THE FOURTEENTH ANNUAL SETON HALL LAW/NEW JERSEY INTELLECTUAL PROPERTY LAW ASSOCIATION

LECTURE SERIES

VIEWS FROM THE BENCH WITH

THE HONORABLE PAULINE NEWMAN

A COLLECTION OF JUDGE NEWMAN'S RECENT DISSENTING OPINIONS

810 F.3d 1283
United States Court of Appeals,
Federal Circuit.

CLEARCORRECT OPERATING, LLC,
ClearCorrect Pakistan (Private), Ltd., Appellants
v.
INTERNATIONAL TRADE COMMISSION,
Appellee
Align Technology, Inc., Intervenor.

No. 2014–1527.
|
Nov. 10, 2015.

NEWMAN, Circuit Judge, dissenting.

Today's culture, as well as today's economy, are founded on advances in science and technology. As the Industrial Revolution advanced, and recognizing the importance to the nation of technology-based industry, the Tariff Acts of 1922 and 1930 were enacted to provide additional support to domestic industries that dealt in new and creative commerce, by providing an efficient safeguard against unfair competition by imports that infringe United States patents or copyrights. The International Trade Commission correctly applied the Tariff Act and precedent to encompass today's forms of infringing technology.

The new technologies of the Information Age focus on computer-implemented methods and systems, whose applications of digital science provide benefits and conveniences not imagined in 1922 and 1930. Throughout this evolution, Section 337 served its statutory purpose of facilitating remedy against unfair competition, by providing for exclusion of imports that infringe United States intellectual property rights.

Until today.

The court today removes Section 337 protection from importations that are conducted by electronic transmission. The court's reason is that electronically transmitted subject matter is not "tangible," and that only tangible imports are subject to exclusion. This holding is contrary to Section 337, and conflicts with rulings of the Supreme Court, the Federal Circuit, the Court of Customs and Patent Appeals, the Court of International Trade, the International Trade Commission, the Customs authorities, and the Department of Labor. I respectfully dissent.

Infringement is not here at issue; the only issue is the Section 337 cease and desist order.

The imports are infringing "digital models, digital data, and treatment plans for use in making incremental dental positioning adjustment appliances," produced for ClearCorrect in Pakistan and imported into the United States by electronic transmission. The International Trade Commission found, and it is not disputed, that the imported data sets are "virtual three-dimensional models" of a patient's teeth, and that the imports are used in the United States to make a three-dimensional physical model of the dental appliance. *Certain Digital Models, Digital Data, & Treatment Plans for Use in Making Incremental Dental Positioning Adjustment Appliances, the Appliances Made Therefrom, & Methods of Making the Same*, Inv. No. 337–TA–833, at 17 (April 10, 2014) ("Comm'n Op.").

Infringement of the Align Technology patents is not at issue. The only issue is whether the Section 337 remedy is available to exclude the infringing digital subject matter. The Commission, reviewing the "plain language of the statute, its legislative history and purpose, pertinent case law, and the arguments of the parties and public commenters," held that "the digital data sets at issue ... are true articles of international commerce that are imported into the United States, and their inclusion within the purview of section 337 would ***1305** effectuate the central purpose of the statute." Comm'n Op. at 55.

The Commission issued a Cease and Desist Order against "importing (including through electronic transmission)" the digital models, digital data, and orthodontic plans that were found to infringe the Align patents. Order (April 3, 2014). The panel majority now revokes that Order, holding that imports reaching the United States by electronic transmission are not subject to Section 337. This ruling is contrary to the statute and contrary to precedent; and if there were there doubt as to the intended scope of Section 337, the Commission's ruling requires deference.

The Commission correctly held that section 337 applies to imports of infringing digital goods.

Section 337 of the Tariff Act of 1930, as amended, makes unlawful:

> (B) The importation into the United States, the sale for importation, or the sale within the United States after importation ... of articles that—
>
> (i) infringe a valid and enforceable United States patent or ... copyright ...; or
>
> (ii) are made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent.

19 U.S.C. § 1337(a)(1)(B)(i)-(ii).

The Commission determined that ClearCorrect's infringement of the Align patents in the United States, and infringement by the process practiced for ClearCorrect in Pakistan, is subject to Section 337. The court's rejection of that ruling is in contravention of the text and the purpose of Section 337 of the Tariff Act.

Section 337 was enacted to facilitate the protection of American industry against unfair competition by infringing imports. The statute was designed to reach "every type and form" of unfair competition arising from importation. The Senate Report stated: "The provision relating to unfair methods of competition in the importation of goods is broad enough to prevent every type and form of unfair practice and is, therefore, a more adequate protection to American industry than any antidumping statute the country has ever had." S.Rep. No. 67–595 at 3 (1922).

Our predecessor Court of Customs and Patent Appeals emphasized that this purpose is "to give to industries of the United States, not only the benefit of the favorable laws and conditions to be found in this country, but also to protect such industries from being unfairly deprived of the advantage of the same and permit them to grow and develop." *Frischer & Co. v. Bakelite Corp.*, 17 CCPA 494, 39 F.2d 247, 259 (1930).

Until today, this Tariff Act provision has been interpreted to implement this protective incentive. In *In re Northern Pigment Co.*, 22 CCPA 166, 71 F.2d 447 (1934), the court applied Section 337 to reach products produced abroad by a process patented in the United States, stating that "if unfair methods of competition or unfair acts in the importation of articles into the United States are being practiced or performed by any one, they are to be regarded as unlawful, and the section was intended to prevent them." *Id.* at 455. This ruling is codified at Section 1337(a)(1)(B)(ii), *supra*.

Over the decades, the International Trade Commission and the Court of Customs and Patent Appeals implemented Section 337 "to provide an adequate remedy for domestic industries against unfair methods of competition and unfair acts initiated by foreign concerns operating beyond ***1306** the in personam jurisdiction of domestic courts." *Sealed Air Corp. v. Int'l Trade Comm'n,* 68 CCPA 93, 645 F.2d 976, 985 (1981). The Federal Circuit reiterated this purpose, stating in *Lannom Mfg. Co. v. Int'l Trade Comm'n,* 799 F.2d 1572 (Fed.Cir.1986), that "the purpose of section 337 from its inception was to provide relief to United States industry from unfair acts, including infringement of United States patents by goods manufactured abroad." *Id.* at 1580.

Congress again considered Section 337 during the process of enacting the Omnibus Trade and Competitiveness Act of 1988, Pub.L. No. 100–418 § 1341, 102 Stat. 1107, stating that:

> As indicated by the scope of its language, section 337 was intended to cover a broad range of unfair acts not then covered by other unfair import laws. However, over the years, patent, copyright, and trademark infringement were recognized as unfair trade practices within the meaning of section 337, and today section 337 is predominantly used to enforce U.S. intellectual property rights.

S.Rep. No. 100–71 (1987) at 130. The Act itself reiterated the purpose to provide "a more effective remedy for the protection of United States intellectual property rights" through exclusion of infringing imports. Omnibus Trade and Competitiveness Act of 1988, Pub.L. No. 100–418 § 1341(b), 102 Stat. 1107, 1212.

This court recently reaffirmed that "the legislative history consistently evidences Congressional intent to vest the Commission with broad enforcement authority to remedy unfair trade acts." *Suprema, Inc. v. Int'l Trade Comm'n,* 796 F.3d 1338, 1350 (Fed.Cir.2015) (en banc).

The purpose of Section 337 to provide a facilitated remedy against infringing imports is beyond dispute. The panel majority's removal of this remedy from a preeminent form of today's technology is a dramatic

withdrawal of existing rights, devoid of statutory support and of far-reaching impact. The majority's ruling, that digital goods cannot be excluded under Section 337 because digital goods are "intangible," is incorrect.

The Commission correctly held that Section 337 is not limited to the kinds of technology that existed in 1922 or 1930.

Patents are for things that did not previously exist, including kinds of technology that were not previously known. The panel majority, rejecting today's digital technologies and overruling the International Trade Commission, holds that Section 337 does not apply to digital technology forms that the majority describes as "intangible." It is not disputed that digital information, such as the data sets and models here imported, is patentable subject matter and can be infringing subject matter. There is no basis for excluding imported infringing subject matter from Section 337, whatever the form of the subject matter.

The Supreme Court in *Fortnightly Corp. v. United Artists Television, Inc.*, 392 U.S. 390, 88 S.Ct. 2084, 20 L.Ed.2d 1176 (1968), considered "a statute that was drafted long before the development of the electronic phenomena with which we deal here," stating that "[w]e must read the statutory language ... in the light of drastic technological change." *Id.* at 395–96, 88 S.Ct. 2084. This rule aptly applies to the Tariff Acts of 1922 and 1930.

The Court has referred to adaptation of the copyright statute to new technologies, observing in *Twentieth Century Music Corp. v. Aiken*, 422 U.S., 151, 95 S.Ct. 2040, 45 L.Ed.2d 84 (1975), that although Congress did not revise the Copyright Act of 1909 following the advent of radio (and television), "copyright law was quick to ***1307** adapt to prevent the exploitation of protected works through the new electronic technology." *Id.* at 158, 95 S.Ct. 2040. The Court noted the "ultimate aim" of the copyright law "to stimulate artistic creativity for the general public good," and stated that "[w]hen technological change has rendered its literal terms ambiguous, the Copyright Act must be construed in light of this basic purpose." *Id.* at 156, 95 S.Ct. 2040.

The Commission has previously dealt with Section 337 importation in the form of digitally distributed software and digital files, stating that "[h]aving found that respondents' software contributorily infringes the claims in issue, we are of the view that our remedial orders must reach that software." *Certain Hardware Logic Emulation Systems*, Inv. No. 337–TA–383, USITC Pub. 3089, at 18 (March 1998). The court's ruling today contravenes Commission precedent, as well as our own.

The Federal Circuit dealt with the nature of digital files in *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1321 (Fed.Cir.2009). The court rejected the argument that digital files such as computer software are not a "material or apparatus" subject to infringement as set forth in the Patent Act at 35 U.S.C. § 271(c). This reasoning applies to the "articles" subject to infringement as set forth in the Tariff Act at 19 U.S.C. § 1337. The court's decision today is a distortion of the statute's language and purpose, for Section 337 is designed to cover infringing subject matter; and digital software, as noted in *Lucent*, can be infringing subject matter.

Until today, Section 337 applied to all patented technologies, including digital technologies, whatever the path of importation. The court's exclusion of digital products and data technologies imported by electronic transmission has no support in statute, precedent, or policy.

The Commission correctly held that "articles" in the Tariff Act means "articles of commerce."

The Commission held that the term "articles" in the Tariff Act is intended to include all infringing imported "articles of commerce." The Commission stated that "the statutory construction of 'articles' that hews most closely to the language of the statute and implements the avowed Congressional purpose for Section 337 encompasses within its scope the electronic transmission of the digital data sets at issue in this investigation." Comm'n Op. at 36.

The panel majority holds that the term "articles" in the Tariff Act excludes imported digital articles, but in a different section, the Tariff Act definition of "article" is unchanged from the 1922 and 1930 statutes:

> The term "article" includes any commodity, whether grown, produced, fabricated, manipulated, or manufactured.

19 U.S.C. § 1332(e)(1); Tariff Act of 1930, Part II, § 332, 46 Stat. 590, 699 (1930); Tariff Act of 1922, Part II, § 318(b), 42 Stat. 858, 947 (1922). This definition is

striking in its breadth, and is commensurate with the stated purpose to reach "every type and form of unfair practice," *see* Senate Rep. No. 67–595, *supra*.

Digital articles of commerce did not exist when the Tariff Act was first enacted. However, the intention to omit unforeseen, later-discovered technologies cannot be imputed to this statute, and is negated by the all-inclusive breadth of the definition that was written.

Nonetheless, the panel majority rules that the digital data sets and digital models that are here imported are not "material things" and therefore are excluded from Section 337. Maj. Op. at 1297. Citing definitions in dictionaries of the 1920s, the ***1308** majority rules that digital goods are "intangible," and that infringing imports when electronically transmitted are excluded from the Tariff Act.

However, the Tariff Act did not lock Section 337 into the technology in existence in 1922 or 1930. It cannot have been the legislative intent to stop the statute with the forms of "article" then known. Further, the particles and waveforms of electronics and photonics and electromagnetism are not intangible, although not visible to the unaided eye.[1]

Section 337 was written in broad terms, whereby no field of invention, past, present, or future, was excluded. It is not reasonable to impute the legislative intent to exclude new fields of technology, and inventions not yet made, from a statute whose purpose is to support invention.

The court nonetheless imputes this legislative purpose to the Tariff Act, placing weight on selected definitions of "article" in dictionaries of the 1920s, while dismissing unselected definitions as "imprecise at best." Maj. Op. at 1292. Thus the court arbitrarily rejects the definition in the leading dictionary of the era, Webster's New International Dictionary of the English Language, 1924 Edition, and the 1934 Second Edition, which define "article" broadly and generally, as "a thing of a particular class or kind as distinct from a thing of another class or kind; a commodity; as, an article of merchandise." Merchandise, in turn, is defined as "the objects of commerce; whatever is usually bought and sold in trade; wares; goods."

Precedent has long recognized that "article" in the Tariff Act was intended to be all-encompassing. The Court of Customs and Patent Appeals in 1940, citing Webster's New International Dictionary, explained that, in the Tariff Act of 1930, "Congress said: 'and paid upon all articles when imported from any foreign country.' Unquestionably, Congress meant, by employing that language, to include under the word 'articles' any provided-for substance, material or thing of whatever kind or character that was imported into this country." *United States v. Eimer & Amend*, 28 C.C.P.A. 10, 12, 1940 WL 4014 (1940).

The Commission defined "articles" in Section 337 to encompass "articles of commerce." Comm'n Op. at 40. The Supreme Court defined "articles of commerce" to include pure information, holding in *Reno v. Condon*, 528 U.S. 141, 120 S.Ct. 666, 145 L.Ed.2d 587 (2000), that the Commerce Clause applies to interstate transmission of information in motor vehicle records sold or released "into the interstate stream of business." *Id.* at 148, 120 S.Ct. 666.

Although data sets carrying information, imported by electronic or photonic or electromagnetic transmission, are not mentioned in the dictionaries of the 1920s, no reason has been shown to exclude them from articles of commerce. No dictionary, and no statutory constraint, limits "articles" to items that are grossly "tangible." Data carried by electronic particles or waves constitute articles of commerce, and may be imported, bought and sold, transmitted, and used.

My colleagues' removal of digital goods from the Tariff Act is devoid of definitional or statutory support. The Commission correctly defined "articles" in Section 337 as meaning articles of commerce, including digital articles and electronic commerce.

1309** ***The Commission correctly held that importation of infringing articles is not restricted to specific kinds of carriers or modes of entry.

It is not disputed that the digital data sets and digital models of teeth are imported. Importation subject to Section 337 does not depend on the mode of entry into the territory of the United States:

> Importation ... consists in bringing an article into a country from the outside. If there be an actual bringing in it is importation regardless of the mode in which it is effected. Entry through a customs house is not of the essence

of the act.

Cunard S.S. Co. v. Mellon, 262 U.S. 100, 122, 43 S.Ct. 504, 67 L.Ed. 894 (1923).

The Bureau of Customs and Border Protection has established that Internet transmission is "importation" into the United States. *See* HQ 114459 (Sept. 17, 1998) ("We further find that the transmission of software modules and products to the United States from a foreign country via the Internet is an importation of merchandise into the customs territory of the United States"). The Customs rulings reflect the accepted view that digital products are "articles of commerce," "goods," or "merchandise."

The Customs statute classifies software as "merchandise" under 19 U.S.C. § 1401(c). *See* HQ114459 ("we find that the subject software modules and products are 'merchandise' and 'goods' ..."); *see also* Heading 8523, USHTS (2015) (Rev.2) (classifying software for importation duties). Although the panel majority argues that the Tariff Schedule exempts telecommunications transmissions from import duties, *see* General Note 3(e)(ii), HTSUS (2015) (Rev.2), it is established that telecommunications transmissions, including electronically imported software, are within the purview of the Customs service. The Court of International Trade stated in *Former Employees of Computer Sciences Corp. v. U.S. Secretary of Labor*, 30 Ct. Int'l. Tr. 124, 414 F.Supp.2d 1334 (2006):

> General Note 3(e) supports the conclusion that telecommunications transmissions, which would include transmissions of software code via the Internet, are exempt from duty while acknowledging that they are goods entering into the Customs boundaries of the United States.

Id. at 131, 414 F.Supp.2d 1334.

Exemption from import duty is not exemption from patent infringement. The court now discards established protocols and practices concerning electronic and digital technologies, although it is beyond debate that digital articles are "goods" or "merchandise" and may be bought and sold and patented and imported. Today's ruling discards the Tariff Act's purpose of protecting domestic industry from unfair trade in the importation of this vast and powerful body of commercial articles that may infringe United States patents.

The Commission correctly held that electronic importation of digital goods is subject to the trade laws.

My colleagues on this panel do not dispute that the Patent Act applies to the subject matter that is imported, although they hold that the Tariff Act does not apply, thereby rendering Section 337 incapable of performing its statutory purpose.

Section 337 does not distinguish between digital goods imported electronically and digital goods imported as embedded in a physical medium. My colleagues hold that importation of infringing digital data can be excluded when the data are carried on discs or other storage media, but cannot be excluded when carried in packets or ***1310** waves by wired or wireless transmission. This distinction has long been discarded as unjustifiable, and in the context of Section 337 and other Trade statutes and rulings, precedent is universally contrary.

The Commission explained in *Hardware Logic Emulation Systems*, *supra*, that "it would be anomalous for the Commission to be able to stop the transfer of a CD–ROM or diskette containing respondents' software, but not be able to stop the transfer of that very same software when transmitted in machine readable form by electronic means." *Id.* at 29.

Reaching the same logical conclusion, the Department of Labor, interpreting the Trade Act for purposes of Trade Adjustment Assistance, stated that "[s]oftware and similar intangible goods that would have been considered articles, for the purposes of the Trade Act, if embodied in a physical medium will now be considered to be articles regardless of their method of transfer." *IBM Corporation Global Services Division, Piscataway, NJ; Middletown, NJ; Notice of Revised Determination on Remand*, 71 FR 29183–01 (May 19, 2006). And as mentioned *supra*, the Customs service holds that "[t]he fact that the importation of the merchandise via the Internet is not effected by a more 'traditional vehicle' (e.g., transported on a vessel) does not influence our determination." HQ 114459 at 2.

To further illustrate, Congress rejected the distinction the court creates, in the context of trade negotiations. The recently enacted Bipartisan Congressional Trade Priorities and Accountability Act of 2015 covers "digital trade in goods and services" and states that "[t]he principal negotiating objectives of the United States ... are ... to

ensure that electronically delivered goods and services receive no less favorable treatment under trade rules and commitments than like products delivered in physical form." Pub L. No. 114–26, § 102(a)(6) and (a)(6)(B)(i), 129 Stat. 320, 325 (2015).

Although various forms of wired and wireless transmission have become commonplace, within nations and across borders, the panel majority has locked the International Trade Commission into technological antiquity. The court ignores precedent and logic, and removes a vast body of technology from the protection of a statute designed for its protection.

Difficulty of enforcement is not grounds for discarding a remedial statute.

