No. 16-

In The
Supreme Court of the United States

ETHICON ENDO-SURGERY, INC.,

Petitioner,

v.

COVIDIEN LP AND MICHELLE K. LEE, DIRECTOR, U.S. PATENT AND TRADEMARK OFFICE.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

Steven D. Maslowski
Jason Weil
AKIN GUMP STRAUSS HAUER & FELD LLP
2 Commerce Square
Suite 4100
Philadelphia, PA 19103
(215) 965-1200

Philip S. Johnson
JOHNSON & JOHNSON
1 Johnson & Johnson Plaza
New Brunswick, NJ 08933
(732) 542-2368

Pratik A. Shah
Counsel of Record
Z.W. Julius Chen
AKIN GUMP STRAUSS HAUER & FELD LLP
1333 New Hampshire Avenue, NW
Washington, DC 20036
(202) 887-4000
pshah@akingump.com

Counsel for Petitioner

QUESTION PRESENTED

The Leahy-Smith America Invents Act, following established principles of administrative law, sets up a scheme in its newly established inter partes patent challenge proceedings that requires separate decisions to be made for institution and adjudication by two different decisionmakers: The Act provides that "[t]he Director" of the U.S. Patent and Trademark Office "shall determine whether to institute an inter partes review under this chapter," 35 U.S.C. § 314(b), and that "[t]he Patent Trial and Appeal Board shall *** conduct each inter partes review instituted under this chapter," *id.* § 316(c).

The Director subsequently promulgated a regulation providing that "[t]he Board institutes the trial on behalf of the Director." 37 C.F.R. § 42.4(a). As a result, the separate statutory functions in sections 314 and 316(c) are now combined before a single panel of the Board, which first decides whether to institute inter partes review and then rules on the merits.

The question presented is:

Whether the Leahy-Smith America Invents Act permits the Patent Trial and Appeal Board instead of the Director to make inter partes review institution decisions.

PARTIES TO THE PROCEEDINGS

Petitioner Ethicon Endo-Surgery, Inc., was the patent owner before the Patent Trial and Appeal Board and the appellant in the court of appeals.

Covidien LP was the petitioner before the Patent Trial and Appeal Board and the appellee in the court of appeals.

Michelle K. Lee, Director, U.S. Patent and Trademark Office, intervened in the court of appeals.

RULE 29.6 DISCLOSURE

Ethicon Endo-Surgery, Inc. is a subsidiary of Ethicon, Inc., which is a subsidiary of Johnson & Johnson. No publicly held company directly owns 10% or more of Ethicon Endo-Surgery, Inc. stock.

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INTRODUCTION

This petition, which arises out of the Patent Trial and Appeal Board's invalidation of Petitioner Ethicon Endo-Surgery, Inc.'s patent in an inter partes review proceeding, presents a fundamental question of statutory interpretation common to the over thousand such proceedings filed annually at the U.S. Patent and Trademark Office (PTO). The Leahy-Smith America Invents Act (Act or AIA) explicitly commits the threshold, discretionary decision to *institute* inter partes review to the *Director* of the PTO. In equally explicit terms, the AIA charges the *Board* with *conducting* any inter

partes review instituted by the Director. Following a longstanding policy of separation-of-functions whereby adjudicatory officers inside an agency (such as administrative law judges or, here, administrative patent judges) are insulated from discretionary executive functions, Congress intended this scheme to protect patent owners against harassment by would-be patent challengers.

Disregarding the AIA's bifurcated decisionmaking structure and the Patent Act's other limits on the statutory power to delegate her functions, the Director has promulgated a regulation diverting all institution decisions from the Director to the Board. Under that regulation, gatekeeping institution decisions and merits adjudication are now combined in the Board.

The Federal Circuit below sustained the validity of that regulation, but it did so only by: (i) disregarding the separation of functions between the Director and the Board that Congress made explicit in the AIA; (ii) relying on expansive notions of "inherent" administrative powers; and (iii) disparaging one of this Court's precedents. As Judge Newman notes in her dissent from the denial of rehearing en banc, "[i]gnoring the statutory division of responsibility is contrary to the plain text and carefully designed structure of the America Invents Act, and imperils the public confidence in the fairness and correctness of these proceedings." App., *infra*, 42a.

Because the PTO's commingling of decisionmakers departs from unambiguously expressed congressional intent as well as established administrative law principles, and radically distorts

the central new mechanism for addressing questions of patent validity, this Court should grant certiorari.

OPINIONS BELOW

The opinion of the court of appeals (App., *infra*, 1a-38a) is reported at 812 F.3d 1023. The order and opinion respecting the court of appeals' denial of rehearing en banc (App., *infra*, 39a-48a) is reported at 826 F.3d 1366.

JURISDICTION

The court of appeals entered its judgment on January 13, 2016. Ethicon timely filed a petition for rehearing en banc, which was denied on June 22, 2016. This Court has jurisdiction pursuant to 28 U.S.C. § 1254(1).

RELEVANT STATUTORY AND REGULATORY PROVISIONS

The relevant statutory and regulatory provisions are reproduced at App., *infra*, 107a-138a.

STATEMENT OF THE CASE

A. Statutory and Regulatory Framework

1. The AIA creates a process called "inter partes review," which "allows a third party to ask the U.S. Patent and Trademark Office to reexamine the claims in an already-issued patent and to cancel any claim that the agency finds to be unpatentable in light of prior art." *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2136 (2016) (citation omitted). Congress separated inter partes review into two distinct phases with two distinct decisionmakers.

First, "[t]he Director [of the PTO] shall determine whether to institute an inter partes review." 35 U.S.C. § 314(b). Such review "may," in the Director's discretion, be "authorize[d]" and "instituted" only when "the Director determines *** that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." *Id.* § 314(a); *see, e.g.,* AIA, Pub. L. No. 112-29, § 6(c)(2)(B), 125 Stat. 284, 304 (2011) (permitting the Director to set a limit upon the number of inter partes review proceedings in the first years after the Act goes into effect). The "decision to deny a petition is a matter committed to the Patent Office's discretion." *Cuozzo*, 136 S. Ct. at 2140.

If the Director finds institution appropriate, "the Director's determination under [section 314(a)]" is communicated to the petitioner and patent owner in writing. 35 U.S.C. § 314(c). The "Director, in his or her discretion, may join *** part[ies] to that inter partes review" that "the Director *** determines" also have filed petitions "warrant[ing] the institution of an inter partes review," *id.* § 315(c), and "may determine the manner in which the inter partes review *** may proceed"—"including providing for stay, transfer, consolidation, or termination"—in relation to "another proceeding or matter involving the patent *** before the Office," *id.* § 315(d). In doing so, "the Director" may protect a patent owner from such a proceeding by "tak[ing] into account whether, and reject[ing] the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office." *Id.* § 325(d). No appeal may be taken from

"[t]he determination by the Director whether to institute an inter partes review." *Id.* § 314(d).

Second, following institution, "[t]he Patent Trial and Appeal Board shall, in accordance with section 6 [of title 35], conduct each inter partes review instituted under this chapter." 35 U.S.C. § 316(c). Section 6 specifies that the "Board shall *** conduct inter partes reviews" by at least "3-member panels" comprised of "administrative patent judges *** appointed by the Secretary [of Commerce]." *Id.* § 6(a)-(c); *see Cuozzo*, 136 S. Ct. at 2137. Other sections provide for further development of the record, including discovery, briefing, and an oral hearing, 35 U.S.C. § 316(a)—culminating in the Board's issuance of a "final written decision with respect to the patentability" of the claims at issue, *id.* §§ 316(e), 318(a). The Board's final written decision is appealable to the Federal Circuit. 28 U.S.C. § 1295(a)(4)(A); 35 U.S.C. § 141(c).

2. The Director is required to prescribe regulations governing inter partes review, taking into account "the effect of any such regulation on the economy, the integrity of the patent system, the efficient administration of the Office, and the ability of the Office to timely complete proceedings instituted under this chapter." 35 U.S.C. § 316(a)-(b). In 2012, the Director promulgated regulations providing (as relevant here) that "[t]he Board institutes the trial on behalf of the Director." 37 C.F.R. § 42.4(a); *see also id.* § 42.2 (defining "trial" to include inter partes review). The Director explained that "[s]ection 42.4(a) specifically delegates the determination to institute a trial to the Board." 77 Fed. Reg. 48612, 48616 (Aug. 14, 2012).

B. Factual and Procedural History

1. Petitioner Ethicon holds U.S. Patent No. 8,317,070 ("the '070 patent"), which is directed to surgical staplers used to staple, secure, and seal tissues during surgeries. App., *infra*, 3a. In 2010, Respondent Covidien LP began selling surgical staplers—touted as one of its most successful product lines ever—that achieved $1 billion in sales within three years of introduction to the market. *Id.* at 6a-7a.

2. In 2013, Covidien filed a petition for inter partes review, seeking cancellation of all claims of the '070 patent. In support of institution, Covidien submitted (among other documents) eight purported prior art references and a 100+-page expert declaration by a former employee construing the '070 patent claims and labeling them unpatentable. C.A. App. A172-173, A464-576, A580; App., *infra*, 66a.

Exercising authority delegated pursuant to 37 C.F.R. § 42.4(a), "the Board *** determined to institute an *inter partes* review" on the ground that Covidien had satisfied "[t]he standard for instituting an *inter partes* review *** set forth in 35 U.S.C. § 314(a)." App., *infra*, 78a-79a. According to the Board's 24-page institution decision, there was a "reasonable likelihood" that the '070 patent claims, as construed by the Board, were obvious in light of a combination of prior art references. *Id.* at 78a (quoting 35 U.S.C. § 314(a)). In reaching that conclusion, the Board repeatedly "credit[ed] the testimony of Covidien's expert witness *** [concerning what] one with ordinary skill in the art would have known." *Id.* at 92a-104a.

Following a "trial" at which no live testimony was heard, the Board—specifically, the same three-member panel that instituted review—issued a final written decision invalidating the '070 patent claims for the same reasons set forth in the institution decision. As an initial matter, the Board held that it was "not persuaded that a change in claim construction from that issued in the Decision to Institute is merited." App., *infra*, 56a-59a. As to obviousness, the Board found that "[Ethicon's] evidence is entitled to less weight than [Covidien's] evidence," again relying on Covidien's expert witness declaration and finding that such evidence "has not been rebutted." *Id.* at 59a-67a.

3. Ethicon appealed to the Federal Circuit on the ground that the AIA precludes the Director from delegating her institution authority to the Board.[1] The Director intervened. The Federal Circuit upheld the Board's final written decision in a split decision.[2]

a. The majority declared that "[t]here is nothing in the statute or legislative history of the statute indicating a concern with separating the functions of initiation and final decision." App., *infra*, 15a. Noting the impracticality of the Director personally

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[1] Ethicon also appealed (unsuccessfully) the Board's invalidation of the '070 patent claims on the merits. App., *infra*, 21a-24a. That aspect of Ethicon's appeal is not at issue here.

[2] The Federal Circuit did not accept Respondents' suggestion that Ethicon had waived the question presented, and was unanimous in rejecting the argument that 35 U.S.C. § 314(d) precluded its resolution on appeal. App., *infra*, 9a-10a. That holding comports with this Court's decision in *Cuozzo*, 136 S. Ct. at 2139-2142.

handling each institution decision, the majority relied upon the general principle that agency heads ordinarily possess "inherent" authority to delegate their functions to their subordinates. *Id.* at 15a-20a.

Despite rejecting Ethicon's reliance on (*inter alia*) *Cudahy Packing Co. v. Holland*, 315 U.S. 357 (1942) (in which this Court inferred an absence of an implied authority to delegate where Congress had provided an explicit but limited authority to delegate) as a precedent "lower courts no longer follow," App., *infra*, 17a, the majority acknowledged that delegation authority must yield to congressional intent to preclude a particular delegation. But it found no such congressional intent with respect to delegation of the institution function to the Board. The majority discounted Congress's (i) explicit division of inter partes review into an institution determination by the Director and a subsequent trial by the Board, 35 U.S.C. §§ 314, 316(c); (ii) provision of express delegation authority to the Director only for the officers and employees she appoints or hires (and thus not authorizing delegations to the judges of the Board, who are appointed by the Secretary of Commerce), *id.* § 3(b)(3)(B); and (iii) delineation of the Board's jurisdiction as including only the "conduct" of inter partes review proceedings, *id.* § 6(b)(4), not the institution of such proceedings. App., *infra*, 16a-20a.

The majority further concluded that "Congress's vesting of broad rulemaking powers in the head of the agency is an alternate source of authority to delegate." App., *infra*, 20a. In its view, Congress "intended the Director to have power by rulemaking to define the structure of inter partes review,

including the power to subdelegate tasks assigned to her in the interest of efficiency." *Id.* Finding Congress to have been "ambiguous" as to whether institution "requires [the Director's] personal participation," the majority deferred to the Director's regulation as a "permissible interpretation of the statute." *Id.* (citing *Chevron USA Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842-843 (1984)).

The majority rejected any due process or separation-of-functions concerns arising from collapsing the institution and adjudication function into a single decisionmaker. It characterized both the institution decision and the final written decision as "adjudicative" and therefore discounted the relevance of the Administrative Procedure Act's (APA) prohibition on "investigative or prosecuting" personnel participating in final adjudicative decisions. App., *infra*, 12a-13a & n.3 (quoting 5 U.S.C. § 554(d)).

b. Judge Newman dissented. She explained that the question was not whether the Director could delegate the institution determination at all; all parties agreed that it would be permissible for the Director to delegate the determination to an examiner or solicitor, for example. App., *infra*, 26a-27a. Instead, the question was whether that delegation could be made to the Board—a purely adjudicative body—when the statute "divided the functions of institution and trial into separate bodies within the PTO." *Id.* at 26a.

Judge Newman concluded that "proceedings in which the Board makes both decisions *** cannot be reconciled with the statute," which "repeats several

times the requirement that the Director make the institution decision." App., *infra*, 26a, 35a. Noting the criticism of "actual or perceived bias" stemming from a system in which "administrative patent judges are put in the position of defending their prior decisions to institute the trial," Judge Newman further observed that Congress's goal to provide "rigorous inquiry and confident adjudication as a surrogate for district court litigation" is served only by dividing the institution and final-decision functions. *Id.* at 26a, 32a (citation and internal quotation marks omitted).

4. Ethicon filed a timely petition for rehearing en banc, supported by trade associations, corporations, and legal academics as *amici*. The Federal Circuit denied the petition.

Judge Newman authored a further dissent from the denial of rehearing en banc. She warned that "[i]gnoring the statutory division of responsibility is contrary to the plain text and carefully designed structure of the America Invents Act, and imperils the public confidence in the fairness and correctness of these proceedings." App., *infra*, 42a.

REASONS FOR GRANTING THE WRIT

The question presented affects a fundamental aspect of every inter partes review proceeding: whether the Board, the ultimate adjudicator, may replace the Director (or her proper delegee) as the institution decisionmaker. The government cannot avoid the unambiguous instruction, repeated throughout the AIA, that the *Director* is responsible for *instituting* inter partes review, while the *Board* is responsible for *conducting* it. The AIA therefore

leaves no room for a regulation that delegates the institution function to the Board—a body that Congress made clear shall have the power only to conduct any inter partes review already instituted by the Director.

In attempting to avoid the plain text of the AIA, the Federal Circuit assumed that the Director possesses an "inherent" authority to delegate her statutorily specified duties, ostensibly buttressed by *Chevron* deference. Because the Patent Act elsewhere limits the Director's authority to delegate her duties only to officers and employees whom she appoints and hires, it follows that the Director may not delegate such duties to the administrative law judges whom the Secretary of Commerce appoints to the Board. The Federal Circuit and the Director have no license to expand the scope of that delegation authority in the name of expediency—particularly where, as here, the delegation violates the text of the AIA.

Beyond the statute's terms and structure, a system in which the Board institutes inter partes review on a finding of a reasonable likelihood of invalidity, and thereafter tests that finding in an inter partes review trial, runs headlong into established administrative law limits. As this Court has explained, in order to guard against the propensity of a single decisionmaker to uphold its prior actions, Congress has long required (most notably, through the APA) a separation of executive and adjudicative functions below the level of an agency head. It was thus no accident that Congress, in enacting the AIA, envisioned that an executive officer (the Director or a proper delegee) would make

the discretionary decision to institute inter partes review, and that the judges of the Board would conduct that review independent of preconceived notions formed in the institution phase.

The Director's removal of the separation-of-functions safeguard fundamentally alters the nature of inter partes review—to the detriment of the innovative community and the public. The Board's final decisions not only bear the taint of prejudgment; they unsurprisingly result in the affirmance of institution decisions and the invalidation of patent claims in the vast majority of cases. Given the rapid growth of inter partes review into the primary means for reviewing patent validity, this Court should grant certiorari to ensure that those proceedings are conducted as Congress intended.

I. THE DIRECTOR'S DELEGATION OF THE INSTITUTION DECISION TO THE BOARD CONTRAVENES THE STATUTE

Congress "establishe[d] a two-step procedure for inter partes review: the *Director's* decision whether to institute a proceeding, followed (if the proceeding is instituted) by the *Board's* conduct of the proceeding and decision with respect to patentability." *St. Jude Med., Cardiology Div., Inc. v. Volcano Corp.*, 749 F.3d 1373, 1375-1376 (Fed. Cir. 2014) (emphasis added). That considered choice to entrust those two decisions to distinct decisionmakers, plainly stated in the AIA, cannot be overridden by regulation. *See Federal Election Comm'n v. Democratic Senatorial Campaign Comm.*, 454 U.S. 27, 32 (1981) ("[Courts] must reject administrative constructions of the statute, whether reached by adjudication or by rule-making, that are

inconsistent with the statutory mandate or that frustrate the policy that Congress sought to implement.").

A. The AIA Requires The Director To Institute Inter Partes Review

1. The AIA assigns a different decisionmaker to each phase of inter partes review.

Contrary to the Federal Circuit's conclusion that "nothing in the statute *** indicat[es] a concern with separating the functions of institution and final decision," App., *infra*, 15a, that concern is replete throughout the provisions governing inter partes review. As Judge Newman observed in dissent, "[t]he bifurcated design of post-grant review is clear not only from the language of [AIA] §§ 314(a) and 316(c), but pervades the structure of these post-grant proceedings. Congress unambiguously placed these separate determinations in different decisionmakers, applying different criteria." *Id.* at 28a.

Most fundamentally, the AIA expressly (and repeatedly) assigns the threshold institution decision to the Director—not to the Board. It specifies the standard under which "[t]he *Director* may *** authorize an inter partes review to be instituted," 35 U.S.C. § 314(a) (emphasis added); the deadline by which "[t]he *Director* shall determine whether to institute an inter partes review," *id.* § 314(b) (emphasis added); the steps the Director shall take to "notify the petitioner and patent owner, in writing, of the *Director's* determination under subsection (a)" to institute inter partes review, *id.* § 314(c) (emphasis added); and that "[t]he determination by the *Director*

whether to institute an inter partes review *** shall be final and nonappealable," *id.* § 314(d) (emphasis added). *See also id.* § 315(c) (permitting Director to join parties "[i]f the *Director* institutes an inter partes review") (emphasis added); *id.* § 325(d) (specifying that "the *Director* may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office") (emphasis added). Nowhere does the AIA refer to an institution decision by the Board or otherwise contemplate the Board's participation in that stage of the proceeding.

Instead, the AIA limits the Board's authority to *post*-institution adjudication. The provision governing the "[c]onduct of inter partes review" states that the "Board shall *** conduct each inter partes review instituted under this chapter." 35 U.S.C. § 316(c). The provision establishing the Board likewise enumerates "conduct[ing] inter partes reviews"—but not instituting inter partes reviews—as one of the Board's "[d]uties." *Id.* § 6(b)(4).[3] And the sole decision assigned to the Board is a "final written decision with respect to *** patentability" that is necessary only "i[f] an inter partes review is instituted and not dismissed." *Id.* § 318(a).

The terms and structure of the AIA thus foreclose the reassignment of the institution decision from the Director to the Board at every turn. *See*

[3] The other enumerated duties concern reviewing decisions in examination and reexamination proceedings, as well as conducting derivation proceedings. 35 U.S.C. § 6(b)(1)-(3).

Gomez v. United States, 490 U.S. 858, 872 (1989) (explaining that a "carefully defined grant of authority" in a statute "should be construed as an implicit withholding of [other] authority"); *see also Russello v. United States*, 464 U.S. 16, 23 (1983) ("Congress acts intentionally and purposely in the disparate inclusion or exclusion.").

This case is not one in which "the [AIA] contains *** a gap" that may be filled by the reasonable interpretation of the Director. *Cuozzo*, 136 S. Ct. at 2142. Quite the opposite, the AIA "is clear" that the Director—not the Board—is responsible for instituting inter partes review. *Id.* As such, "that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Chevron*, 467 U.S. at 842-843; *Cuozzo*, 136 S. Ct. at 2142 ("[T]he [PTO] must follow the statute."). The Federal Circuit's invocation of *Chevron* deference, App., *infra*, 20a—particularly when coupled with a purported exercise of the Director's "inherent" delegation authority that independently conflicts with the Patent Act (*see* pp. 15-21, *infra*)—is no answer.

2. The Director may not delegate the institution decision to the Board.

a. The Federal Circuit acknowledged (as it must) that the AIA consistently refers to the Director's institution decision and the Board's final written decision on the merits. App., *infra*, 15a. The court nonetheless opined that both decisions could be made by the Board because "the Director" has "inherent authority and general rulemaking authority" to delegate the institution function to the

Board. *Id.* at 20a. Neither of those supposed sources of authority can surmount the self-evident separation of decisionmakers that Congress demanded.

As Judge Newman explained, the Federal Circuit's reasoning misses the proper inquiry:

> [F]ram[ing] the issue as a simple exercise of the Director's rulemaking and/or delegation authority *** obscures the legislative point; the Director may generally subdelegate, and may exercise procedural rulemaking authority, with regard to these proceedings. Here, however, the statute creates an explicit distinction between the institution phase assigned to the Director, and the merits phase conducted by the [Board]. The question presented, therefore, is whether the PTO may ignore the explicit statutory provision and congressional intent to the contrary. The answer is unequivocally no.

App., *infra*, 46a.

Judge Newman is correct. Although agency heads generally have authority to delegate their tasks, Congress may explicitly or implicitly circumscribe delegation by either restricting that authority or the delegee's ability to undertake delegated tasks. *See Fleming v. Mohawk Wrecking & Lumber Co.*, 331 U.S. 111, 121 (1947) (delegation authority may be limited "by express provision *** or by implication"); *Halverson v. Slater*, 129 F.3d 180, 188-189 (D.C. Cir. 1997) (holding that "Congress's evident intent to circumscribe the [delegee's] operations within narrow geographic and functional

boundaries *** necessarily limits the Secretary's [statutory delegation] authority"). That is true where the statute elsewhere provides for general delegation authority, *see United States v. Giordano*, 416 U.S. 505, 514 (1974) ("Despite § 510 [general delegation authority], Congress does not always contemplate that the duties assigned to the Attorney General may be freely delegated."), or where "a rule-making power" serves as "an adequate source of authority to delegate," *Fleming*, 331 U.S. at 121. At bottom, the question is whether a "provision in the *** Act negative[s] the existence of such authority" or "the absence of such authority [can] be fairly inferred from the history and content of the Act." *Id.* at 121-122.

