# United States Court of Appeals for the Federal Circuit

2007-1534
(Reexamination No. 90/006,785)

IN RE MELVIN J. SWANSON
and PATRICK E. GUIRE

Robert M. Asher, Bromberg & Sunstein LLP, of Boston, Massachusetts, argued for appellants.

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Appealed from: United States Patent and Trademark Office
Board of Patent Appeals and Interferences

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Appeal from the United States Patent and Trademark Office, Board of Patent Appeals and Interferences.

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DECIDED: September 4, 2008

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Before LOURIE, BRYSON, and GAJARSA, Circuit Judges.

GAJARSA, Circuit Judge.

This is an appeal from the United States Patent and Trademark Office's ("PTO") Board of Patent Appeals and Interferences ("Board"). The Board upheld the examiner's rejection of claims 22-25 of U.S. Patent No. 5,073,484 ("the '484 patent") in a reexamination proceeding. In re Swanson, No. 2005-0725, Reexamination No. 90/006,785 (B.P.A.I. May 29, 2007). Previously, this court had affirmed a district court judgment that claims 22 and 23 of the '484 patent were not invalid. Abbott Labs. v. Syntron Bioresearch, Inc., 334 F.3d 1343 (Fed. Cir. 2003) ("Abbott Labs. II"). We hold that under 35 U.S.C. § 303(a), as amended in 2002, despite consideration of U.S. Patent No. 4,094,647 ("Deutsch") in the initial examination and our prior decision, there was a substantial new question of patentability regarding whether Deutsch anticipated and made obvious claims 22-25 that made reexamination warranted. As the patentee

does not raise additional objections to the Board's rejections over Deutsch, the Board's finding that claims 22-25 of the '484 patent were anticipated and would have been obvious in light of Deutsch is affirmed.

I.

A. The '484 Patent

The '484 patent was filed on February 23, 1983, by Melvin Swanson and Patrick Guire. The patent discloses a method of quantitatively analyzing small amounts of biological fluids, such as milk, blood, and urine, or other solutions, to detect the presence of a particular substance (the analyte). In the method disclosed, one or more "reaction zones" containing a bound reactant are spaced out on a test strip made of a liquid-permeable solid. '484 patent col.2 ll.6-10. A test solution is applied to the test strip and moves along a flow path, encountering these reactant-containing zones sequentially. When a solution containing the requisite analyte reaches each of the reaction zones, a predetermined product forms. Id. col.2 ll.12-14. Selected detectors in the reaction zones indicate, preferably by a change of color, the presence of analyte, reactant, or predetermined product. Id. col.8 ll.47-54. The specification does not limit the invention to any one type of detection and suggests that the analyte can be "substantially all chemical substances that are reactive with a reactant to form a product." Id. col.7 ll.16-19.

Claim 22, the independent claim at issue, is characteristic of the patent and claims a method of detection in which the analyte and reactant form a ligand-antiligand binding pair:

> A method for analysis of an analyte which is a member of a ligand-antiligand binding pair in a test solution comprising the steps of:

(a) providing a non-diffusively immobilized reactant in each of one or more reaction zones spaced successively along a flow path defined by a liquid permeable medium, wherein said reactant is the other member of said binding pair and is capable of binding with the analyte to form a predetermined product;

(b) flowing said solution along the medium and sequentially through the reaction zone(s); and

(c) detecting the presence of analyte, said reactant or said predetermined product in the reaction zone(s), wherein the number of zones in which detection occurs is related to the presence [sic] of analyte solution.

Id. col.18 ll.9-25. A preferred embodiment is an immunoassay, in which the ligand-antiligand pair is an antigen-antibody pair.

In addition to claim 22, there are three dependent claims relevant to this appeal: claims 23, 24, and 25. Claim 23 limits the ligand-antiligand pair by requiring that one part of the pair be "labeled with a chemical moiety, and wherein such detecting step comprises detecting the presence of said chemical moiety." Id. col.18 ll.26-30. Claims 24 and 25 additionally limit the chemical moiety to including an enzyme and being a radioisotope, respectively. Id. col.18 ll.31-34.

B. Prior Art

U.S. Patent No. 4,094,647 ("Deutsch") also discloses a method of detecting ligand-antiligand binding pairs in order to determine the presence of a ligand (the analyte) in a biological fluid sample. In Deutsch, a test strip is prepared in which a reagent is immobilized in a downstream portion of the strip and the test solution is applied to the other end. The edge of the strip is then immersed in "developing fluid" which progresses upstream. Deutsch col.3 ll.59-62. When the developing fluid reaches the test solution, the two liquids combine and advance through the reaction zone(s) to

the terminating end. Id. col.3 ll.63-64. If analyte is present, it binds with the reagents in the reaction zones and forms a detectable product. The detectable product may be labeled with "any chemical substance or moiety having a detectable characteristic" including radioactivity. Id. col.8 ll.60-67. A preferred embodiment is an immunoassay, or immunoreaction, in which the reactant contains an antibody capable of specifically binding to the antigen in the test sample.

