IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

MERCK SHARP & DOHME LLC, Plaintiff, v. THE JOHNS HOPKINS UNIVERSITY, Defendant.	Civil Action No. 22-cv-03059-JRR

THE JOHNS HOPKINS UNIVERSITY'S
OPENING CLAIM CONSTRUCTION BRIEF

JHU 2161
Merck Sharp v. Johns Hopkins
IPR2024-00649

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Exhibit No.	Description
Exhibit 1	U.S. Patent No. 11,591,393 ("'393 Patent")
Exhibit 2	U.S. Patent No. 11,649,287 ("'287 Patent")
Exhibit 3	U.S. Patent No. 11,643,462 ("'462 Patent")
Exhibit 4	U.S. Patent No. 11,629,187 ("'187 Patent")
Exhibit 5	U.S. Patent No. 11,634,491 ("'491 Patent")
Exhibit 6	U.S. Patent No. 10,934,356 ("'356 Patent")
Exhibit 7	U.S. Patent No. 11,325,974 ("'974 Patent")
Exhibit 8	U.S. Patent No. 11,325,975 ("'975 Patent")
Exhibit 9	U.S. Patent No. 11,339,219 ("'219 Patent")
Exhibit 10	File History of U.S. Patent App. No.17/465,101 ('393 Patent), (March 22, 2022 Declaration of Andrew Pardoll, M.D.) (JHU_MERCK00003298-3497)
Exhibit 11	NEJM Article citations (Google Scholar)
Exhibit 12	Compiled excerpts of Merck IPR Nos. 2024-00240; 2024-00622; 2024-00623; 2024-00624; 2024-00625; 2024-00647; 2024-00648; 2024-00649; and 2024-00650 against Asserted Patents.
Exhibit 13	File History of U.S. Patent App. No.17/465,101 ('393 Patent), (01.10.2023 Notice of Allowance) (JHU_MERCK00013514-3522

Pursuant to Local Rule 805(1)(g) and the Scheduling Order (ECF No. 57), The Johns Hopkins University ("JHU") respectfully submits this Opening Claim Construction Brief in support of its proposed constructions of the disputed claim terms of U.S. Patent Nos. 11,591,393 ("'393 Patent") (Ex. 1); 11,649,287 ("'287 Patent") (Ex. 2); 11,643,462 ("'462 Patent") (Ex. 3); 11,629,187 ("'187 Patent") (Ex. 4); 11,634,491 ("'491 Patent") (Ex. 5); 10,934,356 ("'356 Patent") (Ex. 6); 11,325,974 ("'974 Patent") (Ex. 7); 11,325,975 ("'975 Patent") (Ex. 8); and 11,339,219 ("'219 Patent") (Ex. 9) (the "Asserted Patents").

I. INTRODUCTION

The JHU invention at the heart of this litigation was a triumph of basic research, dramatically changed cancer therapy and has saved countless lives. While the financial and publicity benefits to Merck Sharp & Dohme LLC ("Merck") have been substantial, they pale in comparison to Merck's immense greed. While repeatedly and publicly crediting JHU researchers for their pioneering invention, Merck has used JHU's patented invention without the right to do so. Merck has made billions of dollars from its willful infringement of JHU's rights but has not shared a penny with JHU, thereby depriving JHU of the funding needed to create the world's next important inventions.

There can be no doubt that Merck's infringement is and has been willful. Merck knew about the Asserted Patents when they were pending before the Patent Office and approached JHU about a license in 2017. Merck then chose to play the odds and await issuance of the patents before continuing those license discussions. When the parties finally reengaged, Merck chose not to take a license and to instead continue using JHU's patents without right or compensation. Merck then filed this suit against JHU premised on a fanciful breach of contract claim alleging that it is a co-owner of the Asserted Patents—a claim that it never once mentioned during the preceding six years

of discussions between the parties. And most recently, Merck challenged the validity of the Asserted Patents—patents it claims to own—at the Patent Office.

Now, rather than concede its obvious infringement, Merck has ginned up ten claim construction disputes for the Court to resolve. Nine of these terms use simple unambiguous words readily understood by those of skill in the art to mean what they say. These terms require no construction. Construction of the tenth term is a simple matter because the specification explains what the term means. Rather than accept the ordinary meaning of these claim terms, as would be consistent with Federal Circuit authority, Merck asks this Court to instead accept constructions created out of whole cloth in order to fashion noninfringement defenses where there are none.

Merck's proposed constructions violate the most basic tenet of patent claim construction: "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). Abiding by this principal, JHU proposes that the words of the claims should be afforded the full scope of their ordinary meaning. In contrast, Merck asks the Court to ignore the plain words of the claims and (in one case) the meaning found in the specification, while pointing to nothing in the intrinsic record that comes close to the clear and unequivocal disavowal of claim scope required before a court can consider deviating from the plain meaning of the claim terms. JHU's proposed constructions are correct and, respectfully, should be adopted by the Court in their entirety.

II. THE ASSERTED JHU PATENTS

The Asserted Patents describe and claim methods for treating a group of cancer patients with the drug pembrolizumab ("Pembro"). Pembro is sold by Merck under the brand name Keytruda®. Pembro is a member of a class of drugs known as anti-PD-1 antibodies. The JHU inventions relate generally to using anti-PD-1 antibodies or Pembro to treat patients in response to

determining the patient's cancer has a particular genetic marker known as high microsatellite instability ("MSI-H") or DNA mismatch repair deficiency ("dMMR").

The patented inventions arose from the work of JHU researchers trying to understand why, in a previous study they conducted, one cancer patient had a complete recovery when treated with an anti-PD-1 drug similar to Pembro, while 32 other patients showed no response to the same drug. Solving this immensely difficult problem required the collaboration of two typically discrete research groups—a group of leaders in cancer immunology and a group of leaders in cancer genetics. Together, the JHU researchers ultimately hypothesized that the one patient's anomalous response might be related to what was later determined to be his MSI-H status. Anxious to determine whether their hypothesis had any merit, the JHU researchers sought funding and support for a clinical trial.

The researchers approached Merck. Merck had acquired Pembro, which was developed years earlier by another company, as part of a sequence of corporate acquisitions. Under Merck's management, work on Pembro languished, and the drug had not been approved by FDA for any indication at the time of JHU's approach. Skeptical of JHU's idea, Merck declined to fund the trial. Merck did agree to supply Pembro for the trial, but otherwise left JHU on its own to design, develop, conduct and fund the clinical trial—tasks commonly undertaken by pharmaceutical companies. Confident in the importance to cancer patients of their hypothesis if it proved correct, the JHU researchers obtained philanthropic funding, instead, and conducted all aspects of the clinical trial themselves. The results of this JHU research were nothing short of amazing. Patients who had been given days or weeks to live recovered and were on their way to ultimately being cancer free.

