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**IN THE UNITED STATES DISTRICT COURT  
 FOR THE CENTRAL DISTRICT OF CALIFORNIA**

<p>20 _____ )          21 REGENERON PHARMACEUTICALS, )          INC. )          22 )          23 Plaintiff, )          24 )          v. )          25 )          AMGEN INC. )          26 )          Defendant. )          27 )          28 _____ )</p>	<p>Case No. 2:24-cv-264-JWH-Ex          Hon. John W. Holcomb            AMGEN’S OPPOSITION TO          REGENERON’S <i>EX PARTE</i>          APPLICATION FOR SCHEDULING          ORDER</p>
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1           Regeneron’s *Ex Parte* Application for Scheduling Order should be denied  
2 because it does not satisfy any of the requirements for *ex parte* relief. *See Mission*  
3 *Power Eng’g Co. v. Cont’l Cas. Co.*, 883 F. Supp. 488 (C.D. Cal. 1995). There is no  
4 emergency or irreparable prejudice, Regeneron is not without fault in creating this  
5 situation, and it does not meet the procedural requirements discussed in *Mission*  
6 *Power*.

7           Amgen apologizes for burdening the Court with this filing on a Saturday  
8 evening. Amgen understands that a response to an *ex parte* application is typically  
9 due within 24 hours, so it responds today to ensure compliance with the Court’s  
10 procedures.

11           There is no reason this Court must immediately decide Regeneron’s request to  
12 have its *preferred schedule* for preliminary injunction proceedings. When filing an  
13 *ex parte* motion, courts in this District have said: “There had better be a fire.”  
14 *Mission Power*, 883 F. Supp. at 492. Here, there is no imminent harm set to befall  
15 Regeneron. As Regeneron knew before filing this *ex parte* application, Amgen  
16 cannot begin commercial marketing of its biosimilar aflibercept product until the  
17 date identified by Regeneron in its application. (Application at 9:6-7; Trask Decl.  
18 Ex. 2 at 1 (1/16/24 email from J. Labbe to D. Berl).). The parties’ scheduling  
19 disputes can be briefed and resolved through normal procedure.

20           Tellingly, Regeneron does not even reference *Mission Power* let alone attempt  
21 to satisfy its stringent requirements, including the requirements that Regeneron must  
22 establish and substantiate “irreparable prejudice” and that Regeneron was “without  
23 fault in creating the crisis.” *Mission*, 883 F. Supp. at 492. Neither factor is met here.  
24 Nor does Regeneron’s application comply with the *Mission Power* requirement to  
25 file a separate, stand-alone motion seeking substantive relief and limiting the *ex*  
26 *parte* issue to the dates on which the merits of that motion will be briefed and heard.  
27 *Id.*

28

1           Regeneron served its summons on Friday January 12. (Dkt. 36.) That same day,  
2           Regeneron provided Amgen with a proposed preliminary injunction schedule. (Trask  
3           Decl. Ex. 2 at 2-4.) One business day later, on Tuesday January 16, Amgen  
4           responded to Regeneron with an alternative schedule. (Trask Decl. Ex. 2 at 1; Ex. 3.)  
5           On Thursday January 18, Regeneron declared the parties to be at an impasse but  
6           waited until Saturday January 20 at 2:00 A.M. to file its *ex parte* application,  
7           demanding immediate entry of its desired schedule, serving the application on  
8           Amgen later that morning. Such tactics are expressly discouraged in *Mission Power*  
9           and this Court’s Standing Order (at 15).

10           Making matters worse, Regeneron did not even properly protect Amgen’s  
11           highly confidential competitively sensitive information, which was designated as  
12           confidential under 42 U.S.C. § 262(l)(1). This information remained available to the  
13           public as of the filing of this paper. Amgen has asked Regeneron to immediately  
14           remedy this situation, but because Regeneron chose to file its papers on a weekend,  
15           it has not yet been able to remove the filing from the public record. Regeneron’s  
16           actions violate 42 U.S.C. § 262(l)(1)(H), which provides that “[t]he disclosure of any  
17           confidential information in violation of this paragraph shall be deemed to cause  
18           [Amgen] to suffer irreparable harm for which there is no adequate legal remedy and  
19           the court shall consider immediate injunctive relief to be an appropriate and  
20           necessary remedy for any violation or threatened violation of this paragraph.”  
21           Amgen respectfully requests that, in addition to denying Regeneron’s application,  
22           the Court order the immediate withdrawal of documents containing Amgen’s  
23           confidential information from the public docket.

24           Even though Regeneron has yet to file a motion for a preliminary injunction  
25           against Amgen, Amgen is and has been willing to discuss a reasonable schedule and  
26           is prepared to present its position to the Court. But Regeneron’s attempt to resolve  
27           the dispute using the *ex parte* procedure is improper. Far from any real-world crisis  
28           that requires this Court’s emergency intervention, Regeneron’s submission makes

1 clear that it seeks entry of its preferred schedule for strategic reasons: to bolster  
2 Regeneron’s pending motion to transfer this case for pretrial purposes to West  
3 Virginia. But the Judicial Panel on Multidistrict Litigation is not due to hear  
4 Regeneron’s motion until March 28, 2024. (Trask Decl. Ex. 7 at 2, JPML Dkt. entry  
5 7.) And while the JPML has yet to rule on the merits of the transfer motion,  
6 Regeneron similarly tried to manufacture an emergency there, requesting expedited  
7 consideration of its motion to transfer, which the JPML promptly denied. (*Id.*)

8 Having lost its bid to expedite in front of the JPML, Regeneron now urges this  
9 Court to bypass the normal noticed motions procedure to grant it urgent *ex parte*  
10 relief, which relief is centered on Regeneron’s *assumption* that it will succeed in its  
11 attempt to transfer this case to West Virginia. Amgen will fully brief the reasons  
12 why Regeneron’s transfer motion should be denied in its opposition to the transfer  
13 motion, due to be filed before the JPML on February 2, 2024. (Trask Decl. Ex. 7 at  
14 1, JPML Dkt. entry 6 (setting JPML briefing schedule).) To the extent the Court  
15 believes these issues are relevant to the scheduling of preliminary injunction  
16 proceedings in this case, Amgen would welcome the opportunity to present these  
17 issues in full to the Court.

18 \* \* \*

19 Amgen respectfully requests that the Court either deny Regeneron’s *Ex Parte*  
20 Application or issue a schedule for Amgen to file an opposition addressing the  
21 reasons Regeneron’s proposed schedule is not right for this case. Amgen requests  
22 that, in addition to denying this application, the Court order Regeneron to take any  
23 and all steps necessary to remove the documents that contain Amgen’s confidential  
24 information from the public docket immediately and that Regeneron certify that it  
25 has instituted more stringent precautionary measures to ensure that no further  
26 disclosure of Amgen confidential information occurs.

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Dated: January 20, 2024

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