Here, the Federal Circuit acknowledged but gave short shrift to those principles. App., *infra*, 16a (stating that delegation may be precluded by "evidence of a contrary congressional intent," such as "the enabling statute" and "legislative history") (citation and quotation marks omitted). As an initial matter, the AIA's express division of labor between the Director (instituting review) and the Board (conducting review) itself forecloses the former from delegating away her statutorily specified institution authority to the latter.

In addition, Congress made clear that the Director may delegate her duties only to officers and employees whom she appoints or hires. *See* 35 U.S.C. § 3(b)(3) (providing that "[t]he Director shall *** appoint such officers, employees *** , and agents of the Office as the Director considers necessary" and "delegate to them such of the powers vested in the Office as the Director may determine"). There is no similar provision authorizing unconstrained

delegation to officials whom she does not appoint, such as the Board's administrative law judges who are "appointed by the Secretary [of Commerce]." *Id.* § 6(a). Congress certainly could have imbued the Director with that broader delegation authority, but the fact that it did not "lend[s] support to the view that when Congress desired to give authority to delegate, it said so explicitly." *Fleming*, 331 U.S. at 121.

This Court's decision in *Cudahy Packing Co. v. Holland*—finding "fairly inferable that the grant of authority to delegate the power of inspection and the omission of authority to delegate the subpoena power shows a legislative intention to withhold the latter"—underscores that point. 315 U.S. at 364. The AIA's omission of certain PTO officials (including the Board's judges) from its authorization to delegate to other PTO officials is meaningful. The Federal Circuit's backhanded dismissal of *Cudahy* on the supposed ground that "lower courts no longer follow it" cries out for this Court's attention. App., *infra*, 17a (quoting 1 RICHARD J. PIERCE, JR., ADMINISTRATIVE LAW TREATISE § 2.7, at 125 (5th ed. 2010)).

b. The Federal Circuit discounted all of those statutory and precedential limits on delegation on the view that "Congress obviously assumed that the Director would delegate" rather than "review every petition" herself. App., *infra*, 18a; *see id.* at 20a ("Congress undoubtedly intended the Director to have power by rulemaking *** to subdelegate tasks assigned to her in the interest of efficiency."). That purported efficiency justification cannot surmount the AIA's text, but it is a *non sequitur* in any event.

Although "the Director, as head of the PTO, regularly assign[s] tasks to subordinate officers" in situations such as (re)issuing patents, *id.* at 18a (citing 35 U.S.C. § 131, 132(a), 251(a)), those delegations shed no light on whether the delegation of the institution decision *to the Board* specifically is lawful here.

Even on its own terms, the Federal Circuit's expediency concern is unfounded. Precluding delegation of the institution decision to the Board would not force the Director herself to review every inter partes review petition. As Judge Newman observed, "[o]f course, the Director may designate an examiner or solicitor to conduct this initial review." App., *infra*, 27a (Newman, J., dissenting). Had the Director done so, there would be no issue.

But delegating the institution duty to the Board is another matter. Even beyond the statutory impediments to such a delegation, the Board's administrative law judges are particularly ill-suited to exercise the sort of executive discretion the AIA vested in the Director with respect to institution and associated procedural matters. Indeed, the Federal Circuit all but ignored the fact that Congress armed the Director with the ability (i) to protect the operation of the inter partes review system by declining to institute review even where the statutory threshold is met, and (ii) to determine the manner in which inter partes review and related PTO proceedings should proceed. *See* pp. 22-24, *infra*.

Nor is there any basis to read section 3(b)(3) as anything but a constraint on the Director's authority to delegate the institution decision to the Board. The Federal Circuit took the view that section 3(b)(3) fails

to impose that constraint because it is not directed at a particular "function" and does not expressly limit the Director's authority to delegate to other independently appointed officials. App., *infra*, 19a. But there is no reason to treat express authority to delegate particular functions differently from express authority to delegate to particular officials; either way, Congress's provision of limited express delegation authority indicates that Congress did not intend to permit other delegations by implication. To hold otherwise would furnish the Director with an unbounded delegation authority that renders section 3(b)(3)(B) entirely superfluous. *See Corley v. United States*, 556 U.S. 303, 314 (2009) (rejecting interpretation "at odds with one of the most basic interpretive canons" of avoiding surplusage).

At any rate, considering section 3(b)(3) together with the scope of the Board's authority—something the Federal Circuit did not do—demonstrates that Congress's delegation scheme *does* cabin the Director's inherent or implied delegation authority by function. The Director may freely delegate to her appointees, but with respect to other PTO officials she may assign only those tasks consistent with the scope of the authority that Congress conferred on those officials. *See Gomez*, 490 U.S. at 864 ("When a statute creates an office to which it assigns specific duties, those duties outline the attributes of the office. Any additional duties performed pursuant to a general authorization in the statute reasonably should bear some relation to the specified duties."). With respect to inter partes review, the only jurisdiction that Congress conferred on the Board is

the power to "conduct" inter partes review. 35 U.S.C. § 6(b)(4).

B. Congress Did Not Sanction A Departure From Established Administrative Law Principles

Not only is the principle of inherent delegation authority insufficient to trump the text and structure of the AIA, but a longstanding principle of administrative law confirms Congress's choice to limit the Board's role to conducting—not instituting—inter partes review. As the Federal Circuit acknowledged, App., *infra*, 12a n.3, the APA generally precludes the combination of executive and adjudicative functions below the level of agency head. *See* 5 U.S.C. § 554(d) (prohibiting an "employee or agent engaged in the performance of investigative or prosecuting functions for an agency in a case" from "participat[ing] or advis[ing] in the decision"); *Martin v. Occupational Safety & Health Review Comm'n*, 499 U.S. 144, 151 (1991) ("[U]nder the Administrative Procedure Act (APA) [an agency] generally must divide enforcement and adjudication between separate personnel[.]"). Congress enacted this provision to "ameliorate the evils from the commingling of functions" by separating the "discretionary work of the administrator," like "initiat[ing] action," from the work "of the [administrative] judge." *Wong Yang Sung v. McGrath*, 339 U.S. 33, 42, 46 (1950) (citation and quotation marks omitted).

Concern over those evils is doubly borne out here. In the final written decision, the same three administrative law judges that instituted inter partes

review explained that they were "not persuaded that a change in claim construction from that issued in the Decision to Institute is merited," and credited the same evidence of obviousness on which the institution decision was based. App., *infra*, 56a-67a. More broadly, "[t]he Board has reversed course and found patentability after institution in just 9% of *inter partes* reviews." *Id.* at 47a (Newman, J., dissenting from denial of rehearing en banc). At the very least, those statistics raise the specter of "prejudgment" that the APA's separation-of-function's provision guards against. *Id.*; *see Wong Yang Sung*, 339 U.S. at 42 ("Commission decisions affecting private rights and conduct lie under the suspicion of being rationalizations of the preliminary findings which the commission *** presented to itself.") (citation and quotation marks omitted).

The Federal Circuit rejected the application of the APA's separation-of-functions provision here because it concluded that both the institution and final decisions are "adjudicatory decisions" and do not combine adjudicative and executive functions. App., *infra*, 13a. Not so. The AIA reflects Congress's intent to make the institution decision a discretionary, executive gatekeeping determination distinct from the purely adjudicatory function of deciding patentability. It is plain that institution is not solely an adjudicative function because the AIA does not require the Director to institute an inter partes review whenever the institution standard is satisfied—*i.e.*, whenever there is a "reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged." 35 U.S.C. § 314(a). Rather, the Act provides the

Director with *discretion* to institute an inter partes review (or not) when that standard is met. *Id.* (Director "may" institute); *see Kingdomware Techs., Inc. v. United States*, 136 S. Ct. 1969, 1977 (2016) ("the word 'may' *** implies discretion"); *see also* 157 CONG. REC. S1377 (daily ed. Mar. 8, 2011) (statement of Sen. Kyl) (explaining that the AIA reflects a legislative judgment that it is better to turn away some petitions that otherwise satisfy the threshold for instituting review than for the PTO to develop a backlog). That the Director's institution decision is non-appealable—thereby conferring unreviewable discretion on the Director—reinforces that it is an executive function. *See* 35 U.S.C. § 314(d); *Cuozzo*, 136 S. Ct. at 2140.

The Director's role in inter partes review is also infused with discretion in other respects. In making the institution determination, Congress contemplated that the Director would take into account considerations outside of the merits of the petition at hand, including considerations regarding the operations of the PTO. *See, e.g.*, 35 U.S.C. § 316(b) (requiring the Director to consider, *inter alia*, the economy, the integrity of the patent system, and the efficient administration of the Office in adopting inter partes review regulations); AIA, Pub. L. No. 112-29, § 6(c)(2)(B), 125 Stat. at 304 (permitting the Director to set a limit upon the number of inter partes review proceedings in the first years after the Act goes into effect). Similarly, "the Director, in his or her discretion, may join *** a party" that separately files a petition that "the Director *** determines warrants the institution of an inter partes review." 35 U.S.C. § 315(c). And in the face of related PTO proceedings,

"the Director may determine the manner in which the inter partes review *** may proceed, including providing for stay, transfer, consolidation, or termination"—regardless of the merits. *Id.* § 315(d).

Because the statute contemplates that the Director's threshold management of inter partes review—including the unreviewable institution decision—would turn on factors beyond the application of the institution standard to a particular petition, it is a quintessentially executive function akin to the administrative prosecutorial function. *Cf. Heckler v. Chaney*, 470 U.S. 821, 831 (1985) (An agency decision whether to initiate an enforcement action "often involves a complicated balancing of a number of factors," including "not only *** whether a violation has occurred, but whether agency resources are best spent on this violation or another," whether taking action "best fits the agency's overall policies," and "whether the agency has enough resources.").

The Board, as an adjudicative body, is not equipped to make these sorts of discretionary determinations. And assigning the institution decision to that body turns an executive function into a wholly adjudicative one. *See* App., *infra*, 78a-79a (instituting inter partes review based exclusively on section 314(a) reasonable likelihood standard without consideration of other factors). The AIA forecloses that result.

II. THE DIRECTOR'S DELEGATION OF INSTITUTION AUTHORITY TO THE BOARD IS AN EXCEPTIONALLY IMPORTANT ISSUE OF PATENT LAW AND ADMINISTRATIVE LAW

The commingling of inter partes review decisionmakers, as endorsed by the Federal Circuit, subverts congressional intent, flouts statutory limits on the exercise of delegation authority, and contravenes established administrative law principles. It also undermines a decades-long effort, culminating in the enactment of the AIA, to "correct flaws in the [U.S. patent] system that ha[d] become unbearable, and to accommodate changes in the economy and the litigation practices in the patent realm." H.R. REP. NO. 112-98, pt. 1, at 38-39 (2011). And worse still, it "has devastating consequences for the public confidence in post-grant proceedings and the patent system as a whole." App., *infra*, 47a (Newman, J., dissenting from denial of rehearing en banc). This Court's review is thus of undeniable importance.

A. The Decision Below Unduly Expands Agency Authority

By relying on two atextual agency powers—inherent delegation authority plus *Chevron* deference—the Federal Circuit has swept aside statutory constraints on the Director's delegation authority both generally (35 U.S.C. § 3(b)(3)) and with respect to inter partes review institution decisions specifically (*id.* §§ 314, 316(c)). In doing so, as explained above, the Federal Circuit has trampled on longstanding precedents of this Court that dictate

a nuanced statutory analysis of limits on an agency head's delegation authority, and that require the separation of an agency's executive and adjudicative functions. *See* pp. 15-24, *supra*.

In particular, the Federal Circuit's invocation of the Director's "inherent" delegation authority, coupled with its application of *Chevron* deference to the Director's general rulemaking authority, App., *infra*, 20a, confers on an agency head essentially carte blanche to delegate her powers unless Congress (unrealistically) creates even more specific and explicit limits than already present in the Patent Act. That significant expansion of agency authority, as well as the need to harmonize the administrative law applied to the PTO with general principles of administrative law applied to other agencies, warrants this Court's review.

B. Disregard Of The Statutory Safeguards Governing Inter Partes Review Demands Intervention

The creation of inter partes review was a "[k]ey [e]lement[]" of long overdue patent reform. Press Release, The White House, President Obama Signs America Invents Act, Overhauling the Patent System to Stimulate Economic Growth, and Announces New Steps to Help Entrepreneurs Create Jobs (Sept. 16, 2011).[4] But it was not without controversy. The legislative "record is replete with *** concerns of commentators, patentees, and the PTO" that inter

[4] https://www.whitehouse.gov/the-press-office/2011/09/16/president-obama-signs-america-invents-act-overhauling-patent-system-stim.

partes review would "increase the risks faced by patent holders and dampen their enthusiasm for investing in the development and commercialization of their patented technologies." App., *infra*, 43a (Newman, J., dissenting from the denial of rehearing en banc) (citation and quotation marks omitted). Congress addressed those concerns by "meticulously incorporat[ing] safeguards against *** harassment of patentees" and "carefully design[ing] post-grant procedures"—of which "[t]he Director's institution decision" is critical. *Id.* at 43a-44a; *see id.* at 45a ("Independence of the two decision-makers is crucial to achieving the statutory purpose.").

In allowing those statutorily mandated safeguards to be removed by regulation for sake of expediency, the Federal Circuit vitiated the careful balance struck by Congress and "[t]hreaten[ed] the viability of this new system." App., *infra*, 31a (Newman, J., dissenting). The more than 4,000 petitions for inter partes review to date—at least three times as many as initially anticipated—make clear that such proceedings "have become the new frontier of patent litigation." *Id.* at 31a & n.1.; Michelle K. Lee, *PTAB Update: Proposed Changes to Rules Governing PTAB Trial Proceedings*, Director's Forum: A Blog from USPTO's Leadership (Aug. 19, 2015) (providing statistics).[5] But that new frontier at a minimum bears the "taint of prejudgment," App., *infra*, 47a (Newman, J., dissenting from denial of rehearing en banc), that naturally arises when

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[5] http://www.uspto.gov/blog/director/entry/ptab_update_proposed_changes_to.

"administrative patent judges are put in the position of defending their prior decisions to institute the trial," *id.* at 32a (Newman, J., dissenting) (citation and internal quotation marks omitted). Strikingly, according to the PTO's latest statistics, 85% of patents that reach a final written decision are invalidated in whole or in part. USPTO, Patent Trial and Appeal Board Statistics 10 (July 31, 2016)[6]; *see also* App., *infra*, 47a (Newman, J., dissenting from denial of rehearing en banc) ("[J]ust 15.2% of instituted claims survive[] *inter partes* review."). A patent system with "th[os]e numbers do[es] not bode confidence," App., *infra*, 47a (Newman, J., dissenting from denial of rehearing en banc), let alone "promote innovation" or "benefit[] the public," H.R. REP. NO. 112-98, pt. 1, at 40; *see also* Richard Baker, *America Invents Act Cost the U.S. Economy Over $1 Trillion*, Patently O (June 8, 2015) (discussing economic impact of inter partes review).[7]

At stake, therefore, is not only the fair and lawful operation of the inter partes review system, but the strength of the patent system as a whole. In granting certiorari in *Cuozzo*, 136 S. Ct. 2131, this Court signaled the importance of ensuring that inter partes review functions as Congress intended. And as evidenced by the number of certiorari petitions challenging various facets of inter partes review, *e.g.*, *Merck & Cie v. Gnosis S.p.A.*, No. 16-125 (U.S.)

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[6] http://www.uspto.gov/sites/default/files/documents/2016-07-31%20PTAB.pdf.

[7] http://patentlyo.com/patent/2015/06/america-invents-trillion.html.

(standard of review); *Cooper v. Square, Inc.*, No. 16-76 (U.S.) (violation of Article III); *MCM Portfolio LLC v. Hewlett-Packard Co.*, No. 15-1330 (U.S.) (violation of Article III and Seventh Amendment), the manner in which those proceedings are conducted continues to be a subject of pressing concern to stakeholders—including *amici* that urged the Federal Circuit to reconsider the decision below. Because this case constitutes the most straightforward way to restore the promise of inter partes review as enacted by Congress, this Court's review is warranted.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

Philip S. Johnson
JOHNSON & JOHNSON

Pratik A. Shah
Counsel of Record
Steven D. Maslowski
Z.W. Julius Chen
Jason Weil
AKIN GUMP STRAUSS
HAUER & FELD LLP

Counsel for Petitioner

September 20, 2016

APPENDIX TO THE PETITION FOR A WRIT OF CERTIORARI

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United States Court of Appeals for the Federal Circuit

ETHICON ENDO-SURGERY, INC.,
Appellant

v.

COVIDIEN LP,
Appellee

2014-1771

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2013-00209.

Decided: January 13, 2016

PHILIP STATON JOHNSON, Johnson & Johnson, New Brunswick, NJ, argued for appellant. Also represented by STEVEN D. MASLOWSKI, RUBEN H. MUNOZ, JASON WEIL, Akin, Gump, Strauss, Hauer & Feld, LLP, Philadelphia, PA; PRATIK A. SHAH, HYLAND HUNT, Washington, DC.

KATHLEEN DALEY, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, Washington, DC, argued for appellee. Also represented by J. MICHAEL JAKES; J. DEREK MCCORQUINDALE, Reston, VA.

KATHERINE TWOMEY ALLEN, Appellate Staff, Civil Division, United States Department of Justice, Washington, DC, argued for intervenor MICHELLE K. LEE. Also represented by BENJAMIN C. MIZER, MARK R. FREEMAN; NATHAN K. KELLEY, SCOTT WEIDENFELLER, STACY BETH MARGOLIES, Office of the Solicitor, United States Patent and Trademark Office, Alexandria, VA.

Before NEWMAN, DYK and TARANTO, *Circuit Judges*.

Opinion for the court filed by *Circuit Judge* DYK.

Dissenting opinion filed by *Circuit Judge* NEWMAN.

DYK, *Circuit Judge*.

Ethicon Endo-Surgery, Inc. ("Ethicon") owns U.S. Patent No. 8,317,070 ("the '070 patent"). Covidien LP ("Covidien") petitioned the United States Patent and Trademark Office ("PTO") for inter partes review of claims 1-14 of the '070 patent. The PTO, through a panel of the Patent Trial and Appeals Board ("PTAB" or "Board"), granted the petition. On the merits, the same Board panel found

all challenged claims invalid as obvious over the prior art. Ethicon appeals, asserting that the Board's final decision is invalid because the same Board panel made both the decision to institute and the final decision. Ethicon also asserts that the Board erred in finding the claims obvious.

We first hold that 35 U.S.C. § 314(d) does not preclude us from hearing Ethicon's challenge to the authority of the Board to render a final decision. On the merits we hold that neither the statute nor the Constitution precludes the same panel of the Board that made the decision to institute inter partes review from making the final determination. We also find no error in the Board's determination that the '070 patent claims would have been obvious over the prior art. Accordingly, we affirm.

BACKGROUND

The claims of the '070 patent are directed to a surgical device used to staple, secure, and seal tissue that has been incised. As the specification describes, a typical embodiment can both make the incision and simultaneously apply lines of staples on opposing sides of the incision. '070 Patent col. 7 ll. 5-31. As is commonly done during endoscopic procedures, a surgeon will insert the device into the patient and will pull a trigger to latch onto a desired tissue. Once attached, the surgeon will then pull another trigger, which causes a blade to move, cutting the desired tissue. Simultaneously, rows of staples on either side of the cutting blade are actuated against a staple forming surface, both securing and sealing the newly-cut tissue.

Claim 1 is representative of the claimed invention:

> A surgical stapling device comprising an end effector that comprises:
>
> > a circular anvil having a staple forming surface;
> >
> > a plurality of staples facing the staple forming surface of the anvil, each staple comprising a main portion and two prongs, wherein the two prongs each comprise a first and a second end, wherein the first ends are connected to opposite ends of the main portion, and wherein the *two prongs extend non-parallelly from the main portion*; and
> >
> > a staple driver assembly comprising a plurality of staple drivers, wherein each staple driver supports one of the plurality of staples and is configured such that, when the staple driver assembly is actuated, each staple driver drives the staple into the staple forming surface of the anvil, wherein a *first quantity of the staples have a first pre-deformation height*, measured from a lower surface of the main portion to the second end of the first prong, and *a second quantity of the staples having a second pre-deformation height*,

> measured from a lower surface of the main portion to the second end of the first prong, *wherein the first height is less than the second height*, such that when the staple driver assembly is actuated, the first quantity of staples have a different formed staple length than the second quantity of staples.

(emphases added).

Surgical staplers were not new at the time of the '070 patent. As the patent specification itself describes, these types of devices were well known and had been commonly used. '070 Patent col. 1 ll. 45-47. The '070 patent claims two primary aspects of stapler design: the use of staples of different pre-formed and formed heights (i.e., heights before and after stapling) and the use of staples with nonparallel legs. It is undisputed that both of these improvements, separately, were also well-known in the prior art. Thus, the purported inventive aspect of the '070 patent is the combination of these two features in a surgical stapler. The patent discloses no particular synergy resulting from the combination.

According to the prior art disclosures and the specification, the use of staples of different pre-formed and formed heights is beneficial in a number of ways. For example, "rows of inside staples [can] serve to provide a hemostatic barrier, while the outside rows of staples with larger formed heights [can] provide a cinching effect where the tissue transitions from the tightly compressed hemostatic

section to the non-compressed adjacent section." '070 Patent col. 2 ll. 8-12. This is beneficial because these staples of different sizes "decrease[] leakage rates . . . and provide[] short and long-term tissue strength" after incision. J.A. 290. The use of these different sized staples thus allows this type of device to be used on a broader range of tissue thicknesses. As is uncontested, these staples of varying pre-formed and formed heights were first disclosed 25 years ago by prior art references Tyco Healthcare International Publication No. WO 2003/094747 and U.S. Patent No. 4,941,623.

The primary benefit of using non-parallel legs on staples is that the staple legs press against the side of the staple cartridge and stay in the cartridge without falling out. J.A. 454. As is also uncontested, the use and benefit of these staples was previously disclosed in a 1970 U.S. Patent, No. 3,494,533, and were well known by those in the field, even according to Ethicon's own expert, who testified that he used nonparallel staples "maybe 50 or 75 percent of the time" in his practice.

In 2010, Covidien began selling surgical staplers that, Ethicon contends, embody the claimed invention of the '070 patent. The brochures for these staplers, featuring what Covidien called "Tri-Staple technology," tout "progressive staple heights" that allow "consistent performance over a broader range of tissue thickness." J.A. 1101, J.A. 1126. Notably absent from these brochures, though, was any mention of non-parallel legs on the staples. The staplers using this technology were very successful, achieving over $1 billion in product sales within the

first three years of their introduction to the market. According to Covidien, the Tri-Staple devices are likely to be one of their most successful product lines ever.

Covidien filed a petition with the PTO on March 25, 2013, requesting inter partes review of claims 1-14 of the '070 patent on the ground that the claims would have been obvious over the prior art. The Board granted the petition on August 26, 2013.

