IN THE UNITED STATES DISTRICT COURT FOR
THE DISTRICT OF MARYLAND, NORTHERN DIVISION

*

CLASSEN IMMUNOTHERAPIES, INC.,

*

Plaintiff,

*

v. CIVIL NO.: WDQ-04-2607

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BIOGEN IDEC, *et al.*,

*

Defendants.

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MEMORANDUM OPINION

Classen Immunotherapies ("Classen") sued Biogen IDEC ("Biogen") and GlaxoSmithKline ("GSK") for patent infringement.[1] For the following reasons, GSK's motion to dismiss will be granted as to the contributory and willful infringement claims, and denied as to all other claims.

I. Background[2]

Classen owns patents number 6,420,139 ("the '139 patent"), 6,638,739 ("the '739 patent"), and 7,008,790 ("the '790 patent")

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[1] Classen initially named other defendants, including Merck & Co., Inc., but Biogen and GSK are the sole defendants named in the second amended complaint.

[2] For the motion to dismiss, the well-pled allegations in the complaint are accepted as true. *Brockington v. Boykins*, 637 F.3d 503, 505 (4th Cir. 2011). A court may consider "documents incorporated into the complaint by reference, and matters of which a court may take judicial notice" on a 12(b)(6) motion. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007). A court may take judicial notice of matters of public record. *Clark v. BASF Salaried Emps.' Pension Plan*, 329 F. Supp. 2d 694, 697 (W.D.N.C. 2004), *aff'd*, 142 F. App'x 659 (4th Cir. 2005).

(collectively "the patents in suit"). Each patent protects a method of choosing an immunization schedule for infants which minimizes the likelihood of developing chronic immune-mediated disorders[3] or common infectious diseases. ECF No. 172 ¶¶23-29. Though the methods vary among the patents in suit, each involves comparing or screening immunization schedules, determining which schedule minimizes the likelihood of acquiring at least one disease or disorder, and immunizing patients according to that schedule ("the patented methods"). *Id.* ¶¶23, 26, 29. Classen obtained the first of the patents in suit in June 2002. ECF No. 176-5 at 2.

GSK manufactures, licenses, and sells vaccines.[4] *Id.* ¶6. In developing the vaccines, GSK places them in clinical studies to determine their effect on the acquisition of chronic immune-mediated disorders. *Id.* ¶6. The vaccines come with "instructions and/or recommendations on . . . proper immunization schedules for vaccines and information on potential associations between vaccinations scheduling and immune-mediated conditions and by administration of vaccines according to the patented method." *Id.* ¶¶8, 36, 43, 50.

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[3] It appears that chronic immune-mediated disorders are autoimmune diseases, such as diabetes. *See* ECF No. 61 at 5.

[4] Including Rotarix, Cevarix, Boostrix, Pediarix, Infarix MMR, ENGERIX-B, and RECOMBIVAX. ECF No. 72 ¶6.

GSK's services include:

> [I]mmuniz[ing] and/or induc[ing] others to immunize or contribute to the immunization of people, according to an immunization schedule, which reduces the risk of the person developing at least one chronic immune-mediated disorder, including diabetes, selected by screening a plurality of immunization schedules from at least a first immunization schedule, and a second different immunization schedule, where at least one schedule difference is the time between birth and the first dose of the immunogen, prior to selection each schedule was used to immunize different groups of people with one or more doses of one or more infectious disease-causing organism-associated immunogens, other than BCG or pertussis immunogen, and the effectiveness of the different immunization schedules in protecting against or inducing a chronic immune-mediated disorder was compared, potentially identifying which immunization schedule may be identified as a lower risk immunization schedule with regard to the risk of developing said chronic immune-mediated disorder(s).

ECF No. 172 ¶24. These processes involve all steps of the methods described in claims 1-29, 36-60, 62-67, 69, and 70 of the '139 patent. *Id.* ¶25.

GSK also:

> [I]mmunize[s] and/or induce[s] others to immunize or contribute to the immunization of people, according to an immunization schedule, selected by screening a plurality of immunization schedules from at least a first immunization schedule, and a second different immunization schedule, prior to selection each schedule was used to immunize different groups of people with one or more doses of one or more infectious disease-causing organism-associated immunogens, and the effectiveness of the different immunization schedules in protecting against or inducing a chronic immune-mediated disorder was compared, potentially identifying which immunization schedule may be identified as a lower risk immunization schedule with

> regard to the risk of developing said chronic immune-mediated disorder(s).

ECF No. 172 ¶27. These processes involve all steps of the methods described in claims 1-6, 8-16, 19-85, 88-103, 107-110, 112, and 113 of the '739 patent. *Id.* ¶28.

