UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

ABBOTT LABORATORIES, Plaintiff/Counter-Defendant, v. GRIFOLS DIAGNOSTIC SOLUTIONS INC., GRIFOLS WORLDWIDE OPERATIONS LIMITED, and NOVARTIS VACCINES AND DIAGNOSTICS, INC., Defendants/Counter-Plaintiffs.	)	No. 19 C 6587 Judge Sara L. Ellis

OPINION AND ORDER

Abbott Laboratories ("Abbott") brought this declaratory judgment action against Defendants Grifols Diagnostic Solutions Inc. ("Grifols Diagnostic"), Grifols Worldwide Operations Limited ("Grifols Worldwide"), and Novartis Vaccines and Diagnostics, Inc. ("Novartis"), asserting that the claims of U.S. Patent No. 7,205,101 ("the '101 Patent") are invalid. Defendants deny that the claims of the '101 Patent are invalid, and they filed a counterclaim asserting that Abbott infringes the '101 Patent.[1] The parties now seek construction of several terms in the '101 Patent, as well as a term in U.S. Patent No. 5,156,949 ("the '949 Patent"), on which Abbott relies for its obviousness-type double patenting argument. The Court held a claim construction hearing on February 25, 2022, and now construes the disputed terms as set forth below.

BACKGROUND

The '101 Patent, titled "Human Immunodeficiency Virus (HIV) Nucleotide Sequences, Recombinant Polypeptides, and Applications Thereof," relates to the diagnosis, prevention, and

[1] For simplicity, the Court does not refer to Defendants' additional designation as Counter-Plaintiffs.

treatment of HIV, the virus that causes acquired immunodeficiency syndrome ("AIDS"). In particular, the '101 Patent is "directed to nucleotide sequences, such as DNA, encoding human immunodeficiency virus polypeptides, the use of such nucleotide sequences in diagnostic procedures and in the production of recombinant protein, as well as the use of such proteins in diagnostic, prophylactic, and therapeutic applications." JAppx0049.

By 1984, three groups had independently identified the suspected cause of AIDS, with those isolates called lymphadenopathy-associated virus ("LAV"), human T-cell lymphotropic virus type III ("HTLV-III"), and AIDS-associated retrovirus ("ARV"). Later, it became clear that these three isolates are all strains of the same virus, collectively named HIV.

Because an individual infected with HIV can transmit the virus to others while remaining asymptomatic for years, a focus at that time was developing the ability to accurately screen large numbers of asymptomatic individuals (e.g., healthy appearing blood donors) to detect for HIV infection. A potential solution was to produce proteins from HIV's outer layer, called the envelope ("env"), using recombinant (as opposed to natural) means. In the spring of 1984, a team from Chiron Corporation ("Chiron") began working on creating a recombinant DNA env-based immunoassay. By October 1, 1984, Chiron had run sequence reactions on DNA fragments that spanned what has since been determined to be HIV's entire env layer. In connection with this work, Chiron filed U.S. Patent Application No. 06/667,501 ("the '501 Application") on October 31, 1984.

Although Chiron ultimately abandoned the '501 Application, a number of patents trace their origins to the '501 Application. This includes the '949 Patent, titled "Immunoassays for Antibody to Human Immunodeficiency Virus Using Recombinant Antigens," as well as the '101 Patent, for which Chiron filed a patent application on April 17, 1995. The '101 Patent issued on

April 17, 2007, and claims priority, through several divisional and continuation applications, to the '501 Application. Novartis, which later acquired Chiron, and Grifols Worldwide jointly own the '101 Patent.

LEGAL STANDARD

"Judicial 'construction' of patent claims aims to state the boundaries of the patented subject matter, not to change that which was invented." *Fenner Invs., Ltd. v. Cellco P'ship*, 778 F.3d 1320, 1323 (Fed. Cir. 2015). Not all claims require construction, only those in dispute and only to the extent necessary to resolve the dispute. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

The Court generally gives claim terms their plain and ordinary meaning as understood by a person of ordinary skill in the art. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005). Where the "plain and ordinary meaning of the disputed claim language is clear," such as where the term "is comprised of commonly used terms" that have "no special meaning in the art," the Court may conclude that no construction is necessary. *Summit 6, LLC v. Samsung Elecs. Co.*, 802 F.3d 1283, 1291 (Fed. Cir. 2015); *see also Phillips*, 415 F.3d at 1314 ("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."). But to the extent the plain and ordinary meaning does not resolve the parties' dispute or is not apparent, the Court must construe the claim term. *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1360–61 (Fed. Cir. 2008).

