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

REGENERON PHARMACEUTICALS, INC., Plaintiff, v. MYLAN PHARMACEUTICALS INC., and BIOCON BIOLOGICS INC., Defendants.	Civil Action No. 1:22-cv-00061-TSK

DEFENDANTS' EXPEDITED MOTION FOR ENTRY OF A SCHEDULING ORDER

On December 5, 2023, Defendants Mylan Pharmaceuticals Inc. ("Mylan") and Biocon Biologics Inc. ("Biocon") (collectively, the "Biocon Defendants") submitted a brief response to Plaintiff Regeneron Pharmaceuticals, Inc.'s ("Regeneron") Motion to Convene Status Conference. (Dkt. No. 652-1). On January 30, 2024, the Court denied Regeneron's motion, finding no need to convene. (Dkt. No. 685). However, there are critical developments arising after Regeneron filed its motion that necessitate expedited[1] entry of a scheduling order in the ongoing litigation against the Biocon Defendants. Those events include: (1) issuance of the Court's Memorandum Opinion and Order Following Bench Trial; and (2) Regeneron's motion before the Judicial Panel on Multidistrict Litigation ("JPML" or "MDL") requesting, among other things, coordinated pretrial

[1] The Biocon Defendants were originally planning to provide this request today as a supplement to their response to Regeneron's Motion to Convene Status Conference. However, with the Court's Order this morning denying Regeneron's motion, Biocon is presenting its request to the Court as a new motion. Given the timing considerations and risk of further prejudice described herein, the Biocon Defendants respectfully request expedited action on this motion. Biocon and its predecessors have undertaken significant investment in obtaining and maintaining its position in front of other aflibercept biosimilar applicants. Absent expedited consideration, Biocon will be deprived of the benefits of that position.

proceedings in this Court involving the litigations of four other defendant groups. The Biocon Defendants oppose any attempt by Regeneron to further delay adjudication of the patents asserted against them over 17 months ago, and for the reasons described herein, with this motion the Biocon Defendants respectfully request entry of an expedited schedule to address the remaining issues following the June 2023 trial in this matter.

An expedited schedule will allow the Biocon Defendants to achieve a level of certainty and finality with regard to the asserted patents that remain in the case. The Biocon Defendants were subjected to a rapid first wave litigation, where Regeneron chose a subset of its patent claims for the first wave trial. There remain 18 patents[2] asserted against the Biocon Defendants that were not litigated in the first wave trial in June 2023 (the "Remaining Patents"). With the first wave complete, and the Court having entered its decision, the Biocon Defendants now seek certainty on those Remaining Patents. Multiple developments make further delay inequitable and entitle Defendants to that certainty on an expedited basis. Several other aflibercept biosimilar applicants (who filed well after Biocon) have now been sued; Regeneron is seeking from the JPML some level of consolidation among the cases; and Regeneron has thus far refused to engage in discussions regarding the scope and timing of the subsequent phase of the litigation. But the Biocon Defendants are at least a year and a half ahead of the other (later-filed) applicants, have already completed the first wave trial, already completed *Markman* proceedings, and already taken substantial discovery on most of the Remaining Patents. Thus, the Biocon Defendants are uniquely

[2] Of the original 24 asserted patents, (*see* Dkt. No. 1, at 3), three were litigated at the June 2023 trial, and three others have been disclaimed in their entirety by Regeneron. Immediate judgment in the Biocon Defendants' favor on those disclaimed patents is proper on the undisputed facts for the reasons described in Defendants' Motion for Summary Judgment. (Dkt. No. 679).

situated compared to each of the other biosimilar applicants, have already been delayed by nearly 18 months from achieving patent certainty, and would be prejudiced by any further delay.

I. BACKGROUND.

The Biocon Defendants' biosimilar aflibercept application was filed with the FDA in late 2021, precipitating suit in August 2022, almost a year and a half before any other aflibercept biosimilar applicant was sued. (*Compare* Dkt. No. 1 (filed August 2022), *with Regeneron Pharms., Inc. v. Celltrion, Inc.*, Case No. 23-cv-00089, Dkt. No. 1 (N.D.W. Va.) (filed November 2023)). Regeneron asserted 24 patents in the initial suit, consistent with the parties' engagement in the BPCIA patent dance. (*See* Dkt. No. 1, at 3). With the filing of the suit, Regeneron also submitted a Motion Requesting Expedited Status Conference, in which it sought an expedited schedule. (Dkt. No. 7). In its request, in exchange for an expedited schedule, Regeneron represented to the Court that it would narrow to three patent families, (Dkt. No. 90, at 22:8-15), and no more than 25 claims from six total patents, (*id.*, at 23:2-13); it later committed to narrowing to no more than 12 claims before trial, (Dkt. No. 174, at 4 n.1). The Court granted Regeneron's request, and trial was scheduled for June 2023. (Dkt. No. 87). Consequently, the parties immediately initiated discovery and document production; in parallel, the parties also commenced claim construction on six of Regeneron's patents from three different patent families, including subject matter spanning dosing regimens, formulations, and upstream and downstream manufacturing methods. (*See id.*; *see also* Dkt. No. 88 (stipulation identifying initial patents)). Discovery was taken on these six patents, until the case was narrowed to four, which proceeded through expert discovery, and eventually a two-week trial on three of those patents: two dosing regimen patents (U.S. Patent Nos. 10,888,601 and 11,253,572) and a formulation patent (U.S. Patent No. 11,084,865). Following post-trial briefing and closing arguments, the Court issued its decision on December 27, 2023. (Dkt. No. 664). Following that decision, the Biocon Defendants

have diligently sought Regeneron's position regarding the scope of any subsequent litigation on the Remaining Patents, but Regeneron has not responded to those requests.

Beginning in November of 2023, nearly 16 months after the Biocon Defendants' suit was filed, Regeneron initiated litigation against a second group of aflibercept biosimilar applicants. *See, e.g.*, *Regeneron Pharms., Inc. v. Celltrion, Inc.*, Case No. 23-cv-00089 (N.D.W. Va.) ("the Celltrion Action"); *Regeneron Pharms., Inc. v. Samsung Bioepis Co., Ltd.*, Case No. 23-cv-00094 (N.D.W. Va.) ("the First Samsung Action"); *Regeneron Pharms., Inc. v. Formycon AG*, Case No. 23-cv-00097 (N.D.W. Va.) ("the Formycon Action"); *Regeneron Pharms., Inc. v. Samsung Bioepis Co., Ltd.*, Case No. 23-cv-00106 (N.D.W. Va.) ("the Second Samsung Action"); *Regeneron Pharms., Inc. v. Amgen, Inc.*, Case No. 24-cv-00264 (C.D. Cal.) ("the Amgen Action"). Those parties have been and continue to be engaged in disputes over service, jurisdiction, and preliminary injunction proceedings. Each of the other aflibercept biosimilar applicants (other than Amgen) have filed motions to dismiss for personal jurisdiction, seeking removal to different U.S. District Courts. (*See, e.g.*, The Celltrion Action, Dkt. Nos. 68-69; The First Samsung Action, Dkt. No. 47; The Formycon Action, Dkt. No. 57; The Second Samsung Action, Dkt. No. 14). And those parties litigating before this Court are subject to an injunction briefing and hearing schedule that goes out to May 2024, with resolution of their various disputes possibly extending beyond May 2024, while Amgen will not even appear before the California Court to discuss injunction proceedings until April 2024. (*Compare* The Celltrion Action, Dkt. No. 61, *with* The Amgen Action, Dkt. No. 51).

II. ARGUMENT.

A. The Biocon Defendants Need Certainty on the Remaining Patents.

The Biocon Defendants have litigated a first wave to a final decision, with a focus on the three patents Regeneron felt were its strongest. The Defendants invalidated two of those three

patents (the two dosing regimen patents expiring in 2032), (Dkt. 664, at 312-13), and have obtained favorable unpatentability decisions on a host of Regeneron's other dosing regimen patents before the Patent Trial and Appeal Board ("PTAB").[3] But numerous patents remain. What remains may be the dregs of Regeneron's portfolio, consisting of a hodge-podge of patents that the Biocon Defendants do not infringe or that are invalid—which explains why they did not make Regeneron's cut for assertion in the first wave trial. The Biocon Defendants are nevertheless entitled to finality on those Remaining Patents.

In the first wave, the Biocon Defendants moved quickly, based on a schedule Regeneron demanded, in an effort to chase what it claimed to be a statutory automatic permanent injunction (which, it turns out, was not even feasible). The parties engaged in significant and wide-ranging discovery in an unprecedented amount of time. Now the shoe is on the other foot. After the nearly 18-month delay that the Biocon Defendants endured to allow Regeneron to take its hand-picked initial patents to trial, the Biocon Defendants are entitled to freedom-to-operate certainty; the Biocon Defendants are seeking to achieve this certainty via an October 2024 trial, following a schedule commensurate with what Regeneron was afforded in the initial phase.[4] The Biocon Defendants and Regeneron have been in discussions regarding an expedited Federal Circuit appeal

[3] *See, e.g.*, *Mylan Pharms. Inc. v. Regeneron Pharms., Inc.*, 2022 WL 16841860 (P.T.A.B. Nov. 9, 2022) (Final Written Decision); *Mylan Pharms. Inc. v. Regeneron Pharms., Inc.*, 2022 WL 16842073 (P.T.A.B. Nov. 9, 2022) (same); *Mylan Pharms. Inc. v. Regeneron Pharms., Inc.*, 2024 WL 111108 (P.T.A.B. Jan. 9, 2024) (same); *Mylan Pharms. Inc. v. Regeneron Pharms., Inc.*, 2024 WL 110383 (P.T.A.B. Jan. 9, 2024) (same); *see also Biocon Biologics Inc. v. Regeneron Pharms., Inc.*, IPR2024-00201, Paper 11 (P.T.A.B. Jan. 16, 2024) (Institution Decision).

[4] Biocon does not concede that each of the Remaining Patents are eligible and/or suitable for trial, but to the extent Regeneron is able to convince this Court otherwise and any patents survive fact and expert discovery, Biocon deserves a quick trial to litigate remaining issues.

of the first wave issues. The Biocon Defendants thus seek a subsequent trial on a schedule that would align with the anticipated timing of that Federal Circuit appeal decision.

Regeneron argued previously that the "the legislative history confirms that the BPCIA was designed to facilitate 'litigat[ing] patent disputes quickly and efficiently.'" (Dkt. No. 7, at 5 (quoting *Assessing the Impact of a Safe and Equitable Biosimilar Policy in the United States: Hearing Before the Subcomm. on Health of the H. Comm. on Energy & Commerce*, 110th Cong. 119 (2007))). That is even more applicable here, where the Biocon Defendants' certainty on the Remaining Patents already has been delayed almost a year and a half. Biocon and its predecessors invested significant amounts of time, revenue, and effort in preparing and submitting the first aflibercept biosimilar application. They have been at the forefront of the effort to get a lower cost anti-VEGF drug to market for treating angiogenic eye disorders, and they filed their application with the FDA well before any other biosimilar applicants. The Biocon Defendants deserve to maintain that lead—no further delay is warranted.

B. The Biocon Defendants Sit in a Unique and Advanced Position Compared to the Other Biosimilar Applicants.

The Biocon Defendants have already completed trial and received a court decision on three of Regeneron's central patents, while other parties have not yet even begun, and will be mired in jurisdictional fights for months before even commencing litigation proper. *See* Section I, *supra*. In addition, the Biocon Defendants have already completed *Markman* proceedings pertaining to most of the Remaining Patents (dosing regimen (6 patents), formulation (4 patents), and CDM (4 patents)), (Dkt. No. 427); completed most fact discovery; and completed expert discovery on a number of claims of the core patents. In other words, the Biocon Defendants are uniquely situated. Recognizing this, the Court should place the Biocon Defendants on track to reach a final trial with

minimal and expedited discovery, without subjecting them to the ongoing procedural entanglements confronting the other aflibercept applicants.

Further, in its MDL transfer brief, Regeneron has identified 13 patents-in-common across the six biosimilar aflibercept cases.[5] (*In re Aflibercept Patent Litig.*, MDL No. 3103, Dkt. No. 1-1 at 4 n.1 (J.P.M.L. Jan. 11, 2024) ("MDL Brief")). The Biocon Defendants already have taken discovery on most of these in the first wave, many of the claims have been held invalid before the PTAB, and the remaining Biocon-specific issues can be addressed with limited discovery. For example, of the dosing regimen patents, the four claims asserted from U.S. Patent Nos. 10,888,601 and 11,253,572 at the June 2023 trial have been held invalid by this Court; all challenged claims of U.S. Patent Nos. 9,669,069; 9,254,338; 10,130,681; and 10,888,601 have been held unpatentable by the PTAB; and two additional *inter partes* reviews directed to claims of U.S Patent Nos. 10,888,601 and 11,253,572 have been instituted by the Board and Biocon has moved to join those proceedings.[6] Of the formulation patents, U.S. Patent No. 11,084,865 already has been litigated by the Biocon Defendants at the June 2023 trial, with an expedited appeal soon underway. Other claims in that family have been (recently) disclaimed after being challenged at the PTAB. (*See, e.g.*, *Celltrion, Inc. v. Regeneron Pharms., Inc.*, IPR2023-00462, Paper 35 (P.T.A.B. Jan. 22, 2024) (Regeneron's Unopposed Motion to Terminate); Dkt. No. 679-3 (U.S. Patent No. 10,464,992 Disclaimer)). The members of the CDM family already have been the subject of some

[5] U.S. Patent Nos. 9,222,106; 9,254,338; 9,816,110; 10,130,681; 10,415,055; 10,464,992; 10,669,594; 10,888,601; 11,084,865; 11,066,458; 11,104,715; 11,253,572; and 11,306,135.

[6] Biocon's joinder motion in the '601 patent IPR has been granted. *See Biocon Biologics Inc. v. Regeneron Pharms., Inc.*, IPR2024-00201, Paper 11 (P.T.A.B. Jan. 16, 2024). Biocon's '572 patent IPR joinder motion remains pending, but Regeneron has informed the Board that it does not oppose joinder in view of the grant of joinder in the '601 patent IPR. *See Biocon Biologics Inc. v. Regeneron Pharms., Inc.*, IPR2024-00298, Paper 8 at 2 (P.T.A.B. Jan. 26, 2024). Thus, joinder in the '572 patent IPR is expected, as well.

fact discovery. But further, Regeneron has conceded non-infringement of those patents in view of the Court's claim construction, (Dkt. No. 433), and further discovery on those patents by the Biocon Defendants is unnecessary, pending any appeal. Regeneron also has been provided with substantial discovery pertaining to the M710 manufacturing process. What remains are a smattering of patents for which the Biocon Defendants have advanced non-infringement positions, and such patents should require little-to-no additional discovery, to the extent they are even trial-eligible.

In contrast, for the later-filed biosimilar applicants, both sides will likely aggressively pursue discovery on multiple fronts, on multiple continents, on different manufacturing processes; they will likely further engage, *de novo*, in written discovery, fact depositions (Samsung, *e.g.*, has ***52 patents*** asserted against it, likely requiring ***dozens*** of fact depositions), full *Markman* briefing, and full expert discovery and trial preparation, which could be delayed by possible Hague procedures necessary for discovery in South Korea and Europe.

Lastly, the differences between the products and manufacturing processes of the different aflibercept biosimilar applicants further distinguishes those cases from the Biocon Defendants'. While certain details have not been publicly disclosed, one can surmise from the patents being asserted against Samsung, Celltrion, Formycon, and Amgen that unique formulations are at issue, with competitor formulations likely including different ingredients. In addition, the manufacturing processes are likely to be different given that each biologic manufacturer typically uses a proprietary process specific to that company. In fact, the other biosimilar applicants have been sued on at least a dozen additional patents that have not been asserted against, or identified in the

patent dance against, the Biocon Defendants.[7] This means that non-infringement defenses across multiple patent families are likely to be disparate and unique to each defendant, not to mention highly confidential, which will further complicate any possible consolidation of the Biocon Defendants with those of the other, later-filed biosimilar applicants.

In sum, the Biocon Defendants have already completed trial on the patents Regeneron felt were its key patents, and require only a limited amount of additional discovery to prepare for a second wave trial (to the extent one is required). The other defendants have not even begun, and it may be months before a decision is made on preliminary issues, including jurisdiction and venue.

C. No Prejudice to Regeneron—There is Substantial Prejudice to the Biocon Defendants Without Expedited Certainty.

Regeneron has argued to this Court for an expedited schedule of its own once before. (*See* Dkt. No. 7). Thus, it is clearly not prejudiced by such a scenario. By contrast, the Biocon Defendants will stand to lose a substantial amount of their investment in being ahead of other aflibercept biosimilar applicants if not granted expedited adjudication and/or dismissal of the Remaining Patents.

Not only that, but the public interest is harmed by allowing the Remaining Patents to delay entry of competition to the EYLEA market. *See, e.g.*, *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 100 (1993) ("[O]ur prior cases have identified a strong public interest in the finality of judgments in patent litigation … [and] emphasized the importance to the public at large of resolving questions of patent validity…" (citing, *e.g.*, *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313 (1971))); *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1354

[7] These patents include, *e.g.*, U.S. Patent Nos. 7,771,997; 9,315,281; 9,562,238; 9,932,605; 10,905,786; 10,918,754; 11,268,109; 11,312,936; 11,525,833; 11,549,154; 11,680,930; 11,732,024. (*See* