**IN THE UNITED STATES DISTRICT COURT**
**FOR THE NORTHERN DISTRICT OF WEST VIRGINIA**
**AT CLARKSBURG**

| | |
|---|---|
| REGENERON PHARMACEUTICALS, INC.,<br><br>Plaintiff,<br><br>v.<br><br>MYLAN PHARMACEUTICALS INC.,<br><br>Defendant. | Case No.: 1:22-cv-00061-TSK |

**MYLAN PHARMACEUTICALS INC.'S RESPONSE TO**
**MOTION REQUESTING EXPEDITED STATUS CONFERENCE**

For at least the reasons set forth below, the Court should (1) deny Regeneron's motion for an expedited status conference (and trial date) in its entirety, and (2) permit this case to proceed on an appropriate schedule that does not prejudice Mylan or the Court. Regeneron provides no valid reason that would justify its extraordinary proposal to set trial for 10 months, let alone a plan to conduct discovery and otherwise resolve the complex scientific and legal issues in dispute. As ordered, Mylan will confer with Regeneron on an appropriate schedule and submit the parties' meeting report on September 23, 2022. First Order and Notice Regarding Discovery and Scheduling Conference (Dkt. No. 19) (Aug. 10, 2022). Mylan is prepared to discuss these issues with the Court at a scheduling conference in the normal course as necessary.

## I. INTRODUCTION.

Based on an erroneous premise regarding permanent injunctive relief, Regeneron seeks an unprecedented schedule in a complex biopharmaceutical matter in which Regeneron chose to assert *24* patents. Regeneron's premise is that "in all likelihood" it will lose any right to permanent injunctive relief unless it receives an appellate decision prior to May 18, 2024. Regeneron's

claimed need does not exist. Rushing to trial in fewer than 10 months on a complex, 24 patent case—which even Regeneron concedes is not possible—is not only legally unnecessary, but transparently designed to prejudice Mylan's ability to engage in meaningful discovery, and will unduly burden both the parties and the Court.

*First*, practically speaking, Regeneron's proposed trial date of June 2023 is simply not feasible—indeed, Regeneron's Complaint puts at issue 566 patent claims across 24 asserted patents stemming from 11 separate patent families with a collective 33 unique inventors, across a wide range of non-overlapping technology areas (e.g., cell culture process patents, protein purification patents, assay patents, cell line patents, method of treatment patents, formulation patents, among others). Even if Regeneron's justification for such an expedited schedule is correct (it's not), it would not justify denying the parties a reasonable time to conduct fact and expert discovery in a complex biosimilar patent infringement action like this one.

What's more, the problem would not be solved by Regeneron's proposal for a unilateral and self-serving selection of 12 patents for the case's initial stage, at least because Regeneron's so-called "reasonable subset" includes patents from only 4 of the 11 families. Regeneron does not propose to waive its claims as to the 12 remaining "unselected" patents and does not even offer a proposal to timely resolve these patents, thus leaving the door open for Regeneron to assert those patents against Mylan at any time in the future, including on the eve of trial or a potential product launch. Accordingly, Regeneron's so-called "solutions" only serve to delay patent clarity and resolution on the merits in addition to increasing the likelihood of rushed motion practice.

*Second*, Regeneron's premise is simply wrong. Contrary to Regeneron's assertion, it will not be deprived of any opportunity for injunctive relief absent a "final court decision" (e.g., a Federal Circuit decision) before May 18, 2024, as explained in more detail below. Regardless of

when Mylan's biosimilar is approved by FDA, Regeneron can seek injunctive relief to the extent it can satisfy the requirements for such extraordinary relief, just as any litigant can do. Simply put, Congress intentionally designed the biosimilar regulatory pathway to be independent from the patent dispute framework—the resolution of patent disputes does not affect the timing of FDA approval and vice versa.

*Third*, Regeneron's proposal is not only unrealistic and contrary to the statute, it also disrupts the careful balance created by Congress that was designed, in part, to allow the biosimilar applicant to control the scope and timing of litigation. Regeneron essentially seeks to rob Mylan of one of the benefits of availing itself of the optional patent dispute provisions of the Biologics Price Competition and Innovation Act (BPCIA). Regeneron's proposal skews the balanced incentives for biosimilar applicants to make substantial pre-suit disclosures of their regulatory application, manufacturing information, and defenses—all the while delaying patent certainty for potentially 8+ months.

