IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BRISTOL-MYERS SQUIBB CO., E. R. SQUIBB & SONS, L.L.C., ONO PHARMACEUTICAL CO., LTD., and TASUKU HONJO, Plaintiff, v. MERCK & CO., INC. and MERCK SHARP & DOHME CORP., Defendant.	)	Civil Action No. 15-572-GMS

ORDER

WHEREAS, on July 7, 2015, the plaintiff Bristol-Myers Squibb Co., E. R. Squibb & Sons, L.L.C., Ono Pharmaceutical CO., LTD., and Tasuku Honjo (collectively "Bristol-Myers") filed this patent infringement action against the defendant Merck & Co., Inc. and Merck Sharp & Dohme Corp., (collectively "Merck"). (D.I. 1)[1];

WHEREAS, presently before the court is Merck's Motion to Dismiss the Complaint. (D.I. 5, 6);

WHEREAS, the court having considered the motion, the parties' positions as set forth in their papers, as well as the applicable law;

IT IS HEREBY ORDERED THAT:

[1] Bristol-Myers alleges that Merck induces or contributes to infringement of the United States Patent No. 9,073,994 ("the '994 Patent") by making and selling pembrolizumab, which Merck sells in the United States under the name Keytruda® for the treatment of patients with melanoma. (D.I. 1 at ¶¶ 19–25, 29.)

Merck's Motion to Dismiss the Complaint (D.I. 5) is DENIED.[2]

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[2] Federal Rule of Civil Procedure 12(b)(6) provides for dismissal where the plaintiff "fail[s] to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements," are inadequate to state a claim. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). In considering a motion to dismiss, the court "accept[s] all factual allegations as true, construe[s] the complaint in the light most favorable to the plaintiff, and determine[s] whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008).

Merck argues that the '994 Patent claims ineligible subject matter pursuant to 35 U.S.C. § 101. (D.I. 6 at 10-11.) According to Merck, the '994 Patent is directed to a natural phenomenon and the patent claims do not transform such natural phenomenon into a patent-eligible invention because the claims contain no inventive concept. (*Id.*) Merck asserts that the '994 patent claims that the natural phenomenon is the body's own mechanism for regulating the immune system. (*Id.* at 6.) Specifically, T cells, which are part of the immune system, attack and kill cells that the immune system sees as foreign, such as cancer cells. (*Id.*) Merck claims that the '994 patent recites no inventive contribution beyond the natural phenomenon itself. (*Id.* at 2). Thus, according to Merck, the '994 patent covers a patent ineligible subject matter. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1298 (2012). A patent infringement claim that asserts infringement of claims that are invalid fails to state a claim on which relief can be granted. Therefore, Merck asserts that Bristol-Myers' infringement claims should be dismissed with prejudice. (D.I. 6 at 19-20.)

Bristol-Myers responds that the '994 patent is a method of treatment claim that merely relies on the human body's ability to respond to the disease. (D.I. 15 at 2.) Bristol-Myers further asserts that Merck's argument "misses the point that *every* method of therapeutic treatment at its basic level relies on the biological activity of the patient's immune system." (*Id.* at 9). According to Bristol-Myers, the '994 patent relies on the body's immune system via the PD-1 pathway, but adds the step of administering a composition of anti-PD-1 antibodies for the treatment of metastatic melanoma to induce an immune response that would not otherwise occur in the patient's natural state. (D.I. 15 at 17).

Section 101 describes the general categories of patentable subject matter as "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." 35 U.S.C. § 101. There are, however, exceptions to these broad classifications. "Laws of nature, natural phenomena, and abstract ideas are not patentable." *Alice*, 134 S. Ct. at 2354 (quoting *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2216 (2013)). The contours of these exceptions have been the subject of much debate in recent years. *See id.* ("[W]e tread carefully in construing this exclusionary principle lest it swallow all of patent law. At some level, all inventions . . . embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas." (internal citation and quotations marks omitted)).

The Supreme Court's decision in *Alice* reaffirmed the framework first outlined in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012), used to "distinguish[] patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts." *Alice*, 134 S. Ct. at 2355.

