**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| MERCK KGaA, et al., | ) | |
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| Plaintiffs, | ) | |
| | ) | |
| v. | ) | Civil Action No. 22-1365-GBW-CJB |
| | ) | CONSOLIDATED |
| HOPEWELL PHARMA VENTURES, INC., et al., | ) | |
| | ) | |
| Defendants. | ) | |

## REPORT AND RECOMMENDATION

In this Hatch-Waxman action filed by Plaintiffs Merck KGaA, Merck Serono SA and Ares Trading SA (collectively, "Plaintiffs") against Defendants Hopewell Pharma Ventures, Inc., Aurobindo Pharma USA Inc., Aurobindo Pharma Limited, Apotex Inc. and Apotex Corp. (collectively, "Defendants"),[1] Plaintiffs allege infringement of United States Patent Nos. 7,713,947 (the "'947 patent") and 8,377,903 (the "'903 patent" and together with the '947 patent, the "asserted patents" or the "patents-in-suit").[2] Presently before the Court is the matter of claim

[1] This matter has been consolidated with Civil Action No. 23-39-GBW-CJB for all purposes, including trial, (D.I. 20), and with Civil Action No. 23-655-GBW-CJB for all purposes, except trial, (D.I. 56).

[2] The '947 patent (which issued in May 2010) and the '903 patent (which issued in February 2013) are found in various parts of the record, including at D.I. 68, exs. A-B. Herein, the Court will cite them by their patent numbers only. These two patents-in-suit share a common specification, and so the Court will follow the parties' lead and generally cite to the specification in the '947 patent. (*See* D.I. 67 at 1 n.3) It should be understood that the cited portions of the '947 patent are also found in the '903 patent.

Plaintiffs previously also asserted a third patent in these consolidated cases: United States Patent No. 10,849,919 (the "'919 patent"). (*See* D.I. 1; Civil Action No. 23-39-GBW-CJB, D.I. 1; Civil Action No. 23-655-GBW-CJB, D.I. 1) However, they no longer assert the '919 patent against any Defendant. (D.I. 37; D.I. 64; Civil Action No. 23-655-GBW-CJB, D.I. 26)

construction. (D.I. 70; D.I. 71) The Court recommends that the District Court adopt the constructions set forth below.

## I. BACKGROUND

Plaintiffs allege that Defendants have infringed claims 36, 38, 39 and 41-46 of the '947 patent and claims 17, 19, 20 and 22-27 of the '903 patent by submitting their respective Abbreviated New Drug Applications seeking approval to market generic versions of Plaintiffs' MAVENCLAD® product. (D.I. 67 at 1, 7 n.5) The asserted patents generally describe a regimen for treating certain forms of multiple sclerosis. (*Id*. at 1, 5) The recited methods of treatment in the asserted patents' claims are described as having four periods: (1) an initial treatment period in which the immunosuppressive drug cladribine is administered (the "induction period"); (2) a cladribine-free period; (3) a treatment period following the induction period and the cladribine-free period, in which cladribine is again administered (the "maintenance period"); and (4) a second cladribine-free period. (*See, e.g.*, '947 patent, col. 3:53-65; D.I. 67 at 2, 4) Further relevant facts will be addressed as necessary in Section III.

Plaintiffs commenced this now-consolidated action on October 17, 2022. (D.I. 1) The matter was thereafter referred to the Court to hear and resolve all pre-trial matters up to and including expert discovery matters. (D.I. 50) On December 27, 2023, the parties filed their motions for claim construction, (D.I. 70; D.I. 71), and the Joint Claim Construction Brief, (D.I. 67). The Court conducted a *Markman* hearing on January 30, 2024. (D.I. 137 (hereafter, "Tr.")

## II. STANDARD OF REVIEW

The Court has often set out the relevant legal standards for claim construction, including in *Vytacera Bio LLC v. CytomX Therapeutics, Inc.*, Civil Action No. 20-333-LPS-CJB, 2021 WL 4621866, at *2-3 (D. Del. Oct. 7, 2021). The Court hereby incorporates by reference its

discussion in *Vytacera Bio* of these legal standards and will follow them herein. To the extent that consideration of the disputed terms necessitates discussion of other, related legal principles, the Court will discuss those principles in Section III below.

