Hennen*, 13 Pet. 230, 259–260 (1839). The Government contends that APJs would then be inferior officers under *Free Enterprise Fund*. But regardless whether the Government is correct that at-will removal by the Secretary would cure the constitutional problem, review by the Director better reflects the structure of supervision within the PTO and the nature of APJs' duties, for the reasons we have explained. See *supra*, at 12, 20–21.

In sum, we hold that 35 U. S. C. §6(c) is unenforceable as applied to the Director insofar as it prevents the Director from reviewing the decisions of the PTAB on his own. The Director may engage in such review and reach his own decision. When reviewing such a decision by the Director, a court must decide the case "conformably to the constitution, disregarding the law" placing restrictions on his review authority in violation of Article II. *Marbury* v. *Madison*, 1 Cranch 137, 178 (1803). We add that this suit concerns only the Director's ability to supervise APJs in adjudicating petitions for inter partes review. We do not address the Director's supervision over other types of adjudications conducted by the PTAB, such as the examination process for which the Director has claimed unilateral authority to issue a patent. See Reply Brief for Arthrex, Inc. 6.

We also conclude that the appropriate remedy is a remand to the Acting Director for him to decide whether to rehear the petition filed by Smith & Nephew. Although the APJs' appointment by the Secretary allowed them to lawfully adjudicate the petition in the first instance, see *Freytag*, 501 U. S., at 881–882, they lacked the power under the Constitution to finally resolve the matter within the Executive Branch. Under these circumstances, a limited remand to the Director provides an adequate opportunity for

review by a principal officer. Because the source of the constitutional violation is the restraint on the review authority of the Director, rather than the appointment of APJs by the Secretary, Arthrex is not entitled to a hearing before a new panel of APJs. Cf. *Lucia*, 585 U. S., at ___–___ (slip op., at 12–13).

* * *

Today, we reaffirm and apply the rule from *Edmond* that the exercise of executive power by inferior officers must at some level be subject to the direction and supervision of an officer nominated by the President and confirmed by the Senate. The Constitution therefore forbids the enforcement of statutory restrictions on the Director that insulate the decisions of APJs from his direction and supervision. To be clear, the Director need not review every decision of the PTAB. What matters is that the Director have the discretion to review decisions rendered by APJs. In this way, the President remains responsible for the exercise of executive power—and through him, the exercise of executive power remains accountable to the people.

The judgment of the United States Court of Appeals for the Federal Circuit is vacated, and the cases are remanded for further proceedings consistent with this opinion.

It is so ordered.

SUPREME COURT OF THE UNITED STATES

Nos. 19–1434, 19–1452 and 19–1458

UNITED STATES, PETITIONER
19–1434 *v.*
ARTHREX, INC., ET AL.

SMITH & NEPHEW, INC., ET AL., PETITIONERS
19–1452 *v.*
ARTHREX, INC., ET AL.

ARTHREX, INC., PETITIONER
19–1458 *v.*
SMITH & NEPHEW, INC., ET AL.

ON WRITS OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

[June 21, 2021]

JUSTICE GORSUCH, concurring in part and dissenting in part.

For most of this Nation's history, an issued patent was considered a vested property right that could be taken from an individual only through a lawful process before a court. *Oil States Energy Services*, *LLC* v. *Greene's Energy Group*, *LLC*, 584 U. S. ___, ___–___ (2018) (GORSUCH, J., dissenting) (slip op., at 8–10). I continue to think this Court's recent decision in *Oil States*—upsetting this traditional understanding and allowing officials in the Executive Branch to "cancel" already-issued patents—departed from the Constitution's separation of powers. But it would be an even greater departure to permit those officials to withdraw a vested property right while accountable to no one within the Executive Branch. Accordingly, I join Parts I and II of the

Court's opinion. Respectfully, however, I am unable join the Court's severability discussion in Part III.

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On the merits, I agree with the Court that Article II vests the "executive Power" in the President alone. This admittedly formal rule serves a vital function. If the executive power is exercised poorly, the Constitution's design at least ensures "[t]he people know whom to blame"—and hold accountable. *Morrison* v. *Olson*, 487 U. S. 654, 729 (1988) (Scalia, J., dissenting). As Hamilton explained, the President's "due dependence on the people and . . . due responsibility" to them are key "ingredients which constitute safety in the republican sense." The Federalist No. 70, p. 424 (C. Rossiter ed. 1961). Or as Madison put it, "no principle is more clearly laid down in the Constitution than that of responsibility." 1 Annals of Cong. 462 (1789). Without presidential responsibility there can be no democratic accountability for executive action.

Of course, the framers recognized that no one alone can discharge all the executive duties of the federal government. They "expected that the President would rely on subordinate officers for assistance." *Seila Law LLC* v. *Consumer Financial Protection Bureau*, 591 U. S. ___, ___ (2020) (ROBERTS, C. J.) (slip op., at 2). But the framers took pains to ensure those subordinates would always remain responsible to the President and thus, ultimately, to the people. Because it is the President's duty to take care that the laws be faithfully executed, Art. II, §3, the framers sought to ensure he possessed "the power of *appointing*, *overseeing*, *and controlling* those who execute the laws." 1 Annals of Cong. 463 (Madison) (emphasis added).

To this end, the Constitution provided for a chain of authority. Several constitutional provisions reflect this structure. See Calabresi & Prakash, The President's Power To

Execute the Laws, 104 Yale L. J. 541, 570–599 (1994); Lawson, Appointments and Illegal Adjudication: The American Invents Act Through a Constitutional Lens, 26 Geo. Mason L. Rev. 26, 57–58 (2018). The Appointments Clause, for example, vests the President with the power to appoint "Officers of the United States" with "the Advice and Consent of the Senate," and to appoint "inferior Officers . . . alone" when Congress authorizes him to do so. Art. II, §2, cl. 2.

By definition, an "'inferior officer' . . . has a superior." *Edmond* v. *United States*, 520 U. S. 651, 662 (1997). To be an "inferior" officer, then, one must be both "*subordinate* to a[n] officer in the Executive Branch" and "under the direct control of the President" through a "chain of command." *Morrison*, 487 U. S., at 720–721 (Scalia, J., dissenting). In this way, the "text and structure of the Appointments Clause" *require* a "reference to hierarchy." Calabresi & Lawson, The Unitary Executive, Jurisdiction Stripping, and the *Hamdan* Opinions: A Textualist Response to Justice Scalia, 107 Colum. L. Rev. 1002, 1018–1020 (2007). Only such an understanding preserves, as Madison described it, the "chain of dependence," where "the lowest officers, the middle grade, and the highest"—each and every one—"will depend, as they ought, on the President." 1 Annals of Cong. 499 (Madison). And where the President, in turn, depends "on the community," so that "[t]he chain of dependence" finally "terminates in the supreme body, namely, in the people." *Ibid.*

I agree with the Court, too, that the statutory regime before us breaks this chain of dependence. In the America Invents Act of 2011 (AIA), Congress authorized the inter partes review (IPR) process, which permits anyone to file a petition asking the Patent and Trademark Office to "cancel" someone else's patent. 35 U. S. C. §311. Congress assigned the power to decide an IPR proceeding to a specific group of officials—the Patent Trial and Appeal Board (PTAB). Under the AIA's terms, three members from the PTAB—often,

as here, administrative patent judges (APJs)—sit on a panel to decide whether to cancel a patent. §6(c). After the three-member panel issues its decision, a party may seek rehearing from another three-member panel. *Ibid.* But only a PTAB panel—and no other official within the Executive Branch—may grant rehearing. *Ibid.* If that fails, a losing party's only recourse is to seek judicial review in the Court of Appeals for the Federal Circuit, which reviews the PTAB's factual findings under the deferential substantial evidence standard of review. See §319; *Oil States*, 584 U. S., at ___ (slip op., at 4).

Under this statutory arrangement, APJs are executive officers accountable to no one else in the Executive Branch. A panel of bureaucrats wields unreviewable power to take vested property rights. This design may hold its advantages for some. Often enough, the Director of the Patent and Trademark Office and the President may be happy to wash their hands of these decisions. But by breaking the chain of dependence, the statutory scheme denies individuals the right to be subjected only to *lawful* exercises of executive power that can ultimately be controlled by a President accountable to "the supreme body, namely, . . . the people."

*

The real question here concerns what to do about it. In Part III of its opinion, the Court invokes severability doctrine. *Ante*, at 19–22. It "sever[s]" Congress's statutory direction that PTAB decisions may not be reviewed by the Director of the Patent Office—in that way reconnecting APJs to the chain of command and subjecting their decisions to a superior who is, in turn, ultimately accountable to the President. See *ibid.*

I don't question that we might proceed this way in some cases. Faced with an application of a statute that violates the Constitution, a court might look to the text of the law in

question to determine what Congress has said should happen in that event. Sometimes Congress includes "fallback" provisions of just this sort, and sometimes those provisions tell us to disregard this or that provision if its statutory scheme is later found to offend the Constitution. See, *e.g.*, *Bowsher* v. *Synar*, 478 U. S. 714, 718–719 (1986); see also Walsh, Partial Unconstitutionality, 85 N. Y. U. L. Rev. 738, 780–781 (2010).

The problem here is that Congress has said nothing of the sort. And here it is the combination of separate statutory provisions that conspire to create a constitutional violation. Through some provisions, Congress has authorized executive officers to cancel patents. §§6(b)(4), 318(a). Through others, it has made their exercise of that power unreviewable within the Executive Branch. See §§6(c), 318(b). It's the combination of these provisions—the exercise of executive power and unreviewability—that violates the Constitution's separation of powers.

Nor is there only one possible way out of the problem. First, one could choose as the Court does and make PTAB decisions subject to review by the Director, who is answerable to the President through a chain of dependence. See Duffy, Are Administrative Patent Judges Unconstitutional? 77 Geo. Wash. L. Rev. 904, 911 (2009). Separately, one could specify that PTAB panel members should be appointed by the President and confirmed by the Senate and render their decisions directly reviewable by the President. See Lawson, 26 Geo. Mason L. Rev., at 57. Separately still, one could reassign the power to cancel patents to the Judiciary where it resided for nearly two centuries. See *Oil States*, 584 U. S., at ___–___ (GORSUCH, J., dissenting) (slip op., at 8–10). Without some direction from Congress, this problem cannot be resolved as a matter of statutory interpretation. All that remains is a policy choice.

In circumstances like these, I believe traditional remedial principles should be our guide. Early American courts did

not presume a power to "sever" and excise portions of statutes in response to constitutional violations. Instead, when the application of a statute violated the Constitution, courts simply declined to enforce the statute in the case or controversy at hand. See *Seila Law*, 591 U. S., at ___ (THOMAS, J., dissenting in part) (slip op., at 15); see also Walsh, N. Y. U. L. Rev., at 769. I would follow that course today by identifying the constitutional violation, explaining our reasoning, and "setting aside" the PTAB decision in this case. See *Novartis AG* v. *Torrent Pharmaceuticals Ltd.*, 853 F. 3d 1316, 1323–1324 (CA Fed. 2017) (holding that the standard in 5 U. S. C. §706 governs judicial review of PTAB decisions).

The Court declines to follow this traditional path. Instead, it imagines that, if Congress had known its statutory scheme was unconstitutional, it would have preferred to make the policy choice the Court makes for it today. Faced with an unconstitutional combination of statutory instructions—providing for the exercise of executive power and its unreviewability—the Court *chooses* to act as if the provision limiting the Director's ability to review IPR decisions doesn't exist. Having done that, the Court gifts the Director a new power that he never before enjoyed, a power Congress expressly withheld from him and gave to someone else—the power to cancel patents through the IPR process. Effectively, the Court subtracts statutory powers from one set of executive officials and adds them to another.

While the Court has in relatively recent years proclaimed the power to proceed in this fashion, it has never paused to explain how this "severance doctrine" comports with traditional judicial remedial principles. See *Barr* v. *American Assn. of Political Consultants, Inc.*, 591 U. S. ___, ___ (2020) (GORSUCH, J., concurring in judgment in part and dissenting in part) (slip op., at 5). Or with the fact that the judicial power is limited to resolving discrete cases and controversies. *Murphy* v. *National Collegiate Athletic Assn.*, 584

U. S. ___, ___–___ (2018) (THOMAS, J., concurring) (slip op., at 2–3). Or with the framers' explicit rejection of allowing this Court to serve as a council of revision free to amend legislation. See Mitchell, The Writ-of-Erasure Fallacy, 104 Va. L. Rev. 933, 954–960 (2018). Let alone with our constant admonitions that policy choices belong to Congress, not this Court. *E.g.*, *Pereida* v. *Wilkinson*, 592 U. S. ___, ___ (2021) (slip op., at 16). And certainly none of the early cases the Court cites today proceeded as it does. See *ante*, at 19, 22.

Nor does the Court pause to consider whether venturing further down this remedial path today risks undermining the very separation of powers its merits decision purports to vindicate. While the Court's merits analysis ensures that executive power properly resides in the Executive Branch, its severability analysis seemingly confers legislative power to the Judiciary—endowing us with the authority to make a raw policy choice between competing lawful options. No doubt, if Congress is dissatisfied with the choice the Court makes on its behalf today, it can always reenter the field and revise our judgment. But doesn't that just underscore the legislative nature of the Court's judgment? And doesn't deciding for ourselves which policy course to pursue today allow Congress to disclaim responsibility for our legislative handiwork much as the President might the PTAB's executive decisions under the current statutory structure?

Instead of confronting these questions, the Court has justified modern "severance" doctrine on assumptions and presumptions about what Congress would have chosen to do, had it known that its statutory scheme was unconstitutional. See, *e.g.*, *Seila Law*, 591 U. S., at ___ (slip op., at 32) ("We will presume that Congress did not intend the validity of the statute in question to depend on the validity of the constitutionally offensive provision" (internal quotation marks omitted)). But any claim about "congressional intent" divorced from enacted statutory text is an appeal to

mysticism. Short of summoning ghosts and spirits, how are we to know what those in a past Congress might think about a question they never expressed any view on—and may have never foreseen?

Let's be honest, too. These legislative séances usually wind up producing only the results intended by those conducting the performance: "When you are told to decide, not on the basis of what the legislature said, but on the basis of what it *meant*, . . . your best shot at figuring out what the legislature meant is to ask yourself what a wise and intelligent person *should* have meant; and that will surely bring you to the conclusion that the law means what you think it *ought* to mean." Scalia, Common Law Courts in a Civil-Law System, in A Matter of Interpretation: Federal Courts and the Law 18 (A. Gutmann ed. 1997); see also *United States* v. *Public Util. Comm'n of Cal.*, 345 U. S 295, 319 (1953) (Jackson, J., concurring) (describing that process as "not interpretation of a statute but creation of a statute"). The crystal ball ends up being more of a mirror.

Our case illustrates the problem. The Court apparently believes that Congress would have wanted us to render PTAB decisions reviewable by the Director. This regime is consistent with the "'standard federal model'" for agency adjudication. Walker & Wasserman, The New World of Agency Adjudication, 107 Cal. L. Rev. 141, 143–144 (2019). It's easy enough to see why a group of staid judges selecting among policy choices for itself might prefer a "standard" model. But if there is anything we know for certain about the AIA, it is that Congress *rejected* this familiar approach when it came to PTAB proceedings. Multiple *amici* contend that Congress did so specifically to ensure APJs enjoy "independence" from superior executive officers and thus possess more "impartiality." Brief for Fair Inventing Fund as *Amicus Curiae* 20–21 (quoting legislative history that Congress desired a "'fairer'" and "'more objective'" process); see also, *e.g.*, Brief for New Civil Liberties Alliance as *Amicus*

Curiae 6 (Congress sought "to preserve the independence of those conducting inter partes review"); Brief for US Inventor Inc. as *Amicus Curiae* 22 ("[I]t is plainly evident that Congress would not have enacted an APJ patentability trial system that was more political than the one they did enact"); Brief for Cato Institute et al. as *Amici Curiae* 20 (It was a "conscious congressional decision to provide individuals with the power to adjudicate (and often destroy) vested patent rights with some level of independence"). All of which suggests that the majority's severability analysis defies, rather than implements, legislative intent. At the least, it is surely plausible that, if faced with a choice between giving the power to cancel patents to political officials or returning it to courts where it historically resided, a Congress so concerned with independent decisionmaking might have chosen the latter option.

My point here isn't that I profess any certainty about what Congress would have chosen; it's that I confess none. Asking what a past Congress would have done if confronted with a contingency it never addressed calls for raw speculation. Speculation that, under traditional principles of judicial remedies, statutory interpretation, and the separation of powers, a court of law has no authority to undertake.

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If each new case this Court entertains about the AIA highlights more and more problems with the statute, for me the largest of them all is the wrong turn we took in *Oil States*. There, the Court upheld the power of the Executive Branch to strip vested property rights in patents despite a long history in this country allowing only courts that authority. See 584 U. S., at ___–___ (GORSUCH, J., dissenting) (slip op., at 8–10). In the course of rejecting a separation-of-powers challenge to this novel redistribution of historic authority, the Court acknowledged the possibility that permitting politically motivated executive officials to "cancel"

patents might yet raise due process concerns. *Id.*, at ___ (slip op., at 17). But the Court refused to consider those concerns in *Oil States* because, it said, no one had "raised a due process challenge." *Ibid.*

It was my view at the time that the separation of powers—and its guarantee that cases involving the revocation of vested property rights must be decided by Article III courts—is *itself* part of the process that is due under our Constitution. See Chapman & McConnell, Due Process as Separation of Powers, 121 Yale L. J. 1672, 1801–1804 (2012). Any suggestion that the neutrality and independence the framers guaranteed for courts could be replicated within the Executive Branch was never more than wishful thinking. The Court's decision in *Oil States* allowing executive officials to assume an historic judicial function was always destined to invite familiar due process problems—like decisions "favor[ing] those with political clout, the powerful and the popular." *Thryv*, *Inc.* v. *Click-To-Call Technologies*, *LP*, 590 U. S. ___, ___ (2020) (GORSUCH, J., dissenting) (slip op., at 20). After all, "[p]owerful interests are capable of amassing armies of lobbyists and lawyers to influence (and even capture) politically accountable bureaucracies." *Oil States*, 584 U. S., at ___ (same) (slip op., at 3).

Already in the AIA's short tenure these problems have started coming home to roost—even with supposedly "independent" APJs. The briefs before us highlight example after example. I leave the interested reader to explore others. See, *e.g.*, Brief for TiVo Corporation as *Amicus Curiae* 6–13; Brief for 39 Aggrieved Inventors as *Amici Curiae* 14–23; Brief for Joshua J. Malone as *Amicus Curiae* 9–11. Here just consider the tale of a patent attorney at one of the world's largest technology companies who left the company to become an APJ. See Brief for US Inventor Inc. as *Amicus Curiae* 12. This private advocate-turned-APJ presided over dozens of IPRs brought by his former company. *Ibid.* In

those proceedings, the company prevailed in its efforts to cancel patents damaging to its private economic interests 96% of the time. *Ibid.* After six years of work, the APJ decided he had done enough, resigned, and (yes) returned to the company. *Ibid.* Without a hint of irony, that company has filed an *amicus* brief in this case to inform us, as a self-described "frequent user of the IPR process," about "the benefits of the system." Brief for Apple Inc. as *Amicus Curiae* 3. Nor is that the only large technology company to have its attorneys rotate in and out of the PTO to similar effect. See Brief for B. E. Technology, LLC, as *Amicus Curiae* 17 (discussing a Google attorney). *Oil States* virtually assured results like these.

That's not the end of the constitutional problems flowing from *Oil States* either. The Director has asserted "plenary authority" to personally select which APJs will decide an IPR proceeding. Brief for United States 5–6. Thus, any APJs whose rulings displease the party currently in power could soon find themselves with little to do. The PTAB has even "claimed the power through inter partes review to overrule final judicial judgments affirming patent rights." *Thryv*, 590 U. S., at ___ (GORSUCH, J., dissenting) (slip op., at 20). And this menu of constitutional problems is surely just illustrative, not exhaustive.

Today's decision at least avoids the very worst of what *Oil States* could have become—investing the power to revoke individual's property rights in some unaccountable fourth branch controlled by powerful companies seeking a competitive advantage. Alignments between the moneyed and the permanent bureaucracy to advance the narrow interests of the elite are as old as bureaucracy itself. Our decision today represents a very small step back in the right direction by ensuring that the people at least know who's responsible for supervising this process—the elected President and his designees.

Still, I harbor no illusions that today's decision will resolve

all the problems. Even if our judgment demands some degree of democratic accountability in the IPR process, it does not begin to fix the revolving door or any of the other due process problems *Oil States* ignored. No doubt, challenges involving those aspects of the IPR process will come. When they do, I hope this Court will come to recognize what was evident for so much of our history—that the process due someone with a vested property right in a patent is a proceeding before a neutral and independent judge.

SUPREME COURT OF THE UNITED STATES

Nos. 19–1434, 19–1452 and 19–1458

UNITED STATES, PETITIONER
19–1434 *v.*
ARTHREX, INC., ET AL.

SMITH & NEPHEW, INC., ET AL., PETITIONERS
19–1452 *v.*
ARTHREX, INC., ET AL.

ARTHREX, INC., PETITIONER
19–1458 *v.*
SMITH & NEPHEW, INC., ET AL.

ON WRITS OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

[June 21, 2021]

JUSTICE BREYER, with whom JUSTICE SOTOMAYOR and JUSTICE KAGAN join, concurring in the judgment in part and dissenting in part.

I

I agree with JUSTICE THOMAS' discussion on the merits and I join Parts I and II of his dissent. Two related considerations also persuade me that his conclusion is correct.

First, in my view, the Court should interpret the Appointments Clause as granting Congress a degree of leeway to establish and empower federal offices. Neither that Clause nor anything else in the Constitution describes the degree of control that a superior officer must exercise over the decisions of an inferior officer. To the contrary, the Constitution says only that "Congress may by Law vest the Appointment of such inferior Officers, as they think proper, . . . in

the Heads of Departments." Art. II, §2, cl. 2. The words "by Law . . . as they think proper" strongly suggest that Congress has considerable freedom to determine the nature of an inferior officer's job, and that courts ought to respect that judgment. See *Lucia* v. *SEC*, 585 U. S. ___, ___–___ (2018) (BREYER, J., concurring in judgment in part and dissenting in part) (slip op., at 9–10). In a word, the Constitution grants to Congress the "authority to create both categories of offices—those the President must fill with the Senate's concurrence and 'inferior' ones. . . . That constitutional assignment to Congress counsels judicial deference." *In re Sealed Case*, 838 F. 2d 476, 532 (CADC) (R. Ginsburg, J., dissenting), rev'd *sub nom. Morrison* v. *Olson*, 487 U. S. 654 (1988). Article I's grant to Congress of broad authority to enact laws of different kinds concerning different subjects—and to implement those laws in ways that Congress determines are "necessary and proper"—suggests the same. Art. I, §8, cl. 18.

Even a small degree of "judicial deference" should prove sufficient to validate the statutes here. For one, the provisions at issue fall well within Article I's grant to Congress of the patent power. Nothing in them represents an effort by the "Legislative Branch [to] aggrandize itself at the expense of the other two branches." *Buckley* v. *Valeo*, 424 U. S. 1, 129 (1976) (*per curiam*). There is accordingly no general separation-of-powers defect that has arisen in other cases. See, *e.g., Metropolitan Washington Airports Authority* v. *Citizens for Abatement of Aircraft Noise, Inc.*, 501 U. S. 252, 277 (1991).

For another, Congress' scheme is consistent with our Appointments Clause precedents. They require only that an inferior officer be "directed and supervised at some level," *Edmond* v. *United States*, 520 U. S. 651, 663 (1997), and the Administrative Patent Judges (APJs) are supervised by two separate Senate-confirmed officers, the Secretary of Commerce and the Director of the Patent and Trademark Office

(PTO). Even were I to assume, with the majority, that the Director must have power to "control" the APJs, the statutes grant the Director considerable control. As the Court recognizes, the Director "fixes" their "rate[s] of pay," decides "whether to institute inter partes review," "selects the APJ's" who will preside at each particular proceeding, "promulgates regulations governing inter partes review," "issues prospective guidance on patentability issues," and "designates past PTAB decisions as 'precedential' for future panels." *Ante,* at 10. All told, the Director maintains control of decisions insofar as they determine policy. The Director cannot rehear and decide an individual case on his own; but Congress had good reason for seeking independent Board determinations in those cases—cases that will apply, not create, Director-controlled policy.

Finally, Congress' judgment is unusually clear in this suit, as there is strong evidence that Congress designed the current structure specifically to address constitutional concerns. See *In re DBC*, 545 F. 3d 1373, 1377–1380 (CA Fed. 2008) (explaining amendment to address defects in prior appointment process).

Second, I believe the Court, when deciding cases such as these, should conduct a functional examination of the offices and duties in question rather than a formalist, judicial-rules-based approach. In advocating for a "functional approach," I mean an approach that would take account of, and place weight on, why Congress enacted a particular statutory limitation. It would also consider the practical consequences that are likely to follow from Congress' chosen scheme.

Wiener v. *United States*, 357 U. S. 349 (1958), provides a good example of the role that purposes and consequences can play. In that case, the Court considered whether, in the face of congressional silence on the matter, the President had the constitutional or statutory authority to remove without cause a member of the War Claims Commission.

Justice Frankfurter, writing for a unanimous Court, said that Congress sought to create a commission that was "'entirely free from the control or coercive influence, direct or indirect,' of either the Executive or the Congress." *Id.,* at 355–356 (quoting *Humphrey's Executor* v. *United States*, 295 U. S. 602, 629 (1935)). He then asked why Congress might want to deny the President the power to remove a commissioner. Because, he answered, the "intrinsic judicial character" of the Commission's duties required that it be able to adjudicate claims solely on the merits of each claim free of external executive pressure. 357 U. S., at 355. "Congress did not wish to have hang over the Commission the Damocles' sword of removal by the President for no reason other than that he preferred to have on that Commission men of his own choosing." *Id.,* at 356. The Court has subsequently used the functional approach reflected in *Wiener* to resolve all manner of separation-of-powers disputes, including disputes under the Appointments Clause. See, *e.g., Buckley*, 424 U. S., at 126 (distinguishing employees from officers by asking if the individual exercises "significant authority"); *Mistretta* v. *United States*, 488 U. S. 361, 409 (1989) (asking whether a statute "prevents the Judicial Branch from performing its constitutionally assigned functions").

In this suit, a functional approach, which considers purposes and consequences, undermines the Court's result. Most agencies (and courts for that matter) have the power to reconsider an earlier decision, changing the initial result if appropriate. Congress believed that the PTO should have that same power and accordingly created procedures for reconsidering issued patents. Congress also believed it important to strengthen the reconsideration power with procedural safeguards that would often help those whom the PTO's initial decision had favored, such as the requirement that review be available only when there is a "reasonable likelihood" that the patent will be invalid. 35 U. S. C.

§314(a). Given the technical nature of patents, the need for expertise, and the importance of avoiding political interference, Congress chose to grant the APJs a degree of independence. These considerations set forth a reasonable legislative objective sufficient to justify the restriction upon the Director's authority that Congress imposed. And, as JUSTICE THOMAS thoroughly explains, there is no reason to believe this scheme will prevent the Director from exercising policy control over the APJs or will break the chain of accountability that is needed to hold the President responsible for bad nominations. *Post*, at 7–10 (dissenting opinion).

The Court does not take these realities into account. Instead, for the first time, it examines the APJs' office function by function and finds, in *Edmond*, a judicially created rule: "Only an officer properly appointed to a principal office may issue a final decision binding the Executive Branch in [inter partes review] proceeding[s]." *Ante,* at 19. As an initial matter, I agree with JUSTICE THOMAS that this rule has no foundation in *Edmond* or our Appointments Clause precedents. *Post*, at 10–11.

More broadly, I see the Court's decision as one part of a larger shift in our separation-of-powers jurisprudence. The Court applied a similarly formal approach in *Free Enterprise Fund* v. *Public Company Accounting Oversight Bd.*, 561 U. S. 477 (2010), where it considered the constitutional status of the members of an accounting board appointed by the Securities and Exchange Commission. It held that Congress could not limit the SEC's power to remove those members without cause. The Court also applied a formalist approach in *Seila Law LLC* v. *Consumer Financial Protection Bureau*, 591 U. S. ___ (2020), where it held that Congress could not protect from removal without cause the (single) head of the Consumer Financial Protection Bureau. My dissent in the first case and JUSTICE KAGAN's dissent in the second explain in greater detail why we believed that this

shift toward formalism was a mistake.

I continue to believe that a more functional approach to constitutional interpretation in this area is superior. As for this particular suit, the consequences of the majority's rule are clear. The nature of the PTAB calls for technically correct adjudicatory decisions. And, as in *Wiener*, that fact calls for greater, not less, independence from those potentially influenced by political factors. The Court's decision prevents Congress from establishing a patent scheme consistent with that idea.

But there are further reasons for a functional approach that extend beyond the bounds of patent adjudication. First, the Executive Branch has many different constituent bodies, many different bureaus, many different agencies, many different tasks, many different kinds of employees. Administration comes in many different shapes and sizes. Appreciating this variety is especially important in the context of administrative adjudication, which typically demands decisionmaking (at least where policy made by others is simply applied) that is free of political influence. Are the President and Congress, through judicial insistence upon certain mechanisms for removal or review, to be denied the ability to create independent adjudicators?