To be clear, a protracted litigation provides no benefit to the parties or to the Court. Mylan has every incentive to litigate the present patent disputes "quickly and efficiently," but disagrees that either party must sacrifice its respective ability to reasonably litigate this case under the Federal Rules. For the reasons set forth herein, Regeneron fails to show that the June 2023 trial date it seeks is necessary, equitable, or otherwise justified, and thus, its motion should be denied, allowing the parties to engage in the ordinary case-scheduling process leading to a reasonable trial date.

## II. BACKGROUND.

### A. The "Patent Dance" Under The BPCIA.

Through the BPCIA, Congress amended the Public Health Service Act and the Patent Act in an effort to balance the goals of competition and innovation. BPCIA § 7001(b), Pub. L. No.

111-148. To expedite competing "biosimilars" to market, Congress created an abbreviated regulatory approval pathway that allows a biosimilar applicant (here, Mylan) to rely, in part, on the data supporting the previous approval of a reference biologic product (here, EYLEA® (aflibercept)). 42 U.S.C. § 262(i)(2), (k). In exchange, Congress granted the reference product sponsor (RPS) (here, Regeneron) 12 years of marketing exclusivity, independent of any patent protection to which it is entitled.

In addition to the new regulatory pathway, Congress also created a flexible patent resolution framework through which the biosimilar applicant and the RPS could identify patents to be litigated in connection with the proposed biosimilar. By way of an optional multi-stage process commonly referred to as the "patent dance," the biosimilar applicant and RPS may exchange information and negotiate a final patent list that is either generated by agreement or through the simultaneous exchange of patent lists. 42 U.S.C. § 262(*l*)(2)-(*l*)(6). Each biosimilar applicant must also provide advance notice to the RPS at least 180 days before the first commercial marketing of the biosimilar. 42 U.S.C. § 262(*l*)(8)(A).

**B. Mylan And Regeneron Engaged In The "Patent Dance."**

Mylan submitted its biologics license application (BLA) for its aflibercept biosimilar on October 29, 2021. Following FDA acceptance of Mylan's BLA, Mylan and Regeneron engaged in a series of information exchanges and negotiations in which Mylan attempted to narrow the list of patents to be litigated from the list of ***31 patents*** initially identified by Regeneron pursuant to 42 U.S.C. § 262(*l*)(3)(A). Despite several attempts, the parties failed to agree on a final and complete list of patents which would be the subject of an action for patent infringement under Section 262(*l*)(6)(A).

During negotiations, Regeneron suggested asserting 12 of the patents in a first litigation, but refused to provide any clarity on how it intended to proceed with respect to the remaining set

of patents—effectively holding the remaining patents over Mylan's head to be asserted in yet later litigations. Mylan made clear that it wanted to efficiently litigate and/or resolve the disputes between the parties, but also needed some level of certainty that Regeneron was not holding back patents from immediate litigation only to later assert them on the eve of trial or launch as the basis for emergency relief. Mylan expressed concern that reserving patents until an unspecified later date would result in hurried and disorderly motion practice that would unnecessarily burden the Court by forcing the Court and the parties to adjudicate complex legal and scientific concepts instantaneously, on anywhere from 1 to 19 additional patents.

To narrow the issues, Mylan made representations about its product; produced information from a third-party cell culture vendor; offered to waive any damages limitations with respect to certain patents; and requested covenants-not-to-sue on any patents Regeneron did not intend to immediately assert. Regeneron not only rejected these proposals, it threatened to immediately sue on all 31 patents if Mylan pushed to litigate more than the 12 patents Regeneron unilaterally identified. Notably, at no point during these negotiations did Regeneron ever disclose its plans to seek a trial date in ten (10) months.

Since Mylan and Regeneron were unable to reach agreement, on July 5, 2022, Mylan and Regeneron engaged in a simultaneous exchange of patent lists under 42 U.S.C. § 262(*l*)(5)(A). Despite the fact that Regeneron's identified patents are not infringed and/or invalid, Mylan was compelled to identify 25 of those patents on its list in order to obtain the certainty that it seeks because Regeneron refused to drop them from its "patent dance" list.[1] Mylan believes a subset of these patents could be prioritized for trial, ***provided that*** Mylan receives actual certainty that the

[1] Mylan did not include 6 patents from Regeneron's list of 31, because, as Regeneron itself admitted, those patents do not cover the current Mylan BLA product that is undergoing FDA review.

remaining patents cannot be asserted against Mylan, as well as reasonable limits as to which patents may be the subject of a preliminary injunction motion.