In its June 9, 2014, final decision, the same panel of the Board that instituted the inter partes review rejected all of Ethicon's arguments and found all challenged claims of the '070 patent obvious under 35 U.S.C. § 103. It noted that Ethicon admitted that all of the recited elements of the patent claims were found in the prior art. Relying on Covidien's expert testimony, the Board concluded that one of skill in the art would have been motivated to combine the prior art staplers disclosing staples of varying heights with staples of non-parallel legs to securely hold the staples in the cartridge because the benefits of both were well known at the time of the invention. Further, the Board found no suggestion in the prior art teaching away from combining these elements. The Board alternatively found that it would have been obvious to try to combine non-parallel staples with the prior art devices disclosing staples of varying heights because of the "limited choice" of staple designs. J.A. 15. Finally, it found that Ethicon's evidence of secondary considerations did "not overcome the strong case of obviousness." J.A. 19.

Ethicon appeals. We have jurisdiction under 28 U.S.C. § 1295(a)(4)(A). We review the Board's factual findings for substantial evidence and its legal conclusions de novo. *In re Baxter Int'l, Inc.*, 678 F.3d 1357, 1361 (Fed. Cir. 2012).

DISCUSSION

I

Ethicon challenges the final decision of the Board, arguing that the final decision should be set aside because it was made by the same panel that made the decision to institute inter partes review.

The America Invents Act[1] ("AIA") gives the Director the authority to determine whether an inter partes review should be initiated, and the Director has delegated this authority to the Board.[2] The statute specifically gives the Board the power to decide the ultimate question of patent validity. *See* 35 U.S.C. § 318 (requiring that "the Patent Trial and Appeal Board shall issue a final written decision with respect to the patentability of any patent claim

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[1] The relevant portions of the Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) have been codified in Title 35 of the U.S. Code.

[2] *See* 35 U.S.C. § 314(a) ("The Director may not authorize an inter partes review to be instituted unless the Director determines that the information presented in the petition . . . and any response . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition."); 37 C.F.R. § 42.4(a) (stating that the "Board institutes the trial on behalf of the Director").

challenged by the petitioner"). The PTO has determined that, in the interest of efficiency, the decision to institute and the final decision should be made by the same Board panel, in line with the purposes of the AIA, which requires the Director consider the "efficient administration of the [PTO], and the ability of the [PTO] to timely complete proceedings" in promulgating regulations. 35 U.S.C. § 316(b). Ethicon contends that this combination of functions is improper because the statutory text and structure, guided by constitutional principles, require that the decision to institute not be made by the same panel of the Board that makes the ultimate decision and, in fact, that the statute does not authorize the Director to delegate the institution decision to the Board at all.

A

Before we can turn to the substantive questions raised by Ethicon's challenge, we must first decide whether we have jurisdiction to address the combination of functions issue. The PTO, as intervenor, argues that 35 U.S.C. § 314(d) bars us from considering this issue on appeal because it is an issue concerning the institution of an inter partes review proceeding.

Section 314(d) provides that "[t]he determination by the Director *whether to institute an* inter partes *review* shall be final and nonappealable." 35 U.S.C. § 314(d) (emphasis added). Section 314(d) here plainly "prohibits review of the decision to institute [inter partes review] even after a final decision." *In re Cuozzo Speed Techs., LLC*, 793 F.3d

1268, 1273 (Fed. Cir. 2015). It does not, however, preclude review of the final decision. Indeed, § 319 specifically provides for appeal of a final decision: "[a] party dissatisfied with the final written decision of the Patent Trial and Appeal board . . . may appeal the decision." 35 U.S.C. § 319; *see also Versata Dev. Grp., Inc. v. SAP Am., Inc.*, 793 F.3d 1306, 1322 (Fed. Cir. 2015).

Here, Ethicon does not challenge the institution decision, but rather alleges a defect in the final decision. It argues that the final decision is invalid because it was made by the same panel that instituted inter partes review. Section 314(d) does not prevent us from hearing a challenge to the authority of the Board to issue a final decision.

B

On the merits, Ethicon argues that having the same panel make the decision to institute and then later decide the merits of the inter partes review raises "serious due process concerns." Appellant's Br. 35. According to Ethicon, because the panel of the Board is first exposed to a limited record consisting of the petition and patent holder's preliminary response, there is a risk that the panel may prejudge the case before seeing a full record, thereby depriving a patent holder of a due process right to an impartial decision maker. Ethicon argues that to avoid these constitutional concerns, we must construe the statute to preclude the Director from delegating the decision to institute to the same panel of the Board that makes the final decision. We disagree with Ethicon and conclude that, where, as

here, there are no other separate procedural-fairness infirmities alleged, the PTO's assignment of the institution and final decisions to one panel of the Board does not violate due process under governing Supreme Court precedent.

The leading case involving due process and the combination of functions is the Supreme Court's decision in *Withrow v. Larkin*, 421 U.S. 35 (1975). In *Withrow*, the question was whether a physician's due process rights had been violated by a state medical board's suspension of his license when the same board both investigated, and then later adjudicated, the issue. *Id.* at 46. The Court held that there was no due process violation, finding that combining the investigative and adjudicatory functions in a single body does not raise constitutional concerns. *Id.* at 58. Similarly, the Court found no due process violation where Administrative Law Judges determine Social Security disability benefits and, at the preliminary stage, "investigate facts and develop the arguments both for and against granting benefits," *Sims v. Apfel*, 530 U.S. 103, 111 (2000), and "act[] as an examiner charged with developing the facts." *Richardson v. Perales*, 402 U.S. 389, 410 (1971). In fact, "[t]he Supreme Court has never held a system of combined functions to be a violation of due process, and it has upheld several such systems." 2 Richard J. Pierce, Jr., *Administrative Law Treatise* § 9.9, p. 892 (5th ed. 2010).

Lower courts have also rejected due process challenges to systems of adjudication combining functions in an agency. *See, e.g.*, *Riggins v. Goodman*, 572 F.3d 1101, 1112 (10th Cir. 2009) (no

due process concerns in a system for deciding whether to terminate tenured public employees which combined investigative and adjudicatory functions); *In re Seidman*, 37 F.3d 911, 924-26 (3d Cir. 1994) (no due process violation in combining "functions of investigation, prosecution and adjudication" in the Director of the Office of Thrift Supervision when banker was sanctioned); *NLRB v. Aaron Bros. Corp.*, 563 F.2d 409, 413 (9th Cir. 1977) (no due process violation when Regional Director of the NLRB "exercised both investigative and adjudicative responsibilities in connection with the issuance and resolution of [an] unfair labor practice complaint"); *Jonal Corp. v. Dist. Of Columbia*, 533 F.2d 1192, 1197 (D.C. Cir. 1976) (no due process violation simply because of combined functions when contract dispute was decided by officials appointed by officer representing the government). And we have held that there is no due process issue when, in the anti-dumping context, a Department of Commerce official makes both the decision to institute and then the final determination. *NEC Corp. v. U.S.*, 151 F.3d 1361, 1374 (Fed. Cir. 1998). Ethicon cites no case to the contrary.

Here, combining the decision to institute with the final decision in a single panel is less problematic than the situation in *Withrow*.[3] The Board first

[3] Note that the Administrative Procedure Act prohibits "[a]n employee or agent engaged in the performance of investigative or prosecuting functions for an agency" from participating "in the decision . . . except as witness or counsel." 5 U.S.C. § 554(d). However, the APA imposes no separation

decides whether a petition demonstrates a likelihood of success on the merits, and, if it does, makes a decision to institute inter partes review. During the merits, the Board decides whether the petition actually succeeds. Both the decision to institute and the final decision are adjudicatory decisions and do not involve combining investigative and/or prosecutorial functions with an adjudicatory function. The inter partes review procedure is directly analogous to a district court determining whether there is "a likelihood of success on the merits" and then later deciding the merits of a case. *See, e.g.*, Fed. R. Civ. P. 65; *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). As *Withrow* also made clear, "pretrial involvements," such as "issuing or denying a temporary restraining order or a preliminary injunction" do not "raise any constitutional barrier against the judge's presiding" over the later trial. *See Withrow*, 421 U.S. at 56.

Lastly, Ethicon argues that the Board panel's exposure to a limited record in the decision to institute improperly biases it so as to disqualify it from making the final decision on the merits. But, as *Withrow* held, adjudicators are afforded a "presumption of honesty and integrity" and even "exposure to evidence presented in nonadversary investigative procedures is insufficient in itself to impugn the fairness of [adjudicators] at a later adversary hearing." *Withrow*, 421 U.S. at 47, 55. As the Court has also made clear, "opinions held by

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obligation as to those involved in preliminary and final decisions.

judges as a result of what they learned in earlier proceedings" are "not subject to deprecatory characterization as 'bias' or 'prejudice.'" *Liteky v. U.S.*, 510 U.S. 540, 551 (1994).[4]

To rise to the level of presenting actual bias, the challenger must show that an adjudicator is exposed to unofficial, "extrajudicial" sources of information. *See Liteky,* 510 U.S. at 554. For example, the Supreme Court in *Withrow* pointed to a case in which a judge in a criminal context improperly served as a "one-man grand jury," charged two witnesses who appeared before him in the grand jury proceeding with criminal contempt, and then tried and convicted them. 421 U.S. at 53. In line with traditional ethical rules that generally prohibit judges from being witnesses in cases in which they preside, *see, e.g.*, Fed. R. Evid. 605, the problem in that case was that the judge "called on his own personal knowledge and impression of what had occurred in the grand jury room and his judgment

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[4] *See also Hortonville Joint Sch. Dist. No. 1 v. Hortonville Educ. Ass'n*, 426 U.S. 482, 493 (1976) ("Mere familiarity with the facts of a case gained by an agency in the performance of its statutory role does not . . . disqualify a decisionmaker."); *Goldberg v. Kelly*, 397 U.S. 254, 271 (1970) ("[P]rior involvement in some aspects of a case will not necessarily bar a welfare official from acting as a decision maker."); *Mangels v. Pena*, 789 F.2d 836, 838 (10th Cir. 1986) (finding that adjudicator's pre-hearing exposure to an investigative report did not violate due process); *Vanelli v. Reynolds Sch. Dist. No. 7*, 667 F.2d 773, 776 (9th Cir. 1982) (finding that a school board's participation in an initial termination decision did not render the board impermissibly biased when it conducted a subsequent termination hearing).

was based in part on this impression, the accuracy of which could not be tested by adequate cross-examination." *In re Murchison*, 349 U.S. 133, 138 (1955). There is no allegation of exposure to extra-judicial information here. We see no due process concerns in combining the functions of initial decision and final disposition in the same Board panel.

C

We now turn to Ethicon's statutory arguments. Ethicon argues that the history, structure, and content of the AIA reflect a congressional intent to withhold the power of the Director to delegate to the Board the power to institute inter partes review. This was allegedly designed to insulate the Board as final decision maker from the supposed taint of the decision to institute the proceeding. Ethicon argues that because Congress (1) specifically gave the Director the power to institute, *see, e.g.*, 35 U.S.C. § 314(a), (2) did not explicitly give the Director authority to delegate the institution decision to the Board, and (3) gave the Board the power to make the final determination, Congress intended to keep the functions of institution and final decision separate.

There is nothing in the statute or legislative history of the statute indicating a concern with separating the functions of initiation and final decision. Ethicon ignores the longstanding rule that agency heads have implied authority to delegate to officials within the agency, even without explicit statutory authority and even when agency officials have other statutory duties. Congress regularly gives

heads of agencies more tasks than a single person could ever accomplish, necessarily assuming that the head of the agency will delegate the task to a subordinate officer. For example, more than 100 years ago, the Supreme Court in *Parish v. United States* found that the Surgeon General had properly delegated authority to an assistant Surgeon General to place orders with vendors because "it is impossible for a single individual to perform in person all the duties imposed on him by office." 100 U.S. 500, 504 (1879).

The implicit power to delegate to subordinates by the head of an agency was firmly entrenched in *Fleming v. Mohawk Wrecking & Lumber Co.*, where the Supreme Court held the administrator of an agency could delegate the power to sign and issue subpoenas to regional administrators despite absence of an explicit authorization in the statute. 331 U.S. 111, 122 (1947). "When a statute delegates authority to a federal officer or agency, subdelegation to a subordinate federal officer or agency is presumptively permissible absent affirmative evidence of a contrary congressional intent." *U.S. Telecom Ass'n v. FCC*, 359 F.3d 554, 565 (D.C. Cir. 2004); *see also Kobach v. U.S. Election Assistance Comm'n*, 772 F.3d 1183, 1190 (10th Cir. 2014) (finding that the courts of appeals that have spoken on the issue are "unanimous in permitting subdelegations to subordinates . . . so long as the enabling statute and its legislative history do not indicate a prohibition on subdelegation"). The general principle is so well accepted that the Supreme Court has called it "unexceptional." *See United States v. Giordano*, 416 U.S. 505, 514 (1974).

Ethicon argues that *Cudahy Packing Co. of Louisiana v. Holland*, 315 U.S. 357 (1942), holds that affirmative authority to delegate is required. The Supreme Court has not cited *Cudahy* since 1958 "and the lower courts no longer follow it." 1 Richard J. Pierce, Jr., *supra* § 2.7, p. 125. Despite some language in *Cudahy* suggesting that express authority to delegate is required, the Supreme Court later clarified in *Fleming* that the *Cudahy* decision was based on explicit legislative history that "showed that a provision granting authority to delegate had been eliminated when the bill was in Conference." *Fleming*, 331 U.S. at 120. Thus, *Cudahy* simply stands for the unremarkable proposition that congressional intent to preclude delegation can sometimes be found in the legislative history.[5] Ethicon can point to no legislative history or any other aspects of the AIA here suggesting that delegation by the Director to the Board is impermissible.

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[5] Ethicon's reliance on our previous decision in *Splane v. West*, 216 F.3d 1058 (Fed. Cir. 2000) is also misplaced. *Splane* cannot be read to require express authorization in light of the Supreme Court's *Fleming* case (not cited in *Splane*), which makes clear that express authorization is not required. Ethicon, in addition, relies on two inapposite D.C. Circuit cases finding no delegation to outside agencies—*Shook v. D.C. Fin. Responsibility & Mgmt. Assistance Auth.*, 132 F.3d 775, 782 (D.C. Cir. 1998) and *Halverson v. Slater*, 129 F.3d 180, 185-86 (D.C. Cir. 1997). These cases are not applicable to the current situation because "[t]he presumption that subdelegations are valid absent a showing of contrary congressional intent applies only to" subdelegations, not delegations to outside agencies. *U.S. Telecom Ass'n*, 359 F.3d at 565. "There is no such presumption covering subdelegations to outside parties." *Id*.

Quite the contrary, Congress obviously assumed that the Director would delegate. Before the AIA, the Director, as head of the PTO, regularly assigned tasks to subordinate officers. *See, e.g.*, 35 U.S.C. § 131 ("the Director shall issue a patent"); § 132(a) ("the Director shall notify the applicant" of a rejection of a patent application); § 251(a) ("the Director shall" reissue amended patents). This carried over to the AIA, where Congress assigned the Director the decision to institute, necessarily assuming that the popularity of inter partes review and the short time frame to decide whether to institute inter partes review would mean that the Director could not herself review every petition.[6]

Ethicon finally argues that the existence of 35 U.S.C. § 3(b)(3)(B), which allows the Director to delegate duties to officers and employees she appoints, evidences a congressional purpose to cabin the Director's authority with respect to delegation. *See* 35 U.S.C. § 3(b)(3) (providing that "[t]he Director shall . . . appoint such officers . . . as the Director considers necessary, . . . and delegate to them such of the powers vested in the Office as the Director may

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[6] *See* 35 U.S.C. § 314 (authorizing the Director to institute inter partes review, but requiring that the decision to institute be made within 3 months of either when a response was filed or could have been filed); H.R. Rep. No. 110-314, Patent Reform Act of 2007, at 3 (2007) ("With fewer limitations on future challenges and a larger universe of patents open to challenge, CBO expects that the number of inter partes proceedings would increase under the bill. Based on information from PTO, CBO expects at least 100 additional employees would be necessary to handle that increase in patent challenges.")

determine"). Ethicon argues that this means that the Director cannot delegate to other officers of the PTO, like members of the Board, whom she does not appoint. Ethicon primarily relies on one sentence from the Supreme Court's decision in *Fleming* stating that a provision "specifically authoriz[ing] delegation *as to a particular function*" may "lend[] support to the view that when Congress desired to give authority to delegate, it said so explicitly." 331 U.S. at 121 (emphasis added).

Section 3(b)(3) is not such a provision. Not only does it not delegate a "particular function," but it is not primarily a delegation provision at all. It is, instead, a source of authority for the Director to appoint subordinates and assign them tasks. This is a situation where Congress has "mention[ed] a specific official only to make it clear that this official has a particular power rather than to exclude delegation to other officials." *United States v. Mango*, 199 F.3d 85, 90 (2d Cir. 1999). It is not a provision delegating a specific named function to a specific named official. *See Giordano*, 416 U.S. at 513; *Mango*, 199 F.3d at 90. It would indeed be strange to read § 3(b)(3) as limiting delegation to the Deputy Director, who is appointed by the Secretary of Commerce and not the Director, *see* 35 U.S.C. § 3(b)(1), who would then be left with no other tasks other than to step in the shoes of the Director "in the event of [her] absence or incapacity." *See* 35 U.S.C. § 3(b)(1). Thus, § 3(b)(3) cannot be read to limit the ability of the Director to delegate tasks to agency officials not mentioned in § 3(b)(3). We conclude that

the Director here has the inherent authority to delegate institution decisions to the Board.

Moreover, Congress's vesting of broad rulemaking powers in the head of the agency is an alternate source of authority to delegate. As the Supreme Court noted in *Fleming*, "rule-making power may itself be an adequate source of authority to delegate a particular function, unless by express provision of the Act or by implication it has been withheld." 331 U.S. at 121. Here, Congress gave the Director broad rulemaking power to "govern the conduct of the proceedings in the Office," 35 U.S.C. § 2(b)(2), and to "establish[] and govern[] inter partes review under this chapter," 35 U.S.C. § 316(a)(4). Congress undoubtedly intended the Director to have power by rulemaking to define the structure of inter partes review, including the power to subdelegate tasks assigned to her in the interest of efficiency. The Director promulgated a regulation allowing the Board to institute inter partes review "on behalf of the Director." 37 C.F.R. § 42.4(a). This rule itself is entitled to *Chevron* deference. *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842-43 (1984). The reference to "the Director" in the statute is ambiguous as to whether it requires her personal participation and the regulation is a permissible interpretation of the statute. *See Chevron*, 467 U.S. at 842-43; *Cuozzo*, 793 F.3d at 1279; *Cooper Techs. Co. v. Dudas*, 536 F.3d 1330, 1335 (Fed. Cir. 2008).

In short, both as a matter of inherent authority and general rulemaking authority, the Director had authority to delegate the institution decision to the Board. There is nothing in the

Constitution or the statute that precludes the same Board panel from making the decision to institute and then rendering the final decision.

II

We now turn to the merits of the Board's decision finding the claims of the '070 patent obvious in view of the prior art. Obviousness is a question of law based on underlying factual findings, including: (1) the level of ordinary skill in the art; (2) the scope and content of the prior art; (3) the differences between the claims and the prior art; and (4) secondary considerations of nonobviousness, such as commercial success, long-felt but unmet needs, failure of others, and unexpected results. *See KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 406 (2007); *Graham v. John Deere Co. of Kan. City*, 383 U.S. 1, 17-18 (1966).

Ethicon does not challenge the Board's finding that all of the claim elements are found in the prior art, nor does it challenge the Board's determination that a person of ordinary skill would have been motivated to combine those prior art elements to come up with the invention in the '070 patent. Ethicon instead argues that the Board did not properly take into account the secondary considerations of non-obviousness.

First, Ethicon argues that the Board failed to consider the commercial success of an allegedly infringing Covidien device. Our case law establishes that for evidence of commercial success to be relevant, "the patentee must establish a nexus

between the evidence of commercial success and the patented invention." *Wyers v. Master Lock Co*, 616 F.3d 1231, 1246 (Fed. Cir. 2010).

Ethicon argues that the Board failed to afford Ethicon a presumption of nexus between the commercial success of an allegedly infringing product made by Covidien and the patented features. It contends that because it showed that the Covidien devices were infringing, the commercial success of those devices is a strong secondary indication of non-obviousness which the Board ignored. However, regardless of any presumption of nexus, Ethicon's own evidence demonstrates that other non-patented features and features known in the prior art underlay the commercial success of Covidien's allegedly infringing product. "[I]f the commercial success is due to an unclaimed feature of the device" or "if the feature that creates the commercial success was known in the prior art, the success is not pertinent." *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1312 (Fed. Cir. 2006).

As the Board recognized, the Covidien products contained numerous unclaimed features, "such as ergonomic design, precise articulation, and reloads that provide simpler selection and reduced inventory," which may instead have been responsible for the commercial success of the products. J.A 19. Other unclaimed features, such as "[u]ncompromised staple line strength" and "[s]uperior [l]eak [r]esistance," are touted in brochures advertising the Covidien products. J.A. 1101. The Board concluded that, in light of these unclaimed features, Ethicon had "not shown sufficient credible evidence that the

sales of the [Covidien devices] are the result of the claimed invention." J.A. 19. We agree.

In addition, the Board had substantial evidence before it that the commercial success of the Covidien products was primarily attributable to a single feature present in the prior art, varying staple heights, rather than the combination of prior art features that is the alleged invention of the '070 patent. The evidence demonstrates that the Covidien products were successful because of their "graduated compression design and progressive staple heights, which provide less stress on tissue during compression and clamping." J.A. 1126. In addition, the varied staple heights allowed for "[b]roader indicated tissue thickness ranges" and "[c]onsistent performance over a broader range of tissue thicknesses." J.A. 1101. As the Board found and Ethicon concedes, the use of staples of different heights was well known in the prior art at the time of the '070 patent. J.A. 9. Nowhere does Ethicon demonstrate, or even argue, that the commercial success of the Covidien products is attributable to the *combination* of the two prior art features—varied staple heights and non-parallel staple legs—that is the purportedly inventive aspect of the '070 patent.

Lastly, Ethicon argues that the Board failed to weigh its evidence demonstrating a long-felt but unresolved need. Here, Ethicon only pointed to a single passage in a marketing brochure (and expert testimony based on that marketing brochure) touting the advantages of the Covidien products to demonstrate long-felt need. But at most, these demonstrate a long-felt need for staples of different

heights (a feature in the prior art), not the combination of features that is the invention here. As the Board found, this single brochure "does not support the assertion that there was a long-felt but unresolved need in the industry" for the claimed invention. J.A. 21. The Board did not err in concluding the asserted claims would have been obvious.

AFFIRMED

COSTS

Costs to appellee.

United States Court of Appeals for the Federal Circuit

ETHICON ENDO-SURGERY, INC.,
Appellant

v.

COVIDIEN LP,
Appellee

2014-1771

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2013-00209.

NEWMAN, *Circuit Judge*, dissenting.

I respectfully dissent, for the majority's holdings are contrary to the Leahy-Smith America Invents Act, Pub. L. No. 112-29, 25 Stat. 284 (2011) (codified at Title 35 of the United States Code). The post-grant proceedings established by the Act were intended as "quick and cost effective alternatives to litigation." H.R. Rep. No. 112-98, pt. 1, at 48 (2011). That legislative plan has been repeatedly thwarted

by the implementing bodies, administrative and judicial.

These post-grant proceedings were designed to provide rigorous inquiry and confident adjudication as a surrogate for district court litigation, with the added benefits of administrative expertise and efficiency. As part of this new agency procedure, the Act established a threshold step called "institution" by the Director of the PTO followed by trial and adjudication, by a new adjudicatory body established in the PTO. The "institution" step is a carefully designed threshold, whereby only meritorious challenges will be considered. And as a safeguard of administrative objectivity, the legislation divided the functions of institution and trial into separate bodies within the PTO.