Second, the Constitution is not a detailed tax code, and for good reason. The Nation's desires and needs change, sometimes over long periods of time. In the 19th century the Judiciary may not have foreseen the changes that produced the New Deal, along with its accompanying changes in the nature of the tasks that Government was expected to perform. We may not now easily foresee just what kinds of tasks present or future technological changes will call for. The Founders wrote a Constitution that they believed was flexible enough to respond to new needs as those needs developed and changed over the course of decades or centuries. At the same time, they designed a Constitution that

would protect certain basic principles. A principle that prevents Congress from affording inferior level adjudicators some decisionmaking independence was not among them.

Finally, the Executive Branch and Congress are more likely than are judges to understand how to implement the tasks that Congress has written into legislation. That understanding encompasses the nature of different mechanisms of bureaucratic control that may apply to the many thousands of administrators who will carry out those tasks. And it includes an awareness of the reasonable limits that can be placed on supervisors to ensure that those working under them enjoy a degree of freedom sufficient to carry out their responsibilities. Considered as a group, unelected judges have little, if any, experience related to this kind of a problem.

This is not to say that the Constitution grants Congress free rein. But in this area of the law a functional approach, when compared with the highly detailed judicial-rules-based approach reflected in the Court's decision, is more likely to prevent inappropriate judicial interference. It embodies, at least to a degree, the philosopher's advice: "Whereof one cannot speak, thereof one must be silent."

II

For the reasons I have set forth above, I do not agree with the Court's basic constitutional determination. For purposes of determining a remedy, however, I recognize that a majority of the Court has reached a contrary conclusion. On this score, I believe that any remedy should be tailored to the constitutional violation. Under the Court's new test, the current statutory scheme is defective only because the APJ's decisions are not reviewable by the Director alone. The Court's remedy addresses that specific problem, and for that reason I agree with its remedial holding.

* * *

In my view, today's decision is both unprecedented and unnecessary, and risks pushing the Judiciary further into areas where we lack both the authority to act and the capacity to act wisely. I respectfully dissent.

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ON WRITS OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

[June 21, 2021]

JUSTICE THOMAS, with whom JUSTICE BREYER, JUSTICE SOTOMAYOR, and JUSTICE KAGAN join as to Parts I and II, dissenting.

For the very first time, this Court holds that Congress violated the Constitution by vesting the appointment of a federal officer in the head of a department. Just who are these "principal" officers that Congress unsuccessfully sought to smuggle into the Executive Branch without Senate confirmation? About 250 administrative patent judges who sit at the bottom of an organizational chart, nestled under at least two levels of authority. Neither our precedent nor the original understanding of the Appointments Clause requires Senate confirmation of officers inferior to not one, but *two* officers below the President.

I

The Executive Branch is large, and the hierarchical path from President to administrative patent judge is long. At the top sits the President, in whom the executive power is vested. U. S. Const., Art. II, §1. Below him is the Secretary of Commerce, who oversees the Department of Commerce and its work force of about 46,000. 15 U. S. C. §§1501, 1513. Within that Department is the United States Patent and Trademark Office led by a Director. 35 U. S. C. §§1, 2(a), 3(a) (also known as the Under Secretary of Commerce for Intellectual Property). In the Patent and Trademark Office is the Patent Trial and Appeal Board. §6(a). Serving on this Board are administrative patent judges. *Ibid.*

There are few statutory prerequisites to becoming an administrative patent judge. One must be a "perso[n] of competent legal knowledge and scientific ability" and be "appointed by the Secretary." *Ibid.* The job description too is relatively straightforward: sit on the Board along with the Director, the Deputy Director, the Commissioner for Patents, the Commissioner for Trademarks, and other administrative patent judges. *Ibid.*

The Board adjudicates both appellate and trial disputes. See §6(b). It may directly review certain decisions made by patent examiners, and it may hold its own proceedings to determine the patentability of patent claims. As relevant here, it conducts inter partes review, which "offers a second look at an earlier administrative grant of a patent." *Cuozzo Speed Technologies, LLC* v. *Lee*, 579 U. S. 261, 279 (2016). Inter partes review—and all other types of Board hearings—must be "heard by at least 3 members" of the Board. §6(c).

In this suit, Smith & Nephew, Inc., and Arthrocare Corp. (collectively, Smith & Nephew) filed a petition challenging some of Arthrex, Inc.'s patent claims. After deciding that there was a reasonable likelihood that Smith & Nephew would prevail, the Director instituted review. §314(a). A

panel of three administrative judges ultimately agreed with Smith & Nephew that the disputed claims were unpatentable. The Director did not convene a panel to rehear that decision. Nor is there any suggestion that Arthrex sought rehearing from the Board or from the Director. Instead, Arthrex appealed the Board's decision to the United States Court of Appeals for the Federal Circuit.

On appeal, Arthrex argued that the Federal Circuit must vacate the Board's decision. According to Arthrex, administrative patent judges are constitutionally defective because they are principal officers who were neither appointed by the President nor confirmed by the Senate. The Federal Circuit agreed in part. The court held that administrative patent judges *are* principal officers. 941 F. 3d 1320, 1335 (2019). But the court professed to transform these principal officers into inferior ones by withdrawing statutory removal restrictions. *Id.,* at 1338.

The Court now partially agrees with the Federal Circuit. Although it cannot quite bring itself to say so expressly, it too appears to hold that administrative patent judges are principal officers under the current statutory scheme. See *ante*, at 10–14. But it concludes that the better way to judicially convert these principal officers to inferior ones is to allow the Director to review Board decisions unilaterally. *Ante*, at 21 (plurality opinion); *ante*, at 7 (BREYER, J., concurring in part and dissenting in part).

That both the Federal Circuit and this Court would take so much care to ensure that administrative patent judges, appointed as inferior officers, would remain inferior officers at the end of the day suggests that perhaps they were inferior officers to begin with. Instead of rewriting the Director's statutory powers, I would simply leave intact the patent scheme Congress has created.

II

The Constitution creates a default process to appoint all

officers: The President "by and with the Advice and Consent of the Senate, shall appoint Ambassadors, other public Ministers and Consuls, Judges of the supreme Court, and all other Officers of the United States." Art. II, §2. But Congress has discretion to change the default process for "inferior" officers: "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." *Ibid.*

A

The Court has been careful not to create a rigid test to divide principal officers—those who must be Senate confirmed—from inferior ones. See, *e.g.*, *Edmond* v. *United States*, 520 U. S. 651, 661 (1997) (the Court has "not set forth an exclusive criterion"); *Morrison* v. *Olson,* 487 U. S. 654, 671 (1988) ("We need not attempt here to decide exactly where the line falls between the two types of officers"). Instead, the Court's opinions have traditionally used a case-by-case analysis. And those analyses invariably result in this Court deferring to Congress' choice of which constitutional appointment process works best.[1] No party (nor the

[1] This Court has found a vast range of positions to be inferior, including a district court clerk, *Ex parte Hennen*, 13 Pet. 230, 258 (1839) ("that a clerk is one of the inferior officers contemplated by . . . the Constitution cannot be questioned"); election supervisors tasked with registering names, inspecting and scrutinizing the register of voters, and counting the votes cast, *Ex parte Siebold*, 100 U. S. 371, 380, 398 (1880) ("Congress had the power to vest the appointment of the supervisors in question in the circuit courts"); a vice consul who temporarily carried out the duties of the consul, *United States* v. *Eaton*, 169 U. S. 331, 343 (1898) ("The claim that Congress was without power to vest in the President the appointment of a subordinate officer called a vice-consul, to be charged with the duty of temporarily performing the functions of the consular office, disregards both the letter and spirit of the Constitution"); a United States Commissioner, entrusted with "issu[ing] warrants," "caus[ing] the offenders to be arrested and imprisoned, or bailed, for trial," "sit[ting] as

majority) has identified any instance in which this Court has found unconstitutional an appointment that aligns with one of the two processes outlined in the Constitution.

Our most exhaustive treatment of the inferior-officer question is found in *Edmond*. There, we evaluated the status of civilian judges on the Coast Guard Court of Criminal Appeals who were appointed by the Secretary of Transportation. As in all previous decisions, the Court in *Edmond* held that the Secretary's appointment of the judges complied with the Appointments Clause.

Recognizing that no "definitive test" existed for distinguishing between inferior and principal officers, the Court set out two general guidelines. 520 U. S., at 661–662. First, there is a formal, definitional requirement. The officer must be lower in rank to "a superior." *Id.*, at 662. But according to the Court in *Edmond*, formal inferiority is "not enough." *Ibid.* So the Court imposed a functional requirement: The inferior officer's work must be "directed and supervised at some level by others who were appointed by

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judge or arbitrator in such differences as may arise between the captains and crews of any vessels belonging to the nations whose interests are committed to his charge"; "institut[ing] prosecutions" and who enjoys "to a certain extent, independen[ce] in their statutory and judicial action," *United States* v. *Allred*, 155 U. S. 591, 594–595 (1895); *Go-Bart Importing Co.* v. *United States*, 282 U. S. 344, 352–354 (1931) ("United States commissioners are inferior officers"); an independent counsel, charged with "'full power and independent authority to exercise all investigative and prosecutorial functions,'" *Morrison*, 487 U. S., at 661, 661–662, 671–672; special trial judges within the United States Tax Court "who exercise independent authority" and may "hear certain specifically described proceedings" and may "render the decisions of the Tax Court in declaratory judgment proceedings and limited-amount tax cases," *Freytag* v. *Commissioner*, 501 U. S. 868, 870–871, 882 (1991); judges on the Coast Guard Court of Criminal Appeals, *Edmond*, 520 U. S., at 653; and members of the Public Company Accounting Oversight Board who "determin[e] the policy and enforc[e] the laws of the United States," *Free Enterprise Fund* v. *Public Company Accounting Oversight Bd.*, 561 U. S. 477, 484, 511 (2010).

Presidential nomination with advice and consent of the Senate." *Id.*, at 663. Because neither side asks us to overrule our precedent, I would apply this two-part guide.

There can be no dispute that administrative patent judges are, in fact, inferior: They are lower in rank to at least two different officers. As part of the Board, they serve in the Patent and Trademark Office, run by a Director "responsible for providing policy direction and management supervision for the Office and for the issuance of patents and the registration of trademarks." 35 U. S. C. §3(a)(2)(A). That Office, in turn, is "[w]ithin the Department of Commerce" and "subject to the policy direction of the Secretary of Commerce." §1(a). The Secretary, in consultation with the Director, appoints administrative patent judges. §6(a).

As a comparison to the facts in *Edmond* illustrates, the Director and Secretary are also functionally superior because they supervise and direct the work administrative patent judges perform. In *Edmond*, the Court focused on the supervision exercised by two different entities: the Judge Advocate General and the Court of Appeals for the Armed Forces (CAAF). The Judge Advocate General exercised general administrative oversight over the court on which the military judges sat. *Edmond*, 520 U. S., at 664. He possessed the power to prescribe uniform rules of procedure for the court and to formulate policies and procedure with respect to the review of court-martial cases in general. *Ibid.* And he could remove a Court of Criminal Appeals judge from his judicial assignment without cause, a "powerful tool for control." *Ibid.*

The Court noted, however, that "[t]he Judge Advocate General's control over Court of Criminal Appeals judges is . . . not complete." *Ibid.* This was so for two reasons. He could "not attempt to influence (by threat of removal or otherwise) the outcome of individual proceedings." *Ibid.* And, he had "no power to reverse decisions of the court." *Ibid.*

But this lack of complete control did not render the military judges principal officers. That is because one of the two missing powers resided, to a limited degree, in a different entity: the CAAF. *Ibid.* CAAF could not "reevaluate the facts" where "there [was] some competent evidence in the record to establish each element of the offense beyond a reasonable doubt." *Id.*, at 665. Still, it was "significant . . . that the judges of the Court of Criminal Appeals ha[d] no power to render a final decision on behalf of the United States unless permitted to do so by other Executive officers." *Ibid.* Having recounted the various means of supervision, the Court held that the military judges were inferior officers. Consistent with the Constitution, Congress had the power to vest the judges' appointments in the Secretary of Transportation. *Id.*, at 665–666.

The Director here possesses even greater functional power over the Board than that possessed by the Judge Advocate General. Like the Judge Advocate General, the Director exercises administrative oversight over the Board. Because the Board is within the Patent and Trademark Office, all of its powers and duties are ultimately held by the Director. 35 U. S. C. §3(a)(1). He "direct[s]" and "supervis[es]" the Office and "the issuance of patents." §3(a)(2)(A). He may even "fix the rate of basic pay for the administrative patent judges." §3(b)(6). And ultimately, after the Board has reached a decision in a specific case, the Director alone has the power to take final action to cancel a patent claim or confirm it. §318(b).

Also like the Judge Advocate General in *Edmond*, the Director prescribes uniform procedural rules and formulates policies and procedures for Board proceedings. Among other things, he has issued detailed regulations that govern "Trial Practice and Procedure" before the Board. 37 CFR pt. 42 (2020); see also *ibid.* (prescribing regulations governing, *inter alia*, discovery, oral argument, termination of trial, notice, privilege, filing fees, etc.); see also 35 U. S. C.

§§2(b)(2), 316(a)(4), 326(a)(4). He has designed a process to designate and de-designate Board decisions as precedential. Patent Trial and Appeal Board, Standard Operating Procedure 2 (Revision 10), pp. 1–2 (Sept. 20, 2018) (SOP2). He may issue binding policy directives that govern the Board. §3(a)(2)(A). And he may release "instructions that include exemplary applications of patent laws to fact patterns, which the Board can refer to when presented with factually similar cases." 941 F. 3d, at 1331. His oversight is not just administrative; it is substantive as well. §3(a)(2)(A).

The Director has yet another "powerful tool for control." *Edmond*, 520 U. S., at 664. He may designate which of the 250-plus administrative patent judges hear certain cases and may remove administrative patent judges from their specific assignments without cause. See §6(c). So, if any administrative patent judges depart from the Director's direction, he has ample power to rein them in to avoid erroneous decisions. And, if an administrative patent judge consistently fails to follow instructions, the Secretary has the authority to fire him. 5 U. S. C. §7513(a); 35 U. S. C. §3(c); *Cobert* v. *Miller*, 800 F. 3d 1340, 1351 (CA Fed. 2015) (interpreting §7513(a) to allow removal for "'[f]ailure to follow instructions or abide by requirements [that] affec[t] the agency's ability to carry out its mission'").[2]

To be sure, the Director's power over administrative patent judges is not complete. He cannot singlehandedly reverse decisions. Still, he has two powerful checks on Board decisions not found in *Edmond*.

Unlike the Judge Advocate General and CAAF in *Edmond*, the Director *may* influence individual proceedings.

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[2] Although not applicable to any who served on the Board in this suit, a small subset of administrative patent judges are subject to a slightly different removal standard. See 83 Fed. Reg. 29324 (2018); see also 5 U. S. C. §7543(a); 5 CFR pt. 359 (2020); Brief for United States 5, n. 1.

The Director decides in the first instance whether to institute, refuse to institute, or de-institute particular reviews, a decision that is "final and nonappealable." 35 U. S. C. §314(d); see also §314(a). If the Director institutes review, he then may select which administrative patent judges will hear the challenge. §6(c). Alternatively, he can avoid assigning *any* administrative patent judge to a specific dispute and instead designate himself, his Deputy Director, and the Commissioner of Patents. In addition, the Director decides which of the thousands of decisions issued each year bind other panels as precedent. SOP2, at 8. No statute bars the Director from taking an active role to ensure the Board's decisions conform to his policy direction.

But, that is not all. If the administrative patent judges "(somehow) reach a result he does not like, the Director can add more members to the panel—including himself—and order the case reheard." *Oil States Energy Services, LLC* v. *Greene's Energy Group, LLC*, 584 U. S. ___, ___ (2018) (GORSUCH, J., dissenting) (slip op., at 3). There is a formalized process for this type of review. The Director may unilaterally convene a special panel—the Precedential Opinion Panel—to review a decision in a case and determine whether to order rehearing *sua sponte*. SOP2, at 5. (Any party to a proceeding or any Board member can also recommend rehearing by the Precedential Opinion Panel. *Ibid.*) The default members of the panel are the Director, the Commissioner for Patents, and the Chief Administrative Patent Judge. *Id.*, at 4. So even if *all* administrative patent judges decide to defy the Director's authority and go their respective ways, the Director and the Commissioner for Patents can still put a stop to it. And, if the Commissioner for Patents is running amuck, the Director may expand the size of the panel or may replace the Commissioner with someone else, including his Deputy Director. *Ibid.* Further, this panel is not limited to reviewing whether there is "competent evidence" as the CAAF was. It can correct anything

that may "have been misapprehended or overlooked" in the previous opinion. 37 CFR §41.79(b)(1). This broad oversight ensures that administrative patent judges "have no power to render a final decision on behalf of the United States unless permitted to do so by other Executive officers." *Edmond*, 520 U. S., at 665.

B

The Court today appears largely to agree with all of this. "In every respect" save one, the plurality says, "[administrative patent judges] appear to be inferior officers." *Ante*, at 20–21. But instead of finding it persuasive that administrative patent judges seem to be inferior officers—"an understanding consistent with their appointment"—the majority suggests most of *Edmond* is superfluous: All that matters is whether the Director has the statutory authority to individually reverse Board decisions. See *ante*, at 10; see also *ante*, at 20 (plurality opinion).

The problem with that theory is that there is no precedential basis (or historical support)[3] for boiling down "inferior-officer" status to the way Congress structured a particular agency's process for reviewing decisions. If anything, *Edmond* stands for the proposition that a "limitation upon review does not . . . render [officers] principal officers." 520 U. S., at 665. Recall that the CAAF could not reevaluate certain factual conclusions reached by the military judges on the Court of Criminal Appeals. *Ibid.* And recall that neither CAAF nor the Judge Advocate General could "attempt to influence" individual proceedings. *Id.*, at 664. Yet, those constraints on supervision and control did not matter because the Court in *Edmond* considered all the means of supervision and control exercised by the superior officers. Although CAAF could not reevaluate everything, "[w]hat is significant" is that CAAF could oversee the military judges

[3] See Part IV, *infra.*

in other ways: The military judges could not render "a final decision on behalf of the United States unless permitted to do so by other Executive officers." *Id.*, at 665. Here, the Director cannot singlehandedly reevaluate individual decisions, but he still directs and "supervises . . . the Board members responsible for deciding patent disputes." *Oil States Energy Services*, 584 U. S., at ___ (GORSUCH, J., dissenting) (slip op., at 3).

C

Perhaps the better way to understand the Court's opinion today is as creating a new form of intrabranch separation-of-powers law. Traditionally, the Court's task when resolving Appointments Clause challenges has been to discern whether the challenged official qualifies as a specific sort of officer and whether his appointment complies with the Constitution. See *Lucia* v. *SEC*, 585 U. S. ___, ___ (2018) (slip op., at 1) ("This case requires us to decide whether administrative law judges . . . qualify as [officers of the United States]"). If the official's appointment is inconsistent with the constitutional appointment process for the position he holds, then the Court provides a remedy. *Id.*, at ___ (slip op., at 12). Otherwise, the Court must conclude that the "appointments at issue in th[e] case are . . . valid." *Edmond*, 520 U. S., at 666.

Today's majority leaves that tried-and-true approach behind. It never expressly tells us whether administrative patent judges are inferior officers or principal. And the Court never tells us whether the appointment process complies with the Constitution. The closest the Court comes is to say that "the source of the constitutional violation" is *not* "the appointment of [administrative patent judges] by the Secretary." *Ante*, at 23 (plurality opinion). Under our precedent and the Constitution's text, that should resolve the suit. If the appointment process for administrative patent judges—appointment by the Secretary—does not violate

the Constitution, then administrative patent judges must be inferior officers. See Art. II, §2, cl. 2. And if administrative patent judges are inferior officers and have been properly appointed as such, then the Appointments Clause challenge fails. After all, the Constitution provides that "Congress may by Law vest the Appointment of . . . inferior Officers . . . in the Heads of Departments." *Ibid.*

The majority's new Appointments Clause doctrine, though, has nothing to do with the validity of an officer's appointment. Instead, it polices the dispersion of executive power among officers. Echoing our doctrine that Congress may not mix duties and powers from different branches into one actor, the Court finds that the constitutional problem here is that Congress has given a specific power—the authority to finally adjudicate inter partes review disputes—to one type of executive officer that the Constitution gives to another. See *ante*, at 21 (plurality opinion); see also, *e.g.*, *Stern* v. *Marshall*, 564 U. S. 462, 503 (2011) (assignment of Article III power to Bankruptcy Judge); *Bowsher* v. *Synar*, 478 U. S. 714, 728–735 (1986) (assignment of executive power to a legislative officer). That analysis is doubly flawed.

For one thing, our separation-of-powers analysis does not fit. The Constitution recognizes executive, legislative, and judicial power, and it vests those powers in specific branches. Nowhere does the Constitution acknowledge any such thing as "inferior-officer power" or "principal-officer power." And it certainly does not distinguish between these sorts of powers in the Appointments Clause.

And even if it did, early patent dispute schemes establish that the power exercised by the administrative patent judges here does not belong exclusively to principal officers. Nonprincipal officers could—and did—render final decisions in specific patent disputes, not subject to any appeal to a superior executive officer. In 1793, Congress provided that resolution of disputes, where two applicants sought a

patent for the same invention, "shall be submitted to the arbitration of three persons" chosen by the Secretary or by the parties, and that "the decision or award . . . , delivered to the Secretary of State . . . or any two of them, shall be final, as far as respects the granting of the patent." Act of Feb. 21, 1793, §9, 1 Stat. 322–333. In 1836, Congress allowed applicants to appeal the denial of a patent application to "a board of examiners, to be composed of three disinterested persons, who shall be appointed for that purpose by the Secretary of State." Act of July 4, 1836, §7, 5 Stat. 119–120. The Board had the power "to reverse the decision of the Commissioner, either in whole or in part," and the decision governed "further proceedings." *Ibid.* These two early examples show, at a minimum, that the final resolution of patent disputes is not the sole preserve of principal officers.

More broadly, interpreting the Appointments Clause to bar any nonprincipal officer from taking "final" action poses serious line-drawing problems. The majority assures that not every decision by an inferior officer must be reviewable by a superior officer. *Ante*, at 19. But this sparks more questions than it answers. Can a line prosecutor offer a plea deal without sign off from a principal officer?[4] If faced with a life-threatening scenario, can an FBI agent use deadly force to subdue a suspect? Or if an inferior officer temporarily fills a vacant office tasked with making final decisions, do those decisions violate the Appointments

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[4]And all this contemplates that it is easy to distinguish between a principal and inferior officer. But recall that the default appointment scheme for *all* officers—inferior and principal alike—is Presidential appointment and Senate confirmation. Senate confirmation says nothing about whether an officer is principal or inferior for constitutional purposes. Cf. 2 Opinion of Office of Legal Counsel 58, 59 (1978) (concluding that United States Attorneys "can be considered to be inferior officers," even though Congress has never "exercised its discretionary power to vest the appointment of U. S. Attorneys in the Attorney General").

Clause?[5] And are courts around the country supposed to sort through lists of each officer's (or employee's) duties, categorize each one as principal or inferior, and then excise any that look problematic?

Beyond those questions, the majority's nebulous approach also leaves open the question of how much "principal-officer power" someone must wield before he becomes a principal officer. What happens if an officer typically engages in normal inferior-officer work but also has several principal-officer duties? Is he a hybrid officer, properly appointed for four days a week and improperly appointed for the fifth? And whatever test the Court ultimately comes up with to sort through these difficult questions, are we sure it is encapsulated in the two words "inferior officer"?

D

The majority offers one last theory. Although the parties raise only an Appointments Clause challenge and the plurality concedes that there is no appointment defect, *ante,* at 23, the Court appears to suggest that the *real* issue is that this scheme violates the Vesting Clause. See Art. II, §1, cl.1; see also a*nte*, at 13–14 (citing *Free Enterprise Fund* v. *Public Company Accounting Oversight Bd.*, 561 U. S. 477, 496 (2010)); *Myers* v. *United States*, 272 U. S. 52, 135 (1926)). According to the majority, the PTAB's review process inverts the executive "chain of command," allowing administrative patent judges to wield "unchecked . . . executive power" and to "dictat[e]" what the Director must do. *Ante*, at 11, 14. This final offering falters for several reasons.

First no court below passed on this issue. See 941 F. 3d,

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[5] See *Eaton*, 169 U. S., at 343 ("The claim that Congress was without power to vest in the President the appointment of a subordinate officer called a vice-consul, to be charged with the duty of temporarily performing the functions of the consular office, disregards both the letter and spirit of the Constitution").

at 1327 (addressing whether "the [administrative patent judges] who presided over this *inter partes* review were . . . constitutionally appointed"). Given that this Court is generally one "of review, not of first view," it is unclear why we would grant relief on this ground. *Cutter* v. *Wilkinson*, 544 U. S. 709, 718, n. 7 (2005).

Second, the idea that administrative patent judges are at the *top* of the chain of command is belied not only by the statutory scheme, see *supra,* at 7–10, but also by the majority's own refusal to ever name these judges principal officers. See *ante,* at 19.

Third, even if the chain of command were broken, Senate confirmation of an administrative patent judge would offer no fix. As Madison explained, the Senate's role in appointments is an *exception* to the vesting of executive power in the President; it gives another branch a say in the hiring of executive officials. 1 Annals of Cong. 463 (1789). An Article II Vesting Clause problem cannot be remedied by stripping away even more power from the Executive.

Fourth, and finally, historical practice establishes that the vesting of executive power in the President did not require that every patent decision be appealable to a principal officer. As the majority correctly explains, these sorts of final decisions were routinely made by inferior executive officers (or, perhaps, by mere executive employees). See *ante*, at 17–18. If no statutory path to appeal to an executive principal officer existed then, I see no constitutional reason why such a path must exist now.

Perhaps this Vesting Clause theory misunderstands the majority's argument. After all, the Court never directly says that any law or action violates the Vesting Clause. The Court simply criticizes as overly formalistic the notion that both Clauses do exactly what their names suggest: The Appointments Clause governs only appointments; the Vesting Clause deals just with the vesting of executive power in the President. *Ante*, at 13. I would not be so quick to stare

deeply into the penumbras of the Clauses to identify new structural limitations.

III

In the end, the Court's remedy underscores that it is ambivalent about the idea of administrative patent judges *actually* being principal officers. Instead of holding as much explicitly, the Court rewrites the statutory text to ensure that the Director can directly review Board decisions. *Ante*, at 21–22 (plurality opinion). Specifically, the Court declares unenforceable the statutory provision that "prevents the Director from reviewing the decisions of the [Board] on his own." *Ante*, at 22. And as a remedy, the Court "remand[s] to the Acting Director for him to decide whether to rehear the petition." *Ibid.* In that way, the Court makes extra clear what should already be obvious: Administrative patent judges are inferior officers.

But neither reading of the majority's opinion—(1) that administrative patent judges are principal officers that the Court has converted to inferior officers, or (2) that administrative patent judges are inferior officers whose decisions must constitutionally be reversible by the Director alone—supports its proposed remedy.

Take the principal officer view. If the Court truly believed administrative patent judges are principal officers, then the Court would need to vacate the Board's decision. As this Court has twice explained, "the 'appropriate' remedy for an adjudication tainted with an appointments violation is a new 'hearing before a properly appointed' official." *Lucia*, 585 U. S., at ___ (slip op., at 12) (quoting *Ryder* v. *United States*, 515 U. S. 177, 183, 188 (1995)). If administrative patent judges are (or were) constitutionally deficient principal officers, then surely Arthrex is entitled to a new hearing before officers untainted by an appointments

violation. But, the Court does not vacate the Board's decision. In fact, it expressly disavows the existence of an appointments violation. *Ante*, at 23 (plurality opinion).

The quasi-separation-of-powers view fares no better. If we accept as true the Court's position that the Appointments Clause inherently grants the Director power to reverse Board decisions, then another problem arises: No constitutional violation has occurred in this suit. The Board had the power to decide and lawfully did decide the dispute before it. The Board did not misinterpret its statutory authority or try to prevent direct review by the Director. Nor did the Director wrongfully decline to rehear the Board's decision. Moreover, Arthrex has not argued that it sought review by the Director. So to the extent "the source of the constitutional violation is the restraint on the review authority of the Director," *ibid.*, his review was not constrained. Without any constitutional violation in this suit to correct, one wonders how the Court has the power to issue a remedy. See *Carney* v. *Adams*, 592 U. S. ___, ___ (2020) (slip op., at 4) (Article III prevents "the federal courts from issuing advisory opinions").

Perhaps the majority thinks Arthrex should receive some kind of bounty for raising an Appointments Clause challenge and *almost* identifying a constitutional violation. But the Constitution allows us to award judgments, not participation trophies.

IV

Although unnecessary to resolve this suit, at some point it may be worth taking a closer look at whether the functional element of our test in *Edmond*—the part that the Court relies on today—aligns with the text, history, and structure of the Constitution. The founding era history surrounding the Inferior Officer Clause points to at least three different definitions of an inferior officer, none of which requires a case-by-case functional examination of exactly how

much supervision and control another officer has. The rationales on which *Edmond* relies to graft a functional element into the inferior-officer inquiry do not withstand close scrutiny.