The court argues that violation of Section 337 by electronic transmission into the United States, such as via the Internet or other cloud technologies, may be difficult to track and enforce. This argument, whatever the present state of science, cannot apply to the facts of this case, for the electronically imported digital goods are produced by the Pakistani affiliate of the United States importer, who is subject to the Commission's Cease–and–Desist Order.

Cease-and-desist orders as a remedy for Section 337 violations are not new, including orders relating to infringement by digital importation. *See Hardware Logic Emulation Systems, supra,* at 3 (ordering that respondent "shall not ... import (including electronically) into the United States, or use, duplicate, transfer, or distribute by electronic means or otherwise, within the United States, hardware logic emulation software that constitutes covered product").

Even if enforcement were difficult, difficulty of enforcing a remedial statute is not grounds for judicial elimination of all remedy. *See Bally/Midway Mfg. Co. v. Int'l Trade Comm'n,* 714 F.2d 1117, 1122 (Fed.Cir.1983) (rejecting the position that absence of remedy precludes a finding of ***1311** violation of Section 337). The court stated that "Congress did not intend the Commission to consider questions of remedy when the agency determines whether there is a violation." *Id.* at 1123.

My colleagues' reliance on possible difficulty of enforcement against electronic transmission of infringing digital data and related articles, although not at issue in this case, merely adds imprecision to judicial guidance in this commercially important area.

The Commission's ruling requires judicial deference in accordance with Chevron.

It is not disputed that the digital data sets and digital models for teeth alignment, produced in Pakistan and imported into the United States, infringe the patents of Align Technology. The Commission recognized that this technology is subject to Section 337. This ruling is a reasonable statutory interpretation.

If Section 337 were deemed ambiguous as applied to these fields of technology and commerce, the Commission's well-reasoned interpretation, amid extensive corroboratory rulings, is entitled to judicial deference. "[I]f the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute." *Chevron U.S.A. Inc. v. Nat. Res. Def. Council, Inc.,* 467 U.S. 837, 843, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984). A permissible construction is one that is "rational and consistent with the statute." *Sullivan v. Everhart,* 494 U.S. 83, 88–89, 110 S.Ct. 960, 108 L.Ed.2d 72 (1990) (quoting *N.L.R.B. v. United Food & Commercial Workers Union, Local 23, AFL–CIO,* 484 U.S. 112, 123, 108 S.Ct. 413, 98 L.Ed.2d 429 (1987)). "If the agency interpretation is not in conflict with the plain language of the statute, deference is due." *Nat'l R.R. Passenger Corp. v. Boston & Maine Corp.,* 503 U.S. 407, 417, 112 S.Ct. 1394, 118 L.Ed.2d 52 (1992).

The rule of deference to the Commission's reasonable statutory interpretation has long been recognized by the Federal Circuit. *E.g., TianRui Grp. Co. v. Int'l Trade Comm'n,* 661 F.3d 1322, 1332 (Fed.Cir.2011) ("We have held that the Commission's reasonable interpretations of section 337 are entitled to deference."); *Kinik Co. v. Int'l Trade Comm'n.,* 362 F.3d 1359, 1363 (Fed.Cir.2004) ("To the extent that there is any uncertainty or ambiguity in the interpretation of § 337(a) and its successor § 1337(a)(1)(B)(ii), deference must be given to the view of the agency that is charged with its administration."); *Enercon GmbH v. Int'l Trade Comm'n,* 151 F.3d 1376, 1381 (Fed.Cir.1998) ("As the agency charged with the administration of section 337, the ITC is entitled to appropriate deference to its interpretation of the statute.").

"Congress cannot, and need not, draft a statute which anticipates and provides for all possible circumstances in which a general policy must be applied to a specific set of facts. It properly leaves this task to the authorized

agency." *Micron Tech., Inc. v. United States,* 243 F.3d 1301, 1312 (Fed.Cir.2001). To the extent that new technologies are involved in these infringing importations, deference is appropriate to the agency's reasonable application of the statute it is charged to administer. *See Nat'l Cable & Telecommunications Ass'n, Inc. v. Gulf Power Co.*, 534 U.S. 327, 339, 122 S.Ct. 782, 151 L.Ed.2d 794 (upholding agency interpretive authority where the statute involved "technical, complex, and dynamic" subject matter that "might be expected to evolve in directions Congress knew it could not anticipate.").

On any standard, the Commission's determination is reasonable, and warrants ***1312** respect. The panel majority's contrary ruling is not reasonable, on any standard.

CONCLUSION

The Commission's ruling is consistent with the language, structure, and purpose of Section 337, and decades of precedent concerned with digital data, electronic transmission, and infringing importation. From the court's erroneous departure from statute and precedent, I respectfully dissent.

844 F.3d 1344
United States Court of Appeals,
Federal Circuit.

IN RE: ETHICON, INC., a Johnson & Johnson Company, Appellant

2015-1696
|
Decided: January 3, 2017

Newman, Circuit Judge, **dissenting**.
United States Patent No. 7,591,844 ("the '844 Patent") is for a balloon-expandable vascular stent having a drug-eluting coating of a copolymer of vinylidene fluoride and hexafluoropropylene in about 85/15 weight percent monomer ratio. Novelty is not disputed. On this *inter partes* reexamination requested by Boston Scientific Scimed and Abbott Laboratories, the PTAB held that the prior art rendered obvious the claimed vascular stent. I cannot agree, for no reference or combination of references, or common knowledge or common sense, teaches or suggests or motivates the claimed stent.

Claim 1 was accepted as representative:

> 1. A device for intraluminal implantation in a vessel comprising a balloon-expandable stent and a pharmaceutical agent-containing coating, said coating comprising a biocompatible polyfluoro copolymer that comprises about eighty-five weight percent vinylidine fluoride [VDF] copolymerized with about fifteen weight percent hexafluoropropylene [HFP] and at least one pharmaceutical agent intermixed with said copolymer, wherein said coating has not been subjected to a maximum temperature greater than 60° C during the coating process or afterward, thereby providing an adherent coating that remains adhered to the device upon expansion of the balloon-expandable stent.

***1353** '844 Patent, col. 37, l. 59–col. 38, l. 3. It was generally agreed that the novelty and advantages are due to the specific copolymer coating material for the balloon-expandable stent.

The references cited by the PTO Board recite thousands of polymer and copolymer components for stent coating materials, but not the copolymer of the '844 Patent, although this copolymer was known for other uses. There is no hint, no suggestion, of its use as a drug-eluting coating in a vascular stent, nor were its advantages foreseen. Nonetheless the Board deemed it obvious,[1] and this court agrees. I respectfully dissent.

Errors of fact, analysis, and law

The Board relied on three groups of references, and the court has followed this pattern on appellate review. The Board's first set of references was cited to show that polymer-coated vascular stents were known; the second set was "consulted" to show various polymers used in medical devices and structures unrelated to vascular stents; and the third set was cited to show that the '844 Patent's copolymer was known for unrelated uses such as clothing, boots, helmets, electrical tapes, and linings for tanks and storage vessels. No reference or combination of references teaches or suggests or motivates or otherwise renders obvious the '844 Patent's vascular stent.

The coated vascular stent references (Tuch)

The Board provided a foundation for its analysis with the first set of references, focusing on the Tuch patent, which shows polymer-coated drug-eluting vascular stents. Such vascular stents were known, and the '844 Patent so states. U.S. Patent No. 5,824,048 (the Tuch reference) names hundreds of monomers encompassing thousands of polymers and copolymers, and states that they may all be usable for vascular stents in various conditions. However, the specific '844 Patent's copolymer is not mentioned, and although the list includes one of the '844 Patent's comonomers, vinylidene fluoride, the other known monomer, hexafluoropropylene, is not mentioned. This silence cannot render obvious the omitted copolymer, for nothing in Tuch suggests selection of this omitted copolymer from the thousands of polymeric and other

potential stent materials listed by Tuch:

> The polymer may be either a biostable or a bioabsorbable polymer depending on the desired rate of release or the desired degree of polymer stability, but a bioabsorbable polymer is probably more desirable since, unlike a biostable polymer, it will not be present long after implantation to cause any adverse, chronic local response. Bioabsorbable polymers that could be used include poly(L-lactic acid), polycaprolactone, poly(lactide-coglycolide), poly(hydroxybutyrate), poly(hydroxybutyrate-co-valerate), polydioxanone, polyorthoester, polyanhydride, poly(glycolic acid), poly(D,L-lactic acid), poly(glycolic acid-co-trimethylene carbonate), polyphosphoester, polyphosphoester urethane, poly(amino acids), cyanoacrylates, poly(trimethylene carbonate), poly(iminocarbonate), copoly(ether-esters) (e.g. PEO/PLA), polyalkylene oxalates, polyphosphazenes and biomolecules such as fibrin, fibrinogen, cellulose, starch, collagen and hyaluronic acid. Also, biostable polymers with a relatively low chronic tissue response such as polyurethanes, silicones, and polyesters could be used ***1354** and other polymers could also be used if they can be dissolved and cured or polymerized on the stent such as polyolefins, polyisobutylene and ethylene-alphaolefin copolymers; acrylic polymers and copolymers, vinyl halide polymers and copolymers, such as polyvinyl chloride; polyvinyl ethers, such as polyvinyl methyl ether; polyvinylidene halides, such as polyvinylidene fluoride and polyvinylidene chloride; polyacrylonitrile, polyvinyl ketones; polyvinyl aromatics, such as polystyrene, polyvinyl esters, such as polyvinyl acetate; copolymers of vinyl monomers with each other and olefins, such as ethylene-methyl methacrylate copolymers, acrylonitrile-styrene copolymers, ABS resins, and ethylene-vinyl acetate copolymers; polyamides, such as Nylon 66 and polycaprolactam; alkyd resins; polycarbonates; polyoxymethylenes; polyimides; polyethers; epoxy resins; polyurethanes; rayon; rayon-triacetate; cellulose, cellulose acetate, cellulose butyrate; cellulose acetate butyrate; cellophane; cellulose nitrate; cellulose propionate; cellulose ethers; and carboxymethyl cellulose.

Tuch, col 5, ll. 16–53.

The Tuch encyclopedia cannot be taken to teach or suggest or motivate that the unmentioned copolymer of the ’844 Patent should be identified and used in a vascular stent. “[T]he breadth of these choices and the numerous combinations indicate that these disclosures would not have rendered the claimed invention obvious to try.” *Leo Pharma. Prods., Ltd. v. Rea*, 726 F.3d 1346, 1356–57 (Fed. Cir. 2013). Nothing in the Tuch reference, or any other reference, suggests use of the ’844 Patent’s copolymer for vascular stents, even for experimentation:

> [A]n invention would not have been obvious to try when the inventor would have had to try all possibilities in a field unreduced by direction of the prior art.

Bayer Schering Pharma AG v. Barr Labs., Inc., 575 F.3d 1341, 1347 (Fed. Cir. 2009).

However, the Board deemed it irrelevant that the ’844 Patent’s copolymer was omitted by Tuch, and erroneously found that this copolymer was “a prior art element used for its established function.” The Board stated:

> It is unnecessary that Tuch disclose any shortcomings in its list of polymers for the ordinary skilled worker to have found it obvious to have employed an alternative polymer for its coating since it is obvious to use a prior art element for its established function.

Board Op. at 10–11. This finding has no support, for Tuch does not lead to the undisclosed copolymer of the '844 Patent or any established function in the drug-eluting vascular stents to which Tuch is directed. The "established function" of this copolymer is shown in the prior art to be quite different, as in the cited Lo reference, discussed *post*.

Tuch does not provide substantial evidence of the '844 Patent's copolymer as a stent material or possible stent material. The "substantial evidence" standard of judicial review of Board findings "involves examination of the record as a whole, taking into account evidence that both justifies and detracts from an agency's decision." *In re Gartside*, 203 F.3d 1305, 1312 (Fed. Cir. 2000). The Tuch reference as a whole, with its massive listing of thousands of polymers and copolymers but not the '844 copolymer, does not provide substantial evidence of any suggestion or any reason to select the '844 Patent's copolymer for use in drug-eluting vascular stents.

"Consultation" of the Tu reference

Perhaps recognizing the inadequacy of Tuch, the Board "consulted" the Tu *et al.* reference, U.S. Patent No. 4,816,339. Tu describes multilayered "suturable vascular ***1355** implants" having "improved luminal hydrophobicity, compliance, strength and elasticity." Tu, col. 2, ll. 7–11. The first Tu layer is made of poly(tetrafluoroethylene), the second layer is "a mixture of poly(tetrafluoroethylene) and elastomer," and an optional third layer is made of "elastomer." Tu, col. 3, ll. 48–65. Tu states that the elastomer may be selected from a diverse group of polymers and copolymers, including the '844 Patent's copolymer components:

> The elastomer is preferably selected from the group consisting of polyvinylidene fluoride co-hexafluoropropylene, poly(tetrafluoroethylene-coperfluoro(methylvinylether)), poly(tetrafluoroethylene-co-propylene), poly(vinylidene-co-chlorotrifluoroethylene), silicones, fluorosilicones, fluoroalkoxy phosphazenes, segmented copolyester ether, styrene butadiene block copolymers, polyethers[,] acrylonitrile butadienes, isoprenes, polyurethanes, and mixtures thereof.

Tu, col. 4, ll. 30–39. Tu's preferred elastomers are a copolymer of tetrafluoroethylene and propylene, and silicone. Tu, col. 4, ll. 61–66; col. 5, l. 7. The Board stated:

> The reason to consult Tu is because Tuch's list of polymers is clearly not exhaustive in view of Tuch's description of broad classes of polymers, such as vinyl halide polymers and copolymers, and polyvinylidene halides. Tuch 6. Tuch also uses the transitional phrase "such as" in prefacing the list of biostable polymers and in reciting specific examples of the broader classes, indicating that Tuch did not confine the skilled worker to the explicit list, but contemplated polymers outside of it.

Board Op. at 7. Tu does not state that its multilayered suturable implants are useful in vascular stents, or suggest selection of any of its materials for this purpose. Tu cannot be read as teaching that its materials enlarge the listing of suitable stent polymers in Tuch, to place the Tu materials in the Tuch disclosure. The Tu devices are different products requiring different properties for different purposes.

The Board states that it consulted Tu "for teaching of a medical device comprising VDF:HFP." Board Op. at 3. Tu does not mention vascular stents, and suggests no composition or properties for such use. It is apparent that the Tu multilayered structure differs from a vascular stent, and the Board did not find otherwise. Also, as an additional difference Tu requires "curing" at a temperature of about 150° C to about 350° C, Tu, col. 7,

ll. 66–68; col. 9, ll. 12–14, excluding the ’844 Patent product’s temperature ceiling of “60° C during the coating process or afterward.” ’844 Patent, col. 37, l. 66–col. 38, l. 1.

The Board states that Tu shows that the VDF:HFP copolymer “has the properties described in Tuch as useful for its stent coating.” Board Op at. 14. The Tuch properties are not the properties of Tu’s multilayered suturable vascular implants. Tu states that its implants have elasticity “because of the arrangement of layers”:

> The biologically compatible material of the present invention has excellent compliance, strength and elasticity because of the arrangement of layers of poly(tetrafluoroethylene), poly(tetrafluoroethylene)/elastomer , elastomer and fibrous elastomers.

Tu, col. 2, ll. 31–35. This is not a teaching or suggestion of the ’844 Patent’s copolymer-coated drug-eluting stent.

Ignoring all of these discrepancies, the Board ruled that since a VDF:HFP copolymer with undefined monomer ratio is usable as Tu’s optional third elastomer layer, it would have been obvious to use it in the Tuch stent. Neither Tuch nor Tu so suggests. The Board’s ruling illustrates the “insidious” exercise of decisional hindsight, whereby that which the inventor taught is ***1356** used by the decision-maker to reconstruct the invention. This fallacy has long been rejected:

> To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher.

W.L. Gore & Assocs., Inc. v. Garlock, Inc., 721 F.2d 1540, 1553 (Fed. Cir. 1983).

Tu does not provide substantial evidence for selecting the ’844 Patent’s copolymer in a vascular stent. The Board acknowledged that neither Tuch nor Tu suggests the 85/15 monomer ratio of vinylidene fluoride and hexafluoropropylene. The ’844 Patent demonstrates differences in the properties of various monomer ratios, in that the 85/15 copolymers are “semicrystalline,” and that copolymers with a 60.6/39.4 ratio are “marketed as elastomers.” ’844 Patent, col. 20, ll. 22–27. This evidence weighs against reliance on the Tu reference to teach the 85/15 copolymer for properties suitable for a vascular stent.

The Supreme Court guides that “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 Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418, 127 S.Ct. 1727, 167 L.Ed.2d 705 (2007). Tu does not fill the gaps in Tuch to render obvious the selection of this specific copolymer and ratio for use in the Tuch stent, for Tu provides no reason for a person of ordinary skill to select the 85/15 copolymer for use in Tuch.

The Lo reference

The Board’s third set of references, represented by Lo, does not shift this balance. The Board cited U.S. Patent No. 3,178,399 (the Lo reference), a 50-year-old patent that shows that the ’844 copolymer in 85/15 ratio was a known product with known uses. Copolymers of vinylidene fluoride and hexafluoropropylene having comonomer ratios similar to the ’844 Patent’s 85/15 ratio are described in the Lo reference as having a

> unique combination of tensile strength and reversible elongation properties and are especially suitable as durable, flexible coatings for application to various fabric surfaces. These surfaces may, in a preferred form of application, take the form of protective clothing (for example, as suits, boots, gloves, helmets and other wearing apparel) and other articles of manufacture which are comprised of exposed surfaces which may be subjected to bending, folding, or other forms of distortion in the course of performing their function under special environmental conditions. They may also be used in film form

> (either oriented or unoriented) e.g. in electrical tapes, magnetic recording tapes, etc., and as protective coatings on tanks, storage vessels and the like.

Lo, col. 10, ll. 27–39. None of these uses has any relation to a vascular stent or any biological application. However, from Lo's uses as boot and helmet coatings and electrical tapes, the Board stated that "Lo describes copolymers of vinylidene fluoride (VDF) and hexafluoropropylene (HFP) which have flexibility, elasticity, and extensibility," Board Op. at 5, and from this selection out of context the Board extracted obviousness of use in a drug-eluting vascular stent. Lo's range of uses of this known copolymer, undifferentiated as to monomer ratio and copolymer properties, does not fill the gaps in Tuch and Tu to suggest use for a drug-eluting vascular stent.

The Board erred in its analysis, collecting the elements of the '844 Patent's stent from assorted sources, and placing them in ***1357** the template of the '844 claim. The only guide to this reconstruction is the '844 Patent itself. *See Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138 (Fed. Cir. 1985) ("The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time."). The Court has reinforced that "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was independently known in the prior art." *KSR Int'l Co.*, 550 U.S. at 418–19, 127 S.Ct. 1727. Neither the record nor the law supports the Board's conclusion that a person of ordinary skill would be motivated to select this Lo copolymer for use in a vascular stent.

The objective evidence

The "secondary considerations" are part of the obviousness determination. *See Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17–18, 86 S.Ct. 684, 15 L.Ed.2d 545 (1966) ("Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented."); *W.L. Gore*, 721 F.2d at 1555 (objective evidence "should when present always be considered as an integral part of the analysis.").

The Board erred in declining to consider the evidence of copying, commercial success, and medical acclaim. Such evidence "may often be the most probative and cogent evidence in the record." *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983), for the objective evidence reflects the "temporal and technical perspective" of the invention. *Mintz v. Dietz & Watson, Inc.*, 679 F.3d 1372, 1378 (Fed. Cir. 2012).