## III. DISCUSSION

The parties set out two disputed terms for the Court's review: "induction period" and "maintenance period." Both terms implicate the same disputed issue, and so the Court will address both terms together. The parties' proposed constructions are set out in the chart below:

| **Term** | **Plaintiffs' Proposed Construction** | **Defendants' Proposed Construction** |
|---|---|---|
| "induction period" | "initial treatment period" | "initial treatment period during which the total dose of cladribine is higher than the total dose of cladribine administered in a subsequent maintenance period" |
| "maintenance period" | "treatment period that follows the induction period and the cladribine-free period" | "treatment period that follows the induction period and the cladribine-free period and during which the total dose of cladribine is lower than the total dose of cladribine administered in the induction period" |

(D.I. 80, ex. B at 2, 6-7; Plaintiffs' *Markman* Presentation, Slide 2; Defendants' *Markman* Presentation, Slide 2) The sole dispute between the parties is whether the total dose of cladribine administered during the induction and maintenance periods can be the same (which would be permitted by Plaintiffs' constructions), or whether the total dose of cladribine administered during the maintenance period *must always be lower* than the dose administered during the induction period (as is required by Defendants' constructions). (D.I. 67 at 17-18; Tr. at 5-6)

By way of background, in both of the asserted patents, there are claims in which it is explicitly specified that the total dosage in the maintenance period is "lower" than the dosage in the induction period. ('947 patent, cols. 16:65-17:2, 17:39-43, 18:17-22, 18:50-55 (claims 1, 12, 20 and 28); '903 patent, cols. 16:65-17:3, 17:32-36 (claims 1 and 9)) And in both patents, there are claims, like claims 36 and 39 of the '947 patent and claims 17 and 20 of the '903 patent, wherein the dose administered in the maintenance period is not facially described as being required to be "lower" than the dose administered in the induction period. ('947 patent, col. 19:16-27 (claim 36 noting that the total dose of cladribine at the end of the induction period is "from about 1.7 mg/kg to about 3.5 mg/kg" and the total dose at the end of the maintenance period is "about 1.7 mg/kg"); *id*., col. 20:5-7 (claim 39, which is dependent on claim 36, noting that the total dose at the end of the induction period is "about 1.7 mg/kg"); '903 patent, col. 18:13-24 (claim 17 noting that the total dose of cladribine at the end of the induction period is "from about 1.7 mg/kg to about 3.5 mg/kg" and the total dose at the end of the maintenance period is "about 1.7 mg/kg"); *id*., col. 18:31-33 (claim 20, which is dependent on claim 17, noting that the total dose at the end of the induction period is "about 1.7 mg/kg").

The Court now turns to the parties' arguments, which can roughly be broken down into two categories. First the parties address how the claim language and the specification bear on their disputes. And then the parties argue about how certain of the patentee's statements made during prosecution should impact the outcome. The Court will take up each category of argument in turn.

### A. The Claim Language and the Specification

After reviewing the claim language and the specification of the asserted patents, the Court has concluded that they strongly support Plaintiffs' proposed constructions. It comes to this conclusion for the following reasons:

- It is beyond doubt that certain of the patents' claims facially permit—simply as a matter of the plain and ordinary meaning of the words used therein—that the total dosage in the induction period and the maintenance period *could be* the same. For example, it is undisputed that in a vacuum, the wording of claims 36 and 39 of the '947 patent and claims 17 and 20 of the '903 patent could allow that the total dose in the induction period and total dose in the maintenance period would be exactly 1.7 mg/kg—again, in light of the literal wording used in those claims. (D.I. 67 at 23; Plaintiffs' *Markman* Presentation, Slides 11-12; Tr. at 47 (Defendant's counsel acknowledging this); *id.* at 75 (Plaintiffs' counsel noting the same))

- As was noted above, some of the patents' claims specify that the maintenance period dose must be "lower" than the induction period dose. And so it is reasonable to assume that where certain other claims do *not* specify this, then those claims are meant to allow for a world in which the dose administered in the induction and maintenance periods are not always required to be "lower" (i.e., they could be the same). Were this not so (and were Defendants' constructions correct), then there would be some amount of redundancy in the claims. (*See* D.I. 67 at 55; Tr. at 45-46) In other words, were Defendants' constructions accurate, there would have been no need for some claims (e.g., claims 1, 12, 20 and 28 of the '947 patent and claims 1 and 9 of the '903 patent) to have specified that the maintenance period must be "lower"—if the claim language (including the claims' use of the term "maintenance period") otherwise *required* that this be so. "It is highly disfavored to construe terms in a way that renders them void, meaningless, or superfluous." *Wasica Fin. GmbH v. Cont'l Auto. Sys., Inc*., 853 F.3d 1272, 1288 n.10 (Fed. Cir. 2017)); *see also Akzo Nobel Coatings, Inc. v. Dow Chem. Co*., 811 F.3d 1334, 1340 (Fed. Cir. 2016) (explaining that constructions rendering claim language superfluous are disfavored) (citing cases); *Merck & Co., Inc. v. Teva Pharms. USA, Inc*., 395 F.3d 1364, 1372 (Fed. Cir. 2005) (same). And Defendants' position would in fact render certain claims' use of "lower" superfluous.

