1-31-2014

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

Mark Arrington
S.J. Quinney College of Law, University of Utah

Shaun Mathur
S.J. Quinney College of Law, University of Utah

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

---

BRIEF FOR THE APPELLEE

Mark Arrington
Shaun Mathur
Humongous Law Firm
1500 Showtime Street
Capital City, Ramblin. 99999

Attorneys for the Defendant-Appellee

CERTIFICATE OF INTEREST

Counsel for the appellees, the Natural Anonymous Rights Foundation, certify the following:

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

   Natural Anonymous Rights Foundation

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

   Natural Anonymous Rights Foundation

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 Defendant-Appellee

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

CASES

TABLE OF AUTHORITIES
(Continued)

Page(s)

TABLE OF AUTHORITIES
(Continued)

Page(s)

FEDERAL STATUTES

FEDERAL RULES

SECONDARY SOURCES

STATEMENT OF RELATED CASES

Pursuant to Federal Circuit Rule 47.5, appellee Natural Anonymous Rights Foundation 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

The district court had jurisdiction pursuant to 28 U.S.C. § 1338(a). This Court has jurisdiction over ABC Laboratories, Inc.'s ("ABC") timely appeal from a final judgment pursuant to 28 U.S.C. § 1295.

STATEMENT OF THE ISSUES

1. Did the district court correctly deny ABC's motion to remand where ABC's breach of license claim necessarily raises the '287 patent's scope and validity, which are substantial patent issues and capable of federal court resolution without disrupting the federal-state balance?
2. Did the district court correctly invalidate the '287 patent under 35 U.S.C. § 101 where the claimed cDNA sequence exists in nature as an identical and active pseudogene and the method claim is only an application of a law of nature?

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 the 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"). In ruling the court had 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. But the court relied on Supreme Court precedent and 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 affirm the district court's ruling because the district court correctly (1) exercised arising under jurisdiction over ABC's breach of license claim under 28 U.S.C. § 1338(a) and (2) invalidated the '287 patent's composition and method claims under 35 U.S.C. § 101.

First, the district court correctly exercised jurisdiction because ABC's claim satisfies the *Grable* test. ABC's claim necessarily raises the '287 patent's scope because a court must interpret the patent to determine whether NARF's test falls within the patent's scope. A court must also evaluate the '287 patent's validity because the enforceability of the license depends on the '287 patent's validity. The parties dispute both issues because the issues are dispositive of this case. The issues are also substantial to the entire patent system because they present a novel patent issue that will affect the numerous

patent applications pending at the PTO. Finally, exercising jurisdiction will not disrupt the federal-state court balance because *Grable*'s high bar ensures that only certain contract claims arise under the patent law. Thus, this Court should affirm the district court's denial of ABC's motion to remand.

Second, the district court correctly applied the Supreme Court's holding in *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.* to invalidate the '287 patent. Under § 101 of the Patent Act, products of nature are not patent eligible but products of human ingenuity are. Here, the '287 patent's cDNA claim is identical to naturally occurring genomic DNA. While a rare exception, the claimed cDNA is a product of nature and not patent eligible. In addition, ABC's method claim is not patent eligible under § 101 because the claim is drawn to patent ineligible cDNA. The step comparing the cDNA sequence to a test subject does not sufficiently transform the application of a known law of nature into a patent eligible method. Therefore, this Court should affirm the district court's grant of NARF's motion for summary judgment, invalidating the '287 patent.

STANDARD OF REVIEW

A district court's exercise of jurisdiction under 28 U.S.C. § 1338(a) is an issue of law 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*. *Crown Operations Int'l, Ltd. v. Solutia Inc.*, 289 F.3d 1367, 1375 (Fed. Cir. 2002). However, this Court reviews factual findings for clear error. *Hewlett-Packard Co. v. Acceleron LLC*, 587 F.3d 1358, 1361 (Fed. Cir. 2009).