The JHU research was so novel that it resulted in the FDA granting the ***first ever*** approval for a tissue/site-agnostic cancer therapy based on a biomarker. Ex. 10 at JHU_MERCK00003397-99. The FDA explained the importance of JHU's discovery when it announced its pioneering approval:

> This is an important first for the cancer community . . . Until now, the FDA has approved cancer treatments based on where in the body the cancer started—for example, lung or breast cancers. We have now approved a drug based on a tumor's biomarker without regard to the tumor's original location.

Id. at JHU_MERCK00003495-97. JHU's discovery that the MSI-H/dMMR marker can be a useful tool to prescribing physicians treating cancer patients has dramatically changed the field of cancer therapy and saved countless lives. *See e.g.*, *Id.* at JHU_MERCK00003483-86, 3488-93.

JHU's discovery has also resulted in billions of dollars of revenue for Merck. The story of JHU's invention and Merck's good fortune in having supplied Pembro to the JHU researchers is memorialized in a Forbes article, written by a former Merck insider: "Good Luck Coming In Over The Transom—It was Pasteur who famously observed that fortune favors the prepared mind—and Merck was the beneficiary of just this sort of good fortune when Merck's leaders received a call from legendary JHU cancer researcher Bert Vogelstein, saying, 'We need to talk.'" *Id.* at JHU_MERCK00003478-79.

Following that fateful day in 2013, and countless hours spent by JHU researchers conducting clinical trials, the results of JHU's research were announced to the scientific community. On May 30, 015, Dr. Dung Le, a professor of oncology at JHU stood before a packed house at the 51st annual meeting of the American Society of Clinical Oncology ("ASCO") in Chicago, Illinois. *Id.* at JHU_MERCK00003392-95. The oncology community had gathered to hear the details of JHU's groundbreaking clinical trial. Dr. Le's talk was viewed by thousands of the world's leading cancer researchers. *Id.* That same day, and with carefully orchestrated timing,

those same results were published in the New England Journal of Medicine ("NEJM")—the world's leading medical journal—in an article entitled "PD-1 Blockade in Tumors with Mismatch-Repair Deficiency." *Id*. at JHU_MERCK00003379-90. As yet another objective indication of the groundbreaking nature of JHU's discovery, Dr. Le's article has been cited by nearly 10,000 academic papers. *See, e.g.*, Ex. 11.

III. LEGAL STANDARDS

A. Claim Construction

Claim construction is a question of law, "engaging in much the same task as the judge would be in construing other written instruments, such as deeds, contracts, or tariffs." *Teva Pharma. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837 (2015). "The purpose of claim construction is to resolve 'disputed meanings and technical scope, to clarify and when necessary to explain what the patentee covered by the claims, for use in the determination of infringement' or invalidity." *Promptu Sys. Corp. v. Comcast Corp.*, 92 F.4th 1372, 1380 (Fed. Cir. 2024) (quoting *U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997)). "[T]he construction of claims is simply a way of elaborating the normally terse claim language[] in order to understand and explain, but not to change, the scope of the claims." *Embrex, Inc., v. Serv. Eng'g Corp.*, 216 F.3d 1343, 1347 (Fed. Cir. 2000). "[O]nly those [claim] terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy." *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999). Where the words of a claim are unambiguous and easily understood by those of skill in the art in view of the patent's specification, the Court need not replace the words selected by the patent applicant and approved by the Patent Office with other words to satisfy its claim construction role. *U.S. Surgical*, 103 F.3d at 1568 ("The *Markman* decisions do not hold that the trial judge must repeat or restate every claim term in order to comply

with the ruling that claim construction is for the court. Claim construction . . . is not an obligatory exercise in redundancy.”).

“The claim construction analysis must begin and remain centered on the claim language itself” because 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*, 415 F.3d 1303, 1312. Accordingly, a court must “look to the words themselves . . . to define the scope of the patented invention.” *Aventis Pharms. Inc. v. Amino Chems. Ltd.*, 715 F.3d 1363, 1373 (Fed. Cir. 2013) (citing *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). The claims provide important guidance by showing both “the context in which a term is used” and “[d]ifferences among claims.” *Phillips*, 415 F.3d at 1314-15.

The “words of a claim are generally given their ordinary and customary meaning.” *Id*. at 1312. That is the meaning “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 1313 “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.

There are only two exceptions to the general rule of giving claim terms their ordinary and customary meaning: “(1) when a patentee sets out a definition and acts as his own lexicographer, or (2) when the patentee disavows the full scope of a claim term either in the specification or during prosecution.” *Unwired Planet, LLC v. Apple Inc.*, 829 F.3d 1353, 1358 (Fed. Cir. 2016); *Thorner v. Sony Comput. Entm’t Am. LLC*, 669 F.3d 1362, 1367 (Fed. Cir. 2012) (“It is the claims that define the metes and bounds of the patentee’s invention . . . The patentee is free to choose a broad

term and expect to obtain the full scope of its plain and ordinary meaning unless the patentee explicitly redefines the term or disavows its full scope.”).

In the event the ordinary meaning of a claim is not apparent, then a court may look to “the words of the claim themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.” *Phillips*, 415 F.3d at 1313. In general, courts engaging in claim construction follow a hierarchy of evidence: (i) claim language, (ii) other intrinsic evidence—i.e., the specification, the remainder of the patent, and the prosecution history, and (iii) extrinsic evidence—i.e., evidence that is external to the patent and prosecution history, such as expert testimony, dictionaries, or treatises. *Id*. at 1317.