GSK also:

> [I]mmunize[s] and/or induce[s] others to immunize or contribute to the immunization of people, with one or more doses of one or more immunogens which induce protective immunity to one or more infectious diseases when administered according to one or more immunization schedules, by considering the association between said immunization schedule and one or more chronic immune-mediated disorders by a) considering the incidence, prevalence or frequency of a chronic immune-mediated disorder in a first group comprising humans where the majority receive an immunization schedule comprising said one or more immunogens relative to that in at least one other group comprising humans where the majority receive a different immunization schedule, or b) considering the risk of said chronic immune-mediated disorder associated with said immunization schedule relative to at least one other immunization schedule of said one or more immunogens, and screening one or more potential recipients and identifying at least one human subject who would be expected to be immunized safely with[] said one or more immunogens according to said immunization schedule reflective of the analysis from above, and immunizing said human against said one or more infectious disease.

Id. ¶30. These processes involve all steps of the method described in claim 1 of the '790 patent. *Id.* ¶31.

GSK has:

- Conducted or disseminated studies that followed the patented methods, including studies:

    - Cited in a brief submitted to the Food and Drug Administration ("FDA") for a meeting held February 20, 2008,
    - Cited in a Pediarix package insert,
    - Cited in a Boostrix package insert,
    - Cited in a Cevarix package insert,
    - Published at Clinical Vaccine Immunology doi: 10.1128/CVI.00539-10,
    - Published in Pediatrics in December 2001; 108(6):E112,
    - Entitled "Analysis of Adverse Events of Potential Autoimmune Aetiology in a Large Integrated Safety Database of As04 Adjuvanted Vaccines,"
    - Entitled "Timing of Routine Immunizations and Subsequent Hay Fever Risk." ECF No. 172 ¶¶10-16, 18.
- Conducted a clinical trial on January 31, 2001 "that utilized [Classen's] patented screening methods." *Id.* ¶17.
- Allowed an employee to reference Classen's studies in a National Partnership of Immunization ("NPI") pamphlet on vaccine safety. *Id.* ¶19.
- "[P]roduc[ed] and provid[ed] products to health care providers that evaluate material independently and/or sponsored and/or distributed by Defendants, relating [to] the efficacy and/or risk of alternative immunization schedules, the health care providers make a determination of the appropriate immunization schedule and vaccinate according to the appropriate schedule." *Id.* ¶8.
- "[A]ctively encourag[ed] health providers to" follow the patented methods. *Id.* ¶7.

GSK "actively encourage[s] health providers to" choose and administer vaccines according to the patented methods. The health providers include: "physicians, Phy[sician's] Assistants, Nurses, clinics, health workers, health institutions . . ., the US government, Kaiser Permanente, the American Academy of Pediatrics, Harvard University, [the] Childern's Hospital of Philadelphia, and . . . organizations which have completed the [patented method]," each of which is "influenced and induce[d] to infringe by" GSK's "intentional actions." ECF No. 172 ¶22.

In 1999 GSK attended a conference "which considered Classen's research." *Id.* ¶20. The patents in suit were not obtained until 2002. ECF No. 176-5 at 2. GSK employees cited "3 of Classen's papers" in a vaccine safety pamphlet, and "the document admits that when applying the patented analysis, there is risk of vaccine induced autoimmunity."[5] *Id.* ¶19.

GSK "ha[s] been notified of [Classen's] rights in the patents in suit [and] . . . with full knowledge of those rights, wil[l]fully proceeded to infringe." *See* ECF No. 172 ¶¶38, 45, 52.

On August 10, 2004, Classen sued Biogen, GSK, Chiron Corporation, Kaiser-Permanente, Inc., and Merck & Company for infringement of the '139 and '739 patents, and two other patents it owns (numbers 5,728,385 and 5,723,283). ECF No. 1. On November 3, 2004, Classen filed a four count amended complaint adding several companies related to Kaiser Permanente. ECF No. 4. On November 19, 2004, Merck counterclaimed against Classen. ECF No. 24. On July 22, 2005, the Court dismissed the amended complaint as to Chiron Corporation and the Kaiser defendants, and dismissed counts I, II, and IV against GSK and Biogen. ECF No. 77. On December 14, 2005, the Court granted Merck's motion for summary judgment of non-infringement and Classen's motion to

[5] The second amended complaint does not note when the pamphlet was made. *See* ECF No. 172 ¶19.

dismiss count III with prejudice. ECF No. 128. On August 16, 2006, the Court denied Classen's motion for reconsideration of the December order and granted Merck's motion for summary judgment on unpatentability of the patents, and denied Merck's motion for summary judgment on the grounds of anticipation. ECF No. 152. Classen and Merck cross-appealed the August decision. ECF Nos. 153, 155.

