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 sta-

> ple 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 non-parallel 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 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

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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").

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 devel-

oping 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 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

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[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 obligation as to those involved in preliminary and final decisions.

Court has also made clear, "opinions held by 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 was based in part on this impression,

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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).

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.

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

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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.*

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 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 subordi-

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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.").

nates 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, entrepre-

neurs, 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 war-

ranted 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.

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

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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.

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 marker 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)); c*f. 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.'" *Se. 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.