IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ENDO PHARMACEUTICALS INC. and MALLINCKRODT LLC, Plaintiffs, v. ACTAVIS INC. and ACTAVIS SOUTH ATLANTIC LLC, Defendants.	:	Civil Action No. 14-1381-RGA

ORDER ADOPTING REPORT AND RECOMMENDATION

The United States Magistrate Judge made a Report and Recommendation dated September 23, 2015. (D.I. 51). Plaintiffs filed objections (D.I. 56), to which Defendants responded. (D.I. 63). My review of these objections is *de novo*. FED. R. CIV. P. 72(b)(3).

The Magistrate Judge recommended that Defendants' Motion to Dismiss Counts I, III and IV of Plaintiffs' Complaint (D.I. 11) be granted. (D.I. 51 at 19). Specifically, the Magistrate Judge concluded that U.S. Patent No. 8,808,737 (the "'737 patent") was facially invalid under 35 U.S.C. § 101, because it is directed to patent-ineligible subject matter. (*Id.* at 1). Because this conclusion would invalidate the patent, the Magistrate Judge did not address Defendants' additional argument that Plaintiffs alleged insufficient facts to support a claim for induced infringement under 35 U.S.C. § 271(b). (*Id.* at 18).

Plaintiffs first argue that the Magistrate Judge erred in finding that the claimed method was directed to a law of nature, because it "is instead directed to a new and useful process (the altered treatment regimen) that provides a practical, tangible benefit (relief of pain) in a

particular patient population." (D.I. 56 at 6). Second, Plaintiffs argue that the Magistrate Judge's reliance on the similarities between the '737 patent's representative claim and the claim involved in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012), was in error because the claim at issue in *Mayo* did not require that anyone act upon or apply the method in a tangible way, while claim 1 of the '737 patent actually requires that the lower dose be administered. (*Id.* at 7–8). Third, Plaintiffs contend that the Magistrate Judge failed to apply the Federal Circuit's decision in *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057 (Fed. Cir. 2011), which "distinguished between a pharmaceutical patent claim that is merely directed to a natural law itself, and a claim (like the method-of-treatment claims at issue here) that applies that natural law in a new and useful away." (*Id.* at 9). Fourth, relying on the District of Maryland's decision in *Classen*—upon remand after the Supreme Court decided *Mayo*—Plaintiffs criticize the Magistrate Judge's statement that "nor is the relationship between renal impairment and this drug unknown." (D.I. 51 at 16–17). Specifically, Plaintiffs contend that this relationship was not previously known, by reiterating that the patentee's discovery was that "the bioavailability of controlled released oxymorphone is affected by renal function or that renally impaired patients could or should be treated safely and effectively by administering to them a reduced [] dosage of controlled release oxymorphone." (D.I. 56 at 11). Lastly, Plaintiffs make a policy argument, seizing upon dicta from *Mayo*, that the reasoning employed by the Magistrate Judge's Report and Recommendation would in effect invalidate all pharmaceutical method-of-treatment patents using an existing, well-known compound. (*Id.* at 13).

Defendants respond by arguing that the specification of the '737 patent, and Plaintiffs' briefing, essentially admit that the claims are directed to a natural law, namely that "the bioavailability of oxymorphone is increased in patients with renal impairment." (D.I. 63 at 6).

Defendants provide a side-by-side comparison of the claim limitations at issue in *Mayo* and those of Claim 1 of the '737 patent, arguing that the Supreme Court's *Mayo* analysis—and the Magistrate Judge's reliance upon it—is directly on point. (*Id.* at 7–8). Defendants also point out that the Federal Circuit's *Classen* decision predated *Mayo*. (*Id.* at 9). They argue that the principle from *Classen* upon which Plaintiffs rely was effectively overruled by the Supreme Court in *Mayo*, as it rejected the argument that the mere "inclusion of an application step" rendered otherwise non-patentable subject matter patentable. (*Id.*). Lastly, in rebutting Plaintiffs' policy argument, Defendants argue that the Magistrate Judge's Report and Recommendation "stands only for the unremarkable proposition that one cannot observe the way the body metabolizes an old drug used for an old purpose, and seek to patent the use of that knowledge." (*Id.* at 11).