- The asserted patents include reference to an Example 1, which describes a study of 60 patients with relapsing forms of clinically definite multiple sclerosis. ('947 patent, col. 14:23-24) In this study, patients were assigned to one of three treatment groups: Group 1, Group 2 or Group 3. (*Id*., col. 14:29-39) The patients in Group 1 did not receive any cladribine in the induction period; the patients in Group 2 received a total dose of "about 1.75 mg/kg" in the induction period; and the patients in Group 3 received a total dose of "about 3.5 mg/kg" in the induction period. (*Id*., col. 15:48-64) In the maintenance period, all of the groups received a dose of about 1.75 mg/kg of cladribine. (*Id*., cols. 15:65-16:3 (noting that the maintenance period dose is the same as Group 2's induction period dose); D.I. 67 at 34 (same); Tr. at 56) This means that the patients in Group 2 could possibly have received the exact same dose in the maintenance period as they received in the induction period (e.g., exactly 1.75 mg/kg). And so Defendants' construction would render impossible what Example 1 appears to suggest *is* possible—i.e., that there can be a treatment regimen in which the dose administered in the maintenance period is the same as the dose administered in the induction period. (D.I. 67 at 3-4, 23-24, 47; Tr. at 11-12)[3]

- It is true that (as Defendants point out) the specification references various embodiments wherein a four-period treatment regimen is discussed, and that in these embodiments, the total effective dose administered in the maintenance period is described as being "lower" than the dose administered in the induction period. ('947 patent, cols. 8:25-42, 9:35-52, 9:63-10:33, 10:44-61, 12:58-13:6) However, in multiple places, including in column 13, the specification additionally sets out a listing of "further preferred embodiment[s]"—and in doing so, it describes one such embodiment as providing that "the total dose of [c]ladribine reached at the end of the induction period is about 1.7 mg/kg" and

[3] During the *Markman* hearing, even Defendants' counsel acknowledged that Group 2 referenced in the patents' Example 1 could have been given the same dosage in the induction period as they were in the maintenance period. (Tr. at 57) Counsel argued that this was not problematic for Defendants because this portion of Example 1 is not a claimed embodiment. (*Id*. at 57-58) But the Court sees no indication that the relevant embodiment is not claimed. Indeed, certain claims in the patents require an induction period and a maintenance period wherein the total dose of cladribine in both periods is "about 1.7 mg/kg[.]" (*See, e.g.*, '947 patent, col. 20:5-7; '903 patent, col. 18:30-32) That sounds very similar to what is described regarding Group 2 of Example 1. (D.I. 67 at 47)

another as providing that "the total dose of [c]ladribine reached at the end of the maintenance period is about 1.7 mg/kg." (*Id*., cols. 13:10-12, 13:25-27; D.I. 67 at 22; *see also* '947 patent, cols. 8:53-56, 9:27-31) Obviously, if you took the teachings from these portions of the patent and applied them both to a particular four-period dosing regimen, you could end up with a regimen that allows for the same dose in both the induction period and the maintenance period (e.g., 1.7 mg/kg). (D.I. 67 at 24; Tr. at 51-52)[4] And the patent certainly is not saying in column 13 that you *should not* do that or *cannot* do that.

