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ABC Laboratories, Inc. v. Natural Anonymous Rights Foundation : Brief for the Appellant

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13-1993

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

ABC LABORATORIES, INC.,
Plaintiff-Appellant,

v.

NATURAL ANONYMOUS RIGHTS FOUNDATION,
Defendant-Appellee.

Appeal From The United States District Court For The District Of Ramblin

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BRIEF FOR THE APPELLANT

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CERTIFICATE OF INTEREST

Counsel for the appellant, ABC Laboratories, Inc., certify the following:

1. The full name of every party represented by the undersigned is:

   ABC Laboratories, Inc.

2. The name of the real party in interest represented by the undersigned is:

   ABC Laboratories, Inc.

3. All parent corporations and any publicly held companies that own ten percent or more of the stock of the party represented by the undersigned are:

   None.

4. The names of all law firms and the partners or associates that appeared for the party now represented by the undersigned in the trial court or are expected to appear in this court are:

   Humongous Law Firm (Mark Arrington; Shaun Mathur).

/s/ Mark Arrington
MARK ARRINGTON

/s/ Shaun Mathur
SHAUN MATHUR

Attorneys for Plaintiff-Appellant

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STATEMENT OF RELATED CASES

Pursuant to Federal Circuit Rule 47.5, appellant ABC Laboratories, Inc. provides as follows:

(a) There have been no previous appeals in this case.

(b) It is aware of no other case that will directly affect or be directly affected by the Court's decision in this case.

STATEMENT OF JURISDICTION

ABC Laboratories, Inc. ("ABC") contests the district court's subject matter jurisdiction. The Natural Anonymous Rights Foundation ("NARF") invoked district court jurisdiction under 28 U.S.C. § 1338(a). This Court's jurisdiction over ABC's timely appeal from a final judgment is under 28 U.S.C. § 1295.

STATEMENT OF THE ISSUES

1. Did the district court err when it denied ABC's motion to remand and exercised arising under jurisdiction where ABC's state law breach of license claim does not require a court to determine the '287 patent's scope or validity, which are insubstantial patent issues, and exercising jurisdiction would flood federal courts with state contract claims?
2. Did the district court err when it granted NARF's motion for summary judgment and invalidated the '287 patent where synthetically created cDNA is patent eligible under 35 U.S.C. § 101 and the '287 patent's method claim, which is drawn to the application of that cDNA and the newly discovered PNKY gene, is sufficiently transformative?

STATEMENT OF THE CASE AND FACTS

I. ABC Laboratories, Inc. ("ABC") And The '287 Patent

Masochistic Indomitable Neurotic Drive ("MIND") Syndrome is a rare disease that usually leads to embryonic death shortly after conception in mammals. Record Facts at ¶ 1 (hereinafter

"RF"). In rare cases of survival, "MIND Syndrome causes megalomania paired with extreme intelligence, and uncontrollable urges to make repeated attempts to take over the world." *Id.*

ABC discovered a genetic sequence associated with MIND Syndrome. *Id.* ABC filed a patent application with the United States Patent and Trademark Office ("PTO") shortly after making its discovery. *Id.* at ¶ 2. The PTO then issued U.S. Patent No. 8,000,287 ("the '287 patent") to the private institution.

The '287 patent teaches that DNA molecules exist in every human cell and encode a person's entire genome. *Id.* The DNA double helix contains "crossbars," which consist of two chemically joined nucleotides. *Id.* DNA nucleotide sequences encode information for making amino acids, which are the building blocks for proteins. *Id.* The patent also teaches that different portions of a DNA strand encode for different genetic traits. *Id.* at ¶ 3. These different portions, or sequences of nucleotides, are "genes." *Id.* Not every nucleotide within a gene codes for proteins, however. *Id.* The protein coding sequences are "exons," and the non-coding sequences are "introns." *Id.*

The broadest claim of the '287 patent claims "[a]n isolated cDNA associated with [MIND] Syndrome, wherein the cDNA has the nucleotide sequence set forth in SEQ. ID NO:1." *Id.* at ¶ 4. The claimed cDNA sequence contains only the coding exons without the non-coding introns. *Id.* ABC isolated the claimed sequence from

the genomic PNKY gene found in human embryos carrying the syndrome. *Id.* at ¶ 5. ABC isolated the sequence by reverse transcription of the mRNA molecules that create the proteins associated with MIND Syndrome. *Id.* at ¶ 6. ABC used well-known techniques to make its discovery. *Id.*

The '287 patent also discloses and claims a method to screen embryos using the claimed sequence. *Id.* at ¶ 9. The method consists of extracting an embryo's PNKY gene and comparing it to the claimed sequence. *Id.* Geneticists and fertilization technicians can then determine if the embryo's PNKY gene includes the claimed sequence associated with MIND Syndrome. *Id.* Specifically, the '287 patent claims:

> 10. A method for screening human embryos for a PNKY gene associated with [MIND] Syndrome in an embryo, the steps of the method comprising:
>
> comparing a first sequence of a PNKY gene extracted from the embryo with a second sequence of a PNKY gene set forth in SEQ. ID NO. 1; and
>
> segregating the embryo if the comparing shows that the first sequence includes all components of the second sequence.

