

**United States Court of Appeals
for the Federal Circuit**

PREGIS CORPORATION,
Plaintiff-Cross Appellant,

v.

**DAVID J. KAPPOS, UNDERSECRETARY OF
COMMERCE FOR INTELLECTUAL PROPERTY
and DIRECTOR, UNITED STATES PATENT and
TRADEMARK OFFICE,**
Defendants-Appellees,

AND

FREE-FLOW PACKAGING INTERNATIONAL, INC.,
Defendant-Appellant.

2010-1492, -1532

Appeals from the United States District Court for the
Eastern District of Virginia in Case No. 09-CV-0467,
Judge Gerald Bruce Lee.

Decided: December 6, 2012

JAMES E. DABNEY, Fried Frank Harris Shriver, of New
York, New York, argued for plaintiff-cross appellant.
With him on the brief were STEPHEN S. RABINOWITZ and
HENRY C. LEBOWITZ; JOHN F. DUFFY, of Washington, DC.

SCOTT R. MCINTOSH, Attorney, Appellate Staff, Civil Division, United States Department of Justice, of Washington, DC, argued for defendants-appellees. With him on the brief were TONY WEST, Assistant Attorney General, and NEIL H. MACBRIDE, United States Attorney. Of counsel on the brief were RAYMOND T. CHEN, Solicitor, and SCOTT WEIDENFELLER, Associate Solicitor, United States Patent and Trademark Office, of Alexandria, Virginia.

ROBERT FRANCIS ALTHERR, JR., Banner & Witcoff, LTD., of Washington, DC, argued for defendant-appellant. With him on the brief were JOSEPH M. POTENZA, BRADLEY C. WRIGHT, CHRISTOPHER B. ROTH and NINA L. MEDLOCK.

Before PROST, CLEVINGER, and REYNA, *Circuit Judges*.

REYNA, *Circuit Judge*.

Free-Flow Packaging International, Inc. (“Free-Flow”) appeals the denial of its motions for judgment as a matter of law after a jury verdict of noninfringement and invalidity of certain claims of U.S. Patent Nos. 7,325,377 (“Fuss ’377”), 7,526,904 (“Fuss ’904”), and 7,536,837 (“Perkins ’837”). Pregis Corporation (“Pregis”) cross-appeals the dismissal of its claim seeking judicial review under the Administrative Procedure Act of the decision of the United States Patent and Trademark Office (“PTO”) to issue Fuss ’377, Fuss ’904, Perkins ’837, and U.S. Patent No. 7,361,397 (“Perkins ’397”) (collectively, the “Free-Flow Patents”). Because we conclude the district court correctly denied Free-Flow’s motions for judgment as a matter of law regarding obviousness, and correctly dismissed Pregis’ claim for judicial review under the Administrative Procedure Act, this court affirms.

I. BACKGROUND

Free-Flow and Pregis are competitors in the air-filled packaging cushion industry. Air-filled cushions are used to fill space in shipping boxes carrying lightweight items that do not take up all the available space in a box. Demand for lightweight packaging rose rapidly beginning in about 1999 due to the growth of internet retail sales. “Air-pillow” packaging emerged as a preferred alternative to polystyrene foam, “peanuts,” or crumpled paper as filling material. Free-Flow and Pregis both manufacture pre-configured plastic film and machines that inflate and seal the film to produce air-pillow packaging.

Free-Flow holds three patents relating to air-filled packaging technology for which infringement and validity are at issue on appeal: the Fuss ’377, Fuss ’904, and Perkins ’837 patents. These patents claim priority to applications filed in late 1999 and early 2000. Fuss ’377, issued February 5, 2008, claims an apparatus for making air-filled packing cushions from a preconfigured plastic film material. The apparatus comprises a feed mechanism for drawing the edge of the film along a path, an elongated guide member adapted to be inserted into a channel in the preconfigured film material to inject air into the film, and a sealing mechanism to close the air-filled film chambers. The sealing mechanism comprises a pair of blocks disposed on opposite sides of the film and a pair of belts that carry the film past the blocks, “wherein at least one of the blocks has a source of heat” used to seal the film. Fuss ’377 col. 8, ll. 1–29. Fuss ’904, issued May 5, 2009, is a continuation of the Fuss ’377 patent and claims a system for making air-filled cushions. The system comprises a preconfigured film with cushion chambers and a longitudinally extending channel near the edge of the film, and an apparatus for inflating and sealing the preconfigured film. Fuss ’904 col. 7, l. 56 –

which represented a 136% increase over the three year period.