The claims provide critical guidance by showing both “the context in which a term is used” and “[d]ifferences among claims.” *Id*. at 1314-15; *see also id*. (“For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim.”). The specification also is “always highly relevant” and “may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess.” *Id*. at 1317. But the specification must be used with care: “it is improper to read limitations from a preferred embodiment described in the specification—even if it is the only embodiment—into the claims absent a clear indication in the intrinsic record that the patentee intended the claims to be so limited.” *Dealertrack, Inc. v. Huber*, 674 F.3d 1315, 1327 (Fed. Cir. 2012); *Unwired Planet*, 829 F.3d at 1359 (“[W]e have repeatedly held that it is ‘not enough that the only embodiments, or all of the embodiments, contain a particular limitation’ to limit claims beyond their plain meaning.”); *Promptu Sys. Corp.*, 92 F.4th at 1379 (“Our case law has long recognized that particular features recited in the specification

merely as aspects of embodiments, and not expressly or even implicitly identifying requirements of the invention, do not narrow a claim term that is otherwise broader in its ordinary meaning.") After all, a "patentee need not 'describe in the specification every conceivable and possible future embodiment of his invention.'" *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002) (quoting *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1344 (Fed. Cir. 2001)). "To disavow claim scope, the specification must contain 'expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope.'" *Cont'l Circuits LLC v. Intel Corporation*, 915 F.3d 788, 797 (Fed. Cir. 2019) (citing *Retractable Techs., Inc. v. Becton, Dickinson & Co.*, 653 F.3d 1296, 1306 (Fed. Cir. 2011) (quoting *Epistar Corp. v. Int'l Trade Comm'n*, 566 F.3d 1321, 1335 (Fed. Cir. 2009)).

While a patent's prosecution history may be considered as part of the claim construction process, such consideration should also be done with caution because this document "represents an ongoing negotiation between the 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. Thus, similar to purported disclaimers in the specification, "[t]o operate as a disclaimer, the statement in the prosecution history must be clear and unambiguous, and constitute a clear disavowal of scope." *Cont'l Circuits*, 915 F.3d at 798. "Absent a clear disavowal in the specification or the prosecution history, the patentee is entitled to the full scope of its claim language." *Home Diagnostics, Inc. v. LifeScan, Inc.*, 381 F.3d 1352, 1358 (Fed. Cir. 2004).

Although courts are permitted to consider extrinsic evidence, like expert testimony, dictionaries, and treatises, such evidence is generally of less significance than the intrinsic record. *Phillips*, 415 F.3d at 1317. Extrinsic evidence may not be used "to contradict claim meaning that

is unambiguous in light of the intrinsic evidence." *Id.* at 1324. Dictionaries are particularly unhelpful where the meaning of the term is readily apparent to even lay judges and juries such that construction involves little more than application of the widely accepted meaning of the commonly used word. *Durr Sys. v. EFC Sys.*, No. GJH-18-2597, 2021 WL 5178240, at *11 (D. Md. Nov. 8, 2021).

B. Indefiniteness

Because Merck has indicated an intent to address the invalidity defense of indefiniteness during the claim construction process, JHU provides the Court with a brief discussion of relevant precedent. A claim is definite when it "inform[s] those skilled in the art about the scope of the invention with reasonable certainty." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 910 (2014). A finding of indefiniteness renders a claim invalid and, as such, must be proven by clear and convincing evidence. *Id.* at 902. Because questions of indefiniteness require a high burden of proof to resolve, and are better considered in connection with other challenges to patent validity, courts in this Circuit often decline to resolve them during claim construction, instead deferring consideration of such issues until summary judgment or trial to allow for a fully developed record. *See, e.g.*, *G.W. Aru, LLC v. W.R. Grace & Co. -Conn.*, No. JKB-22-2636, 2023 WL 7170356, at *19 (D. Md. Oct. 30, 2023) (declining to decide indefiniteness at the Markman stage, in part, because Defendant failed to cite any evidence "that shows that a POSITA would not understand the objective boundaries of the term."); *see also Gilead Scis. Inc. v. Mylan, Inc.*, No. 14CV99, 2015 WL 1534067, at *2 (N.D. W. Va. Apr. 6, 2015) ("[M]any judges have elected to wait and tackle indefiniteness at the summary judgment stage" due to "the high burden of proof on the party challenging a patent claim for indefiniteness," "the fact that a claim is not indefinite merely because the parties dispute its meaning," and "the dispositive effect of a ruling on indefiniteness.");

Trs. of Purdue Univ. V. Wolfspeed, Inc., No. 21-840, 2024 WL 1178864, at *6 (M.D.N.C., Mar. 19, 2024) (same).

IV. PROPOSED INTERPRETATION OF DISPUTED CLAIM TERMS

A. "in response to" ('393 patent, '287 patent, '462 patent, '187 patent, '491 patent)

JHU's Construction	Merck's Construction
Plain and ordinary meaning, which is: "in response to"	"as the reaction specifically to"

The term "in response to" is clear on its face and requires no construction. Where "the plain and ordinary meaning of the disputed language is clear, the district court does not err by declining to construe the term." *Summit 6, LLC v. Samsung Elecs. Co.*, 802 F.3d 1283, 1291 (Fed. Cir. 2015) (District Court did not err by declining to construe "being provided to" because the phrase "is comprised of commonly used terms; each is used in common parlance and has no special meaning in the art."). "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." *Phillips*, 415 F.3d at 1314.

As the Federal Circuit in *Promptu* instructed, "a claim construction, if needed at all, should help resolve, not add to, uncertainty in the understanding the finder of fact is to use in applying a claim term." 92 F.4th at 1380. Merck's proposed construction does just the opposite; it disregards the plain words and meaning of the simple claim phrase "in response to" and replaces it with a narrow and ambiguous phrase—"as the reaction specifically to." Adopting Merck's proposed construction would leave the factfinder with the following perplexing claim language: "[***as the reaction specifically to***] ***determining*** that the colorectal cancer is microsatellite instability high or

DNA mismatch repair deficient[.]" *E.g.*, Ex. 1 ('393 Patent) at claim 1 (alteration reflecting Merck's proposed language). In contrast to the instruction in *Promptu*, such a construction would create confusion and uncertainty for the factfinder and invite more litigation as the parties further dispute the meaning of this obscure language.

Merck's proposed construction apparently (although given the ambiguous nature of its proposal, it is unclear) seeks to deprive JHU of the full scope of the claims that it secured during prosecution before the Patent Office. *Phillips*, 415 F.2d at 1320; *see also Kara Tech Inc., v. Stamps.com Inc.*, 582 F.3d 1341, 1348 (Fed. Cir. 2009) ("The patentee is entitled to full scope of his claims, and we will not limit him to his preferred embodiment or import a limitation from the specification into the claims."). There is no basis for Merck's construction of the words of the disputed phrase—"in response to." The phrase is unambiguous and would be understood by a person of ordinary skill and, for that matter, a lay person, to mean what it says. *See Promptu*, 92 F.4th at 1378 (rejecting district court's narrow construction of "back channel," "we see nothing in the meaning of the quite general term 'channel' that limits" the back channel's path in the manner required by the district court's construction.).