A

Early discussions of inferior officers reflect at least three understandings of who these officers were—and who they were not—under the Appointments Clause. Though I do not purport to decide today which is best, it is worth noting that administrative patent judges would be inferior under each.

1

The narrowest understanding divides all executive officers into three categories: heads of departments, superior officers, and inferior officers. During the Constitutional Convention, James Madison supported this view in a brief discussion about the addition of the Inferior Officer Clause. 2 Records of the Federal Convention of 1787, p. 627 (M. Farrand ed. 1911) (Farrand); see also Mascott, Who Are "Officers of the United States," 70 Stan. L. Rev. 443, 468, n. 131 (2018). Gouverneur Morris moved to add the clause. But Madison initially resisted. He argued that it did "not go far enough if it be necessary at all [because] Superior Officers below Heads of Departments ought in some cases to have the appointment of the lesser offices." 2 Farrand 627. The motion nonetheless passed. The crux of Madison's objection appears to rely on the idea that there are three types of officers: inferior officers, superior officers, and department heads. Congress could vest the appointment of inferior officers in the President, the courts, or a department head. But the others must be appointed by the President with Senate confirmation.

Some held a second understanding: Inferior officers encompass nearly *all* officers. As Justice Story put it,

"[w]hether the *heads of departments* are inferior officers in the sense of the constitution, was much discussed, in the debate on the organization of the department of foreign affairs, in 1789." 3 Commentaries on the Constitution of the United States 386, n. 1 (1833) (emphasis added). Proponents of this understanding argued that the Secretary of State should be an inferior officer because he was inferior to the President, "the Executive head of the department." 1 Annals of Cong. 509. In other words, inferior officers would encompass *all* executive officers inferior to the President, other than those specifically identified in the Constitution: "Ambassadors, other public Ministers and Consuls." Art. II, §2.

The constitutional text and history provide some support for this rationale. By using the adjective "such" before "inferior Officers," the Clause about inferior officers could be understood to refer back to "all other Officers of the United States, whose Appointments are not herein otherwise provided for, and which shall be established by Law." *Ibid.*; see also 2 S. Johnson, A Dictionary of the English Language (6th ed. 1785) (defining "such" to mean "[c]omprehended under the term premised, like what has been said"). And to be "inferiour" means simply to be "[l]ower in place"; "[l]ower in station or rank of life" and "[s]ubordinate" to another officer. 1 *ibid.* Department heads are officers, and they are lower in rank and subordinate to the President. See U. S. Const., Art. II, §1.

But others disagreed, contending this went "too far; because the Constitution" elsewhere specifies "'the principal officer in each of the Executive departments.'" 1 Annals of Cong. 459. These Framers endorsed a third understanding, which distinguished just between inferior and principal officers. See *id.*, at 518 ("We are to have a Secretary for Foreign Affairs, another for War, and another for the Treasury; now, are not these the principal officers in those departments"). A single officer could not simultaneously be both.

Ultimately, this group won out, "expressly designat[ing]" the Secretary of the Department of Foreign Affairs as a "principal officer," not an inferior one. *Edmond*, 520 U. S., at 663 (quoting Act of July 27, 1789, ch. 4, §§1–2, 1 Stat. 28–29).

This principal-inferior dichotomy also finds roots in the structure of the Constitution, which specifically identifies both principal officers (in the Opinions Clause and the Twenty-fifth Amendment) and inferior officers (in the Appointments Clause). And it comports with contemporaneous dictionary definitions. A "principal" officer is "[a] head" officer; "a chief; not a second." 2 Johnson, Dictionary of the English Language. Other executive officers would, by definition, be lower than or subordinate to these head officers.

The principal-inferior officer divide played out in other contexts as well. In the debate over removability of officers, Representative Smith indicated that he "had doubts whether [an] officer could be removed by the President" in light of the impeachment process. 1 Annals of Cong. 372. Madison disagreed, arguing that impeachment alone for all removals "would in effect establish every officer of the Government on the firm tenure of good behaviour; not the heads of Departments only, but all the inferior officers of those Departments, would hold their offices during good behaviour." *Ibid.*

State constitutions at the founding lend credence to this idea that inferior officers encompass all officers except for the heads of departments. For example, the 1789 Georgia State Constitution provided that "militia officers and the secretaries of the governor . . . shall be appointed by the governor." Art. IV, §2. But "[t]he general assembly may vest the appointment of inferior officers in the governor, the courts of justice, or in such other manner as they may by law establish." *Ibid.* The law thus distinguished between secretaries and inferior officers. Similarly, the Delaware Constitution directed that "[t]he State treasurer shall be

appointed annually by the house of representatives, with the concurrence of the Senate." Art. VIII, §3 (1792). But "all inferior officers in the treasury department" were to be "appointed in such manner as is or may be directed by law." §6.

Although not dipositive, this Court has adopted the nomenclature of the principal-inferior distinction. See, *e.g.*, *ante,* at 5–6; *Edmond*, 520 U. S., at 661 ("distinguishing between principal and inferior officers for Appointments Clause purposes"); *Buckley* v. *Valeo*, 424 U. S. 1, 132 (1976) (*per curiam*) ("Principal officers are selected by the President with the advice and consent of the Senate. Inferior officers Congress may allow to be appointed by the President alone, by the heads of departments, or by the Judiciary"); cf. *Lucia*, 585 U. S., at ___ (THOMAS, J., concurring) (slip op., at 2) ("While principal officers must be nominated by the President and confirmed by the Senate, Congress can authorize the appointment of 'inferior Officers' by 'the President alone,' 'the Courts of Law,' or 'the Heads of Departments'"); *United States* v. *Germaine*, 99 U. S. 508, 511 (1879) ("the principal officer in" the Opinions Clause "is the equivalent of the head of department in the other"). And in reasoning adopted unanimously by the Court, at least one opinion defined "principal officers" for purposes of the Appointments Clause to be "ambassadors, ministers, heads of departments, and judges." *Freytag* v. *Commissioner*, 501 U. S. 868, 884 (1991).

2

Regardless of which of the three interpretations is correct, all lead to the same result here. Administrative patent judges are inferior officers.

Start with the broadest understanding. A careful read of the Appointments Clause reveals that the office of "administrative patent judge" does not appear amidst the offices of ambassador, consul, public minister, and Supreme Court

judge the Constitution identifies. See Art. II, §2, cl. 2. So, if inferior officers are all executive officers other than those with special appointment processes laid out in the Constitution, then administrative patent judges squarely fit.

Administrative patent judges also fall on the inferior-officer side of the inferior-principal divide. It is agreed that administrative patent judges are not the heads of any department. See *ante*, at 8; Brief for Arthrex, Inc., 5–6 (noting that the Secretary of Commerce is the relevant "department head"). Thus, to the extent a "principal officer . . . is the equivalent of the head of department," administrative patent judges are not one. *Germaine*, 99 U. S., at 511.

And under the Madisonian tripartite system, administrative patent judges would still be inferior. These judges are not heads of departments. Nor are they "superior officers." An administrative patent judge is not "[h]igher" than or "greater in dignity or excellence" to other officers inferior to him. 2 Johnson, Dictionary of the English Language (defining "Superiour"). Tellingly, neither respondent nor the majority identify a *single* officer lower in rank or subordinate to administrative patent judges. Surely if "[w]hether one is an 'inferior' officer depends on whether he has a superior," then whether one is a superior officer depends on whether he has an inferior. *Edmond*, 520 U. S., at 662; see also *Morrison*, 487 U. S., at 720 (Scalia, J., dissenting) ("Of course one is not a 'superior officer' without some supervisory responsibility"). In contrast, an administrative patent judge *is* lower in rank and subordinate to both the Director and the Secretary.

* * *

To be clear, I do not purport to have exhausted all contemporaneous debates, sources, and writings. Perhaps there is some reason to believe that the inherent nature of an inferior officer requires that all of their decisions be directly appealable to a Senate-confirmed executive officer.

But the majority does not identify one. And, without any justification in the text, in the history, or in our precedent, I would not impose that requirement.

B

If anything, the Court's functional prong in *Edmond* may merit reconsideration. The *Edmond* opinion highlighted three justifications for its decision to require more than just a lower rank and a superior officer. But having reviewed the history, it is worth checking whether these reasons are sound. They may not be.

First, *Edmond* highlighted the Constitution's use of the term "inferior officer." 520 U. S., at 663. Were the Appointments Clause meant to identify only lower ranking officers, then the Constitution could have used the phrase "'lesser officer.'" *Ibid.* But Madison's objection to the Inferior Officer Clause pokes a hole in this distinction. After all, Madison used almost exactly this "lesser officer" phrasing: He urged a broader clause so that "superior officers" could "have the appointment of the *lesser offices*." 2 Farrand 627 (emphasis added). If Madison understood the two terms to be interchangeable, perhaps this Court should too.

Second, *Edmond* flagged that the Appointments Clause was designed "to preserve political accountability relative to important Government assignments." 520 U. S., at 663. But the accountability feature of the Appointments Clause was not about accountability for specific *decisions* made by inferior officers, but rather accountability for "'a bad nomination.'" *Id.*, at 660 (quoting The Federalist No. 77, p. 392 (M. Beloff ed. 1987)). The Appointments Clause "provides a direct line of accountability for any poorly performing *officers* back to the actor who selected them." Mascott, 70 Stan. L. Rev., at 447 (emphasis added).

And third, *Edmond* noted that legislation adopted by early Congresses revealed that inferior officers were subject to the discretion and direct oversight of the principal officer.

520 U. S., at 663. Take, for example, the Act establishing the Department of War: It referred "to the Secretary of that department as a 'principal officer,'" and provided that "the Chief Clerk, would be 'employed' within the Department as the Secretary 'shall deem proper,' as an 'inferior officer.'" *Edmond*, 520 U. S., at 664 (quoting ch. 7, 1 Stat. 49–50).

But not every officer was neatly categorized as a principal officer or an inferior one. For example, the Act of Congress Establishing the Treasury Department created "the following officers, namely: a Secretary of the Treasury, to be deemed head of the department; a Comptroller . . . , and an Assistant to the Secretary of the Treasury, which assistant shall be appointed by the said Secretary." Act of Sept. 2, 1789, ch. 12, §1, 1 Stat. 65. The statute does not label the Comptroller as a principal officer or a department head. Nor is he expressly designated as an inferior officer. Moreover, his duties extended beyond doing merely what the Secretary deemed proper. The Comptroller's statutory power and authority included "countersign[ing] all warrants drawn by the Secretary of Treasury," "provid[ing] for the regular and punctual payment of all monies which may be collected," and "direct[ing] prosecutions for all delinquencies of officers of the revenue, and for debts that are, or shall be due to the United States." §3, *id.,* at 66. This quasi-judicial figure's "principal duty seems to be deciding upon the lawfulness and justice of the claims and accounts subsisting between the United States and particular citizens." 1 Annals of Cong. 611–612 (Madison); see also *ante*, at 14–15. Yet at least one early legislator (with no recorded objections) thought "the Comptroller was an inferior officer." 1 Annals of Cong. 613 (Stone).

Given the lack of historical support, it is curious that the Court has decided to expand *Edmond*'s "functional" prong to elevate administrative patent judges to principal-officer status (only to demote them back to inferior-officer status). Perhaps the Court fears that a more formal interpretation

might be too easy to subvert. A tricky Congress could allow the Executive to sneak a powerful, Cabinet-level-like officer past the Senate by merely giving him a low rank. Maybe. But this seems like an odd case to address that concern. And, even if this suit did raise the issue, the Court should be hesitant to enforce its view of the Constitution's spirit at the cost of its text.

* * *

The Court today draws a new line dividing inferior officers from principal ones. The fact that this line places administrative patent judges on the side of Ambassadors, Supreme Court Justices, and department heads suggests that something is not quite right. At some point, we should take stock of our precedent to see if it aligns with the Appointments Clause's original meaning. But, for now, we must apply the test we have. And, under that test, administrative patent judges are both formally and functionally inferior to the Director and to the Secretary. I respectfully dissent.

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Patent Trial and Appeal Board
PRECEDENTIAL
Standard Operating Procedure 2
Designated: 5/5/20

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE INC.,
Petitioner,

v.

FINTIV, INC.,
Patent Owner.

Case IPR2020-00019
Patent 8,843,125 B2

Before WILLIAM M. FINK, *Vice Chief Administrative Patent Judge*, and LINDA E. HORNER and LYNNE E. PETTIGREW, *Administrative Patent Judges*.

FINK, *Vice Chief Administrative Patent Judge*.

ORDER
Conduct of the Proceeding
Supplemental Briefing on Discretionary Denial
35 U.S.C. § 314(a) and 37 C.F.R. § 42.5(a)

I. INTRODUCTION

Petitioner, Apple, Inc., filed a Petition in this case on October 28, 2019, challenging certain claims of U.S. Patent No. 8,843,125 B2 (Ex. 1001, "the '125 patent") owned by Patent Owner, Fintiv, Inc. Paper 1 ("Pet."). Patent Owner filed a Preliminary Response on February 15, 2020. Paper 10 ("Prelim. Resp."). In its Preliminary Response, Patent Owner requests that the Board apply its discretion under 35 U.S.C. § 314(a) to deny institution of the requested proceeding due to the advanced state of a parallel district court litigation in which the same issues have been presented and trial has been set for November 16, 2020. Prelim. Resp. 22–26 (citing *NHK Spring Co. v. Intri-Plex Techs., Inc.*, IPR2018-00752, Paper 8 (PTAB Sept. 12, 2018) (precedential, designated May 7, 2019)). Although Petitioner addressed the issue briefly in the Petition, at that time no trial date had been set. *See* Pet. 7. In light of the apparent change in status of the parallel proceeding, the panel has determined that supplemental briefing on the issue of discretionary denial is necessary in this case to give Petitioner an opportunity to respond. This Order discusses the factors relevant to the Board's decision on whether to apply its discretion under 35 U.S.C. § 314(a) to deny institution. This Order authorizes the parties to file supplemental briefing addressing facts in this case relevant to these factors.

II. DISCRETIONARY DENIAL UNDER *NHK*

In *NHK*, the patent owner argued the Board should deny institution under 35 U.S.C. § 314(a) because institution of a trial at the PTAB would be an inefficient use of Board resources in light of the "advanced state" of the parallel district court litigation in which the petitioner had raised the same invalidity challenges. IPR2018-00752, Paper 8. The Board denied

institution, relying in part on § 314(a). Specifically, under § 314(a) the Board considered the fact that the parallel district court proceeding was scheduled to finish before the Board reached a final decision as a factor favoring denial.[1] The Board found that the earlier district court trial date presented efficiency considerations that provided an additional basis, separate from the independent concerns under 35 U.S.C. § 325(d),[2] for denying institution. Thus, *NHK* applies to the situation where the district court has set a trial date to occur earlier than the Board's deadline to issue a final written decision in an instituted proceeding. In a case where, in contrast to the facts present in *NHK*, the district court has set a trial date *after* the Board's deadline to issue a final written decision in an instituted proceeding, the Board may be less likely to deny institution under 35 U.S.C. § 314(a) based on district court trial timing depending on other factors as set forth below.[3]

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[1] *See* 35 U.S.C. § 316(a)(11) (2018) (requiring issuance of a final written decision within one year of institution, absent extension up to six months for good cause).

[2] Section 325(d) provides that the Director may elect not to institute a proceeding if the challenge to the patent is based on the same or substantially the same prior art or arguments previously presented to the Office.

[3] *See Polycom, Inc. v. directPacket Research, Inc.*, IPR2019-01233, Paper 21 at 13 (PTAB Jan. 13, 2020) (declining to apply discretion to deny institution when district court trial is scheduled to occur months after the statutory deadline for completion of the IPR); *Iconex, LLC v. MAXStick Products Ltd.*, IPR2019-01119, Paper 9 at 10 (PTAB Dec. 6, 2019) (same).

A. The Parties' Arguments

In the Petition, Petitioner argues that although a parallel district court proceeding is ongoing involving the challenged patent, the Board should not exercise authority to deny institution under *NHK* because, at the time of the Petition filing, "no preliminary injunction motion has been filed, the district court has not been presented with or invested any time in the analysis of prior art invalidity issues, and no trial date has been set." Pet. 7. Petitioner also argues that it timely filed its petition within the statutorily prescribed one-year window, and that declining to institute IPR here would "essentially render nugatory" the one-year filing period of § 315(b). *Id.* Petitioner also argues that declining to institute an IPR based on a parallel district court litigation "ignores the common scenario, contemplated by Congress, of obtaining a district court stay based on institution." *Id.*

In its Preliminary Response, Patent Owner has raised several factors that it contends weigh in favor of exercising authority to deny institution under *NHK*, including an earlier trial date (six months prior to the projected deadline for a final written decision if the Board institutes a proceeding),[4] significant overlap between issues raised in the Petition and in the district court proceeding (identical claims and arguments), and investment in the district court trial (claim construction already issued). *See* Prelim. Resp. 23–27.

[4] After the filing of the Petition, the district court entered a scheduling order setting a trial date to occur prior to projected deadline for a final written decision in this matter. Ex. 2009 (setting trial date of November 16, 2020).

B. Factors Related to a Parallel, Co-Pending Proceeding in Determining Whether to Exercise Discretionary Institution or Denial

As with other non-dispositive factors considered for institution under 35 U.S.C. § 314(a), an early trial date should be weighed as part of a "balanced assessment of all relevant circumstances of the case, including the merits."[5] Consolidated Trial Practice Guide November 2019 ("TPG")[6] at 58. Indeed, the Board's cases addressing earlier trial dates as a basis for denial under *NHK* have sought to balance considerations such as system efficiency, fairness, and patent quality.[7] When the patent owner raises an argument for discretionary denial under *NHK* due to an earlier trial date,[8] the Board's decisions have balanced the following factors:

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[5] *See Abbott Vascular, Inc. v. FlexStent, LLC*, IPR2019-00882, Paper 11 at 31 (PTAB Oct. 7, 2019) (declining to adopt a bright-line rule that an early trial date alone requires denial in every case).

[6] *Available at* https://www.uspto.gov/TrialPracticeGuideConsolidated.

[7] *See Magellan Midstream Partners L.P. v. Sunoco Partners Marketing & Terminals L.P.*, IPR2019-01445, Paper 12 at 10 (PTAB Jan. 22, 2020) (citing "unnecessary and counterproductive litigation costs" where district court would most likely have issued a decision before the Board issues a final decision); *Intel Corp. v. VLSI Tech. LLC*, IPR2019-01192, Paper 15 at 11 (PTAB Jan. 9, 2020) ("When considering the impact of parallel litigation in a decision to institute, the Board seeks, among other things, to minimize the duplication of work by two tribunals to resolve the same issue."); *Illumina, Inc. v. Natera, Inc.*, IPR2019-01201, Paper 19 at 6 (PTAB Dec. 18, 2019) ("We have considered the positions of the parties and find that, on this record, considerations of efficiency, fairness, and the merits of the grounds in the Petition do not weigh in favor of denying the Petition.").

[8] To the extent we refer to such a denial of institution as a "denial under *NHK*," we refer to *NHK*'s § 314(a) denial due to the earlier trial date in the district court and not the independent basis for denial under § 325(d).

1. whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted;
2. proximity of the court's trial date to the Board's projected statutory deadline for a final written decision;
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 proceeding are the same party; and
6. other circumstances that impact the Board's exercise of discretion, including the merits.

These factors relate to whether efficiency, fairness, and the merits support the exercise of authority to deny institution in view of an earlier trial date in the parallel proceeding. As explained below, there is some overlap among these factors. Some facts may be relevant to more than one factor. Therefore, in evaluating the factors, the Board takes a holistic view of whether efficiency and integrity of the system are best served by denying or instituting review. *See* TPG at 58 (quoting 35 U.S.C. § 316(b)).

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

A district court stay of the litigation pending resolution of the PTAB trial allays concerns about inefficiency and duplication of efforts. This fact has strongly weighed against exercising the authority to deny institution under *NHK*.[9] In some cases, there is no stay, but the district court has denied

[9] *See Precision Planting, LLC v. Deere & Co.*, IPR2019-01052, Paper 19 at 10 (PTAB Jan. 7, 2020) (finding that the district court stay of the parallel district court case rendered moot the patent owner's argument for discretionary denial of the petition); *Apotex Inc. v. UCB Biopharma Sprl*,

a motion for stay without prejudice and indicated to the parties that it will consider a renewed motion or reconsider a motion to stay if a PTAB trial is instituted. Such guidance from the district court, if made of record, suggests the district court may be willing to avoid duplicative efforts and await the PTAB's final resolution of the patentability issues raised in the petition before proceeding with the parallel litigation. This fact has usually weighed against exercising authority to deny institution under *NHK*,[10] but, for reasons discussed below, proximity of the court's trial date and investment of time are relevant to how much weight to give to the court's willingness to reconsider a stay.[11, 12] If a court has denied a defendant's motion for a stay

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IPR2019-00400, Paper 17 at 31–32 (PTAB July 15, 2019) (finding that the district court stay of the parallel district court case predicated on the *inter partes* review means that the trial will not occur before the Board renders a final decision).

[10] *See Abbott Vascular*, IPR2019-00882, Paper 11 at 30–31 (noting district court's willingness to revisit request for stay if Board institutes an *inter partes* review proceeding).

[11] *See DMF, Inc. v. AMP Plus, Inc.*, Case No. 2-18-cv-07090 (C.D. Cal. July 12, 2019) (denying defendants' initial motion to stay without prejudice to their renewing the motion should PTAB grant their IPR petition); *id.* (Dec. 13, 2019) (denying renewed motion to stay after PTAB instituted, in part, because in the interim claim construction order had issued, trial date was fast approaching, and discovery was in an advanced stage).

[12] It is worth noting that the district court, in considering a motion for stay, may consider similar factors related to the amount of time already invested by the district court and proximity of the trial date to the Board's deadline for a final written decision. *See Space Data Corp. v. Alphabet Inc.*, Case No. 16-cv-03260, slip op. at 3 (N.D. Cal. Mar. 12, 2019) (denying motion to stay where the court had ruled on a motion for partial summary judgment and issued a *Markman* order, and fact and expert discovery are closed, and thus "much work has been completed"); *Intellectual Ventures I LLC v. T-*

pending resolution of a PTAB proceeding, and has not indicated to the parties that it will consider a renewed motion or reconsider a motion to stay if a PTAB trial is instituted, this fact has sometimes weighed in favor of exercising authority to deny institution under *NHK*.

One particular situation in which stays arise frequently is during a parallel district court *and* ITC investigation involving the challenged patent. In such cases, the district court litigation is often stayed under 28 U.S.C. § 1659 pending the resolution of the ITC investigation. Regardless, even though the Office and the district court would not be bound by the ITC's decision, an earlier ITC trial date may favor exercising authority to deny institution under *NHK* if the ITC is going to decide the same or substantially similar issues to those presented in the petition. The parties should indicate whether there is a parallel district court case that is ongoing or stayed under 28 U.S.C. § 1659 pending the resolution of the ITC investigation. We

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Mobile USA, Inc., Case No. 2-17-cv-00577 (E. D. Tex. Dec. 13, 2018) (denying motion to stay after dispositive and *Daubert* motions had been filed and the court had expended material judicial resources to prepare for the pretrial in three weeks); *Plastic Omnium Advanced Innovation and Research v. Donghee Am., Inc.*, Case No. 1-16-cv-00187 (D. Del. Mar. 9, 2018) (denying motion for stay after PTAB's institution of *inter partes* reviews because the court "has construed the parties' disputed claim terms, handled additional discovery-related disputes, begun reviewing the parties' summary judgment and *Daubert* motions . . . and generally proceeded toward trial" and "[d]elaying the progress of this litigation . . . would risk wasting the Court's resources"); *Dentsply Int'l, Inc. v. US Endodontics, LLC*, Case No. 2-14-cv-00196, slip op. at 5 (E.D. Tenn. Dec. 1, 2015) (denying motion for stay pending *inter partes* review because a stay at this point in the proceedings "would waste a significant amount of the time and resources already committed to this case by the parties and the Court").

recognize that ITC final invalidity determinations do not have preclusive effect,[13] but, as a practical matter, it is difficult to maintain a district court proceeding on patent claims determined to be invalid at the ITC. Accordingly, the parties should also indicate whether the patentability disputes before the ITC will resolve all or substantially all of the patentability disputes between the parties, regardless of the stay.[14]

2. proximity of the court's trial date to the Board's projected statutory deadline

If the court's trial date is earlier than the projected statutory deadline, the Board generally has weighed this fact in favor of exercising authority to deny institution under *NHK*. If the court's trial date is at or around the same time as the projected statutory deadline or even significantly after the projected statutory deadline, the decision whether to institute will likely implicate other factors discussed herein, such as the resources that have been invested in the parallel proceeding.[15]

3. investment in the parallel proceeding by the court and parties

The Board also has considered the amount and type of work already completed in the parallel litigation by the court and the parties at the time of the institution decision. Specifically, if, at the time of the institution decision, the district court has issued substantive orders related to the patent

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[13] *See Texas Instruments v. Cypress Semiconductor Corp.*, 90 F.3d 1558 (Fed. Cir. 1996) (holding that an invalidity determination in an ITC section 337 action does not have preclusive effect).

[14] *See infra* § II.A.4.

[15] *See, e.g., infra* § II.A.3, § II.A.4.

at issue in the petition, this fact favors denial.[16] Likewise, district court claim construction orders may indicate that the court and parties have invested sufficient time in the parallel proceeding to favor denial.[17] If, at the time of the institution decision, the district court has not issued orders related to the patent at issue in the petition, this fact weighs against exercising discretion to deny institution under *NHK*.[18] This investment factor is related to the trial date factor, in that more work completed by the parties and court in the parallel proceeding tends to support the arguments that the parallel proceeding is more advanced, a stay may be less likely, and instituting would lead to duplicative costs.

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[16] *See E-One, Inc. v. Oshkosh Corp.*, IPR2019-00162, Paper 16 at 8, 13, 20 (PTAB June 5, 2019) (district court issued preliminary injunction order after finding petitioner's invalidity contentions unlikely to succeed on the merits).

[17] *See Next Caller, Inc. v. TRUSTID, Inc.*, IPR2019-00963, Paper 8 at 13 (PTAB Oct. 28, 2019) (district court issued claim construction order); *Thermo Fisher Scientific, Inc. v. Regents of the Univ. of Cal.*, IPR2018-01370, Paper 11 at 26 (PTAB Feb. 7, 2019) (district court issued claim construction order). We note that the weight to give claim construction orders may vary depending upon a particular district court's practices. For example, some district courts may postpone significant discovery until after it issues a claim construction order, while others may not.

[18] *See Facebook, Inc. v. Search and Social Media Partners, LLC*, IPR2018-01620, Paper 8 at 24 (PTAB Mar. 1, 2019) (district court proceeding in its early stages, with no claim constructions having been determined); *Amazon.com, Inc. v. CustomPlay, LLC*, IPR2018-01496, Paper 12 at 8–9 (PTAB Mar. 7, 2019) (district court proceeding in its early stages, with no claim construction hearing held and district court having granted extensions of various deadlines in the schedule).

As a matter of petition timing, notwithstanding that a defendant has one year to file a petition,[19] it may impose unfair costs to a patent owner if the petitioner, faced with the prospect of a looming trial date, waits until the district court trial has progressed significantly before filing a petition at the Office. The Board recognizes, however, that it is often reasonable for a petitioner to wait to file its petition until it learns which claims are being asserted against it in the parallel proceeding.[20] Thus, the parties should explain facts relevant to timing. 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] If, however, the evidence shows

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[19] *See* 35 U.S.C. § 315(b) (2018) (setting a one-year window from the date on which the petitioner, real party in interest, or privy of the petitioner is served with a complaint alleging infringement of the patent in which to file a petition).

[20] *See* 157 Cong. Rec. S5429 (Sept. 8, 2011) (S. Kyl) (explaining that in light of the House bill's enhanced estoppels, it is important to extend the deadline for allowing an accused infringer to seek *inter partes* review from 6 months, as proposed in the Senate bill, to one year to afford defendants a reasonable opportunity to identify and understand the patent claims that are relevant to the litigation). Our discussion of this factor focuses on the situation where the petitioner also is a defendant in the parallel litigation. If the parallel litigation involves a party different than the petitioner, this fact weighs against exercising authority to deny institution under *NHK*. *See infra* § II.A.5.

[21] *See Intel Corp.*, IPR2019-01192, Paper 15 at 12–13 (finding petitioner was diligent in filing the petition within two months of patent owner narrowing the asserted claims in the district court proceeding); *Illumina*, IPR2019-01201, Paper 19 at 8 (finding petitioner was diligent in filing the

that the petitioner did not file the petition expeditiously, such as at or around the same time that the patent owner responds to the petitioner's invalidity contentions, or even if the petitioner cannot explain the delay in filing its petition, these facts have favored denial.[22]

4. overlap between issues raised in the petition and in the parallel proceeding

In *NHK*, the Board was presented with substantially identical prior art arguments that were at issue in the district court (as well as those previously addressed by the Office under § 325(d)). IPR2018-00752, Paper 8 at 20. Thus, concerns of inefficiency and the possibility of conflicting decisions were particularly strong. Accordingly, if the petition includes the same or substantially the same claims, grounds, arguments, and evidence as presented in the parallel proceeding, this fact has favored denial.[23] Conversely, if the petition includes materially different grounds, arguments,

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petition several months before the statutory deadline and in response to the patent being added to the litigation in an amended complaint).