II. PROCEDURAL HISTORY

This action began on April 29, 2009, when Pregis filed suit in the United States District Court for the Eastern District of Virginia seeking a declaratory judgment of noninfringement and invalidity of the Fuss '377 patent. Pregis also took the unusual step of suing the PTO, its then-acting Director John J. Doll, and Free-Flow under the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701–706, to prevent the issuance of two then-pending Free-Flow patent applications. Those two applications issued as the Fuss '904 and Perkins '837 patents.

Pregis then amended its complaint to allege that the issuance of the patents by the PTO was arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law. Pregis alleged that the PTO failed to discharge its statutory duty to determine whether the claims of the patents were nonobvious over the prior art as required by 35 U.S.C. § 103(a), and that the PTO's stated reasons for issuing the patents were insufficient to support the conclusion that the allowed claims were nonobvious. Pregis sought judgment to hold unlawful and set aside the actions of the PTO in issuing the Perkins '837 and Fuss '904 patents. Pregis also amended its complaint to include claims for declaratory judgment of noninfringement and invalidity of the Fuss '904 and Perkins '837 patents. Free-Flow filed counterclaims for infringement of the Fuss '377, Fuss '904, and Perkins '837 patents, and further alleged infringement of the Perkins '397 patent. In response, Pregis added the Perkins '397 patent to its APA claims.

The district court dismissed Pregis' APA claims for lack of subject matter jurisdiction on August 14, 2009. In

a bench ruling, the court held “the Patent Act and its own scheme clearly expresses Congress’ intent to preclude putative third party infringers from seeking judicial review” under the APA of PTO decisions to issue patents. J.A. 3775.

A jury trial was held on February 1–25, 2010 on the issues of infringement and obviousness. The jury returned a verdict finding all asserted claims of Fuss ’377 (claims 1, 3, and 4), Fuss ’904 (claims 4, 6, 7, and 10), and Perkins ’837 (claims 1–3 and 5–14) invalid as obvious, but found the asserted claims of Perkins ’397 not invalid. The jury found none of the asserted claims of the Fuss ’337, Perkins ’837, or Perkins ’397 patents infringed, and found only claim 10 of Fuss ’904 infringed. The jury found no willful infringement and awarded zero damages to Free-Flow. The district court denied Free-Flow’s post-trial motions for judgment as a matter of law as to infringement, willful infringement, validity, and damages. *Pregis Corp. v. Doll*, No. 1:09-cv-467, slip op. at 3 (E.D. Va. Aug. 10, 2010).

Free-Flow appeals the denial of its motions for judgment as a matter of law as to validity and infringement of the Fuss ’904, Fuss ’377 and Perkins ’837 patents. On appeal, Free-Flow does not contest the district court’s denial of judgment as a matter of law as to infringement of the Perkins ’397 patent. Pregis cross-appeals the dismissal of its APA claims, the district court’s grant of summary judgment in favor of Free-Flow on Pregis’ additional invalidity defenses, and additional rulings by the district court including the jury instructions and burden of proof applied to the invalidity defenses. This court has jurisdiction over the appeal and cross-appeal under 28 U.S.C. § 1295(a)(1).

