IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

GENENTECH, INC. and CITY OF HOPE, *Plaintiffs*, v. AMGEN INC., *Defendant*.	Civ. No. 17-1407- CFC, Consol.
GENENTECH, INC. and CITY OF HOPE, *Plaintiffs*, v. AMGEN INC., *Defendant*.	Civ. No. 18-924-CFC

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MEMORANDUM OPINION

March 9, 2020
Wilmington, Delaware

CONNOLLY, UNITED STATES DISTRICT JUDGE

Genentech, Inc. and City of Hope (collectively, Genentech) brought these patent infringement actions against Amgen, Inc. pursuant to the Biologics Price Competition and Innovation Act (BPCIA), 42 U.S.C. § 262. Pending before me is the matter of the construction of the disputed claim term "following fermentation" in United States Patent Number 8,574,869 (the Kao or #869 patent). The Kao patent teaches methods and means of preventing disulfide bond reduction during the manufacturing of therapeutic antibodies. #869 patent at 1:17–22.

I initially heard argument on the meaning of "following fermentation" and other disputed claim terms at two *Markman* hearings convened in April 2019. C.A. No. 17-1407, D.I. 340; C.A. No. 18-924, D.I. 182.[1] In memorandum opinions issued in June 2019, I explained that I was unable to construe "following fermentation" based solely on the intrinsic evidence, and I ordered a hearing "to determine if 'following fermentation' can be construed by resort to extrinsic evidence or is invalid for indefiniteness." D.I. 256 at 19.[2]

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[1] *See Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996) ("[T]he construction of a patent, including terms of art within its claim, is exclusively within the province of the court").

[2] Identical documents were usually filed in both cases. In addition, the memorandum opinions' discussions of "following fermentation" are identical. Accordingly, all citations are to the docket for C.A. No. 18-924 unless otherwise noted.

The parties thereafter presented me with extrinsic evidence in the form of affidavits, treatises, articles, reports, and competing expert testimony at an evidentiary hearing on October 16, 2019. D.I. 372; D.I. 373. Based on the extrinsic evidence and my reconsideration of the intrinsic evidence in light of that extrinsic evidence, I have concluded that a person of ordinary skill in the art (POSITA) would understand "following fermentation" to mean "after the earlier of harvesting or purification has begun," and I will construe the term accordingly.

I set forth the legal standards that govern claim construction in my earlier memorandum opinions. *See* D.I. 256 at 3–5. Rather than repeat those standards here, I incorporate by reference the earlier memorandum opinions. I write primarily for the parties and, to a large degree, presume familiarity with the underlying technology.

I.

Claim 1 of the Kao patent teaches

> [a] method for the prevention of the reduction of a disulfide bond in an antibody expressed in a recombinant host cell,
>
> comprising, *following fermentation*, sparging the pre-harvest or harvested culture fluid of said recombinant host cell with air,
>
> wherein the amount of dissolved oxygen (dO2) in the pre-harvest or harvested culture fluid is at least 10%.

#869 patent at 107:44–49 (reformatted for clarity and emphasis added). As I explained in my earlier memorandum opinions, the construction of "following fermentation" involves two questions. First, what is "fermentation?" And second, when does "fermentation" end? D.I. 256 at 15.

Unfortunately, as I also discussed in my earlier memorandum opinions, the Kao patent neither defines fermentation nor allows for a cogent inference of fermentation's meaning, let alone when it ends. The patent is plagued by typographical errors and sloppy language; it suggests at times that fermentation is synonymous with "production" and "manufacturing" and at other times that fermentation is distinct from these concepts. *Id.* at 16, 19 n.6. To add to the confusion, the patent does not consistently use or assign meaning to "production" and "manufacturing." *Id.* at 19 n.6. As Genentech's counsel conceded (to his credit) at oral argument, "certain words like manufacturing and production may not be used quite as precisely as one would like in the Kao patent." C.A. No. 17-1407, D.I. 340 at 25:20–22. Resort to extrinsic evidence is therefore necessary. *See Digital Biometrics, Inc. v. Identix, Inc.*, 149 F.3d 1335, 1344 (Fed. Cir. 1998) ("[I]f after consideration of the intrinsic evidence there remains doubt as to the exact meaning of the claim terms, consideration of extrinsic evidence may be necessary to determine the proper construction.").

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