On August 31, 2011 the Federal Circuit held that the '139 and '739 patents, as exemplified by claim 1[6] of the '739 patent, are eligible for patent protection because they involve the physical step of immunization. *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1066 (Fed. Cir. 2011).[7] The Federal Circuit held that the '283 patent was ineligible for patentability because it stated only an idea. *Id.* at 1067.

On January 6, 2012, Merck's remaining counterclaims were dismissed by stipulation. ECF No. 163. On February 3, 2012, Classen filed a second amended complaint against Biogen and GSK, charging infringement of the '139, '739, and '790 patents. ECF

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[6] The Federal Circuit accepted Classen's statement that claim 1 of the '739 patent exemplified the method of the '139 and '739 patents. *Classen*, 659 F.3d at 1060.

[7] The Federal Circuit issued its first decision of the appeal in 2008, *Classen Immunotherapies, Inc. v. Biogen IDEC*, 304 F. App'x 866 (Fed. Cir. 2008). The Supreme Court granted *certiorari*, vacated that judgment, and remanded to the Federal Circuit in light of *Bilski v. Kappos*, 130 S. Ct. 3218 (2010). *Classen Immunotherapies, Inc. v. Biogen IDEC*, 130 S. Ct. 3541 (2010).

No. 172. On March 19, 2012, Biogen answered, and GSK moved to dismiss for failure to state a claim. ECF Nos. 175, 176. Classen opposed GSK's motion. ECF No. 182.

II. Analysis

A. Standard of Review

"A motion to dismiss for failure to state a claim . . . is a purely procedural question not pertaining to patent law." *McZeal v. Sprint Nextel Corp.*, 501 F.3d 1354, 1355-56 (Fed. Cir. 2007). Accordingly, Fourth Circuit law, rather than Federal Circuit law, governs.[8] *See id.* at 1356.

Under Fed. R. Civ. P. 12(b)(6), an action may be dismissed for failure to state a claim upon which relief can be granted. Rule 12(b)(6) tests the legal sufficiency of a complaint, but does not "resolve contests surrounding the facts, the merits of a claim, or the applicability of defenses." *Presley v. City of Charlottesville,* 464 F.3d 480, 483 (4th Cir. 2006).

The Court bears in mind that Rule 8(a)(2) requires only a "short and plain statement of the claim showing that the pleader is entitled to relief." *Migdal v. Rowe Price-Fleming Int'l*

[8] The Fourth Circuit has "not yet considered a motion to dismiss in a patent case with the benefit of the Supreme Court's precedent in *Twombly* and *Iqbal*. The Federal Circuit, however, offered guidance in *McZeal*," and courts within the Fourth Circuit have relied on that guidance. *Adiscov, LLC v. Autonomy Corp.*, 762 F. Supp. 2d 826, 829-32 (E.D. Va. 2011); *see also Wright Mfg. Inc. v. Toro Co.*, No. 11-1373-MJG, 2011 WL 6211172, *1 (D. Md. Dec. 13, 2011).

Inc., 248 F.3d 321, 325-26 (4th Cir. 2001). Although Rule 8's notice-pleading requirements are "not onerous," the plaintiff must allege facts that support each element of the claim advanced. *Bass v. E.I. Dupont de Nemours & Co.*, 324 F.3d 761, 764-65 (4th Cir. 2003). These facts must be sufficient to "state a claim to relief that is plausible on its face." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007).

This requires the plaintiff to do more than "plead[] facts that are 'merely consistent with a defendant's liability'"; the facts pled must "allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (*quoting Twombly*, 550 U.S. at 557). The complaint must not only allege but also "show" that the plaintiff is entitled to relief. *Id.* at 679. "Whe[n] the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged--but it has not shown--that the pleader is entitled to relief." *Id.* (internal quotation marks omitted).

B. GSK's Motion

GSK contends that the second amended complaint fails to state a claim because (1) it does not put GSK on notice of which products or conduct allegedly infringes which of Classen's patents, (2) two claims in the '739 patent are invalid, (3) it does not state a plausible claim for direct infringement, (4) it

does not adequately plead indirect infringement, and (5) it does not adequately plead willful infringement. ECF No. 176-1 at 2-3.

1. Breadth of Allegations

GSK contends that the complaint's allegations are so broad that they "fail to provide the required notice of which GSK products or conduct allegedly infringe which of Classen's patents, and in what way." ECF No. 176-1 at 2. Citing no legal authority, Classen argues that it has pled specific allegations of (1) what products and processes infringe on each patent, and (2) whether the infringement is direct or indirect. ECF No. 182 at 7-8.

