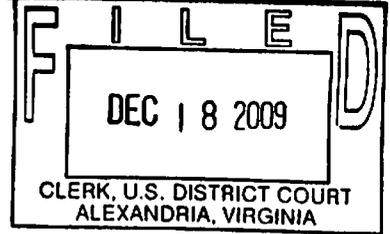


**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF VIRGINIA  
Alexandria Division**



**SIGRAM SCHINDLER** )  
**BETEILIGUNGSGESELLSCHAFT** )  
**MBH** )  
**Plaintiff,** )  
 )  
**v.** )  
 )  
**DAVID J. KAPPOS in his official** )  
**capacity as Undersecretary of** )  
**Commerce for Intellectual Property** )  
**and Director of the United States** )  
**Patent and Trademark Office, et al.,** )  
**Defendants.** )

**No. 1:09cv935**

**MEMORANDUM OPINION**

In this declaratory judgment action, plaintiff (“SSBG”), a patent owner in the midst of an *ex parte* reexamination appeal to the Board of Patent Appeals and Interferences (“BPAI”), challenges a Patent and Trademark Office (“PTO”) regulation—37 C.F.R. § 1.303—as being “in excess of [its] statutory jurisdiction, authority, or limitations, or short of statutory right.”<sup>1</sup> According to plaintiff, although 35 U.S.C. §§ 141 and 306 allow a patent owner aggrieved by an adverse BPAI reexamination decision the option of appealing to the Court of Appeals for the Federal Circuit *or* filing a civil action for review in the District Court for the District of Columbia, the challenged regulation impermissibly limits a patent owner to a Federal Circuit appeal. Defendants disagree, arguing that plaintiff, if aggrieved by a BPAI reexamination

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<sup>1</sup> 5 U.S.C. § 706(2)(C); *see also Emily’s List v. FEC*, 581 F.3d 1, 26 (D.C. Cir. 2009) (Brown, J., concurring) (“In executing the law, . . . the FEC acts contrary to law if it promulgates regulations ‘in excess of [its] statutory jurisdiction.’” (alteration in original) (quoting 5 U.S.C. § 706(2)(C))).

decision, may appeal *only* to the Federal Circuit. Defendants also makes the threshold jurisdictional argument that this declaratory judgment action is not ripe—and may never ripen—and hence must be dismissed.

I.

A.

A brief summary of the pertinent statutory and regulatory framework governing patent issuances and reexaminations is helpful to the disposition of this case. An inventor who files a patent application with the PTO is deemed a patent applicant. Following an examination of the alleged new invention pursuant to the statutory procedural rules and substantive principles governing patentability of inventions,<sup>2</sup> the PTO Director issues either (i) a patent or (ii) a notice of rejection “stating the reasons for such rejection, or objection or requirement, together with such information and references as may be useful in judging of the propriety of continuing the prosecution of his application.”<sup>3</sup> 35 U.S.C. § 131 (2006) (patent issuance); *id.* § 132(a) (application denial). A patent applicant who receives a notice of rejection may persist in his claim for a patent—even where no amendment is made to the application—in which event the PTO will undertake further review of the rejected application and again issue a patent or notice of rejection. *See id.* § 132(a).

Issued patents may also be subject to reexaminations, either *ex parte* or *inter partes*.<sup>4</sup>

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<sup>2</sup> *See* 35 U.S.C. §§ 100-105, 111-122 (2006).

<sup>3</sup> In situations where an application would interfere with a pending patent application or unexpired patent, an interference is declared and the PTO Director gives notice to the parties and directs the BPAI to determine questions of priority and patentability. *Id.* § 135(a).

<sup>4</sup> *See* 35 U.S.C. § 302 (*ex parte* reexamination); *id.* § 311 (*inter partes* reexamination).

Both *ex parte* and *inter partes* reexaminations may be initiated by a “third-party requester,” statutorily defined as “a person requesting *ex parte* reexamination under section 302 or *inter partes* reexamination under section 311 who is not the patent owner.” *Id.* § 100(e). On this request, and on a finding by the PTO Director of a “substantial new question of patentability,” the PTO undertakes a reexamination of the patent in the same manner that it conducts an initial patent application examination. *See id.* §§ 303(a), 305, 314(a).

Patent applicants, patent owners involved in a reexamination, and third-party requesters are authorized, under certain statutory provisions, to appeal a primary examiner’s final decision of patentability to the BPAI. *See id.* §§ 134, 306, 316. The process of seeking court review of BPAI *ex parte* reexamination decisions has long been governed by 35 U.S.C. §§ 141 to 145 and 306. Prior to 1999, patent applicants, patent owners involved in *ex parte* reexamination proceedings,<sup>5</sup> and parties to an interference were permitted to seek court review of BPAI determinations by either: (i) filing an appeal in the Federal Circuit, where review is made solely on the administrative record; or (ii) filing a civil action in the D.C. District Court, where discovery is permitted and a patentability determination is made by the district court *de novo*.<sup>6</sup> *See* 35 U.S.C. §§ 141-146, 306 (1996). Importantly, the two avenues of court review were mutually exclusive: Filing an appeal with the Federal Circuit waived a party’s right to pursue a civil action in the D.C. District Court, and filing a civil action in the D.C. District Court waived a party’s right to appeal to the Federal Circuit. *See id.* §§ 141, 145. In addition, patent applicants

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<sup>5</sup> *Inter partes* reexamination was not available until 1999. *See* American Inventors Protection Act of 1999, Pub. L. No. 106-113, §§ 4601-4608, 113 Stat. 1501, 1501A552-A572.

