IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC. and INTERMUNE, INC., Plaintiff, v. AUROBINDO PHARMA LIMITED, *et al.*, Defendants.	Civil Action No. 19-cv-78 -RGA

MEMORANDUM ORDER

Before the Court is the issue of claim construction of a single term in U.S. Patent Nos. 7,566,729 ("the '729 patent"), 7,635,707 ("the '707 patent"), and 8,592,462 ("the '462 patent"). The Court has considered the Parties' Joint Claim Construction Brief. (D.I. 156). The Court heard oral argument on September 23, 2020.

I. BACKGROUND

Plaintiffs Genentech and InterMune brought cases against Defendants, all of which are pharmaceutical companies, alleging Hatch-Waxman Act patent infringement. (D.I. 1). The cases have been consolidated. Defendants argue that the term "Grade 2 abnormality in one or more biomarkers of liver function" as recited in various asserted claims of the three patents should be construed as indefinite.

II. LEGAL STANDARD

"It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (internal quotation marks omitted). "'[T]here is no magic formula or

catechism for conducting claim construction.' Instead, the court is free to attach the appropriate weight to appropriate sources 'in light of the statutes and policies that inform patent law.'" *SoftView LLC v. Apple Inc.*, 2013 WL 4758195, at *1 (D. Del. Sept. 4, 2013) (quoting *Phillips*, 415 F.3d at 1324) (alteration in original). When construing patent claims, a court considers the literal language of the claim, the patent specification, and the prosecution history. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977–80 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). Of these sources, "the specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315 (internal quotation marks omitted). For considerations of indefiniteness, "a patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014). A showing of "[i]ndefiniteness must be proven by clear and convincing evidence." *See Sonix Technology Co., Ltd. v. Publications International, Ltd.*, 844 F.3d 1370, 1377 (Fed. Cir. 2017).

"[T]he words of a claim are generally given their ordinary and customary meaning. . . . [Which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Id.* at 1312–13 (citations and internal quotation marks omitted). "[T]he ordinary meaning of a claim term is its meaning to [an] ordinary artisan after reading the entire patent." *Id.* at 1321 (internal quotation marks omitted). "In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim

construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." *Id.* at 1314.

When a court relies solely upon the intrinsic evidence—the patent claims, the specification, and the prosecution history—the court's construction is a determination of law. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015). The court may also make factual findings based upon consideration of extrinsic evidence, which "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Phillips*, 415 F.3d at 1317–19 (internal quotation marks omitted). Extrinsic evidence may assist the court in understanding the underlying technology, the meaning of terms to one skilled in the art, and how the invention works. *Id.* Extrinsic evidence, however, is less reliable and less useful in claim construction than the patent and its prosecution history. *Id*.

"A claim construction is persuasive, not because it follows a certain rule, but because it defines terms in the context of the whole patent." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that "a claim interpretation that would exclude the inventor's device is rarely the correct interpretation." *Osram GMBH v. Int'l Trade Comm'n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007) (citation and internal quotation marks omitted).

III. CONSTRUCTION OF "Grade 2 abnormality in one or more biomarkers of liver function"

Plaintiffs' proposed construction: A value obtained from a blood chemistry test of abnormal liver function that meets the grading criteria for a 'Grade 2 adverse effect' set forth in the Common Terminology Criteria for Adverse Events v3.0 (CTCAE) published Aug. 9, 2006 by the National Cancer Institute, as also presented in Table 1 of each of the '729, '707, and '462 patents, and incorporated by reference therein.

Defendants' proposed construction: The term is indefinite.

Court's construction: The term is not indefinite. Plaintiffs' proposed construction is adopted.

Plaintiffs argue that "one or more biomarkers of liver function," which appears in the '729, '707, and '462 patents, is defined in the specification as the five biomarkers alanine transaminase (ALT), aspartate transaminase (AST), bilirubin, alkaline phosphatase (ALP), and gamma-glutamyltransferase (GGT). (D.I. 156 at 6). Plaintiffs contend that the specification consistently identifies "Grade 2 abnormalities" with respect only to these five biomarkers, which are listed in Table 1. (*Id.* at 8).

Defendants contend that a person of ordinary skill in the art (POSITA) would be unable to determine which liver function tests are in fact "biomarkers of liver function." They therefore contend that the claims reciting the disputed term (when it is not further limited[1]) are invalid for indefiniteness. (*Id.* at 21).

Defendants argue that "Grade 2 abnormality in one or more biomarkers of liver function" is indefinite because the phrase has no plain and ordinary meaning and neither the claim language nor the specification[2] indicate the outer boundary of the term. (*Id.* at 16). Defendants point to several instances in the specification where, they argue, "biomarkers of liver function" is not clearly defined. For example, defendants note an instance in the specification which states, "Examples of biomarkers of liver function include, but are not limited to" ALT, AST, bilirubin, ALP, and GGT. (*Id.*).