Id. ABC developed and marketed a screening test based on this method in May 2004. *Id.*

II. The Natural Anonymous Rights Foundation ("NARF")

NARF is a non-governmental organization. RF at ¶ 10. Shortly after ABC made its discovery, NARF-sponsored scientists at Ramblin State University ("the RSU scientists") discovered a genetic sequence associated with MIND Syndrome. *Id.* The RSU

scientists discovered the sequence by isolating DNA mutations unique to human adults that experienced MIND symptoms. *Id.* The studied adults had the exact sequence that ABC disclosed and claimed in the '287 patent. *Id.* at ¶ 11. The sequence was also in the same PNKY gene from which ABC isolated the claimed sequence. *Id.* The sequence the RSU scientists discovered contains only the exons that code for the same proteins as the sequence ABC discovered and claimed in its patent. *Id.* at ¶ 15.

Moreover, the RSU scientists concluded the sequence arose in the studied adults as a processed pseudogene because the sequence had no introns. *Id.* at ¶ 11. Processed pseudogenes are DNA sequences that derive from the same process lab technicians use to create cDNA. *Id.* at ¶ 12. These processed pseudogenes are "naturally occurring cDNA strands in the human genome that are structurally, functionally, and chemically identical to cDNA" created in the laboratory. *Id.* Scientists believe pseudogenes form when a naturally occurring virus reverse transcribes the mRNA associated with the pseudogene. *Id.* Even though most pseudogenes are non-functional, the RSU scientists determined the pseudogene they discovered is active and creates the proteins that cause MIND Syndrome in adults. *Id.* at ¶ 13.

The RSU scientists then created a screening test based on this pseudogene. *Id.* at ¶ 16. The test identifies embryonic and adult versions of MIND Syndrome. *Id.* at ¶ 17. NARF made this

test available to fertilization clinics and embryonic testing suppliers beginning in October 2004. *Id.* at ¶ 16.

III. The License Agreement And Subsequent Dispute

After the PTO issued the '287 patent, ABC sent demand letters to fertilization clinics, end users, and embryonic testing suppliers that used NARF's test. RF at ¶ 18. In the letters, ABC threatened to sue users of NARF's screening test for infringing the '287 patent. *Id.* ABC and NARF then entered into a license agreement, allowing NARF to continue distributing its test, *id.*, in exchange for royalties. *Id.* at ¶ 19.

The license defines the "Licensed Product" as "any test covered by a claim of the ['287] Patent." *Id.* at ¶ 18. The license also states the term of the agreement is tied to the validity of the '287 patent. *Id.* The term clause states:

> This agreement shall remain in full force and effect for the complete term of the ['287] Patent unless (i) all claims of the ['287] Patent are held invalid or unenforceable by a court of competent jurisdiction, in which case the term of this agreement shall end upon the date all appeals from which any corresponding order or judgment have been exhausted, or (ii) either party breaches any provision of this agreement. In the event the ['287] Patent is held invalid or unenforceable by a court of competent jurisdiction, no royalties will be owed under this license.

Id. The agreement covers the fertilization clinics, end users, and embryonic testing suppliers that use NARF's test. *Id.*

In 2010, NARF sought permission from ABC to use the test royalty-free to conduct research on adults. *Id.* at ¶ 23. ABC

refused. *Id.* Nevertheless, in mid-2011, NARF began offering free MIND Syndrome screenings to NARF members. *Id.* at ¶ 24. NARF paid no royalties to ABC for these screenings. *Id.*

ABC subsequently sued NARF in Ramblin state court in December 2011, claiming NARF breached the license agreement. *Id.* at ¶ 25. NARF answered by claiming the '287 patent is invalid and that claim 10 of the '287 patent covers only embryonic testing. *Id.* NARF then removed to the United States District Court for the District of Ramblin pursuant to 28 U.S.C. § 1441. *Id.* NARF also filed a declaratory judgment counterclaim, seeking a declaration that the '287 patent is invalid. *Id.*

ABC timely filed a motion to remand. *Id.* at ¶ 26. In support of its opposition to ABC's motion, NARF submitted a declaration by Professor Elle Vira. *Id.* The declaration states that "nearly [fifty] patent applications [are] pending at the USPTO, which relate to patents for cDNA where the differences between cDNA and gDNA are minimal or nonexistent." *Id.*

IV. The District Court Denies ABC's Motion To Remand And Rules The '287 Patent Is Invalid As A Matter Of Law

The district court denied ABC's motion to remand and granted NARF's motion for summary judgment, invalidating the '287 patent. Conclusions of Law at ¶¶ 1, 4 (hereinafter "CL"). Accepting subject matter jurisdiction, the court recognized that ABC's breach of license claim does not directly arise under the

patent law pursuant to 28 U.S.C. § 1338(a). *Id.* at ¶ 1. In any case, the court ruled ABC's "breach of license claim necessarily required the court to decide unsettled issues of patent law, which establish them as substantial federal issues." *Id.* at ¶ 3.

