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IN THE UNITED STATES DISTRICT COURT
DISTRICT OF UTAH, CENTRAL DIVISION

UNIVERSITY OF UTAH RESEARCH FOUNDATION et al. Plaintiffs, vs. AMBRY GENETICS CORPORATION, Defendant.	**DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION TO DISMISS ANTITRUST COUNTERCLAIMS** CASE NO. 2:13-CV-00640 RJS CASE NO. 2:13-CV-00643 RJS
UNIVERSITY OF UTAH RESEARCH FOUNDATION et al. Plaintiffs, vs. GENE BY GENE LTD., Defendant.	**Honorable Robert J. Shelby**

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Pursuant to the Court's Order of September 20, 2013 (Dkt. No. 147), Defendants Ambry Genetics Corporation and Gene by Gene Ltd. (combined, "Defendants") hereby submit their Opposition to Plaintiff Myriad's Motions to Dismiss ("Motions") Defendants' Counterclaims for Violations Of The Sherman Act ("Antitrust Counterclaims").[1]

I. INTRODUCTION

Defendants bring their Antitrust Counterclaims for monopolization and attempted monopolization under Section 2 of the Sherman Act against Plaintiff Myriad in response to Myriad's bad faith enforcement of its patent claims to maintain its monopoly in the diagnostic testing of human *BRCA1* and *BRCA2* genes in the United States and to attempt to injure competitors, including Defendants, who try to challenge Myriad's monopoly.

In its Motions, Myriad argues that Defendants have failed to plausibly allege that Myriad's enforcement action is "objectively baseless" such that Myriad's suit would fall under the "sham litigation" exception to *Noerr-Pennington* immunity. In doing so, Myriad ignores Defendants' substantial and detailed factual allegations in its Antitrust Counterclaims. Accepting Defendants' factual allegations as true, as a court is required to do on a 12(b)(6) motion to dismiss, *Burnett v. Mortg. Elec. Registration Sys., Inc.*, 706 F.3d 1231, 1235 (10th Cir. 2013), it is clear that Defendants' allegations more than meet the pleading requirements of Rule 8(a), in addition to any plausibility standard under *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007).

[1] Myriad's Motions filed against Ambry and Gene by Gene are essentially the same. For brevity and convenience, Defendants will cite only to Myriad's Motion filed against Ambry (Dkt. No. 95). Likewise, Defendants' Antitrust Counterclaims are essentially the same, and Defendants therefore will cite only to Ambry's counterclaims (Dkt. No. 42).

Myriad brings its infringement suit against Defendants on patent claims that are not patentable subject matter under two recent Supreme Court decisions and Federal Circuit authority: *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S.Ct. 1289 (2012); *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S.Ct. 2107 (2013) ("*AMP IV")*; *Ass'n for Molecular Pathology v. U.S.P.T.O.*, 653 F.3d 1329 (Fed. Cir. 2011) ("*AMP II*"); and *Ass'n for Molecular Pathology v. U.S.P.T.O.*, 689 F.3d 1303 (Fed. Cir. 2012) ("*AMP III*"). The asserted composition claims are not patent eligible under *AMP IV*, which precludes from patent eligibility claims - like Myriad's composition claims asserted here - reciting DNA that is indistinguishable from natural DNA, regardless of whether the recited DNA is cDNA or DNA "isolated" from natural DNA by physical excision or chemical synthesis. Likewise, the asserted method claims are not patent eligible under *Mayo*, *AMP II* and *AMP III*, which preclude from patent eligibility method claims that merely add to otherwise unpatentable subject matter conventional, well understood steps previously engaged in by researchers in the field. Claims failing the standards set forth in *Mayo* and *AMP III*, such as Myriad's method claims asserted here, do not contain the "inventive concepts" required for patent–eligibility.

Pursuing a lawsuit for infringement of patent claims that a plaintiff knows are invalid is precisely the definition of "bad faith" litigation that subjects Myriad to liability under Section 2 of the Sherman Act. *Handgards, Inc. v. Ethicon, Inc. ("Handgards I")*, 601 F.2d 986, 994 (9th Cir. 1979). Consequently, Defendants plausibly alleged that Myriad's suit is "objectively baseless" and Myriad's Motions therefore should be denied.

II. ARGUMENT

A. STANDARD OF REVIEW

When deciding a Rule 12(b)(6) motion to dismiss, a court must "accept as true all well-pleaded factual allegations in the complaint and view them in the light most favorable to the [non-moving party]."[2] *Burnett*, 706 F.3d at 1235. While a complaint "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face,'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (*quoting Twombly*, 550 U.S. at 570), the Federal Rules of Civil Procedure "erect a powerful presumption against rejecting pleadings for failure to state a claim." *Cayman Exploration Corp. v. United Gas Pipe Line Co.*, 873 F.2d 1357, 1359 (10th Cir. 1989). Pursuant to Rule 8(a)(2), a well-pleaded complaint need only contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed.R.Civ.P. 8(a)(2). "[S]pecific facts are not necessary; the statement need only give the defendant fair notice of what the claim is and the grounds upon which it rests." *Khalik v. United Air Lines*, 671 F.3d 1188, 1191 (10th Cir. 2012).