In considering the disputed claim terms, the Court primarily relies on intrinsic evidence, which "includ[es] the claims themselves, the specification, and the prosecution history of the

patent." *Sunovion Pharms., Inc. v. Teva Pharms. USA, Inc.*, 731 F.3d 1271, 1276 (Fed. Cir. 2013). The Court considers a claim term "not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Phillips*, 415 F.3d at 1313. The prosecution history, which "consists of the complete record of the proceedings before the [U.S. Patent and Trademark Office] and includes the prior art cited during the examination of the patent," can help "inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.* at 1317. The presumption of ordinary meaning prevails in all but two situations: (1) "when a patentee acts as his own lexicographer" or (2) "when the patentee disavows the full scope of the claim term in the specification or during prosecution." *Poly-Am., L.P. v. API Indus., Inc.*, 839 F.3d 1131, 1136 (Fed. Cir. 2016).

While the Court must construe claims in light of the specification, it cannot read limitations from the preferred embodiments or specific examples in the specification into the claims. *Enercon GmbH v. Int'l Trade Comm'n*, 151 F.3d 1376, 1384 (Fed. Cir. 1998). "[P]atent coverage is not necessarily limited to inventions that look like the ones in the figures." *MBO Lab'ys, Inc. v. Becton, Dickinson & Co.*, 474 F.3d 1323, 1333 (Fed. Cir. 2007). Thus, while the Court may use the specification to aid in the interpretation of the claims, it may not use the specification as a source for adding extraneous limitations. *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1249 (Fed. Cir. 1998). But the Court may limit the claims based on the specification "where the specification makes clear at various points that the claimed invention is narrower than the claim language might imply." *Alloc, Inc. v. Int'l Trade Comm'n*, 342 F.3d 1361, 1370 (Fed. Cir. 2003).

"In most situations, an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996). But the Court may in its discretion refer to extrinsic evidence, such as dictionaries, treatises, and expert testimony, to help "educate the court regarding the field of the invention and . . . determine what a person of ordinary skill in the art would understand claim terms to mean." *Phillips*, 415 F.3d at 1319; *Vitronics*, 90 F.3d at 1585 n.6 ("Judges are free to consult such resources at any time in order to better understand the underlying technology and may also rely on dictionary definitions when construing claim terms, so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents."). Extrinsic evidence in general, however, is considered "less reliable than the patent and its prosecution history in determining how to read claim terms," *SkinMedica, Inc. v. Histogen Inc.*, 727 F.3d 1187, 1195 (Fed. Cir. 2013) (citation omitted), and "may not be used to vary or contradict the claim language" or "the import of other parts of the specification," *Vitronics*, 90 F.3d at 1584.

ANALYSIS

I. "A 20 bp Sequence of a Human Immunodeficiency Virus (HIV) Genome" ('101 Patent, Claim 1) and "A Env Sequence of HIV" ('101 Patent, Claim 3)

The parties' arguments concerning the construction of "a 20 bp sequence of a human immunodeficiency virus (HIV) genome" in claim 1 and "a env sequence of HIV" in claim 3 overlap, and so the Court considers them together. Their dispute centers around whether the claimed HIV genome refers only to that disclosed in Figure 4 of the '101 Patent, Abbott's proposed construction, or more broadly encompasses all HIV strains, Defendants' proposed construction. The parties agree that the Court's consideration of the meaning of these terms depends on the understanding a person of ordinary skill in the art would have had in 1984, when

Chiron filed the '501 Application. *See Phillips*, 415 F.3d at 1313 (a claim must be construed with "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application"); *E.I. du Pont De Nemours & Co. v. Unifrax I LLC*, 921 F.3d 1060, 1069–70 (Fed. Cir. 2019) (intrinsic evidence includes specification of a parent application where the subject matter is the same as the continuation-in-part application).

As Abbott points out, the term HIV was not adopted until 1986. Thus, the term HIV appears nowhere in the '501 Application. But the '501 Application does use the term "human T-cell lymphotropic retrovirus" (or "hTLR") to refer to the virus "variably referred to as lymphadenopathy virus . . . ; human T-cell lymphotropic virus-III and AIDS-associated retrovirus." AbbottAppx0020–21. As the '101 Patent states, although the "[a]pplicants originally termed [the isolates of HIV-1 and HIV-2] 'human T-cell lymphotropic retrovirus (hTLR)," because an international committee gave those isolates the name HIV, the '101 Patent intends "HIV (and particularly HIV-1) [to] be used herein as an equivalent of hTLR." JAppx0051. In other words, a person of ordinary skill in the art would understand HIV in the '101 Patent to refer broadly to the various strains of hTLR, not only to the one strain that Chiron identified in the '501 Application as Figure 4.