Indeed, Merck did not argue that JHU had imparted a novel meaning to this phrase (or any other phrase in any of the Asserted Patents) or that JHU had disclaimed claim scope during prosecution of any Asserted Patent when it requested *inter partes* review (IPR)[1] of the Asserted Patents. Instead, as JHU urges here, Merck gave the phrase (and every other phrase it challenges before this Court) its plain and ordinary meaning. *See* Ex. 12 at 2 (acknowledging that "claims are typically given their ordinary and customary meanings"). Merck's contention that construction

[1] *Inter partes* review is a proceeding that can be requested by an accused infringer in which the Patent Office is asked to reconsider the patentability of issued patent claims. The Patent Office has discretion to not institute such proceedings.

of the claims was unnecessary when it challenged validity before the Patent Office only to turn around and contend that construction is needed in this litigation is irreconcilable, given that the applicable legal rules of claim construction before this Court are identical to those applied by the Patent Office in IPRs. 37 C.F.R. § 42.100(b) (Claims "shall be construed using the same claim construction standard that would be used to construe the claim in a civil action."); *Phillips*, 415 F.3d at 1313.

Merck does not identify any portion of the specification where JHU acted as its own lexicographer to define "in response to" to mean "as the reaction specifically to" or otherwise clearly disavowed the full scope of the plain meaning of the phrase actually used in the claims. In Appendix A to the Joint Claim Construction Statement ("JCCS") (ECF No. 71-1), Merck identifies passages from the '393 Patent's specification it alleges support its proposed construction. But the cited passages merely discuss the invention story and the phase 2 clinical trial JHU used to validate its hypothesis. *See, e.g.*, ECF No. 71-1 at 1 citing '393 Patent at 3:15-21, 5:45-51, 6:16-18. At most, these passages disclose that anti-PD-1 antibodies such as Pembro are more effective against MSI-H/dMMR tumors and cancers than MSS/NMR proficient tumors and cancers.[2]

The cited passages thus have no bearing on the meaning of the language at issue, and certainly do not evidence disavowal of claim scope with expressions of "manifest exclusion or restriction." *Cont'l Circuits*, 915 F.3d at 797-98. Indeed, the Federal Circuit has repeatedly emphasized that an inventor's description of the best mode or a preferred embodiment does not constitute disavowal of claim scope or limit the invention to that single mode or embodiment. *See Cont'l Circuits*, 915 F.3d at 797-98 (finding "descriptions of the 'present invention'" or phrases

[2] During the meet and confer process, JHU asked Merck to identify with specificity the portions of the intrinsic record that supported its proposed narrowing. Merck declined.

describing a single embodiment such as "one technique" or "can be carried out" in "a way," do not constitute clear disavowal of claim scope); *Unwired Planet*, 829 F.3d at 1359 ("we have repeatedly held that it is 'not enough that the only embodiments, or all of the embodiments, contain a particular limitation' to limit claims beyond their plain meaning."); *see also 10x Genomics, Inc. v. NanoString Techs., Inc.*, No. 21-653-MFK, 2023 WL 2265744, at *4 (D. Del. Feb. 28, 2023) ("a patentee's characterization of a disclosure as important to the invention, or as 'the invention' itself, does not by itself amount to disavowal" and finding that patentee's repeated description of the purpose of the invention as doing x-thing—and how it was different than the prior art that did not do x-thing—was not disavowal) (citing *Thorner*, 669 F.3d at 1365).

Nor did JHU make any statements in the prosecution history that show clear and unambiguous disavowal of claim scope. In fact, when JHU amended current claim 1 (then, claim 2) during prosecution of the '393 Patent to add the term "in response to," the Examiner understood the term to have its common meaning, and she used the shorthand "based on" to express that meaning. *See* Ex. 13 at JHU_MERCK00013521 (explaining that the [prior art] "does not treat the patient ***based on*** a determination of microsatellite instability high or DNA mismatch repair deficient as claimed.") (emphasis added). The Examiner's shorthand expression certainly provides no support for Merck's proposed construction.

Much like statements in the specification, statements by JHU or the Examiner during prosecution at most detail how MSI-H/dMMR tumors are especially susceptible to anti-PD-1 inhibitors and that such a phenomenon was not found in the prior art. Comparing and contrasting the claimed method to that of the prior art during prosecution does not create a clear and unambiguous disavowal of claim scope. *Thorner*, 669 F.3d at 1366. Without a clear disavowal in

the specification or prosecution history, JHU is entitled to the full scope of the claim language. *Home Diagnostics, Inc. v. LifeScan Inc.*, 381 F.3d 1352, 1358 (Fed. Cir. 2004).

B. "therapeutically effective amount of pembrolizumab" ('393 patent, '287 patent, '462 patent, '187 patent, '491 patent)

JHU's Construction	Merck's Construction
Plain and ordinary meaning, which is: "therapeutically effective amount of pembrolizumab" If the Court finds construction necessary: "an amount of pembrolizumab sufficient to produce the desired effect"	"an amount of pembrolizumab that exhibits an improved response in the patient with an MSI-H or dMMR tumor, when compared to a patient with an MSS or MMR proficient cancer" Alternatively: "10 mg/kg every 14 days" or indefinite

Once again, the words of this disputed claim phrase are simple, unambiguous and require no construction. *See Summit 6*, 802 F.3d at 1291. Rather than accept what the claim phrase says, Merck asks this Court to impose either of two narrow constructions. The words of the claim phrase provide no basis for Merck's proposed importation of either "when compared to a patient with an MSS or NMR proficient cancer" or "10 mg/kg every 14 days." It is the claim language that governs the scope of the claim (*Phillips*, 415 F.3d at 1312) and here, the claim language says nothing about comparing a response in one group of patients to another or about a specific dosing regimen.

Courts have repeatedly held that a person of skill would readily understand the plain and ordinary meaning of "therapeutically effective amount." *Pfizer Inc. v. Teva Pharms., USA, Inc.*, 803 F. Supp. 2d 397 (E.D. Va. 2011) (construing "an effective amount [of a compound to treat erectile dysfunction]" to "require[] no construction because a person ordinarily skilling in the art reading the patent would understand its ordinary and customary meaning."); *AstraZeneca AB v. Dr. Reddy's Labs., Ltd*, No. 05-5553 (JAP), 2010 WL 1981790, at *9 (D.N.J. May 18, 2010)

("Because its ordinary and customary meaning would be clear to one skilled in the art, the Court declines to construe 'therapeutically effective amount.' The ordinary meaning of the term as understood by those of ordinary skill in the art shall apply."). The Court should do the same here. A person of skill in the art reading the claims would readily understand the meaning of the term as used in the claims and in the context of the specification. *See Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1323 (Fed. Cir. 2003) (Unless the patentee unequivocally imparted a "novel meaning" to a term, the Court must "indulge a heavy presumption that claim terms carry their full ordinary and customary meaning.").