Furthermore, dismissals on a 12(b)(6) motion are generally disfavored. *See Duran v. Carris*, 238 F.3d 1268, 1270 (10th Cir. 2001) ("[Granting a] motion to dismiss is a harsh remedy which must be cautiously studied, not only to effectuate the spirit of the liberal rules of pleading but also to protect the interests of justice."); *Lone Star Indus., Inc. v. Horman Family Trust*, 960 F.2d 917, 920 (10th Cir. 1992) ("A motion to dismiss for failure to state a claim is viewed with disfavor, and is rarely granted.") (internal quotations omitted).

[2] A motion to dismiss a counterclaim under Rule 12(b)(6) is treated the same as a motion to dismiss a complaint. *E.g.*, *Fabricant v. Sears Roebuck*, 202 F.R.D. 306, 308 (S.D. Fla. 2001).

In antitrust cases, the standard for dismissal on a 12(b)(6) motion is even higher as "dismissal prior to giving the plaintiff ample opportunity for discovery should be granted very sparingly." *Poller v. Columbia Broad. Sys.*, 368 U.S. 464, 473 (1962); *Hosp. Bldg. Co. v. Trs. of Rex Hosp.*, 425 U.S. 738, 746 (1976). Accordingly, courts "should be extremely liberal in construing antitrust complaints." *Pa. ex rel. Zimmerman v. PepsiCo, Inc.*, 836 F.2d 173, 179 (3d Cir. 1988) (quoting *Knuth v. Erie–Crawford Dairy Co-op. Ass'n*, 395 F.2d 420, 423 (3d Cir. 1968)); *see also Abbott Labs. v. Brennan*, 952 F.2d 1346, 1354 (Fed. Cir. 1991), *cert. denied*, 505 U.S. 1205 (1992) ("In an antitrust action the complaint need only allege sufficient facts from which the court can discern the elements of an injury resulting from an act forbidden by the antitrust laws.") (internal quotations and citations omitted). Also, the antitrust counterclaims in this case deal with the question of what is patentable under 35 U.S.C. § 101, and this issue, "while ultimately a legal determination, is rife with underlying factual issues." *Ultramercial, Inc. v. Hulu, LLC*, 722 F.3d 1335, 1339 (Fed. Cir. 2013) (reversing and remanding dismissal under Rule 12(b)(6)).

B. MYRIAD IS NOT IMMUNIZED BY THE *NOERR-PENNINGTON* DOCTRINE

In its Motions, Myriad argues that Defendants' Antitrust Counterclaims are barred by the *Noerr-Pennington* doctrine and should be dismissed. Specifically, Myriad argues that Defendants failed to plausibly allege that Myriad's infringement lawsuit is "objectively baseless" such that it falls under the "sham litigation" exception to *Noerr-Pennington* immunity. Myriad is mistaken. Defendants' Antitrust Counterclaims contain substantial and detailed factual allegations detailing the clear invalidity of the asserted patents and the objective baselessness of

Myriad's lawsuit. Accordingly, Defendants have sufficiently pled that Myriad's bad faith enforcement of the asserted patents is "objectively baseless."

1. The *Noerr-Pennington* Doctrine Does Not Protect Bad Faith Patent Enforcement

A party who petitions the government for action that may have anticompetitive effects is generally immune from antitrust liability. *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc. ("PRE"),* 508 U.S. 49, 56 (1993). This "*Noerr-Pennington*" immunity pertains to instances when a party brings a legitimate claim to a court for judicial resolution. *Eastern R.R. Presidents Conf. v. Noerr Motor Freight*, Inc., 365 U.S. 127, 136 (1961); *United Mine Workers of Am. v. Pennington*, 381 U.S. 657 (1965). However, *Noerr-Pennington* immunity is not absolute. For example, when a plaintiff brings a patent infringement lawsuit in "bad faith" - *i.e.* with knowledge that its patent claims are invalid - then the plaintiff's infringement suit falls under a "sham litigation" exception to *Noerr-Pennington* immunity. *Handgards, Inc. v. Ethicon, Inc. ("Handgards II"),* 743 F.2d 1282 (9th Cir. 1984).

The Supreme Court has clarified that to show an infringement suit is a sham, a claimant needs to satisfy a two-pronged test related to the objective and subjective baselessness of the claims at issue. *PRE*, 508 U.S. at 60. In its motions to dismiss, Myriad only argues that Defendants have failed to plausibly allege that Myriad's lawsuit is objectively baseless, which deals with the first prong of the *PRE* test. To meet the first prong of the *PRE* test, a defendant must show that the plaintiff's lawsuit is "objectively baseless" such that "no reasonable litigant could realistically expect success on the merits." *Id*. At the center of the objective-baselessness inquiry is the concept of "probable cause," meaning that a plaintiff must have "'a reasonable belief that there is a chance that a claim may be held valid upon adjudication.'" *Pers. Dept., Inc.*

v. Prof'l Staff Leasing Corp., 297 Fed.Appx. 773, 780-81 (10th Cir. 2008) (quoting *PRE*, 508 U.S. at 62-63) (unpublished); *Hydranautics v. FilmTec Corp.*, 204 F.3d. 880, 887 (9th Cir. 2000). After demonstrating that a suit is objectively baseless, the claimant must then show that the suit is subjectively baseless, but Myriad has not challenged Defendants' counterclaims with respect to the second prong of the *PRE* test.

