No. 2024-2351

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

REGENERON PHARMACEUTICALS, INC.,

Plaintiff-Appellant,

v.

MYLAN PHARMACEUTICALS INC., AMGEN USA, INC., BIOCON BIOLOGICS INC., SAMSUNG BIOEPIS CO., LTD., CELLTRION, INC., FORMYCON AG,

Defendants,

AMGEN INC.,

Defendant-Appellee.

Appeal from the U.S. District Court for the Northern District of West Virginia
No. 1:24-md-3103-TSK, Chief Judge Thomas S. Kleeh

DEFENDANT-APPELLEE AMGEN INC.'S OPPOSITION TO REGENERON'S REQUEST FOR AN "ADMINISTRATIVE STAY"

Defendant-Appellee Amgen Inc. respectfully submits this opposition to Plaintiff-Appellant Regeneron Pharmaceuticals, Inc.'s September 23, 2024 motion for an injunction pending appeal insofar as that motion seeks an "administrative stay"—in reality, a temporary administrative ***injunction***—while this Court considers Regeneron's motion for an injunction pending appeal. That request should be denied at least for the reasons set forth below. Amgen will respond separately to the merits of the motion for an injunction pending appeal according to the default briefing

schedule under the Federal Rules of Appellate Procedure or any schedule this Court sets.

BACKGROUND

This case concerns the biologic aflibercept, which is FDA-approved to treat serious eye disorders. Regeneron's composition-of-matter patent covering aflibercept expired in June 2023. *See* D. Ct. Dkt. 180-18, Sheridan Ex. 3, at 31.[1] In this case, Regeneron seeks to enforce a formulation patent, U.S. Patent No. 11,084,865 ("the '865 patent"), which covers products that contain ***four*** specific, separately listed structures—a VEGF antagonist (aflibercept), an organic co-solvent, a buffer, and a stabilizing agent. D. Ct. Op. 17-20, 35-37. The asserted claims of the '865 patent list each as a separate limitation, reciting each on a separate line:

> ***a vascular endothelial growth factor (VEGF) antagonist*** fusion protein [*i.e.*, aflibercept],
> an organic co-solvent,
> ***a buffer***, and
> a stabilizing agent[.]

'865 patent at 21:1-5 (claim 26) (emphasis added); *see id.* at 19:29-34 (claim 1). Regeneron markets a product named Eylea that contains those ***four*** distinct components. D. Ct. Op. 3-5.

[1] Citations to "D. Ct. Dkt." refer to the docket for 1:24-cv-00039-TSK-JPM (N.D.W.V.).

Amgen seeks to market a product, ABP 938, that does not. While the patent recites those four distinct structures, ABP 938 only has three. D. Ct. Op. 6-8. Unlike Eylea and all the other biosimilar products against which this patent has been enforced, ABP 938 does not contain a "buffer" that is separate from the VEGF antagonist. D. Ct. Op. 8-10.

Claim Elements	Regeneron EYLEA	Mylan YESAFILI	Formycon FYB203	SB OPUVIZ	Celltrion CT-P42	Amgen ABP 938
	Active Ingredient					
VEGF Antagonist	40 mg/ml aflibercept	40 mg/ml aflibercept	40 mg/ml aflibercept	40 mg/ml aflibercept	40 mg/ml aflibercept	40 mg/ml aflibercept
	Excipients (*i.e.*, Ingredients Other than the Active Ingredient)					
Organic Co-Solvent	Polysorbate 20	Polysorbate 20	Polysorbate 20	Polysorbate 20	Polysorbate 20	Polysorbate 80
Buffer	Phosphate buffer	Histidine buffer	Histidine buffer	Phosphate Buffer	Histidine buffer	NONE
Stabilizing Agent	Sucrose	Trehalose	Sucrose	Sucrose	Trehalose	Sucrose / Trehalose

D. Ct. Dkt. 206 at 1; *see* D. Ct. Op. 9-10. Instead, Amgen discovered a way to prepare the VEGF antagonist so that a separate buffer is unnecessary. The FDA approved ABP 938 on August 23, 2024, *see* D. Ct. Dkt. 253-1, making it "the first FDA-approved ***buffer-free*** fusion protein formulation." D. Ct. Op. 66 (emphasis added).

On September 23, 2024, the district court denied Regeneron's motion for a preliminary injunction against commercial marketing of ABP 938. In a thorough 90-page opinion, the district court held Regeneron had not shown a likelihood of success of proving infringement because ABP 938 lacks the separate "buffer" required by the asserted claims. The court observed that *Becton, Dickinson & Co.*

v. Tyco Healthcare Group LP, 616 F.3d 1249 (Fed. Cir. 2010), sets forth a governing principle: Where a claim lists separate structures, those structures are ***presumed*** to be distinct. D. Ct. Op. 36-37; *see Becton*, 616 F.3d at 1254 ("Where a claim ***lists elements separately***, '***the clear implication*** of the claim language' is that those elements are '***distinct component[s]***' of the patented invention") (emphasis added). Here, the asserted claims list four separate structures separately—a VEGF antagonist, an organic co-solvent, a buffer, and a stabilizing agent. The claims thus are presumed to require a distinct structure corresponding to each of those four limitations. D. Ct. Op. 36-37.