[22] *See Next Caller, Inc. v. TRUSTID, Inc.*, IPR2019-00961, Paper 10 at 16 (PTAB Oct. 16, 2019) (weighing the petitioner's unexplained delay in filing the petition in favor of denial of the petition and noting that had the petitioner filed the petition around the same time as the service of its initial invalidity contentions, the PTAB proceeding may have resolved the issues prior to the district court).

[23] *See Next Caller*, IPR2019-00963, Paper 8 at 11–12 (same grounds asserted in both cases); *ZTE (USA) Inc. v. Fractus, S.A.*, IPR2018-01451, Paper 12 at 20 (PTAB Feb. 19, 2019) (same prior art and identical evidence and arguments in both cases).

and/or evidence than those presented in the district court, this fact has tended to weigh against exercising discretion to deny institution under *NHK*.[24]

In many cases, weighing the degree of overlap is highly fact dependent. For example, if a petition involves the same prior art challenges but challenges claims in addition to those that are challenged in the district court, it may still be inefficient to proceed because the district court may resolve validity of enough overlapping claims to resolve key issues in the petition. The parties should indicate whether all or some of the claims challenged in the petition are also at issue in district court. The existence of non-overlapping claim challenges will weigh for or against exercising discretion to deny institution under *NHK* depending on the similarity of the claims challenged in the petition to those at issue in the district court.[25]

5. whether the petitioner and the defendant in the parallel proceeding are the same party

If a petitioner is unrelated to a defendant in an earlier court proceeding, the Board has weighed this fact against exercising discretion to

[24] *See Facebook, Inc. v. BlackBerry Limited*, IPR2019-00899, Paper 15 at 12 (PTAB Oct. 8, 2019) (different prior art relied on in the petition than in the district court); *Chegg, Inc. v. NetSoc, LLC*, IPR2019-01165, Paper 14 at 11–12 (PTAB Dec. 5, 2019) (different statutory grounds of unpatentability relied on in the petition and in the district court).

[25] *See Next Caller*, IPR2019-00961, Paper 10 at 14 (denying institution even though two petitions jointly involve all claims of patent and district court involves only a subset of claims because the claims all are directed to the same subject matter and petitioner does not argue that the non-overlapping claims differ significantly in some way or argue that it would be harmed if institution of the non-overlapping claims is denied).

deny institution under *NHK*.[26] Even when a petitioner is unrelated to a defendant, however, if the issues are the same as, or substantially similar to, those already or about to be litigated, or other circumstances weigh against redoing the work of another tribunal, the Board may, nonetheless, exercise the authority to deny institution.[27] An unrelated petitioner should, therefore, address any other district court or Federal Circuit proceedings involving the challenged patent to discuss why addressing the same or substantially the same issues would not be duplicative of the prior case even if the petition is brought by a different party.

6. other circumstances that impact the Board's exercise of discretion, including the merits

As noted above, the factors considered in the exercise of discretion are part of a balanced assessment of all the relevant circumstances in the case, including the merits.[28] For example, if the merits of a ground raised in the petition seem particularly strong on the preliminary record, this fact has

[26] *See Nalox-1 Pharms., LLC. v. Opiant Pharms., Inc.*, IPR2019-00685, Paper 11 at 6 (PTAB Aug. 27, 2019) (distinguishing *NHK* because in *NHK*, "the Board considered 'the status of the district court proceeding *between* the parties'" and, in the *Nalox-1* case, the petitioner was not a party to the parallel district court litigations).

[27] *See Stryker Corp. v. KFx Medical, LLC*, IPR2019-00817, Paper 10 at 27–28 (PTAB Sept. 16, 2019) (considering a jury verdict of no invalidity, based in part on evidence of secondary considerations, weighed in favor of denying institution where the unrelated petitioner failed to address this evidence in the petition).

[28] TPG at 58.

favored institution.[29] In such cases, the institution of a trial may serve the interest of overall system efficiency and integrity because it allows the proceeding to continue in the event that the parallel proceeding settles or fails to resolve the patentability question presented in the PTAB proceeding.[30] By contrast, if the merits of the grounds raised in the petition are a closer call, then that fact has favored denying institution when other factors favoring denial are present.[31] This is not to suggest that a full merits analysis is necessary to evaluate this factor.[32] Rather, there may be strengths

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[29] *Illumina*, IPR2019-01201, Paper 19 at 8 (PTAB Dec. 18, 2019) (instituting when "the strength of the merits outweigh relatively weaker countervailing considerations of efficiency"); *Facebook, Inc. v. BlackBerry Ltd.*, IPR2019-00925, Paper 15 at 27 (PTAB Oct. 16, 2019) (same); *Abbott Vascular*, IPR2019-00882, Paper 11 at 29–30 (same); *Comcast Cable Commnc'ns., LLC v. Rovi Guides, Inc.*, IPR2019-00231, Paper 14 at 11 (PTAB May 20, 2019) (instituting because the proposed grounds are "sufficiently strong to weigh in favor of not denying institution based on § 314(a)").

[30] Were a final judgment entered on the patentability issues in the parallel proceeding, the parties may jointly request to terminate the PTAB proceeding in light of the fully resolved parallel proceeding. *See* 37 C.F.R. § 42.72.

[31] *E-One*, IPR2019-00162, Paper 16 at 8, 13, 20 (denying institution based on earlier district court trial date, weakness on the merits, and the district court's substantial investment of resources considering the invalidity of the challenged patent).

[32] Of course, if a petitioner fails to present a reasonable likelihood of prevailing as to unpatentability of at least one challenged claim, then the Board may deny the petition on the merits and may choose not to reach a patent owner's discretionary denial arguments.

or weaknesses regarding the merits that the Board considers as part of its balanced assessment.[33]

C. Other Considerations

Other facts and circumstances may also impact the Board's discretion to deny institution. For example, factors unrelated to parallel proceedings that bear on discretion to deny institution include the filing of serial petitions,[34] parallel petitions challenging the same patent,[35] and considerations implicated by 35 U.S.C. § 325(d).[36] The parties should explain whether these or other facts and circumstances exist in their proceeding and the impact of those facts and circumstances on efficiency and integrity of the patent system.

III. ORDER

The panel requests that the parties submit supplemental briefing, as set forth below, to present on the record facts in this case relevant to the factors discussed above. The supplemental briefing may be accompanied by

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[33] *See id.* at 13–20 (finding weaknesses in aspects of petitioner's challenges).

[34] *See Valve Corp. v. Elec. Scripting Prods., Inc.*, IPR2019-00064, Paper 10 (PTAB May 1, 2019) (precedential); *Valve Corp. v. Elec. Scripting Prods., Inc.*, IPR2018-00752, Paper 8 (PTAB Sept. 12, 2018); *Gen. Plastic Indus. Co. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19 (PTAB Sept. 6, 2017) (precedential as to § II.B.4.i).

[35] TPG at 59–61.

[36] *See Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 (PTAB Feb. 13, 2020) (discussing two-part framework for applying discretion to deny institution under 35 U.S.C. § 325(d)).

documentary evidence in support of any facts asserted in the supplemental briefing, but may not be accompanied by declaratory evidence.

Accordingly, it is

ORDERED that Petitioner is authorized to file a reply to the Preliminary Response, no more than ten (10) pages and limited to addressing the issue of discretionary denial under 35 U.S.C. § 314(a), by March 27, 2020; and it is

FURTHER ORDERED that Patent Owner is authorized to file a sur-reply to Petitioner's reply, no more than ten (10) pages and limited to the issue of discretionary denial under 35 U.S.C. § 314(a), by April 3, 2020.

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NOTE: This order is nonprecedential.

United States Court of Appeals for the Federal Circuit

In re: HULU, LLC,
Petitioner

2021-142

On Petition for Writ of Mandamus to the United States District Court for the Western District of Texas in No. 6:20-cv-00472-ADA, Judge Alan D. Albright.

ON PETITION

Before TARANTO, HUGHES, and STOLL, *Circuit Judges*.

STOLL, *Circuit Judge*.

O R D E R

Hulu, LLC petitions for a writ of mandamus directing the United States District Court for the Western District of Texas to transfer this case to the United States District Court for the Central District of California. We agree with Hulu that the district court clearly abused its discretion in evaluating Hulu's transfer motion and denying transfer. We therefore grant the petition.

I

Plaintiffs SITO Mobile R&D IP, LLC and SITO Mobile, Ltd. (collectively, "SITO") sued Hulu, LLC for patent infringement in the United States District Court for the Western District of Texas on June 2, 2020. Complaint, *Sito Mobile R&D IP, LLC v. Hulu, LLC*, Case No. 6:20-cv-00472, ECF No. 1 (W.D. Tex. June 2, 2020). SITO alleged that Hulu infringed seven of its patents directed to "System[s] and Method[s] for Routing Media"—U.S. Patent Nos. 8,825,887; 9,026,673; 9,135,635; 9,135,636; 9,591,360; 10,009,637; and 10,171,846. Complaint at 8–10 (¶¶ 22–42). In particular, SITO accused the "Hulu Streaming Platform" of infringement based on its delivery of streaming video content in combination with other features, such as revenue sharing with content providers, *id.* at 11–12 (¶¶ 46–47), selections of advertisements by a "media selector," *id.* at 15 (¶ 57), and advertising based on geographic location or statistical information, *id.* at 23, 39 (¶¶ 89, 96). In particular, SITO's complaint points to Hulu's use of two video standards for their "adaptive bitrate streaming techniques"—Dynamic Adaptive Streaming over Hypertext Transfer Protocol (MPEG-DASH) and Hypertext Transfer Protocol Live Streaming (HLS). *Id.* at 7 (¶ 20).

As to the parties, both SITO entities are Delaware companies with their principal places of business in New Jersey. *Id.* at 2 (¶¶ 2–3). Hulu is a Delaware company with its principal place of business in Santa Monica, California, which is within the Central District of California. *Id.* (¶ 4).

On October 2, 2020, four months after SITO filed its complaint, Hulu moved to transfer the case to the Central District of California for convenience under 28 U.S.C. § 1404(a). Hulu's motion explained that it delivers its streaming content via various "third party content delivery networks" or "CDNs" and that potential witnesses from those CDNs are located in the Central District of

California. App. 80–82;[1] *see also* Answer, *SITO Mobile R&D IP, LLC v. Hulu*, Case No. 6:20-cv-00472, ECF No. 12 at 5 (¶ 20).

On April 28, 2021, the district court denied Hulu's motion to transfer. *SITO Mobile R&D IP v. Hulu, LLC*, Case No. 6:20-cv-00472, 2021 WL 1166772 (W.D. Tex. Mar. 24, 2021) ("*Order*"). The district court analyzed each of the public and private interest factors required under Fifth Circuit precedent, finding two factors (sources of proof and local interest) "slightly" favored transfer, three factors (compulsory process, willing witnesses, and court congestion) weighed against transfer, and three factors (other practical problems, familiarity with relevant law, and conflicts of laws) were neutral or did not apply. *Id.* at *3–9.

Hulu petitioned this court for a writ of mandamus ordering the district court to transfer the case to the Central District of California. We have jurisdiction under the All Writs Act, 28 U.S.C. § 1651(a).

II

Under the All Writs Act, federal courts "may issue all writs necessary or appropriate in aid of their respective jurisdictions and agreeable to the usages and principles of law." 28 U.S.C. § 1651(a). Before a court may issue the writ, three conditions must be satisfied: (1) the petitioner must have "no other adequate means to attain the relief he desires"; (2) the petitioner must show that the right to the writ is "clear and indisputable"; and (3) the court "in the exercise of its discretion, must be satisfied that the writ is appropriate under the circumstances." *Cheney v. U.S. Dist. Court for D.C.*, 542 U.S. 367, 380–81 (2004) (citation and internal quotation marks omitted). In transfer cases, those

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[1] "App." refers to the appendix Hulu filed with its petition for mandamus. "Supp. App." refers to the supplemental appendix filed by SITO with its response.

requirements are generally reduced to a single inquiry: "whether the district court's denial of transfer amounted to a clear abuse of discretion under governing legal standards." *In re TracFone Wireless, Inc.*, No. 2021-136, 2021 WL 1546036, at *2 (Fed. Cir. Apr. 20, 2021) (citing *In re TS Tech USA Corp.*, 551 F.3d 1315, 1319 (Fed. Cir. 2008)).

We follow regional circuit law on § 1404(a) transfer motions. *TS Tech*, 551 F.3d at 1319. The Fifth Circuit requires that when a movant "clearly demonstrate[s] that a transfer is '[f]or the convenience of parties and witnesses, [and] in the interest of justice,'" the district court "should" grant transfer. *In re Volkswagen of Am., Inc.*, 545 F.3d 304, 315 (5th Cir. 2008) (en banc) ("*Volkswagen II*") (second alteration in original) (quoting § 1404(a)). "That determination is focused on a comparison of the relative convenience of the two venues based on assessment of the traditional transfer factors." *In re HP Inc.*, 826 F. App'x 899, 901 (Fed. Cir. 2020) (citing *In re Radmax, Ltd.*, 720 F.3d 285, 288 (5th Cir. 2013)). In asking whether the district court abused its discretion in making that determination, Fifth Circuit law instructs us to consider whether the district court "(1) relies on clearly erroneous factual findings; (2) relies on erroneous conclusions of law; or (3) misapplies the law to the facts." *Volkswagen II*, 545 F.3d at 310 (quoting *McClure v. Ashcroft*, 335 F.3d 404, 408 (5th Cir. 2003)).

In assessing a motion to transfer under § 1404(a), the Fifth Circuit analyzes a number of private and public interest factors. "The private interest factors are: '(1) the relative ease of access to sources of proof; (2) the availability of compulsory process to secure the attendance of witnesses; (3) the cost of attendance for willing witnesses; and (4) all other practical problems that make trial of a case easy, expeditious and inexpensive.'" *Id.* at 315 (quoting *In re Volkswagen AG*, 371 F.3d 201, 203 (5th Cir. 2004) ("*Volkswagen I*")). "The public interest factors are: '(1) the

administrative difficulties flowing from court congestion; (2) the local interest in having localized interests decided at home; (3) the familiarity of the forum with the law that will govern the case; and (4) the avoidance of unnecessary problems of conflict of laws [or in] the application of foreign law.'" *Id.* (alteration in original) (quoting *Volkswagen I*, 371 F.3d at 203).

In denying Hulu's motion for transfer, the district court at least erred in its analysis for each factor that it found weighed against transfer: (1) the availability of compulsory process to secure the attendance of witnesses; (2) the cost of attendance for willing witnesses; and (3) the administrative difficulties flowing from court congestion. We discuss each in turn below.

A

First, the district court erred in finding that the availability of compulsory process to secure the attendance of witnesses weighed against transfer.

Hulu identified several CDNs and revenue sharing content partners that are located in California with many in the Central District of California. App. 77–78, 82. Furthermore, Hulu identified a significant number of potential prior art witnesses that were also based in California. App. 82–83. On the other hand, SITO merely posited that certain third-party witnesses that Hulu had identified (from Apple and Microsoft) may be subject to the compulsory power of both the Western District of Texas and the Central District of California. App. 231 (citing an attorney declaration relying on a location found on maps.bing.com, Supp. App. 16).

The district court did not dispute Hulu's contention that the vast majority of witnesses to be analyzed under this factor would be subject to the compulsory process of the Central District of California. Instead, it determined that this factor weighed against transfer by discounting

Hulu's proposed prior art witnesses and by faulting Hulu for "not show[ing] [that] any potential witness is unwilling to testify" other than one of the specifically identified prior art witnesses. *Order*, 2021 WL 1166772, at *5. This was error for several reasons.

First, even assuming the district court had properly discounted Hulu's proposed witnesses, the evidence before the district court showed, at best, only two potential Hulu prior art witnesses that would be subject to compulsory process by the Western District of Texas in addition to the Central District of California. Thus, this factor would be at most neutral, and certainly not weighing against transfer.

Second, the district court erred by entirely overlooking Hulu's multiple CDN witnesses who Hulu alleged, without dispute, would have knowledge of Hulu's allegedly infringing systems and processes and were located in California. App. 82; *see also* App. 77–78. Thus, even if the district court were correct that prior art witnesses could be discounted, that rationale would not apply to these witnesses, whom the district court failed to mention in analyzing this factor. *See In re Apple, Inc.*, 581 F. App'x 886, 888–89 (Fed. Cir. 2014) (granting mandamus where the district court "ignored the relevant evidence" by "fail[ing] to mention the five other witnesses identified"). Thus, even if the prior art witnesses were neutral for this factor, the additional consideration of these CDN witnesses would push this factor toward favoring transfer.

Third, the district court erred by ignoring all of Hulu's proposed prior art witnesses for the reason that "prior art witnesses are generally unlikely to testify at trial . . . ." *Order*, 2021 WL 1166772, at *5. This categorical rejection of Hulu's witnesses is entirely untethered to the facts of this case and therefore was an abuse of discretion. *See In re Biosearch Techs., Inc.*, 452 F. App'x 986, 987 (Fed. Cir. 2011) ("A motion to transfer under § 1404(a) calls upon the

trial court to weigh a number of case-specific factors based on the individualized facts on record."). Here, certain of Hulu's proposed prior art witnesses directly related to prior art that was specifically mentioned in the asserted patents themselves, heightening their potential relevance. App. 86. The district court provided no analysis whatsoever to cast doubt that these particular prior art witnesses would play a role in an upcoming trial other than speculation that they would be "unlikely to testify at trial" because generally prior art witnesses do not do so. *Order*, 2021 WL 1166772, at *5. Such a bare and generalized analysis cannot be said to be providing "individualized, case-by-case consideration" of the relevant factors, as is required for the analysis of a § 1404(a) motion. *Van Dusen v. Barrack*, 376 U.S. 612, 622 (1964). Furthermore, we have cautioned that "[r]equiring a defendant to show that the potential witness has more than relevant and material information at this point in the litigation or risk facing denial of transfer on that basis is unnecessary." *In re Genentech, Inc.*, 566 F.3d 1338, 1343 (Fed. Cir. 2009). The district court abused its discretion in zeroing out the weight of these witnesses without any case-specific analysis.

Finally, the district court erred in discounting Hulu's proposed witnesses because "Hulu has not shown any potential witness is unwilling to testify [in the Western District of Texas], other than Mr. Newton . . . ." *Order*, 2021 WL 1166772, at *5. In doing so, the district court relied on precedent from a different circuit regarding dismissal for *forum non conveniens*, *id.* (citing *Duha v. Agrium, Inc.*, 448 F.3d 867, 877 (6th Cir. 2006)), which is held to a higher standard of inconvenience, *Volkswagen II*, 545 F.3d at 314 ("[section] 1404(a) venue transfers may be granted upon a lesser showing of inconvenience than *forum non conveniens* dismissals") (internal quotation marks omitted). We are not inclined to think that the Fifth Circuit would adopt this position in this case. To the contrary, we think that the Fifth Circuit would recognize that where, as

here, the movant has identified multiple third-party witnesses and shown that they are overwhelmingly located within the subpoena power of only the transferee venue, this factor favors transfer even without a showing of unwillingness for each witness. *See, e.g., In re HP Inc.*, 2018 WL 4692486, at *3 n.1 (Fed. Cir. Sept. 25, 2018) (noting that at least one case from the Eastern District of Texas has applied a presumption of unwillingness "when there is no indication that a non-party witness is willing"). Here, there is no indication that the third-party witnesses identified by Hulu would be willing, and the vast majority are subject to the compulsory process in the Central District of California.

Overall, comparing the availability of compulsory process to secure the attendance of witnesses in the two forums, we determine that this factor favors transfer. At the very minimum, the district court erred in finding the factor weighed *against* transfer, rather than being neutral. Nothing in the district court's analysis showed a comparative advantage of the Western District of Texas over the Central District of California. At best, as the district court mentioned, two potential prior art witnesses would be equally subject to the compulsory process in both forums. All other things being equal, this might have rendered this factor neutral. But all else was not equal because many other third-party witnesses were only subject to the compulsory power of the transferee venue, and the evidence heavily favored Hulu. Thus, this factor favors transfer.[2]

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[2] Hulu objects to the district court's statement that "Hulu has not shown transfer is clearly more convenient for all of its non-party witnesses" as it applies to the compulsory process factor. *Order*, 2021 WL 1166772, at *5. We agree that this statement seems to be out of place for this factor. Unlike the willing witness factor, the compulsory

B

We next turn to the district court's analysis of the willing witness factor. The district court recognized that this is "the most important factor in a § 1404(a) analysis." *Order*, 2021 WL 1166772, at *5 (citing *Genentech*, 566 F.3d at 1342). The district court also acknowledged that "[i]f a substantial number of witnesses reside in one venue and no witnesses reside in another, th[is] factor will weigh in favor of the venue where witnesses reside." *Id.* (citing *Genentech*, 566 F.3d at 1345). Even though that is precisely the case here, the district court still found this factor weighed against transfer for two reasons. *Id.* at *6. "First, the convenience of party witnesses is typically given little weight because the witnesses' employer could compel their testimony at trial." *Id.* Second, Hulu failed to "identify specific third-party witnesses." *Id.* We conclude that the district court erred in its analysis.

First, the district court did not dispute Hulu's contention that nearly all of the party witnesses are in or near the Central District of California. App. 76–77, 250 n.2, 258, 264–65. And in analyzing the parties' arguments, the district court could identify no witnesses within the Western District of Texas, instead relying entirely on discounting all of Hulu's witnesses located in or near the Central

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process factor is more about the convenience of the litigating parties in making their case rather than the convenience of the unwilling witnesses compelled to testify. Furthermore, to the extent that this statement could have indicated that transfer is inappropriate unless the transferee forum is "more convenient for *all* of [the movant's] non-party witnesses," *id.* (emphasis added), this too would be erroneous, *see Genentech*, 566 F.3d at 1345. However, we do not read this sentence as the actual basis for the district court's decision as to this factor.

District of California. Even if the district court were correct that Hulu's witnesses could be completely discounted, and the district court only considered SITO's employees, it was unrebutted that five out of six of SITO's own full-time employees were located in California, thus tipping this factor toward favoring transfer because the district court did not rely on any witnesses that would have found the Western District of Texas to be more convenient. Thus, at a minimum, it was error to find this factor weighed against transfer. *See TracFone*, 2021 WL 1546036, at *2 (determining that the district court erred in its analysis of the willing witness factor where "several of [movant's] likely employee witnesses resid[e] in the transferee venue and [the district court did not] rely[] on the location of a single potential witness within or even close to Waco, Texas").

Second, the district court erred in entirely discounting Hulu's party witnesses located in the transferee venue because, according to the district court, Hulu "could compel their testimony at trial." *Order*, 2021 WL 1166772, at *6. Although an employer's cooperation in allowing an employee to testify may diminish certain aspects of inconvenience to the employee witness (for instance, the employee is not acting contrary to their employer's wishes), it hardly eliminates the inconvenience. As this court has recognized, "it generally becomes more inconvenient and costly for witnesses to attend trial the further they are away from home[.]" *Genentech*, 566 F.3d at 1343 (citing *Volkswagen II*, 545 F.3d at 317); *see also Volkswagen I*, 371 F.3d at 205 (considering the amount of "time which these fact witnesses must be away from their regular employment"). This is true even if the employer allows for their testimony. The district court's analysis discounting the inconvenience to Hulu's witnesses is fundamentally at odds with the purpose of a transfer for convenience of the witnesses, and it conflicts with the district court's own recognition that "a court must consider the factor of inconvenience to all

witnesses." *Order*, 2021 WL 1166772, at *6 (citing *Genentech*, 566 F.3d at 1342).

Finally, the two potential witnesses identified by SITO located in Texas would not change our conclusion as to this factor. SITO's opposition to Hulu's motion to transfer identified Don Bate, a named inventor of the asserted patents, and Aaric Eisenstein, a licensee of the asserted patents, as potential witnesses that are located in Texas (with only Mr. Eisenstein in the Western District). App. 233–34. Although the district court acknowledged this argument by SITO, *Order*, 2021 WL 1166772, at *6,[3] the district court did not credit these specific witnesses (or mention them) in its analysis. At worst, this would render this factor neutral, but given the overwhelming number of potential witnesses from Hulu in or near California compared to the two from SITO in Texas, we determine that this factor favors transfer.

C

As to the last factor that the district court found weighed against transfer—court congestion—the statistics presented to the court regarding the two forums were remarkably similar. *See Order*, 2021 WL 1166772, at *8. The consideration that the district court assumed tipped the scales toward denying transfer was its own ability to set an early trial date and bring a case to trial earlier than district-wide statistics would suggest. *Id.*

This was error for precisely the same reason described in *In re Apple Inc.*, 979 F.3d 1332 (Fed. Cir. 2020). In

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[3] We note that the district court cited SITO's response at 19–20, but this portion does not discuss willing witnesses. *See* App. 237–38. Based on the sentence preceding the citation, we assume the district court meant to cite SITO's response at 15–16 (App. 233–34), which discusses SITO's witnesses.

granting mandamus directing the district court to transfer in *Apple*, we determined that the district court "misapplied the law to the facts of th[e] case by relying too heavily on the scheduled trial date," explaining that "a court's general ability to set a fast-paced schedule is not particularly relevant to" the court congestion factor. *Id.* at 1344 (citing *In re Adobe Inc.*, 823 F. App'x 929, 932 (Fed. Cir. 2020)). Thus, considering the close similarity of cases per judgeship and average time to trial of the two forums, and disregarding the particular district court's ability to push an aggressive trial date, this factor is neutral. And even if the balance of this factor had tipped slightly against transfer, this slight imbalance alone would not have been enough to tip the scales in favor of denying transfer. *See Apple*, 979 F.3d at 1344 n.5 (citing *Genentech*, 566 F.3d at 1347).

* * *

After correcting these errors by the district court, no factors remain that weigh against transfer and several weigh in favor.[4] Thus, we readily conclude that the district court clearly abused its discretion in denying Hulu's transfer motion. Given that conclusion, we grant Hulu's petition for mandamus.

Accordingly,

IT IS ORDERED THAT:

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[4] Although the district court found that the "local interest" factor weighed slightly in favor of transfer, *Order*, 2021 WL 1166772 at *8–9, we caution the district court that "[l]ocal interests are not a fiction," *In re Samsung Electronics Co., Ltd.*, 2021 WL 2672136, at *7 (Fed. Cir. June 30, 2021). To the extent that the district court discounted the local interest factor based on this reasoning, this was also an error.

Hulu's petition for a writ of mandamus is granted. The April 28, 2021 order is vacated, and the district court is directed to grant Hulu's motion to the extent that the case is transferred to the United States District Court for the Central District of California under § 1404(a).

FOR THE COURT

August 2, 2021
Date

/s/ Peter R. Marksteiner
Peter R. Marksteiner
Clerk of Court

NOTE: This order is nonprecedential.

United States Court of Appeals for the Federal Circuit

In re: JUNIPER NETWORKS, INC.,
Petitioner

2021-156

On Petition for Writ of Mandamus to the United States District Court for the Western District of Texas in No. 6:20-cv-00670-ADA, Judge Alan D. Albright.

ON PETITION

Before DYK, PROST, and HUGHES, *Circuit Judges*.

PER CURIAM.

O R D E R

Juniper Networks, Inc. petitions for a writ of mandamus directing the United States District Court for the Western District of Texas to transfer its case to the United States District Court for the Northern District of California. We recently granted a similar petition in a case involving Juniper because the district court's refusal to transfer amounted to a clear abuse of discretion. *In re Juniper Networks, Inc.*, No. 2021-160, 2021 WL 4343309 (Fed. Cir. Sept. 24, 2021). This case involves remarkably similar facts and many of the same erroneous conclusions. We once

again grant the mandamus petition and direct the district court to transfer.

I.

In July 2020, Correct Transmission, LLC filed suit in the federal district court in Waco, Texas, accusing Juniper's networking products of infringing five of its patents.

Juniper moved to transfer the case to the Northern District of California under 28 U.S.C. § 1404(a), arguing that the Northern District of California was a more convenient forum. Juniper emphasized that 10 of its 12 knowledgeable employees work at Juniper's Northern California headquarters and none work in Texas. And of the eight named inventors of Correct Transmission's asserted patents, two work within 20 miles of that same headquarters, while the remaining inventors reside in Israel. At that time, Juniper had an office in Austin, Texas,[1] but Juniper alleged that its Austin employees had largely worked on unrelated products or have no unique knowledge about the accused products. Juniper also argued that Correct Transmission is a non-practicing entity headquartered in Delaware and appears to have no offices in Texas. In light of this information, Juniper asked the district court to transfer its case to the Northern District of California.

After analyzing the four public and four private interest factors that traditionally govern transfer determinations,[2] the district court denied Juniper's motion, finding

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[1] Juniper's Austin, Texas office closed in March 2021.