To survive a motion to dismiss on the "objective baselessness" prong of the *PRE* test, a claimant need only allege facts that, if proven, would demonstrate that a plaintiff's enforcement litigation constitutes "some abuse of process." *Handgards II*, 743 F.2d at 1294 (discussing *Clipper Exxpress v. Rocky Mountain Motor Tariff Bureau, Inc.*, 690 F.2d 1240, 1253 (9th Cir. 1982)). For example, in *Netflix, Inc. v. Blockbuster, Inc.*, Blockbuster claimed that Netflix brought an objectively baseless "sham" enforcement action based on "clearly invalid and overbroad patents." No. C06-02361, 2006 WL 2458717, at *8 (N.D. Cal. Aug. 22, 2006) (unpublished). On reviewing a motion to dismiss Blockbuster's sham-litigation claim, the court determined that "[i]f [Blockbuster's] allegations . . . are proven, plaintiff may demonstrate the requisite abuse of process to succeed on a sham-litigation claim." *Id.* Accordingly, the court held that Blockbuster had pled enough facts to overcome dismissal of its sham-litigation claim and that resolution of the claim on the motion to dismiss would be "premature." *Id.*

Several courts have held that the mere invocation of "sham litigation" is enough to state a claim and survive dismissal. For example, in *WAKA LLC v. DC Kickball*, the court noted that the "defendants' monopolization counterclaim is somewhat conclusory," but nevertheless determined that the "defendants provide enough factual allegations to put plaintiff on notice of their claim. Specifically, defendants allege both prongs of the sham litigation exception in that

they allege that plaintiff [has] filed a baseless copyright infringement suit with the intent of inhibiting competition." 517 F.Supp.2d 245, 251 (D.D.C. 2007). Consequently, the court rejected plaintiffs' motion to dismiss. *Id.* Similarly, in *TruePosition, Inc. v. Allen Telecom, Inc.*, the court held that "the invocation of the sham litigation doctrine is sufficient to give [plaintiff] notice of the basis of [defendant's] claim. This is particularly true in the context of a Rule 12(b)(6) motion to dismiss, and in light of both the liberal pleading philosophy of the Federal Rules and the court's responsibility to examine the complaint to determine if the allegations provide for relief on any possible theory." No. C.A. 01-823, 2003 WL 151227, at *4, n.4 (D.Del. Jan. 21, 2003) (internal quotations and citations omitted) (unpublished).

Furthermore, the Tenth Circuit has held that it is a question of fact as to whether Myriad's lawsuit is objectively baseless. Myriad argues in its motions to dismiss that its infringement claims are not objectively baseless because it has "probable cause" to bring its suit. Dkt. 42. However, as the Tenth Circuit has noted, the "probable cause concept imports a subjective feature into the objective-baselessness inquiry because the court is called upon to assess what the litigant actually knew or should have known, or believed to be true." *Pers. Dept., Inc.*, 297 Fed. Appx. at 780-81. Accordingly, "the existence of probable cause is often a question of fact," and when there are "genuine factual disputes regarding whether [a plaintiff] had an objectively reasonable basis to file its [lawsuit]," the plaintiff's motion to dismiss should be denied. *Id.*; *see also, In re Relafen Antitrust Litig.*, 346 F.Supp.2d 349, 361 (D.Mass. 2004) ("Here, 'the facts tending to establish the existence or want of existence of probable cause' were disputed, rendering the question inappropriate for decision as matter of law.") (citation omitted)); *New York Jets LLC v. Cablevision Sys. Corp.*, No. 05 Civ. 2875, 2005 WL 3454652, at *2

(S.D.N.Y. Dec. 19, 2005) ("I cannot determine, as a matter of law, that [prior] actions were (or were not) objectively baseless") (unpublished); *In re Neurontin Antitrust Litig.*, No. 02-1390, 2009 WL 2751029, at *22 (D.N.J. Aug. 28, 2009) ("Furthermore, when the predicate facts [regarding the existence of probable cause] of an allegedly sham lawsuit are disputed, sham litigation claims should not be decided by the court as a matter of law") (unpublished); *EchoStar Satellite, L.L.C. v. Viewtech, Inc.*, No. 07-CV-1273, 2009 WL 1668712, at *3 (S.D.Cal. May 27, 2009) (concluding that because the facts were disputed, the court could not determine as a matter of law "whether the litigation is objectively reasonable") (unpublished).

Myriad relies on a few cases in its Motions as support for why the Court should dismiss Defendants' Antitrust Counterclaims. Myriad Br. [Dkt. No. 95] at 6-7. These cases are readily distinguishable from the present action. In *Asahi Glass Co., Ltd., v. Pentech Pharms., Inc.*, for example, Asahi's antitrust claims were dismissed on standing grounds. 289 F.Supp.2d 986, 990-91 (N.D. Ill. 2003). The part of the opinion Myriad relies on – Judge Posner's determination regarding objective baselessness – is *dicta*. *Id.* at 991-94. Moreover, Judge Posner was uniquely informed to determine on a 12(b)(6) motion that the defendant's infringement action was not objectively baseless because he had already personally evaluated infringement claims regarding the patent at issue in a related case and could therefore conclude that the patentee had a colorable patent infringement claim. *Id.* at 992-94.

Myriad also cites to *1-800 Contacts, Inc.*, but it, too, is distinguishable. No. 2:08-CV-983, 2010 WL 988524, at *2 (D. Utah Mar. 15, 2010) (unpublished). In *1-800 Contacts*, the defendant relied on a prior ruling in a different case and in a different court (the Second Circuit) to support its argument that the plaintiff's litigation was objectively baseless. *Id.* at *2-3.

