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

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CLASSEN IMMUNOTHERAPIES, INC.,

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Plaintiff,

*

v. CIVIL NO.: WDQ-04-2607

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BIOGEN IDEC, *et al.*,

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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, the Court will reconsider and deny GSK's motion to dismiss the second amended complaint.

I. Background[2]

Classen Immunotherapies owns three patents[3] for methods for choosing immunization schedules for infants. ECF No. 172 ¶¶23-29. Each patent protects a method of choosing an immunization schedule for infants which minimizes the likelihood of

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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).

[3] Patents number 6,420,139 ("the '139 patent"), 6,638,739 ("the '739 patent"), and 7,008,790 ("the '790 patent") (collectively "the patents in suit").

developing chronic immune-mediated disorders[4] or common infectious diseases. ECF No. 172 ¶¶23-29. Classen obtained the first of the patents in suit in June 2002. ECF No. 176-5 at 2. GSK manufactures, licenses, and sells vaccines. Id. ¶6. In 2004, Classen sued GSK and others, claiming that GSK's studies and informational pamphlets infringed Classen's patents. ECF No. 1.

On August 31, 2011, the Federal Circuit held that two of the patents at issue are eligible for patent protection. *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1066 (Fed. Cir. 2011), *petition for cert. filed* Feb. 28, 2012. On February 3, 2012, Classen filed a second amended complaint against GSK and Biogen, alleging infringement of those patents and a patent that the Federal Court has not considered. ECF No. 172. Biogen has answered the second amended complaint. ECF No. 175.

On May 30, 2012, the Court dismissed part of Classen's second amended complaint for failure to state claims for contributory and willful infringement. ECF No. 195. The Court declined to consider patentability on the motion to dismiss for failure to state a claim. ECF No. 194 at 15. In a footnote, the Court concluded that additional briefing in light of *Mayo*

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

Collaborative Services v. Prometheus Labs, 132 S. Ct. 1289 (2012) ("*Prometheus II*") would not be helpful. Id. at 15 n.13. The Order granted Classen leave to file a third amended complaint. ECF No. 195.

On June 4, 2012, GSK asked the Court to reconsider its order and consider patentability, and renewed its motion to dismiss based upon *Prometheus II*. ECF No. 196. On June 20, 2012, Classen filed its third amended complaint. ECF No. 202. Two days later, it opposed GSK's motion for reconsideration. ECF No. 203. On June 25, 2012, the Supreme Court invited the Solicitor General to file a brief expressing the views of the United States with respect to GSK's petition for a writ of certiorari. ECF No. 206. On July 5, 2012, Biogen answered the third amended complaint and counterclaimed. ECF No. 207. On July 9, 2012, GSK replied to Classen's opposition to the motion for reconsideration. ECF No. 208. On July 12, GSK answered the third amended complaint and counterclaimed. ECF No. 209.

II. Analysis

A. Standards of Review

1. Motion for Reconsideration

Motions for reconsideration of an interlocutory order are governed by Rule 54(b), under which "any order or other decision . . . may be revised at any time before the entry of a judgment adjudicating all the claims and all the parties' rights and

liabilities." Fed. R. Civ. P. 54(b).[5] Thus, when warranted, a district court retains the power to reconsider and modify its interlocutory judgments at any time before final judgment. *Am. Canoe Ass'n v. Murphy Farms, Inc.*, 326 F.3d 505, 514-15 (4th Cir. 2003).[6] Resolution of the motion is "committed to the discretion of the district court," *Id.* at 515, and "the goal is to reach the correct judgment under law." *Netscape Commc'n Corp. v. ValueClick, Inc.*, 704 F. Supp. 2d 544, 547 (E.D. Va. 2010)(internal citations omitted).

Although Rule 60(b) applies only to final judgments, a court may consider the reasons in that rule when deciding whether to grant relief under Rule 54(b).[7] *See Fayetteville Investors v. Commercial Builders, Inc.*, 936 F.2d 1462, 1470 (4th Cir. 1991); *Mateti*, 2009 WL 3633339 at *4.

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[5] *See Mateti v. Activus Fin., LLC*, No. DKC-08-0540, 2009 WL 3633339, *4 (D. Md. Oct. 27, 2009).

