No. 24-__

In the United States Court of Appeals for the Federal Circuit

REGENERON PHARMACEUTICALS, INC.,
Plaintiff-Appellant,

v.

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

AMGEN INC.,
Defendant-Appellee,

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

NONCONFIDENTIAL MOTION TO EXPEDITE APPEAL

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UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number Unassigned

Short Case Caption Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc.

Filing Party/Entity Regeneron Pharmaceuticals, Inc.

Instructions:

1. Complete each section of the form and select none or N/A if appropriate.
2. Please enter only one item per box; attach additional pages as needed, and check the box to indicate such pages are attached.
3. In answering Sections 2 and 3, be specific as to which represented entities the answers apply; lack of specificity may result in non-compliance.
4. Please do not duplicate entries within Section 5.
5. Counsel must file an amended Certificate of Interest within seven days after any information on this form changes. Fed. Cir. R. 47.4(c).

I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

Date: 09/23/2024

Signature: /s/ David I. Berl

Name: David I. Berl

1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	**2. Real Party in Interest.** Fed. Cir. R. 47.4(a)(2).	**3. Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. ☑ None/Not Applicable	Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. ☑ None/Not Applicable
Regeneron Pharmaceuticals, Inc.		

☐ Additional pages attached

4. Legal Representatives. List 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).

☐ None/Not Applicable ☑ Additional pages attached

See Exhibit A		

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

☑ Yes (file separate notice; see below) ☐ No ☐ N/A (amicus/movant)

If yes, concurrently file a separate Notice of Related Case Information that complies with Fed. Cir. R. 47.5(b). **Please do not duplicate information.** This separate Notice must only be filed with the first Certificate of Interest or, subsequently, if information changes during the pendency of the appeal. Fed. Cir. R. 47.5(b).

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).

☑ None/Not Applicable ☐ Additional pages attached

Exhibit A

4. Legal Representatives. List 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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RULE 27(a)(2) STATEMENT

Regeneron Pharmaceuticals, Inc. attempted to confer with Amgen Inc., but Amgen did not respond. Regeneron therefore is filing this motion as an opposed motion.

INTRODUCTION

Pursuant to Federal Rule of Appellate Procedure 2 and Federal Circuit Rule 27, Plaintiff-Appellant Regeneron Pharmaceuticals, Inc. ("Regeneron") respectfully moves this Court for an order expediting this appeal, including the briefing schedule and the date of oral argument.

This is an appeal from the denial of Regeneron's request for a preliminary injunction against Amgen Inc. ("Amgen"). Amgen is the fifth entity to seek FDA approval to market a biosimilar version of Regeneron's blockbuster ophthalmic product Eylea®. The four earlier-filing biosimilar applicants—Mylan Pharmaceuticals Inc. ("Mylan"), Samsung Bioepis Co., Ltd. ("SB"), Formycon AG ("Formycon"), and Celltrion Inc. ("Celltrion")—all were enjoined by the district court based on Regeneron's U.S. Patent 11,084,865 (the "'865 patent"). In issuing those four injunctions, the district court found the '865 patent likely infringed and not invalid, and also recognized the immediate, irreparable harm Regeneron would suffer in the event of a biosimilar launch, including through loss of market share and irreversible price erosion.

Regeneron likewise sought a preliminary injunction against Amgen based on the '865 patent. But the district court inexplicably denied the request. As Regeneron's concurrently-filed Emergency Motion for Injunction Pending Appeal explains, the district court denied preliminary relief only by

backtracking from its prior claim-construction determination in its earlier injunction decisions and adopting an erroneous claim construction that flouts this Court's precedent and ignores key intrinsic evidence, testimony from both sides' experts, and nearly a century of scientific literature.