However, the court noted that the interpretation of the law had since changed in the Second Circuit, and moreover there was sufficient precedent in its own Circuit that supported plaintiff's enforcement action. *Id.* at *3. Here, on the other hand, the law is settled. When it filed suit, Myriad knew that the Supreme Court's opinions in *Mayo* and *AMP IV* and the Federal Circuit's decision in *AMP III* invalidated the patent claims that it is now trying to enforce against Defendants. *See infra* § II.C.

Myriad cites to three final cases for support: *Bio-Technology Gen. Corp. v. Genentech, Inc.*, 267 F.3d 1325 (Fed. Cir. 2001); *Avery Dennison Corp. v. Cont'l Datalabel, Inc.*, No. 10 C 2744, 2010 WL 4932666 (N.D. Ill. Nov. 30, 2010) (unpublished); and *Cornucopia Prods., LLC v. Dyson, Inc.*, 881 F.Supp.2d 1086, 1101-02 (D. Ariz. 2012). In *Bio-Technology Gen. Corp.*, the Federal Circuit affirmed the district court's dismissal of plaintiff's claim that the defendant's prior enforcement action before the International Trade Commission (ITC) was a sham because the district court had properly relied on the ITC record, in which the administrative law judge ultimately held that the plaintiff infringed the defendant's patents. 267 F.3d at 1332. Similarly, in *Avery Dennison*, the court dismissed defendant's argument that the plaintiff brought an objectively baseless enforcement action due to its failure to disclose certain prior art references to the patent examiner, because the record indicated that the patent examiner did consider the references. 2010 WL 4932666, at *5. Finally, in *Cornucopia*, the court disagreed that Dyson's foreign patent enforcement actions - combined with plaintiff's allegation that Dyson threatened to enforce its patents against Cornucopia - constituted sham litigation, because some of Dyson's foreign enforcement actions were successful. 881 F.Supp.2d at 1102.

Not one of these three cases involved patents or claims that a court had previously invalidated. Here, on the other hand, Myriad knew its patent claims against Defendants were invalid before it even initiated this action because the Supreme Court's opinion in *Mayo* and *AMP IV*, along with other precedent, clearly had the effects of rendering its claims patent ineligible. *See infra* § II.C.

2. Defendants Have Pled Sufficient Plausible Facts To Establish That Myriad's Patent Infringement Claims Are Objectively Baseless

Defendants' Antitrust Counterclaims contain substantial and detailed factual allegations showing that Myriad's infringement claims are objectively baseless, and easily satisfy any plausibility standard under *Twombly*. Specifically, Defendants provided over 30 pages of factual allegations regarding Myriad's bad faith conduct, spanning more than 100 paragraphs. *See* Dkt. No. 42 ¶¶ 16-123. Those paragraphs included specific factual allegations regarding Myriad's knowledge of its invalid patent claims before bringing the present enforcement action, such that its claims in the present litigation are objectively baseless. *Id.* ¶¶ 62-91. For example, Defendants alleged that:

- Myriad has in bad faith brought this lawsuit against Defendants on patent claims that it knows are invalid under two Supreme Court decisions and Federal Circuit authority. Dkt. No. 42 ¶ 16.
- Two decisions by the Supreme Court, issued before plaintiffs brought this suit, rebut the presumption by Myriad that it brought this suit in good faith: *AMP IV* and *Mayo*. *Id.* ¶ 62.

- According to the Federal Circuit, with *Mayo* the Supreme Court "made clear that such diagnostic methods in that case essentially claim natural laws that are not eligible for patent." *Id.* ¶ 78.
- The Supreme Court in *AMP IV* unanimously held that isolated DNA is not patent-eligible subject matter, which had the effect of invalidating the claims Myriad currently asserts against Defendants. *Id.* ¶¶ 81-82.
- The Supreme Court in *AMP IV* unequivocally excluded from patentable subject matter synthetic DNA "that may be indistinguishable from natural DNA"; yet, Myriad is attempting to enforce claims in the present litigation that have common subject matter to the invalidated claims. *Id.* ¶¶ 83-85.
- Myriad is asserting method claims in the present litigation that are facially invalid in view of the Supreme Court's decision in *Mayo* and the Federal Circuit's *AMP II* and *AMP III* decisions. *Id.* ¶¶ 86-89.

Accepting these factual allegations as true, as required under Rule 12(b)(6), *Burnett*, 706 F.3d at 1235, it is clear that Defendants have sufficiently pled that the instant suit is objectively baseless. Consequently, Myriad's Motions should be denied.

C. NO REASONABLE LITIGANT COULD REALISTICALLY EXPECT THAT THE ASSERTED CLAIMS ARE VALID AFTER *AMP III*, *AMP IV* AND *MAYO*

When a plaintiff brings a patent infringement lawsuit with knowledge that its patent claims are invalid, as Myriad has done here, the plaintiff is not afforded *Noerr-Pennington* immunity. *Handgards II*, 743 F.2d at 1294-95. Defendants have alleged facts that, when taken as true, sufficiently plead a facially plausible case that Myriad's lawsuit is baseless.