In ruling the '287 patent invalid, the court recognized that non-naturally occurring cDNA is patentable. *Id.* at ¶ 4. But the court ruled the '287 patent lacked patent eligible subject matter under 35 U.S.C. § 101 because "the DNA sequence claimed in the '287 patent was naturally occurring and known to cause the claimed symptoms in at least some individuals afflicted with MIND Syndrome." *Id.* at ¶ 5. ABC appealed under 28 U.S.C. § 1295.

SUMMARY OF THE ARGUMENT

This Court should reverse and vacate the district court's ruling because the district court incorrectly (1) exercised subject matter jurisdiction over ABC's breach of license claim under 28 U.S.C. § 1338(a) and (2) invalidated the '287 patent's cDNA and method claims under 35 U.S.C. § 101.

First, the district court incorrectly exercised arising under jurisdiction because ABC's claim fails the *Grable* test. The '287 patent's scope is not an essential element of ABC's claim because the claim only requires a court to interpret the license and determine the royalties NARF owes ABC. Nor does the claim necessarily raise the patent's validity because courts presume patent validity and NARF raises invalidity as a defense.

Even if ABC's claim implicates a patent question, that question is insubstantial to the patent system because it will not control numerous other cases. Finally, exercising jurisdiction over this case will disrupt the states' ability to develop their own bodies of contract law and overflow federal court dockets. Therefore, this Court should reverse the district court's denial of ABC's motion to remand and vacate the lower court's ruling.

Second, the district court misapplied the Supreme Court's holding in *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.* to invalidate the '287 patent. This Court should correct the lower court and hold the '287 patent's cDNA claim is patent eligible under 35 U.S.C. § 101. Although products of nature are not patent eligible, products of human ingenuity are. In *AMP*, the Court held cDNA, as a product of man, is patent eligible subject matter. The Court's holding was narrow and drew a line for patentability of genetic materials. Thus, ABC's cDNA claim is patentable. Moreover, ABC's method claim is patent eligible. The claim is drawn to the patentable synthetic cDNA that ABC discovered, and its application to the PNKY gene involves more than abstract ideas. Therefore, this Court should reverse the district court's grant of NARF's motion for summary judgment.

STANDARD OF REVIEW

A district court's exercise of jurisdiction under 28 U.S.C. § 1338(a) is a legal issue this Court reviews *de novo*. *In re*

Cambridge Biotech Corp., 186 F.3d 1356, 1368 (Fed. Cir. 1999). This Court also reviews a district court's grant of summary judgment *de novo*, affirming only when the material facts are undisputed and "the moving party is entitled to a judgment as a matter of law." *Crown Operations Int'l, Ltd. v. Solutia Inc.*, 289 F.3d 1367, 1375 (Fed. Cir. 2002). Finally, this Court also reviews a patent claim's subject matter eligibility under 35 U.S.C. § 101 *de novo*. *In re Bilski*, 545 F.3d 943, 951 (Fed. Cir. 2008), *aff'd sub nom. Bilski v. Kappos*, 130 S. Ct. 3218 (2010).

ARGUMENT

This Court should reverse and vacate the district court's ruling because the district court incorrectly (1) exercised arising under jurisdiction over ABC's breach of license claim under 28 U.S.C. § 1338(a) and (2) ruled the '287 patent's cDNA and method claims patent ineligible under 35 U.S.C. § 101.

I. The District Court Incorrectly Denied ABC's Motion To Remand And Exercised Arising Under Jurisdiction Over ABC's Breach Of License Claim.

Removal is proper only if ABC Laboratories, Inc. ("ABC") could have originally brought this state action in federal court. *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 312 (2005). Federal courts, however, "are courts of limited jurisdiction, possessing only that power authorized by Constitution and statute." *Gunn v. Minton*, 133 S. Ct. 1059, 1064 (2013). Congress granted federal district courts exclusive

jurisdiction over "any civil action arising under any Act of Congress relating to patents." 28 U.S.C. § 1338(a). Under this provision and its predecessors, courts have long held contract disputes belong in state court. *See, e.g.*, *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 262 (1979) ("State law is not displaced merely because the contract relates to [an invention] which may or may not be patentable."); *Luckett v. Delpark, Inc.*, 270 U.S. 496, 510 (1926) ("[W]here a patentee complaint makes his suit one for recovery of royalties under a contract of license . . . or for damages for a breach of its covenants . . . he does not give the federal District Court jurisdiction of the cause as one arising under the patent laws.").

As with arising under jurisdiction under 28 U.S.C. § 1331, patent jurisdiction exists only when the face of the plaintiff's well pled complaint presents a patent question. *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 808–09 (1988). The complaint must "set[] up a right under the patent laws as ground for a recovery," *Excelsior Wooden Pipe Co. v. Pac. Bridge Co.*, 185 U.S. 282, 287 (1902), or "make it appear that some right or privilege will be defeated by one construction or sustained by the opposite construction of" the patent law. *Id.* at 286. Patent defenses, however, cannot create jurisdiction even if a defense is the only contested issue in the case. *Christianson*, 486 U.S. at 809. If multiple theories support the plaintiff's claim, then

the claim also does not arise under the patent law, "unless patent law is essential" to each theory. *Id.* at 810. Although recent amendments to the Patent Act allow counterclaims arising under the patent law to provide grounds for removal, Paul R. Gugliuzza, *The Federal Circuit as a Federal Court*, 54 Wm. & Mary L. Rev. 1791, 1808 (2013), the plaintiff remains the master of his suit and may avoid federal jurisdiction by relying on state law. *Caterpillar Inc. v. Williams*, 482 U.S. 386, 392 (1987).