As Regeneron notes and expects, in the event it obtains "pediatric exclusivity" in the near future, the earliest Mylan's BLA is eligible for FDA approval is May 18, 2024. Regeneron Motion (Dkt. No. 7) at 5. Mylan has not yet provided its advance 180-day notice of commercial marketing.

## III. AN EXPEDITED SCHEDULE IS NEITHER NECESSARY NOR WARRANTED.

### A. An Expedited Schedule Is Not Appropriate Nor Feasible Given The Size And Complexity Of The Disputed Issues.

Simply put, a June 2023 trial date would inevitably and improperly constrain Mylan's ability to engage in the discovery process and identify relevant information from all parties to the dispute. That is reason enough to deny Regeneron's motion in its entirety.

Mylan is entitled, under the Federal Rules, to take discovery commensurate in scope with Regeneron's legal claims. The anticipated scope of discovery here is significant considering that there are 33 unique inventors, 24 asserted patents (which collectively comprise a total of 566 claims), and 11 patent families. This case will likely also require that the parties obtain overseas discovery, including discovery subject to the Hague Convention, and discovery from third parties (i.e., unrelated parties), including, but not limited to, cell culture media vendors. The asserted patents also cover a broad array of non-overlapping subject matter, including isolated nucleic acid molecules and methods for manufacturing recombinant proteins (the '959 patent); recombinant host cell lines (the '106, '110, and '055 patents); protein purification methods (the '280, '715, and '283 patents); treatment methods for multiple different indications (e.g., macular degeneration (the '338, '069, '681, '601 and '572 patents), retinal vein occlusion (the '205 patent), and diabetic macular edema/retinopathy (the '879 and '601 patents)); cell culturing/cultivating methods (the '771 and '342 patents); formulations (the '992, '226, '458, and '865 patents); detection methods

(the '594 patent); and compositions (the '625 and '135 patents). Accordingly, Mylan expects to identify at least one expert witness for each of the above technology areas, possibly more, depending on the claims that are at issue. And given Regeneron's use of 5 expert witnesses in a currently pending *inter partes* review challenge to a single patent (the '338 patent), it is very likely that Regeneron will be employing a large number of expert witnesses in this litigation. Moreover, Regeneron does not even purport to address how a June 2023 trial date could be workable in view of the extensive claim construction that will be required and/or dispositive motion practice.

Additionally, while Regeneron acknowledges in its motion that it has "already received access to portions of Mylan's regulatory application" and is "prepared to make an immediate substantial document production to Mylan,"[2] it fails to take into account that Mylan is also entitled to conduct discovery. Regeneron Motion (Dkt. No. 7) at 6. For example, Regeneron's proposal does not appear to contemplate the full scope of the many factual and legal issues potentially at issue, including at least the following:

- whether the claims of the asserted patents are invalid, including based on at least anticipation, obviousness, double patenting, indefiniteness, lack of written description and enablement;
- the scope and construction of the claims of the asserted patents;
- if necessary, whether Regeneron has engaged in inequitable conduct that would preclude enforcement of any valid claims; and
- whether Mylan has infringed and/or is infringing, directly or indirectly, any one of the

[2] Regeneron has provided no indication as to how many documents it intends on producing, stating only that its forthcoming document production will be "substantial," "including the patents and file histories, Regeneron's regulatory filings, key laboratory notebooks, and other scientific and inventor documents." Regeneron Motion (Dkt. No. 7) at 6.

566 potential claims at issue, and if so, whether such infringement is willful. Importantly, many of the above issues may require judicial intervention, whether motions to compel and/or dispositive motion practice. As such, this case will require significant preparation time and judicial involvement before trial.