III. STANDARD OF REVIEW

This court reviews the grant or denial of a motion for judgment as a matter of law under regional circuit law, in this case the United States Court of Appeals for the Fourth Circuit. *Revolution Eyewear, Inc. v. Aspex Eyewear, Inc.*, 563 F.3d 1358, 1370 (Fed. Cir. 2009). The Fourth Circuit reviews a district court’s denial of judgment as a matter of law *de novo*. *In re Wildewood Litigation*, 52 F.3d 499, 502 (4th Cir. 1995). The reviewing court determines “whether a jury, viewing the evidence in the light most favorable to [the prevailing party], could have properly reached the conclusion reached by the jury.” *Id.* Entry of judgment as a matter of law is not appropriate when “there is substantial evidence in the record upon which the jury could find for [the prevailing party].” *Id.*

Federal Circuit law applies to “issues of substantive patent law and certain procedural issues pertaining to patent law.” *Research Corp. Techs., Inc. v. Microsoft Corp.*, 536 F.3d 1247, 1255 (Fed. Cir. 2008); *see also* *Midwest Indus. Inc. v. Karavan Trailers, Inc.*, 175 F.3d 1356, 1359 (Fed. Cir. 1999) (en banc in relevant part). “A determination of infringement is a question of fact that is reviewed for substantial evidence when tried to a jury.” *ACCO Brands, Inc. v. ABA Locks Mfr. Co.*, 501 F.3d 1307, 1311 (Fed. Cir. 2007).

Obviousness under 35 U.S.C. § 103 is a question of law based on underlying facts. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17 (1966); *Med. Instrumentation & Diagnostics Corp. v. Elekta AB*, 344 F.3d 1205, 1220 (Fed. Cir. 2003). What a reference teaches and whether a person of ordinary skill in the art would have been motivated to combine the teachings of separate references are questions of fact. *In re Gartside*, 203 F.3d

1305, 1316 (Fed. Cir. 2000); *Para-Ordnance Mfg. v. SGS Imps. Int'l*, 73 F.3d 1085 (Fed. Cir. 1995). This court reviews a jury's conclusions on obviousness *de novo*, "and the underlying findings of fact, whether explicit or implicit in the verdict, for substantial evidence." *LNP Eng'g Plastics, Inc. v. Miller Waste Mills, Inc.*, 275 F.3d 1347, 1353 (Fed. Cir. 2001).

This court reviews *de novo* the district court's dismissal of Pregis' APA claims against the PTO for lack of subject matter jurisdiction. *Cf. ABB Inc. v. Cooper Indus., LLC*, 635 F.3d 1345, 1348 (Fed. Cir. 2011).

IV. THE ASSERTED CLAIMS OF THE FUSS '377,
FUSS '904, AND PERKINS '837 PATENTS ARE INVALID
FOR OBVIOUSNESS

An obviousness analysis is based on underlying factual inquiries including: (1) the scope and content of the prior art, (2) the differences between the claimed invention and the prior art, (3) the level of ordinary skill in the art, and (4) objective indicia of nonobviousness. *Graham*, 383 U.S. at 17–18; *Eli Lilly & Co. v. Teva Pharm. USA, Inc.*, 619 F.3d 1329, 1336 (Fed. Cir. 2010). "The ultimate judgment of obviousness is a legal determination." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 427 (2007). When a jury has found a claim to be obvious, this court presumes the jury resolved all factual disputes in favor of the verdict. *Agrizap, Inc. v. Woodstream Corp.*, 520 F.3d 1337, 1343 (Fed. Cir. 2008).

Free-Flow does not dispute that the prior art cited at trial, with some modifications, teaches every element of the asserted claims of the Fuss '377, Fuss '904, and Perkins '837 patents. Rather, Free-Flow asserts there was no evidence of a reason to combine the prior art references in the manner required to arrive at Free-Flow's asserted claims. Free-Flow also argues that the prior art taught

away from such combination. This court finds there is substantial evidence to support the factual underpinnings of the jury verdict finding claims 1, 3 and 4 of Fuss '377, claims 4, 6, 7, and 10 of Fuss '904, and claims 1–3 and 5–14 of Perkins '837 invalid for obviousness. We affirm the district court's denial of Free-Flow's motion for judgment as a matter of law on validity of these claims.