- Defendants further argue that their position is correct because the specification actually defines a maintenance period as a period that always involves administration of a lower dose than the dose administered in the induction period. (D.I. 67 at 34, 52-53) But the portion of the specification Defendants cite to here is actually defining a different term—"Maintenance Treatment"—not "maintenance period." This part of the specification reads: "A 'Maintenance Treatment' consists in the sequential succession of (i) *a maintenance period wherein the Cladribine . . . is orally administered at a lower dose than the Cladribine dose orally administered during the induction treatment* and (ii) a Cladribine-free period." ('947 patent, col. 5:6-11 (emphasis added); D.I. 67 at

[4] Defendants argue that the language in this portion of column 13 is not persuasive because it is not explicitly describing examples of *four-period* dosage regimens, and instead simply amounts to a listing of different aspects of what a "further preferred embodiment" could include. ('947 patent, col. 13:7-62) They argue that "every time you see romanette i through iv" or "four romanettes spelled out [to] describe a four-part dosing regimen" in the specification, the dose in the maintenance period is described as being "lower" than the dose in the induction period. (Tr. at 52-53) And so Defendants suggest that while column 13 does state what the Court describes above, its references to the same type of dosage in both the induction period and the maintenance period are not sufficiently "linked together" in a manner suggesting that they are meant to be a part of one dosage regime. (*Id*.) Plaintiffs, for their part, argue that this is an incorrect way to read the specification; they assert that the "further embodiments" described in column 13 are meant to discuss *various possibilities* for the claimed inventions, which include the possibility that the doses administered in the maintenance and induction periods could be the same. (*Id*. at 69-70) The Court agrees with Plaintiffs on this point. In its view, column 13 seems clearly to be discussing various options for how different parts of the claimed dosing regimens could be structured. And there is a "strong presumption against a claim construction that excludes a disclosed embodiment[,]" which is what Defendants' construction would appear to do. *TwinStrand BioScis., Inc. v. Guardant Health, Inc*., Civil Action No. 21-1126-GBW-SRF, 2022 WL 17986012, at *8 (D. Del. Dec. 29, 2022) (quoting *Immunex Corp. v. Sanofi-Aventis U.S. LLC*, 977 F.3d 1212, 1220 (Fed. Cir. 2020)); *Tracktime, LLC v. Amazon.com, Inc*., C.A. No. 18-1518 (MN), 2021 WL 2823163, at *4 (D. Del. July 7, 2021).

34) Because this portion of the patent does not seem to be attempting to define "maintenance period," in the Court's view, it does not really help Defendants' cause.

- But more than that, the patents' definition of "Maintenance Treatment" arguably bolsters *Plaintiffs'* cause. That is because in the above-referenced definition of "Maintenance Treatment," the patentee seems to have gone out of its way to specify *one particular type* of maintenance period that can be utilized—i.e., one wherein the effective dose administered must be lower than the dose administered in the induction period. This seems to imply that there can be *other types* of maintenance periods that are possible (e.g., one where the effective dose administered can be the same as that administered in the induction period). (Tr. at 39) If this were not so, then there would seem to be no reason for the patentee to have noted the specific type of maintenance period (and its relationship to the induction period) that must be utilized during a "Maintenance Treatment." (*See* D.I. 67 at 47; Plaintiffs' *Markman* Presentation, Slide 20) Put differently, if Defendants are correct that every maintenance period relating to the invention must inherently utilize an effective dose of cladribine that is lower than the dose administered in the induction period, then the patentee could have just stated that a "Maintenance Treatment" is "the sequential succession of (i) a maintenance period and (ii) a Cladribine-free period." That it did not is a tell that Defendants' position is not correct here. (Tr. at 13 (Plaintiffs' counsel noting that this definition utilizes "only a subset of all maintenance periods")) Relatedly, the definition of "Maintenance Treatment" also shows that had the patentee clearly wanted to require in all instances that a "maintenance period" must have a lower dose of cladribine administered than that in the induction period, it knew how to do this—in that it could have used the term "Maintenance Treatment" in the claims, or it could have explicitly defined "maintenance period" in this way in the specification. And yet it chose not to. (D.I. 67 at 47)

For these reasons, the above-referenced intrinsic evidence strongly supports Plaintiffs' proposed constructions. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1314-15 (Fed. Cir. 2005) (explaining that the "claims themselves provide substantial guidance as to the meaning of particular claim terms" and that the specification is the "single best guide to the meaning of a disputed term") (internal quotation marks and citation omitted).

### B. Prosecution History

The Court next turns to the parties' arguments regarding the prosecution history of the patents-in-suit. Defendants assert that even if the other intrinsic evidence might support a claim scope consistent with Plaintiffs' constructions, during prosecution of the patents Plaintiffs made statements that amount to prosecution history disclaimer—that is, that they disclaimed the claim scope that they now seek via their constructions.[5] Defendants make this prosecution history disclaimer argument regarding certain events occurring during the prosecution of each of the '947 patent and the '903 patent, respectively. The Court will address those arguments in turn below.