The panel majority states that "there is nothing in the Constitution or the statute that precludes the same Board panel from making the decision to institute and then rendering the final opinion." Maj. Op. at 18. That is incorrect. The statute requires that these proceedings be separated, the first decision required to be made by the Director, and the second decision made by the Board. This court has now endorsed proceedings in which the Board makes both decisions. This procedure cannot be reconciled with the statute.

At the first stage, the Director determines whether the review is to be instituted. 35 U.S.C. § 314(a) ("The Director may not authorize an inter partes review to be instituted unless the Director determines that the information presented in the

petition . . . and any response . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least one of the claims challenged in the petition."). (Of course, the Director may designate an examiner or solicitor to conduct this initial review.)

If instituted by the Director, the Board then conducts a trial on the merits. 35 U.S.C. § 316(c) ("The Patent Trial and Appeal Board shall, in accordance with section 6, conduct each inter partes review instituted under this chapter."). "The statute thus separates the Director's decision to 'institute' the review, § 314, on one hand from the Board's 'conduct' of the review 'instituted' by the Director, § 316(c), and the Board's subsequent 'written decision,' § 318, on the other." *St. Jude Med., Cardiology Div., Inc. v. Volcano Corp.*, 749 F.3d 1373, 1375 (Fed. Cir. 2014).

The threshold determination to institute post-grant review requires the Director to find that there is more-likely-than-not an error in the grant of at least one claim of the patent. When such finding is made by the Director, the newly created independent tribunal in the PTO conducts a full trial, with discovery, testimony, experts, and other trappings of district court litigation. This trial, and the ensuing Board decision, are independent of and give no deference to the Director's decision "to institute" the proceeding. In turn, the Board's decision is not subject to review by the Director or in the district courts, and can be appealed only to this court. Our decision, in turn, cannot be challenged in infringement litigation between these parties.

The bifurcated design of post-grant review is clear not only from the language of §§ 314(a) and 316(c), but pervades the structure of these post-grant proceedings. Congress unambiguously placed these separate determinations in different decision-makers, applying different criteria. The majority's endorsement of the PTO's statutory violation departs not only from the statute, but also from the due process guarantee of a "fair and impartial decision-maker."

I

Post-Grant Proceedings are a Surrogate for District Court Litigation

The America Invents Act is the result of more than six years of discussion, debate, negotiation, and collaboration among innovative industries, independent inventors, legislators, academics, research institutions, entrepreneurs, the concerned public, the intellectual property bar, and the PTO—all seeking to resolve problems that had arisen in the patent system. The key advance of the America Invents Act is its creation of a new procedure for reviewing previously granted patents, to shift determination of patent validity from the courts to the expert agency, to provide "quick and cost effective alternatives to litigation" and thereby to restore the innovation incentive of an effective system of patents. H.R. Rep. No. 112-98, pt. 1, at 48 (2011).

The design and intent of the America Invents Act is that these new PTO proceedings will provide

early, reliable, and less costly adjudication of the major issues of patent validity. *See* 157 Cong. Rec. S5327 (Sept. 6, 2011) (statement of Sen. Leahy) ("This bill will establish a more efficient and streamlined patent system that will improve patent quality and limit unnecessary and counterproductive litigation costs, while making sure no party's access to court is denied.").

These new proceedings were developed in the context of the shortcomings of the then-existing inter partes reexamination system. That system authorized third parties or the patentee to request reexamination on showing a "substantial new question of patentability." 35 U.S.C. § 312(a). Reexamination then proceeded similarly to initial examination, including the right of amendment; appeal could be taken to the Patent Office Board of Appeals and Interferences and then to the courts. Criticism focused on the prevalence of cumulative and harassing attacks, whereby the vitality of the patent could be consumed by multiple and time-consuming proceedings. The America Invents Act sought to address these concerns, as well as the expense and duration of litigation of validity in the district courts.

The America Invents Act requires an initial decision by the Director as to whether post-grant review is warranted at all; this is required to be made within three months of the filing of a petition for review. 35 U.S.C. § 314(b); *see* 157 Cong. Rec. S1376 (Mar. 28, 2011) (statement of Sen. Kyl) ("Among the reforms that are expected to expedite these proceedings are . . . the elevated threshold for

instituting proceedings. The elevated threshold will require challengers to front load their case."). The statute requires petitioners to demonstrate a "reasonable likelihood" of invalidity as to at least one claim, in order for institution to be granted. 35 U.S.C. § 314(a).

Interlocutory appeal of a decision on the question of institution is barred by statute. The legislative record explains that the America Invents Act "eliminates intermediate administrative appeals of inter partes proceedings to the BPAI . . . . By reducing two levels of appeals to just one, this change will substantially accelerate the resolution of inter partes cases." 157 Cong. Rec. S1376 (Mar. 28, 2011) (statement of Sen. Kyl). However, this salutary purpose did not discard the protections of due process.

The threshold institution proceeding is designed to avoid the disadvantages of the prior inter partes practice, for: "The Patent Office has indicated that it currently is forced to accept many requests for ex parte and inter partes reexamination that raise challenges that are cumulative to or substantially overlap with issues previously considered by the Office with respect to the patent." *Id.* The institution step also protects the patent owner from "attacks on patents that raise issues that are substantially the same as issues that were already before the Office with respect to the patent." *Id.*

This institution procedure, which "requir[es] the petitioner to present a prima facie case justifying a rejection of the claims in the patent," *id.* at S1375,

tracks the obligation of a complainant to provide a legally sufficient pleading. Thereafter the adjudicatory body conducts a trial and completes its proceedings within one year (with extension for good cause shown). 35 U.S.C. § 316(a)(11); *see* 157 Cong. Rec. S1366 (Mar. 8, 2011) (Republican Pol. Comm. Leg. Notice S.23 (Feb. 28, 2011) entered by Sen. Kyl) ("These reforms add additional procedural protections to the process by converting the reexamination into an adjudicative proceeding to be known as 'inter partes review.' Inter partes review must be completed with one year of being instituted.").

The America Invents Act requires that the trial be conducted, and the matter finally decided, by a different part of the PTO than makes the decision to institute. These post-grant proceedings have become the new frontier of patent litigation.[1] Threatening the viability of this new system, however, is the disregard of the procedures established by the America Invents Act.

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[1] As of October 31, 2015, the PTO had received more than 4000 petitions under this statute, *see* Patent Trial and Appeal Board Statistics, at 2 (Oct. 31, 2015) *available at* http://www.uspto.gov/sites/default/files/documents/2015-10-31%20PTAB.pdf. Of the 2,450 completed proceedings, the Office instituted more than 1200 trials. *Id.* at 9.

II

The Statutory Separation of the Decision to Institute and the Decision on Validity

The panel majority holds that the decision to institute may be made by the PTAB, not by the Director, and that it may be made by the same PTAB panel that would then conduct the trial and make the validity decision. This violation of the statute has been criticized by practitioners, citing the "actual or perceived bias against the patent owner" because the administrative patent judges are "put in the position of defending their prior decisions to institute the trial." AIPLA, Comments on PTAB Trial Proceedings, at 20 (Oct. 16, 2014), *available at* http://www.uspto.gov/ip/boards/bpai/aipla_20141016.pdf.

It cannot be ignored that this transfer to the Board of the Director's statutory assignment violates the text, structure, and purpose of the America Invents Act. The statutory separation of roles cannot be abrogated by either the PTO or this court.

In defense of abrogation, the panel majority cites a treatise that reports that administrative agencies have been authorized to perform both investigative and adjudicatory functions. Maj. Op. at 10 (citing 2 Richard J. Pierce, Jr., *Administrative Law Treatise* § 9.9, p. 892 (5th ed. 2010).). However, such authorization cannot violate the implementing legislation.

Due process guarantees "a fair trial in a fair tribunal." *In re Murchison*, 349 U.S. 133, 136 (1955). Permitting the same decision-maker to review its own prior decision may not always provide the constitutionally required impartial decision maker. "The right to an impartial decision maker is unquestionably an aspect of procedural due process. . . . This applies to administrative proceedings as well as judicial trials." *NEC Corp. v. United States*, 151 F.3d 1361, 1371 (Fed. Cir. 1998) (internal citations omitted).

As stated in *Matthews v. Eldridge*, "identification of the specific dictates of due process generally requires consideration of three distinct factors," 424 U.S. 319, 335 (1976). The three factors are "the private interest that will be affected by the official action," the "risk of an erroneous deprivation," and the "fiscal and administrative burdens that the additional or substitute procedural requirement would entail." *Id.* Here, the first two factors weigh heavily in favor of the divided decision-making of the America Invents Act, with scant additional burden.

In evaluating administrative processes for prejudgment this court has considered the "bifurcation" of other decision-making processes and the "statutory and regulatory protections" for the party subject to a deprivation. *NEC Corporation*, 151 F.3d at 1371. In *NEC Corporation* this court upheld the bifurcated administrative process involved in antidumping duty proceedings:

> First of all, an antidumping investigation is bifurcated: Commerce makes less-than-fair value determinations for a class or kind of foreign merchandise, and the ITC makes injury determinations. Only if Commerce determines that the merchandise is being sold at less-than-fair value, *see* 19 U.S.C. § 1673(1) (1994), *and* the ITC determines that a domestic industry is materially injured or is threatened with material injury, *see* 19 U.S.C. § 1673(2), does Commerce issue an antidumping order. *See* 19 U.S.C. § 1673. This bifurcation reduces the risk that an improper bias will deprive importers of their due process rights.

151 F.3d at 1373. In contrast, the unitary procedure now implemented by the PTO and ratified by this court enlarges, rather than reduces, the "risk [of] improper bias." *Id*.

If bifurcated decision-making is required to reduce the risk of erroneous deprivation in antidumping proceedings, similar protection is at least as appropriate for post-grant proceedings. And contrary to the panel majority's holding, Congress explicitly provided for exactly that kind of decisional separation in the America Invents Act.

My colleagues also suggest analogy to a district court's preliminary determination of whether there is "a likelihood of success on the merits" for

purposes of responding to a request for preliminary injunction. Maj. Op. at 11 (citing Fed. R. Civ. P. 65). However, such decisions are immediately subject to appeal.

In *Withrow v. Larkin*, 421 U.S. 35, 58 n.25 (1975), the Court expressly reserved the question of "[a]llowing a decisionmaker to review and evaluate his own prior decision." We need not decide this question here, for the possible potential conflict was foreseen by the legislators, and by statute was forestalled. All that is needed is to apply the statute as it was written. The statute divides post-grant authority between the Director, who is responsible for deciding whether to institute review, and the Board of administrative patent judges, charged with conducting the trial and rendering a decision on patent validity. The statute bars the Board from rendering both the institution and final decisions. As this court has recognized, "institution and invalidation are two distinct actions." *Versata Dev. Grp., Inc. v. SAP Am., Inc.*, 793 F.3d 1306, 1319 (Fed. Cir. 2015) ("In addition to being deeply embedded in federal administrative law, the distinction is built into the structure of this particular AIA statute.").

The statute repeats several times the requirement that the Director make the institution decision. *See, e.g.*, 35 U.S.C. § 314(c) (notification must be made of "the Director's determination under subsection (a)"); § 314(d) (the Director may join parties "[i]f the Director institutes an inter partes review"). The Director's institution decision carries a different burden of persuasion, is decided on limited submissions before trial, and is barred from appeal.

In its implementing regulations, the Office excludes all substantive evidence from the patent owner's preliminary response, including expert declarations or other rebuttal evidence. 37 C.F.R. § 42.107(c). Thus the statutory structure favors institution, for the overarching purpose is to provide a forum for early, expeditious review of granted patents. By placing the institution decision in different hands than the trial, Congress acted to preserve the process from human frailty.

The statute is equally clear that it is the Board that conducts the trial and issues a final decision. *See* 35 U.S.C. §§ 316(c), 318(a). This legislative assignment of functions cannot be ignored. *See Corley v. United States*, 556 U.S. 303, 314 (2009) ("[O]ne of the most basic interpretative canons [is] that [a] statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant." (internal citations omitted, alterations in original)); *cf. United States v. Giordano*, 416 U.S. 505, 514 (1974) (holding that where a statute authorized wiretaps only by the Attorney General or any Assistant Attorney General specially designated, the statute "fairly read, was intended to limit the power to authorize wiretap applications" to the expressly named positions).

Statutes must be interpreted to conform to "the design of the statute as a whole and to its object and policy." *Crandon v. United States*, 494 U.S. 152, 158 (1990). The legislative division of these decisional roles is not subject to agency or judicial modification, whether by adjudication or by

rulemaking. The PTO's rulemaking authority does not extend to changing statutorily defined procedures. In promulgating 37 C.F.R. § 42.4 to transfer the Director's institution responsibility to the Board, the PTO departed from the statute. *See Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 213 -14 (1976) ("The rulemaking power granted to an administrative agency charged with the administration of a federal statute is not the power to make law. Rather, it is the power to adopt regulations to carry into effect the will of Congress as expressed by the statute.").

"Although an agency's interpretation of the statute under which it operates is entitled to some deference, 'this deference is constrained by our obligation to honor the clear meaning of a statute, as revealed by its language, purpose, and history." *See Cmty. Coll. v. Davis*, 442 U.S. 397, 411 (1979) (quoting *Teamsters v. Daniel*, 439 U.S. 551, 566 n. 20 (1979)); see *Muwwakkil v. Office of Pers. Mgmt.*, 18 F.3d 921, 925 (Fed. Cir. 1994) ("When an agency's interpretation of a statute it is entrusted to administer is contrary to the intent of Congress, as divined from the statute and its legislative history, we owe it no deference.").

SUMMARY

The post-grant proceedings of the America Invents Act are a pioneering measure to shift several aspects of patent validity from the district courts to the PTO. The legislative purpose is to provide optimum decisional objectivity, in order to restore public confidence in the reliability of patents as

investment incentives; this requires that the PTO proceedings conform to the statute. I respectfully dissent.

United States Court of Appeals for the Federal Circuit

ETHICON ENDO-SURGERY, INC.,
Appellant

v.

COVIDIEN LP,
Appellee

2014-1771

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2013-00209.

ON PETITION FOR REHEARING EN BANC

Before PROST, Chief *Judge*, NEWMAN, LOURIE, DYK, MOORE, O'Malley, REYNA, WALLACH, TARANTO, CHEN, and HUGHES, *Circuit Judges*.[*]

NEWMAN, *Circuit Judge*, dissents from the denial of the petition for rehearing en banc.

PER CURIAM.

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[*] Circuit Judge Stoll did not participate.

O R D E R

Appellant Ethicon Endo-Surgery, Inc. filed a petition for rehearing en banc. A response to the petition was invited by the court and filed separately by the appellee Covidien LP and intervenor Michelle Lee, Director, U.S. Patent and Trademark Office. Several motions for leave to file amici curiae briefs were also filed and granted by the court.

The petition, responses, and briefs of amici curiae were referred to the panel that heard the appeal, and thereafter were referred to the circuit judges who are in regular active service. A poll was requested, taken, and failed.

Upon consideration thereof,

It Is ORDERED THAT:

The petition for rehearing en banc is denied.

The mandate of the court will be issued on June 29, 2016.

FOR THE COURT

June 22, 2016 /s/ Peter R. Marksteiner
Peter R. Marksteiner
Clerk of Court

United States Court of Appeals for the Federal Circuit

ETHICON ENDO-SURGERY, INC.,
Appellant

v.

COVIDIEN LP,
Appellee

2014-1771

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2013-00209.

NEWMAN, *Circuit Judge, dissenting from denial of rehearing en banc.*

The America Invents Act divides *inter partes* review into two distinct phases, heard by two distinct entities. First, the Director makes a threshold institution determination. 35 U.S.C. § 314. If instituted by the Director, the Patent and Trial Appeal Board then conducts a trial and determines the validity of the challenged claims. 35 U.S.C. § 6(b)(4). Ignoring this statutory division of responsibilities, the PTO has assigned the institution decision to the PTAB, 37 C.F.R. § 42.4(a). Under current practice, the same administrative patent

judges responsible for instituting an IPR preside over the merits trial.

Ignoring the statutory division of responsibility is contrary to the plain text and carefully designed structure of the America Invents Act, and imperils the public confidence in the fairness and correctness of these proceedings. "The rulemaking power granted to an administrative agency charged with the administration of a federal statute is not the power to make law. Rather, it is the power to adopt regulations to carry into effect the will of Congress as expressed by the statute." *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 213–214 (1976). I respectfully dissent from the court's denial of *en banc* consideration.

The America Invents Act is, fundamentally, economic legislation. By modifying heavily criticized patent procedures, Congress hoped to increase confidence in the PTO and spur the nation's innovation and investment in new technologies. *See, e.g.*, H.R. Rep. No. 112-98, pt.1, at 40 (2011) ("If the United States is to maintain its competitive edge in the global economy, it needs a system that will support and reward all innovators with high quality patents."); *see also* 153 Cong. Rec. H10284 (daily ed. Sept. 7, 2007) (statement of Rep. Eshoo) ("The rapid pace of innovation and increasingly complex patent filings have strained the Patent and Trademark Office and patent claims of questionable validity have been granted.").

To reaffirm the nation's commitment to predictable and fair patent rights, Congress created

new administrative proceedings, to provide "quick and cost effective alternatives to litigation," H.R. Rep. 112-98 at 48, for the purpose of "improv[ing] patent quality and restor[ing] confidence in the presumption of validity that comes with issued patents in court," *id.*

The legislative record reveals that proposals for postgrant proceedings were quite controversial. *See Patent Act of 2005: Hearing on H.R. 2795 Before the H. Subcomm. on Courts, the Internet, and Intell. Prop.*, 109th Cong. 15 (2005) (Statement of Gary L. Griswold, President, AIPLA) ("AIPLA opposes having a second window for bringing an opposition for the life of a patent. The proposed second window, where the burden of proof is a 'preponderance of the evidence' instead of 'clear and convincing evidence,' will increase the risks faced by patent holders and dampen their enthusiasm for investing in the development and commercialization of their patented technologies."). The record is replete with similar concerns of commentators, patentees, and the PTO.

In response to these concerns, Congress meticulously incorporated safeguards against delay at the PTO and harassment of patentees. *See* H.R. Rep. 112-98, pt. 1 at 48 ("[T]he changes made . . . are not to be used as tools for harassment or delay or a means to prevent market entry through repeated litigation and administrative attacks on the validity of a patent. Doing so would frustrate the purpose of the section for providing quick and cost-effective alternatives to litigation.").

The carefully designed post-grant procedures also ensured that constitutionally mandated patent rights were not abrogated without due process of law. *See James v. Campbell*, 104 U.S. 356, 358 (1881) ("When [the government] grants a patent the grantee is entitled to it as a matter of right, and does not receive it . . . as a matter of grace and favor.").

The Director's institution decision was such a protection: "The Patent Office made clear that a higher threshold is necessary to weed out marginal challenges and preserve the office's own resources." 157 Cong. Rec. S1041 (daily ed. Mar. 1, 2011) (statement of Sen. Kyl); *see also* 154 Cong. Rec. S9987 (daily ed. Sept. 7, 2008) (statement of Sen. Kyl) ("Proposed section 322 includes a number of provisions that are designed to limit the use of post grant review proceedings as a delaying tactic and to mitigate these proceedings' negative impact on efforts to enforce a patent."); *Patent Reform Act of 2007: Hearing Before the Subcomm. on Courts, the Internet, and Intell. Prop. of the H. Comm. On the Judiciary*, 110th Cong. 16 (statement of Rep. Berman) ("Postgrant provides the ability to challenge the validity of a patent and provides mechanisms to prevent harassment.").

By statute, "institution" is an initial determination committed to the discretion of the Director. 35 U.S.C. § 314(a). This initial step permits the Director to reject a petition that is cumulative, harassing, anti-competitive, or non-meritorious; it also permits the Director to decline to institute if the resources of the Office are overburdened. When the Director grants a petition,

the merits trial is conducted by an independent PTAB panel. The panel is authorized to exercise judicial powers, buttressed by discovery, witness testimony, briefs, oral arguments, and the power in the PTAB to amend and cancel claims. *See* 35 U.S.C. § 6(b).

The purpose of the PTAB trial is to correctly and finally determine the validity of challenged claims. Congress repeated multiple times in the statute the requirement that the Director (not the PTAB) makes the institution decision. *See, e.g.*, 35 U.S.C. § 314(c) (notification must be made of "the Director's determination under subsection (a)"); § 314(d) (the Director may join parties "[i]f the Director institutes an inter partes review"). The America Invents Act is equally clear that a panel of the PTAB conducts an instituted review and issues a final written decision on validity. *See* 35 U.S.C. §§ 316(c), 318(a).

The two phases have different evidentiary rules, records, witness and argument structures, burdens of proof, time limits, and rights of appeal. This division of authority protects patentees by ensuring that the threshold decision to institute neither pre-ordains nor prejudices the later decision on the merits. Independence of the two decision-makers is crucial to achieving the statutory purpose.

Congress was well aware that these strictures were binding on the office; a House Report on a predecessor bill commented on the authority of the PTO to promulgate rules contrary to statute. H.R. Rep. No. 110-314, at 45 (2007) ("Where Congress has

seen fit to provide specific limitations or conditions in statute, the USPTO may not surpass or take away these limitations or conditions by promulgated rule."). Congress intended the PTO to use its limited rulemaking authority not to override the text and structure of the statute, but to "address potential abuses and current inefficiencies." H.R. Rep. 112-98, pt. 1 at 48 (2011).

In promulgating 37 C.F.R. § 42.4(a), the PTO ignored this statutory division of responsibilities, and assigned the PTAB to handle both the institution and merits phases of *inter partes* review. This consolidation of decision-makers violates the statute. "When an agency's interpretation of a statute it is entrusted to administer is contrary to the intent of Congress, as divined from the statute and its legislative history, we owe it no deference." *Muwwakkil v. Office of Pers. Mgmt.*, 18 F.3d 921, 925 (Fed. Cir. 1994).

The majority panel decision and the Director frame the issue as a simple exercise of the Director's rulemaking and/or delegation authority. This question obscures the legislative point; the Director may generally subdelegate, and may exercise procedural rulemaking authority, with regard to these proceedings. Here, however, the statute creates an explicit distinction between the institution phase assigned to the Director, and the merits phase conducted by the PTAB. The question presented, therefore, is whether the PTO may ignore the explicit statutory provision and congressional intent to the contrary. The answer is unequivocally no. When the

statute is explicit as to the agency's statutory function, there is no discretion to contravene it.