U.S. Patent No. 3,641,235 ("Weiss") teaches a similar immunoassay method for visually detecting the presence of an analyte in biological fluid. In Weiss, the visual readout is an indicator that is either fixated in the reaction zone in the presence of the analyte or released in the presence of the analyte, in which case the release can be observed by the presence of the indicator material in the fluid front of the test solution moving forward on the strip. Weiss cols. 3-5.

U.S. Patent No. 3,466,241 ("Tom") discloses another immunoassay method, in which one of the reagents comprises "a signal creating system." Tom col.3 ll.1-5, ll.47-49. Tom's signal producing system includes "radioactive substances, enzymes and chromogenic substances . . . ." Id. col.5 ll.1-10.

C. Initial Examination

The examiner initially rejected all the claims in the application that resulted in the '484 patent as obvious under 35 U.S.C. § 103, in light of various combinations of references. Office Action No. 467229, September 7, 1984 ("Original Office Action"). The method claimed in original claim 9 was nearly identical to the one claimed in claim 22 of the issued patent, differing primarily in that it required multiple reaction zones and

did not require that the analyte-reactant pair be a ligand-antiligand binding pair.[1] Claim 9 was rejected (along with claims 1, 2, 4-6, and 8) "under 35 U.S.C. 103 as being unpatentable over either Morison or Bauer et al in view of Peurifoy et al." Id. at 9. The examiner explained that Morison and Bauer each disclose a method that is "basically the same" as that disclosed by the applicants, and that it would have been obvious that the reagent in Morison and Bauer could be separated into multiple reaction zones to permit quantification, as described in Peurifoy. Id. In the application as filed, claim 10 was dependent on claim 9 and added the limitation that the analyte and reactant be a "specific ligand-antiligand binding pair." Claim 11 further specified that the reactant in the ligand-antiligand binding pair of claim 10 include an antibody. The examiner rejected these and similar dependent claims under 35 U.S.C. § 103 "as being unpatentable over either Morison or Bauer et al in view of Peurifoy et al as applied to claims 1, 2, 4-6, 8 and 9 above, and further in view of any one of Ruhenstroth-Bauer et

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[1] Originally filed claim 9 claimed:

> Method for the quantitative analysis of an analyte in a carrier liquid, characterized by the steps of:
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> providing a fluid-permeable solid medium defining a flow path and having predetermined number of successive, spaced reaction zones in the path of flow, said reaction zones having immobilized therein a reactant reactive with the analyte or an analyte derivative or both to result in the formation of a predetermined product;
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> flowing said fluid along the flow path and sequentially through the spaced reaction zones; and
>
> detecting the presence of analyte, analyte derivative, reactant or predetermined product in the reaction zones;
>
> the amount of analyte in the fluid being a function of the number of zones in which such detection occurs.

al, Brown et al and Deutsch et al." Original Office Action at 9. The examiner explained that "it would be obvious that any known reaction within reasons [sic] could be incorporated in the modified method and apparatus of either Morison and [sic] Bauer, as see for example, the immunoreactions of Ruhenstroth-Bauer et al, Brown et al and Deutsch."[2] Id. at 9-10.

The claims were amended, and on December 17, 1991, the '484 patent was granted. Subsequently, the '484 patent was assigned to Surmodics, Inc. ("Surmodics" or "patentee"), the real party at interest in the current proceedings, who exclusively licensed the patent to Abbott Laboratories ("Abbott").

D. Abbott v. Syntron

On December 30, 1998, Abbott sued Syntron Bioresearch, Inc. ("Syntron") for infringement of two patents, one of which was the '484 patent. Syntron counterclaimed that the patents were invalid, claiming, inter alia, that claims 22 and 23 of the '484 patent were invalid in light of Deutsch. On October 4, 2001, the jury returned a special verdict finding that the asserted claims of the patents-in-suit were not infringed and that Syntron had failed to prove by clear and convincing evidence that the claims were anticipated, obvious, or otherwise invalid. The district court entered judgment accordingly. Abbott Labs. v. Syntron Bioresearch, Inc., No. 98-CV-2359 (S.D. Cal. Oct. 12, 2001) ("Abbot Labs I"). Abbott appealed, and Syntron cross-appealed to this court.