The court carefully considered the intrinsic record and found no basis for overcoming that presumption here. D. Ct. Op. 37-57; *see also id.* at 57-77 (finding extrinsic evidence could not overcome presumption either). And ABP 938 undisputedly does not contain separate and distinct structures corresponding to the "VEGF antagonist" and the "buffer." ABP 938 thus does not infringe; one ingredient cannot satisfy the separately listed "VEGF antagonist" and "buffer" limitations, wholly apart from whether the VEGF antagonist has buffering capacity. D. Ct. Op. 79-89.

Regeneron filed a notice of appeal the same day and moved this Court for an emergency injunction pending appeal. In that motion, Regeneron also seeks what it describes as an "immediate administrative stay to preserve the status quo while the

Court considers this application." Motion at vii. Amgen responds only to that request for administrative relief here. It will address Regeneron's request for an injunction pending appeal separately.

ARGUMENT

The Court should deny Regeneron's request for immediate administrative relief, even apart from the shortcomings in its underlying request for an injunction pending appeal.

I. REGENERON FAILS TO CITE ANY AUTHORITY FOR THE ADMINISTRATIVE RELIEF IT SEEKS

Regeneron cites no authority supporting the extraordinary administrative relief it seeks. That lack of authority is sufficient reason alone to deny the request.

Although Regeneron purports to seek an "administrative stay," in reality Regeneron is not seeking to "stay" anything at all. The district court ***denied*** an injunction below, so there is no order compelling anyone to do anything that this Court could "stay." Staying an order denying injunctive relief does not somehow cause an injunction to spring into existence.

The only authority Regeneron cites—*Marine Polymer Technologies, Inc. v. Hemcon, Inc.*, 395 F. App'x 701 (Fed. Cir. 2010)—underscores Regeneron's absence of support. In that case, the district court ***granted*** a permanent injunction, and this Court then issued an administrative stay that "temporarily stayed" the injunction while the Court considered a motion for a stay pending appeal. *Id.* at *1.

Regeneron does not seek any similar temporary stay here—it is asking this Court to ***enjoin*** conduct in the first instance without giving Amgen meaningful opportunity to respond.

II. REGENERON'S OWN DELAYS ARE RESPONSIBLE FOR ITS ALLEGED NEED FOR ADMINISTRATIVE RELIEF

Regeneron's request for immediate administrative relief is a product of Regeneron's own delays. That alone is reason to deny the requested relief.

Under the Biologics Price Competition and Innovation Act ("BPCIA"), a competitor seeking to market a biosimilar product must provide 180 days' notice to the patent owner. 42 U.S.C. § 262(*l*)(8)(A). The patent owner may then move immediately for a preliminary injunction. § 262(*l*)(8)(B). The statute thus seeks to "ensur[e] a defined amount of time for pre-launch litigation" and thereby avoid the "hurried motion practice" that would result if the patent owner learned of the competing product only at the last minute. *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1065-66 (Fed. Cir. 2016). "[P]articularly in light of [these] provisions," courts have denied preliminary injunctive relief when BPCIA plaintiffs "delay[ed] in requesting a preliminary injunction." *Genentech, Inc. v. Amgen Inc.*, 2019 WL 3290167, at *3 (D. Del. July 18, 2019), *aff'd*, 796 F. App'x 726 (Fed. Cir. 2020).

Regeneron had all that notice and more here. Amgen provided Regeneron with all the information Regeneron needed to decide whether to seek injunctive relief, when it provided Regeneron with access to its Biologics License Application

("BLA") in ***September 2023***. D. Ct. Dkt. 199-1 ¶10. Amgen also notified Regeneron of its intent to launch ABP 938 on February 23, 2024. D. Ct. Op. at 12. Regeneron then had nearly six months under the statute in which to seek injunctive relief—and have the district court resolve that request—before Amgen could launch ABP 938. *Id.* Amgen later agreed to extend even that deadline by stipulating that it would forbear from launching its product until at least September 23, 2024. D. Ct. Dkt. 245. Yet Regeneron waited until June 7, 2024—more than 9 months after receiving access to Amgen's BLA, and ***more than 100 days*** after receiving Amgen's 180-day statutory notice—before moving for a preliminary injunction. D. Ct. Op. at 12.

