IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK KGaA, MERCK SERONO SA, and ARES TRADING SA, Plaintiffs, v. HOPEWELL PHARMA VENTURES, INC., et al., Defendants.	C.A. No. 22-1365-GBW-CJB **CONSOLIDATED**

MEMORANDUM ORDER

Pending before the Court is Magistrate Judge Burke's Report and Recommendation ("R&R), dated June 13, 2024 (D.I. 141), resolving two claim construction disputes (D.I. 70; D.I. 71) and adopting Plaintiffs Merck KGaA, Merck Serono SA and Ares Trading SA's (collectively, "Merck") proposed constructions for the claim terms "maintenance dose" and "induction period" in the asserted claims of U.S. Patent Nos. 7,713,947 ("the '947 patent") and 8,377,903 ("the '903 patent") (collectively, the "asserted patents"). The parties' respective constructions of both terms implicate the same disputed issue: whether the total dose of cladribine administered during the induction and maintenance periods in the asserted claims can be the same or whether the total dose of cladribine administered during the maintenance period must always be lower than the dose administered during the induction period. Defendants Hopewell Pharma Ventures, Inc. ("Hopewell"), Aurobindo Pharma USA, Inc. and Aurobindo Pharma Limited ("Aurobindo"), and Apotex Inc. and Apotex Corp. ("Apotex") (collectively, "Defendants") object to the R&R and contend that Judge Burke erred in finding that the "maintenance period" dose in the asserted patents may be ***the same or lower*** than the "induction period" dose. D.I. 146. According to

Defendants, the specification and the prosecution history for each asserted patent requires that the "maintenance period" dose is lower than the "induction period" dose. *See generally id.* Having reviewed the R&R and all related briefing, the Court agrees with Magistrate Judge Burke that the asserted claims do not require the "maintenance period" dose to be lower than the "induction period" dose. D.I. 141 at 18. Accordingly, the R&R is **ADOPTED** in whole, and Defendants' objection to Judge Burke's construction of "maintenance dose" and "induction period" is **OVERRULED.**

I. LEGAL STANDARD

Objections to claim-construction determinations in an R&R are reviewed de novo. *See St. Clair Intellectual Prop. Consultants, Inc. v. Matsushita Elec. Indus. Co.*, 691 F. Supp. 2d 538, 542 (D. Del. 2010); 28 U.S.C. § 636(b)(1); Fed. R. Civ. P. 72(b)(3). Claim construction falls "exclusively within the province of the court," not that of the jury. *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837 (2015) (quoting *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996)). It is proper for courts to "treat the ultimate question of the proper construction of the patent as a question of law in the way that [courts] treat document construction as a question of law." *Id.* at 837.

II. ANALYSIS

"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) (internal citations omitted). Thus, the process of construing claim terms must begin with the words of the claim. *Id.* In this matter, Defendants conceded at the *Markman* hearing that nothing in the claim terms "maintenance period" and "induction period" denotes that the dosage amounts cannot be the same or that the "maintenance period" dose must be lower than the

"induction period" dose. Markman Tr., 39:14-24. And while Defendants contend that such a limitation should be read into the asserted claims, other claims of the asserted patents explicitly disclose a "maintenance period" dose lower than the "induction period" dose. *See, e.g.*, '903 patent, Cl. 1 (disclosing "a maintenance period wherein . . . the total dose of cladribine reached at the end of the maintenance period ***is lower*** than the total dose of cladribine reached at the end of the induction period" (emphasis added)); '947 patent, Cl. 1 (same). Merck contends—and the Court agrees—that the reference to a lower "maintenance period" dose in these unasserted claims is evidence that the lack of any reference to such a requirement in the asserted claims was intentional. D.I. 152 at 2. "This shows, when the patentee wants to claim a [lower maintenance period dose] . . ., the patentee knows how to do it." *In re Jublia*, No. 318CV13635BRMLHG, 2021 WL 100267, at *7 (D.N.J. Jan. 11, 2021); see also *Phillips v. AWH Corp.*, 415 F.3d 1303, 1325 (Fed. Cir. 2005) ("[C]laim terms should not be read to contain a limitation 'where another claim restricts the invention in exactly the [same] manner'" (internal citations omitted)).

Even assuming that the claim language itself was insufficient to resolve the parties' dispute as to the relationship between the "maintenance period" dose and "induction period" dose in the asserted claims, the Court agrees with Judge Burke that the specification of each asserted patent reveals that the asserted claims do not **require** the "maintenance period" dose to be lower. D.I. 141 at 5-7. While Defendants contend that the patent claims should not be read "in a vacuum," D.I. 146 at 2, the Court emphasizes that "[t]he specification is the single best guide to the meaning of a disputed term." *Pressure Prods. Med. Supplies, Inc. v. Greatbatch Ltd.*, 599 F.3d 1308, 1314–15 (Fed. Cir. 2010) (quotations omitted). Here, Defendants cannot dispute that several embodiments in the specification disclose examples where the "maintenance period" dose and "induction period" dose are the same. *See, e.g.*, '947 patent, 15:65-16:3; '903 patent, 18:30-32.

