IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

ENDO PHARMACEUTICALS INC. and MALLINCKRODT LLC,	)	
Plaintiffs,	)	
v.	)	C. A. No. 14-1381-RGA
ACTAVIS INC. and ACTAVIS SOUTH ATLANTIC LLC,	)	
Defendants.	)	

REPORT AND RECOMMENDATION

Presently before the court is Actavis Inc. and Actavis South Atlantic LLC's (collectively, "defendants") motion to dismiss Counts I, III, and IV of plaintiffs' complaint pursuant to FED. R. CIV. P. 12(b)(6).[1] Defendants argue that Endo Pharmaceuticals Inc. ("Endo") and Mallinckrodt LLC's ("Mallinckrodt") (collectively, "plaintiffs") U.S. Patent No. 8,808,737 (the "'737 patent") is facially invalid under 35 U.S. C. §101 because it is directed to patent-ineligible subject matter. For the reasons that follow, the court recommends that defendants' motion be granted.

I. INTRODUCTION

In their complaint,[2] plaintiffs allege defendants infringed the '737 patent and U.S. Patent No. 8,871,779 directly, by contributory infringement and inducing others to infringe, and seek relief including a permanent injunction.

II. JURISDICTION AND VENUE

Pursuant to 28 U.S.C. §1338(a), this court has original jurisdiction as this matter

[1] D.I. 11.
[2] D.I. 1.

relates to patents. No issue regarding proper venue under 28 U.S.C. §1391(d) and §1400(b) is raised.

III. BACKGROUND

A. Parties

Endo is a corporation existing under the laws of Delaware with its principal place of business in Pennsylvania.[3] Mallinckrodt is a Delaware limited liability company with its principal place of business in Missouri.[4] Actavis Inc. is a corporation existing under the laws of Nevada with its principal place of business in New Jersey.[5] Actavis South Atlantic LLC is a Delaware limited liability company with its principal place of business in Florida.[6]

B. Patent-in-Suit

Defendants' motion to dismiss concerns only one of the patents at issue, the '737 Patent.[7] The '737 Patent, entitled "Method of Treating Pain Utilizing Controlled Release Oymorphone Pharmaceutical Compositions and Instruction on Dosing for Renal Impairment," issued on August 19, 2014, and was subsequently assigned to Endo.[8] The '737 Patent's abstract describes the method as follows:

> The invention pertains to a method of using oxymorphone in the treatment of pain by providing a patient with an oxymorphone dosage form and informing the patient or prescribing physician that the bioavailability of

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[3] *Id.* at ¶ 1.
[4] *Id.* at ¶ 2.
[5] *Id.* at ¶ 3.
[6] *Id.* at ¶ 4.
[7] D.I. 12 at 1.
[8] D.I. 1 at ¶ 19.

oxymorphone is increased in patients with renal impairment.[9]

In the "Detailed Description of the Invention" section, the patent describes that the invention "provides methods using oxymorphone in the treatment of pain . . . [, which] may involve steps of providing a patient with a therapeutically effective amount of oxymorphone and informing the patient or the patient's prescribing physician that the bioavailability of oxymorphone is increased in patients with renal impairment."[10]

There are six claims in the '737 Patent.[11] Claim 1, which the parties acknowledge is representative of the other claims, reads as follows:

> 1. A method of treating pain in a renally impaired patient, comprising the steps of:
> a. providing a solid oral controlled release dosage form, comprising:
> i. about 5 mg to about 80 mg of oxymorphone or a pharmaceutically acceptable salt thereof as the sole active ingredient; and
> ii. a controlled release matrix;
> b. measuring a creatinine clearance rate of the patient and determining it to be (a) less than about 30 m[L]/min, (b) about 30 mL/min to about 50 mL/min, (c) about 51 mL/min to about 80 mL/min, or (d) above about 80 mL/min; and
> c. 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;
> wherein after said administration to said patient, the average AUC of oxymorphone over a 12-hour period is less than about 21 ng•hr/mL.[12]

According to the complaint, defendants infringe the '737 Patent by commercially manufacturing, offering for sale, or selling its Generic Oxymorphone ER Tablets and by submitting their ANDA No. 20-3930 to the Food and Drug Administration.[13]

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[9] *Id.*, Ex. A at Abstract.
[10] *Id.*, Ex. A at col. 3:33-39.
[11] *Id.*, Ex. A at 2.
[12] *Id.*, Ex. A at col. 48:7-26.
[13] *Id.* at ¶¶ 36-37, 41-52.

