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

GENENTECH, INC. and CITY OF HOPE,	)	
Plaintiffs,	)	
v.	)	Civ. No. 17-1407-GMS
AMCENIBIC	)	Civ. No. 17-1471-GMS
AMGEN INC.	)	
Defendant,	)	·

### **MEMORANDUM**

The parties have appeared before the court multiple times to dispute the mechanism by which they plan to narrow the number of patents at issue in this case. Set forth below is my summary of issue and my guidance to the parties.

#### I. BACKGROUND

As the product of a patent dance prescribed by the Biologics Price Competition and Innovation Act ("BPCIA"), 42 U.S.C. § 262(*I*), plaintiffs Genentech, Inc. and City of Hope (collectively, "Genentech") have sued defendant Amgen Inc. ("Amgen") for infringement of twenty-six patents based on Amgen's plans to commercialize a biosimilar version of Genentech's Avastin<sup>®</sup>. (D.I. 39 at ¶¶ 31-347). To narrow the case to a manageable number of patents, the parties agreed to an "initial phase of discovery" whereby Genentech would receive certain documents from Amgen and then take depositions to understand those documents. (D.I. 97 at 22:20-23:3, 107:7-12; D.I. 106). With that information, Genentech would reduce the number of

All cites herein are to the docket for Civ. No. 17-1407 unless stated otherwise.

patents on which they claim infringement to no more than eight by August 31, 2018.<sup>2</sup> (D.I. 106 at ¶ 2).

On May 7, 2018, the parties appeared before the court to discuss certain disputes regarding the schedule and discovery. (D.I. 95; D.I. 100). In that status conference, the parties agreed that the depositions used to narrow the number of asserted patents would be in the form a 30(b)(6) deposition, Genentech would provide a deposition notice that set forth the list of topics with "specificity," and Amgen would provide one or more "well-prepared" witnesses to address those topics. (D.I. 100 at 17:24-18, 24:22-26:19, 30:12-15). Amgen agreed to build a date into the schedule for the 30(b)(6) deposition with the understanding that the deposition needed to occur before the August 31 deadline for Genentech to narrow the number of patents. (*Id.* at 30:24-31:4). The parties discussed whether the August 31 deadline provided sufficient time for what they planned to accomplish. I decided to keep the August 31, 2018 deadline for now, but ruled that the date could be extended for good cause. (*Id.* at 32:9-35:13).

Genentech served a 30(b)(6) notice on June 29, 2018 that contained 236 topics (the "Original Notice"). (D.I. 138). Approximately two weeks later, on July 11, 2018, the parties again appeared before the court to discuss certain discovery disputes. (D.I. 135). At that time, Amgen had not yet agreed to a date for the 30(b)(6) deposition. (Hr'g Tr. at 53:23-54:6). Amgen claimed it was "unworkable" to educate witnesses on 236 deposition topics. (*Id.* at 115:14-22). Genentech responded that the number of topics in the Original Notice reflected the fact that the purpose of the deposition was to narrow the number of patents at issue, there were currently 26 patents in the

After the August 31, 2018 deadline, Genentech is permitted to select as many as two additional patents upon a showing of good cause. (D.I. 106 at  $\P$  2).

case, and the topics were "very specific," as Amgen requested. (*Id.* at 70:11-23; 117:7-13, 120:10-14). I counseled Genentech to be "practical" about the number of deposition topics, but made clear that I did not view the issue "as a numbers game." (*Id.* at 70:11-23, 119:7-14). Genentech offered to re-file the notice with "50 topics that [are] narrower [than] the original request." (*Id.* at 132:18-21). Two days later, on July 13, 2018, Genentech served a Revised Notice of Rule 30(b)(6) Deposition (the "Revised Notice"). (D.I. 141).