With regard to the '947 patent's prosecution history, Defendants point out that when the patentee filed its patent application, all of the claims explicitly required that the dose of cladribine administered during the maintenance period must be "lower" than the dose administered during the induction period. (D.I. 68, ex. C (hereinafter, "'947 patent history") at MAVMRK_000000004-07; Tr. at 15) The Examiner subsequently rejected these claims as being unpatentable over two references known as "Bodor" and "Beutler," in view of a third reference known as "Bloom." ('947 patent history at MAVMRK_000000388) The Examiner concluded that together the teachings of Bodor and Beutler provided for a treatment regimen that

[5] The United States Court of Appeals for the Federal Circuit has explained that "because the prosecution history represents an ongoing negotiation between the [United States Patent and Trademark Office (or "PTO")] and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes." *Phillips*, 415 F.3d at 1317. In order for a statement made during prosecution to constitute prosecution history disclaimer, the statement must amount to a "*clear and unmistakable*" disclaimer. *Aylus Networks, Inc. v. Apple Inc.*, 856 F.3d 1353, 1359 (Fed. Cir. 2017) (internal quotation marks and citations omitted, emphasis added). The Federal Circuit has explained that "when a prosecution argument is subject to more than one reasonable interpretation, it cannot rise to the level of a clear and unmistakable disclaimer." *Id.* at 1363 (internal quotation marks and citation omitted).

includes an initial treatment phase (i.e., the induction period), followed by a cladribine-free period, followed by another treatment period (i.e., the maintenance period), followed by another cladribine-free period of up to 10 months. (*Id*. at MAVMRK_000000388-92) That said, she noted that "neither [Bodor nor Beutler] teach that the total dose of cladribine reached at the end of the maintenance [period] is lower than the total dose reached at the end of the induction [period,]" as was then called for by all of the claims. (*Id*. at MAVMRK_000000391-92) Nevertheless, the Examiner found that the Bloom reference taught this additional claim limitation, and she determined that it would have been obvious to one of skill in the art at the relevant time to treat multiple sclerosis with cladribine according to a treatment regimen where the total dosage administered in the maintenance phase was less than the total dosage administered in the induction phase. (*Id*. at MAVMRK_000000392-93)

In a subsequent submission, the patentee included pending claims 54 and 57, which eventually became claims 36 and 39 of the '947 patent—i.e., two claims that do *not* facially include a requirement that the dose administered during the maintenance period must always be lower than that administered during the induction period. (*Id*. at MAVMRK_000000411-12) Additionally, the patentee added a limitation to the original pending independent claims and to other claims that required that the first cladribine-free period of the claimed regimen must be "about 8 and about 10 months." (*Id*. at MAVMRK_000000406-13) In its submission, the patentee appeared to distinguish Bodor on at least both of these grounds—i.e., that Bodor did not teach a cladribine-free period that ranged between about 8-10 months, and that it did not disclose using a dose of cladribine during the maintenance period that was lower than the dose used during the induction period. (*Id*. at MAVMRK_000000415-17; D.I. 67 at 36; Tr. at 16-17)

The patentee also went on to distinguish Beutler on various 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." ('947 patent history at MAVMRK_000000416-17 (internal quotation marks omitted)) As for Bloom, the patentee argued that it failed to teach that a lower dose be administered during the maintenance period than in the induction period. (*Id*. at MAVMRK_000000419 ("[I]t is clear that Bloom does not teach lowering treatment dosages with each successive use of the drug, rather Bloom teaches the tapering [of] the dosage of each drug to maintenance dosages that are maintained throughout the treatment protocol."); *id*. at MAVMRK_000000421 ("Applicant submits that, as discussed above, Bloom fails to teach a 'method of high dose, no dose, low dose' treatment."))