[2] The only other mention of Deutsch in the record provided is similar. Dependant claims 17 and 18 were rejected as obvious over Morison or Bauer et al in view of "any one of Ruhenstroth-Bauer et al, Brown et al and Deutsch et al." Again the examiner explained, "it would be obvious to incorporate any reaction within reason in the apparatus of either Morison or Bauer et al, as see the immunoreactions of the secondary art." Id.

On appeal, we affirmed-in-part and remanded-in-part the judgment of noninfringement of the '484 patent and affirmed the judgment of validity on all asserted claims of the '484 patent. Abbott Labs. v. Syntron Bioresearch, Inc., 334 F.3d 1343 (Fed. Cir. 2003) ("Abbott Labs. II"). In particular, we sustained the judgment that Deutsch did not anticipate the asserted claims, noting that "the burden having been on Syntron to prove by clear and convincing evidence that the claims were anticipated, we cannot conclude that the jury verdict on anticipation was not supported by substantial evidence." Id. at 1357. We explained that the only issue raised regarding anticipation was whether Deutsch teaches "flowing said solution along the medium." We agreed that the jury reasonably could have found it did not because "the jury could have reasonably interpreted the language of the claims standing alone, as requiring that the solution itself provide the required flow." Id.

E. Reexamination

Following the appeal, Syntron filed a request for an ex parte reexamination of the '484 patent, claiming that there was a substantial new question of patentability. See 35 U.S.C. § 303(a). The examiner granted the request. After reviewing the claims in light of prior art, the examiner rejected claims 22, 23, and 25 as anticipated by Deutsch and claims 22 and 23 as anticipated by Weiss under 35 U.S.C. § 102(b), and claim 24 as obvious under 35 U.S.C. § 103 in light of Deutsch and a secondary reference, Tom. Office Action No. 006785, Nov. 15, 2004, at 3-6 ("Reexamination Office Action").

The Board affirmed the examiner's rejections. In re Swanson, No. 2005-0725, Reexamination No. 90/006,785 (B.P.A.I. May 29, 2007). First, the Board rejected the patentee's argument that Weiss lacks detection "in the reaction zone" and agreed with

the examiner that, "detection may occur in a 'reaction zone' by determining if dye has been displaced from the particle or not." Id. at 13. The Board also rejected the patentee's argument that Weiss's invention, which included using an indicator that is adsorbed by the antiligand, and which can be associated and dissociated with the ligand, did not meet the "labeled" requirement of claim 23. Second, the Board affirmed the examiner's finding that Deutsch anticipated claims 22, 23, and 25, rejecting the patentee's argument that Deutsch cannot anticipate the claims since it uses a developing fluid to provide the required flow through the test medium. The Board agreed with the examiner that "the claim is open to additional steps as it uses the term 'comprising'" and that "claim 22 does not contain a limitation requiring that the test solution itself provide the flow." Id. at 17. Lastly, the Board rejected the patentee's claim that reexamination was improper as to Deutsch because Deutsch does not raise "a substantial new question of patentability" as required by 35 U.S.C. § 303. The Board found that the reference did raise a substantial new question of patentability despite having been cited in the original office action because it was not cited in regard to the presently rejected claims and it was not relied upon for the same reason the examiner now relied upon it. The Board also dismissed the patentee's argument that Deutsch could not raise a substantial new question of patentability because a jury had affirmed a finding of validity over the reference and the Federal Circuit had affirmed. Id. at 19.

Surmodics filed this timely appeal, over which we have jurisdiction pursuant to 28 U.S.C. § 1295(a)(4).

Surmodics objects to the rejection of claims 22-25 on two grounds. First, it argues that the Board erred in affirming the examiner's determination that Weiss

anticipated claims 22 and 23. Second, it argues that the reexamination of claims 22-25 on the basis of Deutsch was improper under § 303(a) because Deutsch does not raise a substantial new question of patentability. According to Surmodics, the consideration of anticipation by Deutsch in the district court litigation precludes a finding of a new question of patentability for the purposes of the reexamination, and it argues that to find otherwise would raise substantial questions regarding the constitutionality of the statute. In addition, Surmodics argues that the examiner's consideration of Deutsch in the original proceedings also precludes finding a new question of patentability.

The PTO's rejection based on Weiss did not include any claims not also rejected under Deutsch. As we conclude that neither the district court action nor the initial examination bars the PTO's consideration of Deutsch in the reexamination proceedings, and the patentee does not challenge the rejection of claims 22-25 in light of Deutsch on the merits, we consider only whether Deutsch raised a substantial new question of patentability and do not reach the issue of whether the Board properly found claims 22 and 23 anticipated by Weiss.

II.

