UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

ESOTERIX GENETIC LABORATORIES LLC,	*	
Plaintiff/Counterclaim Defendant,	*	
and LABORATORY CORPORATION OF AMERICA HOLDINGS,	*	
Counterclaim Defendant,	*	
v.	*	Civil Action No. 14-cv-13228-ADB
QIAGEN INC. and QIAGEN MANCHESTER, LTD.,	*	
Defendants/Counterclaim-Plaintiffs.	*	

MEMORANDUM AND ORDER

BURROUGHS, D.J.

I. INTRODUCTION

Plaintiff Esoterix Genetic Laboratories LLC ("Esoterix") filed this action against Defendants Qiagen Inc. and Qiagen Manchester, LTD. (collectively, "Qiagen"), alleging that Qiagen exceeded the scope of the parties' License Agreement, and thereby infringed upon Esoterix's patent rights. Esoterix's operative Complaint [ECF No. 7] ("Compl."), alleged claims for patent infringement (Count I); violation of Massachusetts General Laws Ch. 93A (Count II); breach of contract (Count III); and breach of the duty of good faith and fair dealing (Count IV).

Qiagen moved to dismiss the Complaint, arguing that the patent-in-suit, U.S. Patent No. 7,294,468 (the "'468 Patent"), was invalid because it was directed to a "law of nature," which is not eligible for patent protection under 35 U.S.C. § 101. In a Memorandum and Order dated September 25, 2015, the Court found that the '468 Patent claims were drawn to ineligible subject matter, and that the '468 Patent was therefore invalid. See Esoterix Genetic Labs. LLC v. Qiagen

Inc., 133 F. Supp. 3d 349 (D. Mass. 2015) (hereinafter, "Qiagen I"). Accordingly, the Court dismissed Count I of Esoterix's Complaint, which alleged infringement of the '468 Patent. Id. at 360-61. The Court, however, declined to dismiss Esoterix's state-law claims alleged in Counts II, III, and IV. Id. at 363-64.[1]

Qiagen filed an Amended Answer to the remaining claims. [ECF No. 109]. Qiagen also asserted counterclaims against Esoterix and Esoterix's parent company, Laboratory Corporation of America Holdings ("LabCorp"). See id. ("Counterclaims"). Specifically, Qiagen seeks a declaratory judgment of invalidity with respect to four *additional* patents, which are related to the '468 Patent; namely, U.S. Patent Nos. 7,964,349 ("the '349 Patent"); 8,105,769 ("the '769 Patent"); 8,465,916 ("the '916 Patent"); and 9,035,036 ("the '036 Patent").[2] See Counterclaims, Counts II-V). In addition, Qiagen seeks a declaratory judgment of non-infringement with respect to the four additional patents (Count VI), and a declaratory judgment regarding the parties' respective contractual rights under the operative License Agreement – specifically, that Qiagen does not owe Esoterix any royalties, due to the invalidity of the underlying Licensed Patents. Id. (Count I). Qiagen also seeks restitution of all royalties it paid to Esoterix under the Licensing Agreement after the date that Qiagen first challenged the validity of the '468 Patent. Id. (Count VII). Finally, Qiagen alleges claims against Esoterix and LabCorp for tortious interference with contractual relationships (Count VIII), and tortious interference with prospective business relationships (Count IX).

[1] Notwithstanding the dismissal of Esoterix's federal patent claim, the Court retained subject matter jurisdiction over the case based on diversity jurisdiction. See 28 U.S.C. § 1332.

[2] The Court will refer to these patents—together with the'468 Patent—collectively as "the Licensed Patents."

Presently before the Court are (1) Qiagen's Motion for Judgment on the Pleadings with respect to its Counterclaims [ECF No. 88]; and (2) Esoterix and LabCorp's Cross-Motion to Dismiss Qiagen's Counterclaims. [ECF No. 98]. Qiagen asks the Court to find that the four additional patents-in-suit are ineligible for patent protection under 35 U.S.C. § 101 for essentially the same reasons that this Court invalidated the '468 Patent. Esoterix and LabCorp, however, have moved to dismiss all of Qiagen's Counterclaims, on the grounds that this Court lacks subject matter jurisdiction over them. In the alternative, Esoterix and LabCorp oppose Qiagen's Motion for Judgment on the Pleadings, arguing that the four additional patents-in-suit are drawn to patentable subject matter under § 101.

For the reasons set forth in this Memorandum and Order, Esoterix and LabCorp's Motion to Dismiss is DENIED, and Qiagen's Motion for Judgment on the Pleadings is ALLOWED.