This evidence must be considered along with the entirety of the evidence. *Stratoflex*, 713 F.2d at 1538–39 (objective evidence "is to be considered as part of all the evidence, not just when the decisionmaker remains in doubt after reviewing the art."); *In re Mageli*, 470 F.2d 1380, 1383 (C.C.P.A. 1973) ("[E]vidence bearing on the facts is never of 'no moment,' is always to be considered, and accorded whatever weight it may have."). The response of the marketplace, and copying by competitors, may evidence the improved technology and beneficial properties of an invention. Ethicon's expert Dr. Mikos described the advantages of the '844 Patent's stent over the available drug-eluting stents, and the apparently undisputed copying by the competitors who brought this *inter partes* reexamination. Mikos Decl. at 38–39. Dr. Mikos testified:

> Data on file at Abbott Vascular and relied upon by Abbott in its FDA submissions shows that the PVDF-HFP coated Xience V stent is more thromboresistant (i.e., shows greater tendency to reduce thrombus formation) than other drug-eluting stent coatings.

Mikos Decl. at 39. He stated, "numerous clinicians have also emphasized that the PVDF-HFP polymer used in the Xience V stent shows unexpectedly less inflammation." *Id.*

The Board declined to consider the evidence of superior properties and commercial success, stating:

> This evidence is not persuasive since it does not establish that the reduction in inflammation observed with Xience V is in comparison with the closest prior art as required under *Baxter*, 952 F.2d at 392. Rather, it appears the news articles are reporting that Xience's polymer is less inflammatory than the polymers on existing stents.

Board Op. at 14.

The Board did not identify what it deemed to be an acceptable prior art comparison, except to state that "Patent Owner has not provided sufficient testimony ***1358** that this reduced inflammation would have been unexpected by one of ordinary skill in the art in comparison to the polymers described in Tuch, for example, which teaches stents with polymer coatings, including a homopolymer of VDF (Tuch6)." Board Op. at 14. The Board did not mention the comparative data in the '844 Patent, which compared the 85/15 copolymer with stents coated with the polyvinylidene fluoride (VDF) homopolymer. '844 Patent, col. 19, ll. 22–48. The data in the specification showed that the polyvinylidene fluoride homopolymer "adhered poorly to the stent and flaked off, indicating they were too brittle" when dried at the low temperatures required by the '844 Patent. '844 Patent, col. 19, ll. 36–41.

The '844 Patent also included comparative data with copolymers of vinylidene fluoride and hexafluoropropylene in 92/8 and 91/9 weight percent ratios, and showed the superior results obtained with the 85/15 ratio. '844 Patent, col. 19, ll. 24–28, 36–41. The '844 Patent also compared the 85/15 copolymer with copolymers having a 60.6/39.4 ratio, which were "marketed as elastomers." '844 Patent, col. 20, ll. 22–24. Those copolymers, when mixed with rapamycin and dried at the claimed temperature, produced "a white film, indicating phase separation of the drug and the polymer." '844 Patent, col. 20, ll. 55–60. In contrast, with the 85/15 copolymer "a clear coating, indicating a solid solution of the drug in the polymer, is obtained." '844 Patent, col. 20, ll. 53–55. Additional comparative data in the '844 Patent showed differences in the fraction of drug released over time between the claimed 85/15 copolymer and the 60.6/39.4 copolymer of vinylidene fluoride and hexafluoropropylene without a topcoat. '844 Patent, Figs. 3 and 5; col. 21, ll. 9–24.

These comparisons are evidence of unpredicted results. "Consistent with the rule that all evidence of nonobviousness must be considered when assessing patentability, the PTO must consider comparative data in the specification in determining whether the claimed invention provides unexpected results." *In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995). The Board's refusal to consider this evidence, instead criticizing the "absence" of comparisons with some undefined prior art, is untenable.

SUMMARY

The references cited by the Board provide no teaching or suggestion or motivation to select the specific copolymer and ratio of the claimed '844 Patent's vascular stent, and no basis for expecting that this composition would produce the advantageous properties that are obtained. The Tuch list of stent materials does not lead to selecting the omitted copolymer of 85% vinylidene fluoride and 15% hexafluoropropylene. The Tu multi-layered fabric for medical grafts does not fill this gap in Tuch. And Lo, if anything, leads away from the '844 Patent, for the Lo products are not analogous to vascular stents. No combination of references suggests utilization of the '844 Patent's copolymer in drug-eluting vascular stents.

Substantial evidence does not support the Board's findings and conclusion that a person of ordinary skill in the field of this invention would obviously select the '844 Patent's copolymer from its omission in Tuch, from the multilayered fabrics of Tu, and the non-analogous uses in Lo. From the court's contrary ruling, I respectfully dissent.

842 F.3d 1223
United States Court of Appeals,
Federal Circuit.

SAS Institute, Inc., Appellant
v.
Complementsoft, LLC., Cross–Appellant

2015-1346
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2015-1347
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November 7, 2016

Newman, Circuit Judge, **dissenting** from denial of the petition for rehearing en banc.

Administrative agency practices are required to conform to the authorizing legislation and the statutory purpose. The Patent and Trademark Office ("PTO"), charged with administering the Leahy–Smith America Invents Act ("AIA"), P.L. 112–29, has adopted some implementing practices that are not authorized by the statute and not in accord with the legislative purpose of achieving final resolution of disputed patent validity issues by agency action in place of litigation.

This case concerns the PTO's adoption of the practice whereby on *inter partes* review ("IPR") the PTO may, in its sole discretion, choose to decide some, but not all, of the patent claims that are challenged under the statute. This practice foils the legislative purpose of resolving certain patent issues in an administrative forum, newly available to litigants previously confined to the district court. From my colleagues' refusal to reconsider this agency practice *en banc*, I respectfully dissent.

DISCUSSION

The America Invents Act established a new adjudicatory body called the Patent Trial and Appeal Board ("PTAB"), an administrative tribunal vested with authority to conduct trials including discovery, evidence, testimony, briefs, argument, and final decision. The PTAB's decisions produce estoppel in all subsequent proceedings between the parties, both administrative and judicial. The goal is the efficient and reliable resolution of certain patent disputes without the cost and delay and uncertainty of district court litigation. As explained by Senator Kyl, a principal architect of the legislation, this system "ideally [will] completely substitute for at least the patents-and-printed-publication portion of the civil litigation." 157 CONG. REC. S1376 (daily ed. Mar. 8, 2011) (statement of Sen. Kyl).

This goal was paramount during the years of genesis of the America Invents Act. "It is clearly appropriate to have an administrative process for challenging patent validity, but it should exist within a structure that guarantees a quick—and final—determination." *Patent Reform Act of 2009: Hearing on H.R. 1260, House Comm. on the Judiciary*, 111th Cong. 153 (April 30, 2009) (statement of Rep. Manzullo). The AIA provides for final determination of validity as to the grounds asserted against the claims challenged in the petition.

However, the PTO adopted regulations that authorizes the PTAB to choose to decide some, but not all, of the challenged claims. The practice, called "partial" or "selective" institution, leaves the unselected claims dangling, lacking both finality and estoppel, preventing the expediency and economy and efficiency that motivated the America Invents Act. Senator Kyl stressed a primary purpose of the Act "to force a party to bring all of [its] claims in one forum ... and therefore to eliminate the need to press any claims in other fora." 154 CONG. REC. S9989 (daily ed. Sept. 27, 2008) (statement of Sen. Kyl).

Instead, by "partial institution" the petitioner is not only mired in the proceeding for the claims that the PTAB has selected, but may also be obliged to litigate the other claims in other for a, even though ***1225** those claims were properly presented to the PTAB for adjudication. The matter requires *en banc* correction, for this court has endorsed the PTO's position that "the final order of the Board need not address every claim raised in the petition for review" *Synopsys, Inc., v. Mentor Graphics Corp.*, 814 F.3d 1309, 1311 (Fed. Cir. 2016).

THE STATUTE

The provisions of the AIA form a coherent whole only when all of the properly challenged claims are decided by the PTAB. "The cardinal rule of statutory interpretation [is] that no provision should be construed to be entirely

redundant." *Kungys v. United States*, 485 U.S. 759, 778, 108 S.Ct. 1537, 99 L.Ed.2d 839 (1988). "It is the duty of the court to give effect, if possible, to every clause and word of a statute" *Inhabitants of Montclair Tp. v. Ramsdell*, 107 U.S. 147, 152, 2 S.Ct. 391, 27 L.Ed. 431 (1883).

Relevant statutory provisions include—

35 U.S.C § 311 *Inter Partes* Review

Section 311 authorizes the defined post-grant challenges in the PTO. The purpose is not only to avoid or reduce the burdens and costs and delays of litigation, but potentially to avert litigation. *See* 157 CONG. REC. S1053 (Mar. 1, 2011) (statement of Sen. Whitehouse) ("[T]he bill will improve administrative processes so that disputes over patents can be resolved quickly and cheaply without patents being tied up for years in expensive litigation."); *see also* H.R. REP. NO. 112–98 pt.1 at 48 (2011) ("[T]he purpose of the section is providing quick and cost effective alternatives to litigation."):

> **§ 311(a)** ***In general.***—Subject to the provisions of this chapter, a person who is not the owner of a patent may file with the Office a petition to institute an *inter partes* review of the patent. ....
>
> **(b)** ***Scope.***—A petitioner in an *inter partes* review may request to cancel as unpatentable 1 or more claims of a patent only on a ground that could be raised under section 102 or 103 and only on the basis of prior art consisting of patents or printed publications.

The PTO's then-Director Dudas explained that the majority of validity challenges are on § 102 or § 103 grounds based on reference patents and printed publications. *See Patent Reform: The Future of American Innovation: Hearing Before the Senate Comm. on the Judiciary*, 110th Cong. 7 (2007) (statement of Director Jon Dudas).

The legislative record is unambiguous: the purpose of the AIA procedure is to move these validity challenges into the PTO, whose expertise in technology and experience in the relevant law are intended to produce decisions entitled to estoppel in any judicial or administrative proceeding between these parties or their privies. Senator Grassley explained the intended effect: "If an *inter partes* review is instituted while litigation is pending, that review will completely substitute for at least the patents-and-printed-publications portion of the civil litigation." 157 CONG. REC. S1376 (daily ed. Mar. 8, 2011) (statement of Sen. Grassley). This complete substitution, as enacted by Congress, cannot occur if the validity of only some of the challenged claims is decided, leaving the other challenged claims untouched.

35 U.S.C. § 312 Petitions

Section 312 states the required content of these post-grant petitions. When the specified content is not provided, the petition must be denied. When the specified content is provided, the petition may or may not be "instituted," in the PTO's unchallenged discretion. However, the statute does not contemplate the partial institution ***1226** of only those parts selected by the PTO:

> **§ 312(a)** ***Requirements of petition.*** — A petition filed under section 311 may be considered only if—
>
> ....
>
> **(3)** the petition identified, in writing and with particularity, each claim challenged, the grounds on which the challenge to each claim is based, and the evidence that supports the grounds for the challenge to each claim, including— ....

At enactment Senator Grassley explained that "by requiring petitioners to tie their challenges to particular validity arguments against particular claims, the new threshold will prevent challenges from 'mushrooming' after the review is instituted into additional arguments employing other prior art or attacking other claims." 157 CONG. REC. S1376 (daily ed. Mar. 8, 2011). Emphasis on this requirement pervaded the genesis of the legislation. Senator Kyl explained that the petitioner "must present a full affirmative case" as to every challenged claim. 154 CONG. REC. S9987 (daily ed. Sept. 25, 2008) (statement by Sen. Kyl on S. 3600).

While § 314(d), discussed *infra*, provides that the PTO may refuse to accept any petition in its entirety, it was never contemplated that only some of the challenged claims might be reviewed, nor does § 314(d) provide such discretion, for this defeats the purpose of the proceeding. The legislative record stresses the intent "to eliminate the need to press any claims in other fora." 154 CONG. REC. S9989 (daily ed. Sept. 27, 2008) (statement of Sen. Kyl).

35 U.S.C. § 313 Preliminary response to petition

The patent owner is authorized to respond, and to argue that "no *inter partes* review should be instituted." There is no suggestion of partial institution.

35 U.S.C. § 314 Institution of *inter partes* review

"What the bill does ... is very simple. It says the Patent Office will make an administrative determination before the years of litigation as to whether this patent is a legitimate patent so as not to allow the kind of abuse we have seen." 157 CONG. REC. S5437 (daily ed. Sept. 8, 2011) (Statement of Sen. Schumer on Senate consideration of H.R. 1249). Section 314 provides for the threshold determination of whether to proceed at all and sets time limits for the decision of whether to institute review:

> **§ 314(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 in 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.

In legislative response to the PTO's concern about its ability to meet a sudden increase in workload, the statute provides that the PTO is not obligated to accept every petition, even when meritorious. Senator Kyl explained that this "reflects a legislative judgment that it is better that the Office turn away some petitions that otherwise satisfy the threshold for instituting ***1227** and *inter partes* or post-grant review than it is to allow the Office to develop a backlog of instituted reviews that precludes the Office from timely completing proceedings." 157 CONG. REC. S1377 (daily ed. Mar. 8, 2011) (statement of Sen. Kyl). As part of this expedient, as well as to avert delay due to interlocutory appeal, the Act provides that the threshold decision whether to institute review is not appealable:

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

Thus, when a petition for review is declined, litigation may proceed. The statutory plan is for an alternative to litigation, not duplicative litigation as may arise from partial institution.

35 U.S.C § 315 Relation to other proceedings or actions

A primary focus of the AIA is to avoid the cost and delay and uncertainty of patent litigation. Thus the statute places controls on the relation between these PTO proceedings and district court and ITC litigation. Of particular concern is the effect of partial institution on the integrity of the new estoppel provisions:

> **§ 315(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.

A goal of these new PTO proceedings is finality of decision. As the legislation evolved, it was stressed that "if [such] proceedings are to be permitted, they should

generally serve as a complete substitute for at least some phase of the litigation." S. REP. NO. 110–259, at 67 (2008) (Additional Views of Sen. Specter joined with Minority Views of Sens. Kyl, Grassley, Coburn and Brownback).

The estoppel provisions were controversial. *See, e.g.*, S. REP. NO. 111–18, at 17 (2009) ("Many businesses also have described could-have-raised estoppel as a powerful brake on their use of *inter partes* reexamination. They find this standard vague and uncertain, and fear that if they challenge a patent in an *inter partes* reexamination, they will lose the ability to raise later-discovered prior art against the patent if they are subsequently sued for infringement."). The statute as enacted embodies the dominant policy weight on the benefits of finality and estoppel, as explained by then-Director of the USPTO David Kappos: "Those estoppel provisions mean that your patent is largely unchallengeable by the same party." *Hearing on H.R. 1249 before the Subcomm. on Intell. Prop., Competition and the Internet of the House Comm. on the Judiciary*, 112th Cong. (2011).

***1228** On enactment, Senator Grassley flagged the purpose and significance of the estoppel provisions:

> In addition, the bill would improve the current *inter partes* administrative process for challenging the validity of a patent. It would establish an adversarial *inter partes* review, with a higher threshold for initiating a proceeding and procedural safeguards to prevent a challenger from using the process to harass patent owners. It also would include a strengthened estoppel standard to prevent petitioners from raising in a subsequent challenge the same patent issues that were raised or reasonably could have been raised in a prior challenge. The bill would significantly reduce the ability to use post-grant procedures for abusive serial challenges to patents. These new procedures would also provide faster, less costly, alternatives to civil litigation.

157 CONG. REC. S952 (daily ed. Feb. 28, 2011) (statement of Sen. Grassley). These goals are thwarted by the partial institution practice.

Estoppel cannot arise as to claims that the PTO declined to review. Partial institution negates the purpose that any patent claim challenged by the petitioner and any new claim added during the proceeding could be fully and finally decided, thereby bringing "more certainty in litigation." 157 CONG. REC. S948 (daily ed. Feb. 28, 2011) (statement of Sen. Leahy).

35 U.S.C § 316 Conduct of inter partes review

Section 316 authorizes the PTO Director to issue regulations, sets some evidentiary standards, and provides rules whereby the patent owner may file one motion to amend its claims. The rules here of concern are 37 C.F.R. 42.108(a) ("When instituting *inter partes* review, the Board may authorize the review to proceed on all or some of the challenged claims and on all or some of the grounds of unpatentability asserted for each claim."); 37 C.F.R. 42.108(b) ("At any time prior to institution of *inter partes* review, the Board may deny some or all grounds for unpatentability for some or all of the challenged claims. Denial of a ground is a Board decision not to institute *inter partes* review on that ground."). These practices work against the statutory purpose of final resolution of § 102 and § 103 issues.[1]

The Administrative Procedure Act requires that a reviewing court "shall hold unlawful and set aside agency action, findings, and conclusions found to be in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C). "If the intent of Congress is clear, 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, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842–43, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984).

35 U.S.C. § 318 Decision of the Board

The legislation requires a final decision as to every claim challenged in the petition.

> **§ 318(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 ***1229** 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).

The statute requires the Board's final decision to encompass "the patentability of any patent claim challenged by the petitioner and any new claim added under section 316(d)."

This requirement to render a final decision for each of the challenged claims directly comports with the estoppel provisions. Fidelity to this legislative purpose is a necessity if the AIA's new adjudicatory proceeding is to substitute for major aspects of patent validity litigation.[2] Such substitution will serve the Nation's interest in technological innovation and resultant societal benefits.

CONCLUSION

On this petition for rehearing *en banc*, the judicial obligation is to assure fidelity to the intent of Congress, as expressed in the statute and the legislative record, lest we become complicit in "frustrating the policy that Congress sought to implement:"

> [T]he courts are the final authorities on issues of statutory construction. They must reject administrative constructions of the statute, whether reached by adjudication or by rulemaking, that are inconsistent with the statutory mandate or that frustrate the policy that Congress sought to implement.

Fed. Election Comm'n v. Democratic Senatorial Campaign Comm., 454 U.S. 27, 32, 102 S.Ct. 38, 70 L.Ed.2d 23 (1981). Thus I must, respectfully, dissent from the denial of rehearing *en banc*.

839 F.3d 1375
United States Court of Appeals,
Federal Circuit.

In re: Constantin Efthymiopoulos, Appellant

2016-1003
|
Decided: October 18, 2016

Newman, Circuit Judge, **dissenting**.

This litigation concerns the influenza drug zanamivir, marketed under the trademark Relenza®. The PTAB and now this court rule that it was obvious to administer this drug by oral inhalation, although there is no reference, no prior art, no suggestion, proposing that this mode of application might succeed, or that it should be tried. There was evidence of skepticism even as oral inhalation was evaluated. There was no contrary evidence. The evidence on which the Board and now this court rely is the evidence in the patent application itself, describing oral inhalation, its benefits, and its effectiveness. Upon learning this information from this inventor's disclosure, the Board found that it was obvious, and my colleagues agree that it is obvious to them.

Zanamivir was a known drug for treatment of influenza, administered by nasal inhalation, for the influenza virus was believed to infect the upper respiratory tract. The PTAB recognized that "the Examiner acknowledges that Von Itzstein II does not specifically teach inhalation of the compound through the mouth." PTAB Op. 7. Nor does any other reference teach or suggest treatment of influenza by oral inhalation of this compound or any related compound. My colleagues nonetheless deem this treatment of influenza obvious on the ground that inhalation occurs only through the nose or the mouth. Thus the court rules that the discovery of effective treatment by oral inhalation is obvious to the court, although not obvious to experts, and not suggested in the prior art.