[2] The public interest factors are: "(1) the administrative difficulties flowing from court congestion; (2) the local interest in having disputes regarding activities occurring principally within a particular district decided in that forum; (3) the familiarity of the forum with the law that will govern the case; and (4) the avoidance of unnecessary

that these factors did not favor transfer to the Northern District of California. In particular, the district court agreed that the Northern District of California could more easily access sources of proof. But it found that the Western District of Texas could better compel unwilling witnesses and could likely adjudicate the case faster. The court determined that the remaining five factors were neutral. On balance, the court concluded that Juniper did not show that the transferee venue was clearly more convenient.

Juniper then filed this petition. We have jurisdiction under 28 U.S.C. §§ 1651 and 1295.

II.

We review transfer determinations in cases arising on mandamus from district courts in the Fifth Circuit for a clear abuse of discretion. *See In re TS Tech USA Corp.*, 551 F.3d 1315, 1319 (Fed. Cir. 2008). As discussed above, decisions on motions to transfer weigh four private interest factors and four public interest factors to compare the relative convenience between the venues. *See In re Hulu, LLC*, No. 2021-142, 2021 WL 3278194, at *2 (Fed. Cir. Aug. 2, 2021).

First, although no single factor is dispositive, "[t]he convenience of the witnesses is probably the single most important factor in transfer analysis." *In re Genentech,*

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problems of conflict of laws or in the application of foreign law." *In re Juniper Networks, Inc.*, No. 2021-160, 2021 WL 4343309, at *2 (Fed. Cir. Sept. 24, 2021).

The private interest factors are: "(1) the relative ease of access to sources of proof; (2) the availability of compulsory process to secure the attendance of non-party witnesses whose attendance may need to be compelled by court order; (3) the relative convenience of the two forums for potential witnesses; and (4) all other practical problems that make the trial of a case easy, expeditious, and inexpensive." *Id.*

Inc., 566 F.3d 1338, 1343 (Fed. Cir. 2009) (quoting *Neil Bros. Ltd. v. World Wide Lines, Inc.*, 425 F. Supp. 2d 325, 329 (E.D.N.Y. 2006)). Here, the district court clearly erred when it found this factor neutral.

Juniper identified 10 out of 12 potential employee witnesses and two inventors living or working in the Northern District of California. Correct Transmission, on the other hand, identified no willing witnesses in the Western District of Texas. Citing one of its prior decisions, the district court concluded that this factor was neutral by discounting Juniper's witnesses in Northern California because "interested parties in the litigation . . . are much more likely to accept having to travel to see litigation through to their desired result" and by presuming that "no more than a few party witnesses . . . will testify live at trial." Appx17–18 (citing *Fintiv, Inc. v. Apple Inc.*, No. 6:18-cv-00372-ADA, 2019 WL 4743678, at *5 (W.D. Tex. Sept. 13, 2019)).

We recently rejected the same reasoning in *In re Juniper Networks, Inc.*, No. 2021-160, 2021 WL 4343309 (Fed. Cir. Sept. 24, 2021). The factor that weighs the relative convenience of the forums for potential witnesses is not attenuated "when the witnesses are employees of the party calling them." *Juniper*, 2021 WL 4343309, at *4 (citing *In re Hulu, LLC*, No. 2021-142, 2021 WL 3278194, at *5 (Fed. Cir. Aug. 2, 2021)). Further, "[t]he court's assumption that Juniper would not call many party witnesses was not based on any evidence specific to this case," which we have repeatedly explained is insufficient. *Juniper*, 2021 WL 4343309, at *4 (listing cases). The district court erred when it did not find that this factor weighs strongly in favor of transfer.

Second, the district court erred in its analysis of the local interest factor. It is undisputed that the events underlying these infringement claims occurred mainly in the Northern District of California and not at all in the Western District of Texas. "That is sufficient to give the

transferee venue a greater localized interest in the dispute, which favors transfer." *Juniper*, 2021 WL 4343309, at *4 (citing *In re Samsung Elecs. Co.*, 2 F.4th 1371, 1380 (Fed. Cir. 2021) and *In re Acer Am. Corp.*, 626 F.3d 1252, 1256 (Fed. Cir. 2010)).

In finding that the local interest factor was neutral, the district court relied on the fact that Juniper had "availed itself of the state of Texas to do business," pointing out that Juniper maintained an office in Austin and holds a vendor contract with the state to provide data storage, data communications, and networking equipment products. Appx20. But Juniper's offices in Austin have no relation to this case. And its general contacts and business in Texas are not enough to establish a local interest in the Western District of Texas comparable to that of the Northern District of California. As we recently explained, the local-interest factor does not consider "the parties' significant connections to each forum writ large, but rather the significant connections between a particular venue and *the events that gave rise to a suit*." *In re Apple Inc.*, 979 F.3d 1332, 1345 (Fed. Cir. 2020) (internal quotation marks and citation omitted). In *Apple*, as here, the court "misapplied the law to the facts" when it "heavily weigh[ed]" the defendant's "general contacts with the forum that are untethered to the lawsuit." *Id.*; *see also Juniper*, 2021 WL 4343309, at *5.

And unlike the non-practicing entity in *Juniper*, which was incorporated in Texas and maintained its principal office in Waco, Correct Transmission has not alleged *any* ties to Texas. *Juniper*, 2021 WL 4343309, at *5; *see* Appellee's Br. 27. Correct Transmission's ties with Texas are not even "recent and ephemeral"; they are nonexistent. *See Juniper*, 2021 WL 4343309, at *5. This information supports the local-interest factor. *See* Appx20. In sum, the district court erred in finding this factor neutral.

Third, the district court correctly found that the Northern District of California has better access to sources of proof because Juniper's source code and other relevant files are located primarily at its headquarters in California. Appx16. While electronic storage makes documents more widely accessible, this factor remains relevant. *In re Volkswagen of Am., Inc.*, 545 F.3d 304, 316 (5th Cir. 2008) (en banc); *see In re Radmax, Ltd.*, 720 F.3d 285, 288 (5th Cir. 2013) ("[T]he question is *relative* ease of access, not *absolute* ease of access.").

Fourth, the compulsory-process factor does slightly favor the Western District of Texas, but not to the extent that the district court alleges. Correct Transmission identified two former Juniper employees, one located in Austin, who are unwilling to testify without a subpoena and allegedly have relevant information. But district courts "should assess the relevance and materiality of the information the witness[es] may provide." *Genentech*, 566 F.3d at 1343. Here, the district court described these two witnesses as "key" witnesses without considering the relevance and materiality of their knowledge. Appx17. Juniper asserts that the former employees' information is not material because it is duplicative—current Juniper employees can provide the same information without the need for a subpoena. Correct Transmission disagrees, arguing that one of the witnesses has authored several publications on the accused products and that the other witness led the development teams for hardware platforms used in the accused products. But publications and titles alone do not show that these witnesses have information that Juniper's current employees cannot provide. The availability of current employees who can provide the same information makes this factor weigh only slightly against transfer.

Finally, the district court erred when it concluded that the court congestion factor weighs in favor of the Western District of Texas. We have repeatedly noted that, under a proper analysis that looks to the number of cases per

judgeship and the actual average time to trial rather than aggressively scheduled trial dates, "the Western District of Texas and the Northern District of California show no significant differences in caseload or time-to-trial statistics." *Juniper*, 2021 WL 4343309, at *6. Further, this is the "most speculative" of the factors. *Id.* at *7. "And when other relevant factors weigh in favor of transfer or are neutral, 'then the speed of the transferee district court should not alone outweigh those other factors.'" *Id.* (citing *Genentech*, 566 F.3d at 1347).

In sum, as in recent cases in which this court has granted mandamus, the center of gravity of this action is clearly in the Northern District of California. The district court clearly abused its discretion in denying the motion to transfer. We therefore grant Juniper's petition directing transfer of the case.

Accordingly,

IT IS ORDERED THAT:

The petition is granted. The district court's May 26, 2021 order is vacated, and the district court is directed to transfer this matter to the United States District Court for the Northern District of California.

FOR THE COURT

October 04, 2021
Date

/s/ Peter R. Marksteiner
Peter R. Marksteiner
Clerk of Court

NOTE: This order is nonprecedential.

United States Court of Appeals for the Federal Circuit

In re: GOOGLE LLC,
Petitioner

2021-171

On Petition for Writ of Mandamus to the United States District Court for the Western District of Texas in No. 6:20-cv-00453-ADA, Judge Alan D. Albright.

ON PETITION

Before LOURIE, BRYSON, and TARANTO, *Circuit Judges*.

PER CURIAM.

O R D E R

Google LLC petitions this court for a writ of mandamus directing the United States District Court for the Western District of Texas to transfer this action to the United States District Court for the Northern District of California. We conclude that the district court's refusal to transfer the case constituted a clear abuse of discretion. We therefore grant mandamus directing transfer.

I

Jenam Tech, LLC, filed a complaint in the Waco Division of the Western District of Texas charging Google, a Delaware corporation headquartered in Mountain View, California, with patent infringement. Jenam alleged that Google's use of the Quick UDP Internet Connections ("QUIC") protocol infringes eight patents relating to methods, systems, and computer products for sharing information to detect an idle Transmission Control Protocol connection.

Google moved to transfer the case to the Northern District of California pursuant to 28 U.S.C. § 1404(a). Google noted that Jenam's only registered place of business and its only employee, George Andrew Gordon, are located in the Eastern District of Texas. App. 362. Google further pointed out that a different company based in the Northern District of California, Oso-IP, LLC, appears to handle licensing of Jenam's patents to others. *Id*. Google noted that witnesses knowledgeable about the implementation and maintenance of the protocol and potential prior art reside in the Northern District of California. App. 362–64.

Google also submitted a sworn declaration stating that the "vast majority of the research, design, development, and testing activities related to the QUIC protocol have occurred and continue to occur in Mountain View [California] or Cambridge [Massachusetts]," and "both the source code and technical documents related to Google's QUIC protocol are created and maintained in Mountain View and Cambridge." App. 379. Google stated it was unaware of any potential witnesses or sources of proof in the Western District of Texas.

Jenam responded that Google maintains an office in Austin, Texas, within the Western District of Texas. App. 478. In addition, Jenam argued that the Western District of Texas would be a convenient venue for its own witnesses

and sources of proof. In support of that assertion, Jenam submitted a declaration from the inventor, Robert Paul Morris, who stated that he would "most likely be unwilling to testify in-person at a deposition, hearing or a trial" either in the Western District of Texas or the Northern District of California "during the COVID-19 pandemic." App. 500. If he were required to testify, he stated, "it would be safer and far more convenient . . . for me to drive than to fly," and that he would prefer driving to Waco from his home in Georgia rather driving to California. *Id.* Jenam also noted that the Western District of Texas would be more convenient than the Northern District of California for the patent prosecution attorney, who lives in the Northern District of Texas, and for Mr. Gordon, who lives in the Eastern District of Texas. App. 496.

On July 8, 2021, the district court issued an order denying Google's transfer motion. At the outset, the court found that this action could have been brought in the Northern District of California. The court then analyzed Google's transfer motion by applying the set of private-interest and public-interest factors that the Fifth Circuit has directed courts to use in making transfer decisions under section 1404(a). *See In re Volkswagen of Am., Inc.*, 545 F.3d 304 (5th Cir. 2008) (en banc).

The district court took note of the five factors that were disputed between the parties: (1) the relative ease of access to sources of proof; (2) the availability of compulsory process to secure the attendance of non-party witnesses whose attendance may need to be compelled by court order; (3) the relative convenience of the two forums for potential witnesses; (4) the administrative difficulties flowing from court congestion; and (5) the local interest in having disputes regarding activities occurring principally within a particular district decided by a court within that district.

As for the sources of proof, the district court recognized that Google kept local copies of the documents in the Northern District of California, App. 8–9, but found that it would not be difficult for Google to access those documents electronically from Google's offices within the Western District of Texas, App. 8. As for Jenam's documents, the court found that it would be more convenient for Mr. Gordon to transfer any documents in his possession to the Western District of Texas than to the Northern District of California. App. 9. On those grounds, the court concluded the sources-of-proof factor "weighs solidly against transfer." *Id*.

With respect to the availability of compulsory process, Google identified five third-party witnesses who were located in the Northern District of California and who could be compelled to testify by a court in that district but not by the court in the Western District of Texas. The district court, however, found that Google had failed to show that four of those witnesses would be unwilling to testify at trial in the Western District of Texas; the court therefore discounted those witnesses for purposes of the compulsory process factor. App. 10–11. Finding that only one potential third-party witness was "likely unwilling to testify in Texas" (but could be subpoenaed by a court in the Northern District of California) the district court concluded that the compulsory process factor weighed in favor of transfer, but only slightly so. App. 12 (internal quotation marks omitted).

Addressing the convenience of potential witnesses, the court expressed the view that in patent cases generally, the court "assumes that no more than a few party witnesses—and even fewer third-party witnesses, if any—will testify live at trial" and therefore "long lists of potential party and third-party witnesses do not affect the Court's analysis for this factor." App. 13. Furthermore, the court expressed the view that the convenience of witnesses is not an

important consideration in the case of party witnesses. App. 13. The court recognized that two Google employees who were potential witnesses resided in the Northern District of California. App. 13. However, the court concluded that the inconvenience to those Google employees of traveling to Waco would be equivalent to the inconvenience to Mr. Gordon of traveling to California if the case were transferred there. App. 14. The court therefore determined that the convenience-of-the-witnesses factor was neutral as to party witnesses. *Id.*

As for non-party witnesses, the court recognized that Oso-IP's principal and four former Google employees were potential witnesses and were located in the Northern District of California. *Id.* However, the court found that, as "the sole inventor of the Asserted Patents, the importance of Mr. Morris's testimony outweighs the testimony of Google's former employees." App. 15. The court observed that "[t]he additional travel, lodging, and related costs that Mr. Morris will incur with a 2,600-mile drive to the NDCA over a shorter, 900-mile trip to the WDTX amount to a significant difference of convenience." App. 16. The court also noted that Waco would be more convenient for the patent prosecution attorney, who lives in the Northern District of Texas. The court therefore found that the convenience of non-party witnesses weighed against transfer.

As to which district has the greater local interest in this dispute, the district court acknowledged that the Northern District of California had a local interest in resolving this case because the QUIC protocol was designed and developed in that district. App. 18. However, the court found that the local interest factor was neutral with respect to Google because "both Districts are home to Google facilities, employees, and are significant markets for the allegedly infringing products." *Id.* On the whole, the district court found that the local interest factor weighed against transfer on the ground that the Western District of Texas

had an interest in adjudicating this case because Jenam is a Texas entity. *Id.*

Finally, with respect to the court-congestion factor, the court noted that "[i]f this case is transferred to the [Northern District of California], establishing a new schedule with a new presiding judge would cause greater delay." App. 17. "Because transfer would only prolong this case," the court explained, "this factor weighs against transfer." *Id.* Taking into account the weight it assigned to each of the transfer factors, the district court concluded that Google had not established that the Northern District of California was clearly the more convenient venue for trial, and the court therefore denied Google's transfer motion. App. 19.

II

Our review of transfer rulings is governed by the law of the regional circuit, which in this case is the Fifth Circuit. *See In re TS Tech USA Corp.*, 551 F.3d 1315, 1319 (Fed. Cir. 2008). Under Fifth Circuit law, the governing principles are well settled. Section 1404(a) authorizes a court to transfer a civil action "[f]or the convenience of parties and witnesses, in the interest of justice[.]" Fifth Circuit law provides that a motion to transfer should be granted if "the movant demonstrates that the transferee venue is clearly more convenient." *In re Radmax, Ltd.*, 720 F.3d 285, 288 (5th Cir. 2013) (quoting *Volkswagen*, 545 F.3d at 315) (internal quotation marks omitted).

A district court enjoys broad discretion in making a transfer determination. *See In re Vistaprint Ltd.*, 628 F.3d 1342, 1344 (Fed. Cir. 2010). That deference, however, does not exempt transfer determinations from scrutiny on mandamus. *See In re Samsung Elecs. Co.*, 2 F.4th 1371, 1379 (Fed. Cir. 2021). When a court's denial of a motion to transfer under section 1404(a) clearly contravenes governing legal standards, we have issued mandamus to overturn the

denial of transfer. *See, e.g.*, *In re Apple Inc.*, 979 F.3d 1332 (Fed. Cir. 2020).

Google argues that the transfer analysis here contravenes governing law in four respects. First, the court found that the convenience-of-the-witnesses factor weighed against transfer, even though several witnesses are located in the Northern District of California and none are located in the Western District of Texas. Second, the court found that the local interest factor weighed against transfer even though the events giving rise to this suit occurred in the Northern District of California and not in the Western District of Texas. Third, the court concluded that the court congestion factor weighed against transfer, even though the court did not find that the transferee venue was more congested. Fourth, the court weighed the sources-of-proof factor against transfer despite the fact that there are sources of proof in Northern California and no such sources of proof in the Western District of Texas. In light of those errors, Google contends, the court's refusal to grant transfer here amounts to a clear abuse of discretion.

A

Google's primary argument is that the convenience of willing witnesses must be regarded as weighing heavily in favor of transfer because there are several potential witnesses in the Northern District of California and none in the Western District of Texas. We agree with Google.

In holding that the Western District of Texas is more convenient for willing witnesses, the district court recognized that it is "obviously more convenient for witnesses to testify closer to home," App. 13 (internal quotation marks and citation omitted), but it qualified that observation in two respects. First, the court stated that the convenience-of-the-witnesses factor relates primarily to the convenience of willing non-party witnesses, not party witnesses. *Id*. Second, the court took the position that Mr. Morris's testimony as the inventor was more important than that of the

four former Google employees located in the Northern District of California and therefore that more weight should be given to the relative inconvenience associated with Mr. Morris's travel from Georgia. We disagree with the district court on both points.

First, we have held that the fact that a witness is affiliated with a party "does not negate the inconvenience and cost to those individuals to travel a significant distance to testify." *In re Google LLC*, No. 2021-170, 2021 WL 4427899, at *4 (Fed. Cir. Sept. 27, 2021); *see also Samsung*, 2 F.4th at 1379 (holding that a district court's section 1404(a) analysis "must consider" the convenience of "possible party witnesses"); *In re Hulu, LLC*, No. 2021-142, 2021 WL 3278194, at *5 (Fed. Cir. Aug. 2, 2021) (same); *In re Apple Inc.*, 818 F. App'x 1001, 1003 (Fed. Cir. 2020) (rejecting the view that the convenience of party witnesses is given "little weight"). We have likewise rejected the categorical assumption that defendants are likely to call few if any of the proposed party witnesses that are identified for purposes of supporting transfer motions. *In re Juniper Networks, Inc.*, No. 2021-160, __ F.4th __, 2021 WL 4343309, at *4 (Fed. Cir. Sept. 24, 2021).

Google identified two of its employees and three former employees who reside in the Northern District of California and are likely to testify given their work on the accused protocols, as well as a principal of Oso-IP, who was involved in the prosecution and licensing of the asserted patents. By contrast, Jenam identified as witnesses only its one employee and the prosecuting attorney.

The district court concluded that the inconvenience to the party witnesses effectively cancels out under these circumstances. But that conclusion is not supported by the record. Mr. Gordon is Jenam's only identified party witness who would be more inconvenienced by having to travel to California instead of Waco to testify, and even Mr. Gordon does not live in the Western District of Texas and

would have close to a two-hour drive to travel from his home in Frisco, Texas, to the courthouse in Waco. App. 496. Thus, the district court failed to give sufficient weight to the relative convenience of the transferee forum for the party-affiliated witnesses. *See Samsung*, 2 F.4th at 1379.

The second ground for the district court's ruling on the willing witness factor was its view as to the importance of Mr. Morris's testimony as the inventor of the asserted patents and the relative inconvenience to him of having to travel to California rather than to Waco. However, the court's ruling cannot be squared with our decision in *Apple*, 979 F.3d 1332. There, we concluded that the district court erred in giving more weight to the fact that the inventors and the patent prosecutor residing in New York would need to travel a greater distance to reach the Northern District of California than to reach Waco, Texas, given that transfer would allow several witnesses to testify without having to leave home. *Id.* at 1342. We reasoned that the inventors in that case "will likely have to leave home for an extended period" whether or not the case was transferred, and thus would "only be slightly more inconvenienced by having to travel to California than to Texas." *Id.* (internal quotation marks and citation omitted).

The facts in that case are comparable to the facts in this one. Although the district court emphasized that Mr. Morris would have not have to travel as far from his home in Georgia to reach Waco than to reach the Northern District of California, the difference in distance is not as important as the difference in travel time and the fact that the witness would be required to be away from home for several days in any event. *See Google*, 2021 WL 4427899, at *4 (explaining that "time is [often] a more important metric than distance"). There is no major airport in the Waco Division of the Western District of Texas; consequently, the total travel time from Atlanta, Georgia, to Waco would be only marginally less than the travel time from Atlanta to San Francisco.

Jenam argues that Mr. Morris would likely be unwilling to attend a trial if he were required to drive the extra distance to California. In fact, however, Mr. Morris said he would probably be unwilling to testify in-person at all during the COVID-19 pandemic, and he expressed a preference for being allowed to testify remotely. App. 500. Moreover, while Mr. Morris stated that if he were required to attend the trial, he would prefer to drive rather than to fly, his preference for driving was based on the COVID-19 pandemic. Given that the trial is not likely to be held until 2022 or 2023, it seems quite likely that conditions will have changed sufficiently by the time of the trial that Mr. Morris will no longer be faced with the prospect of having to drive to the site of the trial, whether it is held in Waco or the Northern District of California.

In other similar cases, this court has held that a district court abused its discretion in weighing the convenience of the willing witnesses when there are several witnesses located in the transferee forum and none in the transferor forum. *See In re Genentech, Inc.*, 566 F.3d 1338, 1345 (Fed. Cir. 2009) (holding that where "a substantial number of material witnesses reside within the transferee venue . . . and no witnesses reside within the" transferor venue, a district court "clearly err[s] in not determining" the convenience of willing witnesses "to weigh substantially in favor of transfer"); *see also Apple*, 979 F.3d at 1342; *Google*, 2021 WL 4427899, at *4; *In re TracFone Wireless, Inc.*, 852 F. App'x 537, 540 (Fed. Cir. 2021). Under these circumstances, we agree with Google that this factor weighs strongly in favor of transfer.

B

The second contested factor—having local interests adjudicated locally—also strongly favors transfer. It is undisputed that events that form the basis for Jenam's infringement claims against Google occurred in the Northern District of California where Google developed the

accused protocol at its headquarters. While some development activities took place in Massachusetts, that does not make the transferee venue less favorable, given that none of the underlying events occurred in the Western District of Texas. *See Samsung*, 2 F.4th at 1380 (transfer favored because most, even if not all, of the underlying research, design, and development of the accused products centered on activity within the transferee venue); *see also Juniper*, 2021 WL 4343309, at *4.

The district court weighed against transfer the fact that "both Districts are home to Google facilities, employees, and are significant markets for the allegedly infringing products." App. 18. The problem with the court's analysis is that it relies on Google's general presence in the judicial forum, not on the locus of the events that gave rise to the dispute.

The fact that a party may have a general presence in a particular district does not give that district a special interest in the case. *See Juniper*, 2021 WL 4343309, at *5 ("Juniper's general presence in the Western District of Texas is not enough to establish a local interest in that district comparable to that of the Northern District of California."); *In re Google LLC*, No. 21-144, 2021 WL 3378938, at *1 (Fed. Cir. Aug. 4, 2021); *In re DISH Network L.L.C.*, 856 F. App'x 310 (Fed. Cir. 2021). Instead, what is required is that there be "'significant connections between a particular venue and *the events that gave rise to a suit*.'" *Apple*, 979 F.3d at 1345 (noting that this factor "most notably regards . . . the 'significant connections between a particular venue'" (quoting *In re Acer Am. Corp.*, 626 F.3d 1252, 1256 (Fed. Cir. 2010)) (emphasis in *Apple*)). In addition, Jenam's reference to the sale in the Western District of Texas of Google products that used the accused protocol does not give that district a substantial interest in the dispute. *See In re Hoffmann-La Roche Inc.*, 587 F.3d 1333, 1338 (Fed. Cir. 2009) ("[T]he sale of an accused product offered

nationwide does not give rise to a substantial interest in any single venue."); *TS Tech*, 551 F.3d at 1321.

The district court also weighed against transfer the fact that Jenam is incorporated in Texas. But Jenam's only connection to Texas is an office and a single employee, neither of which is located in the Western District. Under the circumstances, Jenam's status as a Texas entity is insufficient to give the Western District of Texas a local interest in the dispute that is comparable to that of the Northern District of California.

C

The court congestion factor also does not support keeping this case in the Western District of Texas. The court's contrary conclusion was not premised on a difference in docket congestion between the forums, *see Juniper*, 2021 WL 4343309, at *6. Instead, the court based its finding as to the court congestion factor on its view that if the case were transferred to the Northern District of California, "establishing a new schedule with a new presiding judge would cause greater delay." App. 17. We reject that rationale for denying transfer of venue here.

Although the Fifth Circuit in *Peteet v. Dow Chemical Co.*, recognized that granting the motion to transfer in that case "would have caused yet another delay in this protracted litigation," the court added an important qualifier: "Dow's motion to transfer venue was not filed until eighteen months after the case was remanded to the Eastern District of Texas." 868 F.2d 1428, 1436 (5th Cir. 1989). Since *Peteet*, the Fifth Circuit has reiterated that the delay associated with transfer may be relevant only "in rare and special circumstances," *In re Horseshoe Ent.*, 337 F.3d 429, 434 (5th Cir. 2003) (finding error where the district court gave weight to the factor of possibility of delay or prejudice if transfer is granted), and, most recently, clarified that "garden-variety delay associated with transfer is not to be

taken into consideration when ruling on a § 1404(a) motion to transfer," *Radmax*, 720 F.3d at 289.

In light of that precedent, the district court erred in weighing the court congestion factor against transfer. This case is not one in which a movant seeking a transfer of venue has failed to act with reasonable promptness. Google filed its transfer motion within two months of the filing of the initial complaint and within days of the filing of the amended complaint. Nor did the district court point to other special or unique circumstances that would warrant departing from the general rule that the ordinary delay resulting from transfer is not entitled to weight. The district court in essence weighed against transfer that the Northern California court would be unlikely to adopt the same aggressive schedule as previously ordered in this case. But we have repeatedly held that it is improper to assess the court congestion factor based on the fact that the Western District of Texas has employed an aggressive scheduling order for setting a trial date. *Juniper*, 2021 WL 4343309, at *6; *Samsung*, 2 F.4th at 1380–81; *Apple*, 979 F.3d at 1344; *In re Adobe Inc.*, 823 F. App'x 929, 932 (Fed. Cir. 2020).

D

The fourth disputed factor, relating to the sources of proof, also does not favor the Western District of Texas as the more convenient forum. Although the sources-of-proof factor focuses on "the relative access to sources of evidence in the two competing forums," *Juniper*, 2021 WL 4343309, at *6, the district court here identified no sources of proof within the Western District of Texas. The only sources of proof that the court identified as being anywhere in Texas were in the possession of Mr. Gordon, who resides in the Eastern District of Texas. Even putting aside the fact that those sources of proof are outside the forum, the district court here recognized that the bulk of the evidence would likely be coming from the accused infringer.

Moreover, and more importantly, the district court provided no sound basis to disregard the Northern District of California as a convenient forum with respect to the sources of proof. Read fairly, Google's declaration makes clear that source code and technical documents relating to the accused activities, as well as a significant number of documents relating to Google's marketing, finances, and sales, were created and are maintained in the Northern District of California. Although the declaration stated that some evidence would also be located in Massachusetts, we have held that the fact that some evidence is stored in places outside both forums does not weigh against transfer. *See In re Toyota Motor Corp.*, 747 F.3d 1338, 1340 (Fed. Cir. 2014) ("The comparison between the transferor and transferee forum is not altered by the presence of other witnesses and documents in places outside both forums.").

While the district court found that these sources of proof would not be difficult to access electronically from Google's offices in the Western District of Texas, that does not support weighing this factor against transfer. The Fifth Circuit has explained that while electronic storage of documents makes them more widely accessible than was true in the past, the fact that documents can often be accessed remotely does not render the sources-of-proof factor irrelevant. *See Volkswagen*, 545 F.3d at 316 ("That access to some sources of proof presents a lesser inconvenience now than it might have absent recent developments does not render this factor superfluous."). We therefore see no sound basis for the district court having weighed the sources-of-proof factor against transfer; if anything, that factor weighs in favor of transfer.[*]

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[*] The district court found that the fifth factor the parties disputed—the availability of compulsory process—favored transfer, although only slightly. The district court's ruling on that factor, however, was affected by its

E

In sum, the center of gravity of this action is clearly in the transferee district, and decidedly not in the Western District of Texas. Several of the most important factors bearing on the transfer decision strongly favor transfer, and no factor favors retaining the case in the Western District of Texas. In fact, there is nothing at all that ties this case to the Western District of Texas: no witnesses reside there; no evidence is present there; and none of the conduct giving rise to this action took place there. The only connection that the district court identified between this case and the Western District of Texas is that Google has a general presence in the district. As we have previously noted, the court's reliance on that circumstance to justify denying transfer "improperly conflate[d] the requirements for establishing venue under 28 U.S.C. § 1400(b) and the requirements for establishing transfer under § 1404(a)." *Apple*, 979 F.3d at 1346. We therefore grant Google's petition seeking transfer of the case to the Northern District of California.