IV. LEGAL STANDARDS

A. Motion to Dismiss

FED. R. CIV. P. 12(b)(6) governs a motion to dismiss a complaint for failure to state a claim upon which relief can be granted. The purpose of a motion under Rule 12(b)(6) is to test the sufficiency of the complaint, not to resolve disputed facts or decide the merits of the case.[14] "The issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims."[15] A motion to dismiss may be granted only if, after "accepting all well-pleaded allegations in the complaint as true, and viewing them in the light most favorable to plaintiff, plaintiff is not entitled to relief."[16] While the court draws all reasonable factual inferences in the light most favorable to a plaintiff, it rejects unsupported allegations, "bald assertions," and "legal conclusions."[17]

To survive a motion to dismiss, a plaintiff's factual allegations must be sufficient

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[14] *Kost v. Kozakiewicz*, 1 F.3d 176, 183 (3d Cir. 1993).

[15] *Swierkiewicz v. Sorema N. A.*, 534 U.S. 506, 511 (2002) (citations omitted); *see also Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 563 n.8 (2007) ("[W]hen a complaint adequately states a claim, it may not be dismissed based on a district court's assessment that the plaintiff will fail to find evidentiary support for his allegations or prove his claim to the satisfaction of the factfinder.").

[16] *Maio v. Aetna, Inc.*, 221 F.3d 472, 481-82 (3d Cir. 2000) (citing *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1420 (3d Cir. 1997)).

[17] *Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519, 526 (1983) ("It is not . . . proper to assume [plaintiff] can prove facts that it has not alleged or that the defendants have violated the . . . laws in ways that have not been alleged.")*; Morrow v. Balaski*, 719 F.3d 160, 165 (3d Cir. 2013) (quoting *Baraka v. McGreevey*, 481 F.3d 187, 195 (3d Cir. 2007) (citations omitted) (rejecting "unsupported conclusions and unwarranted inferences, or a legal conclusion couched as a factual allegation")).

to "raise a right to relief above the speculative level . . . ."[18] Plaintiffs are therefore required to provide the grounds of their entitlement to relief beyond mere labels and conclusions.[19] Although heightened fact pleading is not required, "enough facts to state a claim to relief that is plausible on its face" must be alleged.[20]

A claim has facial plausibility when a plaintiff pleads factual content sufficient for the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.[21] The plausibility standard does not rise to a "probability requirement" but requires "more than a sheer possibility that a defendant has acted unlawfully."[22] Once stated adequately, a claim may be supported by showing any set of facts consistent with the allegations in the complaint.[23] Courts generally consider only the allegations contained in the complaint, the exhibits attached, and matters of public record when reviewing a motion to dismiss.[24]

B. Indirect Infringement

As a precursor to stating a claim for indirect infringement, inducement, or contributory infringement, a plaintiff must "plead[] facts sufficient to allow an inference

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[18] *Twombly*, 550 U.S. at 555 (citations omitted); *see also Victaulic Co. v. Tieman*, 499 F.3d 227, 234 (3d Cir. 2007) (citation omitted).

[19] *Twombly*, 550 U.S. at 555 (citing *Papasan v. Allain*, 478 U.S. 265, 286 (1986)).

[20] *Twombly*, 550 U.S. at 570; *see also Phillips v. Cty. of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008) ("In its general discussion, the Supreme Court explained that the concept of a 'showing' requires only notice of a claim and its grounds, and distinguished such a showing from 'a pleader's bare averment that he wants relief and is entitled to it.'") (quoting *Twombly*, 550 U.S. at 555 n.3).

[21] *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 556).

[22] *Id.*

[23] *Twombly*, 550 U.S. at 563 (citations omitted).

[24] *See, e.g.*, *Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993) (citations omitted).

that at least one direct infringer exist[]."[25] A plaintiff "need not identify a *specific* direct infringer."[26] Once there are facts sufficient to allow an inference of direct infringement, the court will then look at the individual requirements necessary to plead inducement and contributory infringement.