Without prioritizing 12 of the patents (the problems inherent in this proposal are discussed above), even Regeneron admits its proposed schedule is not feasible. Regeneron, moreover, offers no reasonable mechanism by which a June 2023 trial might possibly occur even with prioritized patents. *Is Regeneron willing to agree to limits on written discovery and/or depositions? Is Regeneron willing to voluntarily dismiss patents that it knows to not be infringed and/or knows to be invalid? Will Regeneron forego the opportunity to amend and/or supplement the hundreds of pages of detailed contentions it served during the patent dance?*

Contrary to Regeneron's (erroneous) suggestion that its proposed June 2023 trial date is somehow essential to its ability to vindicate its patent rights, Regeneron's true motivation in seeking an expedited trial schedule on less than all patents is three-fold: *One*, such an unreasonably expedited pace would inevitably prejudice Mylan's ability to obtain all necessary discovery relevant to pursue its defenses in response to Regeneron's complaint allegations (to Regeneron's advantage). *Two*, Regeneron can hold the remaining patents over Mylan's head, like a modern-day sword of Damocles, effectively threatening to assert them in piecemeal fashion on the eve of trial or product launch—essentially turning one case into several. *And three*, a highly abbreviated schedule in the current district court litigation could be used by Regeneron to argue that Mylan's currently-pending *inter partes* review challenges to the '681 and '601 patents should be denied review. (IPR2022-01225; IPR2022-01226; *see also* IPR2021-00880 and IPR2021-00881 (late-stage IPRs challenging the '069 and '338 patents, with final written decision anticipated by Nov.

2022)).[3] None of these motivations are proper, and they certainly do not warrant the highly prejudicial and burdensome relief that Regeneron seeks.

As such, even if Regeneron had shown a need for a more expedited schedule (it has not), Regeneron has cited no supporting authority demonstrating how this purported need would trump Mylan's due process rights to reasonable discovery for a fair trial. Regeneron cannot simultaneously choose to bring a massive collection of disparate claims and truncate Mylan's rights to discovery and reasonable trial preparation in the face of those claims.

### B. Regeneron's Ability To Obtain Injunctive Relief Is Not Dependent On The Timing Of FDA's Approval Of Mylan's Biosimilar.

Regeneron's purported need for an expedited trial for permanent injunctive relief prior to FDA approval is not only overstated, but legally baseless.

Unlike the patent disputes arising under the Hatch-Waxman Act, Congress did not link FDA approval of biosimilar products to the pendency or outcome of any patent dispute. Critically, under the BPCIA's patent resolution scheme, the filing of an infringement suit does not result in an automatic stay of FDA approval. Instead, Congress created a defined 180-day window during which an RPS, such as Regeneron, could move to enjoin the commercial manufacture or sale of a competing biosimilar upon making the requisite showing for a patent-based injunction. 42 U.S.C. § 262(*l*)(8)(A) (statutory 180-day period for the patent owner to seek an injunction that is triggered

[3] Regeneron's request for expedited scheduling is a thinly veiled tactic Regeneron intends to use to request that the Patent Trial and Appeal Board (PTAB) exercise its discretion to deny institution of two *inter partes* reviews recently filed by Mylan, challenging claims of the currently asserted '681 and '601 patents. Mylan anticipates that Regeneron will ask the PTAB to deny institution under an argument that the district court will reach a decision on the merits before the Board will. *See* Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation (June 21, 2022); *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (P.T.A.B. Mar. 20, 2020). Regeneron hopes to adjudicate the '681 and '601 patents' invalidity in district court, rather than the PTAB, given the lower "preponderance of the evidence standard" applied in PTAB challenges. *See* 35 U.S.C. § 316(e). Notably, Regeneron does not even acknowledge the existence of these PTAB proceedings in its motion.

by a biosimilar's notice of commercial marketing). Furthermore, in contrast to the remedies available under the Hatch-Waxman Act, a court has no authority under Section 271(e)(4)(A) to order FDA to delay the effective approval of a biosimilar as a remedy for patent infringement. 35 U.S.C. § 271(e)(4)(A) (limited to a drug or veterinary biological product). In other words, in enacting the BPCIA, Congress created a patent resolution scheme that is wholly separate from FDA's regulatory review—there simply is no mechanism to alter the timing of FDA approval of a biosimilar based on the filing of a patent infringement suit.