ARGUMENT

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

I. The District Court Correctly Denied ABC's Motion To Remand Because ABC's Breach Of License Claim Necessarily Depends On Resolution Of A Substantial Question Of Patent Law.

The district court correctly denied ABC Laboratories, Inc.'s ("ABC") motion to remand and exercised arising under jurisdiction over ABC's breach of license claim. 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). As with general arising under jurisdiction under 28 U.S.C. § 1331, federal patent jurisdiction exists only when the face of the plaintiff's well pled complaint presents a patent law question. *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 808–09 (1988). Patent defenses, however, cannot create federal patent jurisdiction. *Id.* at 809.

In 2011, Congress amended the Patent Act to extend federal

jurisdiction over counterclaims arising under the patent law. *See* Leahy-Smith America Invents Act, Pub. L. No. 1129-29, § 19(a), 125 Stat. 284, 331 (2011); *see also Univ. of Ky. Research Found., Inc. v. Niadyne, Inc.*, No. 13-16-GFVT, 2013 WL 5943921, at *5 (E.D. Ky. Nov. 5, 2013) (noting the Leahy-Smith America Invents Act allows "counterclaims arising under federal patent law to provide grounds for federal removal jurisdiction"). These amendments abrogated *Holmes Group, Inc. v. Vornado Air Circulation Systems, Inc.*, 535 U.S. 826, 830 (2002), where the Supreme Court held patent law counterclaims cannot create patent jurisdiction. Paul R. Gugliuzza, *The Federal Circuit as a Federal Court*, 54 Wm. & Mary L. Rev. 1791, 1808 & n.86 (2013).

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 cause of action. 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 arising under jurisdiction over a state 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 correctly applied the *Grable* test and exercised arising under jurisdiction over ABC's breach of license claim because federal patent issues are (A) necessarily raised, (B) actually disputed, (C) substantial, and (D) capable of federal court resolution without disrupting the federal-state court division of labor. Thus, this Court should affirm the district court's denial of ABC's motion to remand.

A. The '287 Patent's Scope And Validity Are Necessary Elements Of ABC's Breach Of License Claim.

ABC's claim necessarily raises federal patent law issues. A state claim necessarily raises a federal issue when federal law is an essential element of the claim. *Grable*, 545 U.S. at 315. Here, federal patent issues are essential to ABC's claim because (1) interpretation of the '287 patent's scope determines whether the Natural Anonymous Rights Foundation ("NARF") breached the license, and (2) the license agreement's enforceability depends on the '287 patent's validity.

First, ABC's claim necessarily raises the '287 patent's scope. In *U.S. Valves, Inc. v. Dray*, patent jurisdiction existed because patent law was a necessary element of the breach of license claim. 212 F.3d 1368, 1372 (Fed. Cir. 2000). There, the licensee claimed the patentee-licensor sold products covered by the licensed patents in contravention of the license agreement.

Id. To prove this claim, the licensee had to show the licensed patents covered the products the licensor sold. *Id.* Thus, a court had to interpret the patents and determine whether the products the licensor sold infringed those patents. *Id.*

Similarly, the license between ABC and NARF covers "any test covered by a claim of the ['287] Patent." RF at ¶ 18. To determine whether NARF breached the license by offering adult MIND Syndrome screenings without paying royalties, *id.* at ¶ 24, a court must interpret and define the '287 patent's parameters to determine whether NARF's test infringes and falls within the '287 patent's scope. Therefore, the '287 patent's scope is an essential element of ABC's breach of license claim.

Second, ABC's claim necessarily raises the '287 patent's validity because the term of the license is tied to the '287 patent's validity. *Id.* at ¶ 18. The existence of a valid, and thus enforceable, contract is one of the elements of a breach of contract claim. *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 599 F.3d 1277, 1283 (Fed. Cir. 2010). Here, ABC and NARF contracted around the presumption that issued patents are valid, *Allergan, Inc. v. Sandoz Inc.*, 726 F.3d 1286, 1291 (Fed. Cir. 2013), and agreed at arm's length that the enforceability of the license shall depend on the '287 patent's validity. RF at ¶ 18. Accordingly, the '287 patent's validity is a necessary element of ABC's claim because ABC must establish the validity of the

‘287 patent in order to prove the existence of a valid and enforceable license. Accordingly, ABC’s breach of license claim necessarily raises federal patent issues.