The current practice of assigning the same PTAB panel to both institute and conduct an *inter partes* review is not only contrary to the statute, but has the taint of prejudgment. Many commentators, including the amici curiae in this case, point to the PTO's own statistics as evidence of prejudgment, calling the merits phase "a largely rubber-stamp proceeding." 3M, *et al.* Br. at 3. Whatever the merit of these criticisms, the numbers do not bode confidence. The Board has reversed course and found patentability after institution in just 9% of *inter partes* reviews. *See* PTAB Statistics, at 10 (April 30, 2016) (134 trials of 1511 instituted trials), *available at* http://www.uspto.gov/sites/default/files/documents/2016-4-30%20PTAB.pdf. In covered business method review, the figure is 2%. *Id.* at 11 (3 trials of 180 instituted trials). At the claim level, the numbers tell a similar story. Of the 12,336 claims decided by the Board, the Board invalidated 10,175, or 82.5% of claims. *Id.* at 13. With inclusion of the 1,919 claims disclaimed or cancelled by the patentee, just 15.2% of instituted claims survived *inter partes* review. *Id.*

It is our judicial obligation to ensure agency compliance with statutory text and purpose. The departure by the PTO is not only contrary to the statute, but has devastating consequences for the public confidence in post-grant proceedings and the patent system as a whole. The nation's economic health depends on public confidence in an unbiased

and balanced patent system. I respectfully dissent from the denial of *en banc* reconsideration.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COVIDIEN LP,
Petitioner

v.

ETHICON ENDO-SURGERY, INC.,
Patent Owner

Case IPR2013-00209
Patent 8,317,070

Before SALLY C. MEDLEY, JOSIAH C. COCKS, and GEORGIANNA W. BRADEN, *Administrative Patent Judges.*

BRADEN, *Administrative Patent Judge.*

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. INTRODUCTION

A. Background

Covidien LP ("Petitioner") filed a Petition (Paper 1, "Pet.") on March 25, 2013, requesting *inter partes* review of claims 1-14 of U.S. Patent No. 8,317,070 (Ex. 1001, "the '070 patent") pursuant to 35 U.S.C. §§ 311-319. On August 26, 2013, we granted the Petition, and instituted this *inter partes* review of claims 1-14 on fewer than all of the grounds of unpatentability alleged. Paper 7, "Dec. to Inst.". After institution of trial, the Patent Owner, Ethicon Endo-Surgery, Inc. ("Patent Owner"), filed a Patent Owner Response (Paper 17, "Resp") to the Petition. Petitioner filed a Reply (Paper 21) to the Patent Owner Response.

Counsel for both Petitioner and Patent Owner were present and presented argument at an oral hearing held on April 10, 2014.[1]

The Board has jurisdiction under 35 U.S.C. § 6(c). In this final written decision, issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73, we determine Petitioner has shown by a preponderance of the evidence that all challenged claims are unpatentable under 35 U.S.C. § 103.

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[1] A transcript of the oral hearing is included in the record. Paper 28.

B. The '070 Patent

The '070 patent discloses surgical stapling devices that are "capable of producing staples of different formed lengths" when the staples are applied, for instance, to tissue. (Ex. 1001, Abstract; col. 2, ll. 28-30.) According to the '070 patent:

> Whenever a transsection of tissue is across an area of varied tissue composition, it would be advantageous for the staples that are closest to the cut line to have one formed height that is less than the formed height of those staples that are farthest from the cut line. In practice, the rows of inside staples serve to provide a hemostatic barrier, while the outside rows of staples with larger formed heights provide a cinching effect where the tissue transitions from the tightly compressed hemostatic section to the non-compressed adjacent section.

Id. at col. 2, ll. 4-12. The '070 patent further discloses the use of staples with two prongs that extend from the main portion of the staple body, as shown in Figure 81, reproduced below. *Id.* at col. 27, ll. 57-58; Figures 81, 93.

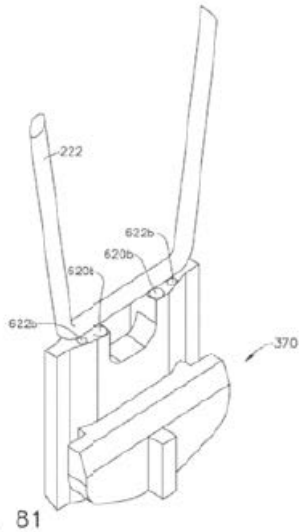

FIG. 81

Figure 81 illustrates an embodiment of a staple with two prongs that extend from the main portion of the staple body.

Claims 1 and 8 are the only independent claims in the '070 patent and are reproduced below (some paragraphing added):

1. A surgical stapling device comprising an end effector that comprises:

a circular anvil having a staple forming surface;

a plurality of staples facing the staple forming surface of the anvil, each staple comprising a main portion and two prongs, wherein the two prongs each

comprise a first end and a second end, wherein the first ends are connected to opposite ends of the main portion, and wherein the two prongs extend non-parallelly from the main portion; and

a staple driver assembly comprising a plurality of staple drivers, wherein each staple driver supports one of the plurality of staples and is configured such that, when the staple driver assembly is actuated, each staple driver drives the staple into the staple forming surface of the anvil,

wherein a first quantity of the staples have a first pre-deformation height, measured from a lower surface of the main portion to the second end of the first prong, and a second quantity of the staples have a second pre-deformation height, measured from a lower surface of the main portion to the second end of the first prong,

wherein the first height is less than the second height, such that when the staple driver assembly is actuated, the first quantity of staples have a different formed staple length than the second quantity of staples.

8. A surgical stapling device comprising:

a non-pivotable anvil having a staple forming surface; and

a staple cartridge facing the anvil, wherein the staple cartridge comprises:

a plurality of staples facing the staple forming surface of the anvil, each staple comprising a main portion and two prongs, wherein the two prongs each comprise a first end and a second end, wherein the first ends are connected to opposite ends of the main portion, and wherein the two prongs extend non-parallelly from the main portion; and

a plurality of staple drivers, wherein each staple driver supports one of the plurality of staples and is configured such that, when the staple drivers are actuated, each staple driver drives the staple into the staple forming surface of the anvil,

wherein a first quantity of the staples have a first pre-deformation height, measured from a lower surface of the main portion to the second end of the first prong, and a second quantity of the staples have a second pre-deformation height, measured from a lower surface of the main portion to the second end of the first prong,

> wherein the first height is less than the second height, such that when the staple driver assembly is actuated, the first quantity of staples have a different formed staple length than the second quantity of staples.

C. Prior Art References Alleged to Support Unpatentability

The following table summarizes the prior art references asserted in the instituted grounds:

Name	Description	Date	Exhibit
Pruitt	US 4,941,623	July 17, 1990	Ex. 1003
Viola	International Publ. No. WO 2003/094747 A1	Nov. 20, 2003	Ex. 1004
Burdorff	US 5,697,543	Dec. 16, 1997	Ex. 1005
Conta	US 4,304,236	Dec. 8, 1981	Ex. 1006
Green	US 3,494,533	Feb. 10, 1970	Ex. 1009

D. Grounds of Unpatentability Instituted

The following table summarizes the challenges to patentability that were instituted for *inter partes* review:

Claim	Grounds	Reference(s)
Claim 1-5, 7, 8, and 10-13	§ 103	Viola and Green
Claim 6, 11, and 14	§ 103	Viola, Green, and Pruitt
Claim 9	§ 103	Viola, Green, and Burdorff
Claim 8 and 10-14	§ 103	Pruitt and Green
Claim 9	§ 103	Pruitt, Green, and Burdorff
Claims 1-7	§ 103	Pruitt, Green, and Conta

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are given their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,766 (Aug. 14, 2012). Claim terms also are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech, Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

If an inventor acts as his or her own lexicographer, the definition must be set forth in the specification with reasonable clarity, deliberateness, and precision. *Renishaw PLC v. Marposs Societa'per Azioni*, 158 F.3d 1243, 1249 (Fed. Cir. 1998). Neither

Petitioner nor Patent Owner contends that the Specification of the '070 patent, as filed, coined a new meaning for any term, different from the ordinary recognized meaning for any term.

1. "two prongs extend non-parallelly from the main portion"

The phrase "two prongs extend non-parallelly from the main portion," which is recited in both independent claims, was construed initially for purposes of the Decision to Institute to mean that the extension of two prongs of a staple are non-parallel relative to each other in extending from the main portion of the staple. Dec. to Inst. 7-9; *see also* Decision on Petitioner's Request for Rehearing, Paper 10. Petitioner asserts that the Specification for the '070 patent does not support such a construction, because nowhere in the patent is there a description of staples with two prongs that are non-parallel relative to each other. Petitioner's Request for Rehearing, Paper 9; Tr. 6-7. However, we reject Petitioner's position and find that Figures 81 (reproduced *supra*) and 93 of the '070 patent illustrate staples with non-parallel legs. Therefore, we are not persuaded that a change in claim construction from that issued in the Decision to Institute is merited.

2. "formed staple length"

Each of claims 1 and 8 requires a plurality of staples identifiable as a "first quantity" of staples having a "first pre-deformation height" and a "second quantity" having a "second pre-deformation height."

Those claims further recite that "when the staple driver assembly is actuated, the first quantity of staples have a different formed staple length than the second quantity of staples."

The terms "height" and "length" are understood generally as being terms that are not necessarily the same in designating measurements of a given structure. However, as discussed in the Decision to Institute, those terms are used throughout the Specification of the '070 patent to designate the same dimension in connection with the extension of prongs of a staple. Dec. to Inst. 9-10. For instance, prongs 225 shown in Figure 12 are designated as having a "length 'P'," which is the dimension of the prongs extending from the main portion 223. Ex. 1001, col. 11, ll. 20-22; *see also* col. 16, ll. 14-16 (describing "prong lengths 'P'"). Elsewhere in the Specification, the dimension "P" for the prongs is designated "prong heights." *Id*. at 19, ll. 25-26. Similarly, in connection with "formed staples" the terms "formed lengths" and "formed heights" are each used in reference to the extension of the prongs from the main portion of the staple after it has been formed. *E.g., id*. at col. 2, ll. 39-44; col. 16, ll. 54-64; col. 19; ll. 65-67. Accordingly, as set forth in the Decision to Institute, in the context of the '070 patent, the "formed staple length" is understood as referencing the distance or "height" that the prongs extend from the main portion of the staple when the staple is formed.

3. "non-pivotable anvil"

Independent claim 8 includes recitation of a "non-pivotable anvil." As is understood from the '070 patent, an "anvil" is a structure having a surface against which staples are driven or fired so as to configure the staple into a "form[ed]"condition. Ex. 1001, Abstract; col. 1, ll. 45-58.

In the Decision to Institute, we determined that the broadest reasonable interpretation consistent with the Specification of the '070 patent is an anvil that does not rotate or swing about a short rod or shaft. Dec. to Inst. 11. During the course of the trial, neither party challenged our construction of the claim term. Therefore, we see no reason to alter the construction set forth in the Decision to Institute.

B. Claims 1-14 – Alleged Obviousness over Viola, Pruitt, and/or Green

Petitioner asserts that claims 1-14 of the '070 patent are unpatentable under 35 U.S.C. § 103(a) over the prior art, specifically arguing that the claims are unpatentable over various combinations of Viola, Pruitt, and/or Green. Pet. 4-5, 58-59. "Section 103(a) [of 35 U.S.C.] forbids issuance of a patent when 'the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.'" *KSR Int'l Co. v. TeleflexInc.*, 550 U.S. 398, 406 (2007). To establish obviousness of a claimed invention, all the claim

limitations must be taught or suggested by the prior art. *See CFMT, Inc. v. Yieldup Int'l Corp*., 349 F.3d 1333, 1342 (Fed. Cir. 2003); *In re Royka*, 490 F.2d 981, 985 (CCPA 1974).

Patent Owner disputes Petitioner's contention that the challenged claims would have been obvious. According to Patent Owner, the prior art fails to teach all of the limitations of the claims, and, specifically, "Viola fails to disclose staples with multiple ***formed*** heights as required by all claims of the '070 patent." Resp. 10. However, Patent Owner's argument is contradictory to Patent Owner's characterization of Viola in a proceeding before the European Patent Office. *See, e.g*., Reply 4; Ex. 1024 at 1; Ex. 1025 at 2; Ex. 1026; Ex. 1027 at 2. Furthermore, during the oral hearing, counsel for Patent Owner admitted that all the recited elements of the patent claims are found in the asserted prior art. Tr. 23-24. Given Patent Owner's admission regarding the prior art, there is no factual dispute that the cited references teach all of the recited elements.

Despite the teaching of all the claim elements in the prior art, Patent Owner maintains that one of skill in the art would not have arrived at the claimed subject matter, because (1) there was no reason to combine the cited prior art references, and (2) the prior art teaches away from the claimed invention. Resp. 21; Tr. 23-24, 26-27. Petitioner argues, to the contrary, that non-parallel staples were well-known in the art, and it would have been obvious to try such staples with the staple devices of Viola or Pruitt. Pet. 58. According to Petitioner, combining non-

parallel staples with the staple devices of Viola or Pruitt would have constituted the mere substitution of one known element for another, and would have yielded predictable results. *Id.*

1. Reason to Combine Teachings of the Prior Art

In making an obviousness determination, "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR*, 550 U.S. at 418. Patent Owner contends that "the evidence fail[s] to show a specific reason why one of ordinary skill in the art would have combined Green with Viola or Pruitt to arrive at the claimed invention." Resp. 21. However, Petitioner argues that one of skill in the art would have been motivated to modify the staple devices of Viola and Pruitt to use Green's stables with non-parallel or "outwardly flaring" legs in order to securely hold staples within corresponding retention slots of a staple cartridge. Pet. 59 (citing Ex. 1009 at col. 13, l. 71-col. 14, l. 4 and Ex. 1010 ¶ 108).

Contrary to Petitioner's argument, Patent Owner contends there are multiple problems with using non-parallel staples, and any benefit bestowed by retaining staples in a staple cartridge would be outweighed by "the overall undesirability of non-parallel staples." Resp. 38. Mr. Ortiz, expert for Patent Owner, testified that alternative methods existed for retaining staples in a staple cartridge (Ex. 2004 ¶¶ 76-78), so one of skill in the art would

not have to rely on non-parallel legs to ensure that staples do not fall out of a staple cartridge. However, Mr. Ortiz testified he had not used the alternative methods he opined on (Ex. 1023 at 72, ll. 11-14 and 64, ll. 19-21); rather, Mr. Ortiz used non-parallel staples "maybe 50 or 75 percent of the time" in his practice (*id.* at 56, ll. 10-15). Mr. Bolanos, expert for Petitioner, testified about the reasons why a skilled artisan would have used staples with non-parallel legs, and stated that he routinely used such staples in his practice. Ex. 1010 ¶ 108; Ex. 1031 ¶ 4-5. Additionally, Mr. Kelly, an expert for Patent Owner in a lawsuit in Germany, testified that the "problem of keeping staples in their pockets is generally solved . . . by bending the tips of the legs of the unloaded staples slightly outward," i.e., having staple legs that are non-parallel. Ex. 1033 at 2.

According to Petitioner, the testimony of Mr. Ortiz and Mr. Kelly contradict Patent Owner's contention that non-parallel staples were not beneficial and would not have been used by one of skill in the art. Reply 6. We agree with Petitioner and find that Patent Owner's evidence is entitled to less weight than Petitioner's evidence as to this issue. Although Mr. Ortiz originally testified that one of ordinary skill in the art would not have been motivated to use staples having non-parallel legs (Ex. 2004 ¶¶ 75, 79, 88), he also testified later, under cross-examination, that he himself used non-parallel staples in practice a majority of the time (Ex. 1023 at 56, ll. 10-15). We find his testimony to be less persuasive than Petitioner's expert testimony of Mr. Bolanos, especially in light of the testimony by

Mr. Kelly in the German lawsuit that the "problem of keeping staples in their pockets is generally solved . . . by bending the tips of the legs of the unloaded staples slightly outward," i.e., by having staple legs that are non-parallel. For all of these reasons, Petitioner has shown, with supporting evidence, that one of skill in the art would have had reason to combine the prior art to arrive at the claimed invention.

2. Teach Away from the Claimed Invention

A reference does not teach away if it merely expresses a general preference for an alternative invention, but does not "criticize, discredit, or otherwise discourage" investigation into the claimed invention. *DePuy Spine Inc. v. Medtronic Sofamor Danek*, 567 F.3d 1314, 1327 (Fed. Cir. 2009) (quoting *In re Fulton*, 391 F.3d 1195, 1201 (Fed Cir. 2004)). "[I]n general, a reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant." *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994).

Patent Owner contends that one of skill in the art would have been led away from using non-parallel staples as disclosed by Green, because

(1) surgical staplers need precise alignment of staples (Resp. 23-32), and

(2) additional force is required to fire non-parallel staples (*id.* 32-38).

Petitioner argues, to the contrary, that the use of non-parallel staples may involve factors such as alignment and force, but such factors would have been understood by those skilled in the art. Reply at 8. According to Mr. Bolanos, expert for Petitioner, alignment and the proper application of force were considerations commonly taken into account when designing staplers. Ex. 1031 ¶ 7. Furthermore, Mr. Ortiz, Patent Owner's expert, testified later, under cross-examination, that the alignment and force analysis he described in his declaration were known to one of skill in the art. *See, e.g.*, Ex. 1023 at 142:22-143:4, 126:17-127:6, 136:24-137:18.

Therefore, we are not persuaded by Patent Owner's argument that certain attributes of non-parallel staples (such as ensuring precise alignment and requiring additional force) would dissuade one of ordinary skill in the art from using such staples. Patent Owner has not directed us to where in Viola or Pruitt there is the suggestion that use of staples with non-parallel legs was unlikely to work. Although Viola and Pruitt do not teach the use of staples with non-parallel legs, the references do not teach away from the use of staples with non-parallel legs. Moreover, Patent Owner has not rebutted Petitioner's showing by demonstrating that the disclosures in Viola, Pruitt, or Green would have led one of ordinary skill in the art to conclude that Green's non-parallel staples were unsuitable for use in the Viola or Pruitt stapling devices.

Therefore, we reject Patent Owner's argument that a skilled artisan would not have found it obvious to use staples with non-parallel legs with staple

devices of Viola or Pruitt because the prior art teaches away from the claimed invention.

3. Obvious to Try Known and Predictable Elements in the Prior Art such as Staples with Non-Parallel Legs

In *KSR*, 550 U.S. at 421, the Supreme Court explained that "obvious to try" may apply when "there are a finite number of identified, predictable solutions" to a known problem. The Court explained that when the path has been identified and "leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense." *Id*. The Federal Circuit elaborated that the identified path must "present a finite (and small in the context of the art) number of options easily traversed to show obviousness." *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F. 3d 1358, 1364 (Fed. Cir. 2008).

Petitioner contends that one of skill in the art would have understood that the devices in Pruitt and Viola could use, or be modified to use, staples with non-parallel legs. Pet. 58; Ex. 1010 ¶ 108. According to Petitioner, staples with non-parallel legs were well known at the time of the alleged invention of the '070 patent (Pet. 58-59), and, in fact, practitioners in the field had the limited option of using staples with parallel legs or non-parallel legs (Tr. 4-5; Reply 6 (citing Ex. 1032 at 50)). Patent Owner contends that the use of non-parallel staples was not obvious. According to Patent Owner, if the use of non-parallel staples was obvious, then Petitioner would have used them prior to the filing of the '070 patent, and would

have advertised their use of such staples. Resp. 43-44; Tr. 21-23. Patent Owner also contends that the prior art would have discussed the use of non-parallel staples. Tr. 21-23.

First, "[i]n many fields there may be little discussion of obvious techniques or combinations, and market demand, rather than scientific literature, may often drive design trends." *KSR*, 550 U.S. at 402. Thus, we give little weight to the absence of advertising by Petitioner of its use of non-parallel staples.

Second, as disclosed in Green, the prior art does discuss the use of non-parallel staples. Ex. 1009. That disclosure is inconsistent with the position taken by Patent Owner that such staples were not known to be used.

Finally, as discussed above, Mr. Ortiz used non-parallel staples "maybe 50 or 75 percent of the time" in his practice (Ex. 1023 at 56, ll. 10-15). Mr. Bolanos, expert for Petitioner, worked for Petitioner and testified that when designing staplers he started with a design premised on non- parallel staples. Ex. 1031 ¶ 4. The testimony of the experts indicates that those of skill in the art knew of non-parallel staples and frequently used such staples. Furthermore, Patent Owner's expert witness testified in a German lawsuit that a person skilled in the art knew that he could choose between two different staple shapes, namely between U-shaped or parallel staples on the one hand, and V-shaped or non-parallel staples, on the other. Reply 6 (citing Ex. 1032 at 50).

Therefore, given the prevalence of non-parallel staples, and the fact that those in the field had but two choices for staple designs, we find it would have been obvious to try non-parallel staples when designing stapling devices, such as those disclosed in Viola and Pruitt. Additionally, the limited choice of two staple designs further supports our finding that a person of skill in the art would have had reason to combine the non-parallel staple of Green with the stapling devices in Viola and Pruitt.

C. Secondary Considerations of Non-Obviousness

Patent Owner contends that Petitioner has failed to meet its burden of showing unpatentability, because the objective indicia of nonobviousness indicate that the claimed subject matter would not have been obvious. Resp. 48-59; Tr. 29. Objective indicia constitute independent evidence of non-obviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966) (holding that tactual inquiries for an obviousness determination include secondary considerations based on evaluation and crediting of objective evidence of nonobviousness); *Mintz v. Dietz & Watson, Inc.*, 679 F.3d 1372, 1378 (Fed. Cir. 2012). Notwithstanding what the teachings of the prior art would have suggested to one with ordinary skill in the art at the time of Patent Owner's invention, the totality of the evidence submitted, including objective evidence of nonobviousness, may lead to a conclusion that the claimed invention would not have been obvious to one with ordinary skill in the art. *In re Piasecki*, 745 F.2d 1468, 1471-1472 (Fed. Cir. 1984).

Secondary consideration factors include (1) unexpected results, (2) commercial success, (3) satisfaction of long-felt need, (4) failure of others, and (5) copying by others. *E.g., Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 291 (Fed. Cir. 1985); *Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 894 (Fed. Cir. 1984). Patent Owner has alleged (1) commercial success, and (2) satisfaction of long-felt but unresolved need. Resp. 48-59. However, as discussed below, the objective indicia argued by Patent Owner do not establish a nexus with the claimed subject matter.

There must be a demonstrated "nexus" between the merits of the claimed invention and the evidence of secondary considerations before that evidence is accorded substantial weight in an obviousness determination. *Simmons Fastener Corp. v. Illinois Tool Works, Inc.*, 739 F.2d 1573, 1575 (Fed. Cir. 1984); *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1539 (Fed. Cir. 1983); *see also In re Huang*, 100 F.3d 135, 140 (Fed. Cir. 1996); *In re Fielder*, 471 F.2d 640, 642 (CCPA 1973). "Nexus" is a legally and factually sufficient connection between the objective evidence and the claimed invention, such that the objective evidence should be considered in determining nonobviousness. *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1392 (Fed. Cir. 1988). In the absence of an established nexus with the claimed invention, secondary consideration factors, such as commercial success and satisfaction of a long-felt but unresolved need, are not entitled to much, if any, weight, and

generally have no bearing on the legal issue of obviousness. *See In re VamcoMachine & Tool, Inc.*, 752 F.2d 1564, 1577 (Fed. Cir. 1985).