Should the Court, however, determine that construction of this phrase is required, JHU proposes a construction similar to that proposed by the patentee in *Pfizer* as an alternative—"an amount of pembrolizumab sufficient to produce the desired effect." *See Pfizer,* 803 F. Supp. 2d at 408 ("If the court does find that the term must be construed, Pfizer proposes "an amount sufficient to produce the desired effect."). This construction aligns with the desired effects sought by the various claims in response to the "therapeutically effective amount" of drug:

- treating microsatellite instability high or DNA mismatch repair deficient colorectal cancer
- reducing the risk of cancer progression or increasing overall survival
- treating colorectal cancer
- reducing the risk of progression of colorectal cancer
- treating a patient having a solid tumor
- prescribing a treatment for a solid tumor
- reducing the risk of progression of a solid tumor
- treating cancer

JHU's proposed alternative construction is also consistent with the Federal Circuit's and other court's recognition that the phrase "effective amount" "has a customary usage." In *Abbott v. Baxter*, 334 F.3d 1274, 1277 (Fed. Cir. 2003), the Federal Circuit reversed the district court's grant of summary judgment of non-infringement because it was based on an erroneous

construction which read into the phrase "effective amount" a limitation requiring a particular water content (above 131 ppm). In addressing the limitation, the Federal Circuit observed that the customary usage of the term in the context of the claims at issue, albeit not its construction, was analogous to an amount sufficient to produce the desired effect of the claim—"preventing degradation by a Lewis acid of a quantity of sevoflurane." *Id*. at 1194. Following the *Abbott* case, a Delaware district court construed "effective amount" in the claim, "A method of decreasing a risk of cardiovascular hospitalization in a patient, said method comprising administering to said patient *an effective amount* of dronedarone," to mean "an amount effective to decrease a risk of cardiovascular hospitalization." *Sanofi v. Glenmark Pharms. Inc.*, No. 14-264-RGA, 2015 WL 5092631, at *15 (D. Del. Aug. 28, 2015). In so doing, the district court observed that "'[e]ffective amount' has a customary usage: the amount that is effective to accomplish the purpose of the claim. In this case, the claim is addressed to decreasing a risk of cardiovascular hospitalization. The proper construction of 'effective amount' is therefore the amount that achieves that goal." *Sanofi*, 2015 WL 5092631, at *15-16 (citing *Abbott*, 334, F.3d at 1277-78).

Merck had no trouble understanding the term when it filed its IPRs against the Asserted Patents. *See* § IV.A., *supra*; Ex. 12. Only now does Merck assert that the term's meaning cannot be understood and asks the Court to import limitations found nowhere in the claims. With regard to Merck's first proposed construction, certainly, JHU knew how to draft claims that include a comparison step similar to the comparison that Merck asks the Court to import into these particular claims. JHU's asserted '219, '974 and '975 Patents all recite in their respective claim 1 "administering an effective amount of pembrolizumab to the patient" and "the patient exhibits an outcome that is improved as compared to a corresponding outcome that would be observed in a reference patient that has been administered pembrolizumab, wherein the reference patient has a

tumor that does not exhibit a MSI-high or a MMR deficiency status." *See, e.g.*, Exs. 7 ('974 Patent), 8 ('975 Patent), and 9 ('219 Patent) at claim 1. When JHU drafted the claims of the '393, '287, '462, '187 and '975 Patents, it specifically chose ***not*** to include such a comparison requirement. The Patent Office, after considering the prior art and the rules applicable to patent drafting, determined these claims, without such a comparison requirement, to be patentable. JHU was free to choose to claim its invention broadly and should "expect to obtain the full scope of its plain and ordinary meaning unless [JHU] explicitly redefine[d] the term or disavow[ed] its full scope." *Thorner*, 669 F.3d at 1367. JHU did neither.

Merck's second proposed construction of "10 mg/kg every 14 days" should also be rejected as it seeks to limit the claims to a single dosage embodiment described by the specification. While the specification mentions the dosage of 10 mg/kg every 14 days used in JHU's clinical trial, it does not specify that this is the only dosing regimen that will be therapeutically effective. *See, e.g.*, Ex. 1 ('393 Patent) at 5:53-61 (detailing that other anti-PD-1 antibodies (besides Pembro) and other administration methods may be used). Accordingly, it would be improper to read the requirements of one embodiment into the claims. *Phillips* at 1323 (cautioning "to avoid the danger of reading limitations from the specification into the claim," as "persons of ordinary skill in the art rarely would confine their definitions of terms to the exact representations depicted in the embodiments."). Even if 10 mg/kg every 14 days were the only dosage described by the specification, it would still be improper to limit the claims to that single embodiment unless there was evidence of a clear intention by the patentee to do so. *See Cont'l Circuits*, 915 F.3d at 797 ("We have expressly rejected the contention that if a patent describes a single embodiment, the claims of the patent must be construed as being limited to that embodiment."); *Dealertrack*, 674 F.3d at 1327; *Unwired Planet*, 829 F.3d at 1359 ("[W]e have repeatedly held that it is 'not enough

that the only embodiments, or all of the embodiments, contain a particular limitation' to limit claims beyond their plain meaning."); *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) ("Even when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction.") (internal quotations omitted).

While Merck must show a clear and unequivocal disclaimer of claim scope in the specification or prosecution history to limit the challenged claims in either manner Merck advances, there is none. Without any textual hook in the claim or any evidence of a lexicographical definition or clear and unmistakable disclaimer, Merck's proposed constructions must be rejected. *MBO Labs., Inc. v. Becton Dickinson & Co.*, 474 F.3d 1323, 1330-31 (Fed. Cir. 2007) (rejecting "construction analysis that does not identify a textual reference in the actual claim language of the claims with which to associate a proffered construction"); *GE Lighting Sols., LLC v. AgiLight, Inc.*, 750 F.3d 1304, 1308-10 (Fed. Cir. 2014) (holding that it was improper to limit the claim scope where the specification contained no evidence that the inventor acted as his own lexicographer to narrowly define the term, nor was there evidence of a disavowal of claim scope in the intrinsic evidence).