The '501 Application and '101 Patent's claim language reflects this understanding, as it differentiates between hTLR or HIV broadly and the strain identified in Figure 4 more specifically. For example, claim 1 of the '501 Application claimed "[a] DNA construct comprising a replication system recognized by a unicellular microorganism and a DNA sequence coding for at least 20bp of a human T-cell lymphotropic retrovirus (hTLR)," while claim 3 specified that the DNA sequence "is substantially as set forth in Fig. 4." AbbottAppx0047. The

'101 Patent does the same, with, for example, claims 1 and 3 referring merely to HIV, but dependent claim 9 requiring the HIV sequence to be "an env sequence of FIG. 4." JAppx0086. Giving different meaning to HIV and hTLR, in contrast to the HIV or hTLR sequence set forth in Figure 4, comports with the doctrine of claim differentiation, which provides that "the presence of a dependent claim that adds a particular limitation raises a presumption that the limitation in question is not found in the independent claim." *Acumed LLC v. Stryker Corp.*, 483 F.3d 800, 806 (Fed. Cir. 2007) (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 910 (Fed. Cir. 2004)). Claim differentiation's presumption "is especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim," in other words, where reading a limitation into the independent claim would render the claims identical in scope. *SunRace Roots Enter. Co. v. SRAM Corp.*, 336 F.3d 1298, 1303 (Fed. Cir. 2003). That would occur if the Court limited all references to HIV to the sequence set forth in Figure 4, and so the Court rejects Abbott's proposed limitation on this basis as well.

Abbott also argues that the claim language at issue must refer to Figure 4 in order to preserve the '101 Patent's validity. Abbott maintains that otherwise, the claims do not comply with the written description requirement of 35 U.S.C. § 112, which requires "the disclosure of the application relied upon [to] reasonably convey[ ] to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010). But the Court does not find it appropriate to consider the validity of the claim in construing the terms here. *See Am. Piledriving Equip., Inc. v. Geoquip, Inc.*, 637 F.3d 1324, 1331 (Fed. Cir. 2011) ("[T]he role of a district court in construing claims is not to redefine claim recitations or to read limitations into the claims to obviate factual questions of infringement and validity but rather to give meaning to the

limitations actually contained in the claims, informed by the written description, the prosecution history if in evidence, and any relevant extrinsic evidence."). Although "claims are generally construed so as to sustain their validity, if possible," *Whittaker Corp. v. UNR Indus., Inc.*, 911 F.2d 709, 712 (Fed. Cir. 1990), the Federal Circuit has "admonished against judicial rewriting of claims to preserve validity," *Rhine v. Casio, Inc.*, 183 F.3d 1342, 1345 (Fed. Cir. 1999). "[I]f the only claim construction that is consistent with the claim's language and the written description renders the claim invalid, then . . . the claim is simply invalid." *Id.*; *see also Phillips*, 415 F.3d at 1327 ("While we have acknowledged the maxim that claims should be construed to preserve their validity, we have not applied that principle broadly, and we have certainly not endorsed a regime in which validity analysis is a regular component of claim construction. Instead, we have limited the maxim to cases in which 'the court concludes, after applying all the available tools of claim construction, that the claim is still ambiguous.'" (citations omitted)). Here, the intrinsic evidence indicates that the '101 Patent's references to HIV are not limited to Figure 4 unless so specified. Whether this construction renders the claim invalid for failure to comply with § 112's written description requirement remains a question for a later day.

Therefore, having considered the parties' arguments, the Court rejects Abbott's attempts to limit the sequence of HIV referred to in claims 1 and 3 to that set forth in Figure 4.[2]

II. "A Recombinant Polypeptide Comprising at Least an Immunogenic Portion of the Envelope (Env) Domain of Said HIV" ('949 Patent, Claim 2)

Abbott maintains that the asserted claims of the '101 Patent are invalid pursuant to the doctrine of obviousness-type double patenting based on claim 6 of the '949 Patent. To discern

[2] Abbott also argues that the entire sequence of HIV required for these claims must exactly match a portion of Figure 4, but its proposed constructions do not reflect this limitation. Because the Court does not find that Figure 4 limits the sequences at issue, it need not further consider Abbott's arguments as to whether the entire base pair sequence must come from Figure 4 or whether the sequence may include matching and mismatching base pairs.

the invalidity of a claim due to obviousness-type double patenting, "the court [first] construes the claim[s] in the earlier patent and the claim[s] in the later patent and determines the differences. Second, the court determines whether those differences render the claims patentably distinct." *AbbVie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Tr.*, 764 F.3d 1366, 1374 (Fed. Cir. 2014) (second and third alterations in original) (citation omitted) (internal quotation marks omitted).