1. No Reasonable Litigant Could Realistically Expect That the Composition Claims Are Valid After *AMP IV*

a. Defendants Have Alleged Facts That Demonstrate That Claim 6 Is Patent Ineligible

The linchpin of Myriad's Motion is that Defendants cannot plausibly claim that the lawsuit is baseless because asserted claim 6 of the '282 Patent (hereinafter "Claim 6") was "upheld by the Supreme Court [in *AMP IV*] and the Federal Circuit (twice) [in *AMP II* and *AMP III*]." Myriad Br. [Dkt. No. 95] at 9-10. Myriad's argument fails because a correct reading of *AMP IV* (as alleged by Defendants) and facts pleaded - when assumed true as the Court must do - presents more than a facially plausible claim that the composition claims brought by Myriad in this lawsuit are unpatentable under § 101. *See Burnett*, 706 F.3d at 1235.

Composition Claim 6 reads onto cDNA that is indistinguishable from natural DNA. Claim 6 recites, "An isolated DNA having at least 15 nucleotides of the [DNA of SEQ ID NO:1]." SEQ ID NO:1 is a contiguous cDNA sequence of *BRCA1*. The '282 Patent teaches that a single exon of *BRCA1* can be larger than 15 nucleotides. *E.g.*, '282 Patent at 54:2-5 ("The nucleotide sequence of BRCA1 exon 4 is shown in SEQ ID NO:11…."), cols. 94-95 (identifying 111 nucleotides of SEQ ID NO:11). Accordingly, Claim 6 reads onto any 15-mer cDNA that matches only a partial DNA sequence of an exon, and therefore that 15-mer cDNA is indistinguishable from the exon sequence that appears in natural DNA.

Defendants pleaded that the *AMP IV* decision contains the bright-line rule that cDNA that is "indistinguishable from natural DNA" is not patent eligible. Specifically, Defendants quoted the rule from *AMP IV* that "cDNA is not a 'product of nature' and is patent eligible under § 101, except insofar as a very short series of DNA may have no intervening introns to remove when

creating cDNA. In that situation, a short strand of cDNA may be indistinguishable from natural DNA." Dkt. No. 42 ¶ 83 (quoting 133 S.Ct. at 2119). Thus, Defendants have pleaded a facially plausible claim that no reasonable litigant would conclude that Claim 6 is patent eligible. *See also* Dkt. No. 79 at n. 4 (Brief of *Amici Curie*)[3] ("[Claim 6] is invalid pursuant to the Supreme Court's holding that cDNA is a product of nature when it consists of nucleotides that comprise genomic DNA short enough to contain no intervening introns. . . . While [C]laim 6 is not part of Myriad's preliminary injunction motion, the fact that it was asserted in the complaints illustrates Myriad's willful disregard of Supreme Court precedent.") (citing *AMP IV*, 132 S.Ct. at 2119).

Also, because Claim 6 covers patent-ineligible subject matter, the entire claim is patent ineligible. *See Ass'n For Molecular Pathology v. U.S.P.T.O.*, 702 F.Supp.2d 181, 230 n.52 (S.D.N.Y 2010) ("*AMP I*") ("To the extent a claim reads on unpatentable subject matter, the entire claim must be deemed invalid.") (citing *Titanium Metals Corp. of Am. v. Banner*, 778 F.2d 775, 782 (Fed. Cir. 1985)); *Animal Legal Def. Fund v. Quigg*, 932 F.2d 920, 929-30 (Fed. Cir. 1991) ("[W]hether patents are allowable for [challenged subject matter] is not a matter of discretion, but of law…Either the subject matter falls within Section 101 or it does not.") (alterations by Gajarsa, J.), *quoted in Smithkline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331,

[3] In adjudicating Myriad's Motions, the Court may consider Plaintiffs' infringement theories set forth in their preliminary injunction moving papers as well statements made in other pleadings in the instant cases, as they are the Court's own files and records and also are matters of public record. *See Tal v. Hogan*, 453 F.3d 1244, 1264-65 n. 24 (10th Cir. 2006) ("[F]acts subject to judicial notice may be considered in a Rule 12(b)(6) motion without converting the motion to dismiss into a motion for summary judgment. This allows the court to take judicial notice of its own files and records, as well as facts which are a matter of public record.") (citations and internal quotations omitted). The Court cannot – and Defendants are not requesting the Court to – take as true that Plaintiffs' claims actually read onto Defendants' accused products. *See id.* ("However, '[t]he documents may only be considered to show their contents, not to prove the truth of [the] matters asserted therein.'") (citation omitted). Defendants merely ask the Court to take notice of the existence of the pertinent statements in these documents.

1360 (Fed. Cir. 2005) (Gajarsa, J., concurring); *cf. Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318, 1328 n.4 (Fed. Cir. 2008) (noting the "long established rule that '[c]laims which are broad enough to read on obvious subject matter are unpatentable even though they [] read on nonobvious subject matter.'") (quoting *In re Lintner*, 458 F.2d 1013, 1015 (CCPA 1972)).

Myriad never addresses the sufficiency of Defendants' factual allegations of patent ineligibility as they pertain to cDNA. Rather, Myriad incorrectly contends that *AMP IV* blessed with patent eligibility under § 101 all of its cDNA-based claims, including Claim 6: "[t]he [*AMP IV*] Court held that all claims directed to 'cDNA' are patentable" and that the Supreme Court broadly held that cDNA is "'not a product of nature' and is patent eligible under § 101." Myriad Br. [Dkt. No. 95] at 9-10 (emphasis added). But that is not what the *AMP IV* Court held. As correctly alleged by Defendants, and as Myriad omits from its arguments, *AMP IV* carved out from patent eligibility cDNA that is "indistinguishable from natural DNA." *See* 133 S.Ct. at 2119; Dkt. No. 42 ¶ 83.