II. BACKGROUND

The Court briefly reviews the factual background of this case, which is set forth in greater detail in the Court's prior Memorandum and Order. See Qiagen I, 133 F. Supp. 3d 349.

The '468 Patent, which is titled "Method to Determine Responsiveness of Cancer to Epidermal Growth Factor Receptor Targeting Treatments," claims a method for determining whether particular types of pharmaceutical compounds are likely to be effective in treating non-small cell lung cancer in a patient, based on the presence or absence of certain nucleotide variances in the patient's genes. See '468 Patent; Compl. ¶¶ 21-24. More specifically, the inventors discovered that there is a positive correlation between the existence of particular naturally-occurring nucleotide variations on a person's epidermal growth factor receptor ("EGFR") gene, and the likelihood that specific pharmaceutical compounds (namely, gefitinib or erlotinib) will be effective in treating non-small lung cancers in that person. See '468 Patent,

519:44-520:49. The patent application was filed on December 4, 2005, and the U.S. Patent and Trademark Office issued the '468 Patent on November 13, 2007.

Previously, all right, title, and interest in the '468 Patent was owned by non-party Genzyme Corporation ("Genzyme"). In 2008, Genzyme entered into a License Agreement (the "License Agreement") with non-party DxS, Ltd. ("DxS"). The License Agreement granted DxS a non-exclusive license to manufacture and sell certain products practicing the claims of specific patents set forth in Schedule A to the License Agreement, including but not limited to the '468 Patent.[3] In exchange for this license, DxS would pay royalties on sales of its products, among other terms and conditions. Compl. ¶¶ 18, 25-32. In or around September 2009, DxS was acquired by a Qiagen entity, and Qiagen therefore assumed DxS's rights and obligations as licensee under the License Agreement. Id. ¶ 20. In December 2010, Genzyme sold certain assets (including all its rights to the '468 Patent, as well as its rights as licensor under the License Agreement) to LabCorp. Id. ¶¶ 2, 21. LabCorp, in turn, created Esoterix as a wholly-owned subsidiary, to control the purchased assets. Thus, at all relevant times, Esoterix held all right, title, and interest in the '468 Patent and served as licensor under the License Agreement. Id. ¶¶ 23-24.

In its Amended Complaint, Esoterix alleges that Qiagen exceeded the scope of the license and breached certain promises made in the License Agreement. The License Agreement only allowed Qiagen to sell certain types of products at certain times, and it drew a key distinction between "Licensed Products" and "Licensed Research Products." Id. ¶¶ 26-29. Licensed Products included diagnostic kits (for determining the presence of EGFR mutations) that would

[3] It is unclear whether Schedule A also expressly referenced the four additional patents-in-suit. The Licensing Agreement is not before the Court.

be marketed and sold for commercial use. Id. ¶ 27. Licensed Research Products were limited to diagnostic kits that would be sold for non-commercial, research use only. Id. ¶¶ 28-29. Under the terms of the License Agreement, Qiagen could only sell Licensed Research Products for non-commercial use until regulatory approval was obtained for commercial use. Id. ¶ 30. Regulatory approval for the test kits was not obtained until July 2013. Id. ¶ 37. Prior to regulatory approval and during the term of the License Agreement, Qiagen paid Esoterix royalties for its purported sales of Licensed Research Products. Id. ¶¶ 34-35. Esoterix, however, alleges that a substantial number of those sales were impermissibly made for commercial use, rather than solely for research purposes, as required by the License Agreement and the non-exclusive patent rights it granted to Qiagen. Id. ¶¶ 36, 38. Thus, Esoterix's Complaint asserts claims against Qiagen for, *inter alia*, breach of the License Agreement, infringement of the '468 Patent, violations of Massachusetts General Laws Chapter 93A, and violations of the duty of good faith and fair dealing.

On September 25, 2015, the Court granted in part Qiagen's Motion to Dismiss, holding that the claims of the '468 Patent were not directed to eligible subject matter under the standard set forth in Alice Corp. v. CLS Bank International, 134 S. Ct. 2347 (2014) and Mayo Collaborative Services v. Prometheus Laboratories, Inc., 132 S. Ct. 1289 (2012). See Qiagen I, 133 F. Supp. 3d at 359-60. The Court held that the method claimed in the '468 Patent was directed to a "law of nature," because it "describes the correlation between a naturally-occurring mutation in a cancer cell, and the likelihood that a particular type of known pharmaceutical compound will be effective in treating that type of cancer." Id. at 358. The Court also held that there was nothing "transformative" in the claims of the '468 Patent that amounted to a novel application of the natural law, or that otherwise warranted patent protection. Id. at 359. Instead,

the Court held that the method claimed in the ’468 Patent (1) identifies a law of nature that explains why a known cancer treatment is more effective in treating a certain population of patients, and (2) tells scientists and doctors that they can “apply” that law of nature by testing for the relevant gene mutations using methods well-known in the art. Id. at 359. Thus, the Court concluded that the ’468 Patent was invalid, and dismissed Esoterix’s corresponding claim for infringement. Id. at 360-61. The Court declined, however, to dismiss Esoterix’s claims for breach of the License Agreement, breach of the duty of good faith and fair dealing, and violations of Chapter 93A, holding that those claims did not depend on the validity of the ’468 Patent. See id. at 363-64.