Regeneron's alleged need for emergency administrative relief thus stems from its own delays during the 180-day notice period. If Regeneron had moved for a preliminary injunction sooner, the district court could have decided the motion sooner, and Regeneron could have sought an injunction pending appeal while still within the 180-day period. The Court should not grant Regeneron extraordinary administrative relief when Regeneron's own delays are the only reason it needs to ask for that relief.

Regeneron's request for administrative relief defies the statutory design. Congress enacted the 180-day notice period precisely to "ensur[e] a defined amount of time for pre-launch litigation" over preliminary injunctive relief. *Amgen*, 827 F.3d at 1065. Congress evidently concluded that 180 days should be sufficient to

resolve such disputes, and here it plainly would have been, had Regeneron moved promptly. Granting Regeneron ***additional*** time to litigate its entitlement to injunctive relief before Amgen can launch its product—by awarding Regeneron an extraordinary "administrative" injunction—would undermine the careful balance Congress struck. It would also invite gamesmanship. Dilatory plaintiffs like Regeneron could delay, and then use the delay they created to justify enjoining competitors at the eleventh hour, well after expiration of the 180-day period.

Regeneron, moreover, did not seek immediate administrative relief from the district court before seeking that relief in this Court. District courts are fully empowered to grant temporary relief, such as a temporary stay or injunction, to afford this Court time to consider any challenge before a decision goes into effect. But Regeneron made no such request; there is no reason it could not have done so (conditionally when it sought a preliminary injunction, after the preliminary injunction was denied, or even simultaneously with the filing in this Court). Had Regeneron done so, the district court—intimately familiar not just with the Amgen proceedings but also with four others involving the same patent, including a two-week bench trial—would have been well positioned to explain that the purported need for such emergency relief is a product of Regeneron's choice to delay for months after receiving Amgen's 180-day notice.

III. REGENERON FAILS TO SHOW ANY LIKELIHOOD OF REVERSAL OF THE DISTRICT COURT'S CLAIM CONSTRUCTION RULING

Finally, the Court should not grant extraordinary administrative relief without at least some scrutiny of Regeneron's likelihood of obtaining reversal of the district court's claim construction ruling. The court's comprehensive and persuasive 90-page opinion speaks for itself. *See, e.g.*, D. Ct. Op. 27-31 (summary). Amgen will respond point-by-point to Regeneron in its forthcoming opposition to the motion for an injunction pending appeal.[2] The fact that the district court ruled in Amgen's favor, despite ruling in Regeneron's favor in each of its other lawsuits, does not make this decision an aberration—it shows that the district court carefully considered the facts and appreciated that this case is different because, unlike all the other products, Amgen's product does not contain four separate ingredients corresponding to the four separate structures in the '865 patent claims.

[2] For now, suffice it to say that Regeneron fails to show any error, let alone reversible error, in the district court's careful analysis. For example, Regeneron urges that the district court disregarded this Court's recent decision in *Google LLC v. EcoFactor, Inc.*, 92 F.4th 1049 (Fed. Cir. 2024). But—as the district court recognized, D. Ct. Op. 36, 61—that case ***confirmed*** that *Becton* establishes a "presumption" that separately listed claim elements require separate structures, and it found that presumption overcome only because—unlike here—the specification expressly disclosed an embodiment where the elements were ***not*** distinct. 92 F.4th at 1058. The district court also addressed at length its prior claim-construction rulings (and Regeneron's prior claim-construction positions) and explained why they supported denying a preliminary injunction here. D. Ct. Op. 21-27, 74-79.

CONCLUSION

The Court should deny Regeneron's request for administrative relief while the Court considers its motion for an injunction pending appeal.

September 24, 2024

Respectfully submitted,

/s/ Jeffrey A. Lamken

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UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case No. 24-2351
Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc.
Filing Party: Defendant-Appellee Amgen Inc.

1. **Represented Entities.** The full names of all entities represented by undersigned counsel in this case. Fed. Cir. R. 47.4(a)(1).

   Amgen Inc.

2. **Real Party in Interest.** The name of the real parties in interest (if the entities named above are not the real parties in interest). Fed. Cir. R. 47.4(a)(2).

   n/a

3. **Parent Corporations and Stockholders.** All parent corporations and any publicly held companies that own 10 percent or more of the stock of the entities. Fed. Cir. R. 47.4(a)(3).

   none

4. **Legal Representatives.** The names of all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4)

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5. **Related Cases.** Other than the originating case(s) for this case, are there related or prior cases that meet the criteria of Fed. Cir. R. 47.5(a)?

   Yes. Please see separate Notice of Related Case Information.

6. **Organizational Victims and Bankruptcy Cases.** Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

   n/a

I certify that the information provided above is accurate and complete to the best of my knowledge.

Date: September 24, 2024 /s/ Jeffrey A. Lamken
Jeffrey A. Lamken