The fact that the Federal Circuit has twice affirmed patent eligibility of Claim 6 – as trumpeted by Myriad, Myriad Br. [Dkt. No. 95] at 10 – is irrelevant to Myriad's Motions. First, both of the cited Federal Circuit cases (decided in 2011 and 2012) pre-date *AMP IV* (decided in 2013) and therefore neither case interprets and applies the holding of *AMP IV*. Second, both Federal Circuit cases explicitly found patent eligible all of the cDNA-based claims-at-issue (including Claim 6), a holding reversed by the Supreme Court's 9-0 *AMP IV* decision. *See, e.g.*, *AMP III*, 689 F.3d at 1333; *AMP IV*, 133 S.Ct. at 2114 (noting that *AMP III* "held that both isolated DNA and cDNA were patent eligible under § 101"), 2119 (holding that cDNA is patent ineligible if indistinguishable from natural DNA); Dkt. No. 42 ¶ 83.

b. Myriad Admits Claim 6 Covers cDNA Indistinguishable From Natural DNA

As Myriad recognizes, Claim 6 is similar to asserted claim 17 of the same ('282) patent. Dkt. No. 95 at 10 n.5 and accompanying text. In addition, the Court must take as true Defendants' allegation that claims 16 and 17 of the '282 Patent are representative of all the composition claims at issue. Dkt. No. 42 ¶ 84; *see Burnett*, 706 F.3d at 1325. Thus, Plaintiffs' infringement theories presented in their Motions for Preliminary Injunctions for claim 17 of the '282 patent inform the scope of Claim 6.

Those infringement theories confirm that Claim 6 covers cDNA that is indistinguishable from natural DNA. Plaintiffs assert that Defendants infringe claim 17 of the '282 patent because "[a]t least some of [Defendants'] primer pairs have a nucleotide sequence complementary to only the exons in the BRCA1 gene," and that "such primer pairs will act to produce DNA molecules [*i.e.*, amplicons] whose relevant nucleotide sequence shares similarity to only part of an exon in the BRCA1 gene." Dkt. No. 98 at 57 (quoting opening briefs; emphasis added by Plaintiffs in Dkt. No. 98). Plaintiffs also recognized that some *BRCA1* exons are so long that primers and amplicons generated therefrom contain only exonic sequences:

> [s]ome exons in each gene are so long that, when the entire gene is fragmented for PCR, some of the resulting fragments consist only of exons (i.e., without any intron fragments). As a result, the entire nucleotide sequence in the primer pairs for those exon fragments, and the resulting DNA molecules, will inevitably share sequence similarity only with part of the exon….

Id. at 57-58.

In short, Plaintiffs have put forth infringement theories that are fatal to Myriad's contention that it had probable cause to assert any of the composition claims at issue, because those facts demonstrate that those claims, as construed by Myriad, cover patent-ineligible subject

matter and therefore are patent ineligible. *See AMP I*, 702 F.Supp.2d at 230 n.52; *Smithkline*, 403 F.3d at 1360 (Fed. Cir. 2005) (Gajarsa, J., concurring); *cf. Muniauction*, 532 F.3d at 1328 n.4 (Fed. Cir. 2008).

c. Myriad Has Not Addressed Defendants' Factual Allegations of The Remainder of the Composition Claims

Defendants also have sufficiently pleaded a facially plausible case that no reasonable litigant would have determined that the Primer Claims are patent eligible after *AMP IV*. Specifically, Defendants have pleaded that compositions of the Primer Claims are indistinguishable from natural DNA and therefore are not patent eligible per *AMP IV*. Dkt. No. 42 ¶¶ 79-85. Myriad never addresses these factual allegations, and, in any event, such allegations are assumed to be true.

2. No Reasonable Litigant Could Realistically Expect That the Asserted Method Claims Are Valid After *Mayo* and *AMP III*

Despite that Myriad carries a heavy burden on a motion to dismiss under Rule 12(b)(6), Myriad's arguments to dismiss Defendants' Antitrust Counterclaims pertaining to the method claims boil down to statements made by the Federal Circuit in *AMP III* affirming the patent eligibility of a claim that is neither asserted here (claim 20 of the '282 patent ("Claim 20")) nor is like any method claim asserted here. Nowhere does Myriad address Defendants' factual averments related to the method claims actually asserted by Myriad. Accordingly, the Court should give short shrift to Myriad's conclusory arguments and deny Myriad's Motions.

a. The Asserted Method Claims Clearly Are Invalid After The Supreme Court's *Mayo* Decisions Because They Lack Inventive Concepts

Defendants have pleaded a facially plausible claim that no reasonable litigant would have asserted any of the method claims at issue here, because they all suffer from the flaw: they each add to the steps of "analyzing and comparing certain DNA sequences" (which *AMP III* found patent ineligible) well-understood, conventional activities of amplification, sequencing and/or hybridizing to patient *BRCA* DNA sequences (or chemically-synthesized exact copies) DNA probes that contain the sequence of the patient's *BRCA* DNA.