[6] "Motions for reconsideration of interlocutory orders are not subject to the strict standards applicable to motions for reconsideration of a final judgment." *Am. Canoe*, 326 F.3d at 514 (*citing* 11 James Wm. Moore et al., *Moore's Federal Practice* § 56.04[3] (3d ed.) ("Rule 60(b) does not govern relief from interlocutory orders . . . .")); *see also Fayetteville Investors v. Commercial Builders, Inc.*, 936 F.2d 1462, 1469 (4th Cir. 1991) ("An interlocutory order is subject to reconsideration at any time prior to the entry of a final judgment.").

[7] Under Rule 60(b), a court may grant relief from a judgment or order for: (1) mistake, inadvertence, surprise, or excusable neglect; (2) newly discovered evidence; (3) fraud or misconduct by the opposing party; (4) voidness; (5) satisfaction; or (6) any other reason that justifies relief. Fed. R. Civ. P. 60(b).

2. Motion to Dismiss for Failure to State a Claim

"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 precedent, rather than that of the Federal Circuit, 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 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,

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[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).

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).

"A technical reading of [the Rules of Civil procedure] appears to prevent defendants from filing successive pre-answer motions to dismiss," but "many courts have interpreted these rules permissively and have accepted subsequent motions on discretionary grounds." *Fed. Trade Comm'n v. Innovative Mktg., Inc.*, 654 F. Supp. 2d 378, 383 (D. Md. 2009).[9] "Such a permiss-

[9] Rule 12(g) generally prohibits successive motions to dismiss, and Rule 12(b) provides that certain defenses--including failure to state a claim--must be raised in a motion to dismiss before filing an answer. Rule 12(h)(2) allows a defendant to raise a failure to state a claim in an answer, in a motion for judgment on the pleadings, or at trial.

ive reading . . . comport[s] with the general spirit of the rules and . . . promot[es] the interests of efficiency."[10]

B. Classen's Motion

GSK asks the Court to reconsider its order denying the motion to dismiss Classen's claims for unpatentability. ECF No. 196-1 at 1. The Court will reconsider its decision.

1. 35 U.S.C. § 101

Patentable subject matter includes any "new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." 35 U.S.C. § 101. The Supreme Court has long recognized an implied exception to § 101: "laws of nature, natural phenomena, and abstract ideas" are not patentable. *Diamond v. Diehr*, 450 U.S. 175, 185 (1981).

An "application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection," but "limiting an abstract idea to one field of use or adding token postsolution components [does] not make [a] concept patentable." *Bilski v. Kappos*, 130 S. Ct. 3218, 3231

[10] *Innovative Mktg., Inc.*, 654 F. Supp. 2d at 383-84. *See also Dart Drug Corp. v. Corning Glass Works*, 480 F. Supp. 1091, 1095 n.3 (D. Md. 1979) (even when a defense can "be raised in a judgment on the pleadings or at trial," it is "far more efficient to [address] the arguments prior to more extensive discovery").

(2010).[11] For example, combining "the abstract idea of hedging risk" in one market with "well-known random analysis techniques to help establish some of the inputs into the equation" does not convert the abstract idea into a patentable process. *Id.*[12]

2. *Prometheus II*

GSK's motion relies on the Supreme Court's recent decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289(2012) [hereinafter *Prometheus II*.

Prometheus Laboratories was the licensee of two patents for a method for optimizing the use of thiopurine drugs to treat autoimmune diseases, in which (1) the doctor administers a drug to the patient, (2) the doctor measures the patient's 6-thoiguanine ("6-TD," a metabolite) levels, and (3) concludes that a reading that the patient's 6-TD levels are less than 230 units "indicates a need to increase the amount" of the drug, and a reading of more than 400 units "indicates a need to decrease the amount of the drug." *Prometheus II*, 132 S. Ct. at 1295. Mayo Collaborative Services ("Mayo") had bought tests that embody the patented process from Prometheus, but in 2004 decided

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[11] *Citing Diamond*, 450 U.S. at, 187, *Parker v. Flook*, 437 U.S. 584, 590 (1978).