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conclusion that any witness who was not shown to be unwilling to testify in the Western District of Texas should be assumed to be a willing witness. App. 10–11. We have held, however, that where the movant has identified multiple third-party witnesses "and shown that they are overwhelmingly located within the subpoena power of only the transferee venue, this factor favors transfer even without a showing of unwillingness for each witness." *Hulu*, 2021 WL 3278194, at *4; *In re HP Inc.,* No. 18-149, 2018 WL 4692486, at 3 n.1 (Fed. Cir. Sept. 25, 2018) ("[W]hen there is no indication that a non-party witness is willing, the witness is presumed to be unwilling and considered under the compulsory process factor."). The court therefore should have found that factor to favor transfer more than "only slightly." App. 12.

Accordingly,

IT IS ORDERED THAT:

The petition is granted. The district court's order denying Google's motion to transfer is vacated, and the district court is directed to grant the transfer motion.

FOR THE COURT

October 06, 2021
Date

/s/ Peter R. Marksteiner
Peter R. Marksteiner
Clerk of Court

s25

cc: United States District Court for the Western District of Texas

United States Court of Appeals for the Federal Circuit

AMGEN INC., AMGEN MANUFACTURING, LIMITED, AMGEN USA, INC.,
Plaintiffs-Appellants

v.

SANOFI, AVENTISUB LLC, FKA AVENTIS PHARMACEUTICALS INC., REGENERON PHARMACEUTICALS INC., SANOFI-AVENTIS U.S. LLC,
Defendants-Appellees

2020-1074

Appeal from the United States District Court for the District of Delaware in Nos. 1:14-cv-01317-RGA, 1:14-cv-01349-RGA, 1:14-cv-01393-RGA, 1:14-cv-01414-RGA, Judge Richard G. Andrews.

Decided: February 11, 2021

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NY; WILLIAM G. GAEDE, III, McDermott, Will & Emery LLP, Menlo Park, CA; CHRISTOPHER B. MEAD, Schertler Onorato & Mead LLP, Washington, DC; JAMES L. HIGGINS, MELANIE K. SHARP, Young, Conaway, Stargatt & Taylor LLP, Wilmington, DE. Plaintiff-appellant Amgen Inc. also represented by SARAH CHAPIN COLUMBIA, McDermott, Will & Emery LLP, Boston, MA; LAUREN MARTIN, Quinn Emanuel Urquhart & Sullivan LLP, Boston, MA.

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STANLEY D. LIANG, Tarrytown, NY, as amicus curiae, pro se.

Before PROST, *Chief Judge*, LOURIE and HUGHES, *Circuit Judges*.

LOURIE, *Circuit Judge*.

Amgen Inc., Amgen Manufacturing, Ltd., and Amgen USA, Inc. (collectively, "Amgen") appeal from a decision of the United States District Court for the District of Delaware granting Judgment as a Matter of Law ("JMOL") of lack of enablement of claims 19 and 29 of U.S. Patent 8,829,165 (the "'165 patent") and claim 7 of U.S. Patent 8,859,741 (the "'741 patent"). *See Amgen Inc. v. Sanofi*, No. CV 14-1317-RGA, 2019 WL 4058927, at *1–2, *13 (D. Del. Aug. 28, 2019) ("*Decision*"). For the reasons set forth below, we affirm.

BACKGROUND

Elevated low-density lipoprotein ("LDL") cholesterol is linked to heart disease. LDL receptors remove LDL cholesterol from the blood stream, thus regulating the amount of circulating LDL cholesterol. The proprotein convertase subtilisin/kexin type 9 ("PCSK9") enzyme regulates LDL receptor degradation. PCSK9 binds to LDL receptors and mediates their degradation, thus decreasing the number of LDL receptors on a cell's surface. Antibodies may bind to and block PCSK9, allowing LDL receptors to continue regulating the amount of circulating LDL cholesterol.

Amgen owns the '165 and '741 patents, which describe antibodies that purportedly bind to the PCSK9 protein and lower LDL levels by blocking PCSK9 from binding to LDL receptors. The '165 and '741 patents share a common written description. *See* Appellants' Br. 10 n.2. The specification discloses amino acid sequences for twenty-six antibodies, including the antibody (designated as "21B12")

with the generic name of evolocumab, marketed by Amgen as Repatha®. *See* '165 patent col. 85 ll. 1–43; Appellants' Br. 11 n.3. As shown for example in Figure 20A of the '165 patent, the specification discloses three-dimensional structures for the antibodies designated 21B12 and 31H4 and shows where those antibodies bind to PCSK9. The '165 and '741 patents claim antibodies that bind to one or more of fifteen amino acids (*i.e.*, "residues") of the PCSK9 protein and block PCSK9 from binding to LDL receptors.

The relevant '165 patent claims are:

> 1. An isolated monoclonal antibody, wherein, when bound to PCSK9, the monoclonal antibody binds to at least one of the following residues: S153, I154, P155, R194, D238, A239, I369, S372, D374, C375, T377, C378, F379, V380, or S381 of SEQ ID NO:3, and wherein the monoclonal antibody blocks binding of PCSK9 to LDLR.
>
> 19. The isolated monoclonal antibody of claim 1 wherein the isolated monoclonal antibody binds to at least two of the following residues S153, I154, P155, R194, D238, A239, I369, S372, D374, C375, T377, C378, F379, V380, or S381 of PCSK9 listed in SEQ ID NO:3.
>
> 29. A pharmaceutical composition comprising an isolated monoclonal antibody, wherein the isolated monoclonal antibody binds to at least two of the following residues S153, I154, P155, R194, D238, A239, I369, S372, D374, C375, T377, C378, F379, V380, or S381 of PCSK9 listed in SEQ ID NO: 3 and blocks the binding of PCSK9 to LDLR by at least 80%.

'165 patent col. 427 l. 47–col. 430 l. 23.

The relevant '741 patent claims are:

> 1. An isolated monoclonal antibody that binds to PCSK9, wherein the isolated monoclonal antibody binds an epitope on PCSK9 comprising at least one of residues 237 or 238 of SEQ ID NO: 3, and wherein the monoclonal antibody blocks binding of PCSK9 to LDLR.
>
> 2. The isolated monoclonal antibody of claim 1, wherein the isolated monoclonal antibody is a neutralizing antibody.
>
> 7. The isolated monoclonal antibody of claim 2, wherein the epitope is a functional epitope.

'741 patent col. 427 ll. 36–57. The claimed antibodies are defined by their function: binding to a combinations of sites (residues) on the PCSK9 protein, in a range from one residue to all of them; and blocking the PCSK9/LDLR interaction.

This is the second time that these patents have been on appeal in our court. Amgen filed suit against Sanofi, Aventisub LLC, Regeneron Pharmaceuticals Inc., and Sanofi-Aventis U.S. LLC (collectively, "Sanofi") on October 17, 2014, alleging infringement of multiple U.S. patents, including the '165 and '741 patents. *Decision* at *1. Amgen and Sanofi stipulated to infringement of selected claims (including '165 patent claims 19 and 29 and '741 patent claim 7) and tried issues of validity to a jury in March 2016. *Id.* During the trial, the district court granted JMOL of nonobviousness and of no willful infringement. *Id.* At the close of the trial, the jury determined that the patents were not shown to be invalid for lack of enablement and written description. *Id.*

Sanofi appealed to this court. Relevant to the current appeal, we held that the district court erred in its evidentiary rulings and jury instructions regarding Sanofi's defenses that the patents lack written description and enablement, and we remanded for a new trial on those

issues. *Amgen Inc. v. Sanofi*, 872 F.3d 1367, 1381–82 (Fed. Cir. 2017). We also vacated the permanent injunction. *Id.*

On remand, the parties tried the issues of written description and enablement to the jury. The jury again found that Sanofi failed to prove that the asserted claims were invalid for lack of written description and enablement. Sanofi moved for JMOL and, in the alternative, for a new trial. *Decision* at *1; J.A. 895. The district court granted Sanofi's Motion for JMOL for lack of enablement and denied the motion for lack of written description. *See Decision* at *17; J.A. 35. The court also conditionally denied Sanofi's motion for a new trial. *Id.* Amgen timely appealed, and we have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1). *See* J.A. 909–10.

DISCUSSION

Whether a claim satisfies the enablement requirement of 35 U.S.C. § 112 is a question of law that we review without deference, although the determination may be based on underlying factual findings, which we review for clear error. *See Alcon Research Ltd. v. Barr Labs., Inc.*, 745 F.3d 1180, 1188 (Fed. Cir. 2014). The statutory basis for the enablement requirement is found in Section 112 of the patent statute, which provides in relevant part that a patent's specification must "enable any person skilled in the art . . . to make and use" the patented invention. 35 U.S.C. § 112(a). The purpose of the enablement requirement is to ensure that the public is told how to carry out the invention, *i.e.*, to make and use it. We have held that such disclosure must be "at least commensurate with the scope of the claims." *Crown Operations Int'l v. Solutia Inc.*, 289 F.3d at 1367, 1378–79 (Fed. Cir. 2002) (citing *Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys.*, 166 F.3d 1190, 1196 (Fed. Cir. 1999)).

"To prove that a claim is invalid for lack of enablement, a challenger must show by clear and convincing evidence

that a person of ordinary skill in the art would not be able to practice the claimed invention without 'undue experimentation.'" *Alcon Research*, 745 F.3d at 1188 (quoting *In re Wands*, 858 F.2d 731, 736–37 (Fed. Cir. 1988)). "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." *Wands*, 858 F.2d at 737. Those factual considerations, which have come to be known as the "*Wands* factors," are:

> (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Id.

As we have stated elsewhere, "[a]fter the challenger has put forward evidence that some experimentation is needed to practice the patented claim, the factors set forth in *Wands* then provide the factual considerations that a court may consider when determining whether the amount of that experimentation is either 'undue' or sufficiently routine such that an ordinarily skilled artisan would reasonably be expected to carry it out." *Alcon Research*, 745 F.3d at 1188 (quoting *Wands*, 858 F.2d at 737). Although a specification does not need to "describe how to make and use every possible variant of the claimed invention, when a range is claimed, there must be reasonable enablement of the scope of the range." *McRO, Inc. v. Bandai Namco Games Am. Inc.*, 959 F.3d 1091, 1100 (Fed. Cir. 2020) (citing *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1244 (Fed. Cir. 2003)) (internal citations omitted).

On appeal, Amgen asks us to reverse the district court's decision holding '165 patent claims 19 and 29 and '741 patent claim 7 invalid for lack of enablement. Amgen

contends that, under a proper analysis of the *Wands* factors, the claims at issue were enabled because no undue experimentation is required to obtain antibodies fully within the scope of the claims. Amgen points to expert testimony purportedly showing that a person of skill in the art can make all antibodies within the scope of the claims by following a roadmap using anchor antibodies and well-known screening techniques as described in the specification or by making conservative amino acid substitutions in the twenty-six examples. Amgen argues that the court erred by focusing on the effort required to discover and make every embodiment of the claims, *see* Appellants' Br. 32 (citing *Decision* at *7), while failing to recognize that Sanofi could not identify any antibody that cannot be made by following the specification's teachings. *See* Reply Br. 4–5; *see also McRO*, 959 F.3d at 1104 ("[A] usual requirement [is] that the challenger identify specifics that are or may be within the claim but are not enabled."). Amgen contends that the embodiments in the patent are structurally representative for the purpose of fulfilling the written description requirement, and such evidence is sufficient to indicate a structure/function correlation establishing enablement. *See* Reply Br. 23–24.

Sanofi responds that the district court properly concluded based on the *Wands* factors that the claims are not enabled because they require undue experimentation. As support for its position, Sanofi contends that there are millions of antibody candidates within the scope of the claims, the disclosures do not provide sufficient guidance, antibody generation is unpredictable, and practicing the full scope of the claims requires substantial trial and error. *See* Appellees' Br. 17–18, 56. According to Sanofi, the functionally defined claims cover a vast scope. *See id.* at 34–41. Sanofi argues that Amgen focused on "the number of antibodies actually known to satisfy the claims, when this court's precedents require examining the number of candidates

that must be made and tested to determine whether they satisfy the claimed function." *Id.* at 18.

We begin by considering the *Wands* case itself, which has become the "go to" precedent for guidance on enablement, and which also involved claims relating to antibody technology. The broadest claim in *Wands* "involve[d] immunoassay methods for the detection of hepatitis B surface antigen by using high-affinity monoclonal antibodies of the IgM isotype." *Wands*, 858 F.2d at 733. The U.S. Patent and Trademark Office Board of Patent Appeals and Interferences had found that undue experimentation would be required for one skilled in the art to make the claimed antibodies used in the methods because "production of high-affinity IgM anti-HBsAg antibodies [was] unpredictable and unreliable." *Id.* at 735. We found, reviewing the facts, that the disclosure adequately taught using hybridoma technology to produce the needed claimed antibodies. *See id.* at 734. We stated that "no evidence was presented by either party on how many hybridomas would be viewed by those in the art as requiring undue experimentation to screen," *id.* at 740, and we accordingly held that the specification fully enabled the claimed invention, *see id.* at 736.

Importantly, although *Wands* gave birth to its eponymous factors, *Wands* did not proclaim that all broad claims to antibodies are necessarily enabled. Facts control and, in this court, so does the standard of review. In considering the *Wands* factors, the district court compared the present case to other cases in which we found lack of enablement due to the undue experimentation required to make and use the full scope of the claimed compounds that require a particular structure and functionality. For example, in *Wyeth & Cordis Corp. v. Abbott Laboratories*, we held that claims covering methods of preventing restenosis with compounds having certain functionality requirements were invalid for lack of enablement. *See* 720 F.3d 1380, 1385–86 (Fed. Cir. 2013). Of particular significance, we held that due to the large number of possible candidates

within the scope of the claims and the specification's corresponding lack of structural guidance, it would have required undue experimentation to synthesize and screen each candidate to determine which compounds in the claimed class exhibited the claimed functionality. *Id.*

Similarly, in *Enzo Life Sciences, Inc. v. Roche Molecular Systems, Inc.*, we found that the claims were similar to those at issue in *Wyeth* in that they required both a particular structure and functionality, and we held that the specification failed to teach one of skill in the art whether the many embodiments of the broad claims would exhibit that required functionality. *See* 928 F.3d 1340, 1345–48 (Fed. Cir. 2019). And, in *Idenix Pharmaceuticals LLC v. Gilead Sciences Inc.*, we affirmed the district court's determination that the claims had both structural and functional limitations, and that undue experimentation would have been required to synthesize and screen the billions of possible compounds because, given a lack of guidance across that full scope, finding functional compounds would be akin to finding a "needle in a haystack." 941 F.3d 1149, 1160–63, 1165 (Fed. Cir. 2019); *see Idenix Pharms. LLC v. Gilead Scis., Inc.*, 2018 WL 922125 (D. Del. Feb. 16, 2018). The district court found that *Wyeth*, *Enzo*, and *Idenix* all support its conclusion that the asserted claims lack enablement. *See Decision* at *9–13.

What emerges from our case law is that the enablement inquiry for claims that include functional requirements can be particularly focused on the breadth of those requirements, especially where predictability and guidance fall short. In particular, it is important to consider the quantity of experimentation that would be required to make and use, not only the limited number of embodiments that the patent discloses, but also the full scope of the claim. As we recently explained:

> [C]onducting the *Wands* analysis has routinely involved concrete identification of at least some

> embodiment or embodiments asserted not to be enabled—including what particular products or processes are or may be within the claim, so that breadth is shown concretely and not just as an abstract possibility, and how much experimentation a skilled artisan would have to undertake to make and use those products or processes.

McRO, 959 F.3d at 1100. We then elaborated in a footnote that:

> In cases involving claims that state certain structural requirements and also require performance of some function (e.g., efficacy for a certain purpose), we have explained that undue experimentation can include undue experimentation in identifying, from among the many concretely identified compounds that meet the structural requirements, the compounds that satisfy the functional requirement.

Id. at 1100 n.2 (citations omitted).

That reasoning applies here. While functional claim limitations are not necessarily precluded in claims that meet the enablement requirement, such limitations pose high hurdles in fulfilling the enablement requirement for claims with broad functional language. *See, e.g.*, *Wyeth*, 720 F.3d at 1384 (finding that practicing the full scope of the claims would require excessive experimentation); *Enzo*, 928 F.3d at 1345 (finding that the specification failed to teach whether the many embodiments would be both hybridizable and detectable upon hybridization); *Idenix*, 941 F.3d at 1155–56 (finding that the broad functional limitation of having efficacy against hepatitis C virus increased the number of nucleoside candidates that would need to be screened).

Each appealed claim in this case is a composition claim defined, not by structure, but by meeting functional limitations. We agree with the district court's finding that the

specification here did not enable preparation of the full scope of these double-function claims without undue experimentation. *See Decision* at *13. The binding limitation is itself enough here to require undue experimentation.

Turning to the specific *Wands* factors, we agree with the district court that the scope of the claims is broad. While in and of itself this does not close the analysis, the district court properly considered that these claims were indisputably broad. The parties dispute the exact number of embodiments falling within the claims. However, we are not concerned simply with the number of embodiments but also with their *functional* breadth. Regardless of the exact number of embodiments, it is clear that the claims are far broader in functional diversity than the disclosed examples.[1] If the genus is analogized to a plot of land, the disclosed species and guidance "only abide in a corner of the genus." *AbbVie Deutschland GmbH & Co. v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1299–300 (Fed. Cir. 2014). Further, the use of broad functional claim limitations raises the bar for enablement, a bar that the district court found was not met.

We also agree with the district court that this invention is in an unpredictable field of science with respect to satisfying the full scope of the functional limitations. One of Amgen's expert witnesses admitted that translating an antibody's amino acid "sequence into a known three-dimensional structure is still not possible." J.A. 3910; *see also Decision* at *9. Another of Amgen's experts conceded that "substitutions in the amino acid sequence of an antibody can affect the antibody's function, and testing would be

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[1] For example, there are three claimed residues to which not one disclosed example binds. *See* J.A. 4283; Appellees' Br. 52. And although the claims include antibodies that bind up to sixteen residues, none of Amgen's examples binds more than nine. *See id.*

required to ensure that a substitution does not alter the binding and blocking functions." J.A. 3891; *see also Decision* at *9. And while some need for testing by itself might not indicate a lack of enablement, we note here the conspicuous absence of nonconclusory evidence that the full scope of the broad claims can predictably be generated by the described methods. Instead, we have evidence only that a small subset of examples of antibodies can predictably be generated.

Although the specification provides some guidance, including data regarding certain embodiments, we agree with the district court that "[a]fter considering the disclosed roadmap in light of the unpredictability of the art, any reasonable factfinder would conclude that the patent does not provide significant guidance or direction to a person of ordinary skill in the art for the full scope of the claims." *Decision* at *11. Here, even assuming that the patent's "roadmap" provided guidance for making antibodies with binding properties similar to those of the working examples, no reasonable factfinder could conclude that there was adequate guidance beyond the narrow scope of the working examples that the patent's "roadmap" produced.

As the district court noted, the only ways for a person of ordinary skill to discover undisclosed claimed embodiments would be through either "trial and error, by making changes to the disclosed antibodies and then screening those antibodies for the desired binding and blocking properties," or else "by discovering the antibodies *de novo*" according to a randomization-and-screening "roadmap." *Id.* Either way, we agree with the district court that the required experimentation "would take a substantial amount of time and effort." *Id.* at *12. We do not hold that the effort required to *exhaust* a genus is dispositive. It is appropriate, however, to look at the amount of effort needed to obtain embodiments outside the scope of the disclosed examples and guidance. The functional limitations here

are broad, the disclosed examples and guidance are narrow, and no reasonable jury could conclude under these facts that anything but "substantial time and effort" would be required to reach the full scope of claimed embodiments.

We therefore conclude that, after weighing the *Wands* factors, the court did not err in concluding that undue experimentation would be required to practice the full scope of these claims.

Finally, Amgen is incorrect that the district court's decision is inconsistent with *Wands* or that our affirmance here would overrule *Wands*. *Wands*, as indicated above, does not hold that antibody screening never requires undue experimentation. The holding in *Wands* was based on the facts of that case and the evidence presented there. Here, the evidence showed that the scope of the claims encompasses millions of candidates claimed with respect to multiple specific functions, and that it would be necessary to first generate and then screen each candidate antibody to determine whether it meets the double-function claim limitations. *See Decision* at *7–13. The facts of this case are thus more analogous to those in *Enzo*, *Wyeth*, and *Idenix*, where we concluded a lack of enablement.

CONCLUSION

We have considered Amgen's remaining arguments but find them unpersuasive. For the reasons above, we affirm the district court's determination that the asserted claims are invalid for lack of enablement.

AFFIRMED

United States Court of Appeals for the Fifth Circuit

United States Court of Appeals
Fifth Circuit
FILED
April 13, 2021
Lyle W. Cayce
Clerk

No. 19-60394

IMPAX LABORATORIES, INCORPORATED, A CORPORATION,

Petitioner,

versus

FEDERAL TRADE COMMISSION,

Respondent.

On Petition for Review of an Order of the
Federal Trade Commission
FTC Docket No. 9373

Before SOUTHWICK, COSTA, and DUNCAN, *Circuit Judges*.

GREGG COSTA, *Circuit Judge*:

Normally, when lawsuits settle the defendant pays the plaintiff. That makes sense as the defendant is the party accused of wrongdoing.

But when a generic drug is poised to enter the market and threaten the monopoly enjoyed by a brand-name pharmaceutical, federal law can incentivize a different type of settlement. The Hatch-Waxman Act delays the entry of the generic drug if the brand-drug manufacturer files a patent infringement suit against the generic. Those patent suits are sometimes settled with the brand-drug plaintiff paying the allegedly-infringing generic.

In return for the payment, the generic agrees to delay its market entry beyond the date when the FDA would allow it to compete. The result is an extension of the brand drug's monopoly.

Given the counterintuitive flow of money in this scenario—to, rather than from, the alleged wrongdoer—such deals are called "reverse payment settlements." The Supreme Court has held that these settlements that extend the brand drug's monopoly can have anticompetitive effects that violate the antitrust laws. *FTC v. Actavis*, 570 U.S. 136, 158 (2013). Reverse payment settlements, however, are not automatically invalid; they are subject to the rule of reason. *Id.* at 159.

In its first post-*Actavis* reverse payment case, the Federal Trade Commission charged Impax Laboratories with antitrust violations for accepting payments ultimately worth more than $100 million to delay the entry of its generic drug for more than two years. The resulting administrative hearing included testimony from 37 witnesses and over 1,200 exhibits. Based on that record, the Commission conducted a rule-of-reason analysis and unanimously concluded that Impax violated antitrust law.

On appeal, we face a narrower task: determining whether the Commission committed any legal errors and whether substantial evidence supported its factual findings. Concluding that the Commission's ruling passes muster on both fronts, we DENY the petition for review.

I.

A.

Anyone who buys pharmaceuticals knows that generic drugs are cheaper than their brand counterparts. The first generic to enter the market typically costs 10 to 25 percent less than the branded drug; those discounts grow to between 50 and 80 percent once other generics enter.

To bring competition to the drug market, the Hatch-Waxman Act promotes entry for these generics. *Actavis*, 570 U.S. at 142. Rather than undergoing the lengthy and costly approval process that a new drug faces, generics can file an Abbreviated New Drug Application with the Food and Drug Administration. *Id.* at 142; 21 U.S.C. § 355(j). If the generic drug is biologically equivalent to a brand drug the FDA has already approved, then the generic can essentially "piggy-back on the pioneer's approval efforts." *Actavis*, 570 U.S. at 142; 21 U.S.C. § 355(j)(2)(A)(i)–(iv). The Act offers an additional carrot to the first generic applicant: it can market its generic drug for 180 days without competition from any other generic manufacturer. *Actavis*, 570 U.S. at 143–44; 21 U.S.C. § 355(j)(5)(B)(iv). During this period of exclusivity, the newly approved generic only faces competition from the brand drug or a generic sold by the brand manufacturer. *Actavis*, 570 U.S. at 143–44. In effect, the statute allows a duopoly during those 180 days. A first-to-file generic often realizes most of its profits, potentially "several hundred million dollars," during this initial six-month period. *Id.* at 143 (quoting C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1579 (2006)).

Generic entry is not so easy when there is a patent for the brand drug. The Hatch-Waxman Act also addresses this common situation. If the brand manufacturer asserts a patent in its initial drug application, then the generic manufacturer must certify in its application that the patent is invalid or that its drug will not infringe the patent. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). If the brand manufacturer disagrees (it likely will), it may file a patent infringement suit. 35 U.S.C. § 271(e)(2)(A). And if it does so within 45 days, the FDA is stayed from approving the generic application until either 30 months have passed or the patent litigation concludes. 21 U.S.C. § 355(j)(5)(B)(iii); *see also Actavis*, 570 U.S. at 143 (describing these procedures). This delay for the first generic's entry also postpones the potential entry of other generics.

They must wait for the same 30-month stay and then for the expiration of the first generic's 6-month exclusivity period before entering the market.

What happens if the patent suit against the first generic settles? The brand manufacturer no longer faces an immediate threat of competition from new generic entrants. The 30-month statutory stay restarts if the brand maker brings a patent suit against another generic that wishes to enter the market. *Actavis*, 570 U.S. at 155 (citing 21 U.S.C. § 355(j)(5)(B)(iii)). Plus, any subsequent generic is not entitled to the exclusivity period. *Id.* That greatly reduces the potential benefit of challenging the brand maker's patent. *Id.* (noting that subsequent generics "stand to win significantly less than the first if they bring a successful" challenge to the patent).

These features of the Hatch-Waxman Act—the period of exclusivity for the first generic; the 30-month stay of the generic's FDA application when the brand maker sues for infringement; and the reduced incentive a subsequent generic has to challenge the brand maker's patent—can lead the brand maker to pay large sums for delaying entry of the first generic maker. *Actavis*, 570 U.S. at 155 (recognizing that these Hatch-Waxman "features together mean that a reverse payment settlement with the first filer . . . 'removes from consideration the most motivated challenger, and the one closest to introducing competition" (quoting Hemphill, *Paying for Delay*, *supra*, at 1586)).

B.

The facts of this case show those incentives in action. The drug at issue is a type of oxymorphone, which is an opioid. Endo, the brand-name drug maker in this case, started selling an extended-release formulation of oxymorphone called Opana ER in 2006. An extended-release pain reliever provides medication to the bloodstream over several hours, as opposed to

immediate-release opioids which are short-acting. When it entered the market, Opana ER was the only extended-release version of oxymorphone.

In late 2007, Impax filed the first application to market generic extended-release oxymorphone. The application did not result in prompt approval of the generic, however, because Endo held patents for Opana ER that would not expire until 2013. Endo sued Impax for patent infringement in January 2008, delaying any FDA approval of the generic for 30 months—until June 2010—unless the litigation concluded earlier.

Early settlement talks failed, with Endo rejecting Impax's proposed entry dates of January 2011, July 2011, December 2011, or January 2012.

The June 2010 expiration of the Hatch-Waxman stay loomed. Delaying Impax's entry beyond the stay period would save Endo millions. Endo had projected that generic entry would cut Opana ER sales by 85 percent within three months and cost it $100 million in revenue within six months.

But extending the period in which it could sell Opana ER without competition was just one of Endo's priorities. The drug maker had something else in the works: It planned to move consumers to a new brand-name drug that would not face competition for years. Endo would remove the original Opana ER from the market, replace it with a crush-resistant version of the drug, and obtain new patents to protect the reformulated drug. While Impax's generic would still eventually reach the market, it would not be therapeutically equivalent to Endo's new branded drug and thus pharmacists would not be able to automatically substitute the generic when filling prescriptions. This automatic substitution of brand drug prescriptions, promoted by state laws, is the primary driver of generic sales. So, if Endo succeeded in switching consumers to its reformulated drug, which would be just different enough from the original formulation to preclude substitution,

the market for Impax's generic would shrink dramatically, preserving Endo's monopoly profits.

The success of this "product hop"[1] depended on the reformulated Opana ER reaching the market sufficiently in advance of Impax's generic entry to allow patients to move away from the original drug before pharmacists started substituting the generic version. This transition period to the reformulated drug would take roughly six to nine months. A successful transition to the reformulated Opana ER before generic entry would mean millions to Endo. The company projected that the reformulated Opana ER would generate about $200 million in annual sales by 2016 if the market transitioned to the new drug before the generic entered. But if the generic launched first, then 2016 sales of the new formulation would fall to $10 million.

The date when Impax could start selling its generic was thus critical. The FDA tentatively approved Impax's application in May 2010. The Hatch-Waxman stay would expire the next month. There were signs that Impax was planning to launch its generic soon thereafter.[2]

With the possible launch date for generic entry imminent, Endo restarted settlement negotiations just three days after the FDA's tentative approval of the generic. The parties settled the patent litigation in June 2010,

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[1] Product hopping can itself be anticompetitive. *See generally New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 643 & n.2, 652–59 (2d Cir. 2015); Alan Devlin, *Exclusionary Strategies in the Hatch-Waxman Context*, 2007 MICH. ST. L. REV. 631, 657 – 673 (crediting Professor Hovenkamp with the "product hop" term).