Generally, a case may arise under the patent law in two ways. *Gunn v. Minton*, 133 S. Ct. 1059, 1064 (2013). First, the most direct path is when patent law creates the cause of action. *Id.* Patent law, however, does not create ABC's breach of license claim. Second, in a "special and small category" of cases, *Empire Healthchoice Assurance, Inc. v. McVeigh*, 547 U.S. 677, 699 (2006), a federal court may exercise jurisdiction over a state law claim if a federal issue is "(1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress." *Gunn*, 133 S. Ct. at 1065 (hereinafter "*Grable* test") (citing *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 314 (2005)).

Here, the district court misapplied the *Grable* test and exercised jurisdiction over ABC's breach of license claim. CL at ¶ 3. The district court erred because (A) ABC's claim does not

necessarily raise the '287 patent's scope or validity, (B) ABC's claim does not implicate a substantial issue of patent law, and (C) federal court resolution of this case would disrupt the congressionally approved federal-state court balance.

A. ABC's Breach Of License Claim Does Not Necessarily Raise The '287 Patent's Scope Or Validity.

ABC's claim does not necessarily raise a federal issue. A state claim necessarily raises a federal issue when federal law is an essential element of the claim. *Grable*, 545 U.S. at 315. First, the '287 patent's scope is not an essential element because ABC's claim only requires a court to interpret the license and determine the royalties that NARF owes ABC. Second, the patent's validity is not an essential element because courts presume patent validity and NARF raises invalidity as a defense.

First, ABC's claim does not necessarily raise the '287 patent's scope. Courts must pay attention to a plaintiff's requested relief when examining whether a claim arises under the patent law. *Bd. of Regents, Univ. of Tex. v. Nippon Tel. & Tel. Corp.*, 414 F.3d 1358, 1362 (Fed. Cir. 2005). Moreover, this Court has held breach of license claims do not arise under the patent law. *Ballard Med. Prods. v. Wright*, 823 F.2d 527, 530 (Fed. Cir. 1987). In *Ballard*, the licensee claimed the patentee-licensor breached the license by manufacturing, selling, and licensing products that fell within the scope of the exclusive

license. *Id.* at 529. Although the scope of the licensed patent controlled the scope of the license, this Court held "that rule of contract law cannot possibly convert a suit for breach of contract into one 'arising under' the patent laws." *Id.* at 530.

Here, as master of its suit, ABC brought a breach of license claim, seeking the state remedy of royalties due under the license. RF at ¶ 25. As in *Ballard*, although the '287 patent's scope may control the scope of the license, that does not suggest ABC's state claim arises under the patent law.

To the extent ABC's claim implicates the '287 patent's scope, ABC's complaint does not raise the patent's scope as an essential element to each of ABC's theories for recovery. If multiple theories support a plaintiff's claim, the claim does not arise under the patent law "unless patent law is essential" to each theory. *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 810 (1988). ABC's claim, however, only requires a court to interpret the license to ascertain each party's unique obligations and the royalties that NARF owes ABC. NARF also raises the patent's scope as a defense. RF at ¶ 25. But patent defenses cannot create jurisdiction. *Christianson*, 486 U.S. at 809. Thus, the '287 patent's scope is not an essential element.

Second, ABC's claim does not necessarily raise the '287 patent's validity. Although the term of the license is tied to the '287 patent's validity, RF at ¶ 18, the patent's validity is

not an essential element because courts presume patent validity. *Allergan, Inc. v. Sandoz Inc.*, 726 F.3d 1286, 1291 (Fed. Cir. 2013). Thus, ABC's complaint does not require ABC to prove the '287 patent's validity in order to recover from NARF. To the extent ABC's claim raises the patent's validity, NARF raises it only as a defense to ABC's state action. RF at ¶ 25. Patent law defenses, however, cannot create federal patent jurisdiction. *Christianson*, 486 U.S. at 809; *see also Intermedics Infusaid v. Regents of Univ. of Minn.*, 804 F.2d 129, 132–33 (Fed. Cir. 1986) (holding state courts may resolve contract claims where the claimant seeks royalties due under a patent license even when the defendant challenges the patent's validity).

In sum, the '287 patent's scope is not an essential element of ABC's breach of license claim because ABC seeks only state law remedies. Nor is the '287 patent's validity an essential element because courts presume patent validity and NARF raises invalidity only as a defense. Thus, ABC's state law breach of license claim does not necessarily raise federal patent issues.

B. ABC's Breach Of License Claim Does Not Implicate A Substantial Issue Of Federal Patent Law.

ABC's claim does not contain a substantial patent issue. An issue is substantial when it is "significant to the federal system as a whole," *Gunn v. Minton*, 133 S. Ct. 1059, 1068 (2013), implicating a "serious federal interest" in litigating

the matter in federal court. *Grable*, 545 U.S. at 313.