Lastly, Merck argues in the alternative that the term "therapeutically effective amount of pembrolizumab" is indefinite under 35 U.S.C. § 112. Merck cannot meet the high burden of showing "by clear and convincing evidence that a skilled artisan could not discern the boundaries of the claim." *Intelligent Verification Sys., LLC v. Microsoft Corp.*, No. 12-525, 2015 WL 12723143, at *4 (E. D. Va. Feb. 25, 2015). The claims are not so abstract or meaningless to render them indecipherable. On its face, the term "therapeutically effective amount of pembrolizumab"

is straightforward and self-explanatory. What's more, the supporting specification includes examples and figures that leave little doubt "that a skilled artisan would have understood the term with reasonable certainty." *Sonix Tech. Co. v. Publ'ns Int'l, Ltd.*, 844 F.3d 1370, 1379 (Fed. Cir. 2017). Given that Merck does not provide any evidence as to why a person of skill in the art would not understand the objective boundary of the term, the Court should reject Merck's argument. *See G.W. Aru*, No. JKB-22-2636, 2023 WL 7170356, at *19 (declining to decide indefiniteness at the Markman stage, in part, because Defendant failed to cite any evidence "that shows that a POSITA would not understand the objective boundaries of the term.").

C. The Risk/Progression Limitations

Merck seeks construction of four similar claim phrases relating to reducing the risk of cancer progression, and in some instances also increasing the patient's overall survival, based on treatment using the claimed methods. Its strategy is essentially the same for these terms as just discussed for the prior claim phrase – importing a comparison step where there is none. Merck also argues in the alternative that each of these claim phrases is indefinite. Again, Merck cannot meet its high burden of showing by clear and convincing evidence that a person of skill could not discern the boundaries of the claim. The terms are straightforward and skilled artisan would understand their meaning with reasonable certainty in view of the examples and figures provided in the specification. As discussed above, the Court should reject Merck's indefiniteness argument.

Because these phrases implicate very similar issues, namely, Merck's effort to import limitations that are not present in the claims (in particular, a comparison step), JHU addresses them together. The claim phrases and the competing positions are provided first, followed by an explanation of why JHU's proposed constructions are correct and Merck's should be rejected.

1. "reducing the risk of cancer progression or increasing overall survival in a human patient who has microsatellite instability high or DNA mismatch repair deficient colorectal cancer" ('393 Patent, claim 14)

JHU's Construction	Merck's Construction
Plain and ordinary meaning, which is: "reducing the risk of cancer progression or increasing overall survival in a human patient who has microsatellite instability high or DNA mismatch repair deficient colorectal cancer"	"the risk of cancer progression or overall survival in a human patient who has microsatellite instability high or DNA mismatch repair deficient colorectal cancer is reduced or increased compared to a patient with an MSS or MMR proficient cancer" or indefinite

2. "reducing the risk of progression of colorectal cancer in a human patient" ('287 Patent, claim 11)

JHU's Construction	Merck's Construction
Plain and ordinary meaning, which is: "reducing the risk of progression of colorectal cancer in a human patient"	"the risk of cancer progression of colorectal cancer in a human patient is reduced when compared to a patient with an MSS or MMR proficient cancer" or indefinite

3. "reducing the risk of progression of a solid tumor" ('187 patent, Claim 11)

JHU's Construction	Merck's Construction
Plain and ordinary meaning, which is: "reducing the risk of progression of a solid tumor"	"the risk of progression of a solid tumor, is reduced when compared to a solid tumor that is MSS or MMR proficient" or indefinite

4. "reducing the risk of cancer progression or increasing overall survival in a human patient" ('491 Patent, claim 16)

JHU's Construction	Merck's Construction
Plain and ordinary meaning, which is: "reducing the risk of cancer progression or increasing overall survival in a human patient"	"the risk of cancer progression or overall survival in a human patient is reduced or increased when compared to a patient with an MSS or MMR proficient cancer" or indefinite

The issue before the Court again is whether any modification to the words of these claim preambles is required based on the intrinsic record. The answer is plainly no. "Reducing the risk of cancer progression" and "increasing overall survival in a human patient" are simple phrases readily understood by a person of ordinary skill in the art in view of the specification. The plain meaning of these phrases would also be readily understood by a lay jury. *Phillips*, 415 F.3d at 1314-15 ("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.").

This is not a situation where the phrases are unclear or susceptible to reasonable but different interpretations. Consequently, Merck does not seek to define either "reducing the risk of cancer progression" or "increasing overall survival in a human patient." Nor did Merck seek to construe the phrases in its IPRs. *See* § IV.A., *supra*; Ex. 12. Instead, Merck's proposed constructions once again seek to import a comparison with a specific hypothetical patient where none is required by the words of the claim. A person of skill in the art (and a reasonable juror for that matter) would understand that no comparison, let alone the specific comparison advanced by Merck, is required by these claim preambles.

Phillips demands that the inquiry into the meaning of claim terms begin and remain centered on the words of the claims themselves. *Phillips*, 415 F.3d at 1312. Here, the words of the claims clearly define the meaning of the claim terms at issue. Claim 14 of the '393 Patent (Ex. 1) is illustrative and claims in part: "A method of **reducing the risk of cancer progression or increasing overall survival** in a human patient who has microsatellite instability high or DNA mismatch repair deficient colorectal cancer, the method comprising . . . ." Claim 14 goes on to

recite "testing . . . a biological sample obtained from a patient" and "treating the patient with a therapeutically effective amount of pembrolizumab." On its face, the claim language explains that performance of the steps of the method may reduce the risk of cancer progression or increase the overall survival of the patient so treated. The claim says nothing about the comparison Merck proposes. In fact, none of the claims that contain the challenged limitations says anything about the comparison Merck proposes.

Of course, JHU knew how to claim a comparison similar to the comparison Merck seeks to graft onto the challenged claims. For example, JHU's claims 23 and 24 of the '287 Patent (Ex. 2) recite respectively: "The method of claim 11 wherein the treatment increases the median progression free survival of patients having colorectal cancer that is microsatellite instability high or DNA mismatch repair deficient ***compared to the median progression free survival of patients having colorectal cancer that is not microsatellite instability high or DNA mismatch repair deficient***"; and "The method of claim 11, wherein the treatment increases the median overall survival of patients having colorectal cancer that is microsatellite instability high or DNA mismatch repair deficient ***compared to the median overall survival of patients having colorectal cancer that is not microsatellite instability high or DNA mismatch repair deficient***." That JHU did not claim such a comparison in the '393, '287, '187 or '491 Patents is strong evidence that the limitation Merck seeks to read into the claims was not intended by the inventors and should be rejected the Court. *See Phillips*, 415 F.3d at 1314 ("Differences among claims can also be a useful guide in understanding the meaning of particular claim terms.").