1. Inducement

35 U.S.C. §271(b) states that: "[w]hoever actively induces infringement of a patent shall be liable as an infringer." To establish induced infringement, a patentee must prove "that the alleged infringer 'knowingly induced infringement and possessed specific intent to encourage another's infringement.'"[27] A plaintiff must aver the alleged infringer had "knowledge that the induced acts constitute patent infringement."[28] This element inherently requires the alleged infringer have knowledge of the patent, and "knew or should have known [its] actions would induce actual infringement."[29] For inducement, a plaintiff must assert "culpable conduct, directed to encourage another's infringement, not merely that the inducer had knowledge of the direct infringer's activities."[30] The culpable conduct may be plead circumstantially.[31]

Further, a court must apply *Twombly* and *Iqbal* in determining whether the

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[25] *In re Bill of Lading Transmission & Processing Sys. Patent Litig.*, 681 F.3d 1323, 1336 (Fed. Cir. 2012).

[26] *Id.* (emphasis in original).

[27] *Ericsson, Inc. v. D-Link Sys. Inc.*, 773 F.3d 1201, 1219 (Fed. Cir. 2014) (quoting *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006)).

[28] *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, (2011).

[29] *DSU Med.*, 471 F.3d at 1306 (citing *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 553 (Fed. Cir. 1990)).

[30] *Id*. 471 F.3d at 1306.

[31] *Id.* (quoting *Water Techs. Corp. v. Calco, Ltd.*, 850 F.2d 660, 668 (Fed. Cir. 1988)).

requisite knowledge and specific intent have been properly pled.[32] The "complaint must contain facts 'plausibly showing that [the alleged indirect infringer] specifically intended [the direct infringer] to infringe [the patent] and knew that the [direct infringer's] acts constituted infringement.'"[33]

2. Infringement of Method Patents

A method patent claims a number of steps . . . the patent is not infringed unless all the steps are carried out."[34] "This principle follows ineluctably from what a patent is: the conferral of rights in a particular claimed set of elements."[35] Under *Muniauction, Inc. v. Thomson Corp.*, all steps of a method patent are not carried out as claimed by the patent unless all are attributable to the same defendant, either because the defendant actually performed those steps or he directed or controlled others who performed them.[36] This principle remains the applicable law: in 2014, the United States Supreme Court "[a]ssumed without deciding that the Federal Circuit's holding in *Muniauction* is correct . . . ."[37] Thus, to survive a motion to dismiss the claim of joint infringement, a plaintiff must plead facts sufficient to allow a reasonable inference that various parties perform all of the claimed steps; and one party exercised the requisite "direction or control," such that performance of every step is attributable to the controlling party.[38]

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[32] *In re Bill of Lading*, 681 F.3d at 1336-37 (internal citations and footnotes omitted).

[33] *Pragmatus AV, LLC v. Yahoo! Inc.*, 2012 WL 6044793, at *14 (D. Del. Nov. 13, 2012), *report and recommendation adopted sub nom. Pragmatus AV, LLC v. Yahoo! Inc.*, 2013 WL 2295344 (D. Del. May 24, 2013) (citing *In re Bill of Lading*, 681 F.3d at 1339)).

[34] *Limelight Networks, Inc. v. Akamai Technologies, Inc.*, 134 S. Ct. 2111, 2117 (2014).

[35] *Id.*

[36] 532 F.3d 1318, 1329 (Fed. Cir. 2008).

[37] *Akamai*, 134 S. Ct. at 2117.

[38] *Pragmatus*, 2012 WL 6044793, at *4 (D. Del. Nov. 13, 2012).

C. Patentability Under 35 U.S.C. §101

Under Section 101 of the Patent Act, patentability is a question of law and a "threshold inquiry."[39] This question, however, "may be informed by subsidiary factual issues."[40] The United States Court of Appeals for the Federal Circuit has recently suggested that "any attack on an issued patent based on a challenge to the eligibility of the subject matter must be proven by clear and convincing evidence."[41]

V. ANALYSIS

Defendants move to dismiss the complaint on the basis that Counts I, III, and IV fail to state a claim upon which relief can be granted under FED. R. CIV. P. 12(b)(6) and the '737 Patent is directed to patent ineligible subject matter under §101. Defendants maintain dismissal is justified because plaintiffs failed to plead sufficient facts to show defendants induced infringement and the claims are directed to the application of a natural law.[42]

A. Patentable Subject Matter

Section 101 defines patentable subject matter as: "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."[43] Section 101 specifies four categories of

[39] *In re Bilski*, 545 F.3d 943, 950-51 (Fed. Cir. 2008), *aff'd*, *Bilski v. Kappos*, 561 U.S. 593 (2010).