Nonetheless, Regeneron seems to suggest that without an expedited schedule that would allow a "final court decision" (e.g., a Federal Circuit appellate decision) prior to approval of Mylan's biosimilar, it would somehow be deprived of the opportunity to seek injunctive relief. Not so. If Regeneron wants to enjoin Mylan prior to any biosimilar launch, Regeneron should use the procedure contemplated by the BPCIA—a motion for preliminary injunction filed within 180 days of Mylan's notice of commercial marketing based on a showing of possible infringement of a valid patent and consideration of the traditional factors for an injunction. 42 U.S.C. § 262(*l*)(8)(B); 35 U.S.C. § 271(e)(4)(B). Likewise, once infringement and validity have been adjudicated, nothing prevents Regeneron from seeking a permanent injunction to enjoin infringement until patent expiry. *See* 35 U.S.C. § 283; *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 393-94 (2006).

Moreover, as Regeneron conveniently neglects to mention, examples from previous BPCIA cases demonstrate that Regeneron would not lose any substantive rights under a more realistic trial schedule, particularly when there is no risk of Mylan launching prior to May 2024 (assuming pediatric exclusivity is granted as Regeneron anticipates). In the majority of BPCIA patent decisions to date, the biosimilar applicant has obtained FDA approval prior to the district

court's decision, which is typically received years in advance of a Federal Circuit decision.[4] Moreover, in 2 of the 3 cases where a court has found infringement liability, a permanent injunction was entered *years* after approval of the biosimilar. *Immunex Corp. v. Sandoz Inc.*, No. 16-cv-01118, Final Judgment and Order of Permanent Injunction (Dkt. No. 719) (D.N.J. Oct. 8, 2019) (Sandoz's etanercept biosimilar (Erelzi®, BLA No. 761042) was approved on August 30, 2016); *see also Immunex Corp. v. Samsung Bioepis Co.*, No. 19-cv-11755, Final Judgment and Order of Permanent Injunction (Dkt. No. 128) (D.N.J. Nov. 3, 2021) (Samsung's etanercept biosimilar (Eticovo®, BLA No. 761066) was approved on Apr. 25, 2019).[5]

Furthermore, Regeneron's purported need for expedited scheduling stands in direct contradiction to its approach in the patent dance and filing this suit. Regeneron took nearly the full statutory period (60 days) to produce its § 262(*l*)(3)(C) statements, and took nearly the entire statutory period (30 days) under § 262(*l*)(6) to file suit. If Regeneron were genuinely interested in

[4] *See, e.g.*, *Janssen Biotech, Inc. v. Celltrion Healthcare Co.*, Nos. 15-cv-10698, 17-cv-11008 (D. Mass.) (district court decisions 9/29/2016 (211 F. Supp. 3d 364) and 7/30/2018 (2018 WL 10910845); Federal Circuit decisions 1/23/2018 (2018 WL 2072723) and 3/5/2020 (796 F. App'x 741), respectively; Celltrion's infliximab biosimilar (Inflectra®, BLA No. 125544) approved 4/5/2016); *Amgen Inc. v. Sandoz Inc.*, No. 14-cv-04741 (N.D. Cal.) (district court decision 12/19/2017 (295 F. Supp. 3d 1062); Federal Circuit decision 5/8/2019 (923 F.3d 1023); Sandoz's filgrastim biosimilar (Zarxio®, BLA No. 125553) approved 3/6/2015); *Amgen Inc. v. Hospira, Inc.*, No. 15-cv-00839 (D. Del.) (district court decision 8/27/2018 (336 F. Supp. 3d 333); Federal Circuit decision 12/16/2019 (944 F.3d 1327); Hospira's epoetin biosimilar (Retacrit®, BLA No. 125545) approved 5/15/2018); *Immunex Corp. v. Sandoz Inc.*, No. 16-01118 (D.N.J.) (district court decision 8/9/2019 (395 F. Supp. 3d 366); Federal Circuit decision 7/1/2020 (964 F.3d 1049); Sandoz's etanercept biosimilar (Erelzi®, BLA No. 761042) approved 8/30/2016); *Amgen Inc. v. Mylan Inc.*, No. 17-cv-01235 (W.D. Pa.) (district court decision 8/21/2019; Mylan's pegfilgrastim biosimilar (Fulphila®, BLA No. 761075) approved 6/4/2018).