The Magistrate Judge applied the two-step framework set forth by the Supreme Court in *Mayo* and *Alice Corp. Pty. Ltd. v. CLS Bank Intern.*, 134 S. Ct. 2347 (2014). (D.I. 51 at 9–10). This framework requires the Court 1) to determine whether the claims are directed to a patent-ineligible concept—such as a law of nature, natural phenomenon, or abstract idea—and, if they are, 2) to determine whether there is an "inventive concept . . . sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the ineligible concept itself." *Alice*, 134 S. Ct. at 2355 (internal quotation marks and alterations omitted). In applying this framework, the bulk of the Magistrate Judge's Report and Recommendation emphasized the factual similarity between representative Claim 1 of the '737 patent and the representative claim at issue in the Supreme Court's *Mayo* decision. (D.I. 51 at 10–16). Because the claim limitations at issue in *Mayo* do in fact mirror the analogous limitations of Claim 1 of the '737 patent, I think it was correct for the Magistrate Judge to do so.

In order to highlight why the *Mayo* comparison is apt, below is a summary of the Supreme Court's reasoning in *Mayo*:

> Beyond picking out the relevant audience, namely those who administer doses of thiopurine drugs, the claim simply tells doctors to: (1) measure (somehow) the current level of the relevant metabolite, (2) use particular (unpatentable) laws of nature (which the claim sets forth) to calculate the current toxicity/inefficacy limits, and (3) reconsider the drug dosage in light of the law. These instructions add nothing specific to the laws of nature other than what is well-understood, routine, conventional activity, previously engaged in by those in the field. And since they are steps that must be taken in order to apply the laws in question, the effect is simply to tell doctors to apply the law somehow when treating their patients.

Mayo, 132 S. Ct. at 1299–1300. Here, the '737 patent similarly tells doctors to take an existing pharmaceutical compound for treating pain and 1) measure the creatinine clearance rate of the patient using an existing method, 2) use an unpatentable law of nature to assess the bioavailability of oxymorphone in light of the patient's creatinine clearance rate, 3) reconsider drug dosage in light of the law, and 4) administer that dosage.[1] (D.I. 1-1 at 42). Much like in *Mayo*, the claims of the '737 patent essentially state the discovery of a natural law and "simply [] tell doctors to apply the law somehow when treating their patients." *Mayo*, 132 S. Ct. at 1300. Accordingly, I agree with the Magistrate Judge's more thorough analysis of this issue. Nevertheless, I will briefly address Plaintiffs' objections.

Plaintiffs' argument that the '737 patent does not claim a law of a nature, but instead "a new and useful process," is thoroughly unconvincing. As the Magistrate Judge points out, Plaintiffs essentially admitted in their briefing that the '737 patent claims a natural law as its invention. (D.I. 18 at 20 ("[I]t is true that the claimed inventions relate to the unexpected discovery that the bioavailability of oxymorphone is increased in patients with renal impairment . . . .")). The abstract of the '737 patent describes a method of treating pain by giving a patient an

[1] I address further below Plaintiffs' argument that this administering step is the inventive leap that differentiates the '737 patent from the claim in *Mayo*.

oxymorphone dosage form—which the specification refers to as a method "widely used in the treatment of acute and chronic pain"—and merely adds "informing the patient or prescribing physician that the bioavailability of oxymorphone is increased in patients with renal impairment." (D.I. 1-1 at 2, 19). After reviewing the '737 patent and the parties' arguments, I agree with the Magistrate Judge's conclusion that the subject matter of the invention is "the connection between the severity of renal impairment and the bioavailability of oxymorphone,"or, in other words, the reaction of the human body of a renally impaired individual to oxymorphone, which is unquestionably a natural law. (D.I. 51 at 13).