We review the Board's legal conclusions including statutory interpretation de novo. In re Am. Acad. of Sci. Tech Ctr., 367 F.3d 1359, 1363 (Fed. Cir. 2004); Stevens v. Tamai, 366 F.3d 1325, 1330 (Fed. Cir. 2004).[3] In interpreting statutes, we give effect

[3] While the Board's statutory interpretation in a particular case is given no deference, deference may be owed to the PTO's interpretation of statutory provisions concerning "the conduct of proceedings in the Office," 35 U.S.C. § 2(b)(2)(A), made pursuant to its rulemaking authority under 35 U.S.C. § 2(b)(2)(A). See Cooper Techs. Co. v. Dudas, No. 2008-1130, __ F.3d__ (Fed. Cir. 2008) (applying Chevron deference to the PTO's interpretation of a statutory provision concerning the conduct of proceedings in the PTO, instituted after notice and comment proceedings and published

to the intent of Congress by "look[ing] not only to the particular statutory language, but to the design of the statute as a whole and to its object and policy." Crandon v. United States, 494 U.S. 152, 158 (1990). We review the Board's findings of fact for substantial evidence. In re Gartside, 203 F.3d 1305, 1316 (Fed. Cir. 2000).

A. The Reexamination Statute and the Amendment to § 303(a)

Any person may file a request for an ex parte reexamination of an issued patent based on prior art patents or printed publications. 35 U.S.C. § 302. Congress intended reexaminations to provide an important "quality check" on patents that would allow the government to remove defective and erroneously granted patents. H.R. Rep. No. 107-120 (2002); see also In re Recreative Techs. Corp., 83 F.3d 1394, 1396-97 (Fed. Cir. 1996) ("The reexamination statute's purpose is to correct errors made by the government . . . and if need be to remove patents that never should have been granted." (quoting Patlex Corp. v. Mossinghoff, 758 F.2d 594, 604 (Fed. Cir. 1985))).

The PTO, however, may only grant a reexamination request if it determines that "a substantial new question of patentability affecting any claim of the patent concerned is raised by the request."[4] 35 U.S.C. § 303(a); see also id. § 304. The "substantial new question of patentability" requirement prevents potential harassment of patentees by "act[ing] to bar reconsideration of any argument already decided by the [PTO], whether

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in the Federal Register). Deference is also given to the PTO's interpretations of its own procedural rules. See Ballard v. Comm'r of Internal Revenue, 544 U.S. 40, 1288-89 (2005) ("An agency's interpretation of its own rule or regulation is entitled to 'controlling weight unless it is plainly erroneous or inconsistent with the regulation.'" (quoting Bowles v. Seminole Rock & Sand Co., 325 U.S. 410, 414 (1945))).

[4] The PTO may also instigate a reexamination proceeding on its own motion if it determines that prior art patents or printed publications raise a substantial new question of patentability. 35 U.S.C. §§ 303-04.

during the original examination or an earlier reexamination." H.R. Rep. No. 96-1307 (1980). This court, in In re Portola Packaging Inc., 110 F.3d 786 (Fed. Cir. 1997), interpreted this statutory intent as precluding reexamination based on "prior art previously considered by the PTO in relation to the same or broader claims." Id. at 791. Congress disagreed with the restrictive scope of reexamination imposed by this court. See H.R. Rep. No 107-120, at 2 ("[T]he Federal Circuit incorrectly interpreted Congress' original intent underlying the reexamination statute and limited the application of the process."). In 2002 Congress amended § 303(a) to include an additional sentence, explaining that the amendment "overturns the holding of In re Portola Packaging Inc., a 1997 Federal court decision imposing an overly-strict limit that reaches beyond the text of the Patent Act." Id. The reexamination statute now provides, in pertinent part:

> Within three months following the filing of a request for reexamination under the provisions of section 302 of this title, the Director will determine whether a substantial new question of patentability affecting any claim of the patent concerned is raised by the request, with or without consideration of other patents or printed publications. . . . The existence of a substantial new question of patentability is not precluded by the fact that a patent or printed publication was previously cited by or to the Office or considered by the Office.

35 U.S.C.A. § 303(a) (2002) (emphasis added). According to the House Report accompanying the Bill, under the amended § 303(a), "the appropriate test to determine whether a 'substantial new question of patentability' exists should not merely look at the number of references or whether they were previously considered or cited but their combination in the appropriate context of a new light as it bears on the question of the validity of the patent." Id.; see also H.R. Rep. No. 107-120, at 3 ("While this bill clarifies that previously considered prior art will not necessarily bar a request for reexamination,

the bill does not eliminate the requirement for a 'substantial new question of patentability' to be present for the agency to permit reexamination.").