[5] No permanent injunction was entered in the third case as the patents-in-suit had expired by the time of trial. *Amgen Inc. v. Hospira, Inc.*, No. 15-cv-00839, Final Judgment (Dkt. No. 393) (D. Del. Sept. 11, 2018) (Retacrit®, BLA No. 125545) (a jury trial was held in September 2017 involving two patents-in-suit, the latest of which expired on January 5, 2016); *see also id.*, Final Jury Instructions (redacted) (Dkt. No. 300) (D. Del. Sept. 7, 2017).

more quickly adjudicating this matter, it would have expedited any of those actions. The Court should not reward a party that purposefully wasted 3 months with an expedited schedule.

But there is more. As noted above, Regeneron offers no particulars regarding how the parties could realistically proceed to trial on up to 12 patents by June 2023, and obtain a district court decision and an appellate decision by May 2024.[6] And for good reason—to date, *no* district court in any BPCIA action has ever resolved a litigation in 10 months in the first instance, even when the disputed issues were resolved through dispositive motion practice and/or involve fewer than 12 patents-in-suit.[7] The bottom line is that there is no need for Regeneron to manufacture this urgency when it will have the opportunity to seek a preliminary injunction, and could seek a permanent injunction, regardless of when Mylan's biosimilar is approved.

---

[6] In 2021, the median time from docketing to disposition of a Federal Circuit appeal was 12 months. Federal Circuit, Median Time to Disposition in Cases Terminated After Hearing or Submission (Table), https://cafc.uscourts.gov/wp-content/uploads/reports-stats/disposition-time/06_Med_Disp_Time_MERITS_table.pdf. Thus, even with a June 2023 trial, it is unlikely there will be an appellate decision prior to approval of Mylan's biosimilar.

[7] *Amgen Inc. et al v. Mylan Inc. et al*., No. 17-cv-01235 (W.D. Pa.) (nearly 23 months from Sept. 22, 2017 complaint to Aug. 21, 2019 district court decision on 1 patent-in-suit and nearly 24 months from complaint to Sept. 17, 2019 stipulation of dismissal for other patent-in-suit following Federal Circuit decision in related case) (two patents-in-suit resolved by motion for judgment on the pleadings and stipulation of dismissal); *Immunex Corporation et al. v. Sandoz Inc. et al.*, No. 16-cv-01118 (D.N.J.) (41.5 months from Feb. 26, 2016 complaint to August 9, 2019 district court decision) (bench trial involving 2 patents-in-suit); *Amgen Inc. et al v. Hospira, Inc.*, No. 15-cv-00839 (D. Del.) (over 35 months from Sept. 18, 2015 complaint to Aug. 27, 2018 district court decision) (jury trial involving 2 patents-in-suit); *Amgen Inc. et al. v. Coherus Biosciences, Inc.*, No. 17-cv-00546 (D. Del.) (10.5 months from May 10, 2017 complaint to Mar. 26, 2018 district court decision) (1 patent-in-suit resolved by a motion to dismiss); *Amgen Inc. et al. v. Sandoz Inc. et al.*, No. 14-cv-04741 (N.D. Cal.) (nearly 38 months from Oct. 24, 2014 complaint to Dec. 19, 2017 district court decision) (1 patent-in-suit resolved by summary judgment); *Janssen Biotech, Inc. et al. v. Celltrion Healthcare Co. et al.*, Nos. 15-cv-10698, 17-cv-11008 (D. Mass.) (over 18.5 months from Mar. 6, 2015 complaint to Sept. 28, 2016 district court decision on 1 patent-in-suit and over 40 months to July 30, 2018 district court decision on other patent-in-suit) (2 patents-in-suit resolved by motions for summary judgment); *Amgen Inc. et al. v. Apotex Inc. et al.*, No. 15-cv-61631 (S.D. Fla.) (13 months from Aug. 6, 2015 complaint to Sept. 9, 2016 district court decision) (bench trial involving 1 patent-in-suit).

### C. By Participating In The Patent Dance, Mylan Has The Statutory Right To Control The Timing And Scope Of Litigation Under The BPCIA.