The court's errors have paved the way for Amgen to launch immediately, thus bypassing the four earlier biosimilar applicants whose pending appeals to this Court—all of which are proceeding on expedited schedules—are nearing completion. *See* Appeal Nos. 24-1965, 24-1966, 24-2082, 24-2083 ("SB Appeal"); Appeal Nos. 24-2009, 24-2019, 24-2156 ("Formycon Appeal"); Appeal No. 24-2002 ("Mylan Appeal"); Appeal Nos. 24-2058, 24-2147 ("Celltrion Appeal"). Allowing Amgen to launch during the pendency of this and the related appeals will disrupt irreversibly the marketplace status quo, causing Regeneron irreparable harm. Even in denying injunctive relief against Amgen, the district court did not reject its repeated findings that such irreparable harms would befall Regeneron in the event of a biosimilar launch.

Regeneron seeks expedition of this appeal, principally through accelerating substantially the deadlines for its own briefing, as follows: Regeneron would file its opening brief on October 3, less than two weeks after its Notice of Appeal and at least *47 days earlier* than required under the default 60-day deadline. Amgen would file its responsive brief by November 7, giving Amgen a total of 35 days to prepare its brief—only five fewer days

than the default 40-day deadline would allow. Regeneron then would file its reply brief within 12 days, by November 19, thus self-expediting by another 9 days relative to the 21-day default deadline. The parties would file the joint appendix no later than November 22. No extensions of the schedule would be granted. Under this schedule, the Amgen appeal could be set for oral argument during the Court's January 2025 sitting, or through a separate scheduling mechanism at the Court's earliest convenience. Regeneron's proposed schedule is summarized below:

Event	**Deadline**
Regeneron's Opening Brief	October 3, 2024
Amgen's Responsive Brief	November 7, 2024
Regeneron's Reply Brief	November 19, 2024
Joint Appendix	November 22, 2024
Oral argument	To be held in January 2025 or at the Court's earliest convenience

BACKGROUND[1]

I. Regeneron's Invention of Eylea

Regeneron invented and developed Eylea, the "revolutionary," leading treatment for the most common causes of blindness, including wet age-related

[1] This Background section is materially identical to that of Regeneron's concurrently filed Emergency Motion for an Injunction Pending Resolution of Appeal.

macular degeneration ("AMD"). *Regeneron Pharm. v. Mylan Pharm.*, --- F. Supp. 3d ----, 2024 WL 382495, at *13, *60 (N.D. W. Va. Jan. 31, 2024) ("*Mylan*"). Eylea's active ingredient is a vascular endothelial growth factor (VEGF) antagonist fusion protein called aflibercept. *Id.* The '865 patent is directed to ophthalmic formulations of aflibercept, including Eylea, at a concentration of 40 mg/mL. *Id.* at *15. The asserted claims recite "ophthalmic formulation[s]" comprising, inter alia, 40 mg/mL of a VEGF antagonist and "a buffer." *Id.*

II. Prior Eylea Litigations

Since October 2021, several applicants have sought FDA approval under the BPCIA to market biosimilars of Eylea. *See In re Aflibercept Pat. Litig.*, 2024 WL 1597512, at *1 (J.P.M.L. Apr. 11, 2024). The first was Mylan, against whom Regeneron proceeded to trial in June 2023. 2024 WL 382495, at *2. The district court found that Mylan infringed the '865 patent, *id.* at *31-33, and that the asserted claims were not invalid, including for lack of written description, *id.* at *41-70. The court issued a permanent injunction against Mylan, finding that Regeneron would be irreparably harmed by launch of Mylan's biosimilar and that the balance of equities and public interest favored injunctive relief. *See In re Aflibercept Pat. Litig.*, No. 24-md-3103, Dkt. 188 at 25-42, 51-67 (N.D.W. Va. 2024) ("Mylan Injunction Decision").[2]

[2] Unless otherwise indicated, all docket citations are to *In re Aflibercept Pat. Litig.*, No. 24-md-3103 (N.D. W. Va.).