1. Commercial Success of Petitioner's Tri-Staple Devices

Patent Owner argues that the commercial success of Petitioner's Tri- Staple devices establishes the requisite nexus with the claims of the '070 patent, and indicates the non-obviousness of the claims. Resp. 52. Specifically, Patent Owner contends that high sales volume of the Tri-Staple products can be mapped to the practice of at least claims 8 and 10 of the '070 patent. *Id.*; Ex. 2004 ¶¶ 130-131. When the patent is said to cover a feature or component of a product, Patent Owner has the burden of showing that the commercial success derives from the feature, in this case use of non-parallel staples and staples of different preformed and formed heights. *See Tokai Corp. v. Easton Enters., Inc.*, 632 F. 3d 1358, 1369 (Fed. Cir. 2011). In other words, in order to establish a proper nexus, Patent Owner must offer proof that the sales were a direct result of the unique characteristics of the claimed invention—as opposed to other economic and commercial factors unrelated to the quality of the patented subject matter. *See In re Huang*, 100 F. 3d 135, 140 (Fed. Cir. 1996). Furthermore, if commercial success is due to an element in the prior art, no nexus exists. *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1312 (Fed. Cir. 2006); *see also Richdel, Inc. v. Sunspool Corp.*, 714 F.2d 1573, 1580 (Fed. Cir. 1983) (holding claimed invention obvious where patent holder "failed to show that such

commercial success . . . was due to anything disclosed in the patent in suit which was not readily available in the prior art").

In arguing for commercial success, Patent Owner relies heavily on marketing material and a 2012 Annual Report to Shareholders from Petitioner that describe Petitioner's Tri-Staple devices and tout the devices as being some of the most successful products for Petitioner. Resp. 55 (citing Ex. 2013, Ex. 2016, Ex. 2019, Ex. 2020, and Ex. 2024). Patent Owner compares the sales for the Tri-Staple devices to products Petitioner previously offered for sale (Petitioner's "legacy devices"), and argues, directing attention to evidence, that as sales for the Tri-Staple devices increased, sales for the legacy devices decreased. *Id*. at 56-57. According to Patent Owner, the evidence shows that Petitioner charges a premium for the Tri-Staple devices compared to the legacy products, and despite the higher price, Petitioner now sells more of the Tri-Staple devices than it sells of the legacy devices. *Id*. at 56.

Patent Owner's expert, Mr. Ortiz, testified that he examined Petitioner's Tri-Staple device, and based on his examination, declared that the device practiced the invention of at least claims 8 and 10 of the '070 patent. Ex. 2004 ¶ 130. Mr. Ortiz also testified that he analyzed how the Tri-Staple devices compared to the legacy products and "under[stood] that the Covidien legacy devices did not include all of the following features in one device: non-parallel staples with multiple pre-formed heights which, when fired, resulted in staples with multiple formed heights." *Id*. at ¶ 136. However, Mr. Ortiz did not

testify that he examined Petitioner's legacy products. According to Mr. Ortiz, "the combination of features [of claims 8 and 10 of the '070 patent] results in a 'truly innovative surgical stapling platform' that Covidien has priced at a premium compared to devices not containing the combination of the patented features." *Id*. at ¶ 140. Patent Owner, thus, concludes that the increased sales for the Tri-Staple devices over the legacy devices is "due to the fact that the [Tri-Staple] devices contain the combination of features in claims 8 and 10 of the '070 patent." Resp. 57; Ex. 2004 ¶ 140.

Petitioner contends, to the contrary, that the commercial success of the Tri-Staple devices is attributable to unclaimed features, such as ergonomic design, precise articulation, and reloads that provide simpler selection and reduced inventory. Reply 15. Therefore, according to Petitioner, any success enjoyed by the Tri-Staple devices is not due to the claimed invention. Tr. 46.

We have considered Patent Owner's Exhibits 2016, 2019, 2020, and 2024, which purport to show that the Tri-Staple devices include the features of claims 1-14. We also have reviewed the testimony of Mr. Ortiz at Exhibit 2004 in detail. First, Patent Owner has not shown sufficient credible evidence that the sales of the Tri-Staple devices are the result of the claimed invention, rather than other features of the Tri-Staple devices. Second, as Patent Owner admitted, all of the elements of the claimed invention are found in the prior art. Tr. 23-24. Therefore, the objective evidence regarding commercial success cited by the Patent Owner does not overcome the

strong case of obviousness established by Petitioner by a preponderance of the evidence.

2. Long-Felt but Unresolved Need for the Invention of the '070 Patent

Patent Owner argues that a long-felt but unresolved need for the invention of the '070 patent indicates the non-obviousness of the claims of '070 patent. Resp. 58. Specifically, Patent Owner contends that Petitioner admits in its own document that there was a long-felt but unresolved need for the invention of the '070 patent. *Id*. Patent Owner cites to a marketing brochure from Petitioner, which states:

> With significant investments into research and development over the years, *Endo GIA Reloads with Tri-Staple Technology and ENDO GIA Ultra Universal staplers have been developed with intent to fulfill the unmet needs of surgeons across different surgical specialties*. Covidien's revolutionary new Endo Stapling system enables surgeons to operate with confidence to handle a broader range of tissue thickness and applications with outstanding clinical performance.

Id. (citing Ex. 2020) (emphasis in original).

Mr. Ortiz, expert for Patent Owner, testified there was an unmet need for a stapling device that

"enables surgeons to operate with confidence to handle a broader range of tissue thickness and applications with outstanding clinical performance." Ex. 2004 ¶ 142. According to Patent Owner, this "unmet need was satisfied with a device that included a 'fixed anvil' and 'improved tissue clamping' (resulting from the use of different preformed and formed non-parallel staples) – all as required by the claims of the '070 patent." Resp. 59 (citing Ex. 2004 ¶ 144).

Petitioner contends the long-felt need of surgeons that is satisfied by the Tri-Staple devices is not attributable to the claimed features, but instead may be due to unclaimed features, such as ergonomic design, precise articulation, and reloads that provide simpler selection and reduced inventory. Reply 15.

Satisfaction of a long-felt but unresolved need is not evidence of nonobviousness, unless it is shown that widespread efforts of skilled workers having knowledge of the prior art had failed to find a solution to the problem. *In re Allen*, 324 F.2d 993, 997 (CCPA 1963); *Toledo Pressed Steel Co. v. Standard Parts, Inc.*, 307 U.S. 350, 356 (1939). Patent Owner has not directed our attention to evidence that there was a widespread attempt by skilled workers in the art for a long period of time to use non- parallel staples with different pre-formed heights to create staples with different formed heights, and that all such attempts failed to achieve successful use of such staples.

Furthermore, even if we consider Petitioner's brochure to be an admission against interest, the

brochure fails to establish the existence of a "long-felt and unresolved" need in the industry, because it does not indicate that the "unmet need" is a persistent one recognized by those of ordinary skill in the art. *See In re Gershon*, 372 F. 2d 535, 539 (CCPA 1967). Thus, Petitioner's brochure does not support the assertion that there was a long-felt but unresolved need in the industry for Patent Owner's invention.

Therefore, we find that Patent Owner's arguments concerning the long-felt but unresolved need for the invention of the '070 patent do not overcome Petitioner's showing of obviousness.

III. CONCLUSION

We have considered the record before us in this *inter partes* review proceeding. We conclude that Petitioner has met its burden of proof, by a preponderance of the evidence, in showing that:

(1) claims 1-5, 7, 8, and 10-13 of the '070 patent are unpatentable under 35 U.S.C. § 103(a) over Viola and Green;

(2) claims 6, 11, and 14 of the '070 patent are unpatentable under 35 U.S.C. § 103(a) over Viola, Green, and Pruitt;

(3) claim 9 of the '070 patent is unpatentable under 35 U.S.C. § 103(a) over Viola, Green, and Burdorff;

(4) claims 8 and 10-14 of the '070 patent are unpatentable under 35 U.S.C. § 103(a) over Pruitt and Green;

(5) claim 9 of the '070 patent is unpatentable under 35 U.S.C. § 103(a) over Pruitt, Green, and Burdorff; and

(6) claims 1-7 of the '070 patent are unpatentable under 35 U.S.C. § 103(a) over Pruitt, Green, and Conta.

This is a final written decision.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1-14 of the '070 patent are determined to be UNPATENTABLE;

FURTHER ORDERED that because this is a final written decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

For PETITIONER:

Kathleen A. Daley
kathleen.daley@finnegan.com

Naveen Modi
naveen.modi@finnegan.com

For PATENT OWNER:

Steven D. Maslowski
smaslowski@akingump.com

Ruben H. Munoz
rmunoz@akingump.com

Patent Trial and Appeal Board

Patent and Trademark Office (P.T.O.)

COVIDIEN LP PETITIONER

v.

ETHICON ENDO-SURGERY, INC. PATENT OWNER

Case IPR2013-00209
Patent 8,317,070
August 26, 2013

For PETITIONER:

Kathleen A. Daley
kathleen.daley@finnegan.com
Naveen Modi
naveen.modi@finnegan.com

For PATENT OWNER:

Steven D. Maslowski
smaslowski@akingump.com
Ruben H. Munoz
rmunoz@akingump.com

Before SALLY C. MEDLEY, JOSIAH C. COCKS, and GEORGIANNA W. BRADEN
Administrative Patent Judges

COCKS
Administrative Patent Judge

DECISION

Institution of *Inter Partes* Review

37 C.F.R. § 42.108

I. INTRODUCTION

Petitioner Covidien LP ("Covidien") requests *inter partes* review of claims 1-14 of U.S. Patent No. 8,317,070 (the "'070 patent") pursuant to 35 U.S.C. §§ 311 et seq.[1] Patent Owner Ethicon Endo-Surgery, Inc. ("Ethicon") filed a preliminary response under 37 C.F.R. § 42.107(b) on June 21, 2013 (Paper 6). We have jurisdiction under 35 U.S.C. § 314.

The standard for instituting an *inter partes* review is set forth in 35 U.S.C. § 314(a), which provides as follows: THRESHOLD -- The Director may not authorize an inter partes review to be instituted unless the Director determines that the information presented in the petition filed under section 311 and any response filed under section 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.

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[1] *See* "Petition for *Inter Partes* Review of U.S. Patent No. 8,317,070" filed March 25, 2013 (Paper 1).

For the reasons set forth *infra*, the Board has determined to institute an *inter partes* review.

A. The '070 Patent (Ex. 1001)

The '070 patent is directed to surgical stapling devices. (Ex. 1001, Abstract.) The '070 patent generally characterizes the invention disclosed therein as one that is "capable of producing staples of different formed length" when the staples are applied, for instance, to tissue. (*Id.* at col. 2, ll. 28-30.) In describing background information in connection with the invention, the '070 patent states:

> Whenever a transsection of tissue is across an area of varied tissue composition, it would be advantageous for the staples that are closest to the cut line to have one formed height that is less than the formed height of those staples that are farthest from the cut line. In practice, the rows of inside staples serve to provide a hemostatic barrier, while the outside rows of staples with larger formed heights provide a cinching effect where the tissue transitions from the tightly compressed hemostatic section to the non-compressed adjacent section.

(Ex. 1001, col. 2, ll. 4-12.)

Claims 1 and 8 are independent claims. Claim 1, reproduced below, is illustrative of the claimed subject matter:

1. A surgical stapling device comprising an end effector that comprises:

a circular anvil having a staple forming surface;

a plurality of staples facing the staple forming surface of the anvil, each staple comprising a main portion and two prongs, wherein the two prongs each comprise a first end and a second end, wherein the first ends are connected to opposite ends of the main portion, and wherein the two prongs extend non-parallelly from the main portion; and

a staple driver assembly comprising a plurality of staple drivers, wherein each staple driver supports one of the plurality of staples and is configured such that, when the staple driver assembly is actuated, each staple driver drives the staple into the staple forming surface of the anvil, wherein a first quantity of the staples have a first pre-deformation height, measured from a lower surface of the main portion to the second end of the first prong, and a second quantity of the staples have a second pre-deformation height, measured from a lower surface of the main portion to the second end of the first prong, wherein the first height is less than the second height, such that when the staple driver assembly is actuated, the first quantity of staples have a different formed staple length than the second quantity of staples.

B. The Prior Art

Covidien relies on the following prior art:

U.S. Patent Application Publication 2007/003466 published February 15, 2007 to Holsten et al. ("Holsten") (Ex. 1002);

U.S. Patent 4,941,623 issued July 17, 1990 to Pruitt ("Pruitt") (Ex. 1003);

International Publication WO 2003/094747 A1 published November 20, 2003 to Viola ("Viola") (Ex. 1004);

U.S. Patent 5,697,543 issued December 16, 1997 to Burdorff ("Burdorff") (Ex. 1005);

U.S. Patent 4,304,236 issued December 8, 1981 to Conta et al. ("Conta") (Ex. 1006);

Japanese Patent Application Publication 2001-87272 published April 3, 2001 to Iwabuchi ("Iwabuchi") (Ex. 1007);

U.S. Patent 5,964,394 issued October 12, 1999 to Robertson ("Robertson") (Ex. 1008); and

U.S. Patent 3,494,533 issued February 10, 1970 to Green et al. ("Green") (Ex. 1009).

C. The Alleged Grounds of Unpatentability

Coviden contends that claims 1-14 are unpatentable under 35 U.S.C. §§ 102 and 103 on the following grounds (Pet. 3-5):

Reference[s]	Basis	Claim[s] challenged
Holsten	§102	1-8 and 10-14

Holsten and Viola	§103	4, 5, 12, and 13
Holsten and Burdorff	§103	9
Pruitt	§102	8 and 10-14
Pruitt and Viola	§103	1-7, 12, and 13
Pruitt and Burdorff	§103	9
Pruitt and Conta	§103	1-7
Pruitt, Conta, and Viola	§103	4 and 5
Viola	§102	1-5, 7, 8, and 10-13
Viola and Pruitt	§103	6, 11, and 14
Viola and Burdorff	§103	9
Holsten and Iwabuchi	§103	4, 5, 12, and 13
Pruitt and Iwabuchi	§103	12 and 13
Pruitt, Conta, and Iwabuchi	§103	4 and 5
Holsten and Robertson	§103	8 and 10-14
Holsten, Robertson, and Viola	§103	12 and 13
Holsten, Robertson, and Burdorff	§103	9
Holsten, and Robertson, and Iwabuchi	§103	12 and 13
Holsten and Green	§103	1-8 and 10-14
Holsten, Viola, and Green	§103	4, 5, 12, and 13
Holsten, Burdorff, and Green	§103	9
Pruitt and Green	§103	8 and 10-14
Pruitt, Viola, and Green	§103	1-7, 12, and 13

Pruitt, Burdorff, and Green	§103	9
Pruitt, Conta, and Green	§103	1-7
Pruitt, Conta, Viola, and Green	§103	4 and 5
Viola and Green	§103	1-5, 7, 8, and 10-13
Viola, Pruitt, and Green	§103	6, 11, and 14
Viola, Burdorff, and Green	§103	9
Holsten, Iwabuchi, and Green	§103	4, 5, 12, and 13
Pruitt, Iwabuchi, and Green	§103	12 and 13
Pruitt, Conta, Iwabuchi, and Green	§103	4 and 5
Holsten, Robertson, and Green	§103	8 and 10-14
Holsten, Robertson, Viola, and Green	§103	12 and 13
Holsten, Robertson, Burdorff, and Green	§103	9
Holsten, Robertson, Iwabuchi, and Green	§103	12 and 13

II. ANALYSIS

A. Claim Construction

The Board construes a claim in an *inter partes* review using the "broadest reasonable construction in light of the specification of the patent in which it

appears." 37 C.F.R. § 42.100(b); *see Office Patent Trial Practice Guide,* 77 Fed. Reg. 48756, 48766 (Aug. 14, 2012). That construction must be consistent with the specification and the claim language should be read in light of the specification as it would be interpreted by one of ordinary skill in the art. *In re Suitco Surface, Inc.*, 603 F.3d 1255, 1260 (Fed. Cir. 2010). Furthermore, claim terms are given their ordinary and customary meaning as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Technology, Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Covidien contends that most of the claim terms of the '070 patent should be given their ordinary and customary meaning. (Pet. 8.) Covidien urges that certain terms, however, warrant individual construction and sets forth proposed meanings in that regard. (*Id*. at 8-13.)

In reviewing the record, including Covidien's petition and Ethicon's preliminary patent owner response, we conclude that all terms should be given their ordinary meaning, but make explicit the construction of the following terms: (1) "two prongs extend non-parallelly from the main portion"; (2) "non-pivotable anvil"; and (3) "formed staple length." (Ex. 1001, cols. 27-28.)

1. "two prongs extend non-parallelly from the main portion"

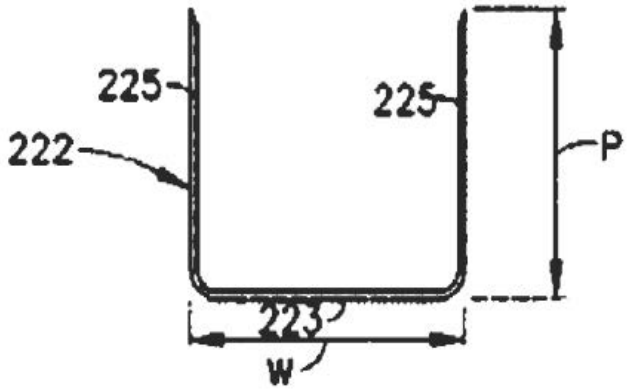
Each of independent claims 1 and 8 is drawn to a "surgical stapling device" and includes recitation of a "plurality of staples" with each staple comprising "a main portion and two prongs." The claims further

require that the prongs are connected to opposite ends of the main portion and that the "two prongs extend non-parallelly from the main portion." (Ex. 1001, col. 27, ll. 56-58; col. 28, ll. 42-45.) Covidien and Ethicon disagree as to the meaning of that quoted phrase. In particular, according to Covidien, the phrase means that the two prongs extend so as to be non-parallel "relative to the main portion." (Pet. 8-9.) On the other hand, Ethicon contends that the non-parallel extension of the prongs is "relative to each other" in so extending from the main portion. (Prelim. Resp. 8-9.) In light of the record before us, we are of the opinion that Ethicon's view is correct in setting forth the ordinary meaning of the phrase and one that is consistent with the '070 patent.

Covidien's position as to the meaning of the pertinent phrase substitutes the term "relative to" for the term "from." Those two terms, however, are not the same. That is, components extending "from" a structure do not extend necessarily "relative to" that structure. Indeed, the recitation that the "prongs" must extend "from" the main portion has a discernible meaning. In that regard, the main portion is the originating point for the extension of the prongs. We do not see any credible reason why, in interpreting the above-noted phrase, the term "from" should be omitted and replaced by ""relative to."

Moreover, the limitation at issue establishes that the extension of the two prongs has two characteristics; namely, the two prongs extend: (1) "non-parallelly"; and (2) "from the main portion." The natural reading of the first characteristic is that the extensions of the prongs, from whatever component, are characterized

as "non-parallelly." The second noted characteristic identifies the component from which the prongs extend, *i.e.*, the main portion. In that interpretation, and as is argued by Ethicon, the configuration of a staple that is excluded from the scope of the claim is that shown on the right, which is a reproduction of Fig. 12 of the '070 patent. In Figure 12, prongs 225 are parallel with one another in extending from main portion 223. Although the staple of Figure 12 was contemplated as a staple "that may be employed with various embodiments of the present invention" (Ex. 1001, col. 4, ll. 1-2), Ethicon contends that such a staple configuration is outside the scope of claims 1-14. (*See* Prelim. Resp. 9-10.) On the other hand, Ethicon argues that a staple shown, for instance, at Figure 81 of the '070 patent (reproduced on right), is within the scope of the claims. In that figure, the prongs 222 are recognizable as extending from a main portion in non-parallel fashion with respect to each other.



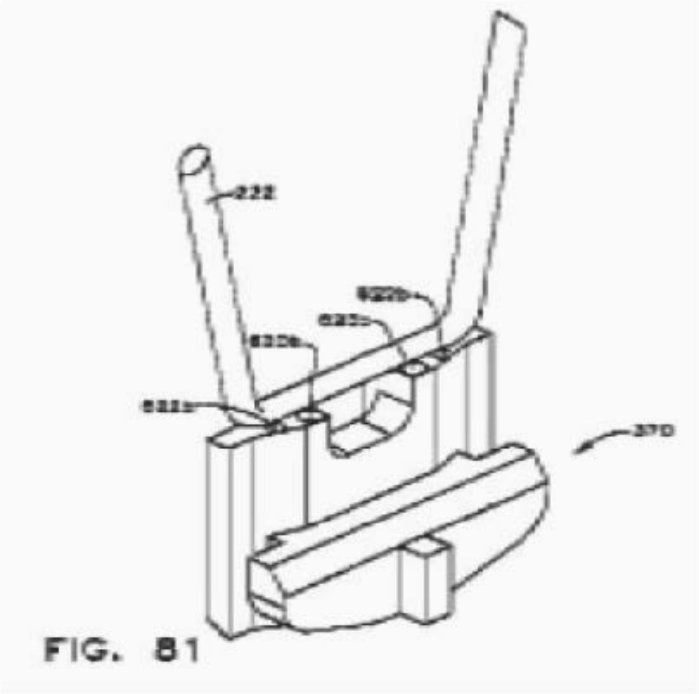


FIG. 81

Covidien's position that the noted limitation requires that the non-parallel extension of the prongs is relative to the main portion encompasses both the configurations depicted above and excludes only a "staple" in which the prongs extend in the same plane, and along the same axis, as the main portion. In such a configuration, the "staple" has prongs and main portion which extend so as to form a straight line, *e.g.*, a straight piece of wire. Yet, review of the record does not reveal that any staple disclosed in the '070 patent, nor any staple disclosed in the prior art, has such a configuration. Indeed, we share Ethicon's view that such a configuration "no longer constitutes a 'staple' in the spirit of the '070 specification," and thus would not be considered a

"staple" configuration to be excluded. (Prelim. Resp. 13.)

As further argued by Ethicon, Covidien's construction of the pertinent phrase would "cover essentially all configurations of staples." (Prelim. Resp. 10-11.) Ethicon contends, however, that the "extending non-parallely" feature at issue was added during prosecution of the underlying application that became the '070 patent, so as to present a staple configuration that is "different from" a staple structure shown, for instance, in Figure 12 reproduced *supra*. (Prelim. Resp. 10.) In support of that contention, Ethicon directs our attention to Exhibit 1014, which is an "Amendment" dated June 17, 2008 in which the phrase at issue was added to claims of the application that became the '070 patent. Those claims, as amended, which ultimately issued as the '070 patent, are described as including staples distinct from "staples" of the prior art. (Ex. 1014, p. 7.)

As discussed above, we do not discern that any portion of the '070 patent, or for that matter any portion of the record, conveys that a straight line of material, such as wire, would be regarded by one of ordinary skill in the art as a "staple."

In considering the record before us, and with the foregoing reasoning in mind, we are not persuaded that Convidien's proposed claim construction is correct. Accordingly, based on this record, we conclude that the broadest reasonable construction of the phrase "two prongs extend non-parallely from the main portion" consistent with the '070 patent is that

the non-parallel extension of those prongs is relative to each other.

2. "formed staple length"

Each of claims 1 and 8 requires a plurality of staples identifiable as a ""first quantity" of staples having a "first pre-deformation height" and a ""second quantity" having a "second pre-deformation height." Those claims recite that "when the staple driver assembly is actuated, the first quantity of staples have a different formed staple length than the second quantity of staples."

Covidien contends that the term "length" in connection with the "formed staple length" should be interpreted as the term "height." (Pet. 10.) In support of that contention, Covidien points to portions of the specification of the '070 patent as using the terms "length" and "height" in a manner characterized by Covidien as "interchangeably." (*Id.* at 10-11.) Ethicon "does not object" to Covidien's proposed construction of "formed staple length" as meaning "formed staple height." (Prelim. Resp. 18.)