[2] If Impax entered the market before resolution of the patent litigation, it would risk paying any damages for its sales in the event Endo later proved infringement. This is called "at risk" entry. *See In re Lipitor Antitrust Lit.*, 868 F.3d 231, 241 (3d Cir. 2017).

just a few days after the patent trial began and less than a week before the FDA fully approved Impax's application.

C.

Under the settlement, Impax agreed to delay launching its generic until January 1, 2013—two and a half years after Impax otherwise could have entered "at-risk." In turn, Endo agreed to not market its own generic version of extended-release oxymorphone until Impax's 180-day Hatch-Waxman exclusivity period concluded in July 2013. Additionally, Endo agreed to pay Impax a credit if sales revenues for the original formulation of Opana ER fell by more than 50 percent between the dates of settlement and Impax's entry. This credit served as an insurance policy for Impax, preserving the value of the settlement in case Endo undermined the generic oxymorphone market by transitioning consumers to the reformulated Opana ER. Endo also provided Impax with a broad license to Endo's existing and future patents covering extended-release oxymorphone. Finally, Endo and Impax agreed to collaboratively develop a new Parkinson's disease treatment, with Endo paying Impax $10 million immediately and up to $30 million in additional payments contingent on achieving sufficient development and marketing progress.

Impax's delayed entry allowed Endo to execute the product hop. In March 2012, Endo introduced its reformulated drug and withdrew the original drug. It publicly stated that the original drug was unsafe, though the FDA later disagreed that safety concerns motivated the withdrawal. Predictably, the market for the original Opana ER shriveled. So Endo had to pay Impax $102 million in credits. Endo subsequently succeeded in securing additional patents, and in 2015 and 2016 secured injunctions that prevented all manufacturers, including Impax, from marketing generic versions of the reformulated drug. But in 2017, the FDA asked Endo to voluntarily withdraw

the reformulated Opana ER from the market due to safety concerns, and it did.

For its part, Impax began marketing original formulation generic oxymorphone in January 2013, despite the damaged market Endo left behind. Because of the injunctions Endo secured against other generics and because Endo eventually withdrew the reformulated Opana ER from the market, Impax's generic is the only extended-release oxymorphone available to consumers today.

D.

The FTC brought separate actions against Endo and Impax alleging that the settlement was an unfair method of competition under the FTC Act and an unreasonable restraint on trade under the Sherman Act. Endo settled. Impax fought the charge and successfully argued that the case should proceed in an administrative proceeding rather than in federal district court where the Commission had first filed.

An administrative law judge determined that the agreement restricted competition but was nevertheless lawful because its procompetitive benefits outweighed the anticompetitive effects. Reviewing both the facts and law *de novo*, 16 C.F.R. § 3.54(a), the Commission reached a different conclusion. It found that Impax had failed to show that the settlement had any procompetitive benefits. Moreover, it determined that the purported benefits Impax identified could have been achieved through a less restrictive agreement. The Commission did not impose any monetary sanctions. It did not even invalidate Impax's agreements with Endo or other drug makers. Instead, it issued a cease-and-desist order enjoining Impax from entering into similar reverse payment settlements going forward.

Impax now petitions for review of the FTC's order.

II.

We review the Commission's ruling, not the ALJ's. *N. Tex. Specialty Physicians v. FTC*, 528 F.3d 346, 354 (5th Cir. 2008); *cf. Shaikh v. Holder*, 588 F.3d 861, 863 (5th Cir. 2009) (noting that we review the decision of the BIA in immigration cases). Any legal conclusions are reviewed *de novo*, though we "are to give some deference to the [FTC]'s informed judgment that a particular commercial practice is to be condemned as 'unfair.'" *N. Tex. Specialty*, 528 F.3d at 354 (quoting *FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447, 454 (1986)).

The "findings of the Commission as to the facts, if supported by evidence, shall be conclusive." 15 U.S.C. § 45(c). That statutory command is "essentially identical" to the substantial-evidence standard that often governs judicial review of agency factfinding. *Ind. Fed'n of Dentists*, 476 U.S. at 454. Substantial evidence is "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Id.* (quoting *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 477 (1951)). We must accept findings supported by such evidence "even if 'suggested alternative conclusions may be equally or even more reasonable and persuasive." *N. Tex. Specialty*, 528 F.3d at 354 (quoting *Colonial Stores, Inc. v. FTC*, 450 F.2d 733, 739 (5th Cir. 1971)). This deferential review should be no more searching than if we were evaluating a jury's verdict. *See District of Columbia v. Pace*, 320 U.S. 698, 702 (1944) (explaining that substantial evidence review is less intrusive than clear error review); 3 STEVEN ALAN CHILDRESS & MARTHA S. DAVIS, FEDERAL STANDARDS OF REVIEW § 15.04 (same); Robert L. Stern, *Review of Findings of Administrators, Judges and Juries: A Comparative Analysis*, 58 HARV. L. REV. 70, 84–86 (1944) (analyzing Justice Jackson's opinion in *Pace*).

III.

A reverse payment settlement is a settlement of patent litigation in which the patentholder gives the alleged infringer cash or other valuable services or property and the alleged infringer agrees not to market its allegedly infringing product until some later date. *See Actavis*, 570 U.S. at 140. These horizontal agreements unlawfully restrain trade, *see* 15 U.S.C. § 1, if they cause anticompetitive effects that outweigh any procompetitive benefits.[3] *See Actavis*, 570 U.S. at 156–59.

This rule-of-reason inquiry uses a burden-shifting framework. *See Ohio v. Am. Express*, 138 S. Ct. 2274, 2284 (2018). The initial burden is on the FTC to show anticompetitive effects. *Id.* If the FTC succeeds in doing so, the burden shifts to Impax to demonstrate that the restraint produced procompetitive benefits. *Id.* If Impax successfully proves procompetitive benefits, then the FTC can demonstrate that any procompetitive effects could be achieved through less anticompetitive means. *Id.* Finally, if the FTC fails to demonstrate a less restrictive alternative way to achieve the procompetitive benefits, the court must balance the anticompetitive and procompetitive effects of the restraint. *Apani Sw., Inc. v. Coca-Cola Enters., Inc.*, 300 F.3d 620, 627 (5th Cir. 2002). If the anticompetitive harms outweigh the procompetitive benefits, then the agreement is illegal. *Id.*

A.

The first question is whether the agreement caused anticompetitive effects or "created the potential for anticompetitive effects." *Doctor's Hosp.*

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[3] Reverse-payment settlements are also sometimes called "pay for delay" agreements. *See FTC v. Watson Pharm., Inc.*, 677 F.3d 1298, 1301 (11th Cir. 2012), *rev'd sub nom. FTC v. Actavis*, 570 U.S. 136 (2013). Following the Supreme Court's lead, we use the term "reverse payment."

of Jefferson, Inc. v. Se. Med. All., Inc., 123 F.3d 301, 310 (5th Cir. 1997); *accord Retractable Techs, Inc. v. Becton Dickinson & Co.*, 842 F.3d 883, 895 (5th Cir. 2016) (noting that an antitrust plaintiff must show that a restraint "had the potential to eliminate, or did in fact eliminate, competition"); *see also Actavis*, 570 U.S. at 157 (noting that the "relevant anticompetitive harm" of a reverse payment settlement is "prevent[ing] the risk of competition"). Such effects may be proved "indirectly," with "proof of market power plus some evidence that the challenged restraint harms competition."[4] *Am. Express Co.*, 138 S. Ct. at 2284.

Anticompetitive effects are those that harm consumers. Think increased prices, decreased output, or lower quality goods. *Id.* Eliminating potential competition is, by definition, anticompetitive. *See, e.g.*, *United States v. Falstaff Brewing Corp.*, 410 U.S. 526, 532–33 (1973) (acquiring potential competitor was anticompetitive both because of current pressure of potential entry and potentially beneficial effects of future entry). Indeed, paying a potential competitor not to compete is so detrimental to competition that normally it is a *per se* violation of the antitrust laws. *See Palmer v. BRG of Ga., Inc.*, 498 U.S. 46, 48–49 (1990); *see also Blue Cross & Blue Shield United of Wis. v. Marshfield Clinic*, 65 F.3d 1406, 1415 (7th Cir. 1995) (Posner, C.J.) (suggesting that market allocation agreements are even more pernicious than price-fixing agreements because the former eliminates all forms of competition); Joshua P. Davis & Ryan J. McEwan, *Deactivating* Actavis*: The Clash Between the Supreme Court and (Some) Lower Courts*, 67 RUTGERS U.L. REV. 557, 559 (2015) (calling "an agreement between horizontal competitors not to compete, the *bête noir* of antitrust law").

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[4] The FTC required that showing of market power to show potential anticompetitive effect under *Actavis*. Impax does not argue that it lacked market power—it held a patent after all—so we need not address that issue further.

Actavis concluded that, in contrast to the typical horizontal agreement to divvy up markets, reverse payment settlements might produce both anti- and procompetitive effects. On the one hand, a brand maker's paying a generic to delay entry "in effect amounts to a purchase by the patentee of the exclusive right to sell its product, a right it already claims but would lose if the patent litigation were to continue and the patent were held invalid or not infringed by the generic product." 570 U.S. at 153–54. In fact, reverse payment settlements may restrict competition even more than typical market allocation agreements because delaying entry of the first generic does not just eliminate one competitor—it prolongs the "bottleneck" that delays entry of other generic competitors. *In re Nexium (Esomeprazole) Antitrust Lit.*, 842 F.3d 34, 41 (1st Cir. 2016). But the existence of patent—a lawful monopoly if valid—points in the other direction. If the patent is valid, then unlike traditional market allocation agreements, a settlement that allows generic entry after the FDA's approval of the drug but still earlier than the patent expiration date may result in more competition than would have existed absent the settlement. *Actavis*, 570 U.S. at 154. Given the potentially countervailing impacts of reverse payment settlements, the Supreme Court applied the rule of reason rather than automatic invalidity. *Id.* at 159.

At this first step of the rule-of-reason analysis, we are just focused on the anticompetitive side of the equation. *Actavis* held that a "large and unjustified" reverse payment creates a likelihood of "significant anticompetitive effects." *Id.* at 158. "[T]he likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification." *Id.* at 159.

In many reverse payment cases, the central dispute is whether there was in fact a reverse payment. HERBERT HOVENKAMP ET AL. IP &

ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW § 16.01 (2018 Supp.); *see, e.g., In re Loestrin 24 Fe Antitrust Litig.*, 814 F.3d 538, 550–51 (1st Cir. 2016) (citing numerous post-*Actvavis* case addressing whether nonmonetary benefits to a generic are reverse payments). The settling party will often contend that any settlement payments are for services rather than for delayed entry. *Id.* That is not the case here. Impax has not challenged the ALJ's original determination "that a large reverse payment helped induce settlement or that the payment was linked to the January 2013 entry date."

That concession makes sense in light of the valuable consideration Impax received in exchange for delaying entry.[5] We will note two significant items. First, Endo committed to not market an authorized generic, which increased Impax's projected profits by $24.5 million. *See King Drug Co. of Florence*, 791 F.3d 388, 394 (3d Cir. 2015) (holding that brand manufacturer commitments to not market a generic drug during the 180-day exclusivity period are "payments" under *Actavis*); *see also Loestrin 24 Fe Antitrust Litig.*, 814 F.3d at 549–53 (explaining that *Actavis* recognized that a reverse payment could include more than just an exchange of money). Second, Endo would pay Impax credits for the shrunken market the latter would inherit if, as expected, Endo timely executed the product hop to the reformulated Opana ER. The $102 million Endo ultimately paid is likely a good approximation of the parties' expected value for these credits. The size of these payments is comparable to other cases where courts have inferred anticompetitive effect. *See In re Wellbutrin XL Antitrust Lit. Indirect Purchaser Class*, 868 F.3d 132, 162 (3d Cir. 2017) (holding that $233 million paid to three generic manufacturers is large under *Actavis*); *Nexium*, 842 F.3d at 50, 54

[5] The Commission also considered the payments to Impax for the Parkinson's research and the licenses Endo granted Impax.

(acknowledging jury finding that a $300–$690 million payment was large); *accord Actavis*, 570 U.S. at 145 (brand manufacturer agreed to pay three generic manufacturers $12 million, $60 million, and an estimated $171–270 million over nine years).

The Commission rejected the argument that just showing a large payment was enough to establish anticompetitive harm. It reasoned that "[e]stablishing that the payment is not otherwise justified is necessary for demonstrating that the payment is purchasing an exclusive right and preventing the risk of competition." *See also Actavis*, 570 U.S. at 158 (stating that "a reverse payment, where large and *unjustified*, can bring with it the risk of significant anticompetitive effects" (emphasis added)).

But the Commission correctly found no such justification. A large reverse payment might be justified if it represents "avoided litigation costs or fair value for services." *Id.* at 156. That is not the case here. The FTC estimated the settlement saved Endo only $3 million in litigation expenses, an amount in the ballpark of the typical cost for litigating pharmaceutical patents. *See* FED. TRADE COMM'N, AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACT 111–12 & n.27 (2011) (estimating average costs in the $5-10 million range based on research from Morgan Stanley); Michael R. Herman, Note, *The Stay Dilemma: Examining Brand and Generic Incentives for Delaying the Resolution of Pharmaceutical Patent Litigation*, 111 COLUM. L. REV. 1788, 1795 n.41 (2011) (noting that litigation expenses can bring the costs of generic entry to about $10 million). Nor did the agreement involve any services that the generic would provide to Endo that could otherwise justify the large payment. Only the services associated with the Parkinson's collaboration could plausibly provide an appropriate basis for the payments. But even assuming that the collaboration is relevant and that the $10 million

Parkinson's research agreement constituted payment for services, over $100 million of Endo's payment remains unjustified.

This large and unjustified payment generated anticompetitive effects. The Commission explained that there "was a real threat of competition from Impax" snuffed out by Endo's agreement to make the reverse payments. The FDA had just approved Impax's generic, allowing it to sell the drug. Impax had taken steps to do so, even though its market entry would be "at risk" of infringement liability. Endo's known product-hop plans increased Impax's incentive to quickly enter the market. The Commission thus had substantial evidence to conclude that the reverse payments replaced the "possibility of competition with the certainty of none."

Impax argues that the Commission needed to do more at this first stage of the rule of reason. Its principal attack on the finding of anticompetitive effect is that the Commission needed to evaluate "the patent's strength, which is the expected likelihood of the brand manufacturer winning the litigation." Impax reasons that if it was highly likely that Endo would win the patent suit, then the reverse payment was not anticompetitive because it allowed the generic to enter the market before the patent expired.

We disagree that *Actavis* requires the Commission to assess the likely outcome of the patent case in order to find anticompetitive effects. The fact that generic competition was possible, and that Endo was willing to pay a large amount to prevent that risk, is enough to infer anticompetitive effect. *Actavis*, 570 U.S. at 157. In fact, *Actavis* squarely rejected Impax's argument: "[T]he size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself." *Id.* at 158; *see also id.* at 157 ("[I]t is normally not necessary to litigate patent validity to answer the antitrust question."); *id.* at 158 (reiterating that a court can assess the

anticompetitiveness of a reverse payment "without litigating the validity of the patent"); *id.* at 159 (stating yet again that the Commission need not "litigate the patent's validity" to establish anticompetitive effects). The idea is that a large reverse payment "itself would normally suggest that the patentee has serious doubts about the patent's survival." *Id.* at 157; *see also* HOVENKAMP, *supra*, § 16.01[D] (explaining that a sizeable reverse payment "raise[s] a strong inference that that the parties believed ex ante that there was a significant chance that the patent was invalid").

Consider this settlement. If the parties thought Endo was highly likely to win the infringement suit, then Impax would have been happy with a deal giving it nothing more than entry months in advance of the likely-valid patent's expiration. *Cf. In re Cipro Cases I & II*, 348 P.3d 845, 865 (Cal. 2015) (noting that a settlement postponing market entry, but not accompanied by a reverse payment, would be a "fair approximation" of the strength of the patent suit). Reverse payments potentially worth nine figures would have been a windfall. The need to add that substantial enticement indicates that at least some portion of that payment is "for exclusion beyond the point that would have resulted, on average, from simply litigating the case to its conclusion." *Id.* at 867; *see also In re Aggrenox Antitrust Lit.*, 94 F. Supp. 3d 224, 240–41 (D. Conn. 2015) (explaining that a plaintiff need not prove that the patent was weak because a "large and unjustified reverse-payment" can show that the parties perceived weakness with the patent that would have made earlier entry likely). "And that fact, in turn, suggests that the payment's objective is to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what *might have been* a competitive market—the very anticompetitive consequence that underlies

the claim of antitrust unlawfulness." *Actavis*, 570 U.S. at 157 (emphasis added).[6]

Impax also argues that the settlement does not look anticompetitive in hindsight. After all, since the settlement Endo has obtained more patents for Opana ER and proven their validity in court. On top of that, the product hop ended up failing once Endo had to take reformulated Opana ER off the market due to safety concerns. So Impax's generic is now the only version of Opana ER on the market.

But it is a basic antitrust principle that the impact of an agreement on competition is assessed as of "the time it was adopted." *See Polk Bros. v. Forest City Enters.*, 776 F.2d 185, 189 (7th Cir. 1985) (Easterbrook, J.); *see also* FTC & DOJ, ANTITRUST GUIDELINES FOR COLLABORATIONS AMONG COMPETITORS § 2.4 (2000) (stating that the agencies "assess the competitive effects of a relevant agreement as of the time of possible harm to competition"). That approach also makes sense in reverse payment cases. *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1306 (11th Cir. 2003) (refusing to consider postagreement invalidation of patent because "reasonableness of agreements under the antitrust laws are to be judged at the time the agreements are entered into"); *Cipro*, 348 P.3d at 870 ("Just as later invalidation of a patent does not prove an agreement when made was anticompetitive, later evidence of validity will not automatically demonstrate an agreement was procompetitive."); 12 PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶ 2046e1, at 399 (4th ed.

[6] In addition to crediting these economic implications of a large reverse payment, the Supreme Court recognized the difficulty of trying a patent case within an antitrust case. *Actavis*, 570 U.S. at 157 (discussing the Eleventh Circuit's concern with "litigat[ing] patent validity" in an antitrust case, but explaining that is not needed for antitrust scrutiny). An Eleventh Circuit colleague apparently familiar with Cajun cuisine called this the "turducken" problem. *Watson*, 677 F.3d at 1315.

2019) (explaining that the "reasonableness of a patent settlement agreement cannot be made to depend on an *ex post* determination" of validity or infringement).

So the focus is on the following facts as they existed when the parties adopted the settlement. Endo agreed to make large payments to the company that was allegedly infringing its patents. In exchange, Impax agreed to delay entry of its generic drug until two-and-a-half years after the FDA approved the drug. Neither the saved costs of forgoing a trial nor any services Endo received justified these payments. Substantial evidence supports the Commissions' finding that the reverse payment settlement threatened competition.

B.

The next rule-of-reason question is whether Impax can show procompetitive benefits. *Am. Express*, 138 S. Ct. at 2284. The Commission concluded it could not. Although the ALJ had recognized that the settlement's license and covenant-not-to-sue provisions benefited competition, the Commission concluded that these procompetitive effects did not flow from the challenged restraint—the reverse payments themselves. As a result, the Commission did not treat Impax's ability to enter the market nine months before the patents expired, and the protection Impax secured against other patents Endo might obtain, as benefits to be weighed against the anticompetitive effects of the reverse payments. After the Commission concluded that the reverse payments lacked any procompetitive benefits, it followed that they "constitute[d] an unreasonable restraint of trade."

The parties and amici vigorously contest the Commission's finding of "no nexus" between the restraint and the procompetitive benefits Impax

asserts. That dispute turns largely on how to define the restraint. Is it limited to the reverse payments or does it extend to the entire settlement agreement?

We need not resolve this question because of an alternative ruling the Commission made. Although the Commission found the reverse payments generated no procompetitive benefits, it went on to assume *arguendo* that Impax could connect the settlement's purported procompetitive effects to the challenged restraint. Even if that was so, the Commission determined that "Impax could have obtained the proffered benefits by settling without a reverse payment for delayed entry—which is a practical, less restrictive alternative." If we conclude that substantial evidence supported this finding of a less restrictive alternative, we can also assume that Impax has proven procompetitive benefits. So we will turn to our review of the "less restrictive alternative" finding.

C.

A restraint is unreasonable when any procompetitive benefits it produces "could be reasonably achieved through less anticompetitive means." *Am. Express*, 138 S. Ct. at 2284; *see generally* 11 AREEDA & HOVENKAMP, *supra*, ¶ 1913, at 395–402; C. Scott Hemphill, *Less Restrictive Alternatives in Antitrust Law*, 116 COLUM. L. REV. 927, 937–42 (2016). The concept traces back to then-Circuit Judge Taft's opinion in *United States v. Addyston Pipe & Steel Co.* Hemphill, *Less Restrictive*, *supra*, at 938 & n.53 (citing 85 F. 271, 282 (6th Cir. 1898) (holding that a restraint of trade is unenforceable unless it is "ancillary to the main purpose of a lawful contract[] and *necessary* to protect the covenantee['s] . . . enjoyment of the legitimate fruits of the contract" (emphasis added))). The less-restrictive-alternative standard applies across a range of antitrust claims and is included in model antitrust jury instructions. *Id.* at 929, 938 & n.50 (citing ABA SECTION OF ANTITRUST LAW, MODEL JURY INSTRUCTIONS IN CIVIL

ANTITRUST CASES A-10 (2005)).[7] The idea is that it is unreasonable to justify a restraint of trade based on a purported benefit to competition if that same benefit could be achieved with less damage to competition. Focusing on the existence of less restrictive alternatives may allow courts to avoid difficult balancing of anticompetitive and procompetitive effects and to "smoke out" anticompetitive effects or pretextual justifications for the restraint. *Hemphill*, *Less Restrictive*, *supra*, at 947–63. When a less restrictive alternative exists, a party's decision to nonetheless engage in conduct "that harms consumers" likely results from a desire "to gain from the resulting consumer harm." *Id.* at 968. The question, in short, is whether "the good [could] have been achieved equally well with less bad." *Id.* at 929.

Actavis recognizes the possibility of less restrictive alternatives to reverse payment settlements. The Court noted that parties to pharmaceutical patent litigation "may, as in other industries, settle in other ways, for example, by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without . . . paying the challenger to stay out prior to that point." 570 U.S. at 158; *see also* 12 AREEDA & HOVENKAMP, *supra*, ¶ 2046c2, at 381–82 (observing that *Actavis* recognizes "that there are better, less anticompetitive ways to settle these disputes").

The Commission found that Impax could have achieved just as much and likely more good (an entry date even earlier than 2013) without the bad (Endo's agreement not to sell a competing generic during the exclusivity period and to pay credits to Impax for the decline of the Opana ER market

[7] The Fifth Circuit Pattern Jury Instructions does not include circuit-specific antitrust instructions, but refer courts and parties to two sources, including the ABA Antitrust Section's proposed instructions. FIFTH CIRCUIT PATTERN JURY INSTRUCTIONS (CIVIL CASES) § 6 (2020).

while Endo executed the product hop). The Commission explained that "[h]olding everything else equal, Impax's acceptance of payment would normally be expected to result in a later entry date than what Impax would have accepted based on the strength of the patents alone." To support its view that Impax could have entered into a settlement without reverse payments that would have resulted in greater generic competition, the Commission relied on industry practice, economic analysis, expert testimony, and adverse credibility findings discounting the testimony of Impax's lead settlement negotiator.

"[T]he existence of a viable less restrictive alternative is ordinarily a question of fact." 11 AREEDA & HOVENKAMP, *supra*, ¶ 1913b, at 398; *accord O'Bannon v. NCAA*, 802 F.3d 1049, 1074 (9th Cir. 2015) (applying clear-error review to district court's finding of less restrictive alternative). So the substantial deference we owe the Commission's factfinding kicks in, in particular on its determination that a no-payment settlement was feasible.

Impax nonetheless tries to lodge legal objections to the finding of a less restrictive alternative. First, it argues that the Commission only recognized what it considers an equally restrictive alternative—the possibility of a settlement with the same entry date but no reverse payments. But the Commission recognized the feasibility of no-payment settlements with both the same[8] or an earlier entry date. Its ultimate ruling relied on an agreement with an earlier entry date as a less restrictive alternative: "A no-payment

[8] Even if Impax's entry date were the same in a no-payment settlement, the arrangement would be less anticompetitive than the actual agreement because it would not include Endo's "payment" of not selling a generic competitor during Impax's six-month exclusivity period. Thus, in a no-payment settlement, there would have been greater price competition during at least those six months. In any event, because the Commission's ultimate finding relied on the feasibility of a no-payment settlement with an earlier entry date, we only consider that agreement as a less restrictive alternative.

settlement allowing *pre-2013 generic entry* would have been a practical alternative for both Impax and Endo, but they chose instead to exchange sizeable payment for *a later* entry date." (emphasis added). Impax does not dispute that an agreement with an earlier entry date would be less restrictive.

Impax does argue that the Commission "flipped the burden of proof" in finding that such a less restrictive settlement was feasible. We disagree. The Commission concluded that there was a "strong showing" of the possibility of less restrictive settlement, and only then asked whether Impax had rebutted that evidence. That is a normal way of evaluating whether a plaintiff has met its burden of persuasion.

So we turn to whether substantial evidence supports the Commission's conclusion that Complaint Counsel had established a less restrictive alternative. First is the fact that most settlements between brand and generic makers do not include reverse payments. The Commission relied on an expert witness who analyzed industry practice and studies showing that from 2004-2009 "only 30 percent of the patent settlements filed with the FTC involved both compensation from the branded firm to the generic firm and restrictions on generic entry." In recent years, reverse payment settlements may have become even rarer; over 80 percent of brand-generic settlements reached within the year following *Actavis* did not include a reverse payment.

Impax suggests this evidence of industry practice is not probative of whether it had the opportunity to enter in a no-payment settlement. But leading scholars have recognized that other parties' "actual experience in analogous situations" can help establish the feasibility or practicality of a less restrictive alternative. 11 AREEDA & HOVENKAMP, *supra*, ¶ 1913b, at 398; *accord* Hemphill, *Less Restrictive*, *supra*, at 984 ("One useful indicia of practicality is that the alternative has been implemented by this or other firms

in similar circumstances."); *see also Ind. Fed'n of Dentists*, 476 U.S. at 454 (recognizing the FTC's expertise about commercial practices). Showing that the alternative is "rooted in real commercial experience" may be especially compelling as the defendant often will not want to acknowledge its willingness to enter into an arrangement that would not have included "the illicit profits arising from an anticompetitive effect." *Id.* at 984–85; *see also* Kevin B. Soter, Note, *Causation in Reverse Payment Antitrust Claims,* 70 STAN. L. REV. 1295, 1336 (2018) (raising concerns about rules that would "tell[] defendants that all they need to do to avoid liability is to insist in settlement talks that the only agreement they would make is an illegal one").

And the Commission did not rely on industry practice alone. It acknowledged but refused to credit the trial testimony of Impax's chief negotiator, who said that Endo was "adamant about preventing pre-2013 entry."[9] The Commission noted that this resolute trial testimony was inconsistent with the witness's prior statements that he could not remember discussing pre-2013 entry dates with Endo. In that earlier testimony, the negotiator said he could not remember if "Impax ever 'tried to get a date earlier than January of 2013'" or whether "Endo ever told Impax that it would 'not settle the litigation' with an entry date before 2013." Doubts about the negotiator's newfound certainty allowed the Commission not just to reject his testimony but also to treat it as evidence of the possibility of pre-2013 entry. *See Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 147 (2000) (discussing the "general principle of evidence law that the factfinder is entitled to consider a party's dishonesty about a material fact as 'affirmative evidence of guilt'"). The Commission further noted that while

[9] The Commission's consideration of this testimony further dispels Impax's claim that the Commission did not find a settlement with an *earlier* entry date to be a viable alternative.

early on Impax had unsuccessfully sought entry dates during 2011 and even January 2012, a significant time gap exists between those proposed entry dates and the 2013 entry date in the final agreement. The professed failure to consider other possible 2012 entry dates thus casts doubt on the notion that an agreement with pre-2013 entry was unachievable.[10]

Finally, economics support the Commission's finding that Endo would have entered into a settlement with an earlier entry date if it could have could have kept the more than $100 million it ended up paying Impax. Hemphill, *Less Restrictive*, *supra*, at 984 (recognizing that a plaintiff could use "expert testimony based on economic theory" to show a likelihood that the parties would have entered into a less restrictive alternative). If everything has a price, then those large payments were the price for Impax's delayed entry. *King Drug*, 791 F.3d at 405 n.23; *Cipro*, 348 P.3d at 871. Such "fairly obvious" observations can show the feasibility of a less restrictive alternative. 11 AREEDA & HOVENKAMP, *supra*, ¶ 1913b, at 398; *see also Ind. Fed'n of Dentists*, 476 U.S. at 454 (holding that deference is due FTC's assessment of business practices).