The result here is entirely consistent with the BPCIA system that Congress designed. There are several options for resolving patent disputes under the BPCIA's patent resolution framework that are primarily dictated by the biosimilar applicant. *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1671-72 (2017) (recognizing that BPCIA was designed to provide the biosimilar applicant with "substantial control" over the timing and scope of patent litigation). Indeed, the Supreme Court recognized that the biosimilar applicant only cedes control of the scope and timing of the litigation when an applicant elects ***not*** to initiate the patent dance. *Id.* at 1675 (when the applicant chooses to not turn over its application and manufacturing information, "[the statute] vests in the [RPS] the control that the applicant would otherwise have exercised over the scope and timing of the patent litigation. It also deprives the applicant of the certainty that it could have obtained by bringing a declaratory-judgment action prior to the marketing its product"). Thus, when the biosimilar applicant elects to participate in the patent dance, as Mylan did here, it controls the number of patents to immediately litigate and the number of patents to reserve for later litigation, if any. 42 U.S.C. § 262 (*l*)(5)(A).

Regeneron's self-selection of which patents to litigate now and which patents to reserve for later is contrary to the design of the BPCIA. Regeneron cannot benefit from Mylan's pre-suit disclosures only to then unilaterally block Mylan's statutory right to control the timing and scope of litigation after suit is filed—and worse, hold a substantial number of patents over Mylan's head to assert later. Over the past 8 months, Mylan has produced confidential and proprietary information about its biosimilar and manufacturing information, as well as detailed contentions setting forth Mylan's non-infringement and invalidity defenses on a patent-by-patent, claim-by-

claim basis.[8] Among other reasons, Mylan subjected itself to such onerous pre-suit information disclosures to control the timing and scope of litigation and to best position itself to make informed judgments at the time of launch. Regeneron's decision to hold back patents now, only to potentially assert them later as the basis for emergency relief, not only increases the risk and uncertainty for Mylan, but also heightens the likelihood that this Court would be forced to decide complex legal and scientific issues in a pressurized context without the benefit of a fulsome evidentiary record.

Despite the foregoing, Mylan will make all reasonable efforts to work with Regeneron to prioritize a subset of patents for trial provided that Mylan receives certainty with respect to the remaining patents, as well as reasonable limits as to which patents may be the subject of a preliminary injunction motion. Mylan is also open to discussing proposals to streamline the issues for the Court and timely resolution.

## IV. CONCLUSION.

The Court should deny Regeneron's motion in its entirety, and allow this case to proceed in the normal course and in a fashion that does not prejudice Mylan's right to fully and fairly defend itself.

Date: August 19, 2022

***/s/ William J. O'Brien***
Gordon H. Copland (WVSB #828)
William J. O'Brien (WVSB #10549)
STEPTOE & JOHNSON PLLC
400 White Oaks Boulevard
Bridgeport, WV 26330
(304) 933-8162
gordon.copland@steptoe-johnson.com
william.obrien@steptoe-johnson.com

[8] Notably, neither Regeneron's Complaint (Dkt. No. 1) nor its Motion Requesting Expedited Status Conference (Dkt. No. 7) contain any allegations of deficiencies related to Mylan's information disclosures. None.

*Of Counsel (pro hac vices forthcoming):*
William A. Rakoczy
Heinz J. Salmen
Eric R. Hunt
Neil B. McLaughlin
Lauren M. Lesko
RAKOCZY MOLINO MAZZOCHI SIWIK LLP
6 W. Hubbard St., Suite 500
Chicago, IL 60654
(312) 527-2157
wrakoczy@rmmslegal.com
hsalmen@rmmslegal.com
ehunt@rmmslegal.com
nmclaughlin@rmmslegal.com
llesko@rmmslegal.com

*Attorneys for Defendant*
*Mylan Pharmaceuticals Inc.*

**CERTIFICATE OF SERVICE**

I hereby certify that on August 19, 2022, I electronically filed the foregoing **"Mylan Pharmaceuticals Inc.'s Response to Motion Requesting Expedited Status Conference"** with the Clerk of the Court by using the CM/ECF system, which will send a notice of filing to all counsel of record.

***/s/ William J. O'Brien***

Gordon H. Copland (WVSB #828)
William J. O'Brien (WVSB #10549)
STEPTOE & JOHNSON PLLC
400 White Oaks Boulevard
Bridgeport, WV 26330
(304) 933-8162
gordon.copland@steptoe-johnson.com
william.obrien@steptoe-johnson.com

*Attorneys for Defendant*
*Mylan Pharmaceuticals Inc.*