Specifically, Defendants used claim 8 of the '441 patent as a claim representative of all method claims, Dkt. No. 42 ¶¶ 86-91, an allegation Myriad did not dispute in its Motions and that the Court in any event must assume to be true for purposes of adjudicating Myriad's Motions. *See Burnett*, 706 F.3d at 1235. Claim 8 recites, "The method of claim 1 wherein a germline nucleic acid sequence is compared by amplifying all or part of a BRCA1 gene from said sample using a set of primers to produce amplified nucleic acids and sequencing the amplified nucleic acids."

Defendants alleged that in *Mayo* the Court held that "an application of a natural law may be patentable if it involves some additional inventive concepts, if the steps in the claimed processes (apart from the natural laws themselves) involve merely well-understood, routine, conventional activity previously engaged in by researchers in the field, then the subject matter is not patentable." Dkt. No. 42 ¶ 76. Defendants based these allegations on the declaration by the Court that "a process that focuses on the use of a natural law [must] also contain other elements or a combination of elements, sometimes referred to as an 'inventive concept,' sufficient to

ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself" and that precluded from "inventive concepts" are applications of the natural law that "involve well-understood, routine, conventional activity previously engaged in by researchers in the field." 132 S.Ct. at 1294.

Defendants also alleged that the Federal Circuit found patent ineligible the method claims at issue in *AMP III*, after the Supreme Court vacated and remanded *AMP II* in light of *Mayo*. Defendants alleged that the Federal Circuit "observed that '[a]lthough the application of a formula or abstract idea in a process may describe patent-eligible subject matter, Myriad's claims do not apply the step of comparing the two nucleotide sequences in a process. Rather, the step of comparing two DNA sequences is the entire process that is claimed." Dkt. No. 42 ¶ 78. Defendants pointed out that one of the method claims found unpatentable in *AMP III* is claim 1 of the '441 patent, from which claim 8 depends. *Id.* ¶ 78.

Defendants further alleged that claim 8 (and each of the other method claims) fails to add the requisite inventive concepts (as required by *Mayo*) to the processes of analyzing and comparing gene sequences, which the Federal Circuit found patent ineligible in *AMP III*. *Id.* ¶¶ 86-89. Defendants also alleged that the specification of the '441 patent itself explicitly teaches that amplification and sequencing were well-understood, routine, conventional activity previously engaged in by experts in the field. *Id.* The Court must assume all of these allegations are true. *See Burnett*, 706 F.3d at 1235.

Accordingly, Defendants have sufficiently pled a facially plausible claim that no reasonable litigant would have asserted any of the method claims at issue here, because the

reasonable litigant would recognize that the asserted method claims lack the inventive concepts required for patent eligibility. *See Iqbal*, 556 U.S. at 678.

b. Myriad's Reliance on Arguments That Do Not Address Directly Defendants' Allegations are Incorrect and Insufficient to Warrant Dismissal

Rather than address these allegations directly, Myriad advances a number of arguments that do not withstand scrutiny. Myriad Br. [Dkt. No. 95] at 11-12. First, Myriad points out that its patents are entitled to a presumption of validity. While true, that is insufficient to overcome a well-pleaded claim for an antitrust violation under *Handgards*.

Second, Myriad claims that the Federal Circuit in *AMP III* found method claims like those asserted here valid. Not so. The *AMP III* court declared invalid all method claims asserted in the *AMP* litigation except for Claim 20 of the '441 patent. The method claims other than Claim 20 asserted in the *AMP* litigation (and here) compare and analyze patient *BRCA1* and *BRCA2* sequences. That subject matter was expressly declared invalid in *AMP II* and *AMP III*. Importantly, Myriad did not appeal that aspect of *AMP III* to the Supreme Court. *AMP IV*, 133 S.Ct. at 2113 (identifying only composition claims at issue on appeal).

By contrast, Claim 20 is neither asserted here nor is similar to any other method claim asserted here. Claim 20 recites a method for screening for potential cancer therapeutics by inserting *BRCA1* variants into cells and using those transformed cells to determine efficacies of

potential therapeutics.[4] Because Claim 20 recites a method completely different from the method claims held patent ineligible in *AMP III* and at issue here, the patent eligibility of Claim 20 cannot provide the justification to warrant dismissal of Defendants' Antitrust Counterclaims in the face of Defendants' allegations. In short, the fact that Claim 20 was held patent eligible by the Federal Circuit is irrelevant to Plaintiffs' Motions. So, too, are the statements on which Myriad relies from *AMP III* for why Claim 20 is patent eligible. *See* Myriad Br. [Dkt. No. 95] at 11.[5]

Finally, Myriad maintains its erroneous argument that if a method claim contains a patent eligible composition of matter, a method claim is *per se* patent eligible. *Id.* at 12. That argument is directly at odds with the *Mayo* decision, where the Supreme Court unanimously held as invalid under Section 101 a method claim that contained a patent-eligible, man-made drug. *See* 132 S.Ct. at 1289.

[4] Claim 20 recites, "A method for screening potential cancer therapeutics which comprises: growing a transformed eukaryotic host cell containing an altered BRCA1 gene causing cancer in the presence of a compound suspected of being a cancer therapeutic, growing said transformed eukaryotic host cell in the absence of said compound, determining the rate of growth of said host cell in the presence of said compound and the rate of growth of said host cell in the absence of said compound and comparing the growth rate of said host cells, wherein a slower rate of growth of said host cell in the presence of said compound is indicative of a cancer therapeutic."