We have not had the opportunity to evaluate the scope of the "substantial new question of patentability" requirement since the 2002 amendment. Thus, this appeal presents issues of first impression. In determining the scope of the substantial new question requirement under the amended statute, "[w]e begin, as always, with the language of the statute." Duncan v. Walker, 533 U.S. 167, 172 (2001). We then turn to the legislative history to further elucidate Congress' intent. See Timex V.I. v. United States, 157 F.3d 879, 882 (Fed. Cir. 1998) ("Beyond the statute's text, [tools of statutory construction] include . . . legislative history."); Deluxe Corp. v. United States, 885 F.2d 848, 850 (Fed. Cir. 1989) (explaining that in a matter of statutory interpretation, "where the text itself does not clearly exclude alternate interpretations, we look first to the legislative history for illumination of the intent of Congress."); Ethicon, Inc. v. Quigg, 849 F.2d 1422, 1426 (Fed. Cir. 1988) (using legislative history in construing a section of the statutory provisions on reexamination); see also Garcia v. United States, 469 U.S. 70, 76 (1984) ("In surveying legislative history we have repeatedly stated that the authoritative source for finding the Legislature's intent lies in the Committee Reports on the bill, which '[represent] the considered and collective understanding of those Congressmen involved in drafting and studying proposed legislation.'").

B. District Court Proceedings

The patentee first argues that the district court's consideration of Deutsch in determining the validity of the '484 patent necessarily precludes the reference from raising a "new" question of patentability in subsequent reexamination proceedings. The

district court and this court did consider the precise question at issue on reexamination: whether Deutsch satisfies the "flowing" limitation of the asserted claims and, thus, anticipates them. And both courts upheld the validity of the '484 patent in light of Deutsch. Nevertheless, the statutory language, legislative history, and different purposes underlying reexamination and federal court proceedings suggest that the determination of a substantial new question is unaffected by these court decisions.

The statute does not define what constitutes a "substantial new question of patentability." However, the language added in the amended statute specifically discusses references "previously cited by or to the Office or considered by the Office," 35 U.S.C. § 303(a) (2002) (emphases added), but does not address any prior citation or consideration by courts. Similarly, the legislative history for both the original and amended reexamination statute suggest that Congress was concerned only with the consideration of issues in prior PTO examinations, not prior civil litigation. For example in passing the original reexamination statute, Congress stated that "this new procedure will permit any party to petition the patent office to review the efficacy of a patent, subsequent to its issuance, on the basis of new information about preexisting technology which may have escaped review at the time of the initial examination of the patent application," and explained that the substantial new question requirement bars "reconsideration of any argument already decided by the office, whether during the original examination or an earlier reexamination." H.R. Rep. No. 96-1307(I), at 3, 7 (1980) (emphasis added). The legislative history of the 2002 amendment similarly states that the test for a substantial new question of patentability should focus on what "the examiner" considered. H.R. Rep. No. 120-107, at 3. Not once in the legislative

history did Congress refer to references or issues addressed in prior civil litigation. See, e.g., H.R. Rep. No. 120-107; H.R. Rep. No. 96-1307(I); cf. Ethicon, 849 F.2d at 1427 (explaining that nothing in the text or legislative history of the reexamination statute supports a finding that one of the purposes of reexamination was to avoid duplication of efforts by the PTO and courts).

The focus on previous examinations rather than prior litigation follows from the fact that "reexamination[s are] conducted according to the procedures established for initial examination," 35 U.S.C. § 305, and PTO examination procedures have distinctly different standards, parties, purposes, and outcomes compared to civil litigation, In re Etter, 756 F.2d 852, 856 (Fed. Cir. 1985). In particular, "the two forums take different approaches in determining validity and on the same evidence could quite correctly come to different conclusions." Ethicon, 849 F.2d at 1428.

In civil litigation, a challenger who attacks the validity of patent claims must overcome the presumption of validity with clear and convincing evidence that the patent is invalid. 35 U.S.C. § 282. If this statutory burden is not met, "[c]ourts do not find patents 'valid,' only that the patent challenger did not carry the 'burden of establishing invalidity in the particular case before the court.'" Ethicon, 849 F.2d at n.3 (internal citations omitted) (emphasis in original). Therefore, "a prior holding of validity is not necessarily inconsistent with a subsequent holding of invalidity," Stevenson v. Sears Roebuck & Co., 713 F.2d 705, 710 (Fed. Cir. 1983), and is not binding on subsequent litigation or PTO reexaminations. See Ethicon, 849 F.2d at 1429 & n.3 (rejecting the PTO's argument that it was bound by a court's decision upholding a patent's validity); Mendenhall v. Cedarapids, 5 F.3d 1557, 1569-70 (Fed. Cir. 1993) ("A prior decision that

a patent has previously survived an attack on its validity serves only to inform the district court . . . ."); cf. In re Trans Texas Holdings Corp., 498 F.3d 1290, 1296-97 (Fed. Cir. 2007) (holding that the PTO during reexamination is not bound by a district court's claim construction).