B. The ‘287 Patent’s Scope And Validity Are Actually Disputed Because Both Issues Are Dispositive Of ABC’s Breach Of License Claim.

ABC and NARF actually dispute federal patent issues. A federal issue is actually disputed when it is significant to the parties and affects the case’s merits. *Gunn v. Minton*, 133 S. Ct. 1059, 1065–66 (2013). Here, ABC and NARF actually dispute the ‘287 patent’s scope and validity because both issues are dispositive of ABC’s breach of license claim.

In *Gunn*, the parties actually disputed a federal patent issue. *Id.* at 1065. There, the dispositive issue of the legal malpractice suit was whether the experimental-use exception to the on-sale bar to patentability would have applied in the underlying patent infringement litigation. *Id.* Thus, application of patent law was outcome determinative of the state law claim.

Similarly, ABC and NARF actually dispute two patent issues. First, to determine whether NARF breached the license, a court must determine whether NARF’s adult screening test falls within the scope of the ‘287 patent. *See U.S. Valves*, 212 F.3d at 1372. This requires a court to interpret the ‘287 patent and determine whether NARF’s adult test infringes the patent. *Id.* If NARF’s adult screening test is not within the scope of claim 10 of the

‘287 patent, RF at ¶ 9 (claiming a “method for screening human embryos for a PNKY gene associated with” MIND Syndrome), then NARF has not breached the license and owes no royalties under the agreement. *See U.S. Valves*, 212 F.3d at 1372. Therefore, the ‘287 patent’s scope is outcome determinative of ABC’s claim.

Second, the ‘287 patent’s validity is also dispositive of ABC’s claim because the license’s term is tied to the patent’s validity. RF at ¶ 18. In other words, the enforceability of the license depends on the ‘287 patent’s validity. *See id.* If the ‘287 patent is invalid, then the license is terminated and unenforceable. Accordingly, ABC and NARF actually dispute the ‘287 patent’s scope and validity.

C. The ‘287 Patent’s Scope And Validity Are Substantial Federal Patent Issues Because Numerous Related Patent Applications Are Pending At The USPTO.

The ‘287 patent’s scope and validity are substantial patent issues. A federal issue is substantial when it is “significant to the federal system as a whole.” *Gunn*, 133 S. Ct. at 1068. ABC’s claim presents substantial patent issues because (1) a judicial interpretation of the ‘287 patent’s scope and validity will affect these parties, the PTO, and the numerous patent applications pending at the PTO; (2) resolution of these issues will have preclusive effects; and (3) federal court resolution of these issues promotes the patent law’s uniformity.

First, an interpretation of the ‘287 patent’s scope and

validity will affect these parties, the PTO, and the numerous patent applications pending at the PTO. In *Gunn*, the legal malpractice claim's patent issue was not a substantial federal issue. *Id.* at 1066. The patent issue—the experimental-use exception's applicability in the prior patent infringement litigation—was "hypothetical" in light of the backward-looking nature of legal malpractice claims. *Id.* at 1067. No matter how the state court resolved the hypothetical "case within a case," it would not alter the fact a federal court invalidated the patentee's patent in the "real-world" patent litigation. *Id.*

Unlike *Gunn*, the '287 patent is not a hypothetical patent because a judicial interpretation of the '287 patent will affect the patent and patent law. In fact, resolution of ABC's claim requires a court to actually—not hypothetically—determine the '287 patent's scope and validity. *See Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 599 F.3d 1277, 1283 (Fed. Cir. 2010) (declaring a state claim may arise under the patent law if the claim requires proving the patent's validity).