[12] That the patents satisfy 35 U.S.C. § 101 does not guarantee that the patents will survive. The processes must also satisfy the other requirements of the Patent Act: they must be novel, nonobvious, and fully and particularly described. *Bilski*, 130 S. Ct. at 3225 (*citing* 35 U.S.C. §§ 102, 103, 112).

to make and sell its own test, which used the same process with slightly different 6-TD levels. *Id.* at 1295-96. Prometheus brought a patent infringement action. *Id.* at 1296.[13]

On March 20, 2012, the Supreme Court held that Prometheus's method was not patentable because it "set forth laws of nature--namely, relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm." *Prometheus II*, 132 S. Ct. at 1296-97. The Supreme Court relied on its longstanding insistence that

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[13] On March 28, 2008, the United States District Court for the Southern District of California found that: (1) Mayo's test infringed the patents, (2) it was necessary to "construe[] the claim's language, 'indicates a need to decrease' (or 'to increase'), as not limited to instances in which the doctor actually decreases (or increases) the dosage level whe[n] the test results suggest that such an adjustment is advisable," but (3) Mayo was entitled to summary judgment because the patents claimed natural laws and were not patentable. *Prometheus II*, 132 S. Ct. at 1296.

On September 16, 2009, the Federal Circuit reversed the District Court, applying the "machine or transformation" test. *Id.* On June 29, 2010, the Supreme Court granted Mayo's petition for *certiorari*, vacated the judgment, and remanded the case for reconsideration in light of *Bilski v. Kappos*, 130 S. Ct. 3218 (2010). *Prometheus II*, 132 S. Ct. at 1296. On remand, the Federal Circuit held that, in light of *Bilski*, "patent eligibility . . . turns on whether Prometheus's asserted claims are drawn to a natural phenomenon, . . . or whether the claims are drawn only to a particular application of that phenomenon." *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 628 F.3d 1347, 1354 (Fed. Cir. 2010) [hereinafter *Prometheus I*]. It concluded that the patents were drawn to an application of the phenomenon, and again reversed the District Court's grant of summary judgment of unpatentability. *Id.* Mayo again petitioned for and obtained *certiorari*.

> a process that focuses on the use of a natural law 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.

Id. at 1294 (*citing Parker v. Flook*, 437 U.S. 584, 594 (1978), *Bilski*, 130 S. Ct. at 3230). Therefore, a "patent . . . could not simply recite a law of nature and then add the instruction 'apply the law.'" *Id.*

The Supreme Court noted that the steps in the patents-in-issue that were not natural laws "involve[d] well-understood, routine, conventional activity previously engaged in by researchers in the field," and protecting the method "would risk disproportionately tying up the use of the underlying natural laws." *Id.* "[A]ppending conventional steps, specified at a high level of generality, to laws of nature . . . cannot make those laws . . . patentable." *Id.* at 1300.

The high court concluded that the steps in the patents-in-issue "simply tell doctors to gather data from which they may[--but need not--]draw an inference in light of the correlations." *Id.* at 1298. It noted that the third step of the patents "simply tell a doctor about the relevant natural laws, at most adding a suggestion that he should take those laws into account when treating his patient," rather than requiring that the doctor apply the law in a new, creative way. *Id.* at 1297. That

instruction was "rather like Einstein telling linear accelerator operators about his basic law [$E=mc^2$] and then trusting them to use it where relevant" in that the "process" amounted to no more than announcing an unpatentable law of nature and suggesting that people who might find it helpful, think about using it when it becomes helpful. *Id.*

3. The Federal Circuit's Opinion in *Classen*

Without the Supreme Court's guidance in *Prometheus II*, the Federal Circuit held that the '139 and '739 patents "include[e] the physical step of immunization on [a] determined schedule," which was more than mere "data gathering or insignificant extra-solution activity," and therefore patentable. *Classen Immuno-therapies*, 659 F.3d at 1066-67. It relied on *Bilski*'s statement that "ingenuity should receive a liberal encouragement," and recognized that "the prohibition against patenting abstract ideas cannot be circumvented by attempting to limit the use of a formula to a particular technological environment or adding insignificant post-solution activity." *Id.* at 1067 (*quoting Bilski*, 130 S. Ct. at 3225, 3230).