<sup>6</sup> Third-party requesters were not permitted to seek court review of a BPAI decision until 2002. *See* Pub. L. No. 107-273, §13106, 116 Stat. 1758, 1900 (2002).

and patent owners involved in *ex parte* reexamination proceedings were afforded only sixty days in which to seek court review in either the Federal Circuit or the D.C. District Court. *See id.* §§ 142, 145.

Prior to 1999, §§ 141 to 145 referenced only patent *applicants*.<sup>7</sup> Nonetheless, patent owners involved in *ex parte* reexamination proceedings were authorized to seek court review of BPAI decisions under § 306, which stated that “[a] patent owner involved in a reexamination proceeding under this chapter [governing *ex parte* reexamination] may appeal under the provisions of section 134 of this title [to the BPAI], and may seek court review under the provisions of sections 141 to 145 of this title.” *Id.* § 306. Thus, § 306’s cross-reference to §§ 141 to 145 effectively applied the court review provisions governing patent *applicants* to patent owners involved in *ex parte* patent reexaminations. Of course, the right to appeal a BPAI reexamination decision accrued only in the event the BPAI rendered a decision “adverse to the patentability of any original or proposed amended or new claim of the patent.” *Id.* § 306; *see also id.* §§ 141, 145 (allowing appeal only where “an applicant is dissatisfied with the decision in an appeal to the [BPAI]”).

In 1999, Congress enacted the American Inventors Protection Act of 1999 (“AIPA”), which: (i) amended the process of appealing PTO primary examiner<sup>8</sup> determinations to the BPAI; (ii) amended the provisions governing court review of BPAI decisions; and (iii) created the *inter*

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<sup>7</sup> Although parties to interference proceedings are also referenced in § 141, they are not treated in § 145.

<sup>8</sup> The AIPA substituted “administrative patent judge” for “primary examiner,” but the 2002 amendments to 35 U.S.C. § 134 deleted “administrative patent judge” in favor of “primary examiner.” For consistency, only the term “primary examiner” will be used here.

*partes* reexamination procedure.<sup>9</sup> With respect to appeals to the BPAI, § 134 was amended to read, in its current incarnation, as follows:

(a) Patent Applicant.—An *applicant* for a patent, any of whose claims has been twice rejected, may appeal from the decision of the primary examiner to the [BPAI], having once paid the fee for such appeal.

(b) Patent Owner.—A *patent owner* in any reexamination proceeding may appeal from the final rejection of any claim by the primary examiner to the [BPAI], having once paid the fee for such appeal.

(c) Third-Party.—A *third-party requester* in an inter partes proceeding may appeal to the [BPAI] from the final decision of the primary examiner favorable to the patentability of any original or proposed amended or new claim of a patent, having once paid the fee for such appeal.

35 U.S.C. § 134(a)-(c) (2006) (emphasis added). The AIPA also added the following to § 141 regarding Federal Circuit review of BPAI decisions:

A patent owner in *any* reexamination proceeding dissatisfied with the final decision in an appeal to the [BPAI] under section 134 may appeal the decision *only* to the United States Court of Appeals for the Federal Circuit.”

AIPA § 4605 (codified as amended at 35 U.S.C. § 141 (2006)) (emphasis added). These AIPA amendments became effective on November 29, 1999. *See id.* § 4608.<sup>10</sup>

Notably, the AIPA left § 306 unchanged, and accordingly still provided that a patent owner involved in an *ex parte* reexamination, after appealing to the BPAI and receiving an adverse determination, may “seek court review under the provisions of sections 141 to 145 of this title.” 35 U.S.C. § 306. As noted *supra*, prior to the AIPA’s enactment, § 306 allowed

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<sup>9</sup> Pub. L. No. 106-113, §§ 4001-4808, 113 Stat. 1501, 1501A552-A591 (codified at scattered sections of 35 U.S.C.).

<sup>10</sup> It is worth noting that although the provisions at issue here were further amended in 2002, these amendments are not material to the disposition of the cross-motions at bar. *See* Patent and Trademark Office Authorization Act of 2002 and Intellectual Property and High Technology Technical Amendments Act of 2002, Pub. L. No. 107-273, §§ 13106, 13202, 116 Stat. 1758, 1900, 1901.

patent owners to appeal to the Federal Circuit *or* file a civil action in the D.C. District Court pursuant to §§ 141 to 145, despite the fact that these provisions on their face applied only to patent applicants. Accordingly, the fact that § 306 continues to cross-reference §§ 141 to 145 following the AIPA’s enactment appears to be in tension with the AIPA amendment to § 141: Although § 145 authorizes a patent applicant—and thus a patent owner under the plain terms of § 306—to file a civil action in the D.C. District Court, § 141 was specifically amended to allow patent owners dissatisfied with a BPAI decision to “appeal the decision *only* to the United States Court of Appeals for the Federal Circuit.” *Id.* § 141 (emphasis added). Despite this tension, the statutory provisions continue to make clear that a patent owner’s right to seek court review of a BPAI decision accrues only after the BPAI renders a “decision adverse to the patentability of any original or proposed amended or new claim of the patent.” *Id.* § 306; *see also id.* §§ 141-145.

