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RICHARDS LAYTON & FINGER

VIA CM/ECF

The Honorable Colm F. Connolly
District Court of Delaware
J. Caleb Boggs Federal Building
844 N. King Street
Wilmington, DE 19801-3555

Re: ***Amgen Inc. et al. v. Hospira, Inc. et al.*, C.A. No. 20-201-CFC**

Dear Chief Judge Connolly:

Following the June 11, 2021 Markman hearing, the Court ordered that the claim term "between about 0.1M and about 1.0" of U.S. Patent No. 8,273,707 ("the '707 Patent") be construed to have its plain and ordinary meaning "between approximately 0.1 M and approximately 1.0 M" and is not a functional limitation. (D.I. 74). The Court further ordered that the case remain stayed until a determination is made as to whether the Court should entertain summary judgment practice on the issue of non-infringement, and that the parties shall jointly submit a status update by July 12, 2021. (D.I. 73).

Pursuant to the Court's Order, counsel for the parties met and conferred on July 2, 2021, July 6, 2021, and July 8, 2021, and jointly submit this letter regarding the parties' respective positions. Defendants propose filing an early motion for summary judgment of noninfringement. Plaintiffs do not object to the filing of such a motion, but believe that limited discovery may be required. Defendants do not agree that additional discovery is necessary, and believe that the briefing schedule for Defendants' motion should be set after the Court resolves this preliminary issue.

Plaintiffs' Position

Based on the Court's construction of the claim term "between about 0.1M and about 1[M]", Plaintiffs will not pursue a literal infringement claim against Defendants as to the '707 Patent. Plaintiffs maintain their infringement claim under the doctrine of equivalents against Defendants as to the '707 Patent. Specifically, with respect to the construed claim term, Plaintiffs contend that the concentration of the second salt used in Defendants' process, in combination with the first salt, the

protein and the specific column, is insubstantially different from the claimed concentration range, and/or performs substantially the same function in substantially the same way to achieve substantially the same result as the claimed concentration range. Plaintiffs further contend that all other limitations of the asserted claims are literally satisfied in Defendants' process.

A. Potential Need for Limited Discovery Under Fed. R. Civ. P. 56(d)

Defendants propose, but have not specified the grounds for, filing a motion for summary judgment of noninfringement under the doctrine of equivalents regarding the claim limitation "between about 0.1M and about 1[M]."[1] To the extent that Defendants' motion raises factual issues, Plaintiffs respectfully submit that limited discovery under Fed. R. Civ. P. 56(d) may be required for Plaintiffs to respond to the proposed motion because little fact discovery and no expert discovery have been exchanged to date.

It is possible that Defendants' motion will be based on purely legal grounds, in which case discovery would presumably not be necessary. However, it is also possible that the motion will be based on an assertion that the concentration of the second salt in the accused process is too low for a reasonable juror to find that it is equivalent to the claimed concentration range. During the meet-and-confer process Plaintiffs asked what would be the basis for the motion but Defendants are not yet able to provide that information.

If, for example, Defendants' motion relies on expert declarations, Plaintiffs submit that it may be necessary to have limited depositions of those experts so that the parties can understand and test the opinions in the declarations. Similarly, to the extent that Defendants argue in their motion that no reasonable jury could find that the second salt is present at a concentration that could perform substantially the same function in substantially the same way to achieve substantially the same result as the claimed concentration range, Defendants' own documents may be relevant to whether there is a genuine dispute of material fact on that issue. This would include documents describing the development of Defendants' HIC step in the accused

[1] Defendants' proposal is not limited to moving for summary judgment for infringement under the doctrine of equivalents, but the only disputed issue for infringement will be infringement under the doctrine of equivalents because Plaintiffs are not pursuing their claims of literal infringement in view of the Court's claim construction.

process, and in particular why certain salt concentrations were selected, and experiments showing the effect of using different salt concentrations. Such discovery would be particularly appropriate here because little information regarding the development of Defendants' HIC step has been produced to Plaintiffs. As required under the BPCIA in the pre-lawsuit exchanges, Defendants provided a copy of their aBLA describing the accused process to Plaintiffs in 2019. But the aBLA provides little detail regarding the development of the process or how the conditions for the HIC step were selected.[2]