SB, Formycon, and Celltrion (the "PI Defendants") followed Mylan in seeking approval of aflibercept biosimilars, and Regeneron sued each last fall. Regeneron moved to preliminarily enjoin the PI Defendants. Each asserted, inter alia, that the '865 patent is invalid for lack of written description. The district court again sustained the '865 patent and granted Regeneron's preliminary injunction motions, again finding that Regeneron would be irreparably harmed by biosimilar launch and that the balance of equities and public interest favored injunctive relief. Dkt. 194 at 54-177 ("SB PI Decision"); Dkt. 247 at 69-199 ("Formycon PI Decision"); Dkt. 248 at 61-178 ("Celltrion PI Decision").

As relevant here, Formycon asserted noninfringement based on a narrowed construction of "buffer." In view of the specification's disclosure and the common understanding that proteins are buffers, the court rejected Formycon's construction, construing "buffer" "according to its ordinary meaning to the POSA: 'a substance that resists changes to pH upon addition of an acid or base within an optimal pH range through a proton-donating component and/or a proton-accepting component, including, for example, histidine, phosphate, and proteins like aflibercept.'" Formycon PI Decision at 46-55. The court found that Formycon infringed the buffer limitation under this construction, *id.* at 55-63, which Formycon has not appealed.

III. Amgen Litigation

The fifth applicant to seek approval for an aflibercept biosimilar was Amgen, which Regeneron sued in the Central District of California in January 2024. Regeneron then successfully moved under 28 U.S.C. § 1407 to centralize the five actions in the Northern District of West Virginia. *See In re Aflibercept*, 2024 WL 1597512, at *1.

Regeneron sought a preliminary injunction against Amgen, advancing the same construction of "buffer" as including proteins like aflibercept that the district court adopted (over Formycon's objection) in *Formycon*. Add26, Add78. On September 23, the court denied Regeneron's motion, determining that Regeneron had failed to show a likelihood of success in proving infringement (largely adopting Amgen's proposed order), because aflibercept did not meet the "buffer" limitation of the claims. Add27-31, Add33-89. Specifically, the district court determined that the 40 mg/mL aflibercept in Amgen's biosimilar could not meet both the "VEGF antagonist" and "buffer" limitations, and Regeneron thus was not likely to succeed on infringement. *Id.* The court did not otherwise construe "buffer," apart from concluding, in direct conflict with its *Formycon* ruling, that it could not be a VEGF antagonist like aflibercept. Add78-79.

Regeneron noticed its appeal the same day the court's decision issued, Dkt. 344, and filed this motion immediately thereafter.

ARGUMENT

A motion to expedite proceedings "is appropriate where the normal briefing and disposition schedule may adversely affect one of the parties, as in appeals involving preliminary or permanent injunctions." *See* Practice Note to Fed. Cir. R. 27. This Court is empowered by Rule 2 of the Federal Rules of Appellate Procedure to impose an expedited appeal schedule when warranted. *See, e.g.*, *AstraZeneca LP v. Breath Ltd.*, No. 13-1312, Dkt. 71 (Fed. Cir. June 5, 2013) (ordering July 1st deadline for cross-appellants' opening brief and appellees' briefs, July 12th deadline for appellants' response/reply brief, and July 19th deadline for cross-appellants' reply brief); *Eli Lilly & Co. v. Actavis Elizabeth LLC*, 2010 WL 3374123, at *1 (Fed. Cir. Aug. 26, 2010) (setting expedited deadlines of 14 days, 14 days, and 7 days for opening, responsive, and reply briefs, respectively); *Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC*, No. 23-1186, Dkt. 11 (Fed. Cir. Dec. 1, 2022) (setting December 16th, January 13th, and January 20th deadlines for opening, responsive, and reply briefs, respectively); *Teva Branded Pharm. Prods. R&D, Inc. v. Amneal Pharms. of N.Y., LLC*, No. 24-1936, Dkt. 29 (Fed. Cir. July 1, 2024) (setting July 30th, August 30th, and September 11th deadlines for opening, responsive, and reply briefs, respectively); *Duramed Pharms., Inc. v. Watson Labs., Inc.*, 426 F. App'x 905 (Fed. Cir. 2011) (ordering opening brief in 7 days, responsive brief 14 days after opening, and reply brief 7 days after responsive);