A patent infringement complaint must allege the specific product or service that infringes the patent, and how it does so, to satisfy Rule 8.[9]

The second amended complaint alleges that the following products and services infringe the patents:

- Activities that allegedly infringe all three patents:
  - Directly infringing by conducting or disseminating studies that followed the patented methods:

[9] *Adiscov, LLC v. Autonomy Corp.*, 762 F. Supp. 2d 826, 829-32 (E.D. Va. 2011) (merely stating that the defendant "manufactures, uses and sells products and services that infringe at least" one claim of the patent, "including legal discovery software and services . . . acting or capable of acting in the manner described in the . . . patent" is not specific enough to overcome a motion to dismiss).

        - Cited in a brief submitted to the FDA for a meeting held February 20, 2008,
        - Cited in a Pediatrix package insert,
        - Cited in a Boostrix package insert,
        - Cited in a Cevarix package insert,
        - Published at Clinical Vaccine Immunology doi: 10.1128/CVI.00539-10,
        - Published in Pediatrics in December 2001; 108(6):E112,
        - Entitled "Analysis of Adverse Events of Potential Autoimmune Aetiology in a Large Integrated Safety Database of As04 Adjuvanted Vaccines,"
        - Entitled "Timing of Routine Immunizations and Subsequent Hay Fever Risk." ECF No. 172 ¶¶10-16, 18.
    - Directly infringing by conducting a clinical trial on January 31, 2001 "that utilized [Classen's] patented screening methods." *Id.* ¶17.
    - Indirectly and directly infringing by administering its vaccines, and encouraging clients, who use GSK's vaccines, to administer them, according to Classen's patented methods. The vaccines are:
        - Rotarix
        - Cevarix
        - Boostrix
        - Pediarix
        - Infarix MMR
        - ENGERIX-B
        - RECOMBIVAX. *Id.* ¶¶6-7.
    - Allowing an employee to refer to, without attributing, Classen's papers in NPI's pamphlet on vaccine safety. *Id.* ¶19.
    - Contributing to infringement "by producing and providing products to health care providers that evaluate material independently and/or sponsored and/or distributed by Defendants, relating [to] the efficacy and/or risk of alternative immunization schedules, the health care providers make a determination of the appropriate immunization schedule and vaccinate according to the appropriate schedule." *Id.* ¶8.
    - Inducing infringement by "actively encourag[ing] health providers to" follow the patented methods. *Id.* ¶7.
- The '139 Patent:

- GSK's services: "[I]mmunize and/or induce others to immunize or contribute to the immunization of people, according to an immunization schedule, which reduces the risk of the person developing at least one chronic immune-mediated disorder, including diabetes, selected by screening a plurality of immunization schedules from at least a first immunization schedule, and a second different immunization schedule, where at least one schedule difference is the time between birth and the first dose of the immunogen, prior to selection each schedule was used to immunize different groups of people with one or more doses of one or more infectious disease-causing organism-associated immunogens, other than BCG or pertussis immunogen, and the effectiveness of the different immunization schedules in protecting against or inducing a chronic immune-mediated disorder was compared, potentially identifying which immunization schedule may be identified as a lower risk immunization schedule with regard to the risk of developing said chronic immune-mediated disorder(s)." ECF No. 172 ¶24.
- The allegations clearly allege direct infringement (immunizing) and indirect infringement ("induce others to immunize or contribute to the immunization of people"). *Id.*
- The alleged direct infringers for the indirect claims are "health care providers . . . health institutions . . . the US government, Kaiser Permanente, the American Academy of Pediatrics, Harvard University, Children's Hospital of Philadelphia, and other government, private and NGO organizations which have completed the steps of the claims including making the claimed comparisons, determinations and immunizing according to the schedule deemed low risk." *Id.* ¶22.
- The acts allegedly infringe claims 1-29, 36-60, 62-67, 69, and 70 of the '139 patent. *Id.* ¶25.

- The '739 patent:
  - GSK's services: "[I]mmunize and/or induce others to immunize or contribute to the immunization of people, according to an immunization schedule, selected by screening a plurality of immunization schedules from at least a first immunization schedule, and a second different immunization schedule, prior to selection each schedule was used to immunize different groups of people with one or more doses of one or more infectious disease-causing organism-associated immunogens, and the effectiveness of the different

immunization schedules in protecting against or inducing a chronic immune-mediated disorder was compared, potentially identifying which immunization schedule may be identified as a lower risk immunization schedule with regard to the risk of developing said chronic immune-mediated disorder(s)." ECF No. 172 ¶27.