The applicant provided the expert opinion of Dr. Hayden, who discussed a large international study in which he participated, and concluded that the "effectiveness of orally inhaled zanamivir as compared with nasal administration ... could be considered an unexpected result":

> In part because uncertainties existed regarding the transmission and pathogenesis of influenza as of the effective filing date of the present application, it was unclear whether oral inhalation of zanamivir with the dry powder inhaler device utilized in the studies would be clinically effective alone for prevention or treatment of naturally occurring uncomplicated influenza. In view of this uncertainty, the clinical effectiveness of orally inhaled zanamivir as compared to nasal administration for prevention of naturally occurring uncomplicated influenza above could be considered an unexpected result. Similarly, the effectiveness of orally inhaled zanamivir without intranasal zanamivir for treatment of naturally occurring uncomplicated influenza alone could be considered an unexpected result.

Decl. of Frederick G. Hayden, M.D. at 7 (filed in U.S. Patent Application No. 08/737,141 Mar. 12, 2013). Both the Board and the court discount Dr. Hayden's opinion because these experiments were not conducted for patent purposes but for scientific purposes, and were not direct comparisons ***1380** with the Board's view of the closest prior art. Dr. Hayden explained that:

> Although this study was not designed to compare directly the effects of zanamivir administration by oral inhalation alone to the effects of zanamivir administration by intranasal administration alone, it nonetheless found that the oral inhalation route alone provided unexpectedly significant activity without requiring intranasal administration for effective treatment of influenza virus illness....

Id. at 3. Dr. Hayden explained that it was unexpected that this study "demonstrated the therapeutic value of drug delivery by the oral inhalation route to the posterior oropharynx (throat) and lower respiratory tract to treat naturally occurring influenza virus infection." *Id.* at 4.

Dr. Hayden also discussed a study that showed that the rate of influenza infection during 5 days of prophylaxis treatment was 6% for nasal inhalation alone—the same as for the placebo group—but was 2–3% for the group that received zanamivir "both by oral inhalation and intranasally." *Id.* at 4, citing Kaiser et al. *Short–Term Treatment with Zanamivir to Prevent Influenza: Results of a Placebo–Controlled Study*, 30 CLINICAL INFECTIOUS DISEASES 587–89 (2000). Dr. Hayden concluded that "[t]he results of this study supported a difference in protection between intranasal zanamivir and orally inhaled zanamivir" and "suggest the importance of delivering zanamivir to the posterior oropharynx and/or lower respiratory tract for the prevention of naturally acquired influenza virus illness." *Id.* at 4–5. As quoted *supra*, Dr. Hayden stated that this result was unpredictable and unexpected. *Id.* at 7.

As stated in *In re Dihrendra Ranchhoddas Merchant*, 575 F.2d 865, 868 (CCPA 1978), "The Board's basic error resides in its determination that Pring was the closest prior art and that absent comparative tests vis-à -vis Pring, there was no rebuttal of what the Board considered a prima facie case." The Board erred in refusing to consider Dr. Hayden's results and in criticizing his tests as not in accordance with the Board's design of patent-oriented directly comparable experiments. The Board disregarded that Von Itzstein I only evaluated administration by nasal administration of a solution. *See* International Patent Application No. WO91/16320 at 54 (Oct. 31, 1991) ("Von Itzstein I") (describing intranasal administration of aqueous solution). The fact that scientific studies did not compare oral inhalation to liquid nasal administration does not mean the comparative evidence can be disregarded entirely. Dr. Hayden explained his conclusions; the Board should have considered them.

The Board did not hold that the result here was expected. However, the Board held that the claimed subject matter was obvious, on a rationale akin to "obvious to try." However, in the unpredictable arts such as medicinal treatment, for a method to be obvious to try, there must be some suggestion in the prior art that the method would have a reasonable likelihood of success.

There is no suggestion in the prior art to pursue oral inhalation, for the teachings of Von Itzstein II must be taken in context. It is noteworthy that there is extensive discussion in Von Itzstein II directed to all of the known forms of oral administration of this product—plus parenteral, topical, rectal, vaginal, and intranasal administration—but Von Itzstein II lacks any mention of oral inhalation. The Von Itzstein II reference, which is the primary reference relied on by the Board, states:

> Pharmaceutical formulations include those suitable for oral, rectal, nasal, topical, (including buccal and sub-lingual), vaginal or parenteral (including intramuscular, sub-cutaneous and intravenous) ***1381** administration or in a form suitable for administration by inhalation or insufflation. The formulations may, where appropriate, be conveniently presented in discrete dosage units and may be prepared by any of the methods well known in the art of pharmacy. All methods include the step of bringing into association the active compound with liquid carriers finely divided solid carriers or both and then, if necessary, shaping the product into the desired formulation.
>
> Pharmaceutical formulations suitable for oral administration may conveniently be presented as discrete units such as capsules, cachets or tablets each containing a predetermined amount of the active ingredient; as a powder or granules; as a solution, a suspension or as an emulsion. The active ingredient may also be presented as a bolus, electuary or paste. Tablets and capsules for oral administration may contain conventional excipients such as binding agents, fillers, lubricants, disintegrants, or wetting agents. The tablets may be coated according to methods well known in the art. Oral liquid preparations may be in the form of, for example, aqueous or oily suspensions, solutions, emulsions, syrups or elixers, or may be presented as a dry product for constitution with water or other suitable vehicle before use. Such liquid preparations may contain conventional additives such as suspending agents, emulsifying agents, non-aqueous vehicles (which may include edible oils), or preservatives.[1]

Australian Patent No. AU–A–27242/92 at 8–9 (April 4, 1993). The description of suitable formulations continues for almost three more pages, but does not mention or suggest oral inhalation. No disclosure of administration of zanamivir by oral inhalation can be found here or anywhere else in the prior art. One wonders how it can nonetheless be obvious, particularly in view of the specific teaching in Von Itzstein I that nasal administration is the mode for administering zanamivir.

To make a *prima facie* case, the prior art must provide, and the Board must identify, a reason or motivation to depart from the prior art; no reference or combination of references has been so identified—even in hindsight.

It cannot be "obvious to try" the only form of oral administration that is absent from the Von Itzstein recitations. In *KSR v. Teleflex* the Court explained that "obvious to try" may arise "where there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp." 550 U.S. 398, 416, 127 S.Ct. 1727, 167 L.Ed.2d 705 (2007). The Board's conclusion relies on a general finding that "inhalation can only be carried out via the nose or the mouth." PTAB Op. 11. But this is a flawed rationale, for Von Itzstein II teaches a totality of "oral, rectal, nasal, topical (including buccal and sub-lingual), vaginal or parenteral (including intramuscular, sub-cutaneous and intravenous) administration or in a form suitable for administration by inhalation or insufflation." Von Itzstein II at 8. The omission of oral inhalation from this compilation of all the "known options" for this drug makes conspicuously clear that oral inhalation was not an "identified predictable solution." The Board's ruling that oral inhalation was nonetheless obvious is not supported by substantial evidence. *See* ***1382** *In re Huai–Hung Kao*, 639 F.3d 1057, 1067 (Fed. Cir. 2011) ("The Board's own conjecture does not supply the requisite substantial *evidence* to support the rejections....").

It was undisputed that, at the time of this invention, it was believed that the influenza virus infected primarily the upper respiratory tract, that is, the nasal passages. It was undisputed that there was not a reasonable expectation that administration to the lower respiratory tract by oral inhalation would be effective. The Von Itzstein references do not show or suggest oral inhalation, either for zanamivir or for any related compounds. The Board's statement that inhalation is "reasonably understood" to include oral inhalation, PTAB Op. 12, is without authority. There was no record showing or supporting such an understanding. There was no suggestion or hint in any reference that treatment by oral inhalation would have a reasonable expectation of success.

This mode of therapy is taught only by this inventor. There was not substantial evidence to support the Board's ruling of obviousness. From the court's flawed analysis

818 F.3d 1380
United States Court of Appeals,
Federal Circuit.

SOUTH ALABAMA MEDICAL SCIENCE FOUNDATION, Appellant
v.
GNOSIS S.P.A., Gnosis Bioresearch S.A., Gnosis U.S.A., Inc., Appellees.

Nos. 2014–1778, 2014–1780, 2014–1781.
|
April 26, 2016.

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

This is the companion to *Merck & Cie v. Gnosis S.p.A.*, No. 14–1777 (*Gnosis I*), decided concurrently. As in *Gnosis I*, the panel majority applied the deferential "substantial evidence" standard of review and, in doing so, adopted the factual findings of the PTAB and affirmed the PTAB's cancellation of U.S. Patent Nos. 5,997,915, 6,673,381, and 7,172,778. For the reasons discussed in my dissent to the denial of *en banc* rehearing in *Gnosis I*, I believe *en banc* consideration is necessary to realign the appellate standard of review of these *inter partes* proceedings with the statutory purpose of the America Invents Act.

This case illustrates the pitfalls of the deferential "substantial evidence" standard. Despite concluding that the PTAB erred in assessing South Alabama Medical Science Foundation's (SAMSF) licensing evidence, the panel majority affirmed the PTAB's obviousness determination, on the ground that it was supported by substantial evidence.

There was extensive evidence of licensing, sublicensing, and relicensing of the SAMSF patents. More than twelve companies have taken sublicenses to the SAMSF patents, and manufacture or sell products practicing the patents. The royalty stream for the SAMSF patents produces millions of dollars in annual revenue. The PTAB did not mention these as objective indicia of non-obviousness. Instead, the PTAB dismissed all of SAMSF's objective evidence for lack of "nexus." This was legal error, as the panel majority held. The majority nonetheless affirmed because "that evidence is not enough to overcome the strong evidence of obviousness ... relied upon by the Board to reach its conclusion of obviousness." *Gnosis II* at 8. This too was legal error, for all of the evidence must be considered together in ***1382** evaluating obviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17, 86 S.Ct. 684, 15 L.Ed.2d 545 (1966); *Leo Pharm. Products, Ltd. v. Rea*, 726 F.3d 1346, 1357 (Fed.Cir.2013) ("Whether before the Board or a court, this court has emphasized that consideration of the objective indicia is part of the whole obviousness analysis, not just an afterthought.")

This is a crowded field of science, with conflicting experimental results, from which it was not reasonably predictable that the compositions that were eventually developed would be biologically effective and commercially successful. Objective indicia such as commercial success "may often be the most probative and cogent evidence [of non-obviousness] in the record," *Procter & Gamble Co. v. Teva Pharm. USA, Inc.*, 566 F.3d 989, 998 (Fed.Cir.2009) (modification in original) (quoting *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed.Cir.1983)). Considerations of biological effect and commercial and public response are a balance to judicial hindsight. *In re Cyclobenzaprine Hydrochloride Extended–Release Capsule Patent Litigation*, 676 F.3d 1063, 1075–76 (Fed.Cir.2012) ("The objective considerations, when considered with the balance of the obviousness evidence in the record, guard as a check against hindsight bias.").

Precedent requires that the objective evidence be considered together with the other evidence relating to the question of obviousness. In turn, my colleagues also err in law, for our appellate role includes assuring that the correct law is applied by the PTAB. Although the panel majority finds substantial evidence to support the PTAB's conclusion, less than all of the evidence was analyzed and weighed by the PTAB. On the entirety of the record, including the objective considerations, the petitioner has not established invalidity by a preponderance of the evidence, as required by statute.

Thus I respectfully dissent from the court's refusal to reconsider this case *en banc*.
818 F.3d 1380
United States Court of Appeals,
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SOUTH ALABAMA MEDICAL SCIENCE FOUNDATION, Appellant
v.
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April 26, 2016.

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This is a crowded field of science, with conflicting experimental results, from which it was not reasonably predictable that the compositions that were eventually developed would be biologically effective and commercially successful. Objective indicia such as commercial success "may often be the most probative and cogent evidence [of non-obviousness] in the record," *Procter & Gamble Co. v. Teva Pharm. USA, Inc.*, 566 F.3d 989, 998 (Fed.Cir.2009) (modification in original) (quoting *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed.Cir.1983)). Considerations of biological effect and commercial and public response are a balance to judicial hindsight. *In re Cyclobenzaprine Hydrochloride Extended–Release Capsule Patent Litigation*, 676 F.3d 1063, 1075–76 (Fed.Cir.2012) ("The objective considerations, when considered with the balance of the obviousness evidence in the record, guard as a check against hindsight bias.").

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Thus I respectfully dissent from the court's refusal to reconsider this case *en banc.*

814 F.3d 1309
United States Court of Appeals,
Federal Circuit.

SYNOPSYS, INC., Appellant
v.
MENTOR GRAPHICS CORPORATION,
Cross–Appellant
Michelle K. Lee, Director, U.S. Patent and Trademark Office, Intervenor.

Nos. 2014–1516, 2014–1530.
|
Feb. 10, 2016.

NEWMAN, Circuit Judge, **dissenting**.

The Leahy–Smith America Invents Act of 2011 changes the way patent validity disputes are resolved—a change at least as significant for this Nation's patent system as the formation of the Federal Circuit in 1982. The purpose is as ambitious as it is necessary: to strengthen the incentive to industrial and technological innovation by restructuring the system for reviewing and adjudicating patent validity.

Today's economic reality is based on continuing advances in science and technology. The system of patents is integral to commercial development of new science and technology, and spurs innovators to create new products and methods of economic value. American industry and entrepreneurship use and rely on the patent system; and as patent activity has increased,[1] so have disputes concerning patent rights.[2]

Congress and the public recognized that the traditional adjudicatory structure is imperfectly adapted to resolution of technologically complex patent validity issues, ***1325** as advancing science, competitive forces, and high stakes meet in the courthouse. It came to be understood that the cost and delay of litigation is a disincentive to commercial activity. When the result is inventions not made and technology not developed, the losers are the public and the Nation's economy.

The Leahy–Smith America Invents Act (AIA) is the product of extensive study by the concerned communities and the Congress. The AIA's purpose is to reinvigorate the foundations of industrial innovation, by providing expeditious and reliable review of patents that had previously been examined and granted. The goal is stability of patent-based property rights, whereby valid patents would be reinforced and invalid patents eliminated, in an economical proceeding conducted by experts in technology and law.

To this end, the AIA established a new adjudicatory body in the Patent and Trademark Office, and vested it with many of the civil litigation powers of the district courts. This new tribunal, named the Patent Trial and Appeal Board (PTAB), would have administrative judges experienced in technology and knowledgeable in the relevant law and policy, and would provide stability, confidence, and reliability to the patent-based foundations of industrial innovation.

The goal is to serve the Nation's traditional innovative spirit and entrepreneurial energy, and thereby to enhance economic growth and industrial strength, while supporting discovery and invention for public benefit. This ambitious project consumed over a decade of evolution, starting with the May 10, 2001 hearing on "Patents: Improving Quality and Curing Defects" before the House Committee on the Judiciary.

The AIA, as enacted, contains balances and compromises, for many interests are affected. I write in dissent because the court's rulings today depart from the text, purpose, and policy of the AIA, and abrogate the careful balance of this new adjudicatory system. The result is that patent validity adjudication is incompletely fulfilling the goals of the AIA.

I list my principal concerns:

1. The court today holds, contrary to the AIA, that the PTAB can "pick and choose" which of the challenged patent claims and issues it will decide in these new proceedings. Maj. Op. at 1316. The court endorses such partial decisions by the PTAB, and "see[s] no inconsistency" with leaving some of the challenged claims and issues undecided. Maj. Op. at 1316. This absence of finality negates the AIA's purpose of providing an alternative and efficient forum for resolving patent validity issues.

Instead, the present practice of partial decision by the PTAB leads to duplicative proceedings in the PTAB and the district courts. Since the AIA provides for a different

standard of proof than in the district courts, this system of partial decision does not achieve the reliability and expedition for which the AIA was enacted, but instead can produce prolonged uncertainty and multiplied proceedings, at increased rather than reduced cost. In the case at bar, validity of all of the challenged claims was not decided by the PTAB, illustrating this concern.

2. The court also misapplies the AIA provision that the decision whether to "institute" these post-grant proceedings is not appealable. The statute requires the PTO Director first to determine, at an initial "institution" phase, whether it is more- ***1326** likely-than-not that at least one claim of the challenged patent is invalid. This threshold phase serves the tripartite purpose of screening out harassing and unfounded petitions, accommodating the PTO's concern about the increased workload, and eliminating the delay and burden of interlocutory appeals.

The non-appealability of the institution determination should not mean that substantive rulings material to the final decision or to the propriety of the entire proceeding are immunized on review of the final decision, if such aspects arose at the institution phase. However, the court holds otherwise, and removes from judicial review any decision during the institution phase—here the question of whether certain prior patent litigation is a statutory or jurisdictional bar. These issues are raised on this appeal, for the court has converted the threshold phase into a source of unappealable substantive rulings, subverting the purpose of the adjudicatory design.

3. The court also supports the PTO's elimination of the statutory designation of different decision-makers for the institution phase and the trial phase. The AIA assigns the former role to the Director and the latter role to the PTAB. The record shows the concern of practitioners that the institution phase would become a short-cut to final judgment. Whatever the convenience to the PTO, there is no authority to violate the statute.

4. A critical aspect of the AIA—the aspect credited with the large influx[3] of petitions for post-grant proceedings—is the easier standard of patent invalidation that is accorded to these PTAB proceedings. Although patents submitted for PTAB review have all been previously examined and granted and carry the statutory presumption of validity, the AIA assigns the standard of preponderance of the evidence for invalidation, whereas the district courts must apply the standard of clear and convincing evidence for invalidation.

The panel majority also supports the PTO's stingy implementation of the statutory authorization for claim amendment. The opportunity to amend is an important part of the balance struck in the AIA. The easier standards and lighter burdens for invalidation in AIA proceedings, including the PTAB's use of the broadest claim interpretation instead of the correct claim interpretation, up-end the delicate balance crafted by Congress. Amendment issues are present in this case.

The America Invents Act made dramatic changes in the way patent disputes are resolved, in the way complex technologies are integrated into the law, in the way a devoted and expert agency is burdened in service to the Nation. It is our judicial responsibility to assure that the agency and its new tribunal are in compliance with the statute. It is our responsibility to assure that the legislative plan is fulfilled.

DISCUSSION

The America Invents Act responds to concerns that the time and cost and uncertainty of resolving patent validity challenges are a disincentive to development and commercialization of new science and ***1327** technology. As stated by Senator Leahy, an architect and principal sponsor of the legislation:

> This legislation is not an option but a necessity.... I also want to ensure the delicate balance we have struck in the post-grant review process and make certain that the procedure is both efficient and effective at thwarting some strategic behavior in patent litigation and at promoting a healthier body of existing patents.

Introduction of Patent Reform Act of 2006, 152 Cong. Rec. S8830 (Aug. 3, 2006) (statement of Sen. Patrick Leahy, Member, Subcomm. on Intellectual Prop. of the S. Comm. on the Judiciary).

Senator Leahy refers to the "delicate balance" that pervades this statute. The legislative record spans a decade[4] of hearings, reports, bills, and debates, with submissions and testimony by the nation's inventors, industries, bar associations, academics, the PTO and other government and public interests; and demonstrates the

breadth of concerned attention throughout the development of this legislation.