Qiagen, through its Counterclaims, now seeks a declaratory judgment that four additional Licensed Patents are invalid, for the same reasons the Court invalidated the ’468 Patent. See Counterclaims, ¶¶ 42-60. Qiagen asserts that the four new patents-in-suit also fall within the Patent Rights licensed in the 2008 License Agreement, because they all claim priority to the patent application that issued the’468 Patent. Qiagen also notes that all of the Licensed Patents share “virtually identical specifications,” and that three out of the four additional patents (*i.e.*, the ’349, the ’769, and the ’916 Patents) claim the same method recited in the ’468 Patent, “albeit using slightly broader or narrower (though equally ineligible) language.” Qiagen further argues that the fourth, ’036 Patent, is equally ineligible because it merely claims “a kit for practicing the methods of the invention,” and is thus directed to the same natural law as the ’468 Patent.

Qiagen also seeks a declaratory judgment regarding the parties’ respective rights under the Licensing Agreement – specifically, that because the Licensed Patents are all invalid, Qiagen is not contractually obligated to pay royalties under the terms of the License Agreement, and is

entitled to recoup all royalties that it paid (under protest), after the date Qiagen first challenged the validity of the '468 Patent. See Counterclaims, ¶¶ 35-41, 65-74.

Qiagen also asserts a claim for declaratory judgment of non-infringement, arguing that "even absent Qiagen's rights under the License Agreement," its test kits do not infringe the claims of the four additional patents-in-suit. Id. ¶¶ 61-64.

Finally, Qiagen alleges that Esoterix and LabCorp wrongfully interfered with Qiagen's customer relations. Id. ¶¶ 75-90. Specifically, Qiagen alleges that Esoterix and LabCorp sent letters to third parties who had purchased test kits from Qiagen, informing them that Esoterix and LabCorp held the patent rights to the Licensed Patents, and instructing the third parties to contact LabCorp to discuss the matter. Id. ¶¶ 30-32. These letters allegedly failed to mention that LabCorp knew the customer had purchased the test kits from Qiagen, a licensee. Further, LabCorp and Esoterix allegedly continued to send these letters even after the FDA granted regulatory approval for commercial sales of the test kits in July 2013, which gave Qiagen the right to sell the kits for all licensed uses. Id. ¶ 32. Qiagen alleges that these letters were improper in motive or means, in that they did not mention Qiagen's license, and were designed to deter third parties from doing business with Qiagen. Id. ¶ 33.

III. MOTION TO DISMISS FOR LACK OF SUBJECT MATTER JURISDICTION

As a threshold matter, Esoterix and LabCorp argue that this Court lacks subject matter jurisdiction over Qiagen's Counterclaims and should therefore decline to reach the invalidity issue raised in Qiagen's Motion for Judgment on the Pleadings. Specifically, Esoterix and LabCorp contend that in January 2016, they gave Qiagen a "covenant not to sue on the Patents," which had the effect of eliminating any case or controversy between the parties concerning the patents-in-suit, and depriving the Court of Article III jurisdiction over Qiagen's Counterclaims.

Article III, Section 2 of the United States Constitution "limits the exercise of judicial power to 'cases' and 'controversies.'" Aetna Life Ins. Co. v. Haworth, 300 U.S. 227, 239 (1937). In this case, Qiagen's counterclaims for declaratory judgment arise out of the Declaratory Judgment Act, which provides that:

> [i]n a case of actual controversy within its jurisdiction . . . any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought.

28 U.S.C. § 2201(a). The phrase "case of actual controversy" in Section 2201 refers to "the type of 'Cases' and 'Controversies' that are justiciable under Article III." MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118, 126-27 (2007) (citing Aetna, 300 U.S. at 240). Accordingly, for the court to have jurisdiction over a declaratory judgment action, the dispute "must be definite and concrete, touching the legal relations of parties having adverse legal interests," and be "a real and substantial controversy admitting of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts." Aetna, 300 U.S. at 240-41. "'Basically, the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.'" MedImmune, 549 U.S. at 127 (quoting Maryland Cas. Co. v. Pacific Coal & Oil Co., 312 U.S. 270, 273 (1941)).

