

**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)

**PUBLIC VERSION**

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GENENTECH, INC.,

Plaintiff,

v.

AMGEN INC.,

Defendant.

C.A. No. 18-924-CFC

**PUBLIC VERSION**

**AMGEN INC.'S LETTER BRIEF REGARDING INDEFINITENESS OF  
"FOLLOWING FERMENTATION"**

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

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Dear Judge Connolly:

Pursuant to this Court’s Order (D.I. 436; D.N. 271)<sup>1</sup>, Amgen Inc. (“Amgen”) respectfully submits its letter brief regarding the indefiniteness of the claim term “following fermentation” in U.S. Patent No. 8,574,869 (the “’869 Patent”).

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The ’869 Patent claims a method involving sparging (*i.e.*, bubbling) certain culture fluid with air “following fermentation.” The scope of the claim term “following fermentation”—in particular, what “fermentation” is, and when “fermentation” ends and “following fermentation” begins—is not reasonably certain to a person of ordinary skill in the art (“POSA”) rendering the scope of the claims themselves uncertain and thus indefinite. *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2124 (2014). The term fails to provide the requisite “clear notice” of when sparging with air is encompassed by the claimed processes. *Id.* at 2129 (“[A] patent must be precise enough to afford clear notice of what is claimed, thereby apprising the public of what is still open to them.”) (citation and internal quotation omitted). The Court should find the claims reciting “following fermentation” indefinite.

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<sup>1</sup> D.I. refers to C.A. No 17-cv-1407 docket items, and D.N. refers to C.A. No. 18-cv-924 docket items.

In attempting to construe “following fermentation,” the Court asked two questions in its claim construction decision: What is “fermentation”? And when does “fermentation” end? D.I. 401 at 16; D.N. 256 at 15. The Court found the ’869 Patent to lack any definition of “fermentation,” and to be filled with such confusion about “fermentation” and the timing associated with it that the intrinsic evidence did not provide an answer to either question. D.I. 401 at 17-21; D.N. 256 at 15-19.

Given the insufficiency of the intrinsic record, the Court now seeks to resolve whether the term “following fermentation” can be construed by resort to extrinsic evidence. D.I. 401 at 21; D.N. 256 at 19. It cannot.

Genentech has pointed to no extrinsic evidence that itself clarifies the meaning of “following fermentation,” or helps make sense of the intrinsic evidence. Relying only on the unsupported opinion of its expert, Genentech argues that “fermentation” has a plain and ordinary meaning to a POSA, namely “cell growth and antibody production phases.” But Genentech cannot square its proposal with the varying scope that “fermentation” has in the art, where it can include, for example, both aerobic and anaerobic processes in some contexts, but only anaerobic processes in others. Declaration of Dr. Michael Glacken ¶56. Nor can it square its proposal with the patent itself, where it is uncertain whether “following fermentation” refers to the theoretical end of biological processes

Genentech now characterizes as “fermentation” or instead to manufacturing steps following a “fermentation” step.

Even if “fermentation” were given the meaning that Genentech ascribes to it (which it should not), “following fermentation” remains ambiguous in light of extrinsic evidence. Determining the end of “fermentation” (whatever it may be) is described in the art in a wide variety of ways, from various methods of measuring optical densities of culture fluids, to depletion of a resource like glucose, to a subjective goal of producing sufficient product. *Id.* ¶¶57-71. These various methods result in multiple potential timepoints for the end of “fermentation”—exactly the uncertainty in claim scope the definiteness requirement is designed to prevent.

Facing the differing usage of “fermentation” in the extrinsic evidence and the lack of a single *objective* standard to mark the end of “fermentation,” Genentech attempts to pivot and argue that the end of “fermentation” (and the start of “following fermentation”) depends on the *subjective* preferences, and affirmative acts, of operators of manufacturing processes. Genentech cannot find refuge in such subjectivity. Genentech argues that an operator can end “fermentation” by deciding to change conditions to end cell growth and antibody production. But determining whether a particular change of conditions has ended cell growth and antibody production requires measurement, and, as discussed

above, different measurement techniques give different results. Neither the '869 Patent nor the extrinsic evidence point to any particular measurement technique for ascertaining the end of “fermentation” with reasonable certainty. *Id.* ¶¶63, 72-75, 80.

Genentech’s proposed construction for the claim term “following fermentation” exacerbates the problem. Genentech proposes that the end of cell growth and antibody production phases are “indicated by a change in the cell culture environment that *substantially* ends cell growth and antibody production.” But adding “substantially”—a term of degree—makes it even more difficult to ascertain the end of “fermentation” by tying it to an unspecified threshold of cell growth and antibody production. *Id.* ¶¶77-79.

Nothing in the intrinsic record provides any guidance regarding the degree to which cell growth and antibody production must be reduced to “substantially” end. *Id.* And Genentech’s expert was unable to provide any specific guidance at his deposition regarding how to determine the substantial end of these processes. *Id.* ¶80. As for Genentech’s favored example of a changed condition—chilling the cells—that purportedly “substantially” ends cell growth, its expert’s testimony that various temperatures of “below 30 degrees” or “about 21 degrees, 22 degrees” qualify simply underscores the arbitrariness of Genentech’s approach to construing the term and the indefiniteness that results from Genentech’s proposal. *Id.* ¶¶80-

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