Defendants contend that "[d]iscovery on 'why' any particular concentration may have been chosen or its 'effect' is not relevant given the Court's construction that the concentration range limitation in the asserted claims is not functional." Plaintiffs respectfully disagree. Plaintiffs understand that the Court determined in its construction that the function of the lower concentration limit is not relevant to literal infringement. But Plaintiffs do not understand that the Court determined that function is irrelevant to infringement under the doctrine of equivalents, for which function is a classic part of the equivalence analysis. *See Warner–Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 40, 117 S.Ct. 1040, 137 L.Ed.2d 146 (1997) ("An analysis of the role played by each element in the context of the specific patent claim will thus inform the inquiry as to whether a substitute element matches the function, way, and result of the claimed element, or whether the substitute element plays a role substantially different from the claimed element."). Plaintiffs respectfully submit that Defendants cannot write out the "functional" limitation of the doctrine-of-equivalents analysis required under the law simply because the Court declined to construe the claim term to have a functional meaning. Indeed, in *Cohesive Technologies, Inc. v. Waters Corporation*, the Federal Circuit precluded application of the doctrine of equivalents because the term was given a functional meaning that it "encompasses particle diameters that perform the same function, in the same way, with the same result" as the claimed particles, the doctrine of equivalents is "unavailable to further broaden the scope of the claim." 543 F.3d 1351, 1372 (Fed. Cir. 2008). That is not the case here.

Therefore, to the extent that Defendants' proposed motion for summary judgment raises factual issues regarding the effect of the salt concentrations used in

[2] Prior to the stay in this action, Plaintiffs requested the production of, *inter alia*, documents describing the development of Defendants' HIC step, which Defendants agreed to produce subject to their objections. However, Defendants never produced such documents prior to the Court's stay of discovery on April 6, 2021.

Defendants' process, Plaintiffs submit that limited discovery on that issue should be permitted.

B. Briefing Schedule

During the meet-and-confer process Defendants proposed that they would file their proposed motion for summary judgment on August 6, 2021. Accordingly, Plaintiffs propose the following schedule, which Plaintiffs respectfully submit is appropriate given the posture of the case and the interests of the parties. In light of scheduling constraints and planned vacations, Plaintiffs respectfully request four weeks to submit their Answering brief.

Deadline	**Proposed Date**
Defendants' Opening Brief and Concise Statement of Facts	August 6, 2021
Plaintiffs' Answering Brief and Concise Statement of Facts	September 3, 2021
Defendants' Reply Brief	September 17, 2021

If, upon review of Defendants' Opening brief, Plaintiffs believe that limited discovery is necessary in order to respond, the parties will confer. If there is agreement, the parties will submit a letter to the Court within fourteen (14) days of Defendants' filing that identifies the discovery sought, and proposes a revised schedule for obtaining such discovery and completing briefing on the summary judgment motion. If the parties do not agree on the need for discovery, Plaintiffs will follow the procedures under Fed. R. Civ. P. 56(d) so that the Court can rule on the issue. Following the Court's ruling the parties will again confer on an appropriate schedule for completing briefing on the summary judgment motion.

Plaintiffs recognize that, if limited discovery under Fed. R. Civ. P. 56(d) is needed and permitted by the Court, resolution of Defendants' proposed motion would likely be delayed. While Plaintiffs are interested in resolving Defendants' motion expeditiously, the accused product is already on the market and neither party will be unduly harmed by such a delay. Plaintiffs are also cognizant of the fact that counsel for both parties are scheduled begin the trial of the co-pending case between the same litigants on September 20, and will try to ensure that whatever schedule is put in place does not unduly burden either party in the preparation for or conduct of the trial.

In the course of preparing this joint letter, Defendants have proposed that the Court resolve the issue of discovery prior to setting a briefing schedule. Plaintiffs respectfully submit that it would be more efficient to proceed as outlined above, so that the Court has a basis on which to decide the need for discovery and since it is possible, depending on the basis for Defendants' summary judgment motion, that there will be no need for further discovery. However, if the Court would prefer to have discovery on the equivalents issues take place prior to any briefing Plaintiffs do not object to such a procedure.