In PTO examinations and reexaminations, the standard of proof—a preponderance of evidence—is substantially lower than in a civil case, In re Caveney, 761 F.2d 671, 674 (Fed. Cir. 1985); there is no presumption of validity, Etter, 756 F.2d at 856; and the "examiner is not attacking the validity of the patent but is conducting a subjective examination of the claims in light of prior art," id. at 857-58. And unlike in district courts, in reexamination proceedings "[c]laims are given 'their broadest reasonable interpretation, consistent with the specification . . . .'" Trans Tex. Holdings, 498 F.3d at 1298 (quoting In re Yamamoto, 740 F.2d 1569, 1571 (Fed. Cir. 1984)). Thus, considering an issue at the district court is not equivalent to the PTO having had the opportunity to consider it. See Ethicon, 849 F.2d at 1427 ("[P]recise duplication of effort does not occur because the PTO and the courts employ different standards of proof when considering validity . . . .").

In Ethicon, we held that because of these differences between reexaminations and court proceedings, the PTO did not have authority to stay a patent reexamination proceeding pending the outcome of a case in a district court given the requirement in 35 U.S.C. § 305 that all reexaminations be conducted with "special dispatch." 849 F.2d at 1425-29. We explained that "the suspension of PTO [reexamination] proceedings does not prevent duplication;" instead, it improperly "precludes access to the forum where there is no presumption of validity." Id. at 1427. In reaching this holding, we noted that

"if the district court determines a patent is not invalid, the PTO should continue its reexamination because, of course, the two forums have different standards of proof for determining invalidity." 849 F.2d at 1428-29. The PTO has recognized that while Ethicon did not directly interpret the meaning of a "substantial new question of patentability," its reasoning is directly applicable to the issue of whether district court proceedings affect the "substantial new question" inquiry. Thus, prior to Ethicon the PTO had held that a substantial new question of patentability would not be found if the same issue had been addressed by a federal court, see In re Wichterle, 213 U.S.P.Q. 868, 869 (Comm'r Pat. & Trademarks 1982), but it revised its position in the wake of Ethicon, instructing examiners that a final court decision of a claim's validity will not preclude a finding of a substantial new question of validity based on the same art "because of the different standards of proof employed by the Federal District Court and the Office," MPEP § 2242.

We agree with the PTO's current position. Section 303's language and legislative history, as well as the differences between the two proceedings, lead us to conclude that Congress did not intend a prior court judgment upholding the validity of a claim to prevent the PTO from finding a substantial new question of validity regarding an issue that has never been considered by the PTO. To hold otherwise would allow a civil litigant's failure to overcome the statutory presumption of validity to thwart Congress' purpose of allowing for a reexamination procedure to correct examiner errors, without which the presumption of validity never would have arisen. See Patlex, 758 F.2d at 604 ("A defectively examined and therefore erroneously granted patent must yield to the

reasonable Congressional purpose of facilitating the correction of governmental mistakes.").

Surmodics argues that this reading of the statute—allowing an executive agency to find patent claims invalid after an Article III court has upheld their validity—violates the constitutionally mandated separation of powers, and therefore must be avoided. We disagree. The Supreme Court has repeatedly held that "Congress cannot vest review of the decisions of Article III courts in officials of the Executive Branch." Plaut v. SpendThrift Farm, 514 U.S. 211, 219 (1995) (citing Hayburn's Cases, 2 U.S. (Dall.) 409 (1792)); see also Chi. & S. Air Lines, Inc. v. Waterman S.S. Corp., 333 U.S. 103, 113-14 (1948) ("It has . . . been the firm and unvarying practice of Constitutional Courts to render no judgments not binding and conclusive on the parties and none that are subject to later review or alteration by administrative action."). But the examiner's rejection of claims in the '484 patent pursuant to reexamination does not disturb this court's earlier holding. There, the court held that Syntron had the burden of proving by clear and convincing evidence that the '484 patent was invalid and concluded that, based on the evidence presented, the jury could have found that this burden was not met. Abbott Labs. II, 334 F.3d at 1357. The examiner did not reverse that holding and find that Syntron had met its burden; instead, the examiner evaluated the '484 patent claims in light of prior art, some of which Syntron had presented at trial, and found that there was a preponderance of evidence supporting invalidity. Cf. Stevenson, 713 F.2d at 710 (holding that issue preclusion is generally not applicable in patent validity judgments). Thus, as discussed, the court's final judgment and the examiner's rejection are not duplicative—they are differing proceedings with different evidentiary standards