Rather, this case is like *Grable* where the meaning of a federal tax statute was a substantial federal issue. 545 U.S. at 315. There, the Court focused on the broader significance of the question and the Federal Government's "strong interest" in being able to collect taxes. *Id.* The IRS also had a "direct interest" in vindicating its administrative action in a federal forum. *Id.*

Similarly, an interpretation of the '287 patent will affect the PTO and other parties. Like the IRS in *Grable*, the PTO has a direct interest in vindicating its decision to issue the '287 patent in a federal forum before judges versed in patent law. *See Grable*, 545 U.S. at 315; *see also Air Measurement Techs., Inc. v. Akin Gump Strauss Hauer & Feld, L.L.P.*, 504 F.3d 1262, 1272 (Fed. Cir. 2007) (noting the federal interest in resolving patent issues in federal court because a federal agency issues patents and federal judges have experience in claim construction and infringement matters). The fact that there are nearly fifty patent applications pending at the PTO that relate to patents for cDNA where "the differences between cDNA and [genomic DNA] are minimal or nonexistent" supports this interest. RF at ¶ 26. Thus, a court's interpretation of the '287 patent's scope and validity will affect not only ABC and NARF, but also the PTO and the numerous patent applications pending at the PTO.

Second, a court's interpretation of the '287 patent's scope and validity will have preclusive effects. In *Gunn*, the asserted patent issue was not novel such that its resolution "would be controlling in numerous other cases." 133 S. Ct. at 1067. The Court also concluded that permitting state courts to adjudicate hypothetical patent issues would not undermine the uniformity of patent law because "federal courts are . . . not bound by state court case-within-a-case patent rulings." *Id.* Therefore, the

possibility that a state court would incorrectly handle a state claim was not, without more, enough to give rise to the federal courts' exclusive patent jurisdiction. *Id.* at 1068.

Unlike the hypothetical issue in *Gunn*, the subject matter eligibility of the '287 patent is a novel issue of patent law. Although the Supreme Court has addressed the patentability of cDNA, the Court overlooked the situation presented here. *See Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2119 & n.8 (2013). As discussed below, *see infra* Part II, the Court overlooked the possibility that an active and identical pseudogene could exist in nature as genomic DNA. *See id.* Resolution of this pure, novel patent issue will control numerous other cases, *see Gunn*, 133 S. Ct. at 1067, because ABC's claim requires a court to determine the parameters of 35 U.S.C. § 101. Therefore, ABC's state claim arises under the patent law because ABC's right to relief "will be defeated by one construction or sustained by the opposite construction of [the patent] laws". *Excelsior Wooden Pipe Co. v. Pac. Bridge Co.*, 185 U.S. 282, 286 (1902).

Additionally, allowing a state court to decide this novel patent issue may have preclusive effects on these litigants and federal courts. The full faith and credit statute, 28 U.S.C. § 1738, applies to federal courts even when a state court "judgment turn[s] on construction of subject matter within the exclusive

jurisdiction of the federal courts." *MGA, Inc. v. Gen. Motors Corp.*, 827 F.2d 729, 732 (Fed. Cir. 1987); *see also Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 350 (1971) (holding a patentee may be estopped from asserting the validity of a patent that was declared invalid in a prior suit against a different defendant). Thus, if a state court concludes that NARF's adult test does not fall within the '287 patent's scope or invalidates the '287 patent, then ABC could not bring a subsequent infringement suit against NARF's customers for using the same test. *See MGA, Inc.*, 827 F.2d at 731, 734 (estopping the patentee from bringing a patent infringement suit against the licensee's customer in federal court after a state court determined the licensee did not breach the license because the accused machine did not fall within the patent's scope). Thus, a federal judge versed in patent law should hear this case because its resolution will have preclusive effects.

