IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No. 1:25-cv-3452-DDD-STV

AMGEN INC., et al.,

Plaintiffs,

v.

GAIL MIZNER MD, in her official capacity as Chair of the Colorado Prescription Drug Affordability Review Board, et al.,

Defendants.

DEFENDANTS' REPLY TO PLAINTIFFS' OPPOSITION TO MOTION FOR LIMITED EXPEDITED DISCOVERY

Defendants hereby submit their Reply to Plaintiffs' Opposition to Defendants' Motion for Limited Expedited Discovery ("Motion") (ECF 34, 41).

REPLY

Defendants' Motion seeks narrowly tailored discovery supported by good cause. Despite the District of Colorado rejecting Amgen's characterization of the drug supply chain as guided by "commonsense economic principles" in March 2025, Amgen continues to support its alleged injuries with these conclusory assertions. Defendants therefore have good cause to request information about Amgen's allegations of harm specific to an Enbrel UPL and the manufacturer's business in Colorado. Defendants' limited expedited discovery targets only essential information for the preliminary injunction and requires Amgen to provide supporting evidence for the claims it introduced, namely irreparable harm and the merits of its federal patent

preemption and due process claims. Amgen alleges that Defendants' discovery delays these proceedings but fails to recognize that any alleged delay could (and should) have been resolved through Defendants offered stay of enforcement of the Enbrel UPL. For these reasons, Defendants request this Court grant their Motion for Limited Expedited Discovery.

I. Defendants have good cause to support limited, expedited discovery.

Discovery is necessary for Defendants to defend against Amgen's alleged harm from an Enbrel UPL, specifically at this preliminary injunction stage and when considering the District of Colorado's Order in *Amgen I*.[1] Courts maintain broad discretion to "alter the timing, sequence, and volume of discovery." *Qwest Commc'ns Int'l, Inc. v. WorldQuest Networks, Inc.*, 213 F.R.D. 418, 419 (D. Colo. 2003). Requests for preliminary injunction are generally an appropriate basis for expedited discovery. *See, e.g., Qwest Commc'ns*, 213 F.R.D. at 419; *Pod-Ners, LLC v. N. Feed & Bean of Lucerne Liab. Co.*, 204 F.R.D. 675, 676 (D. Colo. 2002). Defendants, just like plaintiffs, can obtain expedited discovery as part of a preliminary injunction. *See, e.g., Biomedical Device Consultants & Lab'ys of Colorado, LLC v. Vivitro Labs, Inc.,* No. 23-CV-00867-JLK, 2023 WL 12142531, at *1 (D. Colo. May 9, 2023). "Expedited discovery has been ordered where it would 'better enable the court to judge the parties' interests and respective chances for success on the merits' at a preliminary injunction hearing." *Yokohama Tire Corp. v. Dealers Tire Supply, Inc.*, 202 F.R.D. 612, 613 (D. Ariz. 2001).

Expedited discovery is crucial for Defendants and the Court to judge if Amgen can meet its burden to prove irreparable harm and the likelihood of success on the merits of its claims. Specifically, Amgen must surpass the threshold inquiry to establish that an Enbrel UPL will result in irreparable harm. *See DTC Energy Grp., Inc. v. Hirschfeld*, 912 F.3d 1263, 1270 (10th

[1] "*Amgen I*" refers to *Amgen Inc. v. Mizner*, No. 1:24-cv-810 (D. Colo. May 21, 2024).

Cir. 2018) (“‘[B]ecause a showing of probable irreparable harm is the single most important prerequisite for the issuance of a preliminary injunction, the moving party must first demonstrate that such injury is likely before the other requirements’ will be considered.”). Irreparable harm must be “certain, great, actual and ‘not theoretical.’” *Heideman v. South Salt Lake City*, 348 F.3d 1182, 1189 (10th Cir. 2003) (citing *Wisconsin Gas Co. v. FERC,* 758 F.2d 669, 674 (D.C. Cir. 1985)).