Senator Grassley, a central figure in this effort, described the highlights of the achievement as the final bill neared enactment:

> [T]he bill ... would establish an adversarial inter partes review, with a higher threshold for initiating a proceeding and procedural safeguards to prevent a challenger from using the process to harass patent owners. It also would include a strengthened estoppel standard to prevent petitioners from raising in a subsequent challenge the same patent issues that were raised or reasonably could have been raised in a prior challenge. The bill would significantly reduce the ability to use post-grant procedures for abusive serial challenges to patents. These new procedures would also provide faster, less costly, alternatives to civil litigation.

157 Cong. Rec. S952 (daily ed. Feb. 28, 2011) (statement of Sen. Grassley on S.23). The House Report on the final bill stated the necessity of assuring that serial and duplicative attacks did not result from the new procedures:

> The Committee recognizes the importance of quiet title to patent owners to ensure continued investment resources. While this amendment is intended to remove current disincentives to current administrative processes, the changes made by it are not to be used as tools for harassment or as 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 as providing quick and cost effective alternatives to litigation. Further, such activity would divert resources from the research and development of inventions.

H.R. REP. NO. 112–98, pt. 1, at 48 (2011).

The AIA was signed into law on September 16, 2011, with an effective date of September 16, 2012. The new procedures were promptly invoked. The concerns I outline arose early in implementation of the statute, and continue to this day.

***1328 I**

PTAB Decision of Only Some of the Challenged Claims Is Contrary To the Statute

The America Invents Act vests the PTAB with authority to adjudicate post-grant validity under sections 102 (anticipation) and 103 (obviousness), for these are the principal documentary grounds on which validity is challenged in the courts. These grounds are well suited to resolution by the PTAB whose adjudicators are experienced in technology, for the determination is required to be made from the viewpoint of "a person having ordinary skill in the art to which said subject matter pertains," the words of section 103.

The America Invents Act requires the PTAB to issue a final written decision on the patentability of the challenged claims:

> 35 U.S.C. § 318(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).

The court today holds that, despite the statute, "the final order of the Board need not address every claim raised in the petition for review." Maj. Op. at 1311. However, the statute uses the word "shall." "Shall" is a term of command. *Merck & Co. v. Hi–Tech Pharmacal Co.,* 482 F.3d 1317, 1322 (Fed.Cir.2007) ("Use of the word 'shall'

in a statute generally denotes the imperative.").

A statutory requirement cannot be overridden by agency rule. *See Norwegian Nitrogen Prods. Co. v. United States*, 288 U.S. 294, 315, 53 S.Ct. 350, 77 L.Ed. 796 (1933) ("[A]dministrative practice does not avail to overcome a statute so plain in its commands as to leave nothing for construction."). However, the PTO proposed an administrative Rule authorizing the PTAB to decide which of the challenged claims and issues it would "proceed on":

> 42.108(a). When instituting *inter partes* review, the Board may authorize the review to proceed on all or some of the challenged claims and on all or some of the grounds of unpatentability asserted for each claim.

Changes to Implement Inter Partes Review Proceedings of the Leahy–Smith America Invents Act, 77 Fed.Reg. 7041 (proposed Feb. 10, 2012) (recorded at 37 C.F.R. 42.108(a)).

This proposed Rule was widely criticized, as commentators pointed out that the Rule violated the statute and negated the AIA's purpose of achieving finality of validity review by the PTAB instead of the district court. The Minnesota Intellectual Property Law Association (MIPLA) explained the consequences of the proposed departure from the statute:

> [I]n cases where IPR would be granted under the proposed rule for some requested claims and not others, the result is likely to be a serial or parallel process of IPR review of some claims and Federal district court review of the other claims. Congress, however, appears to have intended that IPR be an alternative system in which a litigant can choose to resolve disputed patent validity in either an IPR setting or through the Federal courts, but not both. Hence, the claim-by-claim approach of § 42.108 would not seem to accomplish the result intended by Congress in this regard.

Comments on Changes to Implement Inter Partes Review Proceedings, MIPLA 2 at 4 ***1329** (April 10, 2012) available at http://www.uspto.gov/sites/default/files/aia_implementation/comment-mipla2.pdf. The MIPLA complained that the proposed partial review raises "fairness and due process" concerns, and is unlikely "to fully achieve the intent of Congress in establishing these proceedings." Id. at 3. The MIPLA urged the PTO to "revert to the language of 35 U.S.C. § 314(a), which contemplates that review will be ordered as to all requested claims." *Id.* at 5.

IBM's chief patent counsel objected that the Rule is contrary to the AIA, stressing the mandatory words of the statute:

> Under provisions of 318(a) final written decisions are required for **all** reviews which are "instituted and not dismissed". The statute makes no provisions for reviews which are "instituted-in-part" or "dismissed-in-part".... The same provision further provides that the Board "***shall*** issue a final written decision with respect to the patentability of ***any patent claim challenged*** by the petitioner and any new claim ..." Thus, any claim challenged in the initial petition in a review that was instituted *must* be decided upon in the final written decision; the statute does not appear to leave discretion to provide a final written decision not addressing any claim that was initially challenged by the petitioner on the basis that the Office determined it to be "not part of the trial". We do not see how the Office squares its attempt to limit the scope of review with the referenced statutory requirements; in essence, the scoping decision amounts to a premature final decision. We believe the Office should, consistent with the statute, allow all challenged claims to be included in the *inter partes* review when it has found a reasonable likelihood of prevailing with respect to one challenged claim.

Comments on Changes to Implement Inter Partes Review Proceedings, IBM 5 at 3 (April 6, 2012) (emphases in original) (parentheticals omitted) available at http://www.uspto.gov/sites/default/files/aia_implementation/comment-ibm5.pdf.

Expressions of concern were also presented by other participants in the process that produced the legislation. *See Comments on Changes to Implement Inter Partes Review Proceedings of the Leahy–Smith America Invents Act, available at* http://www.uspto.gov/patent/laws-and-regulations/americ

a-invents-act-aia/comments-changes-implement-inter-partes-review.

As the panel majority recognizes, Maj. Op. at 1316, the PTO stated that its departure from the statute allows it to "streamline and converge the issues for consideration," to "aid[ ] in the efficient operation of the Office and the ability of the Office to complete the [review] within the one-year timeframe." *Changes to Implement Inter Partes Review Proceedings, Post–Grant Review Proceedings, and Transitional Program for Covered Business Method Patents*, 77 Fed.Reg. 48703 (Aug. 14, 2012) (Response to Comment 60). Criticism of the practice of partial resolution of the challenged claims continued, and the PTO on Aug. 20, 2015 published the following Comment and Response:

> *Comment 12:* Several commenters expressed concern about the Office's practice of allowing institution based on some, but not all, of the grounds presented in a Petition. Commenters are concerned that because the decision on institution is not appealable, and any ground on a challenged claim that is not ***1330** instituted is not reflected in the final, appealable decision, a petitioner has no redress for grounds on which the Office chooses not to institute....
>
> *Response:* The Office appreciates the concern expressed by the comments, but must balance these concerns with the workload in AIA proceedings and the statutory time constraints under which AIA review proceedings must be decided. In order to ensure a fair and efficient process to resolve reviews in a timely fashion, the Office uses partial institution as one tool to manage effectively AIA reviews. The Office is cognizant of the ramifications of partial institution where the grounds are in different statutory classes, or when a reference may be overcome by swearing behind it, and strives to strike an appropriate balance between what can be accomplished during the finite time frame for a trial and fairness to the parties in fully vetting patentability issues on challenged claims. The Office will continue to assess whether such balance is appropriately struck.

80 Fed.Reg. 50739 (Aug. 20, 2015).

Agency convenience is not grounds for negation of a statutory obligation. *See Utility Air Regulatory Grp. v. Environmental Protection Agency*, ––U.S. ––––, 134 S.Ct. 2427, 2446, 189 L.Ed.2d 372 (2014) ("[A]n agency may not rewrite clear statutory terms to suit its own sense of how the statute should operate."). Nonetheless, the PTO continues to adhere to Rule 42.108(a), although it is apparent that the Rule conflicts with the statute, and that "[n]othing in the language of the statute states or suggests that the word 'shall' does not mean exactly what it says." *Gutierrez de Martinez v. Lamagno*, 515 U.S. 417, 434 n. 9, 115 S.Ct. 2227, 132 L.Ed.2d 375 (1995).

The criticized Rule was here applied to the '376 patent of Mentor Graphics, presented for *inter partes* review by Synopsys' petition challenging claims 1–15 and 20–33. Review was instituted on claims 1–9, 11, 28, and 29, the selection apparently made by the PTAB. The PTAB conducted a trial, and issued a decision on the selected claims. The PTAB ruled that claims 5, 8, and 9 were unpatentable, and that claims 1–4, 6, 7, 11, 28, and 29 were patentable. The PTAB did not decide the patentability of claims 10, 12–15, 20–27 and 30–33.

Responding to Synopsys' objection to the incomplete decision, the panel majority states that "the statute is quite clear that the PTO can choose whether to institute inter partes review on a claim-by-claim basis ... and that the Board can pick and choose among the claims in the decision to institute." Maj. Op. at 1315–16. The statutory clarity is ephemeral, and authority to "pick and choose among the claims" does not exist. Neither the AIA nor anything in its voluminous history suggests a legislative plan whereby the Board could decide which of the challenged claims would be decided, leaving the other challenged claims untouched.

The design of the AIA is that the major documentary validity challenges, sections 102 and 103, will be subject to decision by the PTO expert tribunal. As commentators pointed out, if only some of the challenged claims are decided, there is neither complete nor final disposition. Senator Schumer explained this foundation of the legislation:

> What the bill does ... is very simple. It says the Patent Office will make an ***1331** administrative determination before the years of litigation as to whether this patent is a legitimate patent so as not to allow the kind of abuse we have seen.

157 Cong. Rec. S5437 (statement of Sen. Schumer during Senate consideration of H.R. 1249).

When review is instituted, 35 U.S.C. § 318(a) requires the PTAB to issue a Final Written Decision on all of the claims challenged in the petition. The AIA authorizes the Director to decline to institute any requested review, 35 U.S.C. § 314(d), but the AIA does not authorize or contemplate that the PTO would pick and choose which patent claims it will decide. "Administrative construction of a statute which conflicts with the express meaning of the statutory terms can be viewed as authoritative only if it appears that Congress has in fact accepted that construction, and the burden of proof necessarily is on the proponent of the administrative view." *Saxbe v. Bustos*, 419 U.S. 65, 84, 95 S.Ct. 272, 42 L.Ed.2d 231 (1974).

The legislative record emphasizes the purpose of this new PTO tribunal to resolve validity issues, a purpose that collapses if only some of the challenged claims are decided. A Senate Report explained:

> [I]f [such] proceedings are to be permitted, they should generally serve as a complete substitute for at least some phase of the litigation.

S.REP. NO. 110–259, at 67 (Additional Views of Senator Specter Joined with Minority Views of Senators Kyl, Grassley, Coburn and Brownback) (2008). This statement encapsulates the purpose of the legislation, and the record shows that the concerned communities welcomed this new adjudicatory role of the PTO, built on its reputation for excellence.

Chevron Deference Does Not Apply

PTO Rule 42.108(a) is "not in accordance with law," the words of the Administrative Procedure Act, 5 U.S.C. § 706(2)(A). Agency rulemaking authority "does not include a power to revise clear statutory terms," *Utility Air Regulatory Group*, 134 S.Ct. at 2446:

> Under our system of government, Congress makes laws and the President, acting at times through agencies ... "faithfully execute[s]" them. U.S. Const., Art. II, § 3.... The power of executing the laws necessarily includes both authority and responsibility to resolve some questions left open by Congress that arise during the law's administration. But it does not include a power to revise clear statutory terms that turn out not to work in practice.

See also, e.g., *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 213–14, 96 S.Ct. 1375, 47 L.Ed.2d 668 (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....

These concepts are the core of the administrative state. "*Chevron* deference" applies to statutory implementation in fidelity to the statute—not statutory departure from the legislative plan.

Nonetheless, the panel majority, invoking *Chevron* deference, holds that the statute "only requires the Board to address claims as to which review was granted." Maj. Op. at 1317. That is not what the statute says. "[R]easonable statutory interpretation must account for both 'the specific context in which ... language is ***1332** used' and 'the broader context of the statute as a whole.' " *Utility Air Regulatory Group*, 134 S.Ct. at 2442 (omission in original). Partial decision negates the purposes of the America Invents Act, and achieves neither expedition nor economy nor finality nor estoppel.

Senator Kyl explained a central purpose of the America Invents Act is "to force a party to bring all of [its] claims in one forum ... and therefore to eliminate the need to press any claims in other fora." 154 Cong. Rec. S9989. Senator Kyl stressed that this new system "ideally [will] completely substitute for at least the patents-and-printed-publication portion of the civil litigation." 157 Cong. Rec. S1376. This goal is thwarted when the PTAB decides validity of some but not all of the claims challenged in the petition.

The justification offered for partial institution or partial decision of an AIA petition is the workload of the PTO. Maj. Op. at 1316. *See Patent Reform: The Future of American Innovation: Hearing Before the Senate Comm. on the Judiciary*, 110th Cong. 7 (2007) (statement of

Director Jon Dudas) ("[Q]uite frankly, without having the resources available now, we are not certain that we could handle the administration of that many cases."). This concern received a sympathetic response, and the AIA authorizes the Director to refuse to institute any review petition in its entirety, without excuse and without appeal. Senator Kyl explained that this provision

> reflects a legislative judgment that it is better that the Office turn away some petitions that otherwise satisfy the threshold for instituting an *inter partes* or post-grant review than it is to allow the Office to develop a backlog of instituted reviews that precludes the Office from timely completing proceedings.

157 Cong. Rec. S1377 (daily ed. Mar. 8, 2011) (statement of Sen. Kyl).

The PTO can refuse to institute any post-grant challenge, as the statute provides, 35 U.S.C. § 314(d) ("The determination by the Director whether to institute an inter partes review under this section shall be final and nonappealable."). However, when a petition is accepted, the PTAB "shall" decide the challenged claims, 35 U.S.C. § 318(a). Decision of only some of the challenged claims leaves the undecided claims for district court resolution, as this court recognizes, Maj. Op. at 1316–17. In such event, the AIA purpose of replacing the cost and delay of district court validity proceedings instead dissolves into potentially duplicative proceedings in the PTO and the district court, enlarging rather than reducing cost and delay.

The panel majority states that if there is uncertainty as to this statutory obligation of the PTAB, *Chevron* deference requires support of the PTO position. However, *Chevron* states that: "If the intent of Congress is clear, 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 U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842–43, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984). "*Chevron* allows agencies to choose among competing reasonable interpretations of a statute; it does not license interpretive gerrymanders under which an agency keeps parts of statutory context it likes while throwing away parts it does not." *Michigan v. Environmental Protection Agency*, —— U.S. ——, 135 S.Ct. 2699, 2708, 192 L.Ed.2d 674 (2015).

Here there are no "competing reasonable interpretations." *Id.* The command of section 318(a) is clear; the intent of Congress ***1333** is plain in the statute. There is no ambiguity, and no silence; *Chevron* provides no support for "pick and choose" authority. The theory that the PTAB can select what it will decide cannot be found in the legislative record. To the contrary, partial post-grant review eviscerates the purpose of resolving major validity issues in a PTO tribunal instead of in the district court.

The judicial obligation is to assure fidelity to the statute and to the legislative policy, lest we become complicit in frustrating the intent of Congress:

> [T]he courts are the final authorities on issues of statutory construction. They must reject administrative constructions of the statute, whether reached by adjudication or by rulemaking, that are inconsistent with the statutory mandate or that frustrate the policy that Congress sought to implement.

Federal Election Comm'n v. Democratic Senatorial Campaign Comm., 454 U.S. 27, 32, 102 S.Ct. 38, 70 L.Ed.2d 23 (1981).

The Legislative Record Cannot Be Discarded

The panel majority disposes of the legislative record with the remark that "Floor statements by a few members of the legislative branch cannot supplant the text of the bill as enacted." Maj. Op. at 1316. That is not this legislative record.

The record of the AIA starts with a House Judiciary hearing on "Patents: Improving Quality and Curing Defects," on May 10, 2001, and shows the continuing involvement of both parties and both Houses, filling nine fat volumes in the Federal Circuit library. There are statements by Senators and Representatives, statements for government agencies including the PTO, the Department of Commerce, the International Trade Commission, the Department of Health and Human Services, and the Government Accountability Office. There are written submissions and recorded testimony from large and small industries, from labor unions, from

inventors, and from virtually every patent bar association in the nation, as well as from university scientists, law professors, and others. There is interaction, commentary, debate and compromise. The panel majority's dismissal of this record as "a few floor statements" is not easy to fathom.

We have canvassed the entire record, to "add force and life to the cure and remedy, according to the true intent of the makers of the act." *Heydon's Case,* 76 Eng. Rep. 637, 638 (1584). The record shows bipartisan unanimity on the foundational principle of this legislation; that is, that a tribunal within the PTO would be empowered to conduct post-grant review of major patent validity issues, with the intent to provide an expert adjudicatory alternative to litigation. The commentators' views of details in achieving this goal were not unanimous, and balances, trade-offs, and compromises are embodied in the final statute. The court must give effect to this legislative accomplishment.

Statutes are administered 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, 110 S.Ct. 997, 108 L.Ed.2d 132 (1990). The record shows the participation and collaboration among the legislators as well as the concerned communities. *See* 157 Cong. Rec. S1044 (daily ed. Mar. 1, 2011) (statement of Sen. Leahy):

> Mr. President, the Senator [Kyl] has been involved in this right from the beginning. ***1334** We have worked at having a bill that would be in the best interests of the Senate under both Republicans and Democrats across the political spectrum. We have worked very closely together.

Many Senators and Representatives placed comments in the record. Senator Ted Kaufman, of the Senate Judiciary Committee, described PTO post-grant review as "a viable alternative to litigation:"

> The good news is that there are several aspects of the reform effort that are relatively uncontroversial. Just about everyone agrees that we need ... to limit unnecessary litigation costs. So there is much on which we can agree, including ... improving the Patent Office challenge process as a viable alternative to litigation.

Patent Reform in the 111th Congress: Legislation and Recent Court Decisions: Hearing Before the Senate Comm. on the Judiciary, 111th Cong. 205 (2009).

Senator Schumer cited the benefits of this alternative forum for validity determination:

> Too many district courts have been content to allow litigation to grind on while a reexamination is being conducted, forcing the parties to fight in two fora at the same time. This is unacceptable, and would be contrary to the fundamental purpose of ... provid[ing] a cost efficient alternative to litigation.

157 Cong. Rec. S1360–94 (daily ed. Mar. 8, 2011).

Senator Sheldon Whitehouse referred to the cost and delay of litigation:

> Similarly, the bill will improve administrative processes so that disputes over patents can be resolved quickly and cheaply without patents being tied up for years in expensive litigation.

157 Cong. Rec. S1052 (daily ed. Mar. 1, 2011).

The intended benefits were also described by Representative Issa, a member of the House Judiciary Committee and its Subcommittee on Courts, the Internet, and Intellectual Property:

> [The issue of overzealous litigation is] addressed in part in this bill. The creation of a post grant review procedure at the Patent Office will help direct some conflicts away from court to an administrative remedy, hopefully saving vast resources in time and money.