Third, federal court resolution of the '287 patent's scope and validity promotes the patent law's uniformity. In *Gunn*, the Court held state court adjudication of hypothetical patent issues would not undermine the patent law's uniformity. 133 S. Ct. at 1067. That is not the case here because a state court determination will have preclusive effects. *See MGA, Inc.*, 827 F.2d at 732. But requiring a federal court to resolve these patent issues of first impression will promote "the development

of a uniform body of [patent] law." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 162 (1989). Indeed, federal courts have exclusive jurisdiction over patent cases "to reduce the widespread lack of uniformity and uncertainty of legal doctrine that exist[ed] in the administration of patent law." *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 813 (1988). Accordingly, a federal court should adjudicate this case to maintain uniformity in the patent law.

In sum, resolution of the '287 patent's scope and validity will affect numerous other parties and have preclusive effects. Also, federal adjudication of this case promotes patent law's uniformity. Thus, this case presents significant patent issues.

D. Resolving ABC's Breach Of License Claim In Federal Court Will Not Disrupt The Congressionally Approved Federal-State Court Balance.

Federal court resolution of these patent issues will not disrupt the federal-state court balance. A federal court may exercise patent jurisdiction over a state claim if a federal court can resolve the claim without disrupting the federal-state court balance. *Gunn v. Minton*, 133 S. Ct. 1059, 1065 (2013). This inquiry focuses on the appropriate "balance of federal and state judicial responsibilities," *Grable*, 545 U.S. at 314, and recognizes that some state claims "justify resort to the experience . . . [and] uniformity that a federal forum offers." *Id.* at 312. Exercising jurisdiction over this case is proper

because (1) the *Grable* test's high bar limits what state claims arise under the patent law, (2) only rare contract cases present novel patent issues, and (3) exercising jurisdiction will not disrupt the states' interest because *Grable* contemplates that some traditional state claims will arise under federal law.

In *Grable*, the Court held exercising jurisdiction to determine a federal statute's meaning would have a "microscopic effect on the federal-state division of labor" because only "rare state title case[s]" raise contested federal issues. *Id.* at 315. Similarly, exercising jurisdiction over this case will not cause contract cases to flood federal district courts.

First, a party asserting that a state claim arises under the patent law must satisfy the other three prongs of the *Grable* test. This limits the cases that arise under the patent law because the patent issue must not only be raised and disputed, but also substantial to the federal system. *Gunn*, 133 S. Ct. at 1066. This substantiality prong ensures that not all breach of patent license claims arise under the patent law.

Second, only rare contract cases present novel patent issues that will control other cases. These rare cases belong in federal court because federal court resolution of novel patent issues furthers Congress's intent to have a predictable and uniform patent law. *See DSC Commc'ns Corp. v. Pulse Commc'ns, Inc.*, 170 F.3d 1354, 1359 (Fed. Cir. 1999). Indeed, Congress

granted federal courts exclusive jurisdiction over matters arising under patent law to ensure uniformity in the patent law. 28 U.S.C. §§ 1338(a), 1295. Here, ABC's claim presents the novel issue of whether cDNA is patent eligible when an active and identical pseudogene exists in nature. RF at ¶¶ 11–15. Thus, the fact that ABC's claim involves a novel issue ensures that only rare breach of license claims will arise under the patent law.

Third, although states have an interest in developing their own body of contract law, *see Gully v. First Nat'l Bank*, 299 U.S. 109, 114–15 (1936), *Grable* contemplates that some state claims will arise under the patent law when the claim depends on a substantial patent issue. *See* 545 U.S. at 314. Otherwise, fifty state court systems could make different rulings regarding the subject matter eligibility of a class of patents. Congress did not intend this when it enacted §§ 1338 and 1295.

In sum, ABC's breach of license claim arises under the federal patent law. Specifically, the '287 patent's scope and validity are essential elements and dispositive of ABC's claim. These issues are also significant to the federal system because their resolution affects more than just ABC and NARF. Finally, federal court adjudication of ABC's breach of license claim comports with the congressionally approved federal-state court balance. Thus, this Court should affirm the district court's denial of ABC's motion to remand.