Esoterix and LabCorp argue that their covenant not to sue Qiagen for infringement eliminated any case or controversy between the parties regarding the validity of the remaining patents-in-suit. The covenant, which was set forth in a letter from LabCorp and Esoterix to Qiagen, recites as follows:

> Esoterix and LabCorp hereby covenant that they will not sue, assert any claim or counterclaim against, or otherwise participate in any action or proceeding against, Qiagen claiming or otherwise asserting that sales of EGFR test kits for clinical diagnostic purposes or research purposes infringes any claim of the Patent[s], or cause or authorize any person or entity to do so, during the term of the License Agreement. This covenant does not extend to assertions by Esoterix or LabCorp of their rights under the License Agreement, nor does it bar Esoterix or LabCorp from upholding the validity or enforceability of the Patents in response to a challenge to validity or enforceability by Qiagen.

See Declaration of Christopher R. Howe [ECF No. 100], Ex. 2. LabCorp and Esoterix argue that this covenant "removes any risk that LabCorp will sue Qiagen for infringement of the Patents, and thus eliminates any case or controversy that would support a counterclaim seeking a declaratory judgment of invalidity of the Patents."

The Court does not find this argument persuasive, because the covenant did not eliminate the primary dispute raised by Qiagen's Counterclaims – namely, whether Qiagen is obligated to pay royalties to Esoterix and LabCorp under the parties' License Agreement. In fact, the covenant expressly preserves LabCorp's contract rights under the License Agreement, presumably because Esoterix and LabCorp intended to pursue their own claims for breach of contract against Qiagen in this action. Further, the resolution of Qiagen's contract-based Counterclaim regarding its obligation to pay royalties under the License Agreement depends on whether the underlying patents are valid or invalid. In light of this dispute, which is still very much alive, LabCorp and Esoterix's promise not to sue Qiagen for infringement does not moot the case. In fact, the covenant arguably promises nothing more than what the License Agreement already grants to Qiagen—*i.e.*, a license to exploit the patent rights, and corresponding immunity from infringement claims during the term of the License Agreement.

The Supreme Court's holding in MedImmune supports the Court's conclusion that a case or controversy continues to exist. See 549 U.S. 118. In MedImmune, a licensee in good standing

filed an action seeking (1) a declaratory judgment that the licensed patent was invalid; and (2) a corresponding declaration that the licensee was not required to make payments under the parties' license agreement, because its product did not infringe any "valid" patent claim. Id. at 123-24; see also MedImmune, Inc. v. Genetech, Inc., No. 03-cv-2567, 2004 WL 3770589, *1 (C.D. Cal. Apr. 26, 2004). Although the licensee continued paying royalties, it did so "under protest and with reservation of all of [its] rights." 549 U.S. at 121 (alteration in original). The district court dismissed the action for lack of a case or controversy, reasoning that the existence of a license agreement negated any "reasonable apprehension" that the licensee would be sued for infringement. Id. at 122. The Supreme Court disagreed, holding that neither the existence of a license agreement, nor the licensee's decision to continue paying royalties while simultaneously challenging the patent's validity, deprived the Court of jurisdiction. Id. at 129. ("The plaintiff's own action (or inaction) in failing to violate the law eliminates the imminent threat of prosecution, but nonetheless does not eliminate Article III jurisdiction."). Although Esoterix and LabCorp point out that MedImmune did not involve a covenant not to sue, the covenant that Esoterix and LabCorp gave in this case expressly preserves their ability to assert rights under the License Agreement, and to defend the validity of the Licensed Patents in response to Qiagen's invalidity challenges. Thus, the covenant only reinforces the Court's conclusion that there is a live case or controversy between the parties.

Further, the cases that Esoterix and LabCorp rely on are distinguishable. First, Esoterix and LabCorp cite a number of cases involving infringement claims, but that do not involve any licensing arrangements between the parties, or any corresponding claims for royalties. In such cases, a purported infringer files a declaratory judgment action seeking a declaration of invalidity or non-infringement, and the patent holder effectively moots the case or controversy by granting

the alleged infringer a covenant not to sue for infringement. See, e.g., Dow Jones & Co. v. Ablaise Ltd., 606 F.3d 1338, 1346 (Fed. Cir. 2010) ("[A] covenant not to sue for patent infringement divests the trial court of subject matter jurisdiction over claims that the patent is invalid, because the covenant eliminates any case or controversy between the parties."). Here, in contrast, Esoterix did not give Qiagen a covenant not to sue in response to a declaratory judgment action seeking only a declaration of invalidity or non-infringement. Rather, Esoterix sued Qiagen first, affirmatively seeking damages under the parties' License Agreement. Qiagen, moreover, has asserted counterclaims seeking a declaration of rights under the License Agreement. These contract claims will remain viable, regardless of whether Esoterix and LabCorp promise not to sue Qiagen for patent infringement. Accordingly, the covenant not to sue does not moot the parties' dispute.