- The allegations clearly allege direct infringement (immunizing) and indirect infringement ("induce others to immunize or contribute to the immunization of people"). *Id.*
- The alleged direct infringers for the indirect claims are "health care providers . . . health institutions . . . the US government, Kaiser Permanente, the American Academy of Pediatrics, Harvard University, Children's Hospital of Philadelphia, and other government, private and NGO organizations which have completed the steps of the claims including making the claimed comparisons, determinations and immunizing according to the schedule deemed low risk." *Id.* ¶22.
- The acts allegedly infringe claims 1-6, 8-16, 19-85, 88-103, 107-110, 112, and 113 of the '739 patent. *Id.* ¶28.

- The '790 patent:
  - GSK's services: "immunize and/or induce others to immunize or contribute to the immunization of people, with one or more doses of one or more immunogens which induce protective immunity to one or more infectious diseases when administered according to one or more immunization schedules, by considering the association between said immunization schedule and one or more chronic immune-mediated disorders by a) considering the incidence, prevalence or frequency of a chronic immune-mediated disorder in a first group comprising humans where the majority receive an immunization schedule comprising said one or more immunogens relative to that in at least one other group comprising humans where the majority receive a different immunization schedule, or b) considering the risk of said chronic immune-mediated disorder associated with said immunization schedule relative to at least one other immunization schedule of said one or more immunogens, and screening one or more potential recipients and identifying at least one human subject who would be expected to be immunized safely with[] said one or more immunogens according to said immunization schedule reflective of the analysis

from above, and immunizing said human against said one or more infectious disease." *Id.* ¶30.

- The allegations clearly allege direct infringement (immunizing) and indirect infringement ("induce others to immunize or contribute to the immunization of people"). *Id.*
- The alleged direct infringers for the indirect claims are "health care providers . . . health institutions . . . the US government, Kaiser Permanente, the American Academy of Pediatrics, Harvard University, Children's Hospital of Philadelphia, and other government, private and NGO organizations which have completed the steps of the claims including making the claimed comparisons, determinations and immunizing according to the schedule deemed low risk." *Id.* ¶22.
- The acts allegedly infringe claim 1. *Id.* ¶31.

These allegations are more specific than allegations that courts in the Fourth Circuit have held state a claim.[10] They satisfy Rule 8, *Twombly*, and *Iqbal*.[11]

2. Invalidity

GSK contends that, though the Federal Circuit has held that the claims of the '739 patent are eligible for patenting under 35 U.S.C. § 101,[12] claims 109 and 110 of that patent are ineligible under the test that the Federal Circuit enumerated on appeal. ECF No. 183 at 7-8. GSK argues that the Federal

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[10] *See, e.g., W.L. Gore & Assocs., Inc. v. Medtronic, Inc.*, 778 F. Supp. 2d 667, 676 (E.D. Va. 2011) (complaint alleged that the defendants were infringing patent for "an Intraluminal Stent Graft" by "making, using, offering to sell, selling, and/or importing the Talent Abdominal Stent Graft and the Talent Thoracic Stent Graft" without further description).

[11] The complaint satisfies Rule 8 without consideration of contemplated new claims that arise from discovery.

[12] *Classen*, 659 F.3d at 1073.

Circuit considered only claim 1 of the '739 patent in determining eligibility, and claims 109 and 110 are, like the '283 patent held ineligible, purely mental processes not eligible for patent protection. *Id.* at 8.

GSK has identified, and the Court has found, no authority for holding a claim ineligible for patent protection on a motion to dismiss for failure to state a claim.[13] The Court will not revisit the Federal Circuit's acceptance of the proposition that claim 1 is representative, without the benefit of a claim construction hearing. Accordingly, the Court will not dismiss the counts based on claims 109 and 110 at this point.

3. Direct Infringement

GSK next contends that Classen's patents "cover comparing-then-immunizing," and Classen has failed to state a claim because it has pled no "facts that plausibly show GSK has

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[13] *Cf. Bayer Cropscience AG v. Dow Agrosciences LLC*, No. 10-1045-RMB, 2012 WL 1253047, *3 (D. Del. Apr. 12, 2012) ("This is . . . not the appropriate time to rule on disputed issues of fact and claim construction. Nonetheless, Bayer asks the Court to do this very thing. One example is Bayer's argument" about patentability.); *In re Bill of Lading Transmission & Processing Sys. Patent Litigation*, 695 F. Supp. 2d 680, 688 (S.D. Ohio 2010) (claims should not be dismissed if dismissal "implicate[s] the meaning and construction of the claim terms in some significant way"). Because the Court will not consider eligibility on a motion to dismiss, additional briefing in light of *Mayo Collaborative Services v. Prometheus Labs*, 132 S. Ct. 1289 (2012), is not necessary.

immunized anyone after comparing immunization schedules." ECF No. 183 at 9 (emphasis omitted).