II. The Claims In ABC's '287 Patent Are Invalid Under § 101 Because They Are Drawn To Patent Ineligible Subject Matter.

The district court correctly invalidated the '287 patent for lack of patentable subject matter. "Whoever 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). These exceptions prevent inventors from patenting the tools of science and "inhibit[ing] future innovation premised upon them." *Id.* at 1301. For example, mental processes, *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972), and products of nature, such as metals, *Gen. Elec. Co. v. De Forest Radio Co.*, 28 F.2d 641, 642 (3d Cir. 1928), and bacteria, *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948), are patent ineligible under § 101.

In *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, the Supreme Court held isolated genomic DNA is not patent eligible subject matter because it is a product of nature. 133 S. Ct. 2107, 2120 (2013). The Court's holding relied in part on the distinction between *Diamond v. Chakrabarty* and *Funk Bros.* *See id.* at 2116–17. In *Chakrabarty*, the claimed subject matter was a strain of bacteria the inventor genetically modified to break down crude oil. *Diamond v. Chakrabarty*, 447 U.S. 303, 305

(1980). The Court held the bacterium patent eligible because the manmade bacterium was "markedly different" from any naturally occurring bacterium. *Id.* at 309–10.

In *Funk Bros.*, however, the Court held a new combination of unaltered, naturally occurring bacteria patent ineligible. 333 U.S. at 130. The Court recognized that "[h]e who discovers a[n] . . . unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes." *Id.* Following these precedents, the *AMP* Court held genomic DNA "isolated from the surrounding genetic material" patent ineligible. *Ass'n for Molecular Pathology*, 133 S. Ct. at 2120. Synthetically prepared cDNA, however, is a product of human ingenuity not found in nature. *Id.* at 2119. Therefore, cDNA is patent eligible. *Id.*

Despite the Court's holding that cDNA is patent eligibile, all of ABC's claims are invalid because (A) the cDNA claimed in the '287 patent is a product of nature and (B) the method claim covers only nonpatentable abstract ideas.

A. The '287 Patent's cDNA Claim Is Ineligible Subject Matter Because It Is A Product Of Nature.

The '287 patent's cDNA claim is invalid for lack of patentable subject matter because the cDNA is a product of nature. Although the Court held Myriad's cDNA claims patentable, the Court defined when cDNA is and is not patentable. *See Ass'n for Molecular Pathology*, 133 S. Ct. at 2119 & n.8.

In *AMP*, the Court addressed the patentability of Myriad's claims to the BRCA genes. *Id.* at 2112. The claims were drawn to segments of DNA isolated from their surroundings, retaining their entire natural genetic sequence. *Id.* at 2113. The Court held these claims were drawn to patent ineligible products of nature. *Id.* at 2111. But the claimed cDNA versions of those genes were valid. *Id.* at 2119. Specifically, the Court held cDNA is a patentable "product of man" because it is "something new" and "distinct from the DNA from which it was derived." *Id.* Even though nature dictates the cDNA sequence, the "lab technician unquestionably creates something new when cDNA is made." *Id.* Thus, the Court premised its narrow holding on the principle that cDNA is patent eligible because it contains only exons and is distinct from the natural material. *See id.*

The Court also appreciated that cDNA patent eligibility is not so clear. *Id.* at 2119 n.8. Footnote eight states that in rare cases, viral infection of a cell may incorporate processed pseudogenes into the host DNA. *Id.* Pseudogenes are composed of intron-free cDNA. *Id.* The Court noted that in some situations, a "rare phenomenon *might* randomly create a molecule similar to one created synthetically through human ingenuity." *Id.* According to the Court, this possibility does not render a composition of matter nonpatentable. *Id.*

This ambiguity and its importance to this case necessitates

further discussion because 1) the Court intended the product of nature doctrine to trump the product of man doctrine and 2) this case presents an exception to the rule that cDNA is patentable.