Further, Fortinet, Inc. v. Trend Micro Inc., No. 08-cv-5371, 2009 WL 1814598 (N.D. Cal. June 24, 2009), cited by Esoterix and LabCorp, is inapposite. In Fortinet, a licensee filed a declaratory judgment action, seeking a declaration that it had no contractual liability to pay royalties because the underlying patent was invalid. Id. at * 1. Notably, the licensee did not assert any federal patent claims, and the parties were not diverse. After the licensee filed suit, the licensor and patent holder granted a covenant not to sue, in which it "unconditionally" consented not to sue the licensee for patent infringement. The district court granted the licensor's motion to dismiss. Although the court's decision discusses both the Article III case-and-controversy requirement, as well as the need for subject matter jurisdiction, it appears that the court ultimately dismissed the case for lack of subject matter jurisdiction, and not the absence of a case or controversy. The court recognized that the covenant not to sue for infringement did not eliminate the potential threat of a contract claim for royalties, but held that "any case or controversy arising therefrom is not one

over which this Court has subject matter jurisdiction." Id. at *3. In a footnote, the court explained that because the parties were not diverse, it would have no independent subject matter jurisdiction over a state-law contract claim. Id. at *3 n.4. Unlike the court in Fortinet, however, this Court has subject matter jurisdiction over Qiagen's claims pursuant to 28 U.S.C. § 1332, as all parties appear to be of diverse citizenship and the amount in controversy well exceeds $75,000. Thus, Fortinet is not instructive.

As Article III's case-or-controversy requirement appears to be satisfied, and the Court has subject matter jurisdiction over this action, Esoterix and LabCorp's Cross-Motion to Dismiss Qiagen's Counterclaims [ECF No. 98] is DENIED.

IV. QIAGEN'S MOTION FOR JUDGMENT ON THE PLEADINGS

Qiagen moves for Judgment on the Pleadings with respect to Counts II-V of its Counterclaims, in which Qiagen asserts that the '349 Patent, the '769 Patent, the '916 Patent, and the '036 Patent are—like the '468 Patent—ineligible for patent protection under 35 U.S.C. § 101.

A. Legal Standards

Federal Rule of Civil Procedure 12(c) provides that a party may move for judgment on the pleadings "[a]fter the pleadings are closed – but early enough not to delay trial." Fed. R. Civ. P. 12(c). A motion for judgment on the pleadings "is a means of disposing of cases when the material facts are not in dispute and a judgment on the merits can be achieved by focusing on the content of the pleadings." Tavares de Almeida v. Children's Museum, 28 F. Supp. 2d 682, 685 (D. Mass. 1998) (internal quotations and citation omitted). The standard of review for a Rule 12(c) motion is the same as that for a motion to dismiss under Rule 12(b)(6). Frappier v. Countrywide Home Loans, Inc., 750 F.3d 91, 96 (1st Cir. 2014). Thus, the Court must view the facts alleged in the pleadings as true, and construe those facts in the light most favorable to the nonmoving party – in this case, Esoterix and LabCorp. R.G. Fin. Corp. v. Vergara-Nunez, 446

F.3d 178, 182 (1st Cir. 2006). The Court may supplement the facts contained in the pleadings by considering documents fairly incorporated therein and taking judicial notice of appropriate facts. Id.

Although pleading standards "are a matter of regional circuit law," "[r]eview of the substantive patent law embodied in the pleadings" is governed by the law of the Federal Circuit. Bayer Schering Pharma AG v. Lupin, Ltd., 676 F.3d 1316, 1327 (Fed. Cir. 2012). Here, Qiagen argues that the claims of the'349 Patent, the '769 Patent, the '916 Patent, and the '036 Patent are invalid because they are drawn to ineligible subject matter under 35 U.S.C. § 101. Thus, the Court applies the same standard it applied to the claims of the '468 Patent, see Qiagen I, 133 F. Supp. 3d at 354-56, to determine whether the claims of the additional Licensed Patents are patentable under Section 101 of the Patent Act. Although this is primarily a legal issue, see In re Bilski, 545 F.3d 943, 951 (Fed. Cir. 2008), the Court will assume all facts alleged by Esoterix to be true, and construe the patent claims in the light most favorable to Esoterix. See Content Extraction & Transmission LLC v. Wells Fargo Bank, Nat'l Ass'n, 776 F.3d 1343, 1349 (Fed. Cir. 2014) (holding that district court properly resolved defendant's motion to dismiss at the pleadings stage, where it was clear that the patent claims were directed to ineligible subject matter, even when construed in a light most favorable to the patentee).[4]

