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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH

AMGEN INC. and AMGEN MANUFACTURING LIMITED LLC, Plaintiffs, v. FRESENIUS KABI USA, LLC, FRESENIUS KABI SWISSBIOSIM GmbH, FRESENIUS KABI DEUTSCHLAND GmbH, and FRESENIUS KABI AUSTRIA GmbH. Defendants.	**MOTION TO QUASH AMGEN INC.'S AND AMGEN MANUFACTURING LIMITED LLC'S RULE 45 SUBPOENA** Case No. 1:25-mc-00016 The Honorable _____ Magistrate Judge _____ Pending in the United States District Court for the Northern District of Illinois (Case No. 1:24-cv-09555) **[REDACTED VERSION FOR PUBLIC FILING]**

HyClone Laboratories, LLC ("HyClone"), pursuant to Rules 7, 26, and 45 of the Federal Rules of Civil Procedure, respectfully submits its Motion to Quash Amgen, Inc. and Amgen Manufacturing Limited LLC's ("Amgen") Rule 45 Subpoena to HyClone[1].

RELIEF REQUESTED AND SUPPORTING GROUNDS

Amgen is on a fishing expedition in connection with its patent infringement case against Fresenius Kabi USA, LLC and its affiliates ("Fresenius"). That case was commenced in the Northern District of Illinois in October 2024. There is no case schedule, no fact discovery deadline, and no trial date in that case. Within weeks of filing its complaint—and without having received, much less analyzed, all of Fresenius's discovery—Amgen jumped the gun and subpoenaed third-party HyClone for, among other things, HyClone's trade secret information and various categories of documents reasonably in Fresenius' possession.

HyClone is a longstanding Utah-based company, and it is unclear what relationship HyClone has to the underlying litigation. Amgen's attorneys have conclusorily argued that one of HyClone's off-the-shelf products—a cell culture media marketed as HyClone™ Cell Boost™ 7a Supplement ("CB7A")—is relevant to their case. But Amgen has not shown why that product or any of the twenty-two (22) overbroad categories of requested information, particularly those pertaining to the formulation and manufacturing of CB7A, are actually relevant to its dispute with Fresenius. And even if Amgen could show that some aspects of the formulation of CB7A are relevant, Amgen cannot meet its burden to establish that the ***full*** formulation of CB7A is relevant to Amgen's patent claims, which only require ***specific components*** at ***specific concentrations***.

Setting aside relevance (or lack thereof), the Amgen requests directed to the full CB7A formulation are asking HyClone to disclose its most closely guarded trade secret information.

[1] Exhibits are attached to the Declaration of Scott Greene ("Greene Decl."), filed herewith.

Even worse, Amgen has rejected any reasonable compromise proposal—including a fact declaration providing for partial disclosure of only the relevant components of the CB7A formula, or a source code-like inspection of the full formulation—despite that such measures are routinely agreed upon to prevent the inadvertent misuse of highly sensitive information. Requiring HyClone to disclose the full CB7A formulation at all, much less without robust protections, would cause the unacceptable risk of extreme competitive and commercial harm through [redacted]

Finally, all of Amgen's discovery requests are overly broad, extraordinarily burdensome and/or prejudicial. Indeed, there appears to be no dispute that, for many of Amgen's requests, the requested information is readily available from Fresenius—a party to the underlying case. Yet Amgen has not narrowed its requests ***at all***.

For these reasons, Amgen's subpoena should be quashed. Alternatively, to the extent this Court requires disclosure of information relating to the CB7A formulation—which it should not—such disclosure should, at minimum, be carried out pursuant to the terms of a "source code"-like inspection along with additional protections as described further below.

RELEVANT FACTS

Amgen sued Fresenius in the Northern District of Illinois on October 4, 2024, alleging that Fresenius's proposed launch of a biosimilar drug infringes certain Amgen patents. Dkt. 62 at 2-4;[2] Dkt. 1 ¶ 3. CB7A is a cell culture media supplement, which means it is added, often along with other supplements, to cell culture media to supply nutrients to cells used to manufacture drug products. *See* Declaration of Nan Lin, Ph.D ("Lin Decl.") filed herewith, at ¶ 9. CB7A's formulation is proprietary and maintained under the highest levels of trade secrecy. *Id.* ¶¶ 15-27.