The primary invalidating reference presented by Pregis is expired U.S. Patent No. 3,868,285 to Troy ("Troy '285"), which issued in 1975. Troy '285 discloses a machine for making bubble-wrap type cushion material from prefabricated flat film stock. Troy '285 col. 1, ll. 43–47. The Troy '285 machine includes multiple "sealing bands" so that, rather than making a single seal along one edge of the air-filled film, multiple seals are made parallel to the longitudinal edges of the film. This forms smaller sealed chambers to create a "bubble wrap" effect. Troy '285 teaches that its apparatus can be used to "produce a variety of cushionings, each having cells of different shape and volume than the others." Troy '285 col. 12, l. 63 – col. 13, l. 1.

Pregis' technical expert, Dr. Maslen, presented detailed claim charts and testimony explaining how the Troy '285 patent discloses every element of the asserted claims of Fuss '377. Dr. Maslen testified that a person of ordinary skill in the art would need only remove or disable the multiple sealing bands in order to adapt the machine to make larger air pillows rather than bubble wrap.

Dr. Maslen testified that expired U.S. Patent No. 3,660,189 to Troy ("Troy '189"), issued in 1972, and U.S. Patent No. 4,017,351 to Larson ("Larson") each disclose preconfigured plastic films like those required by the system claims of the Fuss '904 and Perkins '837 patents.

Although bubble-wrap packaging is the preferred embodiment disclosed in Troy '189, the patent also teaches that its preconfigured films “can be fabricated directly into inflatables of various types with many uses,” including “[d]isposable cushions or pads for tightly packaging merchandise.” Troy '189 col. 19, ll. 63–70.

Dr. Maslen explained that the Troy '189 film or the Larson film could be fed through the Troy '285 machine by one of ordinary skill in the art, making only technically trivial modifications to the machine. Dr. Maslen testified that the combination of the Troy '189 film or Larson film and the Troy '285 machine, with such modifications, meets all the limitations of the asserted claims of Perkins '837 and Fuss '904. Free-Flow contends Dr. Maslen's testimony was inadequate because he declined to testify as to the legal conclusion that the combination of the prior art teachings he presented rendered the asserted claims “obvious.” The ultimate legal conclusion of obviousness, however, was appropriately left to the district court and to this court on review of the verdict. *See Avia Grp. Int'l, Inc. v. L.A. Gear Cal., Inc.*, 853 F.2d 1557, 1564 (Fed. Cir. 1988) (expert testimony on the ultimate “legal conclusion of obviousness is neither necessary nor controlling”).

Free-Flow's next argument is that the prior art taught away from using the Troy '285 machine in the manner suggested by Dr. Maslen. Larson states that the machines taught by Troy '189 and Troy '285 were “complex and expensive.” Larson col. 1, ll. 41–47. Larson also states that the Troy system's method of “sealing across the full width of the inflated chambers causes wrinkles which tend to leak air through the sealed areas.” *Id.* Dr. Maslen testified that “if you left [the multiple sealers of Troy '285] in, you would perhaps suffer from some wrinkling.” Nonetheless, he opined that by adapting the machine to make air pillow packaging with only a single

seal, the problems of wrinkling and leaky seals would be alleviated.

The record contains substantial evidence to support the jury's implicit finding that the prior art did not teach away. Given the modest modifications required to use the Troy '285 machine to make air pillow packaging, the jury reasonably could find that those skilled in the art would have been motivated to simplify the Troy '285 machine in precisely the way suggested by Dr. Maslen. We are also not persuaded by Free-Flow's argument that removing the mechanism used to create the bubble wrap contravenes the basic teaching of Troy. The mere fact that Troy '285 teaches creation of bubble-wrap as a preferred embodiment does not constitute "teaching away" from other reasonable uses of the Troy '285 machine. *See In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004).

