

Ethicon Endo-Surgery, Inc. v. Covidien LP, 826 F.3d 1366 (2016)

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826 F.3d 1366  
United States Court of Appeals,  
Federal Circuit.

Ethicon Endo-Surgery, Inc., Appellant  
v.  
Covidien LP, Appellee.

2014-1771  
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June 22, 2016

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

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.

#### ON PETITION FOR REHEARING EN BANC

Per Curiam.

#### ORDER

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.

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, 96 S.Ct. 1375, 47 L.Ed.2d 668 (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 \*1367 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

Ethicon Endo-Surgery, Inc. v. Covidien LP, 826 F.3d 1366 (2016)

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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 post-grant 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, AIPPLA) (“AIPPLA 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, 26 L.Ed. 786 (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, *\*1368* 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.

Ethicon Endo-Surgery, Inc. v. Covidien LP, 826 F.3d 1366 (2016)

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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.” [Muwakkil 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.

#### Footnotes

- \* Circuit Judge Stoll did not participate.

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 \*1369 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.

#### All Citations

826 F.3d 1366 (Mem)

Ethicon Endo-Surgery, Inc. v. Covidien LP, 826 F.3d 1366 (2016)

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