[40] *CyberFone Sys., LLC v. Cellco P'ship*, 885 F. Supp. 2d 710, 715 (D. Del. 2012) (citing *In re Comiskey*, 554 F.3d 967, 975 (Fed. Cir. 2009)).

[41] *CLS Bank Int'l v. Alice Corp. Pty. Ltd.*, 717 F.3d 1269, 1304-05 (Fed. Cir. 2013) (Rader, J., concurring-in-part and dissenting-in-part).

[42] D.I. 12 at 1, 6-12.

[43] 35 U.S.C. §101.

inventions eligible for patent protection: processes, machines, manufacturing, and compositions of matter.[44]

The Supreme Court has long held that this section contains an important implicit exception for laws of nature, natural phenomena, and abstract ideas.[45] This exception encompasses the "basic tools of scientific and technological work" and recognizes that authorizing "monopolization of those tools through the grant of a patent might tend to impede innovation more than it would tend to promote it."[46] The Court, however, has been cautious of interpreting this exclusionary principle broadly because to an extent, every invention utilizes, represents, or indicates natural laws or phenomena or abstract ideas, and a broad reading could emasculate the statute.[47] Even though a natural law, phenomenon or abstract idea cannot be patented, the Court recognized that "an application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection."[48] Therefore, an invention is not patentable merely because it involves an ineligible concept.[49]

Courts apply the two-part test established in *Mayo* to evaluate patent eligibility.[50] First, a court must determine if a relevant claim is "directed to one of those patent-

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[44] *Id.*

[45] *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2354 (2014) (citations omitted); *see also Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1293 (2012) (citations omitted).

[46] *Mayo*, 132 S. Ct. at 1293 (citing *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)).

[47] *Id.* at 1293-94; *see also Alice*, 134 S. Ct. at 2354.

[48] *Mayo*, 132 S. Ct. at 1293-94; *Netgear, Inc. v. Ruckus Wireless, Inc.*, 5 F. Supp. 3d 592, 606-07 (D. Del. 2013) (citations omitted).

[49] *Diamond v. Diehr*, 450 U.S. 175 ,187 (1981) (quoting *Parker v. Flook*, 437 U.S. 584, 590 (1978)); *see also Mayo*, 132 S. Ct. at 1293-94.

[50] *Cal. Inst. of Tech. v. Hughes Commc'ns Inc.*, 2014 WL 5661290, at *3 (C.D. Cal. Nov. 3, 2014).

ineligible concepts," *i.e.*, a law of nature, natural phenomenon, or an abstract idea.[51] If so, then the court must ask, "what else is there in the claims before us?"[52] The second step establishes whether an "inventive concept" exists–"an element or combination of elements that is sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [patent-ineligible concept] itself."[53]

Mayo concerned a method for ascertaining the correct dosage of certain autoimmune disease drugs based on how differently they metabolize in individuals.[54] The facts in *Mayo* are highly analogous to the facts in the instant matter. In *Mayo*, the Court observed that the patent was directed to a natural law, "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."[55] The *Mayo* court analyzed each step in Claim 1 of the patent at issue: the administering step, the determining step, and the wherein clause, and concluded that the administering step merely set forth the relevant audience, as "doctors who treat patients with certain diseases with thiopurine drugs," and simply limiting a law of nature to a particular audience or technological environment did not confer patentability.[56] The determining step only advised doctors to discern the concentration of the specific metabolites in a patient's blood by using well-known methods;[57] and the wherein clause merely informed

[51] *Alice*, 134 S. Ct. at 2355 (citing *Mayo*, 132 S. Ct. at 1296-97)).
[52] *Id.*
[53] *Alice*, 134 S. Ct. at 2355 (citation omitted).
[54] *Mayo*, 132 S. Ct. at 1294.
[55] *Id.* at 1296.
[56] *Id.* at 1297.
[57] *Id.* at 1297-98.

physicians of the relevant law of nature and to treat patients accordingly.[58] The *Mayo* court found the claims were directed toward a law of nature because they described "the relationships between the concentration in the blood of certain thiopurine metabolites and the likelihood that the drug dosage will be ineffective or induce harmful side-effects," and because the claimed processes did not convert "unpatentable natural laws into patent-eligible applications of those laws."[59] The court further determined that "the steps in the claimed processes (apart from the natural laws themselves) involve well-understood, routine, conventional activity previously engaged in by researchers in the field."[60]

