IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PERNIX IRELAND PAIN DAC and PERNIX THERAPEUTICS, LLC, *Plaintiffs*, v. ALVOGEN MALTA OPERATIONS LTD., *Defendant*.	§ § § § § § § § § §	Civil Action No. 16-139-WCB

MEMORANDUM OPINION AND ORDER

Before the Court is Alvogen's Motion for Reargument of the Court's May 15, 2018 Summary Judgment Decision that the "PK-Only" Asserted Claims Are Not Invalid Under Section 101. Dkt. No. 226. The motion is DENIED.

A motion for reargument is granted "sparingly," D. Del. L.R. 7.1.5, and may be granted only "if the court has 'patently misunderstood a party, made a decision outside the adversarial issues presented by the parties, or made an error not of reasoning but of apprehension.'" Amgen Inc. v. Amneal Pharm. LLC, No. CV 16-853, 2018 WL 1885664, at *4 (D. Del. Apr. 19, 2018) (quoting Sussex Cty. Senior Serv., Inc. v. Carl J. Williams & Sons, Inc., No. Civ. A. 99-473, 2000 WL 1726527, at *1 (D. Del. Mar. 31, 2000)).

The nine claims at issue in this case can be divided into two groups. Claims 1–4 and 11 of U.S. Patent No. 9,265,760 ("the '760 patent") recite a method of treating pain in certain hepatically impaired subjects using an oral dosage of an extended release of hydrocodone bitartrate as the only active ingredient, wherein the starting dose is the same as it would be for a

non-hepatically impaired subject. Alvogen refers to those claims as the "non-adjustment" claims.[1]

Claims 12, 17, and 19 of the '760 patent and claim 1 of U.S. Patent No. 9,339,499 ("the '499 patent") recite a method of treating pain in certain hepatically impaired subjects using an oral dosage unit consisting of an extended release formulation of hydrocodone bitartrate as the only active ingredient, wherein the dosage unit provides a release profile of hydrocodone that is defined by designated pharmacokinetic factors, as compared to the release profiles in subjects not suffering from renal or hepatic impairment. Alvogen refers to those claims as the "PK-only" claims.

In its motion for reargument, Alvogen first contends that the Court "misapprehended the difference between the two types of claims and did not conduct a separate analysis for the PK-only claims." Dkt. No. 226, at 1. Contrary to Alvogen's contention, the Court was, and is, well aware of the difference between the two groups of claims. In fact, the Court described the difference between the two groups of claims with specificity in the course of its analysis of the parties' contentions in their briefs in support of their cross-motions for summary judgment under 35 U.S.C. § 101. See Dkt. No. 216, at 46.

Alvogen seizes upon a sentence in the Court's opinion immediately following the Court's description of the two types of claims, in which the Court stated that, like the claims in Vanda Pharmaceuticals, Inc. v. West-Ward Pharmaceuticals International, Ltd., 887 F.3d 1117 (Fed. Cir. 2018), "the claims asserted in this case describe a specific dosing regimen to treat a specific

[1] Claims 2 through 4 of the '760 patent add requirements as to the release profile of the hydrocodone in subjects suffering from mild or moderate hepatic impairment as compared to the release profile in subjects not suffering from renal or hepatic impairment. Claim 11 of the '760 patent adds separate specific numerical requirements for the pharmacokinetic factors in subjects not suffering from renal or hepatic impairment, in subjects suffering from mild hepatic impairment, and in subjects suffering from moderate hepatic impairment.

condition based on the patient's medical status." Dkt. No. 216, at 46. According to Alvogen, that sentence does not apply to the "PK-only" claims, thus indicating that the Court ignored those claims in its section 101 analysis.

Although the term "dosing regimen" typically refers to the amount and frequency of the dosage of a drug, the asserted claims do not contain "dosing regimens" in that conventional form. Instead, in the "non-adjustment" claims the dosing level for hepatically impaired subjects is designated as being the same as the dosing level used for normal subjects (and, in claims 2–4 and 11, a dosing level that produces certain pharmacokinetic results. And in the "PK-only" claims, the dosing level for hepatically impaired subjects is designated by the level that results in specific pharmacokinetic results, as compared to the results obtained in subjects not suffering from renal or hepatic impairment.[2]

The fact that certain of the claims do not recite specific dosage amounts and frequencies of administration is not fatal to the patent eligibility of the "PK-only" claims under 35 U.S.C. § 101. A claim to a method of treating an illness is typically more than an expression of a natural law; if it were otherwise, pharmaceutical patents would be hard to come by, as most methods of treatment using pharmaceuticals consist simply of the administration of a drug that affects the human body in a manner that is dictated by laws of nature.