B. Discussion

i. Patentability Under 35 U.S.C. § 101 – The Mayo and Alice Corp. Test

The general standard for patentability is found in Section 101 of the Patent Act, which provides that "[w]hoever invents or discovers any new and useful process, machine,

[4] Esoterix and LabCorb have not argued that there is any dispute about claim construction that would prevent the Court from reaching the Section 101 patentability question on a motion for judgment on the pleadings. See Genetic Techs. Ltd. v. Merial L.L.C., 818 F.3d 1369, 1374 (Fed. Cir. 2016).

manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor." 35 U.S.C. § 101. The United States Supreme Court, however, has "long held that this provision contains an important implicit exception: Laws of nature, natural phenomena, and abstract ideas are not patentable." Alice Corp. Pty. v. CLS Bank Int'l, 134 S. Ct. 2347, 2354 (2014) (internal quotations and citation omitted). "Phenomena of nature, though just discovered . . . are not patentable, as they are the basic tools of scientific and technological work." Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1293 (2012) (quoting Gottschalk v. Benson, 409 U.S. 63, 67 (1972)). Because "monopolization of these tools through the grant of a patent might tend to impede innovation more than it would tend to promote it," id. at 1293, the discovery of natural phenomena is generally not amenable to patent protection. See id.

The Supreme Court has also cautioned, however, against "too broad an interpretation of this exclusionary principle." Id. If taken to extremes, the "law of nature" principle has the potential to "eviscerate patent law," as "all inventions at some level embody, use, reflect, rest upon, or apply laws of nature . . . ." Id. Often, the line separating the patentable from the unpatentable is very thin. While a "scientific truth" may not be a patentable invention, "an *application* of a law of nature . . . to a known structure or process may well be deserving of patent protection." Id. at 1293-94 (emphasis in original) (internal quotations and citations omitted). But "to transform an unpatentable law of nature into a patent-eligible *application* of such a law, one must do more than simply state the law of nature while adding the words 'apply it.'" Id. at 1294 (emphasis in original).

The Supreme Court's recent decisions in Mayo, 132 S.Ct. 1289, and Alice Corp., 134 S.Ct. 2347, establish a two-part test to determine whether patent claims cover eligible subject matter. "First, we determine whether the claims at issue are directed to one of those patent-

ineligible concepts [that include the laws of nature, natural phenomena, and abstract ideas]." Alice Corp., 134 S.Ct. at 2355. "If so, we then ask, '[w]hat else is there in the claims before us?' To answer that question, we consider the elements of each claim both individually and 'as an ordered combination' to determine whether the additional elements 'transform the nature of the claim' into a patent-eligible application." Id. (quoting Mayo, 132 S.Ct. at 1296-97). When conducting the second part of this analysis, the court is searching for an "inventive concept," i.e., "an element or combination of elements that is 'sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the ineligible concept itself.'" Id. (alterations adopted) (quoting Mayo, 132 S. Ct. at 1294).

ii. The '349 Patent, the '769 Patent, the '916 Patent

In Qiagen I, this Court held that the method claims of the '468 Patent were "directed to a law of nature," in that they described the correlation between a naturally-occurring mutation in a cancer cell, and the likelihood that a particular type of known pharmaceutical compound will be effective in treating that type of cancer. 133 F. Supp. 3d at 358. The Court further held that there was nothing "transformative" in the claims that amounted to a novel application of the natural law, or that otherwise warranted patent protection. Id. at 360-61.

Qiagen argues that the Court's prior ruling applies with equal force to the method claims of the '349, '769, and '916 Patents, which are not meaningfully distinct from the '468 Patent. And while Esoterix and LabCorp maintain their position that all the Licensed Patents are valid, they concede that in light of the decision in Qiagen I, the Court is likely to hold the claims of the '349, '769, and '916 Patents to be patent ineligible.