The terms "height" and "length" are understood generally as being terms that are not necessarily the same in designating measurements of a given structure. However, in reviewing the '070 patent, those terms are used throughout the specification to designate the same dimension in connection with the extension of prongs of a staple. For instance, the prongs 225 shown in Figure 12 are designated as having a "length 'P','D' which, as depicted in the reproduction of that figure *supra*, is the dimension of

the prongs extending from the main portion 223. (Ex. 1001, col. 11, ll. 20-22; *see also* col. 16, ll. 14-16 describing "prong lengths 'P'.'D') Elsewhere, the dimension "P" for the prongs is designated "prong heights." (*Id.* at 19, ll. 25-26.) Similarly, in connection with "formed staples" the terms "formed lengths" and "formed heights" are each used in reference to the extension of the prongs from the main portion of the staple after it has been formed. (*E.g., id.* at col. 2, ll. 39-44; col. 16, ll. 54-64; col. 19; ll. 65-67.)

Accordingly, in the context of the '070 patent, the "formed staple length" is understood as referencing the distance or "height" that the prongs extend from the main portion of the staple when the staple is formed.

3. "non-pivotable anvil"

Independent claim 8 includes recitation of a "non-pivotable anvil." As is understood from the '070 patent, an "anvil" is a structure having a surface against which staples are driven or fired so as to configure the staple into a ""form[ed]" condition. (*E.g.*, Ex. 1001, Abstract; col. 1, ll. 45-58.) According to Covidien, in the context of the '070 patent, the term "pivot" and ""rotation" have the same meaning such that "non-pivotable" means "non-rotatable." (Pet. 12.) As support for its position, Covidien submits that the plain meaning of pivot is "[a] short rod or shaft on which a related part rotates or swings." (*Id.*) According to Covidien, based on that meaning, a ""non-pivotable anvil" should be construed as a "non- rotatable anvil." (*Id.*)

Ethicon challenges Covidien's position that the terms "non-pivotable" and ""non-rotatable" have the same meaning. Ethicon explains how, in the context of the '070 patent, an anvil may be regarded as one that is capable of rotation, *i.e.* rotatable, but also incapable of pivoting, *i.e.*, non-pivotable. (Prelim. Resp. 14-17.) In reviewing the '070 patent, we agree with Ethicon that "non-pivotable" does not mean "non-rotatable." Indeed, we observe that the plain meaning of "pivot" offered by Covidien undermines its position that "non-pivotable" means "non-rotatable." The meaning conveys that a component that is pivotable is one that either may rotate or swing about a short rod or shaft. That the term "pivot" itself is associated with an action characterized as either rotation or swinging about a shaft, does not convey that the term ""pivot" means the same thing as "rotate."

Given the term "non-pivotable anvil" its broadest reasonable interpretation that is consistent with the specification of the '070 patent, we construe the term as meaning an anvil that does not rotate or swing about a short rod or shaft.

B. Discussion

Covidien alleges 36 grounds of patentability. Of those grounds, 18 are predicated on Covidien's proposed interpretation of the "extending non-parallelly" feature as not excluding a staple configuration in which two prongs extend parallel in relation to each other from a main prong. For the reasons discussed above, we are not persuaded that such an interpretation is correct. Covidien also proposes alternative grounds based on a construction

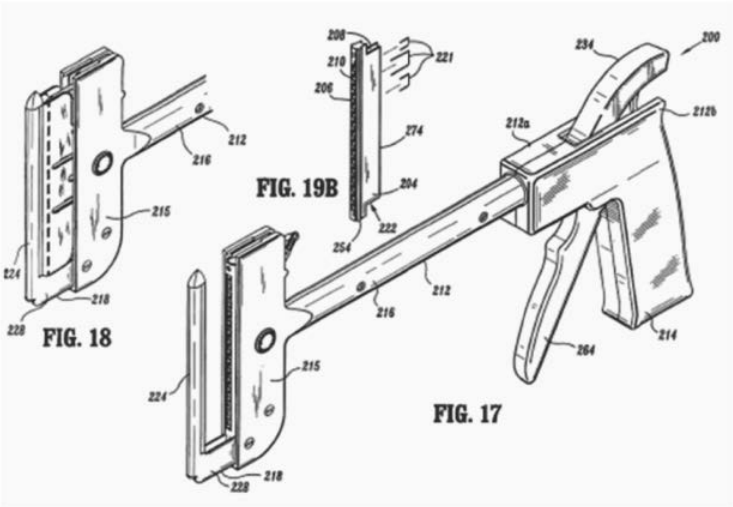
of the ""extending non- parallelly" that is in accord with the construction proposed by Ethicon and which we adopt. Those alternative grounds all rely on the teachings of Green to account for that feature. We focus first on those grounds based on the teachings of Viola and Green.

1. Grounds Based on Viola and Green

Covidien contends that: (1) claims 1-5, 7, 8, and 10-13 are unpatentable over Viola and Green; (2) claims 6, 11, and 14 are unpatentable over Viola, Green, and Pruitt; and (3) claim 9 is unpatentable over Viola, Green, and Burdorff. (Pet. 5.)

a. Claims 1-5, 7, 8, and 10-13

Viola discloses a surgical stapler that employs multiple rows of differently-sized fasteners or staples. (Ex. 1004, Abstract.) An embodiment of Viola's surgical stapler is described in Figures 17-19. Figures 17, 18, and 19B are reproduced below:



As illustrated in the figures above, a surgical stapler 200 includes a handle 214 and a transverse body portion 215 separated by a distally-extending body portion 226. (Ex. 1004, p. 17, ll. 6-10.) A support frame 218 is received by the body portion 215 and includes first leg 224 with an "anvil" (not shown in figure) fastened to the leg. (*Id*. at p. 17, ll. 10-28.) A carrier cartridge incorporating cartridge assembly 222 includes differently-sized fasteners or staples 221 and is supported slidably by support frame 218 and moveable towards first leg 224. (*Id*. at p. 17, ll. 29-32.) The anvil associated with leg 224 neither pivots nor rotates and is thus "non-pivotable" as required by claim 8. Claim 1 requires that the anvil is a "circular anvil." Viola describes that its invention may be applied to "circular" staplers. (*Id*. at p. 21, ll. 11-12.) We credit the testimony of Covidien's expert witness, Henry Bolanos, that one with ordinary skill in the art would have known that a "circular stapler" includes a circular anvil with a

corresponding staple forming surface. (*See* Ex. 1010, ¶ 88.)

Furthermore, with respect to claims 1 and 8, Viola discloses a plurality of staples associated with its surgical stapler with prongs having predeformation heights that are different as between the staples, *e.g.*, staples 221 in Figure 19B. (*See* Ex. 1004, p. 3, ll. 1-13; p17, l. 33 - p. 18, l. 2.) Viola also discloses that the differing lengths of the staples operate to "progressively compress[] tissue" from an outer edge to a knife cut line so as to "ensure effective hemostasis" and "ensure effective anastomotic strength." (*Id*. at p. 10, ll. 11-17; p. 11, ll. 28-32; p. 16, ll. 17-20.) Mr. Bolanos testifies that ""[t]o progressively compress tissue, the staples must squeeze tissue to varying degrees" and that one with ordinary skill in the art would understand, therefore, that Viola discloses that the formed staples have different, formed staple lengths. (Ex. 1010, ¶ 94, pp. 95-96.) We credit that testimony and are persuaded that Viola discloses first and second quantities of staples with different, formed staple lengths.

With respect to the requirement that the staple prongs "extend non-parallelly," Viola discloses only staples with prongs that extend parallel with respect to each other, such as the staples 221 in Figure 19b. However, Green, which is directed to a surgical stapler, discloses staples whose prongs extend in a non-parallel fashion. In particular, as shown in Figure 31 of that reference (reproduced right), the side legs or prongs 105 of a staple extend in a non-parallel manner from a connecting portion 104.

Green also describes the following with respect to Figure 31:

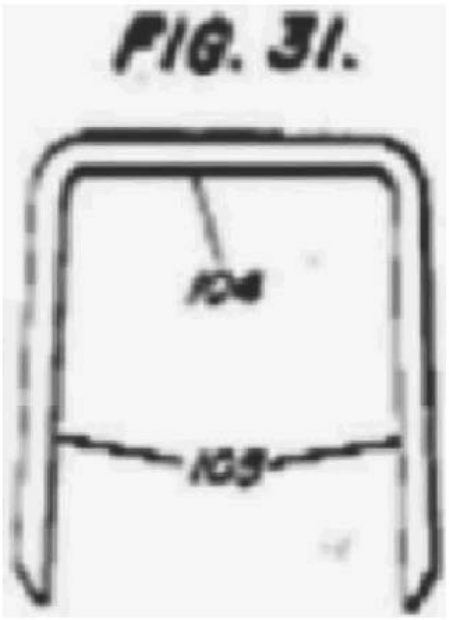


FIGURE 31 shows a staple which is used in an instrument of the type disclosed herein. It should be noted that the staple comprises a back or connecting leg portion 104 and two outwardly flaring side legs 105. Since the staple holding slots in the cartridge are only of a width corresponding to the outer dimension across leg portion 104, the staples are securely held within said slots by the spring action of legs 105 which are necessarily sprung into a parallel relationship by the slot end walls.

(Ex. 1009, col. 13, l. 71 col. 14, l. 4.) Thus, Green attributes a benefit to a staple configuration in which the side legs or prongs of the staple are ""outwardly flaring" or non-parallel with one another in allowing the staple to be "securely held" when arranged within a surgical stapling device. We credit Mr. Bolanos' testimony that a person of ordinary skill in the art would have recognized that the staples disclosed in Viola may be modified so as to assume the configuration set forth in Green to be held securely within the retention slots of Viola's stapling device. (*See* Ex. 1010, ¶ 108.)

Claim 2 depends from claim 1 and adds the feature that a staple driver assembly includes an "outer ring" and an "inner ring" of staple drivers. (Ex. 1001, col. 28, ll. 7-9.) Covidien contends that Viola discloses a staple driver assembly formed from head portion 272 and fingers 276. (Pet. 51.) Those components are shown in Figure 19A. Viola also discloses the following:

> The plurality of distally extending fingers 276 are integrally formed on head portion 272. Each finger 276 has a concave distal surface configured to engage the fasteners 221 housed within cartridge assembly 222. Fingers 276 extend from head portion 272 in a pattern that corresponds to the pattern that fasteners 221 are housed within cartridge assembly 222. For example, the pattern may be two or three staggered rows. Other patterns are also contemplated.

(Ex. 1004, p. 19, ll. 2-7.) Viola further characterizes the configuration of its staples as being that of "outer rows" and "inner rows." (*Id*. at p. 11, ll. 28-32.) Mr. Bolanos testifies that given Viola's disclosure of a circular stapler, a person of ordinary skill in the art would have understood that in such a stapler, fingers 276 would be arranged as multiple rings, rather than multiple rows, and that the rings would be arranged as inner and outer rings. (Ex. 1010, ¶ 89.) We credit Mr. Bolanos' testimony in that regard.

We are satisfied also that Viola discloses: the "handle assembly" features of claim 3; the "wire diameter" requirements of claims 4, 5, 12, and 13; the "knife" arrangement of claim 7; and the configuration of staples in "rows" as set forth in claim 10. (*See* Pet., 48-49; 51-52.) All of those claims depend from either claim 1 or claim 8.

Accordingly, for the foregoing reasons, we are persuaded that Covidien has demonstrated a reasonable likelihood that it will prevail in its contention that claims 1-5, 7, 8, and 10-13 of the '070 Patent are unpatentable over Viola and Green.

b. Claims 6, 11, and 14

Covidien proposes that claims 6, 11, and 14 are unpatentable over Viola, Green, and Pruitt. Claims 6 and 14 depend from claims 1 and 8, respectively, and add that the staple-forming surface of the anvil includes "a plurality of staple forming pockets" composed of first and second quantities of such pockets having, respectively, first and second depths where the first depth is greater than the second.

(Ex. 1001, col. 28, ll. 24-31; col. 30, ll. 1-8.) Claim 11 depends from claim 8 and adds that the staple cartridge includes a "tissue retaining pin for engaging an opening [in] the anvil when the staple cartridge moves toward the anvil into a closed position." (*Id*. at col. 28, l. 66- col. 29, l. 2.)

Pruitt is directed to a surgical stapler and stapling process. (Pruitt, Abstract.) Like Viola, Pruitt describes a stapler that includes multiple rows of staples where the "prong lengths" of one row differs from the prong lengths of other rows. (*Id*.) Pruitt also discloses the presence of an anvil, *e.g*., anvil 17', that incorporates multiple "grooves" having different depths. (Ex. 1003, col. 10, ll. 48-54.) In particular, those grooves are characterized as ""deeper grooves" 8 and "shallow grooves" 8' and operate to receive the staple prongs and generate formed staples. (*Id*.) We credit the testimony of Mr. Bolanos that one of ordinary skill in the art would have recognized Pruitt's variable depth grooves or pockets as a known structural arrangement for forming staples having different formed lengths. (*See* Ex. 1010, ¶ 101.) We also are persuaded by that testimony that a skilled artisan would have modified Viola's anvil to include those variable depth pockets as a known technique to configure staples with different, formed lengths. (*See Id*.)

Pruitt further discloses embodiments in which a staple cartridge 19 includes a "positioning rod" 21. (Ex. 1003, col. 9, ll. 30-35.) Pruitt describes the following in connection with the function of that positioning rod:

> When the anvil and cartridge are positioned against the tissue to be stapled, further advancement of rod **21** will pierce the tissue by pointed end **21'** which will eventually enter an opening . . . in anvil **17** and thereby hold the tissue in position for the stapling operation.

(Ex. 1003, col. 9, ll. 52-57.) We credit Mr. Bolanos' testimony that Pruitt's positioning rod 21 and its operation constitutes the tissue retaining pin and the associated functionality that is required by claim 11. (*See* Ex. 1010, ¶ 53.) We also credit the testimony that one of ordinary skill in the art would have had adequate reason to incorporate Pruitt's positioning rod into Viola's staple cartridge assembly to hold the tissue in appropriate position. (*See id*. at ¶ 103.)

Accordingly, we are persuaded that Covidien has demonstrated a reasonable likelihood that it will prevail in its contention that claims 6, 11, and 14 of the '070 Patent are unpatentable over Viola, Green, and Pruitt.

c. Claim 9

Claim 9 depends from claim 8 and adds "wherein the anvil is slideably moveable toward the staple cartridge to clamp tissue between the anvil and the staple cartridge." Viola describes that its cartridge carrier 238 is "slidably supported" for movement towards leg 224, and thus also towards the anvil affixed to the leg. (Ex. 1004, p. 17, ll. 29-32.) Viola,

however, appears silent as to any sliding motion of the anvil itself.

Covidien points to Burdorff as disclosing a slideably moveable anvil. (Pet. 55; 31-32.) Burdorff is directed to a linear stapler for clamping and stapling into body tissue. (Ex. 1005, col. 1, ll. 5-7.) Burdorff's stapler includes a staple fastening assembly including a staple cartridge and an anvil facing the cartridge for forming staples released from the cartridge. (*Id*. at col. 2, ll. 10-12.) Burdorff also sets forth that "[t]he cartridge and anvil are movable toward each other from a spaced position for positioning tissue between the cartridge and anvil to a closed position for clamping the positioned tissue." (*Id*. at col. 2, ll. 15-19.) In reviewing Burdorff's figures, such as Figures 1 and 2, it is evident that the above-noted movement of the cartridge and anvil is sliding movement. We credit Mr. Bolanos' testimony that one with ordinary skill in the art would have recognized that Viola's stapler device may be configured to have an anvil slideably moveable towards a staple cartridge so as to place the anvil and cartridge in a position for clamping and stapling tissue. (*See* Ex. 1010, ¶ 106.)

Accordingly, we are persuaded that Covidien has demonstrated a reasonable likelihood that it will prevail in its contention that claim 9 of the '070 patent is unpatentable over Viola, Green, and Burdorff.

2. Grounds Based on Pruitt and Green

Covidien also proposes grounds of unpatentability of claims 1-14 involving Pruitt and Green. In particular, Covidien contends that (1) claims 8 and 10-14 are unpatentable over Pruitt and Green; (2) claim 9 is unpatentable over Pruitt, Green, and Burdorff; and (3) claims 1-7 are unpatentable over Pruitt, Green, and Conta. (Pet. 4.)

a. Claims 8 and 10-14

As discussed above, Pruitt discloses a surgical stapler that includes multiple rows of staples with "prong lengths," *i.e.*, pre-deformation heights, which differ between the rows. (Ex. 1003, Abstract.) Pruitt also discloses an anvil 17' that does not rotate or pivot and which includes a staple forming surface including "shallow grooves" 8' and "deeper grooves" 8. (*Id*. at col. 10, ll. 37-64.) Pruitt's Figure 27 is reproduced below and illustrates the appearance of various rows of staples 6 and 7 once they have been formed:

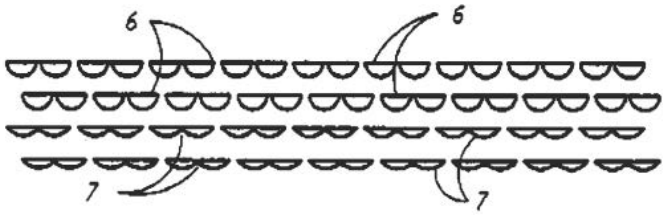


Fig. 27

As depicted in Figure 27 above, upper rows and lower rows of staples, respectively, 6 and 7, include

horizontal main portions or "crowns" of the same size (*see id*. at Abstract), but bent or formed prong lengths that are different in their extension from the crowns as between the upper and lower rows.

In reviewing Pruitt's disclosure, we are satisfied that it discloses all the features of claim 8 with the exception of pre-formed staples each having two prongs that "extend non-parallelly from the main portion," as we interpret that claim phrase (*see supra*). However, Covidien directs us to Green as disclosing staples with prongs that extend in non-parallel fashion relative to one another. (Pet. 58-59.) As with the grounds discussed *supra* involving Viola and Green, we are persuaded that a skilled artisan would have had adequate reason to implement non-parallel prongs onto the pre-deformed staples of Pruitt. (*See* Ex. 1010, ¶ 108.)

Claims 10-14 depend from claim 8. We also are satisfied that Covidien has explained adequately how Pruitt accounts for the features required by claims 10-14. (*See* Pet. 35-37; *see also* Ex. 1010, ¶¶ 52-56.) Accordingly, we are persuaded that Covidien has demonstrated a reasonable likelihood that it will prevail in its contention that claims 8 and 10-14 of the '070 Patent are unpatentable over Pruitt and Green.

b. Claim 9

Like the ground involving Voila, Green, and Burdorff, Covidien contends that Burdorff teaches the slideably-moveable anvil that is required by claim 9. (*See* Pet. 42-43.) For essentially the same

reasons discussed above with respect to Voila, Green, and Burdorff, we are persuaded that a skilled artisan would have appreciated that, based on the teachings of Burdorff, Pruitt's anvil may be configured so as to be slideably moveable. We credit Mr. Bolanos' testimony in that regard. (*See* Ex. 1010, ¶ 77.)

Therefore, we are persuaded that Covidien has demonstrated a reasonable likelihood that it will prevail in its contention that claim 9 of the '070 Patent is unpatentable over Pruitt, Green, and Burdorff.

c. Claims 1-7

We are satisfied that Pruitt taken with Green discloses all the limitations of claims 1-7 with the exception of the "circular anvil" required by claim 1, the "staple driver assembly compris[ing] an outer ring of the staple drivers and an inner ring of the staple drivers" required by claim 2, and "the end effector further [comprising] a knife for cutting tissue clamped by the end effector" required by claim 7. (*See* Pet. 43-44; *see also* Pet. 58-59.) To account for those additional requirements, Covidien points to the teachings of Conta.

Conta is directed to a stapling instrument characterized as an "[a]pparatus for circular surgical stapling of hollow organs." (Ex. 1006, Abstract.) Conta discloses a circular anvil 230 with a staple-forming surface in the form of "two concentric circular arrays of spaced staple clinching grooves" 232. (*Id*. at col. 9, ll. 6-8; Figure 19.) Conta also discloses that its stapling instrument includes a

"knife 168, in the form of an open cup with the rim defining the knife edge 170." (*Id*. at col. 8, ll. 14-15.)

Covidien contends that Conta, including those teachings noted above, discloses the features required by claims 1, 2, and 7. (Pet. 43-44.) Covidien also relies on the testimony of Mr. Bolanos in urging that it would have been obvious to modify Pruitt so as to incorporate the pertinent features. (*Id*. at 44; *see also* Ex. 1010, ¶ 82.) We are persuaded by Mr. Bolanos' testimony.

For the foregoing reasons, we are persuaded that Covidien has demonstrated a reasonable likelihood that it will prevail in its contention that claims 1-7 of the '070 patent are unpatentable over Pruitt, Green, and Conta.

3. Remaining Grounds

The grounds numbered 1-18 in Covidien's petition are premised on an incorrect interpretation of the claim phrase "two prongs extend non-parallelly from the main portion." We do not authorize *inter partes* review on those grounds.

The remaining grounds of unpatentability proposed in Covidien's petition are redundant to those grounds discussed above based on either Viola or Pruitt. We do not authorize *inter partes* review on those redundant grounds.

III. CONCLUSION

For the foregoing reasons, we determine that Covidien's petition establishes that there is a reasonable likelihood that Covidien will prevail with respect to challenges to claims 1-14 of the '070 patent.

The Board has not made a final determination on the patentability of any challenged claim.

IV. ORDERS

After due consideration of the record before us, it is:

ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter partes* review is hereby instituted as to claims 1-14 based on the following grounds of unpatentability:

A. Claims 1-5, 7, 8, and 10-13 are unpatentable under 35 U.S.C. ¶ 103 as obvious over Viola and Green;

B. Claims 6, 11, and 14 are unpatentable under 35 U.S.C. ¶ 103 as obvious over Viola, Green, and Pruitt;

C. Claim 9 is unpatentable under 35 U.S.C. ¶ 103 as obvious over Viola, Green, and Burdorff;

D. Claims 8 and 10-14 are unpatentable under 35 U.S.C. ¶ 103 as obvious over Pruitt and Green;

E. Claim 9 is unpatentable under 35 U.S.C. ¶ 103 as obvious over Pruitt, Green, and Burdorff; and

F. Claims 1-7 are unpatentable under 35 U.S.C. ¶ 103 as obvious over Pruitt, Green, and Conta.

FURTHER ORDERED that all other grounds raised in Covidien's petition are *denied*, either because they are deficient for reasons discussed above or because they are redundant in light of the grounds on the basis of which an *inter partes* review is being instituted;

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial. The trial will commence on the entry date of this decision; and

FURTHER ORDERED that an initial conference call with the Board is scheduled for **11:00 AM Eastern Time on September 26, 2013**. The parties are directed to the Office Patent Trial Practice Guide, 77 Fed. Reg. 48756, 48765-66 (Aug. 14, 2012), for guidance in preparing for the initial conference call, and should come prepared to discuss any proposed changes to the Scheduling Order entered herewith and any motions the parties anticipate filing during the trial.