[2] References to "Dkt." refer to *Amgen, Inc. v. Fresenius Kabi*, No. 1:24-cv-09555 (N.D. Ill.).

Amgen and Fresenius [redacted] *Id.* ¶¶ 31-35. There is little doubt that [redacted] *Id.* Indeed, Amgen asserts that it invests heavily in research for "cell culture and purification methods." Dkt. 1 ¶ 65.

Amgen served its subpoena—with 22 requests—one month after filing its complaint, eight days after discovery opened, and before Amgen and Fresenius could engage in meaningful discovery from one another. Dkt. 1; Dkt. 16 at 2; Ex. A. In Amgen's own words, the underlying action is "in its infancy" and "the assigned judge[] ha[s] not yet had occasion to meaningfully engage with the substantive and discovery-related issues." Dkt. 38 at 5, 7. There is no case schedule or fact discovery deadline. *See, e.g.*, Dkt. 48-1 at 1-2 (joint motion requesting "suspen[sion]" of "all deadlines in the Local Patent Rules"); Dkt. 49 (granting motion). HyClone objected to Amgen's subpoena, and the parties met-and-conferred on December 19, 2024, and January 31, 2025. *See* Ex. B; Ex. F. The parties reached impasse on February 4, 2024. Ex. F.

ARGUMENT

I. REQUEST NOS. 1-4, 7: AMGEN'S REQUESTS FOR THE FULL CB7A FORMULATION SHOULD BE QUASHED

A. Amgen Has Not Shown The Relevance Of The Full CB7A Formulation

Request Nos. 1-4 and 7 seek documents disclosing the full CB7A formulation and related manufacturing methods. Amgen bears the "burden to show the relevancy" of the full scope of those requests and courts have declined to enforce subpoenas based on overbreadth and lack of relevance. *United States v. Xlear, Inc.*, 2022 WL 5246717, at *3 (D. Utah Oct. 6, 2022); *City of Rockford v. Mallinckrodt ARD, Inc.*, 2020 WL 11191830, at *3-5 (N.D. Ill. May 27, 2020). Amgen has not met its burden of showing those requests are relevant and not overbroad.

First, Amgen's attorneys have repeatedly declined to provide any evidence that CB7A is

actually used in connection with the relevant Fresenius proposed biosimilar product. Given Amgen's burden of proof, that alone should be fatal to Amgen's subpoena.

Second, even assuming Fresenius uses CB7A in manufacturing its proposed biosimilar (something Amgen has not shown), Amgen cannot make any showing that the ***full formulation*** of CB7A is relevant because Amgen's claims turn on the presence of ***specific components*** at ***specific concentrations***. Amgen cannot be allowed to force HyClone to disclose its entire trade secret CB7A formulation, when Amgen has no patent claim to which all the components are relevant. For example, Claim 1 of Amgen's U.S. Patent No. 10,167,492 requires there be "10 to 100 ppb copper and from 50 to 1000 nM manganese" in the cell culture. Ex. C at 22-23. But no part of this (or any) patent claim against Fresenius turns on the amount of, for example, [redacted] Therefore, the full CB7A formulation (and, for example, whether it contains [redacted] is not relevant as to Claim 1 of the '492 Patent, because only the amounts of copper and manganese are relevant. This is likewise true of all of Amgen's patent claims. Because those claims are directed to specific components and concentrations, Amgen simply has not shown that it needs to know the ***full*** formulation of CB7A to support its infringement claims.

Third, the presence or absence of any single component in CB7A is not necessarily relevant to Amgen's claims because CB7A is merely a ***supplement***. For example, claim 1 of asserted U.S. Patent No. 9,012,178 requires the presence of certain dipeptides such as Tyr-His. Ex. D at 20. If Amgen can determine from party discovery that, apart from CB7A, Fresenius adds Tyr-His to its cell culture medium, its presence or absence in the CB7A supplement is not relevant or necessary to Amgen's claims. Amgen has a duty to "take reasonable steps to avoid imposing undue burden" on a "person subject to the subpoena" by first seeking such discovery from Fresenius. *Convo Commc'ns, LLC v. Sorenson Commc'ns, LLC*, 2024 WL 3069201 (D. Utah June 19, 2024)

(quoting Rule 45(d)(1)). Amgen has not attempted to first analyze party discovery and thus Amgen has not fulfilled this duty. *See* Dkt. 38 at 5 (stating this matter is "in its infancy"). For at least those reasons, Amgen has failed to meet its burden.