Second, I am not convinced that the distinction Plaintiffs raise between the claim language in *Mayo* and the '737 patent renders the Magistrate Judge's comparison between the two inapt. Below is a side-by-side comparison of the language Plaintiffs highlight:

"indicates a need to [increase/decrease] the amount of said drug subsequently administered to said subject" *Mayo*, 132 S. Ct. at 1295.	"orally administering to said patient, in dependence on which creatinine clearance rate is found, a lower dosage of the dosage form to provide pain relief" (D.I. 1-1 at 42).

The slight difference in phrasing is immaterial, because neither formulation provides any sort of "inventive concept" to suggest that more than just the natural law is being claimed. *See Alice*, 134 S. Ct. at 2355.[2] As the Supreme Court expressly stated in *Mayo*, "to transform an unpatentable law of nature into a patent-eligible *application* of such law, one must do more than simply state the law of nature while adding the words 'apply it.'" *Mayo*, 132 S. Ct. at 1294 (emphasis in original) (citation omitted). Accordingly, Plaintiffs' objections to the Magistrate Judge's *Mayo* comparison are without merit.

[2] In any event, the claim language in *Mayo* undoubtedly contemplates that the stated method is ultimately applied when it refers to "the amount of said drug subsequently administered to said subject." *Mayo*, 132 S. Ct. at 1295, 1299–1300 ("And since they are steps that must be taken in order to apply the laws in question, *the effect is simply to tell doctors to apply the law* somehow when treating their patients." (emphasis added)).

Third, in light of the Supreme Court's 2012 admonition in *Mayo* that a claim must do more than simply state the law of nature while adding the words "apply it," it is difficult to conceive how *Classen*, a 2011 Federal Circuit case, still holds any precedential value, at least with regard to the proposition for which Plaintiffs offer it. Plaintiffs' reliance on *Classen* amounts to an assertion that a mandatory application step is sufficiently transformative to save claims that are otherwise unpatentable under § 101. (D.I. 56 at 9–10). The Supreme Court clearly stated in *Mayo* that this is not the case.[3] Accordingly, I have little trouble rejecting Plaintiffs' arguments based on *Classen*.

Fourth, Plaintiffs' *Classen*-related objections make much of arguing that there is no factual basis in the specification for the Magistrate Judge's statement that: "nor is the relationship between renal impairment and this drug unknown." (D.I. 56 at 11 (quoting D.I. 51 at 16–17)). Because this statement is not essential to the decision, I decline to further address it.[4]

Lastly, I disagree with Plaintiffs' policy argument that the Magistrate Judge's reasoning is so far-reaching that it would invalidate all pharmaceutical method-of-treatment patents that employ an existing pharmaceutical compound. Patentees can still avoid invalidation under § 101 by demonstrating an inventive leap beyond merely claiming a law of nature. Plaintiffs here claimed a widely-used, well-known method of treating pain. The only new aspect of the '737 patent was to tell doctors to adjust the dosage of oxymorphone based upon their discovery of a natural law—namely, how the bodies of individuals with renal deficiencies process the drug. No

[3] In fact, it is difficult to square Plaintiffs' argument with any of the Supreme Court's § 101 jurisprudence since *Classen* was decided in 2011.

[4] In attempting to argue this point, however, Plaintiffs contend that the specification does not in fact disclose that it was previously "known that the bioavailability of controlled release oxymorphone is affected by renal function . . . ." (D.I. 56 at 11). Plaintiffs' emphasis on the fact that this relationship between renal function and the effectiveness of oxymorphone was a new discovery, however, only adds support to the Court's understanding that Plaintiffs merely discovered a natural law (the way the human body reacts to a specific drug) and sought to patent the application of that natural law.

creative steps or inventive leaps aside from the discovery of a natural law are contemplated here. The patent merely tells doctors to apply the natural law. Accordingly, this case is hardly the poster child for a policy argument on the wide-ranging implications of a § 101 rejection of a pharmaceutical method patent.

Thus, Plaintiffs' objections are **OVERRULED** and the Report and Recommendation (D.I. 51) is **ADOPTED**. Accordingly, Defendant's Motion to Dismiss Counts I, III and IV of Plaintiffs' Complaint (D.I. 11) is **GRANTED**.

It is SO ORDERED this 17 day of November, 2015.

Richard G. Andrews
United States District Judge