153 Cong. Rec. 23927–66, (2007) (House consideration and passage of H.R. 1908).

Representative Berman discussed the value of an agency procedure for assuring that issued patents are valid:

> When functioning properly, the patent system encourages and enables inventors to push the boundaries of knowledge and possibility. I support strong, robust protection for quality patents. However, when the system functions improperly, such as allowing an overly broad or obvious patent, the patent system can stifle innovation and harm America's competitiveness in the global economy.... This legislation favors no industry, no person, organization or interest group. It seeks to solve problems that we have identified and have been identified for us by outside experts and agencies.

153 Cong. Rec. 23904–11, (2007) (House consideration of H.R. RES. 636 (rule for debate on Patent Reform Act of 2007)).

Senator Leahy, reporting the Administration's support of the proposed legislation, again mentioned the "alternatives to costly and complex litigation" that would ***1335** be achieved, along with other benefits of the legislation:

> The Administration supports Senate passage of S. 23. As a whole, this bill represents a fair, balanced, and necessary effort to improve patent quality, enable greater work sharing between the United States Patent and Trademark Office (USPTO) and other countries, improve service to patent applicants and the public at the USPTO, and offer productive alternatives to costly and complex litigation.

157 Cong. Rec. S1030 (daily ed. Mar. 1.2011).

The legislators gave attention to assuring the efficiency and effectiveness of this "second window" of agency action. Senators Specter, Kyl, Grassley, Coburn, and Brownback stated in a Senate Report:

> [O]pening up a second window for administrative challenges to a patent only makes sense if defending a patent in such proceedings is not unduly expensive, and if such proceedings substitute for a phase of district-court litigation.... The initiation of the proceedings is likely to lead to a stay in the litigation, which likely will remain in place through the appeal of the PTO's second-window decision.... If second window proceedings are to be permitted, they should generally serve as a complete substitute for at least some phase of the litigation.

S.REP. NO. 110–259 at 66 (2008). The Senators stressed that the second window should be a "complete substitute" for the major validity phase—not a partial disposition.

These goals are forsaken if the PTO decides only some of the challenged claims, restoring the costly litigation procedures and delay that the AIA is designed to replace. The intent and purpose of the legislators, embodied in the enacted legislation and replete in its history, cannot be ignored. Amid universal accolades for assignment to the PTO of post-grant review of major issues of validity, the legislators and collaborators never suggested that the PTO could "pick and choose" which of the challenged claims would be decided. This spurious outcome was not contemplated.

Representative Manzullo stressed the legislative purpose that these PTO proceedings would substitute for district court proceedings, not merely provide another forum for non-final validity debate:

> It is clearly appropriate to have an administrative process for challenging patent validity, but it should exist within a structure that guarantees a quick—and final—determination. Congress must ensure that the administrative

> processes provided for in the bill do not become a vehicle for infringers to avoid justice.

Patent Reform Act of 2009: Hearing Before the House Comm. on the Judiciary, 111th Cong. 153 (2009).

The panel majority supports PTAB partial decision of some of the challenged claims by suggesting that maybe other validity issues would require district court resolution, beyond the section 102 and 103 issues assigned to the PTAB. Maj. Op. at 1316. It is of course possible that claims held valid by the PTAB under sections 102 and 103 would be vulnerable on other grounds. The legislators recognized that not all validity issues are assigned to the PTAB. Senator Kyl explained:

> In this bill, however, the issues that can be raised in the second window are so sharply limited that the goal of flushing out all claims is unattainable. Only 102 ***1336** and 103 arguments based on patents and printed publications can be raised in the second window....

154 Cong. Rec. S9982–93 (daily ed. Sept. 25, 2008) (statement by Sen. Kyl on S. 3600).

The legislators also recognized that sections 102 and 103 are the major grounds of challenge to issued patents, as well as the most demanding of technologic or scientific expertise. The heavy and immediate recourse to the new AIA proceedings attests to the soundness of this principle. The possibility that other grounds of invalidity might also be present does not justify dilution of the provisions directed to sections 102 and 103.

On this vast legislative record, it is surprising to read the panel majority's dismissal of "floor statements by a few members of the legislative branch." Maj. Op. at 1316. To the contrary, the record confirms that throughout the gestation of the America Invents Act, legislators of the House and Senate sought strong and conclusive resolution of the most challenging issues of patent-supported innovation, by providing an effective alternative to district court litigation, whereby the expert agency would reliably and confidently review the validity of granted patents.

Ignoring this purpose, the panel majority holds that "the validity of claims for which the Board did not institute inter partes review can still be litigated in district court. We see no inconsistency in this." Maj. Op. at 1316. To the contrary—it is inconsistent with the entirety of the America Invents Act.

II

The Stay and Estoppel Provisions Are Also Undermined by Partial Decision of Validity Challenges

An *amicus curiae* explained the stay and estoppel provisions of the AIA and their role in resolution of patent disputes:

> The experienced administrative judges at the PTAB evaluate the patentability of the claims identified by a petitioner. Claims that are cancelled for lack of patentability vanish from the litigation entirely. Claims that undergo review, and survive, will return to the district court with statutory estoppel, which prevents the accused infringer from making the same invalidity arguments before the district court that it made before the PTA. Thus, whether or not the patent claims are cancelled or survive, the case is simplified for claims addressed in a PTAB trial. It is therefore no surprise that, as Congress envisioned, courts frequently stay litigation pending PTAB review. But when the PTAB decides to review only some of the challenged claims, but not others, it undermines the intended efficiency of these trials and saddles the district courts with larger and redundant workloads.

SAS Institute *amicus* Br. 6 (Oct 10, 2014).

The stay and estoppel provisions become irrelevant if only some of the challenged claims are decided by the PTAB, leaving other claims unresolved. Yet the court

today sees "no inconsistency" in leaving some claims undecided, because "the validity of claims for which the Board did not institute inter partes review can still be litigated in district court," Maj. Op. at 1316. This is an extreme distortion of the statutory purpose.

Senator Grassley discussed the scope of the litigation stay authorization, as the AIA reached enactment in the Senate:

> Lengthy and duplicative proceedings are one of the worst evils of other systems of administrative review of patents.... Ideally extending could-have-raised estoppel to privies will help ensure that if ***1337** an inter partes review is instituted while litigation is pending, that review will completely substitute for at least the patents-and-printed-publications portion of the civil litigation.

157 Cong. Rec. S1360–94 (daily ed. Mar. 8, 2011).

On the foundational principle that the PTAB proceeding is designed as an alternative to district court litigation, there was extensive commentary from the innovation communities. An example is a letter from the Consortium of Higher Education Institutions, supporting the proposed new system because it would—

> reduce patent litigation costs by establishing the new post-grant procedure noted above, and by significantly improving the current inter partes review procedure, which will provide a lower-cost alternative to civil litigation to challenge a patent throughout its lifetime, while significantly reducing the capacity to mount harassing serial challenges ...

157 Cong. Rec. S1178 (daily ed. Mar. 3, 2011). The PTO Director, testifying for the administration, also supported estoppel, stating that—

> the estoppel needs to be quite strong that says on the second window any issue that you raised or could have raised ... you can bring up no place else. That second window, from the administration's position is intended to allow nothing—a complete alternative to litigation.

Patent Reform: The Future of American Innovation: Hearing Before the Senate Comm. on the Judiciary, 110th Cong. 13 (2007) (statement of Director Jon Dudas).

The court's ruling today inhibits the America Invents Act from achieving its purposes. It is reported that some district courts are declining to stay parallel litigation. *E.g. Invensys Sys. v. Emerson Elec. Co.*, No. 6:12–cv–00799, 2014 U.S. Dist. LEXIS 128454, at *10 (E.D.Tex. July 25, 2014) (district court denying stay where PTAB instituted partial review because "any simplification is likely to be minimal"); *U.S. Nutraceuticals LLC v. Cyanotech Corp.*, No. 5:12–cv–366–Oc–10PRL, 2013 U.S. Dist. LEXIS 163057, at *8 (M.D.Fla. Oct. 15, 2013) (recommending denial of stay pending inter partes review because "the USPTO may authorize the review to proceed on only 'some of the challenged claims' or on only 'some of the grounds of unpatentability asserted for each claim.' 37 C.F.R. § 42.108(a). It is entirely possible, perhaps even likely, that this case will proceed on numerous claims regardless of the outcome of the USPTO proceeding"); *Xilinx, Inc. v. Invention Inv. Fund I LP*, Nos. 5:11–cv–00671–EJD, 5:11–cv–04407–EJD, 2012 WL 6003311, at *4 (N.D.Cal. Nov. 30, 2012) ("the court will have to resolve all claims in dispute as to [claims not currently undergoing inter partes reexamination]. That being the case, waiting for the outcome of reexamination does nothing for that portion of the litigation.").

Similarly for the estoppel provision, it too is undermined by partial decision, for estoppel is effective only when validity is resolved by the PTAB. This provision is important to the AIA structure, as explained by Representative Jackson–Lee, for the purpose of "prohibiting a party from reasserting claims in court that it raised in post-grant review." 153 Cong. Rec. H10,280 (daily ed. Sept. 7, 2007). This view was urged by the PTO as important to the new proceeding:

> We would favor providing for a second-window review to have a different estoppel ***1338** effect than a first-window review ... A

> second-window review, however, will serve as a substitute for court litigation and, as such, should bind not only the patentee but also the challenger as a decision on the merits in litigation would.

Patent Reform: The Future of American Innovation: Hearing Before the Senate Comm. on the Judiciary 110th Cong. 136–137 (2007) (statement of Director Jon Dudas). This position was reiterated by Director Kappos:

> If I can say that in my own words also, that I believe there are significant advantages for patentees who successfully go through the post-grant system—in this case inter partes review—because of those estoppel provisions. Those estoppel provisions mean that your patent is largely unchallengeable by the same party.

America Invents Act: Hearing on H.R. 1249 Before the House Comm. on the Judiciary, 112th Cong. 52–53 (2011) (statement of Director David Kappos).

Instead of vigorously implementing the AIA as it was enacted, the panel majority's rulings today waffle toward the inefficiencies, conflicts, and uncertainties that the America Invents Act was designed to resolve.

III

Rulings at "Institution" Do Not Restrict All Appellate Review

The "institution" phase of the AIA is a threshold proceeding whose primary purpose is to screen out unsupported attacks on validity. As Senator Grassley explained, there is a "higher threshold" for commencing a PTAB proceeding as compared with the filing of a complaint in district court, by requiring a showing that at least one patent claim is more likely than not invalid. This is a safeguard against harassment, tactical delay, and like abuses. This purpose pervades the legislative record, e.g., 157 Cong. Rec. S952 (statement of Sen. Grassley) (describing the AIA's "procedural safeguards to prevent a challenger from using the process to harass patent owners.").

The "institution" decision is, by statute, not appealable. However, information presented and rulings made at this threshold are not immunized from judicial review, when material to the final decision on validity. The court today holds otherwise, stating that "an issue relating to institution does not become appealable simply because the Board mentions that issue in its final decision." Maj. Op. at 1314 n. 4. The court cites *Achates Reference Publishing, Inc. v. Apple Inc.*, 803 F.3d 652 (Fed.Cir.2015), for its statement that the "appealability bar applies to institution decisions 'even if such assessment is reconsidered during the merits phase of proceedings and restated as part of the Board's final written decision.' " Maj. Op. at 1314 n. 4 (quoting *Achates*, 803 F.3d at 658).

Precedent does not require this extended application of *Achates.* In *Versata Dev. Group, Inc. v. SAP Am., Inc.*, 793 F.3d 1306 (Fed.Cir.2015), the court held that when information at the threshold phase is material to the PTAB final decision, this court on appeal is not precluded from reviewing such information. The court stated:

> Congress explained the anomalous nature of a bar to judicial review of final agency action: "Very rarely do statutes withhold judicial review. It has never ***1339** been the policy of Congress to prevent the administration of its own statutes from being judicially confined to the scope of authority granted or to the objectives specified. Its policy could not be otherwise, for in such a case statutes would in effect be blank checks drawn to the credit of some administrative officer or board."

Id. at 1319 (quoting S.Rep. No. 79–752, at 26 (1945)). As stated in *Social Security Board v. Nierotko:*

> Administrative determinations must have a basis in law and must be within the granted authority.... An agency may not finally decide the limits of its statutory power. That is a judicial function.

327 U.S. 358, 369, 66 S.Ct. 637, 90 L.Ed. 718 (1946). These principles are a foundation of the Administrative Procedure Act.

On this appeal, a ruling that the court insulates from

review relates to the one-year bar. The America Invents Act requires that a petition must be filed within one year after the start of any district court litigation on the same patent:

> **35 U.S.C. § 315(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....

Although this issue is presented on this appeal, the panel majority refuses to consider it because it was decided at the "institution" phase. The question is whether a predecessor to Synopsys, in litigation with Mentor Graphics more than a year earlier, raised the one-year bar. The PTAB held that there was no bar. PTAB Op. 14–17. The court today holds that "the PTO's decisions concerning the § 315(b) time bar, including determinations of the real party in interest and rulings on discovery related to such determinations, are non-appealable," even after the PTAB's final written decision. Maj. Op. at 1323.

It is unlikely that such issues material to statutory compliance—issues of privity, standing, and jurisdiction—were intended to be excluded from appellate review. Such a departure from the judicial obligation cannot be presumed. *See Crowell v. Benson*, 285 U.S. 22, 54–55, 52 S.Ct. 285, 76 L.Ed. 598 (1932):

> A different question is presented where the determinations of fact are fundamental or 'jurisdictional,' in the sense that their existence is a condition precedent to the operation of the statutory scheme. These fundamental requirements are ... indispensable to the application of the statute ... because the Congress has so provided explicitly.

The Court in *Crowell* notes that: "In relation to administrative agencies, the question in a given case is whether it falls within the scope of the authority validly conferred." *Id.* at 54 n. 17, 52 S.Ct. 285.

Whether or not the one-year bar here is deemed jurisdictional, it is an essential part of the AIA structure. The correctness of its treatment is subject to the traditional judicial review of agency determinations; the question is not insulated from appeal simply because it was decided at the start of the post-grant proceeding. The Court guides in *Bowen v. Michigan Academy of Family Physicians* that preclusion of judicial review is viewed strictly:

> We begin with the strong presumption that Congress intends judicial review of ***1340** administrative action. From the beginning "our cases [have established] that judicial review of a final agency action by an aggrieved person will not be cut off unless there is persuasive reason to believe that such was the purpose of Congress." *Abbott Laboratories v. Gardner*, 387 U.S. 136, 140, 87 S.Ct. 1507, 18 L.Ed.2d 681 (1967).

476 U.S. 667, 670, 106 S.Ct. 2133, 90 L.Ed.2d 623 (1986) (alteration in original). The appellate court must ensure that an agency's action is not "so extreme as to amount to an abdication of its statutory responsibilities." *Heckler v. Chaney*, 470 U.S. 821, 833 n. 4, 105 S.Ct. 1649, 84 L.Ed.2d 714 (1985). When an agency "exercise[s] its power in some manner. The action at least can be reviewed to determine whether the agency exceeded its statutory powers." *Id.* at 832, 105 S.Ct. 1649.

In sum, "Congress rarely intends to prevent courts from enforcing its directives to federal agencies;" there is "a strong presumption favoring judicial review of administrative action." *Mach Mining, LLC v. EEOC*, ——U.S. ——, 135 S.Ct. 1645, 1651, 191 L.Ed.2d 607 (2015) (quoting *Bowen*, 476 U.S. at 670, 106 S.Ct. 2133). My colleagues' position that no ruling during institution can receive appellate review, even when material to the final decision, cannot be correct.

IV

The AIA Assigns the Decision to "Institute" to the Director, and Assigns the Trial and Final Decision to the PTAB

By statute, the "institution" decision is made by the Director, not by the judges of the Patent Trial and Appeal

Board. The legislative record shows that these functions were deliberately separated. Senator Kyl explained the purpose of avoiding self-review:

> Obviously, subsection (a) alone would not be enough to test the view that PTO has reached an incorrect conclusion on an important legal question because subsection (a) requires the petitioner to persuade PTO that a claim appears to be un-patentable, and PTO is unlikely to be so persuaded if it has already decided the underlying legal question in favor of patentability.

154 Cong. Rec. S9982–93 (Sept. 27, 2008). The separation of these roles helps to ensure that the decision of the PTAB is not a rubber stamp of the institution decision, nor a shortcut on "an important legal question." The PTO's practice of assigning the institution decision to the PTAB is contrary to the statute, and commentators have objected, stating that:

> Currently the same APJs consider an incomplete and preliminary record to decide that the claims being challenged in a petition are likely unpatentable. Those same APJs are then required to make the Final Written Decision—in essence, they are put in the position of defending their prior decision to institute the trial. This creates an actual or perceived bias against the patent owner.

AIPLA Comments on PTAB Trial Proceedings, at 20 (Oct. 16, 2014), available athttp://www.uspto.gov/ip/boards/bpai/aipla_20141016.pdf. *See also* *Ethicon Endo–Surgery, Inc. v. Covidien LP*, No. 2014–1771, 812 F.3d 1023, 2016 WL 145576 (Fed.Cir. Jan. 13, 2016) (**Newman**, J., **dissenting**).

This further contravention of the statute is not supportable.

***1341 V**

The AIA Must Be Applied as a Balanced Whole

The record shows extensive policy balances in the AIA as eventually enacted. Today's concerns focus primarily on procedures adopted after enactment of the statute, such as post-grant use of the "broadest" claim construction; a topic under review elsewhere.[5] And I have previously pointed to issues arising from conflicting final decisions in the PTAB and the district court, see *Fresenius USA, Inc. v. Baxter International, Inc.*, 721 F.3d 1330, 1347 (Fed.Cir.2013) (**Newman**, J., **dissenting**).

In addition, the statutory provision for amending claims for post-grant review has been misapplied. Although the AIA authorizes claim amendment, PTO statistics demonstrate the PTAB's practice of denying almost all motions to amend, as referenced in *Cuozzo*, 793 F.3d at 1288 n. 1 (**Newman**, J., **dissenting**). Updated statistics show little change, *see* Daniel F. Klodowski and David Seastrunk, *Claim and Case Disposition*, AIA BLOG, http://www.aiablog.com/claim-and-case-disposition/ (visited Feb. 5, 2016) (Reporting IPR Substitute Claim Disposition as of Jan. 1, 2016: 446 (94.49%) substitute claims denied, 26 (5.51%) substitute claims granted.)

It devolves upon the court to assure fulfillment of the policy embodied in the statute, with appreciation of the statutory balance and the interrelation of provisions. The availability of amendment in IPR proceedings, as compared with district courts, balances the lighter standard of invalidation for IPR proceedings. A witness stated, in response to questions by Senators Grassley, Coburn, Specter and Kyl:

> [U]nnecessarily restricting the patentee's ability to amend its claims (in contrast with the flexible *inter partes* reexamination process) ... encourage[s] outright invalidation of a patent that may simply require an adjustment in scope.

Patent Reform: the Future of American Innovation: Hearing Before Senate Comm. on the Judiciary, 110th Cong. 45 (Responses of Bruce Bernstein, Chief Intellectual Property and Licensing Officer, InterDigital Communications Corp.).

The amendment opportunity was emphasized. *See id.* at 90 (Post–Hearing question of Sen. Kyl to Mary Doyle) ("24. Under the post-grant review procedure proposed in

S. 1145, a patentee may amend its claims only once as a matter of right, and may further amend only for good cause shown."). Thus the statute provides:

> § 316(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 ***1342** 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.