1) cDNA Is Patent Eligible Except When The cDNA Is Demonstrably A Product of Nature.

The Court focused on the manmade nature of the cDNA when it held Myriad's cDNA claims valid because it was "distinct from" the genomic DNA from which it derived. *Ass'n for Molecular Pathology*, 133 S. Ct. at 2119. To ensure consistent application of the product of man doctrine, the Court addressed the rare possibility of cDNA existing in nature. *Id.* at 2119 n.8.

The Court stated the possibility that a synthetic molecule exists randomly in nature "does not render a composition of matter nonpatentable." *Id.* This statement allows the PTO to issue patents where the claimed subject matter's natural existence is unknown. It also permits courts to invalidate patents when later discovery demonstrates the claimed invention exists in nature. For example, the discovery of a naturally produced chemical would invalidate a patent claiming a manmade version of the chemical.

The Court also endorsed Judge Bryson's observation that the challenger "failed to demonstrate that the pseudogene consists of the same sequence as the BRCA1 cDNA." *Id.* (quoting *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d

1303, 1356 n.5 (Fed. Cir. 2012) (Bryson, J., concurring in part and dissenting in part)). Thus, the challenger failed to show the claimed cDNA was a naturally occurring pseudogene rather than a synthetically created product. *Id.* The Court's adoption of this observation reiterates the rule that a party claiming invalidity must show the claimed invention is identical to a natural product. 35 U.S.C. § 282(a).

Accordingly, a patent claiming a synthetically created product is invalid if research shows that the claimed subject matter exists in nature. This outcome allows for consistent application of the product of man doctrine and comports with the principles underlying the patent law. Specifically, the patent law recognizes that "extensive effort alone is insufficient to satisfy the demands of § 101." *Ass'n for Molecular Pathology*, 133 S. Ct. at 2118. Rather, the inventor must create "something new." *Id.* at 2119; *see also* 35 U.S.C. § 101 (stating that an inventor must invent something "new and useful" to receive a patent). Therefore, the '287 patent's cDNA claim is a product of nature, not a new product of human ingenuity.

2) This Case Presents An Exception To The Rule That cDNA Is Distinct from Its Original DNA.

The cDNA discovered and claimed by ABC is not patent eligible under § 101 because it is a naturally occurring product of nature. The DNA that NARF isolated is identical to the cDNA

that ABC claimed. RF at ¶ 12. Both genetic sequences are identical, intron-free, and actively code for the MIND Syndrome proteins. *See id.* at ¶¶ 10–15. All ABC created was an identical copy of the naturally occurring sequence, possibly without even realizing it. But knowledge of that fact is not relevant to the patentability inquiry. Thus, ABC's cDNA claim is invalid because the claimed cDNA is not a product of human ingenuity. Rather, the claimed cDNA is a patent ineligible product of nature.

B. ABC's Method Claim Is Invalid Because The Claim Covers Well Understood Tools Of Science And Abstract Ideas.

The '287 patent's method claim is invalid because the claim does not transform the ineligible composition into a patentable process. Method claims are patent eligible 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).

In *Parker v. Flook*, the Court considered a method of updating alarm limits. 437 U.S. 584, 585 (1978). The Court held that no inventive concept supported the patent because the only novel feature of the method was the application of an algorithm to an otherwise conventional process. *Id.* at 585, 590.

In *Diamond v. Diehr*, however, the Court held a method applying the Arrhenius equation to a process for curing rubber

patent eligible. 450 U.S. 175, 187 (1981). Although the process applied a known mathematical equation, the method did not seek to preclude its use. *Id.* at 187. Rather, the method integrated the equation into the process as a whole, transforming the claim into a different, patent eligible state. *Id.* at 187, 192.