In the JCCS, Merck identifies the same passages from the '393 Patent's specification as it did for the "therapeutically effective" phrase discussed above, as support for each of its four proposed constructions. *See, e.g.*, ECF No. 71-1 at 6-11. For similar reasons, none of these

passages bears on the construction of the claim phrases, let alone supports the importation of the comparison advanced by Merck. At most, one of these passages explains: "[T]he data from the small phase 2 trial of pembrolizumab to treat tumors with and without deficiency of MMR supports the hypothesis that MMR-deficient tumors are more responsive to PD-1 blockade than are MMR-proficient tumors." Ex. 1 ('393 Patent) at 6:52-56. Nothing about this disclosure (or any of the other portions of the specification cited by Merck) supports the notion that the plain words of the claim terms should be ignored and the comparison Merck proposes must be added. First, even if any of these passages disclosed a relevant preferred embodiment of the claimed inventions (they don't), it would still be improper to import the language Merck seeks because "it is improper to read limitations from a preferred embodiment described in the specification" into the language of a claim. *Dealertrack*, 674 F.3d at 1327; *Unwired Planet*, 829 F.3d at 1359. Second, nothing in the specification of these patents reveals a special definition or the "clear and unmistakable disclaimer" of claim scope required by the Federal Circuit to deviate from the plain language of a claim term. *Cont'l Circuits*, 915 F.3d at 797.

Finally, nothing that Merck identifies in the prosecution histories of these patents provides the required clear and unambiguous disavowal of claim scope to support Merck's proposed importation of a comparison. *Cont'l Circuits*, 915 F.3d at 798.

D. "objective response rate (ORR)" ('974 patent (claim 3), '975 patent (claims 3 and 10), '219 patent (claim 2))

JHU's Construction	Merck's Construction
"the proportion of patients who achieved best overall response of complete response or partial response"	"The proportion of patients in a research sample who achieved best overall response of complete response or partial response"

The term "objective response rate (ORR)" would be readily understood by a person of skill in the art particularly because the specification of the patents makes clear to the person of skill

what the term means. The specification describes ORR in a manner consistent with the understanding a person of skill in the art would afford the phrase after reading the entirety of the patent—"the proportion of patients who achieved best overall response of complete response or partial response." *See e.g.*, Ex. 9 ('219 Patent) at 14:9-11, Ex. 7 ('974 Patent) at 14:9-11, Ex. 8 ('975 Patent) at 14:5-7 ("ORR (irORR) was the proportion of patients who achieved best overall response of CR [complete response] or PR [partial response] (irCR or irPR).").

Merck's proposed construction does not challenge any aspect of JHU's proposal. Instead, Merck seeks to add a requirement that the patient be part of "a research sample." Merck's proposed construction thus, yet again, reads a limitation into the claims that has no support in the words of the claims or in the intrinsic record. The claims at issue say nothing about "in a research sample."[3] There is no basis for reading "in a research sample" into the claims where there has been no clear disavowal or disclaimer in the specification or prosecution history. *Kara Tech*, 582 F.3d at 1348.

Merck's proposed requirement of "in a research sample" also makes no sense when viewed in the context of the claims. For example, independent claim 1 of the '975 Patent (Ex. 8) makes clear that the individual patient and not a research sample is the focus. The claim recites in relevant part "[a] method for treating cancer in ***a patient*** in need thereof." The claim continues by requiring that "***the patient*** exhibits an outcome that is improved." Claim 3, which depends from claim 1, explains that "the outcome that is improved" can be one of three things: (1) an improved objective response rate (ORR); (2) an improved progression-free survival (PFS); or (3) an improved overall survival. Plainly, these outcomes are directed to an assessment of the improvement experienced by the patient undergoing treatment and not to an assessment of "a research sample." For example,

[3] Merck also provides no definition of what its "research sample" is, when it is obtained or how it is defined. Thus, contrary to the Federal Circuit's direction in *Promptu Sys. Corp.*, 92 F.4th at 1380, Merck's proposal creates ambiguity rather than clarity.

the improvement could be "as compared to any other treatment that may be available to the patient (including no treatment)." *Sanofi-Aventis U.S. LLC v. Sandoz, Inc.*, No. 20-804-RGA, 2022 WL 3081587, at *2-4 (D. Del. Aug. 3, 2022) (construing "increasing survival" to mean "increasing any of: overall survival, tumor progression-free survival, pain progression-free survival, or prostate-specific antigen (PSA) progression-free survival as compared to any other treatment that may be available to the patient (including no treatment).").

Like the rest of the terms Merck seeks to construe, Merck did not advance the narrowed construction of objective response rate it seeks here when it challenged the Asserted Patents in IPR proceedings. *See* § IV.A., *supra*; Ex. 12.

E. "an objective response rate of 40% or higher for microsatellite instability high or DNA mismatch repair deficient colorectal cancer patients" ('393 patent (claims 31 and 37), '287 patent (claims 25 and 31))

JHU's Construction	Merck's Construction
"a 40% or higher percentage of microsatellite instability high or DNA mismatch repair deficient colorectal cancer patients who achieved best overall response of complete response or partial response"	"a 40% or higher proportion of microsatellite instability high or DNA mismatch repair deficient colorectal cancer patients in a research sample"

The phrase "objective response rate" is discussed in the section immediately above. Merck's effort to read "in a research sample" into the claim should be rejected for the same reasons. There does not appear to be much dispute about what the rest of the words of this phrase mean.[4] Thus, the construction should be "a 40% or higher percentage of microsatellite instability high or DNA mismatch repair deficient colorectal cancer patients who achieved best overall response of complete response or partial response." This proposed construction is consistent with the

[4] It is unclear why Merck has changed % (percentage) to "proportion" and whether it is drawing a distinction between the two.

specification's definition of the term "objective response rate (ORR)" and the plain and ordinary meaning of the other words of the phrase of which it is a part. *See* Ex. 8 ('975 Patent) at 14:5-7.

Merck's proposed construction, as discussed above, should be rejected because it again seeks to import the ambiguous phrase "in a research sample." The notion of "in a research sample" is not found in the words of the claims. Importation of a narrowing limitation is also not supported by either the specification or the prosecution history because neither contains the clear disavowal or disclaimer of claim scope required to narrow the claims.