Hoffmann-La Roche Inc. v. Apotex Inc., 2012 U.S. App. LEXIS 5804, *3 (Fed. Cir. Mar. 16, 2012) (ordering opening brief in 14 days, responsive brief 14 days after opening, and reply brief 7 days after responsive). As detailed herein, good cause exists to enter the expedited schedule sought by Regeneron by this motion.

I. Expedition Is Warranted Given the Potential Irreparable Harms to Regeneron

On four prior occasions, the district court has upheld the validity of the '865 patent and enjoined biosimilar market entry, determining that such entry would infringe the '865 patent and irreparably harm Regeneron. As Regeneron details in its concurrently filed Emergency Motion for an Injunction Pending Resolution of Appeal, the district court manifestly erred in failing to enjoin Amgen as well.

The district court's erroneous refusal to enjoin Amgen has paved the way for Amgen's imminent launch. Amgen's premature market entry will irreversibly alter the status quo that the district court had, until recently, maintained by enjoining Mylan and the three PI Defendants, finding that their market entry would irreparably harm Regeneron and that the balance of hardships and public interest favored granting injunctive relief. In each of its prior injunction decisions, the court held that biosimilar entry would cause Regeneron to experience harms including (1) loss of sales and market share,

(2) price erosion, (3) disruption of patentee-payor relationships, (4) reputational harm, and (5) increased marketing and training costs. *See* Mylan Injunction Decision at 15-51; SB PI Decision at 117-67; Formycon PI Decision at 135-88; Celltrion PI Decision at 124-69. This Court has recognized each as an irreparable harm, including in the pharmaceutical context. *See Bio-Rad Labs., Inc. v. 10X Genomics Inc.*, 967 F.3d 1353, 1378 (Fed. Cir. 2020) ("increase[d] . . . marketing costs"); *Mylan Institutional LLC v. Aurobindo Pharma Ltd.*, 857 F.3d 858, 872 (Fed. Cir. 2017) ("lost sales, lost research and development, price erosion, and having to directly compete with an infringer"); *Douglas Dynamics, LLC v. Buyers Prods. Co.*, 717 F.3d 1336, 1344-45 (Fed. Cir. 2013) ("lost sales and erosion in reputation"); *Celsis In Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 930-31 (Fed. Cir. 2012) ("Price erosion, loss of goodwill, damage to reputation, and loss of business opportunities are all valid grounds for finding irreparable harm."); *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1382-83 (Fed. Cir. 2006) ("price erosion" and issues with "third-party payors").

In declining to enjoin Amgen, the district court did not dispute or reverse its prior, consistent holdings that Regeneron would incur these irreparable harms upon Amgen's launch. Expedition of this appeal is necessary to rectify the court's errors and prevent Amgen from irreparably harming Regeneron.

II. Expedition Would Maximize Efficiency for the Court by Aligning This Appeal with the Pending Related Appeals

Expedited review also would aid in aligning the Court's resolution of this appeal with that of the pending related appeals involving Mylan and the three PI Defendants—all of which involve injunctive relief based on Regeneron's '865 patent. *See* SB Appeal; Formycon Appeal; Mylan Appeal; Celltrion Appeal. As the Judicial Panel on Multidistrict Litigation recognized in consolidating the Amgen case with the other pending cases, "[t]he '865 patent, . . . which already has been found valid and infringed by Mylan, is asserted against *all* defendants and, according to Regeneron, will be central in every case." *In re Aflibercept*, 2024 WL 1597512, at *2-3. This Court already has designated the Mylan and Celltrion appeals and, separately, the SB and Formycon appeals, as companions.[3] *See* No. 24-1965, Dkt. 38. Like those related appeals, this Amgen appeal involves only the '865 patent, addressing the construction and infringement of that patent. Briefing in the Celltrion appeal will conclude by mid-November, so expediting this appeal on Regeneron's proposed schedule could enable the same panel to hear oral argument in this appeal and Celltrion's appeal. Accordingly, expedited briefing and oral argument would facilitate this Court's maintenance of the status quo while efficiently resolving these related appeals.