(emphasis added). In the context of the statement of Senator Kyl that the legislation provides for one amendment "as a matter of right," the reported implementation is indeed questionable.

The record demonstrates that the statute was well understood as creating a fresh balance, whereby patents could be challenged in opposition-like proceedings, whether or not there was a "case or controversy" as required by Article III. Congress lowered the evidentiary standard of invalidity applied by the courts to granted patents, and authorized limited amendment, thereby allowing correction of flaws in the prior grant. This statute requires implementation in accordance with the legislative purpose.

VI

This New Proceeding Is of Power and Promise

The power and promise of the America Invents Act, and the aspirations held by Congress and the Nation, recognize American innovation and the capability of invention to serve the public and the economy. For so large a change in national practice, adjustment is not surprising. The glitches I have pointed out are readily remediable, and appear to flow from construing isolated statutory provisions. *See Davis v. Mich. Dep't of Treasury*, 489 U.S. 803, 809, 109 S.Ct. 1500, 103 L.Ed.2d 891 (1989) ("[S]tatutory language cannot be construed in a vacuum. It is a fundamental canon of statutory construction that the words of a statute must be read in their context with a view to their place in the overall statutory scheme."). Each provision contributes to the balance established in the statute, as Congressman Berman explained:

> Like all compromises, not everyone received everything they wanted, which is honestly just as it should be. This legislation favors no industry, no person, organization or interest group. It seeks to solve problems that we have identified and have been identified for us by outside experts and agencies.

153 Cong. Rec. 23904–11 (2007) (Rule for debate on Patent Reform Act of 2007). Senator Leahy also commented on concerns that were balanced:

> The array of voices heard in this debate represent virtually all sectors of our economy, all interests in the patent system. They have not been uniform, but they know the legislative process is one of compromise and accommodation where possible, and it has been that way during the 6 years we have been at work on this bill.

157 Cong. Rec. S1349 (daily ed. Mar. 8, 2011).

Congress aspired to revitalize the Nation's patent system, in an era of innovation beyond imagination. I respectfully dissent from the departures from the legislative plan.

812 F.3d 1076
United States Court of Appeals,
Federal Circuit.

SYNOPSYS, INC., Plaintiff–Appellant
v.
Michelle K. LEE, Director, U.S. Patent and Trademark Office, and Under Secretary of Commerce for Intellectual Property, United States Patent And Trademark Office, Mentor Graphics Corporation, Defendants–Appellees.

NEWMAN, Circuit Judge, **dissenting**.

Our Nation's patent system is a foundational aspect of our republic. As the complexity of government progressed, the Administrative Procedure Act (APA) took its place at the core of how the Nation operates. In attuning these aspects to the complexities of patent law, the America Invents Act removed from the standard path of APA review those issues relating to the America Invents Act. Thus by statute all judicial review is consolidated in the Federal Circuit. As such, the district court correctly dismissed this appeal for absence of jurisdiction.

Because the district court did not have jurisdiction, it appropriately dismissed the case on that ground. Absence of jurisdiction does not render a case "moot", as the panel majority posits, for there is nothing to moot. Our necessary role is to decide the question of jurisdiction, for that is what was appealed.

The district court's ruling was in accordance with the statute, and should be affirmed. To the extent that the panel majority has reached some other conclusion, I respectfully dissent.

811 F.3d 466
United States Court of Appeals,
Federal Circuit.

PFIZER, INC., A Delaware Corporation, Wyeth Holdings Corporation, A Maine Corporation, Plaintiffs–Appellants
v.
Michelle K. LEE, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, Defendant–Appellee.

No. 2015–1265.
|
Jan. 22, 2016.

NEWMAN, Circuit Judge, **dissenting**.

I respectfully dissent. The panel majority's ruling on patent term adjustment is in conflict with the Patent Act, for the PTO's admittedly incomplete restriction requirement during patent examination contributed to the delay in issuance of the patent.

The panel majority reasons that Wyeth[1] could have or should have filed a speculative response to the flawed restriction requirement, on the premise that Wyeth should have guessed as to which of the 21 groups the examiner would have chosen for each of the six claims that the examiner erroneously omitted from the requirement for restriction.[2] On the premise that Wyeth might have guessed correctly and that the examiner might have proceeded with the prosecution without correcting his error, my colleagues refuse to include the period of actual delay in the adjustment of the patent term.

Instead of the highly irregular action conjured by the panel majority—an action of uncertain propriety and unlikely responsiveness, an action that could well have backfired, *see* 37 C.F.R. 1.135(b) (an incomplete reply leads to abandonment of the application); MPEP § 711.02—Wyeth telephoned the examiner. The examiner immediately recognized his error, withdrew the flawed Office action, and promptly issued a corrected Office action. The panel majority apparently believes that these events were unnecessary and that Wyeth was at fault in seeking a corrected official action, and thus must suffer denial of the statutory term adjustment for the additional delay.

Thus the panel majority refuses to count the period of delay consumed by the examiner's error and its correction. However, such prosecution delay is within the statutory conditions for Patent Term Adjustment, 35 U.S.C. § 154. The delay occurred, and it cannot be reasonably disputed that the applicant and the examiner acted appropriately to cure the examiner's error.

***477** Despite the PTO's admission of its error, my colleagues propose that the applicant should have proceeded as if the incorrect restriction requirement were correct "because the initial restriction requirement placed the applicant on notice of 'the broad statutory basis for [the rejection of] his claims,' *Chester*, 906 F.2d at 1578, the restriction requirement satisfied the notice requirement of Section 132." Maj. Op. at 476. Thus the panel majority holds that this admitted PTO-caused delay must be treated as if it did not occur, although it necessarily delayed prosecution, for the applicant could not reliably elect which claims to prosecute when some claims had been omitted by the examiner.

The issue is not whether the applicant could have guessed where among the 21 groups the examiner intended to put claims 75, 76, 103, 104, 105, and 106. Nor is the issue whether the error was harmless (the PTO does not argue that its error was harmless), for it is not disputed that the error delayed prosecution. The PTO does not argue that the prosecution could have proceeded in the absence of PTO correction of its failure to account for every claim. The issue is simply whether the delay that necessarily ensued is an " 'A' Delay" subject to inclusion in the term adjustment.

The Wyeth patent application was completed and filed on December 8, 2003. The 14–month deadline for PTO issuance of the first official action was not met, and the incomplete initial restriction requirement was issued by the PTO on August 10, 2005, with response due on February 10, 2006. Wyeth phoned the examiner on February 6, 2006, pointing out the error. The examiner withdrew the flawed restriction requirement, and issued a corrected restriction requirement on February 23, 2006. The patent issued on April 10, 2012.

The PTO issued a Patent Term Adjustment of 1201 days. Pfizer seeks to increase the adjustment by 197 days, measured as the period from the examiner's incomplete

restriction requirement on August 10, 2005 to the issuance of the corrected restriction requirement on February 23, 2006. It is not disputed that the pendency period was lengthened by this amount.

The panel majority holds that this period of delay should be attributed to the applicant, not the PTO. This is indeed curious, for the applicant made no error. The panel majority holds that PTO error does not count if the applicant could have figured out what the examiner might have done if he had not erred. The panel majority appears to believe that this would have eliminated the delay consumed by the correction of the error. However, the prosecution was delayed by the PTO's error.

Patent Term Adjustment was enacted into law in order to compensate for prosecution delays, for patent life is measured from the initial filing date, but patent rights do not arise until the patent is granted. The statute states:

> 35 U.S.C. § 154(b) Adjustment of patent term.—
>
> (1) Patent term guarantees.—
>
> * * * *
>
> the term of the patent shall be extended 1 day for each day after the end of the period specified in clause (i), (ii), (iii), or (iv), as the case may be, until the action described in such clause is taken.

By statute, Patent Term Adjustment accumulates until the PTO issues a notification under Section 132. 35 U.S.C. § 154(b)(1)(A)(i). Section 132 requires a complete Office action, *see* 37 C.F.R. § 1.104(b) ("The examiner's action will be complete as to all matters...."); ***478** MPEP § 707.07 (same). Office actions also include requirements for restriction, *see* 37 CFR § 1.142 ("If two or more independent and distinct inventions are claimed in a single application, the examiner in an Office action will require the applicant in the reply to that action to elect an invention to which the claims will be restricted"); MPEP § 707 (Office action may include restriction requirements); *see also* Responding to Office Actions, USPTO, http://www.uspto.gov/patents-maintaining-patent/responding-office-actions ("Office actions include a restriction requirement, a non-final Office action, and a final Office action.").

Chester v. Miller, 906 F.2d 1574 (Fed.Cir.1990) does not hold otherwise. There, the examiner "specified exactly which claims read on exactly what prior art." *Id.* at 1578. The patent applicant argued that the examiner "had not specified that the ... reference provided written description or enablement of the subject matter of the rejected claims." *Id.* at 1577. The court held only that Section 132 does not require the PTO "to state specifically that a prior art reference describes and enables claims rejected as anticipated." *Id.* at 1578. In *Chester*, the court concluded that the Office action was complete, not that a less-than-complete Office action would comply with Section 132.

In re Hughes, 52 CCPA 1355, 345 F.2d 184 (1965), upon which *Chester* relies, does not attempt to define the requirements of Section 132. There, although the examiner rejected claims under Section 102, the Board rejected the same claims under Section 103 without notifying the applicant that the statutory basis for the rejection had changed. *Id.* at 185. The CCPA observed that "[i]t seems basic to the concept of procedural due process that an applicant at least be informed of the broad statutory basis for rejecting his claim." *Id.* Section 132, the CCPA noted, was intended to ensure compliance with at least this bare minimum. *Id.*

Several MPEP sections provide details, all to the effect that Section 132 requires completeness of the restriction requirement as to all of the claims. *See* MPEP § 814 (duty to account for all claims), § 815 (duty to make restriction requirement complete). Here the restriction was facially incomplete. The applicant is not required to guess, to fill in the blanks erroneously left by the PTO. The applicant's guess cannot bind the PTO. That uncertainty is illustrated here, for the examiner, in the supplemental restriction, classified claim 106 in Group XI whereas the applicant, in its response, believed that claim 106 belonged in Group VI.

Rather than guess, the applicant is entitled to a complete Office action. *See* 37 C.F.R. § 1.104(b). Here, the PTO provided an incomplete action. The delay caused by such a scenario should not be charged against the patent applicant, nor should the applicant be prejudiced by the examiner's error. The panel majority erroneously holds that term adjustment is not available because the applicant, not the PTO, spotted the PTO's error. *See* Maj. Op. at 475–76 (distinguishing *Janssen* and *Oncolytics* on such grounds). Whether the examiner's actions "were outside the normal 'give-and-take process' of patent prosecution," *id.*, should not turn on who recognized the error.

Importantly, this is not a case where a patent applicant persuaded an examiner to withdraw a rejection or restriction on the merits. This case is unlike *University of Massachusetts v. Kappos*, 903 F.Supp.2d 77 (D.D.C.2012) ("*UMass* "), where the district court stated the issue as "whether, *as a matter of law*, when an applicant successfully convinces an Examiner to change a ruling contained in an Office action, regardless ***479** of whether it is classified as a vacatur, that renders the first Office action 'a nullity for purposes of calculating A delay under Section 154(b)(1)(A).' " *Id.* at 86 (emphasis in original). In *UMass* there was no allegation that the restriction requirement was incomplete; only that it "ran counter to the classification scheme devised by plaintiffs." *Id.* at 81. During telephone conversations, the applicant convinced the examiner to change the original groupings. *Id. UMass* does not support the proposition that a facially incomplete Office action does not count for patent term adjustment.

The statutory purpose is clear: when patent issuance is delayed because of proceedings that are not the fault of the applicant, the patent term is extended to compensate for the delay. H.R. Rep. No. 106–287, at 49 (1999) ("Title III amends the provisions in the Patent Act that compensate patent applicants for certain reductions in patent term that are not the fault of the applicant."). My colleagues' statutory interpretation and application are contrary to the letter and purpose of the law. I respectfully dissent.

820 F.3d 432
United States Court of Appeals,
Federal Circuit.

MERCK & CIE, Appellant
v.
GNOSIS S.P.A., Gnosis Bioresearch S.A., Gnosis U.S.A., Inc., Appellees.

No. 2014–1779.
|
April 26, 2016.

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

The America Invents Act created a new tribunal in the Patent and Trademark Office. This tribunal, called the Patent Trial and Appeal Board (PTAB), has several assignments including conduct of the post-grant proceedings authorized by the America Invents Act of 2012. Pub.L. No. 112–29, 125 Stat. 284 (2011) (effective September 16, 2012). In an *inter partes* review, a petitioner's allegations of invalidity on grounds of sections 102 and 103 of Title 35 can lead to PTAB proceedings similar to trial in the district courts, with discovery, evidence, testimony, briefs, hearings, and written decision. The PTAB decision may be appealed to the Federal Circuit, but cannot be taken to remedy by civil action in the district court. *Compare* 35 U.S.C. § 319 *with* 35 U.S.C. § 145.

When the final decision is adverse to the patent owner, the PTAB cancels the affected patent or claims. An important aspect of the America Invents Act is that the final decision produces an estoppel against the petitioner in any ensuing litigation. Thus these PTAB proceedings carry a heavy load, for they affect not only the property rights of the patent owner, but also the potential liability and opportunity of the petitioner.

My concern relates to the Federal Circuit's implementation of its appellate role, for the court has adopted a highly deferential standard of review of these PTAB decisions, instead of the full and fair review that is appropriate to the America Invents Act. The entire thrust of the America Invents Act is that these PTAB proceedings would be an alternative to district court proceedings on these issues, and would receive the same level of appellate review. The highly deferential review standard of "support by substantial evidence" does not assure the intended identity of result for these PTAB and district court determinations.

En banc action is needed to realign the Federal Circuit's standard of review with the legislative purpose. Thus I respectfully dissent from my colleagues' denial of this request for *en banc* consideration.

DISCUSSION

To fulfill the Act's purpose that these PTAB proceedings will be a just substitute for district court proceedings on the designated issues, and will provide confidence and finality for the patent-based innovation communities, the PTAB decision must be subject to full and fair appellate review.

Precedent does not prohibit objective review of PTAB decisions

Although the concurring opinion states that the Court's decision in *Dickinson v. Zurko*, 527 U.S. 150, 119 S.Ct. 1816, 144 L.Ed.2d 143 (1999), leaves no choice but to apply the substantial evidence standard, that view is an unwarranted enlargement. In *Zurko*, the Court held that the PTO is subject to the judicial review framework of the Administrative Procedure Act. *Id.* at 152, 119 S.Ct. 1816 (citing 5 U.S.C. § 706). However, *Zurko* did not prohibit future legislation such as here enacted, where ***437** Congress created a new tribunal with authority to substitute for district court actions and results, and for these proceedings eliminated *de novo* review that is otherwise available for PTO decisions.

Statutes must be implemented 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, 110 S.Ct. 997, 108 L.Ed.2d 132 (1990). The design of the America Invents Act is not only to provide an efficient and economical surrogate for district court determinations of patent validity, but also to bind and estop the petitioner in any infringement proceeding. It is noteworthy that the PTAB is reviewing past PTO actions for error, without the deference that those actions receive in district court.

Viewing the America Invents Act in its entirety, the conclusion is compelled that Congress expected that these PTAB decisions would be reviewed on the same judicial standard as applies to the district court proceedings that are replaced. Our responsibility is to assure that the legislative purpose is implemented in accordance with the design, object, and policy of the statute. *Id.*

The "substantial evidence" standard does not conform to the statutory plan

The record shows a decade of study and evolution, as Congress and the technology-concerned public collaborated to provide an improved system for litigation resolution of the major patent validity issues. *See* H.R.Rep. No. 112–98, pt. 1, at 48 (2011) (*Inter partes* review will provide "quick and cost effective alternatives to litigation"). Nowhere in the record is there a hint of intent to diminish the appellate responsibility of review of validity on the grounds of correctness in law and clear error of fact.

"Substantial evidence" is defined as "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Consol. Edison Co. v. N.L.R.B.*, 305 U.S. 197, 229, 59 S.Ct. 206, 83 L.Ed. 126 (1938). "It must be enough to justify, if the trial were to a jury, a refusal to direct a verdict when the conclusion sought to be drawn from it is one of fact for the jury." *N.L.R.B. v. Columbian Enameling & Stamping Co.*, 306 U.S. 292, 300, 59 S.Ct. 501, 83 L.Ed. 660 (1939). As the Court stated in *Consolo v. Maritime Commission*, 383 U.S. 607, 620, 86 S.Ct. 1018, 16 L.Ed.2d 131 (1966), "the possibility of drawing two inconsistent conclusions from the evidence does not prevent an administrative agency's finding from being supported by substantial evidence." This is the distinction here of concern, for application of the substantial evidence standard can lead to affirmance of a ruling that is not in accordance with the weight of the evidence. It is unlikely that Congress intended to place PTAB decisions in that "rubber-stamp" category—for in PTAB proceedings, with documentary and testamentary evidence presented by both sides, substantial evidence is usually present on both sides.

If on appeal the Federal Circuit simply looks for substantial evidence on the side of the PTAB decision, then the purpose of the America Invents Act to provide a surrogate for district court proceedings is thwarted. The decade of legislative hearings shows that the AIA-provided path of appellate review was intended and expected to be conducted on judicial standards, not on administrative standards. The America Invents Act rests on the foundation that PTAB proceedings will substitute for district court proceedings, and that the Federal Circuit will provide full appellate review. Note the elimination of access to district court review under 35 U.S.C. § 145 for post-grant proceedings, unlike the statute that existed at the time of ***438** *Zurko*. 527 U.S. at 164, 119 S.Ct. 1816 (1999) (highlighting the availability of 35 U.S.C. § 145 and the review of agency action under a clear error standard of review on appeal from a § 145 action).

There is no hint that Congress and the concerned communities contemplated omitting full appellate review by the Federal Circuit, while eliminating district court review and imposing an estoppel against the petitioner, who may not assert in defense to a charge of infringement any ground of invalidity "that the petitioner raised or reasonably could have raised" in the PTAB. 35 U.S.C. § 315(e)(2). With these substantive consequences, it is not reasonable to infer the legislative intent to apply highly deferential review to issues traditionally subjected to appellate review for correctness and clear error.

The standard by which the new PTO tribunal would determine validity was the subject of controversy in the Congress. The American Intellectual Property Law Association testified that: "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." *Patent Act of 2005: Hearing on H.R. 2795 Before the House Subcomm. on Courts, the Internet, and Intell. Prop.*, 109th Cong. 15 (2005). Eventually the preponderance standard was adopted, but with balancing provisions including the estoppel provision and the review path to the Federal Circuit. It is not tenable to assume silent legislative intent to accompany this lightened burden of proving invalidity in the PTAB and restricted path of appeal, with a highly deferential standard of appellate review.

The PTAB proceeding is a trial between private parties, and requires commensurate review

This new proceeding is not an agency grant, but adjudication in accordance with the law of statute and precedent. At issue are property rights that were previously granted, vesting the patent right to exclude. *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."). This too weighs against deferential review of PTAB decision, for cancellation of property rights that the agency previously granted weighs against deferential review, lest any further error be ratified.