Defendants argue that in these passages, Plaintiffs clearly disclaimed the claim scope that it now seeks, by distinguishing the claimed invention from the prior art on the ground that *all of the claims* set out therein disclosed a regimen with a lower dose administered in the maintenance period than that administered in the induction period. (D.I. 67 at 10, 48-49) And although the applicant did add current claims 36 and 39 (which do not have the explicit "lower" dose limitation), Defendants argue that the patentee "did not distinguish [these] newly added claim[s] on the basis of scope or subject matter from its [other] prior claims [that did have the "lower" dose limitation]; rather [it] made its arguments regarding the non-obviousness of a lower maintenance dose *generally and without limitation to any specific pending claims*." (*Id*. at 10 (emphasis added))

In the Court's view, however, Plaintiffs' statements above were not clear enough or unmistakable enough in this regard to amount to prosecution history disclaimer. The Court so concludes for the following reasons:

- As was noted above, in its response to the Examiner, the patentee seemed to be providing at least two bases for why the new claims at issue were not rendered obvious by the prior art: (1) the prior art did not teach a cladribine-free period of between about 8 to 10 months; and (2) the prior art did not teach a maintenance period in which the total dose of cladribine administered is lower than that in the induction period. Additionally, certain of the accompanying claims—i.e., what became claims 36 and 39—included the "about 8 months to about 10 months" cladribine-free period limitation, but *did not* facially include the "lower dose in the maintenance period" limitation. In the Court's view, the most natural way to read this prosecution history excerpt, then, is to conclude that in it, the patentee was providing multiple reasons why a particular included claim could be valid. For claims that included *both* of the above-referenced limitations, the patentee was saying that both of those limitations were not found in the prior art. But for claims like current claims 36 and 39, the patentee was noting that the inclusion of the "about 8 months to about 10 months" limitation—i.e., the only one of these two limitations that was explicitly included in these particular claims—was enough on its own to ensure that the claim was valid. ('947 patent history at MAVMRK_000000406-13; *id*. at MAVMRK_000000415; D.I. 67 at 37; Tr. at 16-20)

- As Plaintiffs argue, it seems really incongruous that in its responsive submission, the patentee would: (1) add new claims (i.e., current claims 36 and 39) that *did not* facially require a lower dose in the maintenance period than in the induction period; (2) include plenty of claims that *did* explicitly require this (which suggests that the absence of such language in now-claims 36 and 39 was intentional); and then (3) nevertheless go on in its statements to the Examiner to disclaim the possibility that current claims 36 and 39 could allow for something other than a lower dosage in the maintenance period than that administered in the induction period. Put differently, as Plaintiffs argue, "it is implausible that Merck simultaneously added claims omitting the 'lower dose' limitation and sought allowance of the same claims on the basis of the prior art's failure to disclose a lower dose."

(D.I. 67 at 36; *see also* Tr. at 20 (Plaintiffs' counsel arguing "Why then turn around and make an argument that disclaims what you just added?"))

- The patentee certainly did not include an explicit, leave-no-doubt-about-it type of statement indicating that its arguments about the "lower dose in the maintenance period" limitation were meant to apply to every single claim listed therein (including now-claims 36 and 39). In other words, it is not as if the patentee said something like: "As to every single proposed claim referenced in this filing, that claim must survive over the prior art at issue because each such claim calls for a lower dose of cladribine in the maintenance period than is used in the induction period." It is *that* kind of a statement, or something like it, that would be "clear and unmistakable" for our purposes here.

The Court next turns to Defendants' arguments about the import of the '903 patent's prosecution history. Those arguments too are not winning ones.

The Court starts first with some relevant background. About a month before the '947 patent issued, Plaintiffs filed a continuation application that became the '903 patent. (D.I. 67 at 11) In that application, the patentee included claims (like what became independent claim 1 of the patent)[6] requiring that the dose of cladribine administered during the maintenance period must be "lower" than the dose administered during the induction period, as well as claims (like independent claims 17 and 20 of the patent) facially allowing a maintenance period in which the dose administered could be the same as that administered in the induction period.[7] (D.I. 69, ex.

[6] The numbers of the claims in this application match what became the numbers of the claims in the issued '903 patent. Therefore, hereafter the Court will simply refer to the claims by their claim number, whether discussing the claims as they existed during prosecution or the final issued claims of the patent.