At trial, Free-Flow presented evidence of copying and commercial success as objective indicia of nonobviousness. As to copying, Pregis representatives conceded that the company's predecessor, Pactiv, analyzed Free-Flow's EZ I machine and "replicated certain unpatented components of it." J.A. 418. Free-Flow's technical expert, Dr. Kazerooni, testified to a litany of features on the accused Pregis AirSpeed 5000 that are "substantially identical" to features of the EZ I machine, but did not show that those features were claimed in the patents in suit. The jury also heard evidence from which it could conclude that the EZ I machine did not embody the Free-Flow Patents at all. Similarly, the jury heard conflicting evidence regarding the nexus between the commercial success of Free-Flow's EZ I and EZ II machines and the claimed features of the Free-Flow Patents. Pregis' expert testified, for example, that factors such as ease of use of the system electronics, cost of supplied film, customer service, and speed of maintenance—none of which were shown to be

related to the claimed elements of the Free-Flow Patents—determine commercial success in the air-pillow packaging industry.

The lack of nexus between the claimed subject matter and the commercial success or purportedly copied features of the EZ I machine renders Free-Flow’s proffered objective evidence uninformative to the obviousness determination. *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1311–12 (Fed. Cir. 2006) (“Evidence of commercial success, or other secondary considerations, is only significant if there is a nexus between the claimed invention and the commercial success.”) Having considered the conflicting evidence, the jury concluded that the asserted claims of Fuss ’377, Fuss ’904, and Perkins ’837 are invalid for obviousness. This court holds that the jury’s underlying factual findings related to obviousness were supported by substantial evidence, and we affirm the legal conclusion that the asserted claims are invalid as obvious.

Because we hold that the asserted claims of the Fuss ’377, Fuss ’904 and Perkins ’837 patents are invalid, this court need not reach, and declines to address, Pregis’ remaining defenses and Free-Flow’s appeal of the denial of its motion for judgment as a matter of law of infringement.

V. ADMINISTRATIVE PROCEDURE ACT CLAIMS

The APA provides that “[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof.” 5 U.S.C. § 702. A PTO decision to issue a patent is an “agency action” under the APA. *See Dickinson v. Zurko*, 527 U.S. 150, 154 (1999). The APA sets forth several limitations on the grant of judicial review set out in § 702. Relevant here, the APA applies “*except to the extent that* -

(1) *statutes preclude judicial review . . .*” 5 U.S.C. § 701(a)(1) (emphasis added). Additionally, the APA authorizes judicial review of final agency actions only if “there is no other adequate remedy in a court.” 5 U.S.C. § 704.

The question here is whether a competitor, who has been sued as an infringer, is entitled under the APA to judicial review of the PTO’s decision to grant the patents in suit. Pregis asserts a right to challenge two distinct aspects of a PTO “decision to issue” a patent: 1) the PTO’s stated reasons for allowing the claims during examination under 35 U.S.C. § 131, and 2) the issuance of the patent itself. Pregis argues the need to permit competitors to challenge the PTO’s stated reasons for allowance is illustrated by the prosecution history of the Perkins ’397 patent. The PTO allowed the claims of Perkins ’397 based on arguments made by Free-Flow’s patent attorney to distinguish a prior art reference. During the litigation of this case, Free-Flow conceded that its attorney’s arguments during prosecution were based on a misunderstanding of the prior art and were incorrect. Thus, at trial, Free-Flow argued Perkins ’397 was patentable over the prior art on a different basis. Pregis argues it should be permitted to bring an APA claim challenging the PTO’s reasons for allowance in addition to an invalidity defense—which is subject to a corresponding presumption of validity—in litigation against the patentee. Pointing to § 702 of the APA, Pregis asserts it was “adversely affected or aggrieved” by the PTO’s action because the Free-Flow Patents “purported to impose a direct regulation and restriction on Pregis’ business by excluding Pregis from making use of subject matter that was in the public domain . . . , and by exposing Pregis to claims for alleged infringement by its direct competitor, [Free-Flow].” Cross-Appellant Br. 55.

The district court dismissed Pregis' APA claims and held that the Patent Act's comprehensive scheme precludes putative third party infringers from seeking judicial review of PTO decisions to issue patents. J.A. 3775–76. The district court based its holding on *Syntex (U.S.A.) Inc. v. United States Patent & Trademark Office*, 882 F.2d 1570 (Fed. Cir. 1989), in which this court affirmed dismissal of a suit against the PTO by a third party reexamination requester.