B. Amgen's Requests For The Full CB7A Formulation Are Unduly Burdensome Because They Require Disclosure Of HyClone's Trade Secret Information

Amgen's Request Nos. 1-4 and 7 should also be quashed as unduly burdensome and prejudicial because they require HyClone to disclose the [redacted] which will result in significant commercial and competitive harm to HyClone.

Under Rule 45(d)(3)(B)(i), the court "may, on motion, quash or modify [a] subpoena if it requires…disclosing a trade secret or other confidential research, development, or commercial information." Once established that "the information sought is a trade secret or confidential research, development[,] or commercial information that might be harmful if disclosed, the burden shifts to the party seeking discovery to establish that disclosure is both relevant and necessary. Then the court must balance the need for confidential information against the possible injury resulting from disclosure." *Int'l Coal Group, Inc. v. Tetra Fin. Grp., LLC*, 2010 WL 2079675, at *2 (D. Utah May 24, 2010); *Velocity Patent LLC v. FCA US LLC*, 2017 WL 11893112, at *4 (N.D. Ill. Nov. 2, 2017). "[N]on-party status weighs ***against*** requiring disclosure." *Int'l Coal*, 2010 WL 2079675, at *1; *Velocity*, 2017 WL 11893112, at *4 (same).

As detailed in Dr. Lin's declaration, "[t]he composition of [CB7A] is protected by the highest levels of trade secrecy and confidentiality." Lin Decl. ¶ 4; *see also id.* ¶¶ 4, 15-27. [redacted] *Id.* ¶ 4; *see also id.* ¶¶ 18-27. In addition, electronic, physical, and legal measures are

employed to maintain the utmost confidentiality of cell culture media product formulations, including that of CB7A. *See id.* ¶¶ 18-27. And [redacted] *Id.* ¶ 4.

The CB7A formulation derives economic value from not being generally known and not being readily ascertainable through proper means. "It is of paramount competitive and commercial importance" that the formulation of CB7A "not fall into the hands of any third parties." *Id.* ¶ 31. "Customers include biopharmaceutical companies who would also be commercially interested in knowing the formulation of our cell culture media products to vertically integrate their supply chain and remove the need for their purchase, including the purchase of [CB7A]. Both Amgen and Fresenius are sophisticated biologics manufacturers [redacted] *Id.* ¶ 32. Indeed, "[if] the full formulation of [CB7A] were revealed to a customer who then proceeded to produce a copy of the cell culture media supplement for [their own] use … we would have no mechanism by which to detect use of that copy." *Id.* ¶ 35.

As explained above and below, Amgen cannot demonstrate relevance or necessity. Additionally, Amgen served this subpoena at the outset of its case and has not determined what information to support its claims can be obtained from Fresenius or other sources. Courts in this district and others have quashed subpoenas under similar circumstances. *See, e.g.*, *Int'l Coal*, 2010 WL 2079675, at *2-3; *Velocity*, 2017 WL 11893112, at *5.[3] This Court should do the same.

C. To The Extent Disclosure Of CB7A Formulation Is Ordered, It Should Be Carried Out As A "Source Code" Inspection With Supplemental Protections

Though HyClone has repeatedly attempted to resolve this matter without involving the

[3] Amgen is also expected to drop many of the 33 currently-asserted patents. In Amgen's recent BPCIA litigation against Celltrion over Celltrion's denosumab biosimilar, Amgen narrowed its asserted patents from 29 in its complaint to just five. *See* Ex. E.

Court, Amgen has refused reasonable alternatives to production of the full CB7A formulation. In December, Amgen refused to accept a fact declaration disclosing only the specific portions of the CB7A formulation that relate to Amgen's patent claims (and subject to provisions like the ones agreed to in the *Regeneron* case below). In January, Amgen rejected HyClone's offer for a "source code"-like inspection of the full CB7A formulation, whereby outside counsel and/or experts review the formula in a secured location and identify the specific components (subject to mutually-agreed limits) for which they desire a paper production (which would be subject to provisions like the ones agreed to in the *Regeneron* case below). Amgen's repeated rejection of reasonable alternatives makes plain Amgen's failure "to avoid imposing undue burden." Rule 45(d)(1).