F. "population of cancer patients" ('356 patent) (claims 23 and 27)

JHU's Construction	**Merck's Construction**
Plain and ordinary meaning, which is: "population of cancer patients" If the Court finds construction necessary: "group of cancer patients"	"all cancer patients in the United States"

The term "population of cancer patients" is clear and unambiguous, means exactly what it says, and is well understood by a person of ordinary skill in the art in view of the specification and would also be easily understood by a lay jury. The court need not construe this term. *See Summit 6*, 802 F.3d at 1291.

Once again, Merck proposes constructions that impose narrowing limitations not found in the words of the claims in direct contravention of black letter patent law and in contravention to the position it took in its IPR. Ex. 12. Starting with the claims themselves, claim 23 of the '356 Patent recites "[a] method for treating cancer in a population of cancer patients in need thereof, comprising . . . ." Nothing in the claim suggests that the claimed population is required to include "all cancer patients in the United States." Merck cannot point to a clear and unambiguous disavowal of claim scope in either the specification of the prosecution history, because there is

none. Instead, Merck's proposed construction appears to be based on a dictionary definition of "population." However, there is no evidence in the intrinsic record, that this narrow definition is the meaning of "population" intended by the inventors. *Durr Sys.*, 2021 WL 5178240, at *11 (rejecting the dictionary definition of "conical" because the ordinary meaning of the term is readily apparent even to lay judges and thus the construction involves little more than the application of the widely accepted meaning of this commonly understood word.). In fact, the dictionary definition provided by Merck says nothing about the United States, instead referencing "a specified area" and "group of persons from which a research sample is drawn." Accordingly, Merck's proposed construction of "population of cancer patients" should be rejected and the phrase instead be afforded the full scope of its plain and ordinary meaning.[5]

G. "observing" ('356 patent) (claim 23)

JHU's Construction	Merck's Construction
Plain and ordinary meaning, which is: "observing"	"recognizing and noting a fact or occurrence"

The word "observing" is used in the claim phrase "***observing*** an objective response rate of about 12% to 96% in the population of cancer patients after administration of pembrolizumab." In this context, "observing" would be understood by a person of skill in the art to mean what it says—observing. Merck's proposed construction again runs afoul of the Federal Circuit's ruling in *Promptu* that "a claim construction, if needed at all, should help resolve, not add to, uncertainty

[5] Merck originally proposed the alternative construction: "a *group* of cancer patients from which a research sample is drawn." Merck withdrew this proposal shortly before the JCCS was filed. In an unsuccessful effort to informally resolve the dispute over the construction of this term, JHU proposed a construction that replaced "population" with "group." If the Court sees a need to replace the word "population" with another word, "group" would be acceptable to JHU and consistent with the understanding of a person of skill in the art.

. . . ." 92 F.4th at 1380. No construction of the word "observing" is required as there is no need to replace a well understood word (selected by the inventors and accepted by the Patent Office) with an uncertain seven-word phrase. *U.S. Surgical*, 103 F.3d at 1568 ("Claim construction . . . is not an obligatory exercise in redundancy.").

There is also no support in the record for replacing the commonly understood word "observing" with the ambiguous and confusing phrase "recognizing and noting a fact or occurrence" as Merck proposes. Those words are found nowhere in the claim or elsewhere in the intrinsic record. If anything, Merck's proposal invites further litigation over what it means to "recognize and note," such as whether recognizing without noting would meet the limitation and what action is required to be deemed "noting" or "recognizing." Merck's proposal also imposes the requirement of a generic "fact or occurrence" when the claim is clear about what the word "observing" relates to—"an objective response rate." To illustrate this point, substituting Merck's proposed construction into the claim language would result in the awkward, redundant language: "[recognizing and noting ***a fact or occurrence***] ***an objective response rate*** of about 12% to 96% in the population of cancer patients after administration of pembrolizumab." Ex. 6 ('356 Patent) at claim 23 (alteration reflecting Merck's proposed language).

As support for its proposed construction, Merck points to portions of the specification that detail the invention story and discuss the phase 2 clinical trial that validated the inventor's hypothesis. ECF No. 71-1 at 16 (citing '393 Patent at 2:11-18, 3:15-21, etc.). But as discussed above, language that details the invention, discloses preferred embodiments, and distinguishes the present invention over the prior art does not amount to "expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." *Cont'l Circuits*, 915 F.3d at 796-97. Here, the cited passages in no way represent an intent by JHU to limit the claim scope in the

manner Merck proposes. And Merck certainly cannot point to a clear and unambiguous disavowal of claim scope in the prosecution history to warrant narrowing the claim in the manner it proposes. Again, without any textual hook in the claim or any evidence of a lexicographical definition or clear and unmistakable disclaimer, Merck's improperly narrow proposed constructions must be rejected. *MBO Labs.*, 474 F.3d at 1330-31; *see also Dealertrack*, 674 F.3d at 1327; *Unwired Planet*, 829 F.3d at 1359; *GE Lighting Sols.*, 750 F.3d at 1308-10.

Merck's proposed construction appears to be based on a dictionary definition rather than on the intrinsic evidence. There is no evidence in the intrinsic record that the narrow definition of "observing" selected from the many other definitions encompassed by the word was intended by the inventors or would be appropriate in the context of the claims. *Durr Sys.*, 2021 WL 5178240, at *11. For example, Merck's own dictionary includes definitions such as "watch," "to make a scientific observation," and "to come to realize," yet Merck offers none of these definitions as its proposed construction. The wide range of definitions for words provided by dictionaries and the variance among dictionaries highlights the problem recognized by *Phillips* with over reliance on extrinsic evidence and explains why the claim construction focus must begin and remain on the claims themselves affording terms the full scope of their ordinary meaning. *Thorner*, 669 F.3d at 1367.

Like the rest of the terms Merck seeks to construe, Merck did not advance the narrowed construction of objective response rate it seeks here when it challenged the Asserted Patents in IPR proceedings. *See* § IV.A., *supra*; Ex. 12.

V. CONCLUSION

For the reasons stated above, JHU respectfully requests that the Court adopt its proposed constructions for the disputed claim terms and reject Merck's proposals in their entirety.

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the above and foregoing document has been electronically filed with the Clerk of Court on May 1, 2024 using the CM/ECF system which does send notification of such filing to all counsel of record.

/s/ Ahmed J. Davis

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