[1] A "Grade 2 abnormality in one or more biomarkers of liver function" is recited in independent claim 1 of the '729 patent, independent claims 1 and 7 of the '707 patent, and independent claims 16 and 21 of the '462 patent. I do not understand any of the independent claims to be asserted in this litigation. Rather, the relevant asserted dependent claims are claims 2-5 of the '729 patent, claims 2, 8, and 10 of the '707 patent, and claims 18 and 23 of the '462 patent. (D.I. 156 at 16 n.10). I note that certain dependent claims of the '729 and '707 patents limit the disputed term. Dependent claim 7 of the '729 patent and dependent claims 4 and 12 of the '707 patent limit "one or more biomarkers of liver function" to the group consisting of ALT, AST, bilirubin, and ALP. Dependent claim 9 of the '729 patent and dependent claims 6 and 14 of the '707 patent limit "one or more biomarkers of liver function" to ALT and AST. Those dependent claims are not at issue for the purpose of claim construction.

[2] The specifications of all three patents are substantially similar. (D.I. 156 at 16 n.11).

Defendants also note what they call "self-contradictory" language as to whether two of the exemplary liver function tests are in fact "biomarkers of liver function." (*Id.* at 26-27). In particular, Defendants point to an AST/ALT ratio in the specification that is described as a "biomarker," as well as language that states, "biomarkers of liver function can exclude gamma-glutamyltransferase." (*Id*. at 26-27).

Defendants have also identified other tests that can be used to assess liver function, but which are not mentioned in the specification. Defendants argue that it would be unclear to a POSITA whether those tests would be included within the claims. (*Id*. at 20-21).

I think that the disputed claim term can be construed with reasonable certainty. I start with the proposition that claims themselves give important context to the dispute. "Biomarkers of liver function" does not stand alone. Those words are part of a prepositional phrase that modifies "Grade 2 abnormality." That context has to be considered.

Here, the specifications of all three patents use the term "biomarkers of liver function" to refer to the five tests—ALT, AST, bilirubin, ALP, and GGT—on a basis sufficient to inform a POSITA as to the scope of the term. The examples included in the patent, Table 1, Table 2, and the definition of "Grade 2 liver function abnormalities" would provide "reasonable certainty" to a POSITA as to the scope of the claims. *See Nautilus*, 572 U.S. at 901. All three patents contain two tables which only list the toxicity criteria for the five tests, ALT, AST, bilirubin, ALP, and GGT. Further, the following language is included after Table 1 and Table 2 in each patent: "'Grade 2 liver function abnormalities' include elevations in alanine transaminase (ALT), aspartate transaminase (AST), alkaline phosphatase (ALP), or gamma-glutamyl transferase (GGT) greater than 2.5-times and less than or equal to 5-times the upper limit of normal (ULN). Grade 2 liver function abnormalities also include elevations of bilirubin levels greater than 1.5-

times and less than or equal to 3-times the ULN." *See, e.g.*, '707 Patent 11:46-53. The patent claims require a "Grade 2 abnormality" and only the five tests—ALT, AST, bilirubin, ALP, and GGT—are defined in terms of the requisite elevation levels that would constitute such a "Grade 2 abnormality." Consequently, a POSITA seeking to understand the term "Grade 2 abnormality in one or more biomarkers of liver function" would look to the specification and find that only the five tests—ALT, AST, bilirubin, ALP, and GGT—are defined in terms of a "Grade 2 abnormality." As a result, a POSITA would be able to determine with "reasonable certainty" which tests constitute "biomarkers of liver function." *See Nautilus*, 572 U.S. at 901. Therefore, the term "Grade 2 abnormality in one or more biomarkers of liver function" is not indefinite.

Defendant's counterarguments fail. While the specification contains potential instances where "biomarkers of liver function" is not unequivocally referring to ALT, AST, bilirubin, ALP, and GGT, a POSITA would nonetheless be able to determine the scope of the term given the specification as a whole. Defendants are correct that each specification states, "Examples of biomarkers of liver function include, but are not limited to" ALT, AST, bilirubin, ALP, and GGT. *See, e.g.*, '707 Patent at 10:28-32. However, this language is only recited in a single instance, and from its context, it does nothing more than state the undisputed fact that there are more biomarkers of liver function than just the five on which the patents focus. The statement appears to be nothing more than background for the ensuing discussion about the five Grade 2 abnormalities.

Defendants identify certain embodiments of the invention that omit assessment of GGT or that appear to use the AST/ALT ratio as a biomarker. Yet, the possible exclusion of GGT in certain embodiments is justified in each patent's specification: "[e]levated gamma-glutamyl transferase has been observed in some patients receiving pirfenidone, without clinical liver

impairment, and thus elevated gamma-glutamyl transferase alone is not necessarily a sign of liver impairment." *See, e.g.,* '707 Patent at 5:48-52. The AST/ALT ratio is referenced as a "biomarker of liver *damage*" which makes it inapplicable to the current claim construction of "biomarkers of liver *function.*" *See, e.g.,* '707 Patent at 10:53-54. Because I conclude that the relevant "biomarkers of liver function" are apparent from the claims and the specification, the extrinsic evidence cited by Defendants of other tests capable of assessing liver function is inconsequential. The claim term "Grade 2 abnormality in one or more biomarkers of liver function" is not indefinite.

IV. CONCLUSION

The term "Grade 2 abnormality in one or more biomarkers of liver function" read in light of the specification and claims reasonably informs a person of ordinary skill in the art as to the scope of the disputed claims and is therefore not indefinite. Plaintiffs' proposed construction is adopted.

IT IS SO ORDERED this 20th day of October 2020.

/s/ Richard G. Andrews
United States District Judge