for validity. See Ethicon, 849 F.2d at 1427. Accordingly, there is no Article III issue created when a reexamination considers the same issue of validity as a prior district court proceeding.[5] And as interpreting a "substantial new question of patentability" to include questions considered by a federal court but never by the PTO does not raise any constitutional concerns, the canon of statutory construction providing that a statute that is ambiguous should be interpreted to avoid raising "grave and doubtful constitutional questions" is not applicable. See Gonzalez v. United States, 128 S. Ct. 1765, 1771 (2008) ("Under the avoidance canon, 'when a statute is susceptible of two constructions, by one of which grave and doubtful constitutional questions arise and by the other of which such questions are avoided, our duty is to adopt the latter.'" (quoting Harris v. United States, 536 U.S. 545, 555 (2002))).

We, therefore, conclude the Board did not err in holding that the prior district court litigation did not prevent the Deutsch reference from raising a "substantial new question of patentability" under § 303(a). As properly interpreted a "substantial new question of patentability" refers to a question which has never been considered by the PTO; thus, a substantial new question can exist even if a federal court previously considered the question.

[5] In contrast, an attempt to reopen a final federal court judgment of infringement on the basis of a reexamination finding of invalidity might raise constitutional problems.

C. Initial Examination

Surmodics also argues that Deutsch does not raise "a substantial new question of patentability" because Deutsch was considered by the PTO during the initial examination and relied on as a secondary reference for rejecting various dependent claims as obvious. Surmodics recognizes that the 2002 amendment to § 303 overrides our prior rule in In re Portola Packaging, where we held that a reference could not raise "a substantial new question of patentability" if it was previously considered by the PTO in reference to the same or broader claims. It nevertheless urges this court to adopt a bright-line rule that "would preclude rejections in reexaminations based solely on references used in a rejection of claims in the original patent prosecution." Appellant Reply Br. 14. We decline the invitation. Such a rule would be plainly inconsistent with the clear text of the amendment. Section 303(a) now mandates that "the existence of a substantial new question of patentability is not precluded by the fact that a patent or printed publication was previously cited by or to the Office or considered by the Office." Thus, under § 303(a) as amended, a reference may present a substantial new question even if the examiner considered or cited a reference for one purpose in earlier proceedings. Nothing in the statute creates an exception to this rule for references considered in the context of a rejection of prior claims. Indeed, such an exception would overwhelm the rule and thwart a central purpose of the amendment, to overrule In re Portola Packaging. In that case, as here, the issue was whether a piece of prior art relied on for a prior rejection could nevertheless create a new question of patentability sufficient to warrant a reexamination. See In re Portola Packaging, 110

F.3d at 787-89. After the amendment to § 303, the answer to that question must be yes.

The 2002 amendment removes the focus of the new question inquiry from whether the reference was previously considered, and returns it to whether the particular question of patentability presented by the reference in reexamination was previously evaluated by the PTO. As was true before the amendment, an "argument already decided by the Office, whether during the original examination or an earlier reexamination" cannot raise a new question of patentability. H.R. Rep. No. 96-1307; see also H.R. Rep. No. 107-120, at 3 (explaining that the amendment did not diminish the "substantial new question requirement" and that "[t]he issue raised must be more than just questioning the judgment of the examiner."). As we explained in In re Recreative Technologies Corp., the substantial new question requirement "guard[s] against simply repeating the prior examination on the same issues and arguments" and bars "a second examination, on the identical ground that had previously been raised and overcome." 83 F.3d at 1396-97. As we recognized even in In re Portola Packaging, a single reference might, alone or in combination, create multiple possible grounds of rejection and thus raise more than one "question of patentability." The bright-line rule in In re Portola Packaging was based on a presumption that the examiner had properly discharged his duties and thus had considered all question of patentability raised by any reference before him. 110 F.3d at 790. Congress, however, has now rejected this presumption of full consideration. Section 303(a) as amended instead requires a more context-specific approach that is based on an analysis of what the PTO actually did.

As the legislative history clarifies, to decide whether a reference that was previously considered by the PTO creates a substantial new question of patentability, the PTO should evaluate the context in which the reference was previously considered and the scope of the prior consideration and determine whether the reference is now being considered for a substantially different purpose. See H.R. Rep. No. 107-120, at 3 ("The appropriate test to determine whether a 'substantial new question of patentability' exists should not merely look at the number of references or whether they were previously considered or cited but their combination in the appropriate context of a new light as it bears on the question of the validity of the patent."); see also 147 Cong. Rec. H5359 (statement of Rep. Berman) ("Ideally, a reexamination could be requested based on prior art cited by an applicant that the examiner failed to adequately consider . . . .").