Interpreting these statutory amendments in 2000, the PTO promulgated a regulation stating: (i) that patent owners involved in *ex parte* reexamination proceedings filed before November 29, 1999 were permitted to appeal an adverse BPAI decision to the Federal Circuit or, alternatively, to file a civil action in the D.C. District Court challenging that decision; and (ii) that patent owners involved in *ex parte* reexamination proceedings initiated on or after November 29, 1999 were not authorized to file civil actions in the D.C. District Court pursuant to § 145.<sup>11</sup> As the PTO explained in the Federal Register, “[t]his date distinction is necessitated by

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<sup>11</sup> The amendment to the regulation was first published in 2000 and codified at 37 C.F.R. §§ 1.301 and 1.303. *See Rules to Implement Optional Inter Partes Reexamination Proceedings*, 65 Fed. Reg. 76756, 76774 (Dec. 7, 2000). Following enactment in 2002 of amendments to Title 35, U.S. Code, the PTO issued the current version of 37 C.F.R. § 1.303 as pertaining to *ex parte* reexaminations. *See Changes to Implement the 2002 Inter Partes Reexamination and Other Technical Amendments to the Patent Statute*, 68 Fed. Reg. 70996, 71007 (Dec. 22, 2003). Subsequent technical amendments to the regulation are irrelevant to this case.

the conforming amendments to 35 U.S.C. § 141.”<sup>12</sup> Whether this challenged regulation, codified at 37 C.F.R. § 1.303, contradicts § 306 is the merits issue presented here.

**B.**<sup>13</sup>

On October 11, 2005, the PTO issued U.S. Patent No. 6,954,453 B1 (“the ’453 patent”) to SSBG. On August 30, 2007, Cisco Systems, Inc. (“Cisco”), a third-party requester under 35 U.S.C. § 302, filed a request for *ex parte* reexamination of the ’453 patent on the ground that there existed a “substantial new question of patentability.” 35 U.S.C. § 303(a). The PTO agreed that there was a substantial new question of patentability and undertook an *ex parte* reexamination of the ’453 patent. Thereafter on August 6, 2008, a PTO primary examiner issued a final rejection of ’453 patent claims 34-36 and 38 on grounds of obviousness,<sup>14</sup> a decision that SSBG’s predecessor-in-title, Teles AG Informationstechnologian, appealed to the BPAI pursuant to § 134(b). In the course of the December 11, 2009 hearing, defendants’ counsel represented that the BPAI reexamination appeal has been fully briefed and was argued orally on December 2, 2009. Counsel for both parties indicated that BPAI decisions typically issue six months to a year following oral argument.

At oral argument, SSBG, by counsel, conceded that it would have no reason, and indeed

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<sup>12</sup> See Rules to Implement Optional Inter Partes Reexamination Proceedings, 65 Fed. Reg. 18154, 18166 (Apr. 6, 2000).

<sup>13</sup> The undisputed material facts set forth here are derived from the parties’ statements of undisputed material facts and from representations made by counsel for the parties in the course of the December 11, 2009 hearing.

<sup>14</sup> See 35 U.S.C. § 103(a) (“A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art . . .”).

no right, to seek court review of a BPAI decision reversing the primary examiner’s final rejection of ’453 patent claims 34-36 and 38 because such a decision would not be “adverse to the patentability of any . . . claim of the patent.” *Id.* § 306. Nonetheless, SSBG seeks a declaration that the challenged regulation— 37 C.F.R. § 1.303—contravenes the court review provision of § 306 and is therefore *ultra vires*. Although the BPAI has not yet rendered its decision, SSBG filed this declaratory judgment action at this time because, it argues, the regulation currently purports to deprive SSBG of its right under § 306—which it may never have the opportunity to exercise—to file a civil action in D.C. District Court, thereby causing SSBG to suffer economic harm. According to SSBG, if a declaratory judgment does not promptly clarify its rights with respect to court review of the BPAI’s decision, it will be forced into a “Hobson’s choice” between: (i) appealing to the Federal Circuit under § 141 and waiving any purported right to file a civil action in the D.C. District Court, where discovery would be available; and (ii) filing a civil action in the D.C. District Court under § 145 in contravention of the challenged regulation, thereby risking loss of any court review in the event the D.C. District Court were to determine that it lacked jurisdiction and issued this determination after expiration of the sixty-day deadline for appealing to the Federal Circuit. In the course of oral argument, defendants, by counsel, emphasized that the challenged regulation was nonbinding and therefore did not have the force of law, and that defendants were not seeking *Chevron* or any other type of deference with respect to judicial review of the regulation.

## II.

At the threshold, defendants argue that the doctrine of ripeness precludes SSBG’s

challenge to the validity of 37 C.F.R. § 1.303 at this time.<sup>15</sup> More precisely, defendants contend that plaintiff's declaratory judgment action does not present a justiciable "case" or "controversy" under Article III of the Constitution because a favorable decision by the BPAI—that is, a decision which reverses the primary examiner's final rejection of '453 patent claims 34-36 and 38—precludes SSBG from seeking court review of the PTO's *ex parte* reexamination proceeding in either the Federal Circuit or the D.C. District Court under § 306.