Recently the Supreme Court in *Alice* reaffirmed the two-step analysis of *Mayo* and further explained that "step two of this analysis [is] a search for an 'inventive concept'–i.e., an element or combination of elements that is 'sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.'"[61] The *Alice* court also clarified "that the steps in the claimed processes (apart from the natural laws themselves) must involve more than well-understood, routine, conventional activities previously known in the industry."[62] The court further noted that a natural law cannot become a patentable application of that natural law simply by inserting the phrase "apply it."[63]

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[58] *Id.* at 1297.
[59] *Id.* at 1294.
[60] *Id.*
[61] *Alice*, 134 S. Ct. at 2355 (citations omitted).
[62] *Genetic Techs. v. Lab. Corp. of Am. Holdings*, 2014 WL 4379587, at *5 (D. Del. Sept. 3, 2014) (citing *Alice*, 134 S. Ct. at 2359).
[63] *Alice*, 134 S. Ct. at 2358; *Mayo*, 132 S. Ct. at 1294.

The Federal Circuit recently addressed §101, in *OIP Technologies, Inc. v. Amazon.com, Inc.*[64] The court affirmed the lower court's holding that the patent covered an abstract idea, price optimization, and lacked an inventive concept sufficient to "transform" it into a patentable application of that abstract idea. In his concurring opinion, Judge Mayer commented on how the district court resolved the patent eligibility issue solely on the pleadings.

> Addressing [Section] 101 at the outset not only conserves scarce judicial resources and spares litigants the staggering costs associated with discovery and protracted claim construction litigation, it also works to stem the tide of vexatious suits brought by the owners of vague and overbroad business method patents. Accordingly, where, as here, asserted claims are plainly directed to a patent ineligible abstract idea, we have repeatedly sanctioned a district court's decision to dispose of them on the pleadings.[65]

1. Whether Claim 1 is Directed to a Natural Law

Resolution of defendants' motion depends on whether representative Claim 1 of the '737 Patent is directed to patent-ineligible subject matter under §101 or is a patent-eligible application of a law of nature.

The *Alice* court reiterated the framework set forth in *Mayo*.[66] Step one of the analysis is to determine whether the claims at issue are "directed to [a] patent-ineligible concept"–here, a natural law.[67] The *Mayo* court provided a broad definition for a law of nature: "[a] patent that . . . describes a relationship that is the consequence of entirely

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[64] 788 F.3d 1359 (Fed. Cir. 2015).
[65] *Id.* at 1364-65 (citations omitted).
[66] *Alice*, 134 S. Ct. at 2355.
[67] *Id.*

natural processes sets forth a natural law."[68]

Here, defendants repeatedly point out that the '737 Patent attempts to cover the natural law that the "bioavailability of oxymorphone is increased in people with impaired kidney function."[69] Indeed, plaintiffs effectively concede the first step of the *Mayo* analysis.[70] They suggest though, that the invention is not related to the natural law, but is a "novel and useful application of that discovery–i.e., to the treatment of renally impaired patients by administering a lower dose of oxymorphone based upon the severity of the renal impairment."[71] The '737 Patent, however, explains that oxymorphone is "widely used" for acute and chronic pain relief, thus showing that the utilization of oxymorphone is not the invention.[72] Therefore, the connection between the severity of renal impairment and the bioavailability of oxymorphone, which the '737 Patent sets forth in detail, is the subject matter of the invention.[73]

2. Whether Claim 1 is Directed to a Patent-Eligible Application of a Natural Law

Because the representative claim of the '737 Patent is directed to a law of nature, the main inquiry is whether it "add[s] *enough* to [its] statement[] of the correlation[] to allow the process to qualify as" a patentable method that *applies* the law of nature.[74]

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[68] *Genetic Techs.*, 2014 WL 4379587, at *10 (quoting *Mayo*, 132 S. Ct. at 1297) (citations omitted).

[69] D.I. 12 at 3.

[70] D.I. 18 at 14 ("it is true that the claimed inventions relate to the unexpected discovery that the bioavailability of oxymorphone is increased in patients with renal impairment").

[71] *Id.*

[72] D.I. 1, Ex. A at 1:19-22.

[73] *Id*., Ex. A.

[74] *Mayo*, 132 S. Ct. at 1297 (emphasis in original).