[7] As in final claims 17 and 20 of the '903 patent, independent claim 17 in the application claimed an induction period where the total dose of cladribine at the end of the induction period "is from about 1.7 mg/kg to about 3.5 mg/kg" and where the total dose at the end of the maintenance period is "about 1.7 mg/kg[.]" ('903 patent history at MAVMRK_000000876) Claim 20, which is dependent on claim 17, claimed additionally that

D (hereinafter, "'903 patent history") at MAVMRK_000000874-78; D.I. 67 at 38; Tr. at 24) Many of those claims (including claims 17 and 20) included a limitation that the initial cladribine-free period must last "from about 8 months to about 10 months[.]" ('903 patent history at MAVMRK_000000874-78)

In December 2011, the Examiner initially rejected the claims in light of Bodor and another prior art reference known as "Grieb," in view of Bloom. (*Id*. at MAVMRK_000000926-31)[8] In response, in March 2012, the patentee argued, *inter alia*, that nowhere in Bodor was there any discussion of "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.'" (*Id*. at MAVMRK_000000948 (emphasis added); *see also* Tr. at 25) Nevertheless, in May 2012, the Examiner maintained the rejection. ('903 patent history at MAVMRK_000000962-68)

In August 2012, the patentee responded to that final rejection. (Tr. at 25) There, the patentee first argued that Bodor was "silent with respect to the administration of cladribine therapy after the cladribine-free period of between about 8 and 10 months" (i.e., as to the use of a maintenance period), and that Grieb's induction period had both a different length and used a different total dose of cladribine than did the proffered claims. ('903 patent history at MAVMRK_000000978; Tr. at 26) Thereafter the patentee expanded on the differences between the claimed regimen and the "two dosing regimens" disclosed in Bodor. ('903 patent history at

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the "total dose of cladribine reached at the end of the induction period is about 1.7 mg/kg." (*Id*. at MAVMRK_000000877)

[8] The Examiner found that Bodor (in view of Grieb) taught every element of the claims except 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, and again pointed to the Bloom reference as disclosing this missing element. ('903 patent history at MAVMRK_000000926-31; *see also* D.I. 67 at 12)

MAVMRK_000000978) It noted that one of those dosing regimens included "an induction period of six months[;]" here, the patentee argued that this regimen "clearly fails to meet the limitations of the claimed invention" (which claimed a 2-to-4-month induction period). (*Id*. at MAVMRK_000000978-79; Tr. at 26) And as to Bodor's second regimen, the patentee argued that it did not invalidate the claimed invention because "nowhere in the teachings of the reference is there any discussion about 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[.]'" ('903 patent history at MAVMRK_000000979 (emphasis added); Tr. at 26-27)

Thereafter, in a new paragraph beginning with the words "Even if . . ." (the "'Even if' paragraph"), the patentee addressed the Examiner's argument that Bodor "implied" that after its cladribine-free period, "'treatment with cladribine is resumed'" (i.e., that Bodor "implied" the existence of a maintenance period). ('903 patent history at MAVMRK_000000979) The patentee stated 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*." (*Id*. (emphasis added)) The "Even if" paragraph ends with the following sentence: "Thus, the combined teachings of the references would not have lead one skilled in the art to a dosing regimen and/or total dosages recited in claims 1, 4, 5, 9, 10, 17, 20, or 21." (*Id*.)

Defendants latch on to this last part of the patentee's August 2012 response in the "Even if" paragraph—arguing that therein, the patentee was conveying that *all* of the claims in the application (including claims 17 and 20, which were referenced in the paragraph's concluding sentence by the patentee) required a lower dosage of cladribine in the maintenance period than

that in the induction period. For the following reasons, however, the Court disagrees that prosecution history disclaimer applies here:

- Defendants' argument appears to make certain of the patentee's above-referenced August 2012 comments to the Examiner seem like non-sequiturs. As was noted above, when the patentee was distinguishing its claims from Bodor, it explained that nowhere in Bodor's teachings was there any mention "about 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[.]'" (*Id.* (emphasis added)) Here, the Court understands the patentee to have been arguing that Bodor did not disclose a maintenance period of any kind, whereas the claimed inventions do include a maintenance period. If Defendants' view of the prosecution history is to be credited, at the same time the patentee was making this statement to the Examiner, it was *also* separately conveying to the Examiner that its invention always required the maintenance period dose of cladribine to be lower than the induction period dose. And yet if that is so, it seems strange that in the above-referenced quotation, the patentee would use the phraseology "at either the *original dosage* or at a lower dosage"—even in reference to describing what Bodor failed to disclose. That is because the point of the patentee's remarks to the Examiner was to contrast Bodor with *what was claimed in its own invention*. In light of this, why would the patentee make reference to the existence of a maintenance period that included a dosage limit that was the same as the "original dosage"—if such a period was simply outside the bounds of its own invention? To the contrary, the patentee's "original dosage" phraseology suggests that the patentee may have been conveying that some of the claims of what was to become the '903 patent (like claims 17 or 20) allowed for a dose in the maintenance period that could be the same as the "original dosage." (D.I. 67 at 25; Tr. at 27, 71)