Several factors are indicative of a "substantial" patent issue. (1) Pure questions of law, *Empire Healthchoice Assurance, Inc. v. McVeigh*, 547 U.S. 677, 700–01 (2006); (2) questions that will control numerous other cases, *Gunn*, 133 S. Ct. at 1067; and (3) questions the Federal Government has a direct interest in litigating in federal court, *Grable*, 545 U.S. at 315, are substantial issues. Here, none of these factors are present.

First, even if ABC's claim requires a court to determine whether NARF's test falls within the '287 patent's scope, that determination is not a pure question of law. "[F]act-bound and situation-specific," *Empire Healthchoice*, 547 U.S. at 699, state claims do not fall within the narrow category of state claims that arise under federal law. *Id.* at 700–01. Rather than require an application of federal law to facts, the state claim should present a pure issue of federal law. *See id.* at 700.

In *Grable*, the interpretation of a federal statute was a "pure issue of law." *See Empire Healthchoice*, 547 U.S. at 700 (discussing *Grable*). But here, determining whether NARF's test falls within the '287 patent's scope is a mixed question of law and fact. *MDS (Canada) Inc. v. Rad Source Techs., Inc.*, 720 F.3d 833, 842 (11th Cir. 2013). Although claim construction is a legal question, whether NARF's test reads on any claim of the '287 patent is a factual question. *WMS Gaming Inc. v. Int'l Game*

Tech., 184 F.3d 1339, 1346 (Fed. Cir. 1999). Thus, this case does not present a pure question of law. Rather, a court must only apply federal law to facts; a task a state court is competent to do. *See Empire Healthchoice*, 547 U.S. at 701.

Even though the '287 patent's subject matter eligibility is a question of law, *In re Bilski*, 545 F.3d 943, 951 (Fed. Cir. 2008), NARF raises invalidity as a defense. RF at ¶ 25. Patent law defenses, however, cannot create arising under jurisdiction. *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 809 (1988). Thus, the fact the '287 patent's validity is a question of law is irrelevant to this Court's substantiality analysis.

Second, resolving the potential patent question here would not control other cases. In *Gunn*, the "hypothetical" patent issue was insubstantial because of the backward-looking nature of legal malpractice claims. 133 S. Ct. at 1066–67. No matter how a state court handled the hypothetical issue, it would not change the fact a federal court invalidated the patent in the "real-world" patent litigation. *Id.* at 1067. Nor would allowing state courts to adjudicate hypothetical patent issues undermine the uniformity of patent law because "federal courts are . . . not bound by state court case-within-a-case patent rulings." *Id.* Moreover, the asserted patent issue was not novel such that its resolution "would be controlling in numerous other cases." *Id.* Thus, the federal courts' familiarity with patent law, alone,

did not justify federal jurisdiction. *Id.* at 1068.

Similarly, a state court interpretation of the '287 patent would not bind federal courts or have preclusive effects. *See Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 350 (1971). Only a federal court's interpretation of the patent would estop ABC in future cases. *Id.* For example, if a federal court declared the '287 patent invalid, the patent would be invalid to the entire world. But if a state court ruled the '287 patent invalid, the patent would be invalid to only these parties. Thus, a state court ruling on the patent's scope or validity would not bind federal courts in subsequent suits.

In addition, the '287 patent's scope and validity are not novel patent issues that will control other cases. As discussed below, *see infra* Part II, cDNA is patentable subject matter. *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2119 (2013). Even if this case presents a novel patent issue, it will surely arise again in an actual patent case where federal courts will have jurisdiction. *See Gunn*, 133 S. Ct. at 1067. If the issue does not arise again, then "it is unlikely to implicate substantial federal interests." *Id.*

Moreover, the possibility that a state court will mishandle a state claim, alone, does not create federal jurisdiction. *See id.* at 1068. Even if a state court errs, that error will affect only these parties—not the entire federal system. *See Blonder-*

Tongue, 402 U.S. at 350. In fact, a state court's interpretation of patent law would have no precedential effect on federal case law. *Byrne v. Wood, Herron & Evans LLP*, 676 F.3d 1024, 1035 (Fed. Cir. 2012) (O'Malley, J., dissenting from the denial of a petition for rehearing *en banc*) (citing *Adventure Outdoors, Inc. v. Bloomberg*, 552 F.3d 1290, 1301 (11th Cir. 2008) (holding a "state court interpretation of the gun statutes will not be controlling in numerous other cases because it will not have precedential effect in the federal system")). Therefore, this case's disposition will not control numerous other cases.

Third, state court resolution of this case would not hinder the government's intent to have uniformity in the patent law. In *Grable*, the meaning of a federal tax statute was a substantial federal issue. 545 U.S. at 315. The Court focused on the broader significance of the question and the government's "strong interest" in collecting taxes. *Id.* The IRS also had a "direct interest" in vindicating its action in a federal forum. *Id.*

Here, the government's interest in ABC's fact-based contract claim is insignificant compared to the government's interest in a legal question affecting its ability to raise revenue. *See MDS (Canada) Inc. v. Rad Source Techs., Inc.*, 720 F.3d 833, 842 (11th Cir. 2013). This case also does not require a court to determine whether a federal agency complied with a federal statute. *See Empire Healthchoice*, 547 U.S. at 700

(noting *Grable* centered on whether the IRS complied with a federal statute). Nor will the result of this private action influence the PTO's decision to issue future patents. *See MDS (Canada) Inc.*, 720 F.3d at 843. Thus, the government does not have an interest in litigating this matter in federal court.

In sum, ABC's claim does not present a pure issue of law that will control numerous other cases. Nor does the government have a direct interest in ABC's state claim. Therefore, ABC's claim does not implicate a substantial patent issue.

C. Federal Court Adjudication Of ABC's Claim Will Disrupt The Federal-State Court Division Of Labor.

Federal court resolution of this state claim will disrupt the federal-state court balance. Even when a federal issue is substantial, a federal court may veto jurisdiction if exercising jurisdiction would disrupt the congressionally approved federal-state court balance. *Grable*, 545 U.S. at 313. This inquiry focuses on the proper "balance of federal and state judicial responsibilities," *id.* at 314, limiting jurisdiction to state claims that "justify resort to the experience" and "uniformity that a federal forum offers on federal issues." *Id.* at 312. Even if ABC's claim raises a substantial patent issue, this Court should veto jurisdiction because exercising jurisdiction will (1) disrupt the states' ability to develop their own bodies of contract law and (2) cause federal court dockets to overflow.

First, state courts have traditionally adjudicated contract disputes. *See, e.g.*, *Luckett v. Delpark, Inc.*, 270 U.S. 496, 510 (1926). Accordingly, exercising arising under jurisdiction over contract claims like this would disrupt the states' ability to develop their own bodies of contract law and provide contractual remedies to their citizens. *See Gully v. First Nat'l Bank*, 299 U.S. 109, 115 (1936). Even while acknowledging Congress's desire for uniformity, this Court has recognized that "Congress was not concerned that an occasional patent law decision of a . . . state court[] would defeat its goal of increased uniformity" in the patent law. *Atari, Inc. v. JS & A Grp., Inc.*, 747 F.2d 1422, 1432 (Fed. Cir. 1984).

Second, exercising jurisdiction over this type of case will cause federal court dockets to overflow. In *Grable*, the Court did not exercise its veto power because only the "rare state title case" will raise a contested federal issue. 545 U.S. at 315. But exercising jurisdiction over contract claims involving a patent would attract "a horde of original filings and removal cases raising other [contract] claims with embedded federal issues." *Id.* at 318. Congress did not intend this result when it granted federal courts jurisdiction over patent cases, not questions. *See Excelsior Wooden Pipe Co. v. Pac. Bridge Co.*, 185 U.S. 282, 286–87 (1902). Thus, even if ABC's claim implicates a substantial patent issue, this Court should veto jurisdiction to

maintain the appropriate federal-state court balance.

In sum, the lower court incorrectly exercised jurisdiction over this case for three reasons. First, the '287 patent's scope and validity are not essential elements of ABC's claim. Second, even if ABC's claim raises a patent issue, that issue is not substantial. Third, federal court resolution of this case would disrupt the states' ability to develop their own bodies of contract law. Thus, this Court should reverse the district court's denial of ABC's motion to remand and vacate its ruling.

II. Even If The District Court Had Jurisdiction, The District Court Incorrectly Granted NARF's Motion For Summary Judgment Because ABC's Patent Claims Are Patent Eligible.

The '287 patent's cDNA and method claims are drawn to patentable subject matter. The Patent Act states, "[w]hoever invents or discovers any new and useful . . . composition of matter, or any new and useful improvement thereof, may obtain a patent." 35 U.S.C. § 101. But laws of nature, natural phenomena, and abstract ideas are not patentable. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1293 (2012) (citing *Diamond v. Diehr*, 450 U.S. 175, 185 (1981)). Thus, inventors cannot patent "the basic tools of science" and "inhibit future innovation premised upon them." *Id.* at 1301. Interpreting these exceptions too broadly, however, could "eviscerate patent law," as all inventions utilize the laws of nature. *Id.* at 1293.

The district court misapplied Supreme Court precedent when it

granted NARF's motion for summary judgment and invalidated the '287 patent. Specifically, the court erred because (A) manmade cDNA is patent eligible, and (B) ABC's method claim is drawn to patent eligible subject matter.

A. Products Of Nature Are Patent Ineligible, But Products Of Man Are Patent Eligible.

ABC's cDNA claim is patentable under § 101 because cDNA is the product of human ingenuity. While realizing the need to strike a "balance between creating incentives that lead to creation, invention, and discovery and imped[ing] the flow of information that might permit, indeed spur, innovation," *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2116 (2013) (alteration in original), the Court has reviewed the patentability of claims derived from nature.