Indeed, this court has twice previously stated that a potential infringer cannot sue the PTO under the APA to attack the validity of an issued patent. In *Syntex*, we framed the jurisdictional issue as whether the patent statute impliedly grants a third party requester a right to review of the PTO's final decision in reexamination. *Id.* at 1572. This court determined in *Syntex* that the Patent Act's "clear, comprehensive statutory scheme" indicates that Congress intended to limit appeals from reexamination to the mechanisms specifically provided for by statute. *Id.* at 1573. The creation of a right in a third party to challenge a result favorable to a patent owner after *ex parte* prosecution cannot be inferred. *Id.* at 1575. We explicitly pointed out that "a potential infringer may not sue the PTO seeking retraction of a patent issued to another by reason of its improper allowance by the PTO." *Id.* at 1576.

In *Animal Legal Defense Fund v. Quigg*, 932 F.2d 920 (Fed. Cir. 1991) ("ALDF"), this court held that plaintiffs, various individual farmers and organizations whose goal is the protection of animals, lacked standing to sue under the APA to enjoin the PTO from issuing patents on multicellular living organisms because the plaintiffs failed to show injury traceable to the PTO's actions, and because plaintiffs were outside the zone of interests addressed by the Patent Act. This court held that the zone of interests

of the patent laws does not extend to “any member of the public who perceives they will be harmed by an issued patent.” *Id.* at 938. In so holding, we specifically declined to “open[] the door to collateral attack on the validity of issued patents” by permitting competitors to sue the PTO to challenge a patent’s validity. *Id.* As we held, “[t]he structure of the Patent Act indicates that Congress intended only the remedies provided therein to ensure that the statutory objectives would be realized.” *Id.*

Both *Syntex* and *ALDF* addressed challenges to PTO determinations in a factual context different from that of this case, but the reasoning expressed by the court in those cases applies here. We affirm the district court’s dismissal of Pregis’ APA claims and hold that a third party cannot sue the PTO under the APA to challenge a PTO decision to issue a patent. The comprehensive legislative scheme of the Patent Act “preclude[s] judicial review” of the reasoning of PTO decisions to issue patents after examination under 35 U.S.C. § 131, and competitors have an “adequate remedy in a court” for the issuance of invalid patents. 5 U.S.C. §§ 701(a)(1), 704.

A. The Patent Act Precludes Review Under the APA

To determine whether a particular statute precludes judicial review, we look to its express language, the structure of the statutory scheme, its legislative history and purpose, and the nature of the administrative action involved. *Block v. Cmty. Nutrition Inst.*, 467 U.S. 340, 345 (1984). There is a “strong presumption” that Congress did not intend to prohibit all judicial review of a type of agency action. *Bowen v. Mich. Acad. of Family Physicians*, 476 U.S. 667, 672 (1986); *Dunlop v. Bachowski*, 421 U.S. 560, 567 (1975).

A statute need not explicitly state that judicial review is unavailable for preclusion to be found. *See Bowen*, 476

U.S. at 671 (“To preclude judicial review under [the APA] a statute, if not specific in withholding such review, must upon its face give clear and convincing evidence of an intent to withhold it.”) (quoting H.R. Rep. No. 1980, 79th Cong., 2d Sess. 41 (1946)). For example, “when a statute provides a detailed mechanism for judicial consideration of particular issues at the behest of particular persons, judicial review of those issues at the behest of other persons may be found to be impliedly precluded.” *Block*, 467 U.S. at 349. As such, judicial review may be precluded when Congressional intent to do so is “fairly discernible in the statutory scheme.” *Id.* at 351 (quoting *Assoc. of Data Processing Serv. Orgs., Inc. v. Camp*, 397 U.S. 150, 157 (1970)).