To begin with, it is well settled that federal court jurisdiction is limited to those cases or controversies enumerated in Article III.<sup>16</sup> To that end, the Supreme Court has developed justiciability doctrines—such as ripeness, standing, mootness, and a prohibition on advisory opinions—that prohibit federal courts from entertaining and deciding questions where no case or

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<sup>15</sup> Defendants also raise the issue of standing. Yet, because the parties' justiciability arguments focus predominantly on ripeness, only that issue is considered here. Nonetheless, it is worth noting that the standing and ripeness doctrines are closely related, as they are both "simply subsets of Article III's command that the courts resolve disputes, rather than emit random advice." *Bryant v. Cheney*, 924 F.2d 525, 529 (4th Cir. 1991). In some cases, a determination that a case is unripe may also be viewed as failing the standing test requirement that the injury be "concrete and particularized" and "actual or imminent, not conjectural or hypothetical." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992) (citations and internal quotation marks omitted) (setting forth three-part constitutional test for standing). As the Fourth Circuit has explained,

[t]hough the justiciability concepts of "standing" and "ripeness" are theoretically distinct, little is gained from an attempt to identify the particular doctrine at work in an individual case. Plaintiff's personal stake in the outcome (standing) is directly limited by the maturity of the harm (ripeness). In any event, both doctrines require that those seeking a court's intervention face some actual or threatened injury to establish a case or controversy.

*Doe v. Duling*, 782 F.2d 1202, 1206 n.2 (4th Cir. 1986).

<sup>16</sup> See *Marshall v. Meadows*, 105 F.3d 904, 906 (4th Cir. 1997) ("One of the bulwark principles of constitutional law is the 'cases' or 'controversies' requirement for justiciability referred to in Article III.").

controversy exists.<sup>17</sup> Importantly, these doctrines preserve the constitutionally mandated separation of powers, conserve judicial resources, improve judicial decisionmaking by requiring concrete controversies, and promote fairness by generally prohibiting the adjudication of the rights of parties not before a court.<sup>18</sup> The Supreme Court has long held that judicial decisions issued pursuant to the Declaratory Judgment Act are not advisory opinions provided that, as the Act requires, the parties present “a case of actual controversy.”<sup>19</sup> 28 U.S.C. § 2201.

Accordingly, where, as here, declaratory relief is sought, a federal court lacks constitutional and statutory jurisdiction to decide the merits of a claim if no case or controversy is presented. *See Whitmore v. Arkansas*, 495 U.S. 149, 155 (1990).

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<sup>17</sup> *See, e.g., United States v. McClure*, 241 Fed. App’x 105, 107 (4th Cir. 2007) (“The Supreme Court has developed a number of constitutional justiciability doctrines from the text of Article III, Section 2, including the prohibition against advisory opinions, the political question doctrine, and the doctrines of standing, ripeness, and mootness.”); *Washlefske v. Winston*, 234 F.3d 179, 179 (4th Cir. 2000) (“Ripeness, like other justiciability doctrines, is rooted in the case or controversy requirement of Article III.”)

<sup>18</sup> *See* Erwin Chemerinsky, *Constitutional Law* 50-52 (3d ed. 2006); *see also* Ronald D. Rotunda & John E. Nowak, *Treatise on Constitutional Law: Substance and Procedure* § 2.13, at 252-53 (4th ed. 2007) (identifying justifications for prohibition on advisory opinions).

<sup>19</sup> *See Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 241 (1937) (upholding Declaratory Judgment Act); *see also Nashville, Chattanooga & St. Louis Ry. v. Wallace*, 288 U.S. 249, 264 (1933) (upholding federal court’s power to issue declaratory judgments prior to enactment of the Declaratory Judgment Act). The prohibition on advisory opinions by federal courts dates back to the nascency of the United States. While serving as Secretary of State in George Washington’s administration, Thomas Jefferson asked the Supreme Court to advise him on legal issues pertaining to America’s neutrality in the war between France and England, such as whether the United States may, “within our own ports, sell ships to both parties, prepared merely for merchandise? May they be pierced for guns?” *See* Henry M. Hart, David L. Shapiro, & Daniel J. Meltzer, *Hart and Wechsler’s The Federal Courts and the Federal System* 78-79 (5th ed. 2003) (reprinting correspondence). The Justices declined to answer Jefferson’s questions, citing a concern that an advisory opinion would violate the separation of powers between the executive and the judiciary. *See id.*

The ripeness doctrine preserves the case or controversy requirement by “preventing judicial consideration of issues until a controversy is presented in ‘clean-cut and concrete form.’” *Miller v. Brown*, 462 F.3d 312, 318-19 (4th Cir. 2006) (quoting *Rescue Army v. Mun. Court of L.A.*, 331 U.S. 549, 584 (1947)). Whether a claim is ripe for adjudication is determined under the two-part test set forth in *Abbott Laboratories v. Gardner*:

The problem is best seen in a twofold aspect, requiring us to evaluate both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration.