Three evidentiary legs—industry practice, credibility determinations about settlement negotiations, and economic analysis—thus supported the Commission's conclusion that Endo would have agreed to a less restrictive settlement. 11 AREEDA & HOVENKAMP, *supra*, ¶ 1914c, at 410 (stating that a finding of less restrictive alternative should be based on alternatives "that are either quite obvious or a proven success"). As for Impax's side of

[10] The case-specific nature of this aspect of the FTC's ruling undermines Impax's concern that the agency's decision would invalidate all reverse payment settlements. So does the FTC's enforcement record. During the first fifteen years of this century, the agency challenged only 6 of the 1336 brand/generic settlements entered into during that period. FTC BUREAU OF COMPETITION, OVERVIEW OF AGREEMENTS FILED IN FY 2016, at 4.

things, of course it would have preferred the settlement that paid it over $100 million. But any reluctance Impax had to agree to a no-payment settlement based on a "desire to share in monopoly rents" cannot undermine the Commission's finding that a less restrictive settlement was viable. *See* Hemphill, *Less Restrictive*, *supra*, at 984–85; *see also* Soter, *supra*, at 1336.

Our question is not whether the Commission could have reached a different result on the less-restrictive-alternative question. It is whether there was evidence that would allow a reasonable factfinder to conclude that a no-payment settlement was feasible. *Ind. Fed'n of Dentists*, 476 U.S. at 454; *see also Ripley v. Chater*, 67 F.3d 552, 555 (5th Cir. 1995) (noting that substantial evidence can even be less than a preponderance). Because there was more than enough evidence to support that unanimous view of the Commissioners, we must uphold their view that a less restrictive alternative was viable. And that means the reverse payment settlement was an agreement to preserve and split monopoly profits that was not necessary to allow generic competition before the expiration of Endo's patent. As a result, Impax agreed to an unreasonable restraint of trade.

* * *

The petition for review is DENIED.

Syllabus

NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States* v. *Detroit Timber & Lumber Co.,* 200 U. S. 321, 337.

SUPREME COURT OF THE UNITED STATES

Syllabus

AMG CAPITAL MANAGEMENT, LLC, ET AL. *v.* FEDERAL TRADE COMMISSION

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

No. 19–508. Argued January 13, 2021—Decided April 22, 2021

The Federal Trade Commission filed a complaint against Scott Tucker and his companies alleging deceptive payday lending practices in violation of §5(a) of the Federal Trade Commission Act. The District Court granted the Commission's request pursuant to §13(b) of the Act for a permanent injunction to prevent Tucker from committing future violations of the Act, and relied on the same authority to direct Tucker to pay $1.27 billion in restitution and disgorgement. On appeal, the Ninth Circuit rejected Tucker's argument that §13(b) does not authorize the award of equitable monetary relief.

Held: Section 13(b) does not authorize the Commission to seek, or a court to award, equitable monetary relief such as restitution or disgorgement. Pp. 3–15.

(a) Congress granted the Commission authority to enforce the Act's prohibitions on "unfair or deceptive acts or practices," 15 U. S. C. §§45(a)(1)–(2), by commencing administrative proceedings pursuant to §5 of the Act. Section 5(*l*) of the Act authorizes the Commission, following completion of the administrative process and the issuance of a final cease and desist order, to seek civil penalties, and permits district courts to "grant mandatory injunctions and such other and further equitable relief as they deem appropriate in the enforcement of such final orders of the Commission." §45(*l*). Section 19 of the Act further authorizes district courts (subject to various conditions and limitations) to grant "such relief as the court finds necessary to redress injury to consumers," §57b(b), in cases where someone has engaged in unfair or deceptive conduct with respect to which the Commission has issued a final cease and desist order applicable to that person, see §57b(a)(2). Here, the Commission responded to Tucker's payday lending practices

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by seeking equitable monetary relief directly in district court under §13(b)'s authorization to seek a "permanent injunction." In doing so, the Commission acted in accordance with its increasing tendency to use §13(b) to seek monetary awards without prior use of the Commission's traditional administrative proceedings. The desirability of the Commission's practice aside, the question is whether Congress, by enacting §13(b) and using the words "permanent injunction," granted the Commission authority to obtain monetary relief directly from courts and effectively bypass the requirements of the administrative process. Pp. 3–6.

(b) Section 13(b) does not explicitly authorize the Commission to obtain court-ordered monetary relief, and such relief is foreclosed by the structure and history of the Act. Section 13(b) provides that the "Commission may seek . . . a permanent injunction." §53(b). By its terms, this provision concerns prospective injunctive relief, not retrospective monetary relief. Section 13(b) allows the Commission to go directly to district court when the Commission seeks injunctive relief pending administrative proceedings or when it seeks only a permanent injunction. Other statutory provisions, in particular the conditioned and limited monetary relief authorized in §19, confirm this conclusion. It is highly unlikely that Congress, without mentioning the matter, would grant the Commission authority to circumvent its traditional §5 administrative proceedings. Pp. 6–10.

(c) The Commission's contrary arguments are unavailing. First, *Porter* v. *Warner Holding Co.*, 328 U. S. 395, and *Mitchell* v. *Robert DeMario Jewelry*, *Inc.*, 361 U. S. 288, did not adopt a universal rule that statutory authority to grant an injunction automatically encompasses the power to grant equitable monetary remedies. Instead, the text and structure of the particular statutory scheme at issue can limit a court's jurisdiction in equity. Second, in enacting §19 two years after §13(b), Congress did not simply create an alternative enforcement path with similar remedies. The Court does not believe Congress would have enacted §19's provisions expressly authorizing monetary relief if §13(b) already implicitly allowed the Commission to obtain that same monetary relief without satisfying §19's conditions and limitations. Third, §19's saving clauses—preserving "any authority of the Commission under any other provision of law" and "any other remedy or right of action provided by State or Federal law," §57b(e)—do not help answer whether §13(b) gave the Commission the authority to obtain equitable monetary relief directly in court in the first place. Fourth, the Act's 1994 and 2006 amendments, which did not modify the specific language at issue here, do not demonstrate congressional acquiescence to lower court rulings that favor the Commission's interpretation of

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§13(b). Fifth, policy arguments that §5 and §19 are inadequate to provide redress to consumers should be addressed to Congress. Pp. 10–14.

910 F. 3d 417, reversed and remanded.

BREYER, J., delivered the opinion for a unanimous Court.

SUPREME COURT OF THE UNITED STATES

No. 19–508

AMG CAPITAL MANAGEMENT, LLC, ET AL., PETITIONERS *v.* FEDERAL TRADE COMMISSION

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

[April 22, 2021]

JUSTICE BREYER delivered the opinion of the Court.

Section 13(b) of the Federal Trade Commission Act authorizes the Commission to obtain, "in proper cases," a "permanent injunction" in federal court against "any person, partnership, or corporation" that it believes "is violating, or is about to violate, any provision of law" that the Commission enforces. 87 Stat. 592, 15 U. S. C. §53(b). The question presented is whether this statutory language authorizes the Commission to seek, and a court to award, equitable monetary relief such as restitution or disgorgement. We conclude that it does not.

I

Petitioner Scott Tucker controlled several companies that provided borrowers with short-term payday loans. The companies, operating online, would show a potential customer a loan's essential terms. When the companies explained those terms, they misled many customers. The companies' written explanations seemed to say that customers could normally repay a loan by making a single payment. And that payment would cost a person who, for example, borrowed $300 an extra $90. (The customer would

likely repay a total of $390.) But in fine print the explanations said that the loan would be automatically renewed unless the customer took affirmative steps to opt out. Thus, unless the customer who borrowed $300 was aware of the fine print and actively prevented the loan's automatic renewal, he or she could end up having to pay $975, not $390. Between 2008 and 2012, Tucker's businesses made more than 5 million payday loans, amounting to more than $1.3 billion in deceptive charges.

In 2012 the Federal Trade Commission filed suit and claimed that Tucker and his companies were engaging in "unfair or deceptive acts or practices in or affecting commerce," in violation of §5(a) of the Act. 15 U. S. C. §45(a)(1). (We shall refer to all of the defendants collectively as Tucker.) In asserting that Tucker's practices were likely to mislead consumers, the Commission did not first use its own administrative proceedings. Rather, the Commission filed a complaint against Tucker directly in federal court. The Commission, relying upon §13(b), asked the court to issue a permanent injunction to prevent Tucker from committing future violations of the Act. Relying on the same provision, the Commission also asked the court to order monetary relief, in particular, restitution and disgorgement. The Commission moved for summary judgment.

The District Court granted the Commission's summary judgment motion. The court also granted the Commission's request for an injunction and directed Tucker to pay $1.27 billion in restitution and disgorgement. The court ordered the Commission to use these funds first to provide "direct redress to consumers" and then to provide "other equitable relief" reasonably related to Tucker's alleged business practices. Finally, the court ordered the Commission to deposit any remaining funds in the United States Treasury as disgorgement.

On appeal, Tucker argued that §13(b) does not authorize the monetary relief the District Court had granted. The

Ninth Circuit rejected Tucker's claim. 910 F. 3d 417 (2018). It pointed to Circuit precedent that had interpreted §13(b) as "empower[ing] district courts to grant any ancillary relief necessary to accomplish complete justice, including restitution." *FTC* v. *Commerce Planet*, *Inc.*, 815 F. 3d 593, 598 (2016); see also *FTC* v. *H. N. Singer*, *Inc.*, 668 F. 2d 1107, 1113 (CA9 1982). Two judges, while recognizing that precedent in many Circuits supported that use of §13(b), expressed doubt as to the correctness of that precedent.

Tucker then sought certiorari in this Court. In light of recent differences that have emerged among the Circuits as to the scope of §13(b), we granted his petition.

II

The Federal Trade Commission Act prohibits, and authorizes the Commission to prevent, "[u]nfair methods of competition" and "unfair or deceptive acts or practices." 15 U. S. C. §§45(a)(1)–(2). The Act permits the Commission to use both its own administrative proceedings (set forth in §5 of the Act) and court actions in exercising this authority. In construing §13(b), it is helpful to understand how the Commission's authority (and its interpretation of that authority) has evolved over time.

Ever since the Commission's creation in 1914, it has been authorized to enforce the Act through its own administrative proceedings. Section 5 of the Act describes the relevant administrative proceedings in some detail. If the Commission has "reason to believe" that a party "has been or is using any unfair method of competition or unfair or deceptive act or practice," it can file a complaint against the claimed violator and adjudicate its claim before an Administrative Law Judge. §45(b). The ALJ then conducts a hearing and writes a report setting forth findings of fact and reaching a legal conclusion. *Ibid.* If the ALJ concludes that the conduct at issue was unfair or misleading, the ALJ will issue

an order requiring the party to cease and desist from engaging in the unlawful conduct. *Ibid.* The party may then seek review before the Commission and eventually in a court of appeals, where the "findings of the Commission as to the facts" (if supported by the evidence) "shall be conclusive." §45(c). If judicial review favors the Commission (or if the time to seek judicial review expires), the Commission's order normally becomes final (and enforceable). §45(g).

In the 1970s Congress authorized the Commission to seek additional remedies in court. In 1973 Congress added §13(b), the provision at issue here. That provision permits the Commission to proceed directly to court (prior to issuing a cease and desist order) to obtain a "temporary restraining order or a preliminary injunction," and also allows the Commission, "in proper cases," to obtain a court-ordered "permanent injunction." 15 U. S. C. §53(b). In the same legislation, Congress also amended §5(*l*) of the Act to authorize district courts to award civil penalties against respondents who violate final cease and desist orders, and to "grant mandatory injunctions and such other and further equitable relief as they deem appropriate in the enforcement of such final orders of the Commission." §45(*l*). Two years later, Congress enacted §19 of the Act, which authorizes district courts to grant "such relief as the court finds necessary to redress injury to consumers," including through the "refund of money or return of property." §57b(b). However, Congress specified that the consumer redress available under §19 could be sought only (as relevant here, and subject to various conditions and limitations) against those who have "engage[d] in any unfair or deceptive act or practice . . . with respect to which the Commission has issued a final cease and desist order which is applicable to such person." §57b(a)(2).

Beginning in the late 1970s, the Commission began to use §13(b), and in particular the words "permanent injunction,"

to obtain court orders for redress of various kinds in consumer protection cases—without prior use of the administrative proceedings in §5. See, *e.g.*, *FTC* v. *Virginia Homes Mfg. Corp.*, 509 F. Supp. 51, 59 (Md. 1981) (relying on §13(b) to order the defendant to notify past customers of their warranty rights); see also D. FitzGerald, The Genesis of Consumer Protection Remedies Under Section 13(b) of the FTC Act 1–2, Paper at FTC 90th Anniversary Symposium, Sept. 23, 2004 (FitzGerald); Beales & Muris, Striking the Proper Balance: Redress Under Section 13(b) of the FTC Act, 79 Antitrust L. J. 1, 3–4 (2013). The Commission used this authority to seek and win restitution and other forms of equitable monetary relief directly in court.

Similarly, in the late 1990s the Commission began to use §13(b)'s "permanent injunction" authority in antitrust cases to seek monetary awards, such as restitution and disgorgement—again without prior use of traditional administrative proceedings. See Complaint in *FTC* v. *Mylan Labs.*, *Inc.*, No. 98–3114 (DC); Complaint in *FTC* v. *The Hearst Trust*, No. 01–734 (DC). In 2003 the Commission issued guidance that limited its use of §13(b) to obtain monetary relief to "exceptional cases" involving a "[c]lear [v]iolation" of the antitrust laws. Policy Statement on Monetary Equitable Remedies in Competition Cases, 68 Fed. Reg. 45821 (emphasis deleted). But in 2012 the Commission withdrew its policy statement and the limitations it imposed. See Withdrawal of the Commission Policy Statement on Monetary Equitable Remedies in Competition Cases, 77 Fed. Reg. 47071.

The result is that the Commission presently uses §13(b) to win equitable monetary relief directly in court with great frequency. The Commission tells us that "the agency [now] brings dozens of [§13(b)] cases every year seeking a permanent injunction and the return of illegally obtained funds." Brief for Respondent 8; see also, *e.g.*, Ohlhausen, Dollars, Doctrine, and Damage Control: How Disgorgement Affects

the FTC's Antitrust Mission 7, Speech at Dechert LLP, NY, Apr. 20, 2016 (Commission sought disgorgement in antitrust cases four times between 2012 and 2016, which is "as many times as the [Commission] pursued such relief in the prior twenty years"). With respect to consumer protection cases, the Commission adds that "there's no question that the agency brings far more cases in court than it does in the administrative process." Tr. of Oral Arg. 49. In fiscal year 2019, for example, the Commission filed 49 complaints in federal court and obtained 81 permanent injunctions and orders, resulting in $723.2 million in consumer redress or disgorgement. See FTC, Fiscal Year 2021 Congressional Budget Justification 5 (Feb. 10, 2020), https://www.ftc.gov/system/files/documents/reports/fy-2021-congressional-budget-justification/fy_2021_cbj_final.pdf. In the same period, the Commission issued only 21 new administrative complaints and 21 final administrative orders.

Our task here is not to decide whether this substitution of §13(b) for the administrative procedure contained in §5 and the consumer redress available under §19 is desirable. Rather, it is to answer a more purely legal question: Did Congress, by enacting §13(b)'s words, "permanent injunction," grant the Commission authority to obtain monetary relief directly from courts, thereby effectively bypassing the process set forth in §5 and §19?

III

Several considerations, taken together, convince us that §13(b)'s "permanent injunction" language does not authorize the Commission directly to obtain court-ordered monetary relief. For one thing, the language refers only to injunctions. It says, "in proper cases the Commission may seek, and after proper proof, the court may issue, a permanent *injunction*." 15 U. S. C. §53(b) (emphasis added). An "injunction" is not the same as an award of equitable monetary relief. Compare, *e.g.*, *United States* v. *Oregon State*

Medical Soc., 343 U. S. 326, 333 (1952) (injunction typically offers prospective relief against ongoing or future harm), with, *e.g.*, 1 D. Dobbs, Law of Remedies §4.1(1) (2d ed. 1993) (restitution typically offers retrospective relief to redress past harm). We have, however, sometimes interpreted similar language as authorizing judges to order equitable monetary relief. See *Porter* v. *Warner Holding Co.*, 328 U. S. 395 (1946); *Mitchell* v. *Robert DeMario Jewelry*, *Inc.*, 361 U. S. 288 (1960).

But if this language alone is not enough, there is more. The language and structure of §13(b), taken as a whole, indicate that the words "permanent injunction" have a limited purpose—a purpose that does not extend to the grant of monetary relief. Those words are buried in a lengthy provision that focuses upon purely injunctive, not monetary, relief. It says (in relevant part):

> "Whenever the Commission has reason to believe—
>
> "(1) that any person, partnership, or corporation is violating, or is about to violate, any provision of law enforced by the Federal Trade Commission, and
>
> "(2) that the enjoining thereof pending the issuance of a complaint by the Commission and until such complaint is dismissed by the Commission or set aside by the court on review, or until the order of the Commission made thereon has become final, would be in the interest of the public—
>
> "the Commission by any of its attorneys designated by it for such purpose may bring suit in a district court of the United States to enjoin any such act or practice. Upon a proper showing that, weighing the equities and considering the Commission's likelihood of ultimate success, such action would be in the public interest, and after notice to the defendant, a temporary restraining order or a preliminary injunction may be granted without bond: *Provided*, *however*, That if a complaint is not

> filed within such period (not exceeding 20 days) as may be specified by the court after issuance of the temporary restraining order or preliminary injunction, the order or injunction shall be dissolved by the court and be of no further force and effect: *Provided further*, That *in proper cases the Commission may seek*, *and after proper proof*, *the court may issue*, *a permanent injunction.*" 15 U. S. C. §53(b) (final emphasis added).

Taken as a whole, the provision focuses upon relief that is prospective, not retrospective. Consider the words "is violating" and "is about to violate" (not "has violated") setting forth when the Commission may request injunctive relief. Consider too the words "pending the issuance of a complaint," "until such complaint is dismissed," "temporary restraining order," "preliminary injunction," and so forth in the first half of the section. These words reflect that the provision addresses a specific problem, namely, that of stopping seemingly unfair practices from taking place while the Commission determines their lawfulness. Cf. §53(a) (providing similar provisional relief where false advertising regarding food, drugs, devices, and cosmetics is at issue). And the appearance of the words "permanent injunction" (as a proviso) suggests that those words are directly related to a previously issued preliminary injunction. They might also be read, for example, as granting authority for the Commission to go one step beyond the provisional and ("in proper cases") dispense with administrative proceedings to seek what the words literally say (namely, an *injunction*). But to read those words as allowing what they do not say, namely, as allowing the Commission to dispense with administrative proceedings to obtain monetary relief as well, is to read the words as going well beyond the provision's subject matter. In light of the historical importance of administrative proceedings, that reading would allow a small statutory tail to wag a very large

dog.

Further, the structure of the Act beyond §13(b) confirms this conclusion. Congress in §5(*l*) and §19 gave district courts the authority to impose limited monetary penalties and to award monetary relief in cases where the Commission has *issued cease and desist orders*, *i.e.*, where the Commission has engaged in administrative proceedings. Since in these provisions Congress explicitly provided for "other and further equitable relief," 15 U. S. C. §45(*l*), and for the "refund of money or return of property," §57b(b), it likely did not intend for §13(b)'s more cabined "permanent injunction" language to have similarly broad scope.

More than that, the latter provision (§19) comes with certain important limitations that are absent in §13(b). As relevant here, §19 applies only where the Commission begins its §5 process within three years of the underlying violation and seeks monetary relief within one year of any resulting final cease and desist order. 15 U. S. C. §57b(d). And it applies only where "a reasonable man would have known under the circumstances" that the conduct at issue was "dishonest or fraudulent." §57b(a)(2); see also §45(m)(1)(B)(2) (providing court-ordered monetary penalties against anyone who engages in conduct previously identified as prohibited in a final cease and desist order, but only if the violator acted with "actual knowledge that such act or practice is unfair or deceptive"). In addition, Congress enacted these other, more limited, monetary relief provisions at the same time as, or a few years after, it enacted §13(b) in 1973.

It is highly unlikely that Congress would have enacted provisions expressly authorizing *conditioned* and *limited* monetary relief if the Act, via §13(b), had already implicitly allowed the Commission to obtain that same monetary relief and more without satisfying those conditions and limitations. Nor is it likely that Congress, without mentioning the matter, would have granted the Commission authority

so readily to circumvent its traditional §5 administrative proceedings. See FitzGerald 1 (arguing that, in the mid-1970s, "no one imagined that Section 13(b) of the [FTC] Act would become an important part of the Commission's consumer protection program" (footnote omitted)).

At the same time, to read §13(b) to mean what it says, as authorizing injunctive but not monetary relief, produces a coherent enforcement scheme: The Commission may obtain monetary relief by first invoking its administrative procedures and then §19's redress provisions (which include limitations). And the Commission may use §13(b) to obtain injunctive relief while administrative proceedings are foreseen or in progress, or when it seeks only injunctive relief. By contrast, the Commission's broad reading would allow it to use §13(b) as a substitute for §5 and §19. For the reasons we have just stated, that could not have been Congress' intent. Cf. *Whitman* v. *American Trucking Assns., Inc.*, 531 U. S. 457, 468 (2001) ("Congress . . . does not . . . hide elephants in mouseholes").

IV

The Commission makes several arguments to the contrary. First, the Commission points to traditional equitable practice and to two previous cases where we interpreted provisions authorizing injunctive relief to authorize equitable monetary relief as well. See *Porter* v. *Warner Holding Co.*, 328 U. S. 395 (1946); *Mitchell* v. *Robert DeMario Jewelry, Inc.*, 361 U. S. 288 (1960). In *Porter* we said that "[n]othing is more clearly a part of the subject matter of a suit for an injunction than the recovery of that which has been illegally acquired and which has given rise to the necessity for injunctive relief." 328 U. S., at 399. In *Mitchell* we said that, "[w]hen Congress entrusts to an equity court the enforcement of prohibitions contained in a regulatory enactment, it must be taken to have acted cognizant of the historic power of equity to provide complete relief in light of

the statutory purposes." 361 U. S., at 291–292. The Commission argues that these cases consequently support the proposition that the traditional equitable "authority to grant an 'injunction' includes the power to grant restorative monetary remedies." Brief for Respondent 21.

The problem for the Commission is that we did not in these two cases purport to set forth a universal rule of interpretation. And both cases involved different statutes. See *Porter*, 328 U. S., at 397 (Emergency Price Control Act provision authorizing courts to issue "'a permanent or temporary injunction, restraining order, or other order'"); *Mitchell*, 361 U. S., at 289 (Fair Labor Standards Act provision authorizing courts to "'restrain violations'" of the Act's antiretaliation ban). In both cases, we recognized that the text and structure of the statutory scheme at issue can, "in so many words, or by a necessary and inescapable inference, restric[t] the court's jurisdiction in equity." *Porter*, 328 U. S., at 398; *Mitchell*, 361 U. S., at 291. Thus in *Porter* we examined "other provision[s] of the [Emergency Price Control] Act" to determine whether they "expressly or impliedly preclud[e] a court from ordering restitution in the exercise of its equity jurisdiction." 328 U. S., at 403. And in *Mitchell* we examined other provisions of the Fair Labor Standards Act before concluding that there was "no indication in the language" that the statute precluded equitable relief in the form of lost wages. 361 U. S., at 294.

Moreover, more recently, we have held, based on our reading of a statutory scheme as a whole, that a provision's grant of an "injunction" or other equitable powers does not automatically authorize a court to provide monetary relief. Rather, we have said, the scope of equitable relief that a provision authorizes "remains a question of interpretation in each case." *Mertens* v. *Hewitt Associates*, 508 U. S. 248, 257 (1993). Our decision in *Meghrig* v. *KFC Western*, *Inc.*, 516 U. S. 479 (1996), is instructive. There, we considered a provision in the Resource Conservation and Recovery Act

that authorizes district courts "to restrain any person who has contributed or who is contributing to the past or present handling, storage, treatment, transportation, or disposal of any solid or hazardous waste," and "to order such person to take such other action as may be necessary, or both." 98 Stat. 3268, 42 U. S. C. §6972(a). The question was whether this language permits courts to award restitution in the form of past cleanup costs. We concluded that, despite *Porter*, the provision's grant of equitable authority does not authorize past cleanup costs because the relevant statutory scheme (as here) contained other "'elaborate enforcement provisions,'" including (as here) provisions that explicitly provide for that form of relief. *Meghrig*, 516 U. S., at 487. Here, the inference against §13(b)'s authorization of monetary relief is strong and follows from the interpretive approach we took in *Meghrig*.

Second, the Commission argues that Congress simply created two enforcement avenues, one administrative and the other judicial, leaving the Commission the power to decide which of the two "separate, parallel enforcement paths" to take. Brief for Respondent 41. To the extent that §19 authorizes "similar relief" as §13(b), the Commission continues, that reflects only the fact that each pathway is an alternative route to "similar endpoints." *Id.*, at 41–42. This statement, however, does not overcome the interpretive difficulties we have set forth, for example permitting the Commission to avoid the conditions and limitations laid out in §19. We cannot believe that Congress merely intended to enact a more onerous alternative to §13(b) when it enacted §19 two years later.

Third, the Commission points to saving clauses in §19, which, it says, save its ability to use §13(b) to obtain monetary relief. See *id.*, at 42. Those clauses preserve "any authority of the Commission under any other provision of law" and preserve "any other remedy or right of action provided

by State or Federal law." 15 U. S. C. §57b(e). Here, however, the question is not one of preserving pre-existing remedies given by other statutory provisions. The question is whether those other provisions (namely, §13(b)) gave that remedy in the first place.

Fourth, the Commission points out that the courts of appeals have, until recently, consistently accepted its interpretation, and that Congress has in effect twice ratified that interpretation in subsequent amendments to the Act. See, *e.g.*, Brief for Respondent 8, and n. 3 (citing the similar conclusions of eight Circuits). But see *FTC* v. *Credit Bureau Center*, *LLC*, 937 F. 3d 764 (CA7 2019); *FTC* v. *AbbVie Inc.*, 976 F. 3d 327 (CA3 2020). We have held that Congress' acquiescence to a settled judicial interpretation can suggest adoption of that interpretation. See, *e.g.*, *Monessen Southwestern R. Co.* v. *Morgan*, 486 U. S. 330, 338 (1988). We have also said, however, that when "Congress has not comprehensively revised a statutory scheme but has made only isolated amendments . . . [i]t is impossible to assert with any degree of assurance that congressional failure to act represents affirmative congressional approval of [a court's] statutory interpretation." *Alexander* v. *Sandoval*, 532 U. S. 275, 292 (2001) (internal quotation marks omitted). We find this latter statement the more relevant here.

The two examples of acquiescence to which the Commission refers do not convince us that Congress acquiesced in the lower courts' interpretation. The Commission first points to amendments that Congress made to the Act in 1994. See §10, 108 Stat. 1695–1696. Those two amendments, however, simply revised §13(b)'s venue, joinder, and service rules, not its remedial provisions. They tell us nothing about the words "permanent injunction" in §13(b).

The Commission also points to amendments made to the Act in 2006. Those amendments modified the scope of §5 so that, where certain conduct in foreign commerce is in-

volved, §5 authorizes "'[a]ll remedies available to the Commission,'" including "'restitution.'" See §3, 120 Stat. 3372. We agree, however, that restitution is available, for example, when the Commission uses its administrative process. See, *e.g.*, 15 U. S. C. §57b(b). That being so, these amendments also tell us nothing about the scope of §13(b).

Fifth, the Commission and its *amici* emphasize the policy-related importance of allowing the Commission to use §13(b) to obtain monetary relief. They suggest that it is undesirable simply to enjoin those who violate the Act while leaving them with profits earned at the unjustified expense of consumers. See, *e.g.*, Brief for Respondent 8–9; Brief for Truth in Advertising, Inc., as *Amicus Curiae* 7–13; Brief for American Antitrust Institute as *Amicus Curiae* 9–21; Brief for National Consumer Law Center et al. as *Amici Curiae* 10–20; Brief for Illinois et al. as *Amici Curiae* 5–11. They point to the billions of dollars that the Commission has returned to consumers as a result of the Commission's §13(b) efforts. See, *e.g.*, Brief for Respondent 8–9; Brief for Illinois et al. as *Amici Curiae* 5.

Nothing we say today, however, prohibits the Commission from using its authority under §5 and §19 to obtain restitution on behalf of consumers. If the Commission believes that authority too cumbersome or otherwise inadequate, it is, of course, free to ask Congress to grant it further remedial authority. Indeed, the Commission has recently asked Congress for that very authority, see Hearing before the Senate Committee on Commerce, Science, and Transportation on Oversight of the Federal Trade Commission, Prepared Statement of the FTC, 116th Cong., 2d Sess., 3–5 (2020), and Congress has considered at least one bill that would do so, see S. 4626, 116th Cong., 2d Sess., §403 (2020) (revising §13 to expressly authorize restitution and disgorgement). We must conclude, however, that §13(b) as currently written does not grant the Commission authority to obtain equitable monetary relief.

* * *

For these reasons, we reverse the Ninth Circuit's judgment, and we remand the case for further proceedings consistent with this opinion.

It is so ordered.