Defendants' Position

Pfizer maintains that the best way to conserve the parties' and the Court's resources is for the Court to permit early summary judgment practice on the issue of noninfringement and maintain the current stay of discovery. The salt concentration range limitation, as construed by the Court, would serve as the basis for Pfizer's motion for summary judgment of noninfringement. As mentioned at the Markman hearing, the concentration of one of the two claimed salts in Pfizer's manufacturing process is substantially below the claimed concentration range. That concentration is set forth in Pfizer's aBLA, which Pfizer provided to Amgen on August 19, 2019 (D.I. 1 ¶ 41), and has not been disputed. Because the concentration of one of the salts in Pfizer's process is substantially below the claimed concentration range, Pfizer does not infringe the asserted claims of the '707 patent either literally or under the doctrine of equivalents.

Amgen proposes that discovery of Pfizer's "own documents may be relevant" to the question of whether there may be infringement under the doctrine of equivalents, including "documents describing the development of [Pfizer's] HIC step in the accused process, and in particular why certain salt concentrations were selected, and experiments showing the effect of using different salt concentrations." Pfizer disagrees. The Court construed the concentration range as not a functional limitation. The discovery Amgen seeks can only be arguably relevant to a functional limitation and would allow for inappropriate importation of the functional limitation in the preamble of increasing the dynamic capacity. Discovery on "why" any particular concentration may have been chosen or its "effect" is not relevant given the Court's construction that the concentration range limitation in the asserted claims is not functional. As the Court acknowledged at the June 11, 2021 hearing, the functional requirement of the claim is set forth in its preamble, which the parties agree is limiting. That Pfizer's process may meet the preamble limitation of increasing dynamic binding capacity does not absolve Amgen of its burden of

proving that Pfizer's process separately meets the concentration range limitation. Whether a person of ordinary skill in the art would consider a certain salt concentration of one salt to be an equivalent of 0.1M should not be linked to increasing dynamic capacity. The additional discovery sought by Amgen on this issue is not relevant.

Amgen further contends that "the concentration of the second salt used in [Pfizer's] process, in combination with the first salt, the protein and the specific column, is insubstantially different from the claimed concentration range, and/or performs substantially the same function in substantially the same way to achieve substantially the same result as the claimed concentration range." As noted above, the Court has determined that the concentration range limitation is not functional. Pfizer disagrees with Amgen's position that the concentration range limitation should be construed one way for the purpose of assessing literal infringement and another way for the purpose of assessing infringement under the doctrine of equivalents. Pfizer also notes that the "function way result" test is not the exclusive test for infringement under the doctrine of equivalents, and the "substantial differences" test may be more suitable here. *Mylan Institutional LLC v. Aurobindo Pharma Ltd.*, 857 F.3d 858, 869 (Fed. Cir. 2017). In any event, like the functional limitation in the preamble, the protein that Pfizer purifies, the hydrophobic interaction chromatography column that Pfizer employs for that purification, and the identity and concentration of the first salt in Pfizer's process are separate claim limitations and are not relevant to Pfizer's alleged infringement of the concentration range limitation for the second salt. The only question for the Court to resolve on summary judgment is whether the substantially lower concentration of the second salt in Pfizer's process can be an equivalent to a salt concentration in the claimed range.

Pfizer believes that summary-judgment briefing, including any expert discovery if necessary, could be completed before the trial in related action 18-1064-CFC-CJB, which is scheduled to begin on September 20, 2021. However, Pfizer respectfully requests that the Court resolve any request by Amgen for additional document discovery before a briefing schedule is set. To the extent the Court is inclined to enter Amgen's schedule proposed above, Pfizer requests that the due date for its reply be set after the trial in the related action. Amgen's schedule would require Pfizer to file its reply brief on the last business day before the start of the trial in the related action. Moreover, the two weeks that Amgen has proposed for Pfizer's

reply would not provide sufficient time for Pfizer to depose Amgen's expert, should that be necessary.

* * *

Should the Court wish to address this issue with the parties, Amgen and Pfizer are available at the Court's convenience.

Respectfully,

/s/ Robert W. Whetzel

Robert W. Whetzel (#2288)

cc: Counsel of Record (via CM/ECF & E-mail)