

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

AMGEN INC. and AMGEN  
MANUFACTURING, LIMITED,

Plaintiffs,

v.

HOSPIRA, INC. and PFIZER, INC.,

Defendants.

Civil Action No. 18-1064-CFC-CJB

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**MEMORANDUM ORDER**

Pending before me is Defendants' Motion for Summary Judgment of Noninfringement of the Asserted Claims of U.S. Patent No. 9,643,997 (D.I. 205). Defendants argue that "summary judgment is appropriate here because there is no genuine dispute that [the] accused [biologics manufacturing] process contains an intervening precipitation step." D.I. 206 at 3; *see also* D.I. 240 at 1–2 ("Amgen fails to raise a genuine dispute of material fact because Amgen has not identified any evidence that [the relevant step of Pfizer's manufacturing process] does not 'remove precipitated impurities.'") (citations omitted). Although Defendants assert as a statement of material fact in their briefing that "Pfizer's manufacturing process contains an intervening precipitation step," D.I. 206 at 2, they did not make

that assertion in the concise statement of facts required by the Scheduling Order.

The terms of the Scheduling Order could not be clearer: “Any motion for summary judgment shall be accompanied by a separate concise statement detailing each material fact as to which the moving party contends that there are no genuine issues to be tried that are essential for the Court's determination of the summary judgment motion (not the entire case).” D.I. 26 at 10. Because Defendants did not comply with the Scheduling Order’s requirements for summary judgment practice, I will deny their motion.<sup>1</sup>

NOW THEREFORE, at Wilmington on this Twentieth day of May in 2021,

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<sup>1</sup> I also note that Plaintiffs deny that the accused process performs a precipitation step, and they cite record evidence from which a jury could infer that the accused process does not perform a precipitation step. Plaintiffs, for example, point to Defendants’ manufacturing batch records, D.I. 233-1, Ex. 8 at -2197, -2201, and a portion of Defendant’s aBLA titled “Description of Manufacturing Process and Process Controls,” D.I. 233-1, Ex. 2 at -4469–70. Neither the batch records nor their cited portion of the aBLA describe the removal of precipitates during the manufacturing process. Plaintiffs’ expert has also testified that the filtration used during Defendants’ manufacturing process would not be appropriate to use in a precipitation step. D.I. 233-1, Ex. 3 ¶ 41 (“In contrast, the precipitation the invention avoids . . . is not the *de minimis* amount that can be removed by [Defendants’ process]. Rather, it is an amount of solid material that would quickly clog all but the coarsest of filters.”).

it is HEREBY ORDERED that Defendants' motion for summary judgment  
(D.I. 205) is DENIED.

  
UNITED STATES DISTRICT JUDGE