Abbott seeks construction of the term "a recombinant polypeptide comprising at least an immunogenic portion of the envelope (env) domain of said HIV," used in claim 2 and incorporated in claim 6 of the '949 Patent. Abbott argues that the Court should construe this term as "a recombinant polypeptide encoded with at least 21 base pairs of the envelope (env) domain of HIV DNA." Abbott points to language in the '949 Patent's specification that discusses the expression of polypeptides, which provides that "[t]he smallest sequence of interest, so as to encode an amino acid sequence capable of specific binding, for example, to a receptor or an immunoglobulin, will be 21 bp, usually at least 45 bp, exclusive of the initiation codon." JAppx0523. According to Abbott, this means that for a recombinant polypeptide to bind to an HIV antibody, as recited in claim 2 of the '949 Patent, the immunogenic portion of the polypeptide must be encoded with at least 21 base pairs of the envelope (env) domain of HIV DNA. On the other hand, Defendants argue that the Court should give the term its plain and ordinary meaning. They maintain that Abbott's proposed construction improperly reads out the requirement of immunogenicity by only addressing the length of the DNA sequence that encodes the polypeptide despite the fact that many other factors also play a role in determining immunogenicity. *See* Crumpton, Michael J., *Protein Antigens: The Molecular Bases of Antigenicity and Immunogenicity*, Doc. 105-4 at 6 ("A protein's capacity to elicit an immune

response reflects a complex series of interacting parameters such as its physical state, the degree of dissimilarity between its structure and the homologous protein of the immunized animal, its rate of catabolism, the amount injected, the species and strain of animal immunized, etc.").

During the claim construction hearing, Abbott agreed to add the phrase "immunogenic portion" back into its proposed definition, and the Court agrees with the need to do so. *See Akzo Nobel Coatings, Inc. v. Dow Chem. Co.*, 811 F.3d 1334, 1340 (Fed. Cir. 2016) (rejecting construction of a term that would "obviate[ ] the import of the word 'collection'"). As for the minimum length of the immunogenic portion, Defendants argue that it could be at least 21 base pairs but also could be less than 21 base pairs. To support this argument, Defendants ignore the specification and instead resort to extrinsic evidence that identifies immunogenic peptides comprised of as few as five or six amino acids, in other words, fifteen or eighteen base pairs. These examples are entirely divorced from the patent, however, and so the Court does not find it appropriate to resort to Defendants' extrinsic evidence given that the specification clarifies that the immunogenic portion of the polypeptide must be at least 21 base pairs in length. *See Alloc, Inc.*, 342 F.3d at 1370 (a court may limit a claim based on the specification "where the specification makes clear at various points that the claimed invention is narrower than the claim language might imply"); *Vitronics*, 90 F.3d at 1584 (extrinsic evidence "may not be used to vary or contradict the claim language" or "the import of other parts of the specification"). Thus, the Court construes the disputed term in claim 2 of the '949 Patent as "a recombinant polypeptide comprising at least an immunogenic portion of at least 21 base pairs of the envelope (env) domain of HIV DNA."

III. "A Method for Replicating DNA Specific for HIV" ('101 Patent, Claims 1 and 17)

Turning back to the '101 Patent, the Court must determine whether the preamble recited in claims 1 and 17 limits the invention. "In general, a preamble limits the invention if it recites essential structure or steps, or if it is 'necessary to give life, meaning, and vitality' to the claim." *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002) (citation omitted). "Conversely, a preamble is not limiting 'where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention.'" *Id.* (citation omitted). To determine whether a preamble serves as a limitation, the Court must consider the entire "patent to gain an understanding of what the inventors actually invented and intended to encompass by the claim." *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257 (Fed. Cir. 1989).

Claim 1 of the '101 Patent claims:

> A method for replicating DNA specific for HIV, which comprises:
>
> (a) providing a DNA construct comprising an origin of replication recognized by a unicellular microorganism and a DNA sequence comprising at least a 20 bp sequence of a human immunodeficiency virus (HIV) genome; and
>
> (b) growing a unicellular microorganism containing said DNA construct under conditions whereby said DNA sequence is replicated.