To get around these clear embodiments, Defendants contend that "[i]t is quite common for a patent specification to describe unclaimed embodiments." D.I. 146 at 3. Yet, there is no indication that the patentee intended to read these embodiments out of the asserted claims, given that the claim language itself does not limit the scope of the claim to a "maintenance period" dose lower than the "induction period" dose. Moreover, the embodiments in the specification that are describing a "maintenance period" dose lower than the "induction period" dose, at most, prove that the "maintenance period" dose **can** be lower. *See, e.g.*, '947 patent, 8:25-42. They do not support Defendants' claim that the "maintenance period" dose must always be lower. In insisting that the asserted claims should be construed to require that the "maintenance period" dose is lower than the "induction period" dose, Defendants ask the Court to ignore certain embodiments of the specification and to read in a limitation from embodiments that support their construction. Our courts have long held, however, that absent unequivocal evidence that the patentee acted as its own lexicographer,[1] courts may not "read a limitation into a claim from the written description." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1248 (Fed. Cir. 1998) ("[T]he claims define the scope of the right to exclude").

With respect to Defendants' claim that the prosecution histories of the asserted patents disclaim administering a "maintenance period" dose that is the same as the "induction period" dose, the Court finds that Defendants have not satisfied their burden to prove prosecution disclaimer. *See* D.I. 146 at 6-8. Indeed, to meet this burden, Defendants were required to show that the patentee "***unequivocally*** disavowed a certain meaning" in a way that is "***clear and unmistakable***." *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1324-26 (Fed. Cir. 2003) (emphasis added). "Where the alleged disavowal is ambiguous, or even 'amenable to multiple

[1] *Jack Guttman, Inc. v. Kopykake Enters., Inc.*, 302 F.3d 1352, 1360 (Fed. Cir. 2002).

reasonable interpretations,'" the Court must "decline[] to find prosecution disclaimer." *Avid Tech., Inc. v. Harmonic, Inc.*, 812 F.3d 1040, 1045 (Fed. Cir. 2016). As Merck notes, this is a heavy burden. D.I. 152 at 5.

Viewing the prosecution history of the '947 patent, for instance, the Court notes—consistently with Judge Burke—that the patentee attempted to distinguish the patent claims from two prior art sources, Beutler and Bodor, on grounds that the prior art did not disclose using a dose of cladribine during the maintenance period that was lower than the dose used during the induction period. D.I. 141 at 9-10; '947 patent history at MAVMRK_000000004-07, MAVMRK_000000391-92. As Judge Burk noted, however, this was one of many grounds that the patentee raised while attempting to distinguish certain claims from the prior art during prosecution. D.I. 141 at 10; *see also* '947 patent history at MAVMRK_000000415-17 (differentiating Bodor on grounds that it also did not teach a cladribine-free period that ranged between about 8-10 months). Indeed, after making this argument, "[t]he patentee [then] went on to distinguish Beutler on various [other] grounds: (1) that it 'fails to teach any period of time that corresponds to a "cladribine-free period" as recited in the instant claims[;]' (2) that 'no passage of Beutler discloses or contemplates cladribine-free periods that range from about 8 to about 10 months'; and (3) that Beutler did not 'teach that the total dose of cladribine reached at the end of the maintenance phase is lower than the total dose reached at the end of the induction phase.'" D.I. 141 at 11 (citing '947 patent history at MAVMRK_000000416-17). Viewing the prosecution history of the'947 patent as a whole, the Court agrees with Judge Burke that the patentee seemingly provided "multiple reasons why a particular included claim could be valid" but did not intend to include the lower dose limitation in every claim of the patent. *Id.* at 11-12.

The prosecution history of the '903 patent is far less equivocal, given that the patentee, on several occasions, argued that a prior art source, Bodor, did not disclose "repeating a treatment course at any point in time at either the original dosage or at a lower dosage in a manner that could be construed as a 'maintenance period.'" *See, e.g.*, '903 patent history at MAVMRK_000000948. Defendants emphasize one instance in which the patentee noted that, even if one assumed that such a period was implied by Bodor, a person of skill in the art would "not have had any reason to reduce the dosage of cladribine administered during the 'maintenance period' as recited in the claims such that the total dosage of cladribine administered to the patient is less than the total dose of cladribine the patient received during the induction period." *See id.* at MAVMRK_000000979. As Judge Burke noted, this "even if" argument is not sufficient to constitute a clear and unequivocal disclaimer in light of the patentee's other statements to the contrary during prosecution. D.I. 141 at 15-16.

In sum, the claim language and the intrinsic evidence support Merck's interpretation that the "maintenance period" dose in the asserted patents may be ***the same or lower*** than the "induction period" dose. The Court therefore **ADOPTS** Judge Burke's R&R construction of the claim terms "maintenance dose" and "induction period" and **OVERRULES** Defendants' objection.

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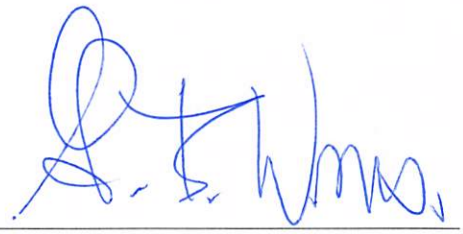
Therefore, at Wilmington this **28th** day of August, 2024, **IT IS HEREBY ORDERED** that:

1. Magistrate Judge Burke's Report and Recommendation, D.I. 141, is **ADOPTED**;
2. "induction period" is construed to mean "initial treatment period"; and
3. "maintenance period" should be construed to mean "treatment period that follows the induction period and the cladribine-free period."



GREGORY B. WILLIAMS
U.S. DISTRICT JUDGE