The Patent Act expressly provides an intricate scheme for administrative and judicial review of PTO patentability determinations that evinces a clear Congressional intent to preclude actions under the APA seeking review of the PTO’s reasons for deciding to issue a patent. First, the Patent Act establishes specific procedures allowing a patent applicant to appeal PTO rejections of patent claims. 35 U.S.C. §§ 134, 141, 145. Second, the statute permits third parties to challenge issued patents through carefully-circumscribed reexamination proceedings. 35 U.S.C. §§ 301–307, 311–318 (2006).¹ Third, putative

¹ Congress extensively revised this scheme with the passage of new post-grant review and *inter partes* review procedures as part of the Leahy-Smith America Invents Act (“AIA”). Leahy-Smith America Invents Act, Pub. L. No. 112-29, sec. 6, 125 Stat. 284 (2011) (to be codified at Chapters 30-32 of Title 35). Because at all times relevant to this appeal the provisions of the AIA governing post-grant review had not yet taken effect, this opinion discusses the Patent Act as it existed prior to the AIA. Nevertheless, the fact that Congress has prescribed detailed new procedures for administrative and judicial

infringers with a sufficiently immediate controversy may challenge the validity of issued patents through a declaratory judgment action, or can raise invalidity as a defense to an infringement suit. 28 U.S.C. § 2201(a); 35 U.S.C. § 282; *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007).

The Patent Act thus presents several mechanisms by which third parties may challenge the PTO's decision to issue a patent, unlike cases in which preclusion of a suit under the APA would leave an agency action entirely free from judicial review. *Cf. Bowen*, 476 U.S. at 678 (holding “it is implausible to think [Congress] intended that there be *no* forum to adjudicate statutory and constitutional challenges to regulations promulgated by the Secretary” for the method by which Medicare Part B payments are calculated) (emphasis original). Having considered and addressed the need for review of PTO patentability determinations, Congress enacted specific procedures allowing third parties to attack the *validity* of issued claims. It is apparent that Congress decided not to provide for third parties to obtain review of the *reasons* for allowance of claims.

The carefully balanced framework of the Patent Act specifies a well-defined process for how, when, where, and by whom PTO patentability determinations may be challenged. Only a patent applicant may challenge an examiner's decision to reject claims in original examination under 35 U.S.C. § 131. The applicant must first bring an administrative appeal to the Board of Patent Appeals and Interferences (the “Board”). 35 U.S.C. § 134(a). The applicant may then appeal the Board's

review of issued patents reinforces the conclusion that Congress intended to preclude other avenues of judicial review.

decision in this court under 35 U.S.C. § 141, or may file suit against the PTO in the United States District Court for the District of Columbia under 35 U.S.C. § 145.² A third party, by contrast, cannot challenge an examiner's decision after original examination, but only may obtain judicial review of PTO decisions confirming patentability by first participating in *inter partes* reexamination.³ 35 U.S.C. §§ 134(c), 141.

The Patent Act thus reflects Congressional intent as to which parties should be permitted to challenge the examiner's patentability determination made during original examination. That the Patent Act dictates the courts in which a disappointed applicant may appeal a patentability determination also shows Congress intended to preclude challenges to such PTO actions under the APA. Every district court of the United States has jurisdiction over an APA claim, while the patent applicant is restricted to review in a single district court or to a direct appeal to the Federal Circuit. 35 U.S.C. §§ 141, 145. Moreover, Congress has protected the interests of competitors and the public through the mechanisms explicitly provided to them in the Patent Act to challenge the validity of issued patents. Preclusion of APA suits challenging the PTO's reasons for issuing a patent therefore does not "threaten realization of the fundamental objectives of the statute" to promote innovation by incentivizing inventors without unduly limiting competition. *Block*, 467 U.S. at 352.

² We note that under the current version of § 145, actions are to be brought in the Eastern District of Virginia, but Congress has retained a statutory scheme that dictates the court in which such actions must be brought.

³ Similarly, under the AIA, a third party may resort to either post-grant review or *inter partes* review after issuance. See AIA secs. 7(b), (c).

We conclude that a Congressional intent to preclude judicial review of the PTO's reasons for issuing patents is "fairly discernible" from the statutory scheme of the Patent Act. *Block*, 467 U.S. at 351. Allowing competitors to collaterally attack issued patents through suits under the APA would destroy the Patent Act's careful framework for judicial review at the behest of particular persons through particular procedures.