Given the extreme levels of protection needed to guard the CB7A formulation, any disclosure of formulation-related information should, at minimum, be carried out initially as a "source code"-like inspection as described above and below. *See, e.g.*, *Drone Techs. v. Parrot*, 838 F.3d 1283, 1300 n.13 (Fed. Cir. 2016) (for a "company's most sensitive and most valuable property," "in 'U.S. litigation, extreme measures are ordered to protect [such] confidentiality'"); *see also Modern Font Applications v. Alaska Airlines*, 2021 WL 364189 at *4-6 (D. Utah Feb. 3, 2021). For any specific components that Amgen's outside counsel and experts have determined are relevant and should be the subject of a paper production, additional protective measures are also required for that paper production. In similar cases, HyClone has reached a typical and reasonable compromise to disclose very limited portions of its formulations in a fact declaration, but only under the most stringent conditions. In one such case, *Regeneron v. Mylan*, No. 22-cv-0061 (N.D.W. Va.) (Dkt. 275 ¶¶ 3-10, Dkt. 91), all parties agreed to a supplemental protective order in connection with HyClone's disclosure via a fact declaration of only very limited portions (i.e. the identity and amount of a handful of components) of the relevant formulation. That

supplemental protective order provided that HyClone's highly-sensitive information would be, *inter alia*, (1) produced only on three copies of copy-proof paper per side; (2) restricted to outside counsel's eyes only and three experts per side; and (3) restricted in the "additional copies, notes, or any other written records" that could be made.[4]

In Amgen's case against Fresenius, the operative protective order is inadequate to protect HyClone's interests. That protective order contemplates production of electronic (and, therefore, reproducible) copies to (1) five in-house counsel for each of Amgen and Fresenius; (2) unlimited "consultants or experts" and support staff; and (3) unlimited support staff for in-house attorneys. Dkt. 70 §§ 4a, 7b. Amgen's refusal to even consider HyClone's proposals for additional protections contravenes well-established case law. As courts have noted, HyClone's "concerns about disclosing [] trade secrets to such a vast group of people … are justified." *Velocity*, 2017 WL 11893112, at *5. Indeed, courts routinely recognize the harms and risks inherent in production of trade secret and commercially sensitive information in easily reproducible form to in-house counsel and employees.[5] *See, e.g.*, *Modern Font*, 2021 WL 364189 at *4-6; *F.T.C. v. Advocate Health Care Network*, 162 F. Supp. 3d 666, 668-674 (N.D. Ill. Feb. 29, 2016).

Accordingly, if the Court were to order disclosure of the full CB7A formulation, the Court should require (i) an initial "source code"-type inspection as described above; and (ii) for any paper

[4] When a small portion of HyClone's sensitive information was inadvertently included by third parties in a sealed stipulation, the parties jointly moved to purge the stipulation from the docket based on HyClone's "legitimate interests"; and the order was quickly granted. *In re: Afilbercept*, MDL No. 24-md-3013 (N.D.W. Va.) (Dkt. 461 and 462)).

[5] As noted in *Modern Font*, *Drone Techs.*, *Velocity*, and other cases, protections against disclosures to in-house employees, including attorneys, are appropriate for highly-sensitive information. Additionally, the risk of accidental violations of protective orders logically increases with the number of people given access, and in BPCIA actions, accidental violations, even by in-house counsel, do occur. *See Regeneron Pharms., Inc. v. Mylan Pharms., Inc.*, No. 22-cv-0061 (N.D.W. Va.) (Dkt. 724 at 2, 6-13) (detailing multiple violations by in-house counsel).

production(s) relating to any specific components (subject to agreed limits) that Amgen's outside lawyers or experts have identified as relevant to its claims, the same protections as those described in the *Regeneron* supplemental protective order.

