IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF TEXAS MARSHALL DIVISION

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NOVARTIS VACCINES AND
DIAGNOSTICS, INC.,
Plaintiff,
V.
WYETH and WYETH
PHARMACEUTICALS, INC.,
Defendants.

CIVIL ACTION NO. 2:08-CV-67-TJW-CE

MEMORANDUM OPINION AND ORDER

Before the Court is Defendants Wyeth's and Wyeth Pharmaceuticals, Inc.'s (collectively "Wyeth") Motion for Reconsideration. (Dkt. No. 219.) For the following reasons, Wyeth's motion is DENIED.

Plaintiff Novartis Vaccines and Diagnostics, Inc. ("Novartis") filed suit against Wyeth for patent infringement of U.S. Patent No. 6,228,620 ("the '620 Patent"). The Court issued a Memorandum Opinion and Order on April 26, 2011 that outlined the Court's claim constructions for the various disputed claim terms. On May 24, 2011, Wyeth filed a motion to reconsider one of the terms the Court construed. Wyeth essentially makes two arguments. First, because Novartis proposed revised constructions merely three days before the claim construction hearing, Wyeth argues it was not offered a fair chance to respond to those constructions. Particularly, Wyeth argues this was prejudicial because the Court adopted Novartis's revised construction for the term that is in dispute in this motion to reconsider. Second, Wyeth argues that the Court's construction of "said recombinant protein consists of a first amino acid sequence . . . and a second amino acid sequence," for which the Court adopted Novartis's revised construction, is incorrect. As a result, Wyeth asks the Court to reconsider that construction.

I. Novartis's "Last-Minute" Revised Constructions

First, the Court addresses the issue of Novartis's revised constructions proposed three days before the claim construction hearing. The Court agrees with Wyeth that Wyeth was not offered a fair chance to respond to the revised constructions. Wyeth was given three days, at most, to consider the revised constructions—while at the same time Wyeth had to prepare for the claim construction hearing and concentrate on its own positions. As a result, to remedy the potential unfairness to Wyeth, the Court will consider Wyeth's motion to change the Court's claim construction under a *de novo* standard, rather than the more demanding standard of a motion for reconsideration. The Court finds that Wyeth has had adequate supplemental briefing on the claim construction dispute regarding the phrase "said recombinant protein consists of a first amino acid sequence . . . and a second amino acid sequence," because Wyeth has briefed the Court on the issue through its motion to reconsider.

II. Construction of the Phrase "said recombinant protein consists of a first amino acid sequence . . . and a second amino acid sequence."

Next, Wyeth asks the Court to construe the phrase "said recombinant protein consists of a first amino acid sequence . . . and a second amino acid sequence," which appears in claim 74 of the '620 Patent. In the Court's Claim Construction Order, this phrase was construed as "at least one protein produced from the spliced DNA or RNA contained in the host cell must contain two and only two amino acid sequences and cannot contain anything other than the two amino acid sequences." (Dkt. No. 205, at 12.) Wyeth asks the Court to construe the phrase as "all recombinant proteins in the host cell lacking all or a portion of the B domain of human factor VIII must contain two and only two amino acid sequences." This is not the same construction

that Wyeth originally proposed.¹

The Court reviews this claim construction dispute under the same legal principles the Court explained in its Claim Construction Order. (*See* Dkt. No. 205, at 2-6.) Wyeth makes primarily the same arguments it made when the Court first considered this claim construction dispute, but Wyeth presents the arguments slightly differently due to its new proposed construction. The specific language the Court is construing, in the context of the claim, reads:

74. A host cell comprising nucleic acid for expression of a recombinant protein lacking all or a portion of the B domain of human Factor VIII, wherein said recombinant protein consists of a first amino acid sequence . . . and a second amino acid sequence . . .