United States Code

Title 5. Government Organization and Employees

Part I. The Agencies Generally

Chapter 5. Administrative Procedure

§ 554. Adjudications

(a) This section applies, according to the provisions thereof, in every case of adjudication required by statute to be determined on the record after opportunity for an agency hearing, except to the extent that there is involved--

(1) a matter subject to a subsequent trial of the law and the facts de novo in a court;

(2) the selection or tenure of an employee, except a1 administrative law judge appointed under section 3105 of this title;

(3) proceedings in which decisions rest solely on inspections, tests, or elections;

(4) the conduct of military or foreign affairs functions;

(5) cases in which an agency is acting as an agent for a court; or

(6) the certification of worker representatives.

(b) Persons entitled to notice of an agency hearing shall be timely informed of--

(1) the time, place, and nature of the hearing;

(2) the legal authority and jurisdiction under which the hearing is to be held; and

(3) the matters of fact and law asserted.

When private persons are the moving parties, other parties to the proceeding shall give prompt notice of issues controverted in fact or law; and in other instances agencies may by rule require responsive pleading. In fixing the time and place for hearings, due regard shall be had for the convenience and necessity of the parties or their representatives.

(c) The agency shall give all interested parties opportunity for--

(1) the submission and consideration of facts, arguments, offers of settlement, or proposals of adjustment when time, the nature of the proceeding, and the public interest permit; and

(2) to the extent that the parties are unable so to determine a controversy by consent, hearing and decision on notice and in accordance with sections 556 and 557 of this title.

(d) The employee who presides at the reception of evidence pursuant to section 556 of this title shall make the recommended decision or initial decision required by section 557 of this title, unless he becomes unavailable to the agency. Except to the extent required for the disposition of ex parte matters as authorized by law, such an employee may not--

> **(1)** consult a person or party on a fact in issue, unless on notice and opportunity for all parties to participate; or
>
> **(2)** be responsible to or subject to the supervision or direction of an employee or agent engaged in the performance of investigative or prosecuting functions for an agency.

An employee or agent engaged in the performance of investigative or prosecuting functions for an agency in a case may not, in that or a factually related case, participate or advise in the decision, recommended decision, or agency review pursuant to section 557 of this title, except as witness or counsel in public proceedings. This subsection does not apply--

> **(A)** in determining applications for initial licenses;
>
> **(B)** to proceedings involving the validity or application of rates, facilities, or practices of public utilities or carriers; or

(C) to the agency or a member or members of the body comprising the agency.

(e) The agency, with like effect as in the case of other orders, and in its sound discretion, may issue a declaratory order to terminate a controversy or remove uncertainty.

United States Code Annotated

Title 35. Patents

Part I. United States Patent and Trademark Office

Chapter 1. Establishment, Officers and Employees, Functions

§ 3. Officers and employees

(a) Under Secretary and Director.--

(1) In general.--The powers and duties of the United States Patent and Trademark Office shall be vested in an Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office (in this title referred to as the "Director"), who shall be a citizen of the United States and who shall be appointed by the President, by and with the advice and consent of the Senate. The Director shall be a person who has a professional background and experience in patent or trademark law.

(2) Duties.--

(A) In general.--The Director shall be responsible for providing policy direction and management supervision for the Office and for the issuance of patents and the registration of

trademarks. The Director shall perform these duties in a fair, impartial, and equitable manner.

(B) Consulting with the Public Advisory Committees.--The Director shall consult with the Patent Public Advisory Committee established in section 5 on a regular basis on matters relating to the patent operations of the Office, shall consult with the Trademark Public Advisory Committee established in section 5 on a regular basis on matters relating to the trademark operations of the Office, and shall consult with the respective Public Advisory Committee before submitting budgetary proposals to the Office of Management and Budget or changing or proposing to change patent or trademark user fees or patent or trademark regulations which are subject to the requirement to provide notice and opportunity for public comment under section 553 of title 5, as the case may be.

(3) Oath.--The Director shall, before taking office, take an oath to discharge faithfully the duties of the Office.

(4) Removal.--The Director may be removed from office by the President. The President shall provide notification of any such removal to both Houses of Congress.

(b) Officers and employees of the Office.--

(1) Deputy Under Secretary and Deputy Director.--The Secretary of Commerce, upon nomination by the Director, shall appoint a Deputy Under Secretary of Commerce for Intellectual Property and Deputy Director of the United States Patent and Trademark Office who shall be vested with the authority to act in the capacity of the Director in the event of the absence or incapacity of the Director. The Deputy Director shall be a citizen of the United States who has a professional background and experience in patent or trademark law.

(2) Commissioners.--

(A) Appointment and duties.--The Secretary of Commerce shall appoint a Commissioner for Patents and a Commissioner for Trademarks, without regard to chapter 33, 51, or 53 of title 5. The Commissioner for Patents shall be a citizen of the United States with demonstrated management ability and professional background and experience in patent law and serve for a term of 5 years. The Commissioner for Trademarks shall be a citizen of the United States with demonstrated management ability and professional background and experience in trademark law and serve for a term of 5 years. The Commissioner for Patents and the Commissioner for Trademarks shall serve as the chief operating officers for the operations

of the Office relating to patents and trademarks, respectively, and shall be responsible for the management and direction of all aspects of the activities of the Office that affect the administration of patent and trademark operations, respectively. The Secretary may reappoint a Commissioner to subsequent terms of 5 years as long as the performance of the Commissioner as set forth in the performance agreement in subparagraph (B) is satisfactory.

(B) Salary and performance agreement.-- The Commissioners shall be paid an annual rate of basic pay not to exceed the maximum rate of basic pay for the Senior Executive Service established under section 5382 of title 5, including any applicable locality-based comparability payment that may be authorized under section 5304(h)(2)(C) of title 5. The compensation of the Commissioners shall be considered, for purposes of section 207(c)(2)(A) of title 18, to be the equivalent of that described under clause (ii) of section 207(c)(2)(A) of title 18. In addition, the Commissioners may receive a bonus in an amount of up to, but not in excess of, 50 percent of the Commissioners' annual rate of basic pay, based upon an evaluation by the Secretary of Commerce, acting through the Director, of the Commissioners' performance as defined in an annual performance agreement between the Commissioners and the Secretary. The annual performance

agreements shall incorporate measurable organization and individual goals in key operational areas as delineated in an annual performance plan agreed to by the Commissioners and the Secretary. Payment of a bonus under this subparagraph may be made to the Commissioners only to the extent that such payment does not cause the Commissioners' total aggregate compensation in a calendar year to equal or exceed the amount of the salary of the Vice President under section 104 of title 3.

(C) Removal.--The Commissioners may be removed from office by the Secretary for misconduct or nonsatisfactory performance under the performance agreement described in subparagraph (B), without regard to the provisions of title 5. The Secretary shall provide notification of any such removal to both Houses of Congress.

(3) Other officers and employees.--The Director shall--

(A) appoint such officers, employees (including attorneys), and agents of the Office as the Director considers necessary to carry out the functions of the Office; and

(B) define the title, authority, and duties of such officers and employees and delegate to them such of the powers vested in the Office as the Director may determine.

The Office shall not be subject to any administratively or statutorily imposed limitation on positions or personnel, and no positions or personnel of the Office shall be taken into account for purposes of applying any such limitation.

(4) Training of examiners.--The Office shall submit to the Congress a proposal to provide an incentive program to retain as employees patent and trademark examiners of the primary examiner grade or higher who are eligible for retirement, for the sole purpose of training patent and trademark examiners.

(5) National security positions.--The Director, in consultation with the Director of the Office of Personnel Management, shall maintain a program for identifying national security positions and providing for appropriate security clearances, in order to maintain the secrecy of certain inventions, as described in section 181, and to prevent disclosure of sensitive and strategic information in the interest of national security.

(6) Administrative patent judges and administrative trademark judges.--The Director may fix the rate of basic pay for the administrative patent judges appointed pursuant to section 6 and the administrative trademark judges appointed pursuant to section 17 of the Trademark Act of 1946 (15 U.S.C. 1067) at not greater than the rate of basic pay payable for

level III of the Executive Schedule under section 5314 of title 5. The payment of a rate of basic pay under this paragraph shall not be subject to the pay limitation under section 5306(e) or 5373 of title 5.

(c) Continued applicability of title 5.--Officers and employees of the Office shall be subject to the provisions of title 5, relating to Federal employees.

(d) Adoption of existing labor agreements.--The Office shall adopt all labor agreements which are in effect, as of the day before the effective date of the Patent and Trademark Office Efficiency Act, with respect to such Office (as then in effect).

(e) Carryover of personnel.--

(1) From PTO.--Effective as of the effective date of the Patent and Trademark Office Efficiency Act, all officers and employees of the Patent and Trademark Office on the day before such effective date shall become officers and employees of the Office, without a break in service.

(2) Other personnel.--Any individual who, on the day before the effective date of the Patent and Trademark Office Efficiency Act, is an officer or employee of the Department of Commerce (other than an officer or employee under paragraph (1)) shall be transferred to the Office, as necessary to carry out the purposes of that Act, if--

(A) such individual serves in a position for which a major function is the performance of work reimbursed by the Patent and Trademark Office, as determined by the Secretary of Commerce;

(B) such individual serves in a position that performed work in support of the Patent and Trademark Office during at least half of the incumbent's work time, as determined by the Secretary of Commerce; or

(C) such transfer would be in the interest of the Office, as determined by the Secretary of Commerce in consultation with the Director.

Any transfer under this paragraph shall be effective as of the same effective date as referred to in paragraph (1), and shall be made without a break in service.

(f) Transition provisions.–

(1) Interim appointment of Director.--On or after the effective date of the Patent and Trademark Office Efficiency Act, the President shall appoint an individual to serve as the Director until the date on which a Director qualifies under subsection (a). The President shall not make more than one such appointment under this subsection.

(2) Continuation in office of certain officers.--(A) The individual serving as the Assistant

Commissioner for Patents on the day before the effective date of the Patent and Trademark Office Efficiency Act may serve as the Commissioner for Patents until the date on which a Commissioner for Patents is appointed under subsection (b).

(B) The individual serving as the Assistant Commissioner for Trademarks on the day before the effective date of the Patent and Trademark Office Efficiency Act may serve as the Commissioner for Trademarks until the date on which a Commissioner for Trademarks is appointed under subsection (b).

United States Code Annotated

Title 35. Patents

Part I. United States Patent and Trademark Office

Chapter 1. Establishment, Officers and Employees, Functions

§ 6. Patent Trial and Appeal Board

(a) In general.--There shall be in the Office a Patent Trial and Appeal Board. The Director, the Deputy Director, the Commissioner for Patents, the Commissioner for Trademarks, and the administrative patent judges shall constitute the Patent Trial and Appeal Board. The administrative patent judges shall be persons of competent legal knowledge and scientific ability who are appointed by the Secretary, in consultation with the Director. Any reference in any Federal law, Executive order, rule, regulation, or delegation of authority, or any document of or pertaining to the Board of Patent Appeals and Interferences is deemed to refer to the Patent Trial and Appeal Board.

(b) Duties.--The Patent Trial and Appeal Board shall--

(1) on written appeal of an applicant, review adverse decisions of examiners upon applications for patents pursuant to section 134(a);

(2) review appeals of reexaminations pursuant to section 134(b);

(3) conduct derivation proceedings pursuant to section 135; and

(4) conduct inter partes reviews and post-grant reviews pursuant to chapters 31 and 32.

(c) 3-member panels.--Each appeal, derivation proceeding, post-grant review, and inter partes review shall be heard by at least 3 members of the Patent Trial and Appeal Board, who shall be designated by the Director. Only the Patent Trial and Appeal Board may grant rehearings.

(d) Treatment of prior appointments.--The Secretary of Commerce may, in the Secretary's discretion, deem the appointment of an administrative patent judge who, before the date of the enactment of this subsection, held office pursuant to an appointment by the Director to take effect on the date on which the Director initially appointed the administrative patent judge. It shall be a defense to a challenge to the appointment of an administrative patent judge on the basis of the judge's having been originally appointed by the Director that the administrative patent judge so appointed was acting as a de facto officer.

United States Code Annotated

Title 35. Patents

Part III. Patents and Protection of Patent Rights

Chapter 31. Inter Partes Review

§ 314. Institution of inter partes review

(a) Threshold.--The Director may not authorize an inter partes review to be instituted unless the Director determines that the information presented in the petition filed under section 311 and any response filed under section 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.

(b) Timing.--The Director shall determine whether to institute an inter partes review under this chapter pursuant to a petition filed under section 311 within 3 months after--

(1) receiving a preliminary response to the petition under section 313; or

(2) if no such preliminary response is filed, the last date on which such response may be filed.

(c) Notice.--The Director shall notify the petitioner and patent owner, in writing, of the Director's

determination under subsection (a), and shall make such notice available to the public as soon as is practicable. Such notice shall include the date on which the review shall commence.

(d) No appeal.--The determination by the Director whether to institute an inter partes review under this section shall be final and nonappealable.

United States Code Annotated

Title 35. Patents

Part III. Patents and Protection of Patent Rights

Chapter 31. Inter Partes Review

§ 315. Relation to other proceedings or actions

(a) Infringer's civil action.--

(1) Inter partes review barred by civil action.--An inter partes review may not be instituted if, before the date on which the petition for such a review is filed, the petitioner or real party in interest filed a civil action challenging the validity of a claim of the patent.

(2) Stay of civil action.--If the petitioner or real party in interest files a civil action challenging the validity of a claim of the patent on or after the date on which the petitioner files a petition for inter partes review of the patent, that civil action shall be automatically stayed until either--

(A) the patent owner moves the court to lift the stay;

(B) the patent owner files a civil action or counterclaim alleging that the petitioner or

real party in interest has infringed the patent; or

(C) the petitioner or real party in interest moves the court to dismiss the civil action.

(3) Treatment of counterclaim.--A counterclaim challenging the validity of a claim of a patent does not constitute a civil action challenging the validity of a claim of a patent for purposes of this subsection.

(b) Patent owner's action.--An inter partes review may not be instituted if the petition requesting the proceeding is filed more than 1 year after 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. The time limitation set forth in the preceding sentence shall not apply to a request for joinder under subsection (c).

(c) Joinder.--If the Director institutes an inter partes review, the Director, in his or her discretion, may join as a party to that inter partes review any person who properly files a petition under section 311 that the Director, after receiving a preliminary response under section 313 or the expiration of the time for filing such a response, determines warrants the institution of an inter partes review under section 314.

(d) Multiple proceedings.--Notwithstanding sections 135(a), 251, and 252, and chapter 30, during the pendency of an inter partes review, if another

proceeding or matter involving the patent is before the Office, the Director may determine the manner in which the inter partes review or other proceeding or matter may proceed, including providing for stay, transfer, consolidation, or termination of any such matter or proceeding.

(e) Estoppel.--

(1) Proceedings before the Office.--The petitioner in an inter partes review of a claim in a patent under this chapter that results in a final written decision under section 318(a), or the real party in interest or privy of the petitioner, may not request or maintain a proceeding before the Office with respect to that claim on any ground that the petitioner raised or reasonably could have raised during that inter partes review.

(2) Civil actions and other proceedings.--The petitioner in an inter partes review of a claim in a patent under this chapter that results in a final written decision under section 318(a), or the real party in interest or privy of the petitioner, may not assert either in a civil action arising in whole or in part under section 1338 of title 28 or in a proceeding before the International Trade Commission under section 337 of the Tariff Act of 1930 that the claim is invalid on any ground that the petitioner raised or reasonably could have raised during that inter partes review.

United States Code Annotated

Title 35. Patents

Part III. Patents and Protection of Patent Rights

Chapter 31. Inter Partes Review

§ 316. Conduct of inter partes review

(a) Regulations.--The Director shall prescribe regulations--

(1) providing that the file of any proceeding under this chapter shall be made available to the public, except that any petition or document filed with the intent that it be sealed shall, if accompanied by a motion to seal, be treated as sealed pending the outcome of the ruling on the motion;

(2) setting forth the standards for the showing of sufficient grounds to institute a review under section 314(a);

(3) establishing procedures for the submission of supplemental information after the petition is filed;

(4) establishing and governing inter partes review under this chapter and the relationship of such review to other proceedings under this title;

(5) setting forth standards and procedures for discovery of relevant evidence, including that such discovery shall be limited to--

(A) the deposition of witnesses submitting affidavits or declarations; and

(B) what is otherwise necessary in the interest of justice;

(6) prescribing sanctions for abuse of discovery, abuse of process, or any other improper use of the proceeding, such as to harass or to cause unnecessary delay or an unnecessary increase in the cost of the proceeding;

(7) providing for protective orders governing the exchange and submission of confidential information;

(8) providing for the filing by the patent owner of a response to the petition under section 313 after an inter partes review has been instituted, and requiring that the patent owner file with such response, through affidavits or declarations, any additional factual evidence and expert opinions on which the patent owner relies in support of the response;

(9) setting forth standards and procedures for allowing the patent owner to move to amend the patent under subsection (d) to cancel a challenged claim or propose a reasonable number of substitute claims, and ensuring that any

information submitted by the patent owner in support of any amendment entered under subsection (d) is made available to the public as part of the prosecution history of the patent;

(10) providing either party with the right to an oral hearing as part of the proceeding;

(11) requiring that the final determination in an inter partes review be issued not later than 1 year after the date on which the Director notices the institution of a review under this chapter, except that the Director may, for good cause shown, extend the 1-year period by not more than 6 months, and may adjust the time periods in this paragraph in the case of joinder under section 315(c);

(12) setting a time period for requesting joinder under section 315(c); and

(13) providing the petitioner with at least 1 opportunity to file written comments within a time period established by the Director.

(b) Considerations.--In prescribing regulations under this section, the Director shall consider the effect of any such regulation on the economy, the integrity of the patent system, the efficient administration of the Office, and the ability of the Office to timely complete proceedings instituted under this chapter.

(c) Patent Trial and Appeal Board.--The Patent Trial and Appeal Board shall, in accordance with section 6, conduct each inter partes review instituted under this chapter.

(d) Amendment of the patent.--

(1) In general.--During an inter partes review instituted under this chapter, the patent owner may file 1 motion to amend the patent in 1 or more of the following ways:

(A) Cancel any challenged patent claim.

(B) For each challenged claim, propose a reasonable number of substitute claims.

(2) Additional motions.--Additional motions to amend may be permitted upon the joint request of the petitioner and the patent owner to materially advance the settlement of a proceeding under section 317, or as permitted by regulations prescribed by the Director.

(3) Scope of claims.--An amendment under this subsection may not enlarge the scope of the claims of the patent or introduce new matter.

(e) Evidentiary standards.--In an inter partes review instituted under this chapter, the petitioner shall have the burden of proving a proposition of unpatentability by a preponderance of the evidence.

United States Code Annotated

Title 35. Patents

Part III. Patents and Protection of Patent Rights

Chapter 31. Inter Partes Review

§ 318. Decision of the Board

(a) Final written decision.--If an inter partes review is instituted and not dismissed under this chapter, the Patent Trial and Appeal Board shall issue a final written decision with respect to the patentability of any patent claim challenged by the petitioner and any new claim added under section 316(d).

(b) Certificate.--If the Patent Trial and Appeal Board issues a final written decision under subsection (a) and the time for appeal has expired or any appeal has terminated, 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.

(c) Intervening rights.--Any proposed amended or new claim determined to be patentable and incorporated into a patent following an inter partes

review under this chapter shall have the same effect as that specified in section 252 for reissued patents on the right of any person who made, purchased, or used within the United States, or imported into the United States, anything patented by such proposed amended or new claim, or who made substantial preparation therefor, before the issuance of a certificate under subsection (b).

(d) Data on length of review.--The Office shall make available to the public data describing the length of time between the institution of, and the issuance of a final written decision under subsection (a) for, each inter partes review.

United States Code Annotated

Title 35. Patents

Part III. Patents and Protection of Patent Rights

Chapter 31. Inter Partes Review

§ 325. Relation to other proceedings or actions

(a) Infringer's civil action.--

(1) Post-grant review barred by civil action.--A post-grant review may not be instituted under this chapter if, before the date on which the petition for such a review is filed, the petitioner or real party in interest filed a civil action challenging the validity of a claim of the patent.

(2) Stay of civil action.--If the petitioner or real party in interest files a civil action challenging the validity of a claim of the patent on or after the date on which the petitioner files a petition for post-grant review of the patent, that civil action shall be automatically stayed until either--

(A) the patent owner moves the court to lift the stay;

(B) the patent owner files a civil action or counterclaim alleging that the petitioner or

real party in interest has infringed the patent; or

(C) the petitioner or real party in interest moves the court to dismiss the civil action.

(3) Treatment of counterclaim.--A counterclaim challenging the validity of a claim of a patent does not constitute a civil action challenging the validity of a claim of a patent for purposes of this subsection.

(b) Preliminary injunctions.--If a civil action alleging infringement of a patent is filed within 3 months after the date on which the patent is granted, the court may not stay its consideration of the patent owner's motion for a preliminary injunction against infringement of the patent on the basis that a petition for post-grant review has been filed under this chapter or that such a post-grant review has been instituted under this chapter.

(c) Joinder.--If more than 1 petition for a post-grant review under this chapter is properly filed against the same patent and the Director determines that more than 1 of these petitions warrants the institution of a post-grant review under section 324, the Director may consolidate such reviews into a single post-grant review.

(d) Multiple proceedings.--Notwithstanding sections 135(a), 251, and 252, and chapter 30, during the pendency of any post-grant review under this chapter, if another proceeding or matter involving

the patent is before the Office, the Director may determine the manner in which the post- grant review or other proceeding or matter may proceed, including providing for the stay, transfer, consolidation, or termination of any such matter or proceeding. In determining whether to institute or order a proceeding under this chapter, chapter 30, or chapter 31, the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office.

(e) Estoppel.--

(1) Proceedings before the Office.--The petitioner in a post-grant review of a claim in a patent under this chapter that results in a final written decision under section 328(a), or the real party in interest or privy of the petitioner, may not request or maintain a proceeding before the Office with respect to that claim on any ground that the petitioner raised or reasonably could have raised during that post-grant review.

(2) Civil actions and other proceedings.--The petitioner in a post- grant review of a claim in a patent under this chapter that results in a final written decision under section 328(a), or the real party in interest or privy of the petitioner, may not assert either in a civil action arising in whole or in part under section 1338 of title 28 or in a proceeding before the International Trade Commission under section 337 of the Tariff Act of 1930 that the claim is invalid on any ground that

the petitioner raised or reasonably could have raised during that post-grant review.

(f) Reissue patents.--A post-grant review may not be instituted under this chapter if the petition requests cancellation of a claim in a reissue patent that is identical to or narrower than a claim in the original patent from which the reissue patent was issued, and the time limitations in section 321(c) would bar filing a petition for a post-grant review for such original patent.

Code of Federal Regulations

Title 37. Patents, Trademarks, and Copyrights

Chapter I. United States Patent and Trademark Office, Department of Commerce

Subchapter A. General

Practice Before the Patent and Trademark Office

Part 42. Trial Practice Before the Patent Trial and Appeal Board

Subpart A. Trial Practice and Procedure

General

§ 42.4 Notice of trial.

(a) Institution of trial. The Board institutes the trial on behalf of the Director.

(b) Notice of a trial will be sent to every party to the proceeding. The entry of the notice institutes the trial.

(c) The Board may authorize additional modes of notice, including:

(1) Sending notice to another address associated with the party, or

(2) Publishing the notice in the Official Gazette of the United States Patent and Trademark Office or the Federal Register.