[3] Regeneron has moved for the Court to reconsider its previous companion-designation order and to designate the Mylan appeal a companion to the SB and Formycon appeals, rather than the Celltrion appeal. No. 24-2002, Dkt. 19.

III. Expedition Would Be Achieved Principally by Regeneron's Self-Expediting, Without Prejudice to Amgen

The briefing schedule Regeneron proposes, moreover, would not prejudice Amgen. Regeneron resorts principally to self-expedition, filing its opening brief on October 3, approximately 47 days before the default deadline. Regeneron proposes that Amgen's usual 40-day response be reduced by only five days, to reflect the urgency of the circumstances but not prejudice Amgen's ability to respond with respect to the single claim-construction issue relevant to this appeal. Regeneron then proposes to serve its reply in just 12 days (including two weekends), shortened from the usual 21. The parties will file the joint appendix by November 22. The appeal thus may be scheduled for the January 2025 oral argument calendar or earlier. Regeneron further requests that no extensions of the schedule be granted.

* * *

Pursuant to Federal Circuit Rule 27(c), Regeneron respectfully submits that an expedited briefing schedule for this motion is appropriate given the urgent circumstances detailed herein. Regeneron proposes the following deadlines for Amgen's opposition brief and Regeneron's reply brief:

Brief	**Deadline**
Regeneron's Motion	Filed on Monday, September 23, 2024

Amgen's Opposition	12:00 noon EDT on Thursday, September 26, 2024
Regeneron's Reply	Friday, September 27, 2024

CONCLUSION

For the foregoing reasons, Regeneron respectfully requests that this Court order the following expedited schedule for this appeal:

Event	**Deadline**
Regeneron's Opening Brief	October 3, 2024
Amgen's Responsive Brief	November 7, 2024
Regeneron's Reply Brief	November 19, 2024
Joint Appendix	November 22, 2024
Oral argument	To be held in January 2025 or at the Court's earliest convenience

SEPTEMBER 23, 2024

Respectfully submitted,

/s/ David I. Berl

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CERTIFICATE OF COMPLIANCE
WITH TYPEFACE LIMITATION AND WORD-COUNT

This motion complies with the type-volume limitation of Federal Rule of Appellate Procedure 27(d)(2)(A). This motion contains 2,439 words, excluding the parts of the motion exempted by Federal Rule of Appellate Procedure 32(f) and Federal Circuit Rule 32(b).

This motion complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6). This motion has been prepared in a proportionally-spaced typeface using Microsoft Word in fourteen-point CenturyExpd BT style.

/s/ David I. Berl
SEPTEMBER 23, 2024 DAVID I. BERL

Attorney for Plaintiff-Appellant

No. 24-___

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ADDENDUM IN SUPPORT OF MOTION TO EXPEDITE

Description	Page Range
Preliminary Injunction Order (Dkt. 343) (CONTAINS CONFIDENTIAL MATERIAL)	Add1-Add90

Confidential Material from Add1-Add90 Omitted

CERTIFICATE OF SERVICE

I certify that today, September 23, 2024, I electronically filed the foregoing Motion and accompanying documents with the Clerk of the Court for the U.S. Court of Appeals for the Federal Circuit using the appellate CM/ECF system. Copies of the foregoing Motion and accompanying documents were served by e-mail on counsel of record and by Federal Express at the following address:

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Suite 6300
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I further certify that all parties required to be served have been served.

SEPTEMBER 23, 2024

/s/ David I. Berl
DAVID I. BERL

Attorney for Plaintiff-Appellant