In *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, the Court held a mixture of naturally occurring bacteria patent ineligible because the patentee did not alter the bacteria in any way. 333 U.S. 127, 128–29, 132 (1948). In *Diamond v. Chakrabarty*, however, scientists genetically modified bacterium to break down components of crude oil. 447 U.S. 303, 305 (1980). The Court held this modified bacterium patentable because the organism was "a product of human ingenuity," not nature. *Id.* at 309.

Most recently, in *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, the Court held Myriad's genomic DNA claims were

invalid products of nature. 133 S. Ct. at 2111. The Court found that Myriad did not create anything and held, "separating [a] gene from its surrounding genetic material is not an act of invention." *Id.* at 2117.

Despite the Court's holding that DNA isolated from its natural environment is patent ineligible, the Court also 1) held that cDNA is patent eligible and 2) drew a line for patenting genetic material. Thus, ABC's cDNA claim is patent eligible.

1) The *AMP v. Myriad* Court Held cDNA Is Patent Eligible Subject Matter Under Section 101.

The *AMP* Court recognized the distinction between genetic material isolated from its natural setting and synthetically created cDNA. *See id.* at 2112. Indeed, that distinction was the Court's basis for stating, "cDNA does not present the same obstacles to patentability as naturally occurring, isolated DNA segments." *Id.* at 2119. The Court then held that synthetically created cDNA is patent eligible subject matter. *Id.* at 2111.

Scientists synthetically create DNA using several known methods. *See id.* at 2112. One method begins with natural mRNA molecules, which the researcher manipulates through several steps to create a new strand of DNA. *See id.* This DNA is cDNA. *Id.* cDNA differs from genomic DNA because it contains only the coding exons without the non-coding introns. *Id.* Although nature dictates the cDNA's sequence, the Court concluded, "the lab

technician unquestionably creates something new when cDNA is made." *Id.* at 2119. Thus, the Court held cDNA is patentable because it is a product of man. *Id.*

2) The *AMP v. Myriad* Holding Was Intentionally Narrow And Drew A Well-Defined Line For Patent Eligibility.

The Court's narrow decision resulted in it holding Myriad's genomic DNA claims ineligible and cDNA claims patent eligible products of human ingenuity. *Id.* at 2119–20. The opinion's final sentence reveals the decision's scope: "[w]e merely hold that genes and the information they encode are not patent eligible under § 101 simply because they have been isolated from the surrounding genetic material." *Id.* at 2120. The Court noted that method claims were not before the Court, and it expressed no opinion on genomic DNA patentability under §§ 102, 103, and 112. *See id.* at 2119–20. But the Court did hold that synthetic DNA, such as cDNA, is patent eligible even though its sequence derives from the natural material. *Id.* at 2119.

ABC's cDNA claim is patentable because ABC synthetically created the cDNA. ABC determined the PNKY gene was responsible for MIND Syndrome and elucidated its sequence. RF at ¶ 5. After identifying the mutation, ABC synthesized the claimed sequence using the mRNA associated with MIND syndrome. *Id.* at ¶ 6. ABC then claimed the cDNA sequence derived from the mutated PNKY gene in the '287 patent. *Id.* at ¶ 4. The product of this process

of synthetically creating cDNA from mRNA is what the Court held patentable in *Ass'n for Molecular Pathology*, 133 S. Ct. at 2119. ABC did not isolate the cDNA from its surrounding material, but created the cDNA using human ingenuity and experimentation. Thus, the claimed cDNA is patent eligible subject matter.

This case, however, presents an unusual occurrence that the Court addressed in a footnote. *Id.* at 2119 n.8. In rare cases, genomic DNA may contain no introns. *Id.* The cDNA derived in such cases is identical to the genomic DNA. RF at ¶ 15. The Court appreciated that such viral-derived "pseudogenes" may occur in rare cases. *Ass'n for Molecular Pathology*, 133 S. Ct. at 2119 n.8. Indeed, the Court noted, "[t]he possibility that an unusual and rare phenomenon *might* randomly create a molecule similar to one created synthetically through human ingenuity does not render a composition of matter nonpatentable." *Id.* The fact the Court addressed the possibility of such a rarity, with language allowing for patentability in such cases, underscores the Court's intent to maintain the line drawn by its holding.

Accordingly, the Court intends that its recent modification to the patent law remain undisturbed and the line it drew remain the law. In sum, the synthetically created cDNA that ABC claimed in the '287 patent is patent eligible.

B. The '287 Patent's Method Claim Is Patentable.

ABC's method claim is drawn to patentable subject matter.

Method claims are patentable if they "transform an unpatentable law of nature into a patent-eligible *application* of such a law, [but] one must do more than simply state the law . . . while adding the words 'apply it.'" *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1294 (2012). A process reciting a law of nature, however, should contain "additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself." *Id.* at 1297.

Although the Court did not have method claims before it in *Ass'n for Molecular Pathology*, 133 S. Ct. at 2119, the Court endorsed Judge Bryson's view that "[a]s the first party with knowledge of the [BRCA] sequences, Myriad was in an excellent position to claim applications of that knowledge. Many of its unchallenged claims are limited to such applications." *Id.* at 2120 (quoting *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303, 1349 (Fed. Cir. 2012) (Bryson, J., concurring in part and dissenting in part)). Thus, methods applying patentable subject matter are valid.