#### II. DISCUSSION

On July 26, 2018, approximately two weeks after receiving the Revised Notice, and almost a month after receiving the Original Notice, the parties had a telephone conference with the court to address Amgen's complaint that the Revised Notice did not comply with the court's instructions from the July 11, 2018 discovery hearing. (D.I. 148). Amgen took the position that Genentech was supposed to pare down the Original Notice by picking 50 topics from the 236. (D.I. 154 at 3:4-7). According to Amgen, Genentech served "an entirely new list that had 49 topics, but ... didn't narrow down the original 30(b)(6) notice at all." (*Id.* at 3:9-11). Instead, the Revised Notice was "actually broader than their original notice" and "actually include[d] new subject matter." (*Id.* at 3:18-22, 4:12-13).

Upon closer examination, I disagree with Amgen's characterization of the Revised Notice. First, Amgen accurately characterized its Original Notice as "very specific." (Hr'g Tr. at 120:10-11). For example, two topics asked verbatim the same question about the individual's involved in Amgen's decision to manufacture any batch or lot of ABP 215, except one topic used the phrase "ABP 215 drug substance" whereas the second topic used instead the phrase "ABP 215 drug

product." (D.I. 138 at Nos. 208, 209). Genentech used twelve deposition topics in the Original Notice to ask about the conductivity and salt concentration of the liquid phase in the cation exchange chromatography process: Each topic requested the exact same information, just at a different step in the process. (Id. at Nos. 141-172). Because these topics were quite narrow, Genentech's decision to combine them in the Revised Notice is not unreasonable and does not appear to be an attempt to evade my instructions from the July 11 conference. Second, almost half of the topics in the Revised Notice—twenty-one to be exact—are unchanged from what Amgen set forth in its Original Notice. (D.I. 141 at Nos. 3, 6, 10, 12, 14, 15, 18, 20, 22, 24, 29, 30, 35, 37, 38, 39, 41, 43, 44, 46, 47). The remaining topics in the Revised Notice combine verbatim a few of the topics from the Original Notice. (Compare, e.g., D.I. 141 at No. 26 to D.I. 138 at Nos. 112, 113). Genentech's combination of more than three topics from the Original Notice into one new topic in the Revised Notice is limited. Only one topic, No. 28, raises new subject matter, but the language regarding the scope of the topic tracks the same language Amgen used to inquire about similar subject matters. (Compare D.I. 141 at No. 28 to D.I. 141 at Nos. 8, 9, 11, 13, 21, 23, 27). Given the foregoing, it appears that Genentech complied with my instructions from the July 11 conference to narrow the number of topics. In addition, very little, if anything, in the Revised Notice should have come as a surprise to Amgen.

If Amgen has other objections to the Revised Notice that the parties cannot resolve through a meet and confer, Amgen may raise those objections with the court. But on the objections Amgen currently presents, I do not find the Revised Notice defective.

The phrases do not have the exact same meaning, but obviously there is significant overlap. A "drug substance" is the active pharmaceutical ingredient without excipients, whereas a "drug product" is the drug substance and its excipients.

### III. CONCLUSION

The court has written this memorandum to guide the parties' continuing efforts to resolve the Rule 30(b)(6) deposition dispute between them as well as other discovery issues that may arise. The court is a limited resource. Every set of litigants is entitled to use its fair share of this resource – but only its fair share. The litigants in this action are coming perilously close to exceeding that limit.<sup>4</sup> An appropriate order will be entered.

Dated: August \_\_\_\_\_\_\_, 2018

NITED STATES DISTRICT JUDGE

The parties have had four status conferences since April 11, 2018 to discuss scheduling and discovery disputes. (See, e.g., D.I. 97, D.I. 100, D.I. 154).

## IN THE UNITED STATES DISTRICT COURT

## FOR THE DISTRICT OF DELAWARE

GENENTECH, INC. and CITY OF HOPE,	)	
Plaintiffs,	)	
v.	)	Civ. No. 17-1407-GMS Civ. No. 17-1471-GMS
AMGEN INC.	j	
Defendant,	)	

## **ORDER**

Consistent with the memorandum issued this same date, IT IS HEREBY ORDERED that:

1. The parties shall apply the concept of reasonableness in the resolution of the issue at hand as well as other discovery disputes that may arise from time to time.

Dated: August \_2\_\_\_, 2018

TED STATES DISTRUCT JUDGE