Complaints that mirror Form 18 of the Federal Rules of Civil Procedure sufficiently state a claim for direct infringement. *Wright Mfg., Inc. v. Toro Co.*, No. 11-1373-MJG, 2011 WL 6211172, *1 (D. Md. Dec. 13, 2011) (*citing McZeal*, 501 F.3d at 1356-57).[14] Form 18 requires assertions of (1) jurisdiction, (2) the plaintiff's ownership of the patent and its patent number, (3) the defendant's infringement, including the manner of infringement,[15] (4) the plaintiff's compliance with the statutory notice requirement, and (5) a demand. Fed. R. Civ. P. Form 18.

The complaint states that GSK and Biogen infringe the '139 patent by

> immuniz[ing] and/or induc[ing] others to immunize . . . according to an immunization schedule, which reduces the risk of the person developing at least one chronic immune-mediated disorder, . . . selected by screening a plurality of immunization schedules . . . where at

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[14] "[A] patentee may . . . proceed against the producer of a device if it performs substantially the same function in substantially the same way to obtain the same result." *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608 (1950). Like direct, literal infringement, the doctrine of equivalents does not require proof of intent, and a claim is stated by following Form 18. *Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 35 (1997).

[15] The complaint need only state that the defendant is infringing "by making, selling, and using [items] that embody the patented invention, and the defendant will continue to do so unless enjoined by this court." Form 18 ¶3.

least one schedule difference is the time between birth and the first dose of the immunogen.

ECF No. 172 ¶24. That allegation implies that choosing the immunization schedule requires "screening a plurality of . . . schedules"--that is, comparing them--before choosing and immunizing. The complaint includes similar allegations of comparing or considering before immunizing, for the '739 and '790 patents. *Id.* ¶¶27, 30.

The complaint need not allege more detail on specific moments of infringement or the names of the infringing products or processes to state a direct infringement claim. *See* Form 18 ¶10 (the defendant infringes "by making, selling, and using [items] that embody the patented invention").[16] Accordingly, the complaint states a direct infringement claim.

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[16] Classen provides more detail, listing particular studies and councils in which GSK allegedly participated which used the "compare-then-immunize" method to test associations between childhood vaccinations and risk of developing immune diseases. *See* ECF No. 172 ¶¶11-16, 18, 20. Whether GSK administered the vaccines is a factual dispute that will not be resolved on a Rule 12(b)(6) motion. *See Presley*, 464 F.3d at 483.

GSK also argues that some of the cited studies took place before Classen obtained the patents. ECF No. 176-1 at 21. The first patent was obtained on July 16, 2002. ECF No. 176-5 at 2 (The patent was not attached to the complaint, but patents are in the public record and may be considered without converting a motion to dismiss into a motion for summary judgment. *Clark*, 329 F. Supp. 2d at 697). This may eliminate the studies cited in paragraphs 10, 17, 19, and 20, but the remaining alleged actions, including the allegedly ongoing activities in paragraph 20, provide sufficient plausible allegations to survive GSK's motion.

4. Induced and Contributory Infringement

GSK contends that Classen has not alleged indirect[17] infringement because it did not adequately plead (1) direct infringement, and (2) specific intent to induce infringement. GSK also argues that the contributory infringement claim fails because Classen has not pled that GSK "sells a component with knowledge that the component is especially designed for use in a patented invention, and is not . . . suitable for substantial noninfringing use." ECF No. 176-1 at 26-29.

i. Direct Infringers

"Indirect infringement, whether inducement to infringe or contributory infringement, can only arise in the presence of direct infringement" by a third party. *Dynacore Holdings Corp.*

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[17] Under § 271(b), one infringes when one "actively induces infringement of a patent." 35 U.S.C. § 271(b). To succeed on a claim of induced infringement, the plaintiff must allege that the defendant (1) actively and knowingly (2) aided and abetted (3) another's direct infringement. *DSU Med. Corp. v. JMS Co., Ltd.*, 471 F.3d 1293, 1305 (Fed. Cir. 2006). (continued)

Under § 271(c), contributory infringement occurs when one "offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use." 35 U.S.C. § 271(c).