B. Adequate Remedies are Available

The APA authorizes judicial review only where the agency action is "made reviewable by statute" or where there is a "final agency action for which there is no other adequate remedy in a court." 5 U.S.C. § 704. As we have held, the PTO's decision to issue a patent during original examination is not "made reviewable by statute." Thus, the review Pregis seeks under the APA is barred by § 704 unless "there is no other adequate remedy" available in court.

The Patent Act provides three different adequate remedies in court for competitors harmed by the PTO's erroneous issuance of a patent. The Patent Act allows any third party to request an *inter partes* reexamination by raising a substantial new question of patentability. 35 U.S.C. §§ 301, 311. A participant in *inter partes* reexamination may obtain judicial review of a PTO decision to allow claims after reexamination by appealing to the Board and then, if necessary, to this court. 35 U.S.C. § 315(b). Additionally, a putative infringer can raise invalidity as a defense to a patent suit or can proactively bring a declaratory judgment action against the patent owner to have the patent declared invalid. 35 U.S.C. § 282. Each of these avenues provides review, in an Article III court, of the validity of patents issued by the PTO.

In litigation against the patentee, the putative infringer can attack the patent on a wide variety of substantive grounds (e.g., failure to comply with the conditions for patentability set forth in Part II of Title 35, or with the written description, enablement, definiteness and other requirements of § 112). 35 U.S.C. § 282(b). These are generally the same criteria on which the PTO reviews patentability, and thus present the same issues that would be raised in a direct challenge to the PTO's reasons for issuing the patent. If successful, the relief granted—invalidation of patent claims—fully relieves the harm caused by the PTO having erroneously issued the patent.

Pregis argues that because not all PTO mistakes are recognized as defenses under § 282, a declaratory judgment action or the defenses in an infringement suit are not an adequate judicial remedy. *See Aristocrat Techs. Australia Pty Ltd. v. Int'l Game Tech.*, 543 F.3d 657, 662-63 (Fed. Cir. 2008) (improper revival of abandoned application is not a cognizable defense to infringement claim). Yet, the specific list of defenses available under § 282 reflects the deliberate judgment of Congress that not every error during prosecution should provide a defense to a claim of patent infringement.

Similarly, Pregis argues that the presumption of validity of an issued patent, which can be overcome only by “clear and convincing evidence,” renders patent litigation an inadequate alternative to review under the APA. Pregis asserts that a civil action under 5 U.S.C. § 702 would not give such weight to the PTO decision being challenged. 5 U.S.C. § 706. Regardless, a suit under the APA would impermissibly alter the burden of proof, set by Congress and confirmed by the Supreme Court, for invalidating a patent. *See* 35 U.S.C. § 282; *Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238, 2246 (2011) (holding

Congress chose the “clear and convincing” standard of proof by stating in § 282 that a patent is “presumed valid”).

Furthermore, a judicial remedy is adequate for purposes of 5 U.S.C. § 704 even if it does not “provide relief identical to relief under the APA, so long as it offers relief of the ‘same genre.’” *Garcia v. Vilsack*, 563 F.3d 519, 523 (D.C. Cir. 2009). A private lawsuit against a third party, such as litigation of patent validity in an action against the patentee, need not be “as effective as an APA lawsuit against the regulating agency.” *Id.* at 525. The alternate remedy in court need only be “adequate” for it to supplant a suit under the APA. *Id.*; 5 U.S.C. § 704. In sum, the fact that the defenses available under 35 U.S.C. § 282, or in a challenge to a patent through *inter partes* reexamination, are not identical to an APA suit does not render the carefully-considered judicial remedies provided by the Patent Act “inadequate.”⁴

VI. CONCLUSION

For the reasons above, this court affirms the judgment of the district court.

AFFIRMED

COSTS

Each party shall bear its own costs.

⁴ Because we hold that third parties are not entitled to judicial review under the APA of PTO decisions to issue patents, we need not address the additional standing issues raised by Free-Flow on appeal.