IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC. and CITY OF HOPE, *Plaintiffs*, v. AMGEN INC., *Defendant*.	C.A. No. 17-1407-CFC (CONSOLIDATED) [redacted] PUBLIC VERSION FILED: March 3, 2020
GENENTECH, INC., *Plaintiff and Counterclaim Defendant*, v. AMGEN INC., *Defendant and Counterclaim Plaintiff*.	C.A. No. 18-924-CFC

GENENTECH'S LETTER-BRIEF CONCERNING
CONSTRUCTION OF "FOLLOWING FERMENTATION"

Dear Judge Connolly,

Genentech respectfully submits that for three reasons, it would be error to construe "following fermentation" to mean "after harvesting has begun."

1. Rather than address the meaning of "following fermentation," the proposed construction elides it, substituting a distinct concept, the beginning of harvest. When something ends and when something else begins are not necessarily the same thing. History "following World War II" is defined by the end of the conflict known by that name (1945), not the beginning of, for example, the Cold War that followed (1947).

The rules of claim construction require respect for such distinctions. A claim cannot be construed to "include something more than, or something different from, what its words express," *White v. Dunbar*, 119 U.S. 47, 51 (1886). Claim construction must address the language the patentee actually used. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc). The claim construction process involves "better understanding the meaning of the claim" but not "changing it" or "making it different from what it is." *White*, 119 U.S. at 51-52.

"Following fermentation" must therefore be defined by when fermentation ends rather than when harvest may begin. The parties' experts agreed that "fermentation" is a biological process whose meaning is well understood. Dr.

Hauser explained that it is "the use of cells to produce a product," Ex. 1 (Kao Hearing Transcript (Oct. 16, 2019)) at 57:1-7, such as, in the specific context of the Kao patent, an antibody. *See also id*. at 108:4-109:23 (explaining that production of the antibody is the second part of "fermentation"). Dr. Glacken understood "fermentation" in the Kao patent's context to refer to "cell culture processes for making antibodies." *Id.* at 144:24-145:19; *see also id*. at 150:13-16 ("fermentation is used synonymous with mammalian cell culture processes for making antibodies" in the Birch review paper), *id.* at 151:16-152:14 (agreeing fermentation can refer to mammalian cell culture processes*), id*. at 161:3-7 (fermentation is "synonymous with the culture*"), id*. at 164:7-13 (agreeing with Dr. Hauser that "production is a subset of fermentation").

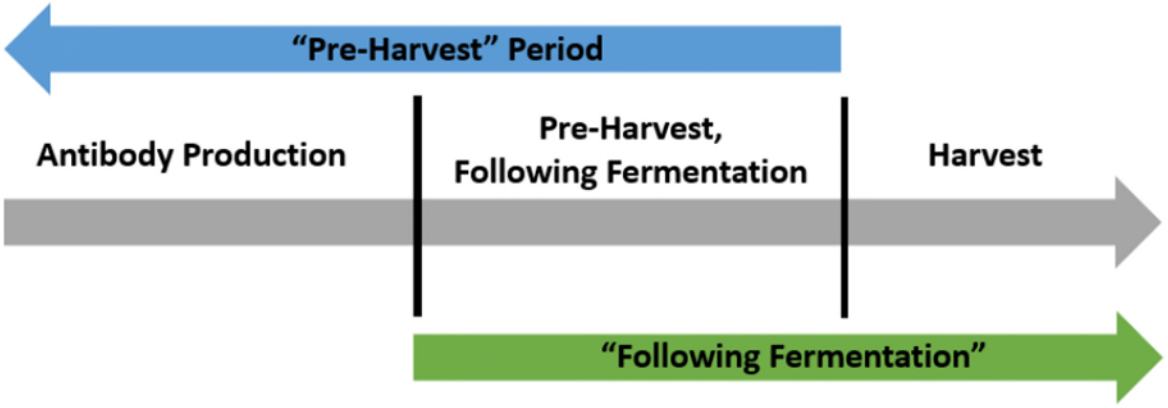
With this agreement on what "fermentation" means, the absence of any dispute over the meaning of "following" should end of the inquiry: the requirement to sparge "following fermentation" refers to sparging the fluid after the cells have made the antibodies. That is the concept intended by Genentech's proposed claim construction, and its proposal during the hearing, that "following fermentation" means "after the production phase has ended." *Id*. at 167:1-9, 170:20-171:12. Alternative phrasings like "after the cells have stopped making antibodies" or "after the cells have stopped producing antibodies" also convey this concept, and any of them would be an appropriate construction of the patent.

2. The proposed construction impermissibly nullifies one of the two embodiments the claims explicitly recite—the method of sparging a "pre-harvest culture fluid" following fermentation. Because sparging of "pre-harvest cell culture fluid" obviously cannot occur "after harvesting has begun," the proposed construction would violate the basic principle of claim construction that "the context of the surrounding words of the claim must also be considered[.]" *Wasica Finance GmbH v. Cont. Auto. Sys., Inc.*, 853 F.3d 1272, 1288 (Fed. Cir. 2017). When the Court previously asked about the meaning of "pre-harvest culture fluid," Genentech explained that it means "culture fluid that will be harvested." D.I. 570 at 3-4.[1] An interpretation that excludes the "pre-harvest" embodiment of the claims cannot be correct. *See Wasica*, 853 F.3d at 1288 (rejecting claim construction for excluding embodiments "expressly covered by the claim").

This embodiment is important. The parties agree that harvest does not always begin immediately after fermentation ends. A simple and common example, discussed at the hearing, arises when fermentation has ended but the manufacturing facility's harvest equipment is not yet ready to receive the culture fluid. Ex. 1 at 177:11-178:5. In that scenario fermentation is over, and pre-harvest culture fluid is waiting to be harvested. *Id.* at 173:8-174:6, 177:11-178:5. During that period the antibodies in the culture fluid are especially susceptible to being

[1] All D.I. citations are to C.A. No. 17-1407 unless otherwise stated.

destroyed by the reducing enzymes in the culture fluid, precisely the problem the claimed methods solve. *Id*. at 173:8-174:6. This period in time is depicted in the figure below:



D.I. 570 at 3-4; Ex. 1 at 173:8-174:6.

The expert Amgen presented at the hearing, Dr. Glacken, suggested that he was unaware of activity between fermentation and harvest. Ex. 1 at 165:3-9. But Dr. Chalmers, the scientific expert who Amgen relied upon during briefing, explained there *is* an additional, required step between fermentation and harvest when antibodies are made using bacterial cells, a manufacturing process that is specifically recited in dependent claim 10. D.I. 326 at 853-56 (¶¶ 42-43, 51). Because bacterial cells generally cannot secrete antibodies into the culture fluid, Dr. Chalmers described how it is necessary to destroy, or "lyse," these cells in order to release the antibodies that are trapped inside: "the first step following fermentation is 'lysis' (necessary to release the antibody into the culture medium),

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