[5] Myriad also points to Judge Bryson's *dicta* in *AMP III*. Judge Bryson's short *dicta* statement on claims not before him is insufficient as a matter of law to overcome the well-pleaded complaint before this Court. Moreover, as demonstrated in the preliminary injunction proceedings, the method claims here violate Section 101 because the undisputed evidence shows that (a) the asserted claims lack an inventive concept, (b) the claims involve routine and well-known techniques, and (c) effectively preempt a woman's access to her *BRCA1* or *BRCA2* genetic information. *See* Defendants' [Proposed] Findings of Fact and Conclusions of Law [Dkt. No. 155] ¶¶ 318-419.

D. DEFENDANTS' CONTENTION THAT MYRIAD'S PATENTS ARE CLEARLY INVALID IS SUPPORTED BY THE ENTRY OF OTHER COMPETITORS

A court may take judicial notice of "facts which are a matter of public record" as well as the contents of public documents, provided the documents are not used to "prove the truth of matters asserted therein." *Tal*, 453 F.3d at 1265.

In the immediate wake of the Supreme Court's ruling in *AMP IV*, several companies in addition to Ambry and Gene by Gene announced that they intended to offer diagnostic testing of human *BRCA1* and *BRCA2* genes in the United States. For example, in addition to Defendants, several other U.S.-based diagnostic testing companies announced their intentions to offer *BRCA1* and *BRCA2* testing in the United States. For example:

- On June 13, 2013, the same day as the Court's ruling in *AMP IV*, Quest Diagnostics Inc. and GeneDX each separately announced their intentions to offer diagnostic testing in the United States of human *BRCA1* and *BRCA2* genes. Joseph Walker, *Quest Diagnostics, after High Court Decision, to Offer Cancer Tests*, Wall St. J., June 13, 2031, *available at* http://online.wsj.com/article/BT-CO-20130613-710005.html; Press Release, PRNewswire, GeneDX to Launch Comprehensive Breast Cancer Genetic Test (June 13, 2013), *available at* http://www.prnewswire.com/news-releases/genedx-to-launch-comprehensive-breast-cancer-genetic-test-211407911.html.
- On June 19, 2013, only a few days after the *AMP IV* ruling, Ethigen announced its launch of *BRCA* testing. Press Release, PR Web, Ethigen Launches Next Generation (NGS) *BRCA* Testing With Expanded Hereditary Cancer Panel (June

19, 2013), *available at* http://www.prweb.com/releases/Ethigen/BRCA/prweb10843704.htm

- On September 20, 2013, Counsyl, Inc. filed a lawsuit against Myriad seeking declaratory judgment of invalidity of claims from many patents Myriad is asserting here. According to the complaint, Counsyl "has developed and prepared to launch genetic tests and related services related to sequencing and analysis of *BRCA1* and *BRCA2* genes." *Counsyl, Inc. v. Myriad Genetics, Inc.*, Case No. 13-CV-4391 (N.D. Cal.), ¶¶ 5-6 (ECF No. 1).
- Prevention Genetics offers a hereditary and ovarian cancer syndrome panel test that includes *BRCA* testing. http://preventiongenetics.com/clinical-dna-testing/test/hereditary-breast-and-ovarian-cancer-syndrome-hboc-expanded-nextgen-sequencing-panel/961/ (last visited Oct. 7, 2013).

These companies, like Defendants, immediately recognized that *AMP III*, *AMP IV* and *Mayo* clearly invalidated Myriad's patents covering *BRCA1* and *BRCA2*, providing further evidence that Myriad's infringement action is objectively baseless.

While the Court does not have to accept the competitive entry as truth of the fact that Myriad's patents are invalid, the fact that several other companies have entered at a minimum makes it a factual question, not appropriate for a 12(b)(6) motion, whether Myriad's claims are objectively baseless. *See Ultramercial*, 722 F.3d at 1339 (reversing and remanding a dismissal under Rule 12(b)(6) and noting that analysis under § 101 "while ultimately a legal determination, is rife with underlying factual issues.").

III. CONCLUSION

For the foregoing reasons, Defendants have sufficiently pled that Myriad's suit is "objectively baseless" and Myriad's Motions should be denied. In the alternative, if the Court disagrees and rules in Myriad's favor, Defendants respectfully request that the Court grant Defendants leave to file amended Antitrust Counterclaims, as leave to amend should be freely given, and such an amendment would not be futile. *See* Fed. R. Civ. P. 15(a)(2); *Brereton v. Bountiful City Corp.*, 434 F.3d 1213, 1219 (10th Cir. 2006).

Respectfully Submitted,

MCDERMOTT WILL & EMERY LLP

DATED: October 7, 2013 By: */s/ William G. Gaede, III*

William G. Gaede, III

Attorneys for Defendants

CERTIFICATE OF SERVICE

On October 7, 2013, I served a copy of the foregoing, by electronic case filing (ECF), by e-filing the above-referenced document(s) utilizing the United States District Court, District of Utah's mandated Electronic Case Filing service, which service automatically e-served a copy of the document(s) upon confirmation of e-filing to all counsel in this case registered to receive e-filing notice, and additionally by electronic transmission by attaching the referenced documents or link to the referenced documents to an electronic mail and transmitting the same to the e-mail addresses indicated below as follows:

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