Determining the scope of an examiner's previous consideration of a reference will generally require an analysis of the record of the prior proceedings to determine if and how the examiner used the reference in making his initial decisions. As we believe that this inquiry is most accurately viewed as a question of fact, we will review the Board's findings regarding the scope of consideration of a reference during prior examinations for substantial evidence. See also H.R. Rep. No. 107-120, at 3 (stating that there should be "substantial evidence" that the examiner "did not properly understand the reference, or did not consider a portion of the reference in making his decision."). However, the ultimate question of whether the reexamination is based on a substantial new question of patentability, in light of how a reference was previously considered, remains a question of law, which we review de novo. While the standard is more flexible than before, we are mindful that Congress intended that the courts

continue to "judiciously interpret the 'substantial new question' standard to prevent cases of abusive tactics and harassment of patentees through reexamination." H.R. Rep. No. 107-120, at 3.

We agree with the Board that whether Deutsch anticipates claims 22-24 raises a substantial new question of patentability under the amended § 303(a). Substantial evidence supports the Board's conclusion that in the initial examination, "Deutsch was relied upon, as a secondary reference," for the limited purpose of "teaching immunoreactions in general, and not for the specific method steps claimed." In re Swanson, No. 2005-0725, Reexamination No. 90/006,785, at 18-19 (B.P.A.I. May 29, 2007). Deutsch was not evaluated as a primary reference that taught or made obvious the specific analytical method claimed. The independent claims, such as original claim 9, were found obvious without any reliance on Deutsch. Deutsch was cited only to reject the dependent claims that limited the analyte-reactant pair used in the method to a ligand-antiligand pair, e.g., original claim 10, or, more specifically, an antigen-antibody pair, e.g., original claim 11. Original Office Action at 9-10. The examiner explained that "it would be obvious that any known reaction within reasons [sic] could be incorporated in the modified method and apparatus of either Morison and [sic] Bauer" and cited to Deutsch as one of three references that disclosed immunoreactions. Id. In other words, since Deutsch and the other secondary references taught immunoreactions, immunoreactions were one type of "known reaction" that could be adopted to the method made obvious for any known reaction (within reason) by Morison and Bauer. Nowhere in its decision did the examiner consider the particular analytical method disclosed by Deutsch.

In light of the extremely limited purpose for which the examiner considered Deutsch in the initial examination, the Board is correct that the issue of whether Deutsch anticipates the method disclosed in claims 22, 23, and 25 was a substantial new question of patentability, never before addressed by the PTO.[6]

On appeal, Surmodics' only argument for why the Board erred in affirming the rejection of claims 22, 23, and 25 as anticipated by Deutsch is the alleged lack of a substantial new question of patentability. Accordingly, any arguments as to the merits of the Board's rejection have been waived. Given our conclusion that Deutsch does raise a substantial new question of patentability, we, therefore, affirm the Board's rejection of claims 22, 23, and 25.

We also affirm the obviousness rejection of claim 24 in view of Deutsch and Tom. Surmodics has not argued the issue separately, but instead has stated that its appeal on this issue depends solely on whether Deutsch raises a substantial new question of patentability with regards to claims 22 and 23. See Appellant's Br. 60 ("The patentability of claim 24 rises or falls with claims 22 and 23. The only question is as to Deutsch and that question is an old one addressed in a final court judgment and by the PTO in the original prosecution."). Thus, in light of our affirmance of the rejection of

[6] In reaching this holding, we do not rely on the fact, discussed by the Board, that claim 22 differed from the rejected claims in the initial patent. While the difference between rejected claims and the claims at issue during a reexamination may be relevant to whether there is a substantial new question of patentability, a change in the scope of a claim will not, in itself, make all questions of patentability of the revised claim "substantial new question[s]." As the limited scope of the examiner's consideration of Deutsch is sufficient to find that anticipation by Deutsch raises a substantial new question of patentability, we need not consider what effect the change in scope of the claims would have had had Deutsch been more fully considered during the initial proceeding.

claims 22 and 23, any argument for why the rejection of claim 24 should nevertheless be reversed has been waived.

## CONCLUSION

The Board did not err in finding that whether Deutsch anticipated claims 22, 23, and 25 of the '484 patent or made obvious claim 24 in combination with Tom raised substantial new questions of patentability sufficient to warrant reexamination. Accordingly, the Board's decision affirming the examiner's rejection of claims 22-25 is affirmed.

## AFFIRMED