v. U.S. Philips Corp., 363 F.3d 1263, 1272 (Fed. Cir. 2004). To adequately plead direct infringement, the plaintiff need only allege facts plausibly showing that there was direct infringement by some type of entity; it need not list the particular organization or the specific instances in minute detail.[18] *See Palmetto Pharms. LLC v. AstraZenica Pharms. LP*, No. 11-0807, 2012 WL 484907, *6 (D.S.C. Jan. 4), *adopted*, 2012 WL 484848 (D.S.C. Feb. 14, 2012).[19]

Classen has alleged that GSK "actively encourage[s] health providers to" choose and administer vaccines according to the patented methods, thereby directly infringing the patents, and that the health providers include: "physicians, Phy[sician's]

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[18] To prove the underlying direct infringement, Classen will have to "either point to specific instances of direct infringement or show that the accused device necessarily infringes the patent in suit." *ACCO Brands, Inc. v. ABA Locks Mfrs. Co., Ltd.*, 501 F.3d 1307, 1313 (Fed. Cir. 2007) (on judgment after trial). However, a complaint states a claim merely by asserting facts that make such instances plausible. *See Palmetto Pharms. LLC v. AstraZenica Pharms. LP*, No. 11-0807, 2012 WL 484907, *6 (D.S.C. Jan. 4, 2012); *Twombly*, 550 U.S. at 570.

[19] Holding that complaint stated a claim for induced infringement when it alleged that "the . . . patent is directly infringed by doctors, other medical professionals, and/or patients, and Defendant--through its package inserts, promotional materials, website, and sales representatives--instructs these third parties how to use CRESTOR® in an infringing manner." *Palmetto*, 2012 WL 484907, *8; *see also Talon Research, LLC v. Hynix Semiconductor Am. Inc.*, No. 11-5058, 2012 WL 1188909, *1 (N.D. Cal. April 9, 2012) ("Talon sufficiently alleges induced infringement claims by pleading (1) direct infringement by Defendants' customers; and (2) Defendants' knowledge of and intent to induce infringement, as inferred from the infringement notices Talon sent to Defendants.").

Assistants, Nurses, clinics, health workers, health institutions . . ., the US government, Kaiser Permanente, the American Academy of Pediatrics, Harvard University, [the] Childern's Hospital of Philadelphia, and . . . organizations which have completed the [patented method]," each of which is "influenced and induce[d] to infringe by" GSK's "intentional actions." ECF No. 172 ¶22.

These allegations do more than merely recite the elements of induced infringement, which would be insufficient. *See Gradient Enters., Inc. v. Skype Techs. S.A.*, No. 10-6712, 2012 WL 864804, *4 (W.D.N.Y. Mar. 13, 2012). Like the complaints in *Palmetto* and *Talon Research*, Classen's complaint alleges that GSK's customers--doctors, other medical professionals, and medical institutions--are directly infringing the patents based on instructions, encouragement, and the vaccines that GSK provides them. ECF No. 172 ¶22. The complaint provides more specificity than is necessary by alleging particular institutions that directly infringe. *Id.* Accordingly, the complaint sufficiently alleges underlying, direct infringement.

ii. Specific Intent

Indirect infringement also requires that the Defendant had the specific intent to cause infringement. Specific intent requires "that the alleged infringer's actions induced infringing acts and that he knew or should have known his

actions would induce actual infringement." *ACCO*, 501 F.3d at 1313. It may be shown by alleging that the defendant continued to induce infringement when it knew of the patent. *Ca. Inst. of Comp. Assisted Surgery, Inc. v. Med-Surgical Servs., Inc.*, No. 10-5067, 2011 WL 672709, *4 (N.D. Cal. Feb. 16, 2011).

Classen has alleged that in 1999 GSK attended a conference "which considered Classen's research." ECF No. 172 ¶20. The patents in suit were not obtained until 2002. ECF No. 176-5 at 2. The method was not patented in 1999; GSK thus cannot have known about the patents at that time.

Classen has also alleged that GSK employees cited "3 of Classen's papers" in a vaccine safety pamphlet, and "the document admits that when applying the patented analysis, there is risk of vaccine induced autoimmunity." ECF No. 172 ¶19. These allegations allow the Court to reasonably infer that the pamphlet cited the papers after the analyses were patented, and the GSK was aware of the patents.