> First, we determine whether the claims at issue are directed to one of those patent-ineligible concepts. If so, we then ask, what else is there in the claims before us? To answer that question, we consider the elements of each claim both individually and as an ordered combination to determine whether the additional elements transform the nature of the claim into a patent-eligible application.

Dated: March 29, 2016

UNITED STATES DISTRICT JUDGE

Id. (internal citations, quotations marks, and alterations omitted). Thus, the court must determine (1) if the patented technology touches upon ineligible subject matter, and (2) whether there are sufficient inventive elements such that the invention is "'significantly more' than a patent on an ineligible concept." *See DDR Holdings, LLC v. Hotels.com, L.P.*, 773 F.3d 1245, 1255 (Fed. Cir. 2014) (quoting *Alice*, 134 S. Ct. at 2355); *see also Alice*, 134 S. Ct. at 2354 ("[A]n invention is not rendered ineligible for patent simply because it involves an abstract concept.").

The '994 patent claims treatment for metastatic melanoma in humans by intravenously administering an effective amount of a composition comprising a human or humanized anti-PD1 monoclonal antibody and a solubilizer in a solution. (D.I. 1-1 at col. 25:22–27.) The '994 patent relies on the scientific fact that blocking activation of the PD-1 pathway enables the patient's T cells to perform their normal biological activity of removing cancer cells. (D.I. 1 at ¶ 5.) By preventing PD-1 ligands from binding to the PD-1 receptor, the anti-PD-1 antibodies prevent the PD-1 pathway from suppressing the immune system, which, in turn, kills and clears the body of the cancer cells. (*Id.*)

First, the court concludes that, contrary to Bristol-Myers contention, (D.I. 15 at 8), the '994 patent touches upon a natural phenomenon by using T cells to activate the immune system. The '994 patent relies on the known scientific fact that blocking activation of the PD-1 pathway causes this effect in the body, which enables the patient's T cells to perform their normal biological activity of removing cancer cells. (D.I. 1 at ¶ 5.) This interaction is a natural phenomenon.

Thus, the remaining question before the court is "whether the claims do significantly more than simply describe these natural relations. To put the matter more precisely, do the patent claims add *enough* to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that *apply* natural laws?" *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1297 (2012).

When the factual allegations in the patent are taken as true and read in the light most favorable to Bristol-Myers, there are, at the very least, material factual disputes that cannot be resolved on a motion to dismiss. Merck contends that the process method consists of administering a synthetic substance through a single step to induce a natural reaction. (D.I. 6 at 13.) Bristol-Myers insists that administering anti-PD-1 antibodies is not a diagnostic step, but provides the treatment itself. (D.I. 15 at 10-14.) Whether the claims amount to an implementation step is a complicated factual determination that the court could better resolve after discovery. (D.I. 15 at 15.)

Additionally, the '994 patent is entitled to a presumption of validity under 35 U.S.C. § 282. (D.I. 15 at 13.) Rarely can a patent infringement suit be dismissed at the pleading stage for lack of patentable subject matter. *See Tuxis Techs., LLC v. Amazon.com, Inc.*, No. 13-1771-RGA, 2014 WL 4382446, at *2 (D. Del. Sept. 3, 2014). ("At the motion to dismiss stage, a patent claim can be found directed towards patent-ineligible subject matter if the only plausible reading of the patent must be that there is clear and convincing evidence of ineligibility.") Here, the determination of the Patent Office that the '994 Patent was patent-eligible is presumed to be correct.

Pursuant to Federal Rule of Civil Procedure 12(b)(6), and after having considered the pleadings in the light most favorable to the Bristol-Myers, the court concludes that Merck has not met its burden to prove by clear and convincing evidence that the '994 Patent is invalid on its face for failing to cover patent-eligible subject matter under 35 U.S.C. § 101. If Rule 12(b)(6) is used to assert an affirmative defense, dismissal is appropriate only if the well-pleaded factual allegations in the complaint, construed in the light most favorable to the plaintiff, suffice to establish the defense. Here there is not clear and convincing evidence that ineligibility is the only plausible reading of the patent. For the reasons stated above, the court concludes that Merck has not met its burden. Accordingly, the court must deny Merck's Rule 12(b)(6) Motion to Dismiss. (D.I. 5.)