After reviewing the relevant patent claims, the Court agrees. Each of the '349, '769, and '916 Patents claim priority to the '468 Patent, and all of the Licensed Patents share virtually identical specifications. Like the'468 Patent, the '349, '769, and '916 Patents claim methods for

treating lung cancer with tyrosine kinase inhibitors, including gefitinib and erlotinib, namely, a method for determining the increased likelihood that the drug treatments will be effective by determining the presence or absence of certain nucleotide variances in the EGFR gene. See ’349 Patent at 3:57-4:14; ’769 Patent at 3:57-4:14; ’916 Patent at 3:57-4:14. Although some of the claims in the ’349, ’769, and ’916 Patents use slightly different language than the claims of the ’468 Patent, or contain slightly different limitations, none of these variations provides a basis for distinguishing the claims from those of the’468 Patent, and Esoterix and LabCorp do not argue otherwise.

Thus, the Court finds that the claims of the ’349, ’769, and ’916 Patents are not drawn to patentable subject matter under § 101, as they too are directed to a “law of nature,” and do not contain any “inventive concept” that would warrant patent protection. See Ormco Corp. v. Align Tech., Inc., 498 F.3d 1307, 1320 (Fed. Cir. 2007) (applying earlier ruling on patent claims’ invalidity to invalidate additional claims in different patents, where none of the differences were “patentably significant”); Exergen Corp. v. Kaz USA, Inc., No. CV 13-10628-RGS, 2015 WL 8082402, at *5 (D. Mass. Dec. 7, 2015) (invalidating patent claims based on prior invalidity ruling on a related patent, where the new claims were not “patentably distinct” from the invalidated claims).

iii. The ’036 Patent

The claims of the ’036 Patent, unlike the ’468, ’349, ’769, and ’916 Patents, are not method claims. Instead, Claim 1 of the ’036 Patent claims:

> A kit comprising:
>
> a. at least one nucleic acid probe designed to detect a nucleotide variance within exons 18, 19, 20 or 21 of the EGFR gene, wherein detection is based on specific hybridization to the nucleotide variance sequence, wherein the nucleic variance comprises [specified genetic

variations]; and wherein the nucleic acid probe comprises a detectable label;

b. products and reagents required to carry out an annealing reaction; and

c. instructions.

'036 Patent 525:18-47 (alteration added).[5] The patent's specification, however, once again describes the invention as a "novel method to determine the likelihood of effectiveness of an epidermal growth factor receptor (EGFR) targeting treatment in a patient affected with cancer." '036 Patent 10:61-67. The specification goes on to explain that "[t]he method comprises detecting the presence or absence of at least one nucleic acid variance in the kinase domain of the erbB1 gene of said patient," and that "the presence of at least one variance indicates that the EGFR targeting treatment is likely to be effective." '036 Patent 10:66-11:1. Thus, it would appear that the '036 Patent claims an apparatus through which one can detect the presence or absence of the particular genetic mutation that correlates to an increased likelihood of effectiveness of erlotinib or gefitinib in treating certain cancers.

Qiagen argues that although the '036 Patent nominally recites a physical "kit," these claims are nonetheless directed to the same non-patentable law of nature identified in the'468 Patent. The Court agrees with this assessment. While the '036 Patent claims are formally directed to an apparatus, and not a method like the other Licensed Patents, the Court "must look past drafting formalities and let the true substance of the claim" guide its analysis when examining patentability under Section 101. CLS Bank Int'l v. Alice Corp. Pty., 717 F.3d 1269,

[5] Claims 2-15 of the '036 Patent are dependent on Claim 1. Claim 16 is another independent claim, in which the inventors claim "a nucleic acid probe" substantially similar to the probe described in Claim 1(a). Claim 16 does not, however, claim a "kit," products or reagents, or instructions. See '036 Patent 527:14-36. Claims 17 through 26 are dependent on Claim 16. Thus, while the Court's discussion focuses on Claim 1, it is also applicable to each of the remaining claims in the '036 Patent.

1288 (Fed. Cir. 2013), aff'd, 134 S. Ct. 2347 (2014). "[D]iscrete claims reciting subject matter only nominally from different statutory classes may warrant similar substantive treatment under § 101 when, in practical effect, they cover the same invention." Id.; see also Bancorp Servs., L.L.C. v. Sun Life Assur. Co., 687 F.3d 1266, 1277 (Fed. Cir. 2012) ("[T]he form of the claims should not trump basic issues of patentability.") A review of the '036 Patent's specification confirms that it covers the same underlying invention as the '468 Patent – *i.e.*, the discovery that a naturally-occurring genetic mutation correlates to an increased likelihood of effectiveness of certain cancer drugs. The '036 Patent identifies the same natural law as the '468 Patent, describes the same method claimed in the '468 Patent, and claims a kit on which to practice that method. Thus, the claims of the '036 Patent are "method claims in the guise of a device." CLS Bank Int'l, 717 F.3d at 1288. For the reasons explained in Qiagen I, such claims are directed to a natural law under the standards set forth in Alice Corp. and Mayo.[6]

