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-SRF (CONSOLIDATED) [redacted]
GENENTECH, INC., Plaintiff, v. AMGEN INC., Defendant.	C.A. No. 18-924-CFC-SRF REDACTED PUBLIC VERSION

AMGEN INC.'S LETTER RESPONSE REGARDING COURT'S CONSTRUCTION OF "FOLLOWING FERMENTATION"

C.A. No. 17-1407-CFC-SRF:

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Dear Judge Connolly:

In its February 18, 2020 Oral Order, the Court informed the parties that it is inclined to construe "following fermentation" to mean "after harvesting has begun." Adhering to the Court's admonition in inviting a response, Amgen responds as follows.

The Court's construction of "following fermentation" reflects the specification's description of the purported invention as preventing disulfide bond reduction at a particular point in the manufacturing process after harvesting has begun—not during processes occurring in the production vessels: "In particular, the invention concerns the prevention of disulfide bond reduction during harvesting of disulfide-containing polypeptides, including antibodies, from recombinant host cell cultures." ('869 Patent at 1:19-22, D.I. 516, C.A. 17-1407, at Appx42; D.I. 376, C.A. 18-924, at Appx42.) "In particular, the invention concerns methods for preventing the reduction of disulfide bonds of recombinant proteins during processing following fermentation." (*Id.* at 20:9-11.)

Figure 23 of the '869 Patent (copied below) depicts the distinction between fermentation and harvest, indicating that harvest comes ***after*** the culture fluid has left the production vessels. (*Id.* at Fig. 23 (highlight added).)

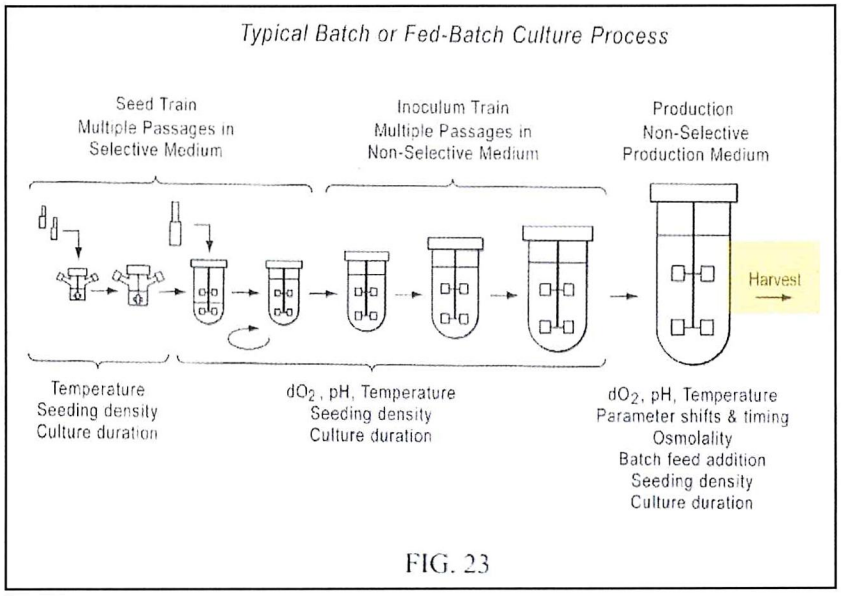

FIG. 23

The patent also provides examples of addressing disulfide bond reduction ***following completion of the cell culture process*** by treating the fluid during and/or after the harvest process: "Disulfide bond reduction can be inhibited (i.e., partially or fully blocked) by using one or more Trx inhibitors and/or applying non-directed approaches [*e.g.*, air sparging] following completion of the cell culture process, preferably to CCF prior to harvest [*i.e.*, pre-harvest culture fluid] or in the HCCF immediately after harvest [*i.e.*, harvested culture fluid]." (*Id.* at 23:54-58.)

Amgen does not sparge culture fluid that has left the bioreactor. Thus, under the construction of "following fermentation" as "after harvesting has begun," Genentech will have no objective basis to continue its infringement allegations in

the above-captioned cases. Genentech, however, refuses to yield.

On the heels of the Court's proposed construction, Amgen initiated a meet and confer to confirm that the construction, once made final, would finally compel Genentech's withdrawal of its '869 Patent infringement claims. But Genentech indicated that such a construction would merely ignite further dispute over the meaning of "harvesting." Genentech further indicated—contrary to basic canons of claim construction—that it will at that time seek to define "harvesting" in light of [redacted] not by the understanding of the ordinary artisan at the time of the purported invention and in light of the '869 Patent specification.[1]

Genentech's effective promise to foment continuing dispute in the hope of pouring a self-serving, after-the-fact meaning into "harvesting" regrettably requires resolution at the claim construction stage. *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co., Ltd.*, 521 F.3d 1351, 1362-63 (Fed. Cir. 2008).

The solution, however, is straightforward. Amgen requests that the Court simply make explicit what is already implicit in its construction, *i.e.*, that "harvesting" is "separating of cells or cellular debris from culture fluid using

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[1] "[A] court may not use the accused product or process as a form of extrinsic evidence to supply limitations for patent claim language." *Wilson Sporting Goods Co. v. Hillerich & Bradsby Co.*, 442 F.3d 1322, 1331 (Fed. Cir. 2006).

centrifugation or filtration." This flows not only from the instrinsic evidence, but from Genentech's own admissions.

The patent explains that "[f]ollowing fermentation proteins are purified." ('869 Patent at 26:41.) The "[p]rocedures for purification of proteins" include "centrifugation" or "filtration." (*Id.* at 26:41, 26:52-53.)

The patent further explains in its background section that, "[t]ypically, harvesting includes centrifugation and filtration to produce a Harvested Cell Culture Fluid (HCCF)." ('869 Patent at 2:3-4.) The patent reiterates in its "Compositions and Methods of the Invention" section that the "harvested cell culture fluid (HCCF) … is obtained after harvesting by centrifugation, filtration, or similar separation methods." (*Id.* at 22:3-5.)

In the context of the claim language, "pre-harvest … culture fluid" refers to the fluid that is sparged, not the timing of sparging. To fall within the claimed method under the Court's proposed construction of "following fermentation," the "pre-harvest … culture fluid" must be sparged after harvesting has begun, *i.e.*, in the centrifuge or filtration system where separation of the cells or cellular debris from the fluid begins.

In written testimony, oral testimony, briefing, and counsel's argument to the Court, Genentech has itself confirmed that "harvesting" is the separation of cells and cellular debris from culture fluid through centrifugation or filtration.

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