387 U.S. 136, 149 (1967); *see also Franks v. Ross*, 313 F.3d 184, 194-95 (4th Cir. 2002) (citation omitted) (balancing fitness and hardship in determining ripeness). With respect to the first prong, “[a] case is fit for judicial decision when the issues are purely legal and when the action in controversy is final and not dependent on future uncertainties.” *Miller*, 462 F.3d at 319. The hardship prong, by contrast, “is measured by the immediacy of the threat and the burden imposed on the [plaintiff] who would be compelled to act under threat of enforcement of the challenged law.” *Charter Fed. Sav. Bank v. Office of Thrift Supervision*, 976 F.2d 203, 208-09 (4th Cir. 1992). Distilled to their essence, the requirements of fitness and hardship contemplate that “a claim is not ripe for adjudication if it rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all.” *Texas v. United States*, 523 U.S. 296, 300 (1998).<sup>20</sup>

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<sup>20</sup> It is worth noting that the “[r]ipeness requirements are relaxed in First Amendment cases because of the potential chilling effect of unconstitutional restrictions on free speech.” *Pearson v. Leavitt*, 189 Fed. App’x 161, 163 (4th Cir. 2006) (citing *Forsyth County v. Nationalist Movement*, 505 U.S. 123, 129-30 (1992)). Often, these cases involve pre-election challenges to election laws. *See, e.g., Miller*, 462 F.3d at 318-21 (finding plaintiff candidate’s challenge to Virginia’s open primary law to be ripe despite fact that, should no other candidate run in the primary, plaintiff would automatically be named nominee and challenged law would never be implicated). Here, no First Amendment values are at issue and thus there is no justification for relaxing the ripeness requirements.

Importantly, the Supreme Court has also made clear that the burden of proving ripeness rests with the party bringing suit. *See Miller*, 462 F.3d at 319 (citing *Renne v. Geary*, 501 U.S. 312, 316 (1991)).

The distinction between ripe and unripe matters is well illustrated by contrasting the Supreme Court’s decisions in *Abbott Laboratories* and *Toilet Goods Association v. Gardner*,<sup>21</sup> decided on the same day.<sup>22</sup> In *Abbott Laboratories*, the Food and Drug Administration (“FDA”) promulgated a regulation requiring that a prescription drug’s “established name”—*i.e.*, the name designated by the Secretary of Health, Education, and Welfare—accompany all uses of its proprietary or trade name on prescription drug labels. *See* 387 U.S. at 138. Violations of this regulation were punishable by civil and criminal sanctions. Thirty-seven drug manufacturers and the Pharmaceutical Manufacturers Association challenged the regulation as exceeding the FDA’s statutory authority. The Supreme Court, stating and then applying the two-part ripeness test, first found that the issue presented was fit for judicial review because the question whether the FDA regulation exceeded the statute was purely legal in nature. Specifically, the Supreme Court held (i) that “no claim is made here that further administrative proceedings are contemplated,” (ii) that “the Government made no effort to justify the regulation in factual terms,” and (iii) that the regulation at issue was a “final agency action.” *Id.* at 149-52. As to the hardship prong of the ripeness test, the Supreme Court explained that the FDA regulations had a direct and immediate impact on the drug manufacturers’ day-to-day activities. *Id.* at 152. Without a declaratory

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<sup>21</sup> 387 U.S. 158, 161 (1967).

<sup>22</sup> *See generally* 33 Charles Alan Wright & Charles H. Koch, Jr., *Federal Practice and Procedure* § 8418, at 469-73 (2006) (comparing *Abbott Laboratories* with *Toilet Goods*).

judgment promptly clarifying the law, the manufacturers would be faced with the choice of either: (i) chang[ing] all their labels, advertisements, and promotional materials; . . . destroy[ing] stocks of printer matter; and . . . invest[ing] heavily in new printing type and new supplies”; or (ii) continuing to use material that it believed in good faith to comply with the statute, but not the regulation, thereby “risk[ing] serious criminal and civil penalties for the unlawful distribution of ‘misbranded’ drugs.” *See id.* at 152-53. For these reasons, the Supreme Court concluded that the matter was ripe for judicial review and that preenforcement review would not violate the constitutional case or controversy requirement.

By contrast, the Supreme Court in *Toilet Goods* held unripe a challenge to a different FDA regulation that authorized the agency, in its discretion, to suspend certification service to manufacturers of cosmetic color additives where the manufacturer denied a duly authorized FDA employee free access to the manufacturer’s facilities. *See* 387 U.S. 158, 161 (1967). Applying the two-part test, the Supreme Court first found, in contrast to *Abbott Laboratories*, that the regulation was not fit for judicial review. Although the regulation was a final agency action challenged purely on legal grounds, these facts were outweighed by the uncertainty concerning “whether or when such an inspection will be ordered and what reasons the Commissioner will give to justify his order” because judicial evaluation of the regulation’s ability to facilitate “efficient enforcement” of the statute depended on its application. *Id.* at 163-64. The Supreme Court further distinguished *Abbott Laboratories* in applying the second ripeness prong. Specifically, the Supreme Court found the claimed hardship insufficient because “no primary conduct [was] affected” by the regulation such that the manufacturers would suffer “irremediable adverse consequences flow[ing] from requiring a later challenge”; a manufacturer faced only

suspension of its certificate pending judicial review and was not subject to “seizure of goods, heavy fines, adverse publicity for distributing ‘unadulterated’ goods, and possible criminal liability.” *Id.* at 164-65. Accordingly, the Supreme Court denied preenforcement review on ripeness grounds.