- The Court acknowledges that the ending of the key "Even if" paragraph is confusing. In the bulk of that paragraph, the patentee is focused on distinguishing Bodor on the ground that Bodor would not teach a regimen in which the dosage in the maintenance period is lower than that in the induction period. But the paragraph ends with the sentence "[t]hus, the combined teachings of the references would not have led one skilled in the art to a dosing regimen and/or total dosages recited in claims 1, 4, 5, 9, 10, 17, 20, or 21." Claims 17 and 20 do not

include an explicit limitation requiring that the maintenance period dosage be "lower"—but yet the patentee made reference to them in this paragraph. Was the patentee thus suggesting that even *those* claims, in all instances, required that the maintenance period dosage must be lower than the induction period dosage? Defendants assert that this is the case. However, the Court does not agree that this is the correct read. Instead, the sentence's mention of "the combined teachings of the references" seems to indicate that the patentee's intent here was to sum up all of the arguments it had made in the paragraphs above about how one could distinguish each of the claims from all of the prior art at issue. (Tr. at 29-30)[9] Those arguments included not only the one made in the "Even if" paragraph about certain claims' use of a lower dosage in the maintenance period, but also arguments about how, *inter alia*, Bodor could be distinguished due to other aspects of its "dosing regimen"—such as the fact that Bodor did not disclose the use of any maintenance period at all. Such an argument could have been enough to distinguish claims 17 and 20 from Bodor, even were Plaintiffs' proposed constructions here correct. (D.I. 67 at 40; Tr. at 29-30; Plaintiffs' *Markman* Presentation, Slides 39-40)

- It seems illogical for the patentee to include a claim in the application like claim 20, which calls for a total dosage in the maintenance period that reads as the same as that in the induction period (i.e., both are "about 1.7 mg/kg"), and then in the "Even if" paragraph to state that *in this claim too* the maintenance period dosage must *always be lower* than the induction period dosage. (D.I. 67 at 40; Tr. at 31) If the patentee's statement in the "Even if" paragraph were interpreted in this way, it would seem to undercut the very reason for claim 20's existence. (*Id*.)

In sum, as was noted above, there are portions of the relevant prosecution history that are confusing, or where the patentee used language that might, at first glance, give some force to Defendants' position. But for the reasons set out above, in the end the Court believes that the patentee was not disclaiming the claim scope at issue here. At a minimum, the patentee's

[9] The patentee could have made this clearer by simply making this final sentence its own paragraph, but unfortunately it did not do so. (Tr. at 29-30)

statements do not amount to clear and unmistakable disclaimer.[10] And so with the intrinsic evidence otherwise strongly supporting Plaintiffs' positions, the Court will adopt Plaintiffs' proposed constructions.

## IV. CONCLUSION

For the foregoing reasons, the Court adopts the following constructions:

1. "induction period" should be construed to mean "initial treatment period"

2. "maintenance period" should be construed to mean "treatment period that follows the induction period and the cladribine-free period"

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Report and Recommendation. Fed. R. Civ. P. 72(b)(2). The failure of a party to object to legal conclusions may result in the loss of the right to de novo review in the district court. *See Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006); *Henderson v. Carlson*, 812 F.2d 874, 878-79 (3d Cir. 1987).

The parties are directed to the Court's Standing Order for Objections Filed Under Fed. R. Civ. P. 72, dated March 7, 2022, a copy of which is available on the District Court's website, located at http://www.ded.uscourts.gov.

Dated: June 13, 2024

Christopher J. Burke
Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE

[10] Even if statements made in the prosecution history do not amount to disclaimer, they can still be helpful in claim construction. *Shire Dev., LLC v. Watson Pharms., Inc*., 787 F.3d 1359, 1366 (Fed. Cir. 2015) ("Although the prosecution history statements do not rise to the level of unmistakable disavowal, they do inform the claim construction."); (Tr. at 48). For the reasons set out above, the Court believes that the prosecution history at issue can be read in line with Plaintiffs' arguments or, at a minimum, does not clearly contradict Plaintiffs' arguments. Put differently, here the other intrinsic evidence strongly supports Plaintiffs' position, and the prosecution history does not counsel a different path.