JAppx0086. Claim 17 includes the same language, except it limits the DNA sequence to that shown in Figure 4. *Id.* Defendants argue that the preamble—"a method for replicating DNA specific for HIV"—in both these claims constitutes a limitation because it clarifies that the method at issue is *specific for HIV* and not any other types of DNA. In other words, Defendants maintain that the preamble addresses a fundamental feature of the invention, which is reflected throughout the specification. Abbott, on the other hand, argues that the preamble does not

amount to a limitation because the body of the claim defines a structurally complete method and the preamble only states the method steps' intended use. *See Neapco Drivelines LLC v. Am. Axle & Mfg., Inc.*, 847 F. App'x 856, 858 (Fed. Cir. 2021) (determining that the preamble of a method claim could not be construed as limiting because "[t]he claim body defines a structurally complete invention, and the preamble is not essential to understand any claim terms"). Reprising its Figure 4 arguments, Abbott alternatively asks the Court to limit the preamble language so that it refers only to HIV DNA as set forth in Figure 4.

The Court agrees with Defendants that the preamble constitutes a limitation because it reflects a fundamental characteristic of the invention: that the replication method applies only to HIV DNA and not DNA more generally. *See Deere & Co. v. Bush Hog, LLC*, 703 F.3d 1349, 1358 (Fed. Cir. 2012) (preamble was limiting where it described a "fundamental characteristic of the claimed invention" and the specification "underscore[d] the importance" of the preamble as a limitation). And for the reasons already discussed in connection with the first terms at issue, the Court rejects Abbott's alternative argument that the Court should limit the preamble's reference to HIV DNA as set forth in Figure 4.

IV. "DNA Construct" ('101 Patent, Claims 1, 3, and 17)

Defendants propose to construe the term "DNA construct" used in claims 1, 3, and 17 as "a chimeric, human-made construct that does not exist in nature," while Abbott asks the Court to give the term its plain and ordinary meaning. Abbott alternatively argues that Defendants' construction is not helpful because they use the same term they seek to define—construct—in their proposed construction. *See Lecat's Ventriloscope v. MT Tool & Mfg.*, 283 F. Supp. 3d 702, 712 (N.D. Ill. 2018) (rejecting construction of term that relied on the term itself, noting that such a "circular claim construction will not assist the jury as factfinder in understanding this claim

term"). In response to this alternative argument at the claim construction hearing, Defendants proposed using the term "genetic structure" in place of "construct."

Although Abbott maintains that the Court should give the term "DNA construct" its plain and ordinary meaning, the Court agrees with Defendants that the term "DNA construct" requires construction. Defendants' construction makes clear that, as used in the '101 Patent, the term does not refer to a naturally-occurring process. As the claim language reflects, the DNA construct at issue includes an origin of replication and an HIV DNA sequence, components that do not exist together in nature. JAppx0086. And, as the specification indicates, the construct is chimeric because it includes genetic material from distinct organisms and is human-made because it is constructed using various laboratory techniques. JAppx0054. Therefore, the Court adopts Defendants' modified construction of "DNA construct," construing the term to mean "a chimeric, human-made genetic structure that does not exist in nature."

V. "Unicellular Organism" ('101 Patent, Claims 1, 7, and 17)

Finally, the Court considers the term "unicellular organism," which appears in claims 1, 7, and 17. Defendants ask the Court to construe the term as "a single cell microorganism that does not naturally replicate HIV DNA," while Abbott again maintains that the Court should give this term its plain and ordinary meaning. Abbott argues that Defendants' construction includes unnecessary additional details and that the term unicellular does not need further definition to clarify that it refers to a single cell. The Court agrees with Abbott that the term "unicellular organism" does not need construction. The term carries no special meaning in the '101 Patent and is instead readily understandable without further definition.

CONCLUSION

The Court adopts the following constructions for the '101 and '949 Patents:

Claim Term	Construction
"a 20 bp sequence of a human immunodeficiency virus (HIV) genome" ('101 Patent, claim 1)	"a 20 base pair sequence of human immunodeficiency virus (HIV) genome"
"a env sequence of HIV" ('101 Patent, claim 3)	"a env sequence of HIV"
"a recombinant polypeptide comprising at least an immunogenic portion of the envelope (env) domain of said HIV" ('949 Patent, claim 2)	"a recombinant polypeptide comprising at least an immunogenic portion of at least 21 base pairs of the envelope (env) domain of HIV DNA"
"A method for replicating DNA specific for HIV" ('101 Patent, claims 1 and 17)	Preamble is limiting
"DNA construct" ('101 Patent, claims 1, 3, and 17)	"a chimeric, human-made genetic structure that does not exist in nature"
"unicellular microorganism" ('101 Patent, claims 1, 7, and 17)	Plain and ordinary meaning

Dated: April 27, 2022

SARA L. ELLIS
United States District Judge