In sum, the Supreme Court’s contrasting decisions in *Abbott Laboratories* and *Toilet Goods* make clear that a question is fit for judicial review if (i) it is a pure question of law, and (ii) no further agency action is needed to provide context and clarify whether the regulation fulfils the authorizing statute’s mandate. Also clear from these decisions is that cognizable hardship under the ripeness test involves a serious, immediate threat to day-to-day operations, such as the imposition of civil or criminal penalties.

These principles, applied here, compel the conclusion that SSBG’s request for declaratory relief is not ripe and therefore is not justiciable. As to the first prong of the ripeness test, plaintiff argues, and defendants concede, that the challenged regulation is fit for judicial review because a declaratory judgment action as to its validity presents purely a question of law. Evaluation of the regulation does not depend on any PTO action, nor does it require the PTO Director to apply the regulation or to justify its application following issuance of the BPAI’s decision. Thus, the regulation’s validity is a question fit for judicial review under *Abbott Laboratories* and *Toilet Goods*.

By contrast, plaintiff’s regulatory challenge fails on the hardship prong of the ripeness test because SSBG’s claimed hardship is (i) contingent and speculative, (ii) does not affect SSBG’s primary conduct by imposing a cognizable hardship, and (iii) is not irremediable. Dispositive here is the fact that the BPAI has yet to render its decision, and thus at this stage of

the proceeding it is wholly uncertain whether SSBG's right to appeal will ever accrue or be exercised. Specifically, in the event the BPAI decision is not "adverse to the patentability of any original . . . claim of the patent," no right to seek further court review would vest.<sup>23</sup> Simply put, SSBG's claimed hardship is wholly contingent on an event that may never materialize, namely an adverse BPAI decision.<sup>24</sup> It follows that if a declaratory judgment on the merits were to issue now and then be followed later by a BPAI decision favorable to plaintiff, the declaratory judgment would incontestably be an advisory opinion.

SSBG's claimed hardship is plainly distinguishable from the cognizable hardship identified in *Abbott Laboratories*. There, unlike here, the manufacturers' day-to-day activities subjected them to civil and criminal penalties at the time of suit. By comparison, SSBG's day-to-day activities are not affected by any threat of sanctions. Although Dr.-Ing Sigram Schindler asserts in his affidavit that the "existence of 37 C.F.R. §§ 1.303(a) and (d) tends to diminish the value of the Schindler '453 Patent and to threaten SSBG with irreparable harm to its business and property," this statement is not supported by any record evidence and fails for a number of

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<sup>23</sup> 35 U.S.C. § 306; *see also id.* §§ 141-145 (allowing court review of only a BPAI "final decision"); *Bonton v. Merit Sys. Prot. Bd.*, 2000 U.S. App. LEXIS 16989, at \*2 (Fed. Cir. 2000) ("An employee's right to appeal an agency's initial denial of an employee's [within-grade increase] does not vest until the agency affirms the denial after reconsideration . . .").

<sup>24</sup> *See Texas v. United States*, 523 U.S. 296, 300 (1998) ("[A] claim is not ripe for adjudication if it rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all."); *CTIA—The Wireless Ass'n v. FCC*, 530 F.3d 984, 987-88 (D.C. Cir. 2008) (holding challenge to agency action unripe because "the effects of the Commission's action are contingent upon future action by another administrative agency"); *United Transp. Union v. Foster*, 205 F.3d 851, 857 (5th Cir. 2000) ("Ripeness separates those matters that are premature because the injury is speculative and may never occur from those that are appropriate for judicial review."); *RLI Ins. Co. v. John H. Hampshire, Inc.*, 461 F. Supp. 2d 364, 369 (D. Md. 2006) (dismissing claim because it "is predicated upon a future event which may never occur").

reasons. To begin with, “conclusory statements, standing alone, are insufficient to carry [a plaintiff’s] burden to prove hardship under the second prong of the *Abbott Laboratories* test.”<sup>25</sup> Next, even accepting these assertions as true, the Supreme Court in *Abbott Laboratories* found that “possible financial loss is not by itself a sufficient interest” to overcome the ripeness hurdle; rather, a plaintiff must show that the regulation “requires [it] to make significant changes in their everyday business practice.” 387 U.S. at 154. In this case, SSBG makes only a bare allegation of financial loss and fails to show that any tension between the challenged regulation and § 306 affects its daily operations. Moreover, the facts militate against a finding that the value of the ’453 patent is diminished because although claims 34-36 and 38 have been rejected by the primary examiner and thus cannot be enforced, the remaining ’453 patent claims are not affected and therefore can be enforced or licensed.

Further, in the course of oral argument, defendants emphasized that the challenged regulation was an interpretive rule, simply explanatory in nature and a part of the Rules of Practice in Patent Cases, essentially a reference guide for PTO proceedings.<sup>26</sup> In this respect, defendants’ counsel also represented that the challenged regulation was nonbinding, and therefore the PTO did not contend that the challenged regulation was entitled to any form of

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<sup>25</sup> *Cedars-Sinai Med. Ctr. v. Watkins*, 11 F.3d 1573, 1585 (Fed. Cir. 1993) (holding unripe suit challenging Department of Energy determination because BPAI determination might render determination inapplicable); *cf. Mgmt. Ass’n for Private Photogrammetric Surveyors v. United States*, 492 F. Supp. 2d 540, 550 (E.D. Va. 2007) (holding with respect to standing inquiry that specific facts are necessary to support a finding of injury in fact at summary judgment stage).