ABC's method claim is patentable. The claim is distinct from *Mayo*'s method claims and does not claim only routine mechanics of comparison. RF at ¶ 9. Thus, ABC's method claim is patentable because the claim applies 1) a patentable cDNA sequence 2) to the MIND Syndrome biomarker that ABC discovered.

1) The Method Claim Uses Patent Eligible cDNA.

ABC's method claim is drawn to patent eligible cDNA. This Court upheld Myriad's method claims applying patent eligible subject matter because "once one has determined that a claimed composition of matter is patent-eligible subject matter, applying various known types of procedures to it is not merely applying conventional steps to a law of nature." *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303, 1336 (Fed. Cir. 2012). In endorsing this Court's reasoning on the new application of knowledge of the BRCA genes, the Supreme Court indicated that *Mayo* is inapplicable when the subject matter is patent eligible. *See Ass'n for Molecular Pathology*, 133 S. Ct. at 2120. Thus, this Court's reasoning in *AMP* is controlling. And the "comparison" step of ABC's method claim does not change the fact that claim 10 is based on manmade patent eligible subject matter. *Id.* Thus, ABC's method claim is patent eligible.

2) Application Of The Newly Discovered PNKY Gene Involves More Than Abstract Ideas.

Even if ABC's cDNA claim is invalid, ABC's method claim is valid because the method claim is transformative. To determine if a method claim to ineligible subject matter is patentable, the question is whether the patent claim "add[s] *enough* to [the natural laws] to allow the process [the inventors] describe to

qualify as patent-eligible processes that *apply* natural laws." *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1297 (2012). Here, the method claim, which differs from those in *Mayo*, describes a patent eligible method as in *Diamond v. Diehr*, 450 U.S. 175 (1981).

In *Mayo*, the claims only instructed physicians to consider known natural laws when treating patients. 132 S. Ct. at 1298. Physicians administered known drugs and analyzed the patient's blood for a known metabolite. *Id.* at 1297. The claims involved no new assay or biomarker. *Id.* at 1296. Rather, the claims only instructed physicians to modify the amount of drug prescribed according to the levels of the metabolite; activities that scientists in the field previously engaged in. *Id.* at 1298.

Unlike *Mayo*, ABC's method claim applies the subject matter ABC discovered. ABC discovered the MIND Syndrome mutation ABC claimed as cDNA. RF at ¶ 1. Application of a standard chemical assay to the discovered biomarker to probe the existence of the newly understood MIND syndrome is not routine activity. Also, prior to ABC's discovery of the MIND syndrome, there is no indication that any other lab could utilize standard techniques to detect and diagnose the syndrome in embryos or adults. Finally, all of the procedures and elements of the claim in *Mayo* were known in the field, but only the comparison step of the '287 patent's method claim was known at the time of filing; the

MIND syndrome gene was unknown.

In *Diehr*, a method drawn to ineligible subject matter was patentable because the application was transformative as a whole. 450 U.S. at 185. There, the patentee claimed a process for curing rubber based on the Arrhenius equation. *Id.* at 177–78. The general principles of curing rubber and the equation were known at the time but application of the equation to the process resulted in a new process. *See id.* at 177–79. The process included "installing rubber in a press, closing the mold, constantly determining the temperature of the mold, constantly recalculating the appropriate cure time through the use of the formula and a digital computer, and automatically opening the press at the proper time." *Id.* at 187.

The Court held the process was transformative because of the way the process's additional steps integrated the Arrhenius equation into the process as a whole. *See id.* The process claim did not seek a monopoly on all uses of the equation, but "only to foreclose from others the use of that equation in conjunction with all of the other steps in their claimed process." *Id.* at 187. Thus, the process was patentable. *Id.*

Similarly, claim 10 of the '287 patent is patent eligible because it contains a transformative combination of operations. Although genetic manipulations are known in the field, claim 10's comparison and segregation steps integrate the cDNA into

the process as a whole. RF at ¶ 9. Further, the claim does not preclude other uses of the cDNA sequence. Indeed, the method claim is limited to the use of the cDNA sequence in conjunction with the comparison and segregation steps of the claimed process. The claim does not preclude the use of isolated genomic DNA, nor does the claim prevent research on such sequences. Thus, the '287 patent's method claim is patent eligible.

In sum, both the composition of matter claim of the '287 patent and the method claim utilizing the MIND syndrome biomarker are patent eligible. Therefore, ABC's patent is valid.

CONCLUSION

For the reasons stated, this Court should REVERSE the district court's denial of ABC's motion to remand and VACATE the district court's grant of NARF's motion for summary judgment.

DATED this 31st Day of January 2014.

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CERTIFICATE OF SERVICE

We hereby certify that on the 31st day of January 2014, true and correct copies of the foregoing were sent via first-class mail, postage prepaid, to the following:

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CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(A), because it contains 30 pages, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii) and Federal Circuit Rule 32(b).
2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of the Federal Rule of Appellate Procedure 32(a)(6), because it has been prepared in a proportionally spaced typeface using Microsoft Word 2003 in Courier 12 point font.

Dated: January 31, 2014

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