[2] While the dosing regimens in the "PK-only" claims are set forth in an unconventional manner, that is not unusual, as dosing regimens can be measured and designated in many ways other than simply by reference to the amount and frequency of administration of a drug. For example, a direction to administer drug from a bronchial inhaler for short-term relief "until normal breathing is restored," but not for long-term relief, is a dosing regimen, as is a direction to reduce the dosage of a drug administered to a patient from a particular starting amount to the minimum amount necessary to achieve the desired efficacy.

Moreover, a straightforward analysis of the method of treatment claims at issue in this case demonstrates that they are not directed to ineligible subject matter. The point can be demonstrated as follows:

All of the "PK-only" claims asserted in this case begin by reciting a method for treating pain in subjects with mild or moderate hepatic impairment comprising administering an oral dosage of hydrocodone bitartrate as the only active ingredient, wherein the dosage unit comprises an extended release formulation of hydrocodone bitartrate. If the claims at issue ended there, they would plainly not be unpatentable for reciting ineligible subject matter under section 101. The claims might have other infirmities, such as failing to pass muster under sections 102, 103, or 112 of the Patent Act. But they would not be deemed to recited unpatentable subject matter under section 101 for being directed to a natural process. A fortiori, the addition of limitations describing the claimed formulations regarding their pharmacokinetic properties would not render the claims patent-ineligible: Adding limitations to a claim that satisfies section 101 does not convert the claim into one that is directed to unpatentable subject matter. Thus, the Court regards the limitations in the "PK-only" claims as not subjecting those claims to invalidation under section 101.

Aside from the complaint that the Court ignored the "PK-only" claims in its summary judgment opinion, Alvogen's motion for reargument consists of a reprise of arguments made in its original summary judgment briefs on the section 101 issue, although the arguments now focus on the "PK-only" claims. Primarily, Alvogen argues that the "PK-only" claims are more akin to the claims at issue in Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U.S. 66 (2012), than to those discussed in Vanda Pharmaceuticals, Inc. v. West-Ward Pharmaceuticals International Ltd., 887 F.3d 1117 (Fed. Cir. 2018). As explained in the Court's previous

memorandum opinion and order, the Court disagrees. The Federal Circuit in Vanda explained that the claims in Mayo were "directed to a diagnostic method based on the '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.'" 887 F.3d at 1134 (quoting Mayo, 566 U.S. at 77). Importantly, the patent in Mayo "simply describe[d] that relation," and was thus patent ineligible. Id. (quoting Mayo, 566 U.S. at 77). The claims in all of the claims asserted in this action, like the claims in Vanda, are "treatment steps"—that is, directed at a new and useful method of treating pain in a certain population of patients using a specific set of hydrocodone bitartrate formulations. Id. at 1135–36. For that reason, the Court views the claims as not directed to unpatentable subject matter by claiming patent protection for a natural law.

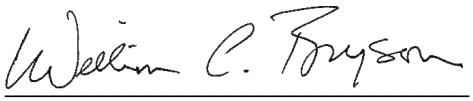
Alvogen argues that there should not be a per se rule that all method of treatment claims are patent eligible, and it points out that section 101 analysis "requires consideration of 'the claimed advance over the prior art.'" Dkt. No. 226, at 5 (quoting Enfish, LLC v. Microsoft Corp., 822 F.3d 1327, 1335 (Fed. Cir. 2016)). However, Alvogen does not argue for, and the Court does not adopt, a per se rule that all method of treatment claims satisfy section 101. But Alvogen would be wrong to read a strong novelty inquiry into section 101 analysis. As the Federal Circuit has explained, the section 101 inquiry evaluates "the focus of the claimed advance over the prior art to determine if the claim's character as a whole is directed to excluded subject matter." Intellectual Ventures I LLC v. Erie Indem. Co., 850 F.3d 1315, 1325 (Fed. Cir. 2017) (quoting Affinity Labs of Texas, LLC v. DIRECTV Dig. LLC, 838 F.3d 1253, 1257 (Fed. Cir. 2016)). In this case, as in Vanda, the invention is a "new way of using an existing drug," 887 F.3d at 1135 (quoting Mayo, 566 U.S. at 87), i.e., by treating a special subpopulation of

patients with a limited genus of formulations of a particular pharmaceutical. That is sufficient for section 101 purposes.

For the reasons stated above and in the Court's original memorandum opinion and order on the parties' cross-motions for summary judgment, the Court concludes that the asserted claims are patent eligible.

IT IS SO ORDERED.

SIGNED this 8th day of June, 2018.



WILLIAM C. BRYSON
UNITED STATES CIRCUIT JUDGE