The Federal Circuit paid special attention to "the distinction between a concrete, physical step of a process claim, . . . [and] data[-]gathering or insignificant extra-solution activity." *Id.* at 1067. It concluded that the '139 and '739 patent claims do not involve "insignificant post-

solution activity"; the immunization requirement, "in accordance with a lower-risk schedule[,] . . . mov[ed] the claims from abstract scientific principle to specific application." *Id.* at 1067-68.[14]

4. Application of *Prometheus II*

GSK contends that, like the *Prometheus* patents, Classen's patents "simply recite a law of nature and then add the instruction 'apply the law.'" ECF No. 196-1 at 48 (*quoting Prometheus II*). Though that sweeping statement arguably encompasses the facts here, *Prometheus II*'s reasoning does not apply.

At this stage of the proceedings, *Prometheus II* does not affect the patentability of Classen's claims. In *Prometheus II*, the patent acknowledged that "scientists routinely measured metabolites as part of their investigations into the relationships between metabolite levels and efficacy and toxicity of thiopurine compounds." 132 S. Ct. at 1298. The Supreme Court was thus able to conclude that the steps involved "well-

[14] The Federal circuit distinguished Classen's patent claims from those in *Prometheus I* because: (1) the facts in *Prometheus I* were "materially different from those in *Classen*, (2) the *Prometheus* claims were "for a method of controlling individualized dosages of a specific drug," and the Classen claims are for a method "to determine general immunization schedules," and (3) one of the Classen patent claims did not involve the "transformative step[]" of immunizing according to the determined schedule, which the court compared to the treatment recommendation in the *Prometheus* patent claims. *Classen Immunotherapies*, 659 F.3d at 1068.

understood, routine, conventional activity previously engaged in by scientists who work in the field." *Prometheus II*, 132 S. Ct. at 1298. There is no information in the record here that allows the Court, on a motion to dismiss for failure to state a claim, to conclude that the Classen patent claims involve "well-understood, routine, [or] conventional activity."[15]

The patents at issue here include the mandatory application step that was missing in the *Prometheus* claims. *Prometheus II*, 132 S. Ct. at 1296-97. Rather than "at most" suggesting a general course of action after the data-gathering step, *id.*, the Classen claims require immunizing according to a particular schedule in *addition* to the data-gathering step, *see* ECF No. 1 ¶¶23, 26, 29.

Classen also contends that *Prometheus II* introduced a new prohibition on using insignificant "post-solution activity" to transform an unpatentable mental process or natural law into patentable subject matter. ECF No. 196-1 at 24. But the Federal Circuit relied on that principle in determining that the '139 and '739 patents crossed the threshold of patentability. *Classen Immunotherapies*, 659 F.3d at 1067-68. *Prometheus II* relied on *Flook* and *Bilski*--both of which predated *Classen*

[15] The '139 patent application noted that "current vaccine trials are not designed to look for complications of diabetes or other chronic immune mediated disorders," ECF No. 20-2 at 12, suggesting that the process was neither routine nor conventional when the application was filed.

Immunotherapies--when it noted that "[p]urely 'conventional or obvious' 'pre-solution activity' is normally not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law." *Prometheus II*, 132 S. Ct. at 1298 (*quoting Flook*, 437 U.S. at 590, *citing Bilski*, 130 S. Ct. at 3230). The distinction between conventional pre- or post-solution activity and significant, new application was clear when the Federal Circuit issued its decision in this case. *See Classen Immunotherapies*, 659 F.3d at 1067 (*citing Bilski*, 130 S. Ct. at 3225).

Accordingly, under *Prometheus II*, the claims still pass the § 101 threshold.[16]

III. Conclusion

For the reasons stated above, reconsideration was granted, and GSK's motion to dismiss will be denied.

8/9/12
Date

William D. Quarles, Jr.
United States District Judge

[16] In a footnote, GSK contends that claims 109 and 110 of the '739 patent should also be dismissed "for . . . the reasons articulated in GSK's March 19, 2012 Memorandum and Motion to Dismiss." ECF No. 196-1 at 15 n.6. GSK has identified no reason for reconsidering the Court's decision not to evaluate the individual claims on the motion to dismiss; the Court will not revisit that aspect of its opinion.