Accordingly, Classen has alleged that GSK encouraged or contributed to infringement with knowledge of the patents, and thus had the specific intent to induce or contribute to infringement.

iii. Special Design for Use in a Patented Invention

To succeed on a claim of contributory infringement, Classen must show that GSK imported or offered to sell "a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use." 35 U.S.C. § 271(c). That a component is "capable of being used in an infringing manner," and comes with instructions for applying the infringing method, does not make it especially made or adapted for use in an infringing method; the plaintiff must allege that the item is not a staple and lacks substantial noninfringing use.[20] *ACCO Brands, Inc. v. ABA Locks Mfrs. Co., Ltd.*, 501 F.3d 1307, 1312-13 (Fed. Cir. 2007); *Golden Blount, Inc. v. Robert H. Peterson Co.*, 365 F.3d 1054, 1061 (Fed. Cir. 2004) ["*Golden Blount I*"]. The existence of an "unusual" configuration or application is not a "substantial noninfringing use." *Golden Blount I*, 438 F.3d at 1363.

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[20] Instructions that direct users to infringe are, however, relevant to prove acts of direct infringement in an indirect infringement claim. *Golden Blount, Inc. v. Robert H. Peterson Co.*, 438 F.3d 1354, 1363 (Fed. Cir. 2006) ["*Golden Blount II*"].

GSK contends that Classen has not alleged that GSK's vaccines, studies, and instruction pamphlets are "especially . . . designed for infringing use" and lack "substantial noninfringing uses." ECF No. 176-1 at 30. Classen counters that the "vaccines are specifically designed to vaccinate and are specifically intended to be administered according to the lowest risk schedule," and GSK has "no intent . . . to have it[s] vaccines used in a higher risk manner." ECF No. 182.

The complaint states that GSK produces and provides to customers vaccines and products "relat[ed to] the efficacy and/or risk of alternative immunization schedules," sells vaccines with "instructions and/or recommendations on . . . proper immunization schedules for vaccines and information on potential associations between vaccinations scheduling and immune-mediated conditions and by administration of vaccines according to the patented method." ECF No. 172 ¶¶8, 36, 43, 50.

Taking all inferences in the light most favorable to Classen, the Court cannot conclude that the complaint alleges GSK's vaccines are unsuitable for noninfringing use. Though it is plausible that GSK's customers administer the vaccines in the manner least likely to cause chronic immune-mediated disorders, as the patented method suggests, Classen has not alleged that no other considerations, such as minimizing other risks, might

influence the method of administration and avoid infringement. *See Golden Blount II*, 438 F.3d at 1363. If Classen proves its allegations, it will not be entitled to relief because it will not have proven that there is no noninfringing use. *See id.* Classen has not stated a claim for contributory infringement.

5. Willful Infringement

Patent infringement is a strict liability offense, but willful infringement can justify enhanced damages. *In re Seagate Tech., LLC*, 497 F.3d 1360, 1368 (Fed. Cir. 2007). "Willful infringement is not established by the simple fact of infringement, even whe[n] the accused" knows about the patents. *Golden Blount II*, 438 F.3d at 1368. The patentee must allege facts showing that the infringer "recklessly disregarded the possibility that certain conduct was infringing." *Weyer v. MySpace, Inc.*, No. 10-0499, 2010 WL 8445305, *4 (C.D. Cal., Jun. 17, 2010) (*citing Seagate*, 497 F.3d at 1370-71).

GSK contends that Classen has not pled facts that plausibly show that it recklessly disregarded the possibility that it was infringing the patents in suit. ECF No. 176-1 at 32. Classen argues that GSK knows about the patents and "can no longer maintain a plausible belief that the patents are invalid," but continues to infringe.[21] ECF No. 182 at 11.

[21] Classen also argues that GSK has tried to refute Dr. Classen's conclusions in its own study, and this effort shows that GSK

Other than the bare allegation that GSK has "been notified of [Classen's] rights in the patents in suit [and] . . . with full knowledge of those rights, wil[l]fully proceeded to infringe," Classen has alleged no facts supporting recklessness. *See* ECF No. 172 ¶¶38, 45, 52. The complaint allows the Court to reasonably infer that GSK knew about the patents, *see* Part II.B.4.ii, *supra*, but mere knowledge of the patents in suit, without an allegation that GSK acted in reckless disregard of a possibility that it was infringing them, does not support a claim for willful infringement. *See Seagate*, 497 F.3d at 1371 (recklessness requires an "unjustifiably high risk of harm that is either known or so obvious that it should be known").

C. Leave to Amend the Complaint

Because it appears that amendment will not be futile, Classen will be granted leave to amend its complaint to plead contributory and willful infringement.

III. Conclusion

For the reasons stated above, GSK's motion to dismiss will be granted as to the contributory and willful infringement claims, and denied as to all other claims.

5/29/12
Date

William D. Quarles, Jr.
United States District Judge

knew of the patent, ECF No. 183, but as that allegation is not in the complaint, the Court did not consider it.