Qiagen further argues that there is nothing "inventive" about the kit claimed in the '036 Patent that would make it eligible for patent protection under Alice Corp. and Mayo. See Alice Corp., 134 S.Ct. at 2355. Again, the Court agrees. A thorough review of the '036 Patent reveals no "inventive concept"—*i.e.*, "an element or combination of elements that is sufficient to ensure

[6] In response to Qiagen's Section 101 arguments, Esoterix and LabCorp point out that the "detectable label" referenced in Claim 1 of the '036 Patent is a man-made invention, and thus the "probe" in Claim 1 is not a "product of nature." See, e.g., Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2111 (2013) (holding that a naturally occurring DNA segment was a "product of nature" and not patent eligible merely because it has been isolated, but that cDNA was patent eligible because it was not naturally occurring). This argument, however, is inapposite. Qiagen does not argue that the '036 Patent claims are ineligible for patent protection because the probe in Claim 1 is a product of nature. Rather, Qiagen argues – and the Court agrees – that regardless of whether the probe in Claim 1 is man-made or naturally occurring, Claim 1 as a whole is "directed to" a "law of nature" under Alice Corp. and Mayo.

that the patent in practice amounts to significantly more than a patent upon the ineligible concept itself." Id. at 2355 (alteration adopted, internal quotations and citation omitted).

First, as the specification explains, it was routine and conventional for a researcher to create a "nucleic acid probe" that would "hybridize" to a particular mutation, once that mutation has been identified. See '036 Patent 18:54-66 ("Those skilled in the art are familiar with the preparation of probes with particular specificities."); 19:29 ("Such hybridization probes are well known in the art."); 21:52-55 ("The presence or absence of variances in the test biological sample may be detected by selective hybridization techniques, known to those of skill in the art and described above."). Similarly, there is nothing inventive about adding a detectable label to the probe, in order to identify when hybridization has occurred. See '036 Patent 31:8 ("Suitable assay labels are known in the art . . . ."); 31:24-29 ("A number of exemplary labels are known in the art and all such labels may be employed in connection with the present invention."). Nor is there anything inventive about including in the kit "products and reagents" for conducting the necessary chemical reaction, and Esoterix and LabCorp do not argue otherwise. See '036 Patent 32:16-49 (describing a kit and reagents). Finally, that the claimed kit contains "instructions" for use does not provide any inventive concept. Esoterix and LabCorp appear to concede that each of these elements was well known in the art.

Instead, Esoterix and LabCorp argue that the kit is patentable because it represents a "technological improvement" which solves the problem "relating to detecting certain gene mutations in connection with lung cancer treatment." [ECF No. 99, pp. 21-22]. The kit claimed in the '036 Patent, however, employs only routine and conventional methods, and is therefore devoid of any inventive value, beyond the discovery of the natural law. As the Federal Circuit recently held:

> [U]nder the Mayo/Alice framework, a claim directed to a newly discovered law of nature . . . cannot rely on the novelty of that discovery for the inventive concept necessary for patent eligibility; instead, the application must provide something inventive, beyond mere "well-understood, routine, conventional activity."

Genetic Techs. Ltd. v. Merial L.L.C., 818 F.3d 1369, 1376 (Fed. Cir. 2016) (quoting Mayo, 132 S.Ct. at 1294).

In sum, the elements of Claim 1 of the '036 Patent—whether considered individually or as a whole—do not provide any "inventive concept" that warrants patent protection. Instead, the '036 Patent identifies the same natural law and unpatentable method that was claimed in the '468 Patent, and claims a "kit" to practice that method by routine and conventional means. Accordingly, there is nothing to distinguish the claims of the '036 Patent from those of the '468 Patent for purposes of a Section 101 patentability analysis.[7]

V. CONCLUSION

For the foregoing reasons, Esoterix and LabCorp's Motion to Dismiss [ECF No. 98] is DENIED. Qiagen's Motion for Judgment on the Pleadings [ECF No. 88] is ALLOWED with respect to Counts II, III, IV, and V of its Counterclaims. The claims of U.S. Patent Nos. 7,964,349; 8,105,769; 8,465,916; and 9,035,036 are drawn to ineligible subject matter under 35 U.S.C. § 101.

SO ORDERED.

Dated: August 31, 2016

/s/ Allison D. Burroughs
ALLISON D. BURROUGHS
U.S. DISTRICT JUDGE

[7] This holding also extends to each of the dependent claims in Claims 2-15, the independent claim in Claim 16, and the dependent claims in Claims 17-26, as none of these claims contains any further limitations that would distinguish them from the kit in Claim 1.