The legislative record shows the evolution of the America Invents Act from a simple "opposition"-like proposal, to a full trial proceeding whose result produces an estoppel. *Compare* H.R.Rep. No. 112–98, pt. 1, at 8 as enacted (describing the PTAB as a "court-like proceeding") *with* Patent Quality Assistance Act of 2004, H.R. 5299, 108th Cong. § 336(a)(2) (2d Sess. 2004) (permitting "opposer in an opposition proceeding" to avoid any estoppel in court proceedings). If the PTAB decision must be sustained if it is supported only by substantial evidence—even if the weight of the evidence would produce a contrary result—then the ambitious design of the America Invents Act collapses. Such an intent cannot be presumed.

Rather, the legislative record provides the expectation that the Federal Circuit will apply the standard judicial criteria for review. These criteria conform to the legislative purpose of providing an efficient and economical surrogate for district court trial, as well as authorizing challenges to patents not yet in litigation. The purpose is to reinforce reliability of the patent- ***439** based incentive to technological innovation, whereby valid patents are recognized and invalid patents are eliminated. *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.").

Post-grant proceedings are not simple administrative actions. The America Invents Act departs from the Administrative Procedure Act in its provisions for appeal directly to the Federal Circuit, eliminates district court review, and imposes estoppel against the petitioner. The substantial evidence standard of review distorts the legislative balance. *En banc* consideration is necessary to realign the appellate standard with the statutory purpose.

807 F.3d 1353
United States Court of Appeals,
Federal Circuit.

PROLITEC, INC., Appellant
v.
SCENTAIR TECHNOLOGIES, INC., Appellee.

No. 2015–1020.
|
Dec. 4, 2015.

NEWMAN, Circuit Judge, **dissenting**.

This appeal is from *inter partes* review of United States Patent No. 7,712,683 (the '683 patent) under the America Invents Act of 2012. Review was requested by ScentAir Technologies, Inc., and proceeded to trial and decision of the Patent Trial and Appeal Board (PTAB), invalidating the patent. This appeal is directed to several aspects of the PTO's and this court's implementation of this new administrative proceeding.

The courts are charged with assuring agency fidelity to law and to legislative purpose. The Supreme Court has stated:

> Reviewing courts are not obliged to stand aside and rubberstamp their affirmance of administrative decisions that they deem inconsistent with a statutory mandate or that frustrate the congressional policy underlying a statute. Such review is always properly within the judicial province, and courts would abdicate their responsibility if they did not fully review such administrative decisions.

N.L.R.B. v. Brown, 380 U.S. 278, 291–92, 85 S.Ct. 980, 13 L.Ed.2d 839 (1965); *see also Bowen v. Michigan Acad. of Family Physicians*, 476 U.S. 667, 672 n. 3, 106 S.Ct. 2133, 90 L.Ed.2d 623 (1986) ("The responsibility of enforcing the limits of statutory grants of authority is a judicial function; ... [w]ithout judicial review, statutory limits would be naught but empty words.") (citation omitted).

Of primary concern is the PTO's treatment of the statutory provisions for claim amendment in these post-grant proceedings. The panel majority holds that the PTAB properly refused entry of an amendment, although Prolitec complied with all of the statutory and regulatory requirements. The amendment would have narrowed the claims, potentially avoiding a dispositively adverse claim construction. ***1366** I respectfully dissent from my colleagues' ratification of this and other departures from the governing statute and the underlying congressional policy.

A

The PTO erred in refusing to enter Prolitec's substitute claim 3

The America Invents Act authorizes limited claim amendment, as follows:

> 35 U.S.C. § 316(d)(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 claims.
>
> (B) For each challenged claim, propose a reasonable number of substitute claims.
>
> ...
>
> (3) Scope of claims.—An amendment under this subsection may not enlarge the scope of the claims of the patent or introduce new matter.

PTO regulations authorize denial of a claim amendment that complies with the statute, but only when:

> (i) The amendment does not respond to a ground of unpatentability involved in the trial; or
>
> (ii) The amendment seeks to enlarge the scope of the claims of the patent or introduce new subject matter.

37 C.F.R. § 42.121(a)(2). "Ground of unpatentability" in this regulation refers to the statutory basis of the petition for *inter partes* review, for the regulations require the petitioner to identify "[t]he specific statutory grounds

under 35 U.S.C. §§ 102 or 103 on which the challenge to the claim is based and the patents or printed publications relied upon for each ground." 37 C.F.R. § 42.104(b)(2).

Prolitec moved to amend by replacing claim 1 with claim 3, which replaced the term "mounted" with the term "permanently joined." The PTAB refused to enter the amendment, and then invalidated claim 1 on the "broadest" interpretation of "mounted" to include other than permanent mounting. Only permanent affixation is described in the specification, and is emphasized as a distinction from Prolitec's prior device, which is the closest prior art.

When a proposed amendment would resolve a dispositive aspect of claim breadth, refusal to enter the amendment is contrary to both the purpose and the text of the America Invents Act.

The PTO has intervened in this appeal to defend the PTAB's refusal of the amendment. However, entry of a compliant amendment is of statutory right, and patentability of the amended claim is properly determined by the PTAB during the IPR trial, not for the first time at the Federal Circuit.

B

The PTO's placement of the burden of proof for amended claims is contrary to statute

I start with the PTO's treatment of the burden of proof, for if the PTO tribunal is to serve as a surrogate for the district courts' determination of patent validity, the same decision-affecting procedural rules should apply in the PTAB as in the district court.

The America Invents Act places the burden of proof on the post-grant petitioner, and provides:

> 35 U.S.C. § 316(e) Evidentiary standards.—In a post-grant review instituted under this chapter, the petitioner shall have the burden of proving a proposition of unpatentability by a preponderance of the evidence.

***1367** That statutory prescription applies whether the "proposition of unpatentability" is for amended or unamended claims. However, the PTAB disregards this statutory requirement by placing on the patentee the burden of proving patentability for a proposed amended claim. The PTAB so held in *Idle Free Systems, Inc. v. Bergstrom, Inc.*, 109 U.S.P.Q.2d 1443, 1459 (PTAB Jan. 7, 2014) ("The burden is not on the petitioner to show unpatentability [of amended claims], but is on the patent owner to show patentable distinction over the prior art of record and also prior art known to the patent owner.") (citing *Idle Free*, Decision on Motion to Amend Claims, § 42.121 at 7, IPR2012–00027 (PTAB June 11, 2013), Paper No. 26) (emphasis omitted).

The America Invents Act does not authorize or suggest such a shift in the statutory burden. The PTO, in its Intervenor's brief, invokes the practice of district court litigation and argues that if the patentee files a motion, it bears the burden of establishing entitlement to grant of the motion. However, this generalization is inapplicable when there are explicit statutory burdens that set a different standard.

The Act requires the PTAB to analyze the patentability of "any new claim added under section 316(d)," 35 U.S.C. § 318(a), again reflecting the statutory directive that the new claim should be added, provided that it qualifies under the statute. The PTAB then determines patentability of the added claim in accordance with the statutory burdens. The statute places the burden of proving invalidity (unpatentability) on the petitioner. As explained by Senator Kyl, "inter partes reexamination is converted into an adjudicative proceeding in which the petitioner, rather than the Office, bears the burden of showing unpatentability." 137 Cong. Rec. S1360, S1375 (daily ed. Mar. 8, 2011). The Act makes no distinction between original and amended claims in *inter partes* review.

My colleagues on this panel depart from the statute in removing from the petitioner the burden of showing unpatentability of amended claims.

C

The preponderance of the evidence is the statutory standard for PTAB validity decisions; judicial review should determine whether the PTAB correctly applied that standard

The PTAB invalidated Prolitec's claims by applying the broadest reasonable construction standard, instead of

determining the correct claim construction in accordance with the specification and the prosecution history. Prolitec argues that its claims, and particularly proposed substitute claim 3, are not invalid when given the correct construction. However, the PTAB reviewed the claims under the broadest reasonable construction standard, and this court reviewed the PTAB decision under the highly deferential substantial evidence standard. With deferential review an incorrect PTAB decision is less likely to be corrected on appeal, contrary to the purpose of the America Invents Act to achieve *correct* determinations of patentability.

The substantial evidence standard is inappropriate in this context. There is no requirement that every administrative decision on every subject must receive deferential review. The standard of review should be attuned to the circumstances. When the America Invents Act assigned to the PTAB the preponderance of the evidence standard for these post-grant procedures, it became inappropriate for the PTAB to give deference to the PTO's prior ruling granting the patent. It also became inappropriate for the PTAB to use the district court's clear and convincing evidence ***1368** standard. The America Invents Act explicitly states that the PTAB should apply the preponderance standard, illustrating the careful balance in the Act; it is the judicial responsibility to assure that this balance is preserved. 35 U.S.C. § 316(e) (requiring proof of unpatentability by a preponderance of the evidence).

Thus, our review of the PTAB's decision must assure that the preponderance of the evidence standard as met. My colleagues err in applying the substantial evidence standard to America Invents Act post-grant appeals.

D

In the evolving state of PTAB practice, Prolitec is entitled to the benefit of PTO interpretations and changes in practice

Prolitec advises that two days after the PTO filed its Intervenor's Brief supporting the PTAB's refusal to accept substitute claim 3, the PTO announced changes with respect to amendment entry. The *Director's Forum: A Blog from USPTO's Leadership: PTAB's Quick–Fixes for AIA Rules Are to Be Implemented Immediately*, available at http://www.uspto.gov/blog/director/entry/ptab_s_quick_fixes_for (Mar. 27, 2015), stated that

> regarding motions to amend, we are contemplating proposed changes to emphasize that a motion for a substitutionary amendment will always be allowed to come before the Board for consideration (i.e., be "entered"), and for the amendment to result in the issuance ("patenting") of amended claims, a patent owner will not be required to make a prior art representation as to the patentability of the narrowed amended claims beyond the art of record before the Office.

This indicates both a retreat from the PTAB's ruling that Prolitec was required to show patentability over "any other prior art reference that also may teach the very limitation," whether or not of record, PTAB Op. at 30, and an acknowledgement that motions to amend are to be entered as of right. However, the PTO imposed the prior rule on Prolitec, and its brief stated that "the Board did not abuse its discretion by requiring Prolitec to come forth with a showing of patentability of its proposed substitute claim over the prior art known to it...." PTO Br. 28. When this rule change was publicly announced, it seems unfair to punish Prolitec for non-compliance with a rule that had already been discarded by the PTO.

Prolitec was not only denied the benefit of the PTO's change of position, but was also denied the right to amend, although this right was granted by the "quick-fix." Prolitec's motion met all of the requirements, and distinguished not only the references of record, but also the references cited by ScentAir and references "within the knowledge of Prolitec." Motion to Amend at 14.

On this appeal, the PTO now concedes that "the patent owner complied with the requirements of rule 42.121." PTO Br. 21. However, the PTO also argues that the proposed amendment was properly "den[ied] ... anyway because the patent owner did not adequately show that the new claims are patentable over the prior art **in general.**" *Id.* (citing *Idle Free*, 109 U.S.P.Q.2d at 1456–61). I emphasize "in general," for such an open-ended expedient has no limits. Indeed, the PTO has also retreated from this position, as the panel majority has recognized.

The panel majority states that on July 15, 2015, the PTAB retreated from that position in *MasterImage 3D, Inc. v. RealD Inc.*, IPR2015–00040, 2015 WL 4383224 (PTAB July 15, 2015). In *MasterImage 3D*, the PTAB stated that

"prior art of record ... refer[s] to: any material art in ***1369** the prosecution history of the patent; ... of record in the current proceeding ...; and ... of record in any other proceeding before the Office involving the patent," and that "prior art known to the patent owner ... should be understood as no more than the material prior art that Patent Owner makes of record in the current proceeding pursuant to its duty of candor and good faith to the Office under 37 C.F.R. § 42.11, in light of a Motion to Amend." *Id.* at 2–3.

My colleagues state that "changes to which the dissent refers were memorialized in *MasterImage 3D.*" Maj. Op. at 1364 n. 1.[1] If so, the PTAB has an obligation to give Prolitec the benefit of that change, for the PTO states in its Intervenor's Brief that this is the only remaining ground in support of the PTAB's denial of the motion to amend.

I take note of fresh uncertainty concerning the right to amend, for on November 3, 2015 the following colloquy took place at the argument of another appeal in which the PTO intervened. I inquired of PTO counsel:

> Court: So it is the position of the Office that ... a patent owner has a statutory right to an amendment?
>
> PTO: The patent owner has a statutory right to file what is called a motion to amend ...
>
> Court: You said to file a motion to amend. Do they have the right to have the motion granted?
>
> PTO: No, Your Honor.
>
> Court: Or only the right to file it?
>
> PTO: Only the right to file a motion.
>
> ...
>
> Court: So there is no right to amend?
>
> PTO: No, Your honor.

Oral Argument, *Synopsys, Inc. v. Mentor Graphics, Inc.*, No.2015–1516 (Argument transcript at 24:39–27:24, November 3, 2015, available at http://oralarguments.cafc.uscourts.gov/default.aspx?fl=2014–1516.mp3).

I assume that such inconsistency will be clarified. Meanwhile, however, Prolitec is entitled to the benefit of changes "memorialized" by the Board while this case was pending. *Landgraf v. USI Film Prods.*, 511 U.S. 244, 264, 114 S.Ct. 1483, 128 L.Ed.2d 229 (1994) (a court must "apply the law in effect at the time it renders its decision") (quoting *Bradley v. Sch. Bd. of Richmond*, 416 U.S. 696, 711, 94 S.Ct. 2006, 40 L.Ed.2d 476 (1974)); R. Pierce, Jr., Administrative Law Treatise § 6.7 ("[A]gencies with the power to adjudicate cases can engage in retroactive lawmaking by replicating the practice of courts ... [t]he Court has consistently upheld that practice.").

In view of this error or uncertainty, we should remand to the PTAB for reconsideration of its denial of the amendment.

E

The PTAB's claim construction requires judicial review for correctness as a matter of law, not deferential review as question of fact

The ′683 invention is an improvement on Prolitec's own prior device, which required ***1370** opening the liquid reservoir to refill the container, a messy procedure subject to leaking and spills, inconsistent scent concentration, clogs, and cross-contamination. Prolitec states that the ′683 device solved these problems by using disposable cartridges where the vacuum/suction created by the venturi effect permits sealed containers to be emptied efficiently by the dispersal mechanism, all while avoiding the mess.

The PTAB found anticipation by the Benalikhoudja reference, which is directed to Prolitec's prior device. A finding of anticipation requires that the same invention was previously known and described, not that a claim can be construed so broadly and incorrectly as to embrace a prior art device. The device of the ′683 patent is not shown in the prior art; it is not the same as the Benalikhoudja device.

Prolitec appeals the construction of three claim terms, stating that the constructions do not conform to the specification. Prolitec states that these terms were incorrectly broadened so as to reach subject matter that is not within the scope of correctly construed ′683 claims.

1.

The PTAB construed the ′683 claims as including a two-chambered system as in the prior art, although the specification and embodiments all show a three-chambered system and explain its advantages over the prior art's two chambers. The PTAB, revising the ′683 invention to eliminate the third chamber, stated that

> claims 1 and 2 require an initial expansion chamber, a head space, and a second/secondary chamber that is secondary in reference to the initial expansion chamber, but not necessarily a separate, third chamber coming after the headspace.

PTAB Op. at 15 (quotations omitted). No reference supports the PTAB's finding that the ′683 device did not "necessarily" constitute a third chamber, and the prior art does not show a structure comparable to the head space in the ′683 patent. Nonetheless, the PTAB and my colleagues on this panel find that Prolitec's three-chamber device is "anticipated" by the prior art two-chamber device. The PTAB stated:

> To the extent Patent Owner means the claims require a second/secondary chamber in addition to requiring a head space, we agree. But, to the extent that Patent Owner argues that the claims require some level of physical separation between the head space and second/secondary chamber, we disagree.

PTAB Op. at 19. This is not the law of anticipation. Anticipation requires that the same invention was previously known; it is apparent from the specification that the PTAB's analysis is not correct.

2.

For the claim element "a diffusion head *mounted* to the reservoir," the PTAB construed the term "mounted" to mean that the cartridge "may be reused through disassembly, refilling, and reassembly." PTAB Op. at 13. The PTAB did not permit Prolitec to amend the claim to replace "mounted" with "permanently joined."

The specification describes the diffusion head as "bonded" to the liquid reservoir, such as by "heat," "ultrasonic welding," "spin welding," or "by use of an adhesive." ′683 Patent, col. 13 ll. 31–33. The permanence of this attachment pervades the description in the patent. Every embodiment in the specification shows permanent attachment of the cartridge, which cannot be disassembled by the end user without destroying it. Prolitec's expert testified that:

> ***1371** If one were to attempt to separate the diffusion head from the liquid reservoir, neither part would be able to be reused and the entire cartridge would be destroyed. Thus, the cartridge in the ′683 patent is an integrated unit that cannot be disassembled without destroying the cartridge.

Decl. of Timothy Shedd, IPR2013–00179, Prolitec Ex.2003, p. 32 (Dec. 13, 2013). The panel majority incorrectly attributes to the expert the position that the cartridge can be removably adhered, a theory that is contrary to the entirety of the specification and testimony.

The panel majority further agrees with the PTAB that the Prolitec cartridge is not a single-use cartridge, because the ′683 patent suggests that used cartridges be returned to the factory "to have the cartridge disassembled, cleaned, any worn or damaged parts replaced, and then refilled and sealed for use." ′683 Patent, col. 11, ll. 9–13. Factory recycling is not contrary to a single-use cartridge in the hands of the consumer. This ruling is incorrect.

3.

The PTAB also misconstrued the ′683 patent's recitation of "second end of the conduit ... fixed in position with respect to the narrow end," col. 16, ll. 12–15, as anticipated by the prior art refillable cartridge. This error again illustrates the incorrectness of the practice of construing these claims "broadly," for this broad construction is not supported by either the specification or the prosecution history. Since post-grant procedures are conducted for issued patents, the claims should be construed correctly, as would a district court and as should the Federal Circuit. The PTAB, having construed

the claims overly broadly, found them invalid, while depriving the patentee of the statutory right to amend.

The PTAB also erred in separately analyzing each incremental difference from the prior art, whereas it is the claimed combination as a whole whose obviousness must be determined. The PTAB, in its acknowledgement of Prolitec's attempt to substitute narrowed claim 3, disposed of it on this improper analysis:

> We understand that Patent Owner maintains that several limitations, which are common to issued claim 1 and proposed claim 3, provide patentable distinctions over the prior art. As we have already held claim 1 to be unpatentable, these limitations cannot distinguish claim 3 over the prior art.

PTAB Op. at 30. This analysis fails the requirement of 35 U.S.C. § 103 that obviousness is determined on the invention as a whole. This is an error of law, and cannot be endorsed on a "substantial evidence" standard of review.

Conclusion

I support bringing PTAB expertise to bear in a post-grant review system. However, the purpose of post-grant review is not to stack the deck against the patentee, but to achieve a correct and reliable result—for innovative enterprise is founded on the support of a system of patents.

The legislative record shows that Congress was aware that the America Invents Act would apply to issued patents that had previously been examined by PTO procedures, and on which patentees may have relied for investment and commercial activity. Returning the patent to the granting agency, amid complaints that the agency too often granted invalid patents, was a long-debated recourse, intended to rehabilitate the innovation incentive. The America Invents Act reflects a careful balance ***1372** of the various interests and needs—and it is the judicial obligation to assure that the administrative mechanisms are faithful to the legislative purpose. The court's rulings today do not meet that obligation. I respectfully dissent.