II. REQUEST NOS. 3, 5-8: AMGEN HAS NOT SHOWN THE RELEVANCE OF CB7A INFORMATION "AT ANY TIME OVER THE LAST 10 YEARS"

Request Nos. 3 and 5-8 seek information on "changes to the composition," "lots and/or batches," "Certificates of Analyses," and "receipts" for CB7A either "at any time over the past 10 years" or without bound. These requests should be rejected for at least two reasons. ***First***, there is an undue burden imposed on a non-party to locate records a decade old, and Amgen has refused to narrow their requests. *See Evangelista v. Univ. of Phoenix*, 2017 WL 6209906, at *2 (D. Utah Dec. 7, 2017) (rejecting "requests in the subpoena seek[ing] all documents…for a period of four or five years" and which seek information "irrespective of date"). ***Second***, Amgen has not shown the relevance of this information because Amgen's claims focus on future conduct. Fresenius, by definition, has not yet launched its biosimilar and ***past*** information regarding CB7A is not relevant. *Sandoz Inc. v. Amgen Inc.*, 582 U.S. 1, 8 (2017). Accordingly, these requests should be quashed.

III. REQUEST NOS. 5-6, 8-18: AMGEN HAS NOT SHOWN IT CANNOT OBTAIN THE REQUESTED INFORMATION FROM FRESENIUS

Request Nos. 5-6, 8-18 seek information that should be sought first from Fresenius. Ex. A at 7.[6,7] During both the December and January meet-and-confers, Amgen refused to represent that it had even attempted to seek these materials from Fresenius. Because Amgen has not established

[6] For Request Nos. 5-7, each container of CB7A as sold has the Lot Number printed on the container. Lin Decl. ¶ 12. Customers may download Certificates of Analysis for their Lot Numbers from the CB7A website. *Id.* ¶ 13. Amgen has made no showing it first attempted and failed to obtain this information from Fresenius.

[7] Request Nos. 12-13 seek "[a]ll communications" between HyClone and "any" domestic or international "government regulatory agency Concerning Fresenius's" proposed denosumab biosimilar(s). Amgen has made no showing that it has attempted and failed to obtain any such correspondence, to the extent it exists, from Fresenius.

that it was unable to get these materials from Fresenius, these requests should be quashed. *See, e.g., Hanks v. Anderson*, 2023 WL 4052737 at *3 (D. Utah June 16, 2023) (requiring nonparty to produce materials obtainable from a party "would be unduly burdensome"); *Convo*, 2024 WL 3069201 at *1 (D. Utah June 19, 2024) (duty to "take reasonable steps to avoid imposing an undue burden or expense" on a non-party); *Int'l Coal*, 2010 WL 2079675, at *2 (limiting non-party discovery based on party production); *see also* Rule 45(d)(3)(A)(iv); Rule 26(b)(2)(C)(i) ("the court must limit … discovery…that…can be obtained from some other source").

IV. REQUEST NOS. 9-22: MANY OF AMGEN'S OTHER REQUESTS SHOULD ALSO BE QUASHED AS OVERBROAD AND VAGUE

Request Nos. 9-19 seek "all" communications or documents regarding numerous broad and burdensome topics. For example, Request No. 14 seeks "[a]ll communications … Concerning Amgen." Request Nos. 14-16 further seek communications between HyClone and "any other third party." Request No. 19 seeks "all" documents regarding 33 patents, many of which Amgen has not even attempted to demonstrate are relevant to CB7A. *See supra* § I. Amgen refuses to narrow these requests while also failing to justify the relevance of such burdensome discovery from a non-party. Courts frequently quash non-party subpoenas with such requests. *See, e.g., City of Rockford*, 2020 WL 11191830, at *3-5 (request for "all communications" "overbroad on its face").

Finally, Request Nos. 20-22 seek vague and overbroad information regarding the "subject matter" of Amgen's already broad requests. These requests should be quashed not only because they are improper discovery-on-discovery, but also—as explained above—because of Amgen's failure to show the relevance of the underlying requests and the undue burden and prejudice those requests impose on HyClone.

CONCLUSION

For the reasons set forth herein, the Court should grant HyClone's motion.

Dated this 4th day of February, 2025.

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of this document and all associated papers were served on February 4, 2025, via email to all counsel of record in the underlying Illinois action as identified below.

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