Courts analyzing this question initially examine each individual step of the claim, and then the claim as a whole.[75]

Here, Claim 1 is directed to a method of administering the correct dosage of oxymorphone for the treatment of pain in patients with impaired kidney function based on a relationship allegedly discovered by the '737 Patent.[76] The claimed method consists of three steps: (1) a "providing" step; (2) a "measuring/determining" step; (3) and an "administering" step.[77]

The providing step is insufficient to make the claim patentable because it simply informs patients and prescribing physicians of the relevant drug to be administered. This step is similar to the "administering" step in *Mayo* because it merely identifies the specific drug for administration. No inventive concept is recited because the '737 Patent specification admits that extended-release oxymorphone has been available on the market,[78] and that oxymorphone is "widely used in the treatment of acute and chronic pain."[79]

The measuring/determining step suffers from similar deficiencies. It only instructs the physician to measure the patient's creatinine level to determine the level of renal impairment using a previously recognized method, the Cockroft and Gault

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[75] *Id.* at 1297-98; *PerkinElmer, Inc. v. Intema Ltd.*, 496 Fed. Appx. 65, 71; *see also Smartgene, Inc. v. Advanced Biological Labs., SA*, 852 F. Supp. 2d 42, 56 (D.D.C. 2012) ("The Court views Claim 1 as a whole but still finds it useful to examine the claim in steps for the purposes of its [Section 101] analysis of the claim as a whole.").

[76] D.I. 1, Ex. A.

[77] Id., Ex. A at col. 48:7-26.

[78] *Id.*, Ex. A at col. 3:40-49.

[79] *Id.*, Ex. A at col. 1:19-22.

equation.[80] As in *Mayo*, this step just directs one to use a well-known method to measure creatinine levels to obtain the necessary information to apply a law of nature.

The administering step simply limits the relevant audience to patients and prescribing physicians, who treat chronic or acute pain with oxymorphone, and instructs the administration of the correct dosage of oxymorphone depending on the severity of the renal impairment, a step very similar to *Mayo*, which limited the relevant audience to "doctors who treat patients with certain diseases with thiopurine drugs."[81]

Lastly, analyzing Claim 1 as a whole, the steps in combination do not transform the natural law into a patentable application of that law. Plaintiffs argue that Claim 1 as a whole, particularly the administering step, is directed to a "new and useful application of [the natural law] which provides actual therapeutic benefits to a specified patient population" and is "not directed to the [] natural law itself."[82] A claim must be directed to an application that is "significantly more than a patent upon the natural law itself" and not merely a recitation of an application.[83]

Plaintiffs rely on the *Classen* series of cases.[84] *Classen Immunotherapies, Inc. v. Biogen IDEC* ("*Classen I*"),[85] involved three method patent claims relating to a connection between an infant immunization schedule and the occurrence of chronic

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[80] *Id*., Ex. A at col. 29:4-15.

[81] *Mayo*, 132 S. Ct. at 1297.

[82] D.I. 18 at 19.

[83] *Mayo*, 132 S. Ct. at 1294 (citations omitted); *see also Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, at *9 (N.D. Cal. Oct. 30, 2013) (holding that an application of a "newly discovered [natural law] will not render a claim patentable if the use of that . . . law of nature . . . is the only innovation contained in the patent").

[84] D.I. 18 at 15-18.

[85] 659 F.3d 1057 (Fed. Cir. 2011).

immune-mediated disorders.[86] The court held two of the three patents were patent eligible, distinguishing the claims of the third patent as failing to transform the abstract idea that "variation in immunization schedules may have consequences" into a patentable application.[87]

Plaintiffs also suggest *Classen Immunotherapies, Inc. v. Biogen IDEC* ("*Classen II*")[88] is instructive.[89] The court readdressed the two patents upheld in *Classen I* following the Supreme Court's decision in *Mayo*.[90] The court distinguished *Mayo* on the ground that, unlike the administering steps in the patents at issue in *Classen*, the patent in *Mayo* stated the administering step to be a well-known, routine activity.[91] The court explained it could not conclude Classen's patent claims involved routine activity because there was "no information in the record" to support that conclusion.[92]

Plaintiffs only argue the administering step turns the natural law into a patentable application. The administering step merely instructs physicians to dispense oxymorphone for the treatment of pain in a well-know manner, while utilizing the natural law to manage the dosage. Unlike *Classen*, the '737 Patent recognizes the use of oxymorphone for pain relief is a well-understood activity."[93] The '737 Patent further acknowledges that kidney impairment is not rare, nor is the relationship between renal