The Court applied these precedents in *Bilski v. Kappos* to invalidate a claimed business method. 130 S. Ct. 3218, 3231 (2010). While the Court did not preclude the patentability of business methods, it held that allowing a patent for hedging risk would "pre-empt use of this approach in all fields, and would effectively grant a monopoly over an abstract idea." *Id.*

In *Mayo*, the Court held the claimed method did not sufficiently transform the application of known laws of nature into a patentable method. 132 S. Ct. at 1298. There, the method claimed steps of administering a known drug, ascertaining a known metabolite's concentrations, and using that information to modify the treatment. *See id.* at 1296–98. The Court determined these steps were nothing more than instructions to a physician on the routine practice of medicine. *Id.* at 1298.

In *AMP*, this Court applied *Mayo* and held comparing two genetic sequences "can be accomplished by mere inspection alone." *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303, 1335 (Fed. Cir. 2012) *aff'd in part, rev'd in part sub nom. Ass'n for Molecular Pathology v. Myriad*

Genetics, Inc., 133 S. Ct. 2107 (2013). There, the claims recited a screening method of comparing a known gene to the test sample and observing the differences. *Id.* at 1334. This Court held claims to "'comparing' or 'analyzing' two gene sequences fall outside the scope of § 101 because they claim only abstract mental processes." *Id.* Accordingly, Myriad's method claims of comparing and analyzing were not sufficiently transformative of "what was otherwise a claim to a natural law." *Id.* at 1335. Myriad's method claims were "only directed to the abstract mental process." *Id.* Therefore, Myriad's method claims to the application of isolated BRCA genes were invalid. *Id.*

Most recently, *Ariosa Diagnostics, Inc. v. Sequenom, Inc.* applied this line of cases to invalidate method claims related to fetal DNA. No. C 11-06391 SI, 2013 WL 5863022, at *7 (N.D. Cal. Oct 30, 2013). There, the claims detected fetal DNA, amplified it, and ran diagnostic tests on that DNA. *Id.* at *1-2. Because "the only inventive concept contained in the patent [was] the discovery of [naturally occurring] cffDNA," the court followed *Mayo* to invalidate the patent. *Id.* at *9.

ABC's method claim falls within the framework of patent ineligible methods. The '287 patent teaches that by extracting and comparing an embryo's PNKY gene to the claimed sequence, technicians can determine whether the embryo includes the MIND Syndrome sequence. RF at ¶ 9. As in *AMP*, the only claimed step

is to "compare" the two sequences. *Id.* Without more, the method claim does not transform the nonpatentable DNA sequence into a patentable application. *Mayo Collaborative Servs.*, 132 S. Ct. at 1294. As discussed above, comparison of nucleotide sequences is not a patent eligible application of a law of nature. ABC's claim does not contain any 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. Therefore, the '287 patent's method claim is invalid.

In sum, the '287 patent's composition and method claims are patent ineligible. The district court correctly invalidated ABC's patent and granted NARF's motion for summary judgment.

CONCLUSION

For the reasons stated, this Court should AFFIRM the lower court's denial of ABC's motion to remand and grant of NARF's motion for summary judgment to invalidate the '287 patent.

DATED this 31st Day of January 2014.

/s/ Mark Arrington
MARK ARRINGTON

/s/ Shaun Mathur
SHAUN MATHUR

Attorneys for Defendant-Appellee

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:

Roman Swoopes
Morrison & Foerster
755 Page Mill Road
Palo Alto, CA 94304-1018
(650)813-5872
rswoopes@mofo.com

Stefan Szpajda
Morrison & Foerster
755 Page Mill Road
Palo Alto, CA 94304-1018
(650)813-5683
sszpajda@mofo.com

/s/ Mark Arrington
MARK ARRINGTON

/s/ Shaun Mathur
SHAUN MATHUR

Attorneys for Defendant-Appellee

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

/s/ Mark Arrington
MARK ARRINGTON

/s/ Shaun Mathur
SHAUN MATHUR

Attorneys for Defendant-Appellee