IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GLAXOSMITHKLINE, LLC, Plaintiff, v. GENENTECH, INC., Defendant.	)	Civil Action No. 10-cv-799 (GMS)

ORDER CONSTRUING THE TERMS OF U.S. PATENT NO. RE41,555

After having considered the submissions of the parties and hearing oral argument on the matter, IT IS HEREBY ORDERED, ADJUDGED, and DECREED that, as used in the asserted claims of U.S. Patent No. RE41,555 ("the '555 Patent")[1]:

1. The term "selectively eluting [the monomeric IgG antibody] from the support" and "the antibody selectively eluted" is construed to mean "eluting such that the concentration of contaminants in the mixture relative to the concentration of monomeric IgG antibody is lower compared to what is applied to the column."[2]

[1] The parties notified the court during the July 22, 2013 *Markman* Hearing that they had agreed to the construction of two formerly-disputed terms in U.S. Patent No. RE40,070 ("the '070 Patent"). Specifically, the parties agreed that, as used in the asserted claims of the '070 Patent, "sequentially" is construed to mean "in order," and "conditioned cell culture medium" is construed to mean "a cell culture medium which has supported cell growth and/or cell maintenance and contains secreted product." *See* Transcript of July 22, 2013 *Markman* Hearing ("Tr.") (D.I. 99) at 18:18-19:7. In the absence of a genuine dispute, the court will not construe these term. *See O2 Micro Int'l.*, 521 F.3d at 1360; *U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997).

[2] The court rejects Genentech's proposed construction of this term as "causing the bound [monomeric IgG antibody] to be separately released from the support." (D.I. 84; D.I. 91.) "When the specification describes a single embodiment to enable the invention, this court will not limit broader claim language to that single application 'unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions that manifest exclusion or restriction." *Abbott Labs v. Sandoz, Inc.*, 566 F.3d 1282, 1288 (Fed. Cir. 2009) (quoting (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) (internal quotations omitted))); *see also Kara Tech. Inc. v. Stamps.com, Inc.*, 582 F.3d 1341 (Fed. Cir. 2009) ("The patentee is entitled to the 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."). Here, contrary to guiding case law, Genentech's proposed construction seeks to import limitations from the specification, limiting the claim scope. Specifically, Genentech's construction requires that the IgG monomer be

2. The term "monomeric IgG antibody" is construed to mean "a monomeric IgG antibody or a monomeric IgG antibody-like protein which may be purified by the protocol described therein."[3]

"bound" to the support before elution, which adds a restriction that is not required by the claims and seemingly ignores the "selective" part of the claim term. It appears that Genentech's proposed construction is derived from certain embodiments in the specification—examples in the specification noted as non-limiting and examples—where the IgG antibody is first bound to the support and then eluted. *See, e.g.*, JA-23 at 9:38-40. Notably, however, and as GSK notes, when the inventors wanted to specify that the IgG should first be bound, they stated this expressly, as they did in original claim 20, which recites a step for "eluting the absorbed antibody." (D.I. 83 at 8 (citing JA-30, JA-31, claims 1, 20).) Thus, Genentech's definition would ignore the full scope of "selectively eluting" by restricting the term to one method of selection—bind-and-elute—rather than allowing it to also encompass "flow-through elution," which is not precluded from the disputed claim term.

Conversely, GSK's construction, which the court adopts in this Order, allows for both bind-and-elute and flow-through elution, as the desired monomer is eluted from the support in either mode. Moreover, this construction gives meaning to the word "selectively," because it encompasses all methods of elution that select a desired monomer by reducing the concentration of contaminants relative to that monomer, which is the intended result of the purification process. (D.I. 88 at 7.) In particular, that understanding of "selectively eluting" is reflected in the patent's comparison of the amount of contaminants before and after elution from the HIC column. *See, e.g.*, JA-25, at Table 3. The court agrees with GSK that, in light of the specification, its proposed construction also explains how purification occurs by noting that after "contacting said mixture with a hydrophobic interaction chromatographic support," the subsequent elution from the support reduces the concentration of contaminants. (D.I. 88 at 8.)

The court notes, as it did during the *Markman* Hearing, that the parties are to meet-and-confer to determine whether there is agreement or whether they can reach agreement on the construction of "elute," which is a term that would likely prove unfamiliar or confusing to the jury in this case. It appeared from the court's discussion with counsel during the *Markman* Hearing that the parties do not agree on this meaning. As the court instructed at that time, should the parties be unable to reach agreement on the construction of this term, the court will await trial to hear from experts, rather than conduct supplemental briefing at this stage. *See* Tr. at 62:2-15.