'620 Patent, at 59:66-60:19 (emphasis added to the portion the Court is construing). Wyeth's

argument is easily boiled down to three points, which the Court will quote out of Wyeth's brief:

- "*Said* recombinant protein," which refers to the antecedent "*a* recombinant protein lacking all or a portion of the B domain of human Factor VIII," means "*one or more* recombinant proteins lacking all or a portion of the B domain of human Factor VIII."
- The closed transitional phrase "consists of" limits the "*said* recombinant protein" to a "first amino acid sequence . . ." "and a second amino acid sequence."
- Therefore, <u>each of the *one or more*</u> recombinant proteins in the claimed host cell "lacking all or a portion of the B domain of human Factor VIII" must be limited to the claimed "first amino acid sequence . . ." "and a second amino acid sequence."

(Wyeth's Br., Dkt. No. 219, at 8-9 (bold/italic emphasis in original, underlining emphasis

added).) The Court disagrees with Wyeth's construction that "all recombinant proteins in the

host cell lacking all or a portion of the B domain of human factor VIII must contain two and only

two amino acid sequences." (emphasis added) Practically, what Wyeth's construction does, is

replaces the underlined portion of the third bullet point above with "all," which is incorrect.

¹ Wyeth originally requested the construction: "any and all proteins produced from the nonnaturally occurring DNA or RNA contained in the host cell must contain two and only two amino acid sequences and cannot contain anything other than the two amino acid sequences."

Wyeth's construction is incorrect because it limits the host cell to having "recombinant protein[s] lacking all or a portion of the B domain of human Factor VIII" that only contain the two claimed amino acid sequences. It is true that "one or more" of the "recombinant protein[s] lacking all or a portion of the B domain of human Factor VIII," that are in the host cell, must be limited to the two amino acid sequences. Due to the "comprising" language after host cell, however, that does not exclude an *additional* "recombinant protein lacking all or a portion of the B domain of human Factor VIII," in the host cell, which is not limited to the two amino acid sequences (e.g., it could contain a third sequence, only one of the two sequences, or different sequences). Because Wyeth's proposed construction precludes that situation, it is contrary to the claim language and cannot be adopted by the Court.

The Federal Circuit law that Wyeth cites does not support its position. Wyeth mainly relies on the case *Baldwin Graphic Sys., Inc. v. Siebert, Inc.*, 512 F.3d 1338 (Fed. Cir. 2008). *Baldwin Graphic*, of course, recognizes that "a" can mean "one or more," *id.* at 1342, and this Court agrees with this rule and has incorporated it into its analysis above. Further, *Baldwin Graphic* recognizes that "[t]he subsequent use of definite articles 'the' or 'said' in a claim to refer back to the same claim term does not change the general plural rule, but simply reinvokes that non-singular meaning." *Id.* The claim in this case also uses the article "said," and the Court agrees that the use of "said recombinant protein" reinvokes the non-singular meaning. But what Wyeth argues, and what *Baldwin Graphic* does not state, is that the use of "said recombinant protein" that refers back "a recombinant protein lacking all or a portion of the B domain of human Factor VIII" (i.e., "*one or more* recombinant protein[s] . . .), requires that <u>all</u> of these particular "recombinant proteins" be limited in the way that the claim describes (i.e., to the two amino acid sequences). Rather, all *Baldwin Graphic* requires, is that the "one or more"

recombinant proteins must be limited to the two amino acid sequences, but that does not preclude, due to the use of "comprising," other recombinant proteins of the same type which are not so limited.

Therefore, the Court rejects Wyeth's construction that includes the language "all." However, in light of the argument made by Wyeth, which is correct, that the "said recombinant protein" is referring back to the "recombinant protein lacking all or a portion of the B domain of human Factor VIII" recited earlier in the claim, the Court will include that clarification in its construction. In all other regards, the Court adopts its prior constructions. (*See* Dkt. No. 205.) As a result, the Court construes the phrase "said recombinant protein consists of a first amino acid sequence . . . and a second amino acid sequence" to be "*at least one recombinant protein lacking all or a portion of the B domain of human Factor VIII that is produced by the spliced DNA or RNA contained in the host cell must contain two and only two amino acid sequences and cannot contain anything other than the two amino acid sequences."*

It is so ORDERED.

SIGNED this 2nd day of September, 2011.

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CHARLES EVERINGHAM IV UNITED STATES MAGISTRATE JUDGE