In opposing discovery, Amgen attempts to bypass the District Court’s previous findings that Amgen would not be injured by an Enbrel UPL. *See Amgen Inc. v. Mizner*, No. 24-CV-00810-NYW-SBP, 2025 WL 947474, at *14 (D. Colo. Mar. 28, 2025). In her Order dismissing Amgen’s first Complaint against the Board, the Honorable Judge Nina Y. Wang specifically found Amgen failed to show it would “necessarily be injured regardless of whether, when, or what UPL may be set due to ‘basic economics and common sense’” and found these arguments “unpersuasive.” *Id.* at *15-16. Amgen’s current allegations, which have not changed since *Amgen I*, do not provide any additional support for why an Enbrel UPL would necessarily affect its price in the supply chain, stating once again that the effect of a UPL is “indisputable and obvious” and a matter of “commonsense economic principles.” ECF 41 at 6. As Judge Wang explicitly recognized, because of “the undisputed complexity of the supply chain and the various rebates, reimbursements, chargebacks, and discounts that are exchanged at various levels of the supply chain,” *Amgen Inc.*, 2025 WL 947474 at *16, Amgen is not necessarily injured by an Enbrel UPL even though it is the drug’s manufacturer. Nevertheless, Amgen continues to seek a finding of harm without discovery about the drug supply chain. *See* ECF 41 at 2 (“‘[N]o evidentiary record is needed to establish’ that a price cap on *Amgen’s* drug will injure

Amgen…"). Given the threshold issues of injury and harm, Defendants must be permitted to seek discovery to defend against Amgen's allegations of harm by an Enbrel UPL.

Amgen also offers a misplaced analogy to the *BIO* case, claiming that the issues here, as in that case, are "purely legal" and therefore can be resolved without discovery. ECF 41 at 5. However, D.C.'s excessive pricing statute at issue in *BIO* was specifically targeted at drug manufacturers. *See Biotechnology Indus. Org. v. D.C.*, 496 F.3d 1362, 1365 (Fed. Cir. 2007). Colorado's UPL statute is not targeted directly at drug manufacturers, but instead, downstream providers and pharmacies in Colorado. *See Amgen Inc.*, 2025 WL 947474 at *14; § 10-16-1407(5), C.R.S.; 3 Colo. Code Reg. 702-9.4.2.C. This difference, and the complexity of the entire supply chain, prompts more than legal questions; for Amgen to prove irreparable harm, this Court must decide if Amgen is injured as the drug's manufacturer. Even further, this Court must specifically address if a UPL on a single drug in a single state's market as applied to only a small portion of that state's insured population constitutes irreparable injury. These are factual disputes. Amgen's attachment of five separate declarations emphasizes these factual disputes, and Defendants should be able to test the facts on which Amgen says the Court should rely.

This Court should disregard Amgen's incorrect statements that Defendants have already agreed that the issues in this case are purely legal. *See* ECF 41 at 2, 4, 7. Amgen cites to Defendants' agreement in *Amgen I* that the case could be resolved on cross-motions for summary judgment without discovery. *Id.* However, Amgen brought that case against the Board in March 2024–almost two years ago–and before the Board had set an Enbrel UPL, both of which Amgen acknowledges. *Id.* at 14. Amgen cannot escape that it must substantiate its alleged injuries now that an Enbrel UPL has been set.