[3] The court rejects Genentech's proposed construction of "a protein of the IgG subclass composed of four polypeptide chains (2 heavy chains and 2 light chains) with a molecular weight of 150,000 daltons." (D.I. 84 at 9.) Claim terms should be construed in a manner consistent with their "ordinary and customary meaning," which is "the meaning that the term would have to a person of ordinary skill in the art in question." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005). Importantly, however, a patentee may "choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent specification or file history." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996); *see also E-Pass Techs., Inc. v. 3COM Corp.*, 343 F.3d 1364, 1369 (Fed. Cir. 2003) ("The patentee may have acted as his own lexicographer and imbued the claim term with a particular meaning or disavowed or disclaimed the scope of coverage, by using words or expressions of manifest exclusion or restriction."). Here, Genentech asserts that the applicants did, in fact, act as their own lexicographer by detailing in the specification that: "While it is appreciated that the 150,000 dalton IgG species is composed of four polypeptide chains (2 heavy chains and 2 light chains), the 150,000 dalton species is referred to herein as a 'monomer' or 'monomeric IgG.'" (D.I. 84 at 9 (citing '555 Patent at 5:61-65).) Genentech asserts that because the "applicants 'clearly, deliberately, and precisely defined' the term monomeric IgG antibody—and indicated that this language should be treated as a definition by, among other things, using quotation marks to 'set off' the term to be defined—the definition provided by the applicant controls." (*Id.* at 8-9 (quoting *Sinorgchem Co. v. Int'l Trade Comm'n*, 511 F.3d 1132, 1136 (Fed. Cir. 2007)).)

While the court agrees with Genentech that the definition an applicant provides for a term controls, it disagrees with the definition Genentech provides as the construction of this term. Specifically, the applicants chose to define the meaning of "antibody" in the specification as: "Unless specifically identified otherwise, the term antibody or immunoglobulin protein also includes antibody-like proteins." (D.I. 83 at 8 (citing JA-20 at 4:18-20).) GSK's proposed construction, which the court adopts, accounts for this by directly applying the definition of antibody set forth in the patent. *See Vitronics*, 90 F.3d at 1584 ("[A] patentee may choose to be his own lexicographer and use

Dated: August 22, 2013

CHIEF, UNITED STATES DISTRICT JUDGE

terms in a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent specification or file history."). Indeed, the patent specification then goes on to define "antibody-like proteins":

> Antibody-like proteins are proteins which may be purified by the protocol described herein, such protocol being modified if necessary by routine, non-inventive adjustments that do not entail undue experimentation. Such proteins include isotypes, allotypes, and alleles of immunoglobulin genes, truncated forms, altered antibodies, such as chimeric antibodies, humanized antibodies and the like, chemically modified forms such as by PEG treatment, and fusion proteins containing an immunoglobulin moiety. These proteins are referred to as antibody-like because they possess or retain sufficient immunoglobulin protein properties (e.g. F_c determinants) to admit to purification by the process of this invention.

'555 Patent at 4:6-18. Contrary to Genentech's assertion that GSK's proposed construction "fails to explain what constitutes an 'antibody-like protein,'" the court's construction coupled with the definition provided in the specification informs the meaning of this term. In reaching this conclusion, the court also rejects Genentech's contention that an antibody-like protein must include at least the F_c portion of an antibody. Rather, the "F_c determinant[]" is provided as an example of the a protein that "retained sufficient immunoglobulin protein properties to . . . admit to purification by the process of this invention," and is not required. (D.I. 88 at 6 (citing '555 Patent at 4:14-18).) Thus, to the extent that other proteins also retain sufficient immunoglobulin protein properties to allow purification by the inventive process, such as F_{ab} fragments, which also have hydrophonic regions and a similar molecular weight to their F_c counterparts, they would fall within the claim scope.

In light of quoted definitions and in consideration of the specification as a whole, the court concludes that the invention is not, as Genentech advances, limited simply to antibodies, but also antibody-like proteins that may not, for example, have a molecular weight of 150,000 daltons because they have been "truncated" or "altered." (D.I. 83 at 9.) Genentech's definition, therefore, should not apply, as it inappropriately limits the scope of the claim term to the definition of the monomeric aspect of a whole antibody vis-à-vis aggregates. (*Id.*) Specifically, that definition is provided in the context of distinguishing the monomeric native antibody from aggregates. In fact, GSK agrees that "monomeric" IgG refers to the 150,000 dalton monomeric species of an IgG antibody as opposed to higher molecular weight species or aggregates in the context of an unaltered IgG antibody. (*Id.*) However, because the patent also encompasses both monomeric IgG antibodies and monomeric IgG antibody-like proteins, GSK's proposed construction is appropriate. *See Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1324 (Fed. Cir. 2002) ("Unjustifiably importing limitations from the specification is the 'cardinal skin of claim construction.'").