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[86] *Id.* at 1059.
[87] *Id.* at 1066-69.
[88] 2012 WL 3264941 (D. Md. Aug. 9, 2012).
[89] D.I. 18 at 17-18.
[90] *Classen II*, 2012 WL 3264941, at *1.
[91] *Id.* at *4.
[92] *Id.*
[93] D.I. 1, Ex. A at col. 1:19-23.

impairment and this drug unknown.[94]

Moreover, a court should consider whether a claim potentially preempts a law of nature when assessing §101 eligibility.[95] The *Mayo* court expressed concern that inventions should "not inhibit further discovery by improperly tying up the future use of laws of nature."[96] The determining step in *Mayo*, was framed in "highly general language covering all processes that make use of the correlations after measuring metabolites, including later discovered processes that measure metabolites, including later discovered processes that measure metabolite levels in new ways,[97] and covered "too much future use of laws of nature," reinforcing its finding of unpatentability.[98]

Throughout the specification of the '737 Patent, there are numerous references, which preempt future inventions and discoveries in this field.[99] For instance, the '737 Patent provides that: "this invention includes *all modifications and equivalents of the subject matter* recited in the claims appended hereto as permitted by applicable law. Moreover, *any combination* of the above described elements in *all possible variations* thereof is encompassed by the invention . . . ."[100] A patent covering the application of a well-known natural law as broadly clearly restricts further advancement in this area of treatment.

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[94] *Id.*, Ex. A at col. 2:18-25 ("Chronic renal failure . . . can be caused by *any number of sources*[, and i]mpaired kidney function results in a potential build up of substances that are typically filtered out by the kidneys, such as . . . some drugs.") (emphasis added).

[95] *Mayo*, 132 S. Ct. at 1301-02.

[96] *Id.* at 1301.

[97] *Id.* at 1302.

[98] *Id.*

[99] D.I. 1, Ex. A at col. 1:19-22, 4:42-60, 47:10-18, 47:51-48:5.

[100] *Id.*, Ex. A at col. 47:19-25 (emphasis added).

Since all references to "individual numerical values" and "numerical values in the various ranges" are broadened by the terms "about or approximately," it is inevitable that a doctor may infringe by checking a patient's creatinine level to determine renal impairment (as it is known in the medical field that renal impairment affects the bioavailability of certain drugs) and lowering the dosage of oxymorphone in response to the lab test findings.

B. Infringement

Regarding their motion to dismiss on the adequacy of plaintiffs' infringement claims, defendants advance that plaintiffs allege insufficient facts of intent to induce and facts supporting the acts of inducement. Defendants further maintain their proposed label does not direct physicians to perform the steps of Claim 1 of the '737 Patent.[101] Plaintiffs respond that defendants current and proposed labels instruct physicians and patients to perform all recited steps of the claimed invention.[102]

In light of the previous determination regarding the infirmities of the patent, defendants' Rule 12(b)(6) arguments, whether the sufficient facts are alleged to support inducement, need not be addressed. Plaintiffs rely on the same or similar facts for induced infringement which demonstrate that the '737 Patent is directed to unpatentable subject matter. A patent found to be patent ineligible under §101 is invalid, and therefore, the court need not decide the adequacy of plaintiffs' claims of inducement.[103]

[101] D.I. 12 at 6-9.

[102] D.I. 18 at 9-10.

[103] *Mayo*, 132 S. Ct. at 1305 ("For these reasons, we conclude that the patent claims at issue here effectively claim the underlying laws of nature themselves. The claims are consequently invalid.").

IV. ORDER & RECOMMENDED DISPOSITION

For the foregoing reasons, it is recommended that defendants' motion to dismiss (D.I. 11) be GRANTED.

Pursuant to 28 U.S.C. § 636(b)(1)(A) and (B), FED. R. CIV. P. 72(b), and D. DEL. LR 72.1, any objections to the Report and Recommendation shall be filed within fourteen (14) days limited to ten (10) pages after being served with the same. Any response is limited to ten (10) pages.

The parties are directed to the Court's Standing Order for Objections Filed under FED. R. CIV. P. 72 dated October 9, 2013, a copy of which is available on the Court's website, located at http://www.ded.uscourts.gov.

Dated: September 23, 2015

/s/ Mary Pat Thynge
UNITED STATES MAGISTRATE JUDGE