Amgen's preliminary injunction motion also opens the door to additional factual development about the pharmaceutical supply chain. The motion relies on general descriptions of the manufacturer's chargeback practices to explain why its wholesalers allegedly "must" purchase Enbrel at a lower price after implementation of an Enbrel UPL and why Amgen is the only party that can absorb those costs associated with wholesalers' reduced prices. ECF 18 at 20-21. These hypothetical harms are vague and insufficient. Amgen relies on "commonsense economic principles" to describe what it characterizes as the inevitably "predictable" reaction of a wholesaler to an Enbrel UPL to buy Enbrel for less. *Id.* at 20. The central and paramount issue in this case is that the prescription drug supply chain is not so simple, as found by Judge Wang. *See Amgen Inc.*, 2025 WL 947474 at *16. Defendants' discovery requires Amgen to substantiate its conclusory statements about the drug supply chain. *See* ECF 34-2, Requests for Production, at ¶¶ 4-5; ECF 34-3, Interrogatories, at ¶¶ 7-8.

Moreover, Amgen fails to identify harm unique to an Enbrel UPL. Defendants' discovery requires Amgen to supply specific information about the chargeback transactions and contractual agreements with its wholesalers that apply to purchases of Enbrel in Colorado as subject to state-regulated insurance plans. *See* ECF 34-2, Requests for Production, at ¶¶ 1-3; ECF 34-3, Interrogatories, at ¶¶ 2-3; ECF 34-3, Requests for Admission, at ¶ 3. Without clarity regarding the market share of Amgen and its wholesalers' businesses that will be affected by an Enbrel UPL, neither Defendants nor this Court can understand or estimate Amgen's alleged financial harms.

Amgen further alleges irreparable harm arising from the Enbrel UPL associated with: (1) lost revenue, (2) updates to its payment systems, (3) anticipated contract negotiations with wholesalers and pharmacy benefit managers, (4) bargaining for formulary positions in 2027 and

beyond, and (5) broader market disruption–all of which it claims have already begun or will soon begin accruing. *See* ECF 18 at 35-37. Amgen fails to associate monetary estimates with any of these alleged harms, leaving Defendants and the Court without any context for Amgen's anticipated scope or impact of this Colorado-specific UPL on a single drug as part of its broader business operations. These various allegations also lack necessary details to determine if they rise to the level of irreparable harm, including but not limited to, technical details related to its payment systems, anticipated number of contracts and specific terms to be renegotiated, and the time and terms related to bargaining for formulary position. Defendants' proposed discovery requests this information to substantiate Amgen's claim of irreparable harm. *See* ECF 34-2, Requests for Production, at ¶¶ 1-3, 6; ECF 34-3, Interrogatories, at ¶¶ 1-6; ECF 34-3, Requests for Admission, at ¶¶ 4-5.

Also without evidentiary support, Amgen also leans on the "extremely thin" profit margins of wholesalers to justify why manufacturer chargeback provisions are necessary and the only available business model. ECF 18 at 21. Defendants' limited discovery requires Amgen to substantiate that claim. *See* ECF 34-2, Requests for Production, at ¶ 4. Defendants' requests for depositions of the three wholesalers who submitted supporting declarations are also essential on this issue. At a minimum, Defendants and this Court must understand what portion of the wholesalers' business with Amgen is associated with an Enbrel UPL, to what extent their profits will change as a result of an Enbrel UPL (if at all), and if there are any alternative methods for recouping what the wholesalers expect will be lost profits—information that is lacking in their short declarations.

At the crux of its merits arguments of federal patent preemption and due process, Amgen argues that any price it receives for Enbrel must "ensure a fair and reasonable rate of return on

investment." ECF 18 at 34. Amgen's motion provides no evidentiary or financial support for why an Enbrel UPL does not provide such a return. Despite Amgen's assertions otherwise, *see* ECF 41 at 10 (Amgen's "claims do not turn on what Amgen, Defendants, or anyone else might consider a 'fair' price"), Amgen itself put these amounts in dispute. Defendants' discovery requires that Amgen provide this crucial missing information that is only in Amgen's possession. *See* ECF 34-2, Requests for Production, at ¶¶ 8-9; ECF 34-3, Interrogatories, at ¶ 9; ECF 34-3, Requests for Admission ¶¶ 1-2, 6. For the same reason, Defendants require information about the Medicare Maximum Fair Price for Enbrel that Amgen recently negotiated with the Centers for Medicare and Medicaid Services that will be effective on January 1, 2026. *See* ECF 34-2, Requests for Production, at ¶ 7.

Defendants clearly demonstrate good cause for each of their limited discovery requests. If Defendants must respond to the preliminary injunction without discovery, they will be left without evidence to show that Amgen cannot meet its burden of proof for the extraordinary relief it requests, while Amgen will have been able to build the unchallenged and untested evidentiary record it desires. Defendants' discovery would provide Defendants and this Court with the necessary information to analyze Amgen's allegations of harm potentially resulting from an Enbrel UPL, as well as the merits of Amgen's claims, and are therefore supported by good cause.

II. Defendants' discovery requests are narrowly tailored to information necessary to respond to the preliminary injunction.

Defendants seek limited information that is specifically targeted to address the allegations of irreparable harm and likelihood of success on the merits raised in Amgen's motion for preliminary injunction. "In applying the 'good cause' standard under Rule 26(d), the court should consider the scope of the requested discovery." *Qwest Commc'ns*, 213 F.R.D. at 420 (citing *Philadelphia Newspapers, Inc. v. Gannett Satellite Information Network, Inc.,* 1998 WL

404820 (E.D. Pa. 1998) (denying motion for expedited discovery where movant's discovery requests were overly broad and not reasonably tailored to the specific issues to be addressed at the preliminary injunction hearing); *In re Websecure, Inc. Securities Litigation,* 1997 WL 770414 (D. Mass. 1997) (finding that expedited discovery was both "particularized" and "necessary to prevent undue prejudice")). Expedited discovery is appropriate when "it requests the production of documents and things which already exist, and the requests are reasonable in scope." *See Pod-Ners*, 204 F.R.D. at 676.

Here, Defendants' discovery requests are particularized and reasonable in scope. The requests are directly targeted at evidence that addresses Amgen's allegations, including the "commonsense economic principles" that govern the drug supply chain (ECF 18 at 20), alleged irreparable harm from an Enbrel UPL (ECF 18 at 35-37), use of chargebacks as wholesalers and manufacturers' only available response to an Enbrel UPL (ECF 18 at 20-21), and why an Enbrel UPL deprives Amgen of a "fair and reasonable rate of return on investment" (ECF 18 at 34-35). Defendants further support each discovery request with specific citations to Amgen's preliminary injunction motion and its attached declarations. *See* ECF 34 at Ex. 2-3. Defendants' requests are also limited in number, including less than ten requests in each category of discovery. Similarly, the requested depositions are targeted only to the authors of Amgen's supporting declarations and exploration of the facts and opinions they elicit.

Moreover, the requested discovery is in Amgen's sole control and could not be obtained through any other means. *See Colorado Montana Wyoming State Area Conf. of the NAACP v. United States Election Integrity Plan*, No. 22-CV-00581-PAB, 2022 WL 1443057, at *3 (D. Colo. May 6, 2022) ("Expedited discovery has been granted in cases where discovery of certain facts is "unusually difficult or impossible."). The drug supply chain is largely shielded by claims

of confidentiality and proprietary information, and drug manufacturers and other supply chain actors use that cloak to hold their contracts, profits, and price negotiations as trade secrets. Amgen makes those exact allegations here, arguing Defendants should not have access to their "confidential and highly sensitive commercial information" through discovery. *See* ECF 41 at 9. However, Amgen has placed those questions and documents front and center. Defendants and the Court cannot determine if Amgen has met its required burden without a substantive showing of the harm it will allegedly suffer because of an Enbrel UPL. Amgen should already have this information compiled to quantify and substantiate its alleged injuries; it follows that Amgen will not be harmed by making that evidence available to Defendants through discovery.

III. The requested limited expedited discovery is not proposed to delay resolution of the preliminary injunction.

Prior to the filing of Amgen's motion for preliminary injunction, Defendants offered Amgen a stay on enforcement of the Enbrel UPL during the pendency of this District Court litigation. *See* ECF 34 at ¶ 2. Amgen declined. *See id.* at Ex. 1. Now, Amgen claims Defendants' requests for discovery are unnecessarily delaying this case. ECF 41 at 13-14. If Amgen had accepted Defendants' offer, made in good faith to avoid unnecessary motions practice, no preliminary injunction would be necessary, and the Parties would have been able to proceed with the previously ordered scheduling conference on January 6, 2026, *see* ECF 6, 40, with discovery proceeding through the normal course. Instead, this Court must now consider Amgen's motion for preliminary injunction and if granted, will provide Amgen only the same relief—a stay on enforcement of the Enbrel UPL during this case—that Defendants offered over a month ago.

As an alternative, Amgen suggests Defendants not oppose the entry of a preliminary injunction, arguing this is consistent with Defendants' offer to stay enforcement. ECF 41 at 15. Defendants wholly reject this contention. Defendants' offer was meant to allow for the orderly

disposition of the case and for the parties to focus their resources on bringing this matter to a final, and not preliminary, resolution, and if accepted by Amgen, would have resulted in faster resolution. *See* ECF 35 at Ex. 1. Amgen now uses that reasonableness against Defendants and suggests they are requesting discovery as a means of delay. ECF 41 at 13-14. Defendants have no such objective, and their actions in this case have only been in response to Amgen's preliminary injunction filing, which by definition involves a ruling on Amgen's claim of irreparable harm and success on the merits—two points Defendants do not concede and must properly defend against, even at these early stages. Moreover, Defendants have not changed course; their filings clarify to this Court that they continue to offer a stay on enforcement of the Enbrel UPL during the pendency of the District Court litigation. Defendants will not concede Amgen's arguments of irreparable harm or likelihood of success on the merits, as agreeing to the imposition of a preliminary injunction would do here.

Moreover, it is unclear what relief Amgen believes this Court can grant above and beyond Defendants' proposed stay of the Enbrel UPL. Amgen alleges entry of a preliminary injunction would give it "more protection and clarity," as well as "comfort" that it would not have to incur the alleged costs associated with implementing an Enbrel UPL during this litigation. ECF 41 at 14. But Amgen's requested injunction does not provide this guarantee. If Defendants were to prevail in this litigation, Amgen must ultimately comply with the UPL. Amgen has not and cannot propose a solution that would allow it "to avoid the costs of preparing to comply with the [Enbrel] price cap." *Id*. at 15. Amgen itself is avoiding the easiest and fastest way to get the equitable relief it is requesting—accepting Defendants' offered stay. For these reasons, this Court should dismiss Amgen's claims of delay and permit Defendants to conduct limited, expedited discovery before ruling on Amgen's preliminary injunction motion.

Defendants respectfully request that this Court grant the Motion for Limited Expedited Discovery and issue an Order authorizing Defendants to conduct discovery as set forth in the Motion, and ordering Amgen to comply with the expedited discovery timelines.

DATED at Denver, Colorado this 24th day of December, 2025.

PHILIP J. WEISER
Attorney General

/s/ Sara Stultz
SARA STULTZ, 54357*
PAWAN NELSON, 49462*
Senior Assistant Attorneys General
NICHOLAS A. DEPETRO, 45287*
REBECCA WALKER, 55290*
Assistant Attorneys General
Ralph L. Carr Colorado Judicial Center
1300 Broadway, 8th Floor
Denver, CO 80203
720-508-6419 (Stultz)
720-508-6578 (Nelson)
720-508-6413 (DePetro)
720-508-6394 (Walker)
Sara.Stultz@coag.gov
Pawan.Nelson@coag.gov
Nick.DePetro@coag.gov
Rebecca.Walker@coag.gov
* *Counsel of Record*