<sup>26</sup> *See Gordon v. Shalala*, 55 F.3d 101, 105 (2d Cir. 1995) (“[A]n interpretive rule is an agency’s intended course of action, its tentative view of the meaning of a particular statutory term, or internal house-keeping measures organizing agency activities.” (quoting *White v. Shalala*, 7 F.3d 296 (2d Cir. 1993))).

*Chevron* deference in connection with judicial review. As it is the statute, and not the regulation, that ultimately governs here, plaintiff cannot be said to be harmed by this informational regulation. Indeed, as the Fourth Circuit has explained, “Congress has not delegated to any agency the power to make policy decisions that bind courts and citizens through [interpretive rules].”<sup>27</sup> Accordingly, plaintiff fails to show that it will suffer from “immediate, direct, and significant” hardship if court review is withheld at this time. *See W. Va. Highlands Conservancy, Inc. v. Babbitt*, 161 F.3d 797, 801 (4th Cir. 1998).

Finally, any hardship to SSBG in deferring declaration of its right to file a civil action in the D.C. District Court is remediable by 28 U.S.C. § 1631. That provision provides that

[w]henver a civil action . . . including a petition for review of administrative action, is noticed for or filed with such a court and that court finds that there is a want of jurisdiction, the court *shall*, if it is in the interest of justice, transfer such action or appeal to any other such court in which the action or appeal could have been brought at the time it was filed or noticed, and the action or appeal *shall* proceed as if it had been filed in or noticed for the court to which it is transferred on the date upon which it was actually filed in or noticed for the court from which it is transferred.

28 U.S.C. § 1631 (emphasis added). In practice, then, provided that SSBG in good faith files a civil action in the D.C. District Court within sixty days of the BPAI’s issuance of an adverse decision, SSBG will still be afforded an appeal in the Federal Circuit in the event that the D.C. District Court determines that it lacks jurisdiction under § 306 and transfers the case to the

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<sup>27</sup> *U.S. Dep’t of Labor v. N.C. Growers Ass’n*, 377 F.3d 345, 354 (4th Cir. 2004) (alteration in original) (quoting 1 K. Davis & R. Pierce, *Administrative Law Treatise* § 3.5 (3d ed. 1994)); *see also Nat’l Org. of Veterans’ Advocates, Inc. v. Sec’y of Veterans Affairs*, 260 F.3d 1365, 1375 (Fed. Cir. 2001) (“An interpretative statement simply indicates an agency’s reading of a statute or a rule. It does not intend to create new rights or duties, but only reminds affected parties of existing duties.” (quoting *Paralyzed Veterans of Am. v. West*, 138 F.3d 1434, 1436 (Fed. Cir. 1998))).

Federal Circuit “in the interest of justice” pursuant to § 1631. To be sure, it is conceivable, as SSBG argues, that the D.C. District Court might refuse to find that a transfer is not in the interest of justice. Yet, this result appears to be very unlikely in the circumstances considering § 1631 states in mandatory terms that a court “shall . . . transfer such action.” *Id.* (emphasis added). At most, then, plaintiff’s contention simply recites the truism that “one does not know for certain how a court will rule on an issue until it does so.” *In re: Xe Servs. Alien Tort Litig.*, \_\_\_ F. Supp. 2d \_\_\_, 2009 U.S. Dist. LEXIS 97994, at \*74 (E.D. Va. Oct. 21, 2009). Such an argument is insufficient to clear the ripeness hurdle.

Plaintiff argues that defendants’ invocation of 28 U.S.C. § 1631 asserts a “novel theory that is not known to have *ever* been successfully applied to transfer an original district court civil action to an appellate court.” Pl.’s Am. Mem. in Supp. at 13 (emphasis added). This argument is factually incorrect, as the D.C. District Court has previously done precisely this. In *Jamison v. FTC*,<sup>28</sup> the plaintiffs filed a civil action in district court challenging an FTC complaint and seeking a preliminary injunction to prevent further enforcement by the agency. Yet, the D.C. Circuit had already declared exclusive jurisdiction over such claims in *Telecomm. Research & Action Ctr. v. FCC (TRAC)*, 750 F.2d 70 (D.C. Cir. 1984). Accordingly, the D.C. District Court found that it lacked jurisdiction over the plaintiffs’ claim under the *TRAC* decision and transferred the case to the D.C. Circuit pursuant to § 1631. *See* 628 F. Supp. at 1552. Particularly compelling is the fact that the D.C. District Court found a transfer to be in the interest of justice even though the plaintiffs knew with some degree of certainty that jurisdiction lay only in the D.C. Circuit. By comparison, SSBG likely presents a stronger case for transfer

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<sup>28</sup> 628 F. Supp. 1548 (D.D.C. 1986).

considering that the jurisdictional question it seeks to clarify here has not yet been decided by any court. Thus, plaintiff's "novelty" argument is patently unpersuasive. The fact that SSBG may be eligible for a transfer from the D.C. District Court to the Federal Circuit, should its jurisdictional challenge in the D.C. District Court fail, strongly suggests that any hardship to SSBG is remediable.

In response to these arguments, plaintiff cites *Pennell v. City of San Jose*<sup>29</sup> as the case most apposite to its ripeness argument. Specifically, in the course of the December 11, 2009 hearing, plaintiff's counsel represented that the Supreme Court found ripeness where a landlord was subject to a city rent control ordinance that allowed a hearing officer to consider "hardship to a tenant" in granting or rejecting a proposed rent increase, despite the fact that there were no hardship tenants living in the landlord's property at the time the landlord challenged the ordinance. This description, however, omits an essential part of the decision. Significantly, the Supreme Court made clear that it accepted appellants' uncontested statement made at oral argument that the Tri-County Apartment House Owners Association already had many hardship tenants, even though none had been specifically identified. Based on its understanding that hardship tenants in fact lived in the appellants' properties, the Supreme Court found the case justiciable under the standing doctrine because "it is not unadorned speculation to conclude that the Ordinance will be enforced against members of the Association." *Pennell*, 485 U.S. at 7-8 (internal citation and quotation marks omitted). Accordingly, *Pennell* does not stand for the proposition, as plaintiff suggests, that a case is justiciable despite the fact that a law's applicability to a given plaintiff is contingent on the occurrence of some future event that may

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<sup>29</sup> 485 U.S. 1 (1988).

never materialize; rather, the Supreme Court's holding in *Pennell* with respect to justiciability is fully consistent with *Abbott Laboratories*. In both cases, the purported hardship was in no way conjectural because the plaintiffs were immediately subject to the challenged law. By comparison, in this case SSBG is not currently subject to the challenged regulation because it presently has no right to seek court review in the absence of an adverse BPAI final decision and, moreover, it may *never* have any such right. *See* 35 U.S.C. §§ 141-145, 306. Thus, plaintiff's invocation of *Pennell* refutes, rather than supports, a finding of ripeness here.

It is also worth noting that defendants cite *Calderon v. Ashmus*,<sup>30</sup> as the case most apposite to their position. In that case, California death row inmates sought a declaration that a six-month statute of limitations, rather than a one-year statute of limitations, did not apply to their habeas petitions because California did not provide adequate counsel for these inmates in collateral proceedings. The Supreme Court unanimously held the issue to be nonjusticiable because a declaratory judgment as to whether California did provide adequate counsel, thereby subjecting the petition to the six-month limitations period, would not resolve the underlying and more fundamental dispute whether the inmate was entitled to federal habeas relief in the first instance. *See* 523 U.S. at 746. Finding that “[t]he disruptive effects of an action such as this are peculiarly great when the underlying claim must be adjudicated in a federal habeas proceeding,” the Supreme Court held that allowing Ashmus to obtain a declaration without first exhausting his state habeas remedies would wrongly force federal courts “to litigate a single issue in a dispute which must await another lawsuit for complete resolution.” *Id.* at 747-48.

Defendants cite *Calderon* for the proposition that “risks associated with choices

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<sup>30</sup> 523 U.S. 740 (1998)

commonly faced by litigants” do not support justiciability, and that SSBG’s claimed “Hobson’s choice” is simply such a choice. *Id.* at 748. Defendants’ argument is persuasive. In the same way that the inmates in *Calderon* were forced to litigate the statute of limitations issue in a habeas proceeding rather than as a declaratory judgment action, thus exposing themselves to the risk that their petition would be deemed untimely if the six-month limitations period were applied in place of the one-year period, SSBG must likewise bear the risk of filing a civil action in the D.C. District Court only to find that it may lack jurisdiction. As noted *supra*, however, SSBG’s claimed risk of losing its right to seek court review is, in practice, not a “Hobson’s choice” at all given the strong likelihood that the D.C. District Court will, if it finds jurisdiction lacking, transfer the case to the Federal Circuit in the interest of justice pursuant to 28 U.S.C. § 1631.

To recapitulate, the Supreme Court’s decision in *Abbott Laboratories* directs federal courts faced with a question of ripeness to evaluate both “the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration.” 387 U.S. at 149. In this case, although plaintiff’s challenge to the PTO’s regulation meets the fitness prong of the ripeness test, it fails to show a cognizable or sufficient hardship to meet the second prong of the test, and hence plaintiff’s claim is not ripe and must be dismissed.

### III.

In sum, plaintiff’s request for a judgment declaring the validity or invalidity of the challenged regulation is unripe because: (i) the BPAI has not yet rendered an adverse decision that would allow SSBG to seek court review of that determination, making the purported hardship contingent and speculative; (ii) plaintiff has not demonstrated that the challenged

regulation creates an immediate, direct, and significant hardship altering its day-to-day activities; and (iii) any hardship is remediable by 28 U.S.C. § 1631. Accordingly, plaintiff does not present a justiciable case or controversy, and thus there is no jurisdiction to reach the merits of whether 37 C.F.R. § 1.303 contravenes 35 U.S.C. § 306.

An appropriate Order will issue.

Alexandria, Virginia  
December 18, 2009

  
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**T. S. Ellis, III**  
**United States District Judge**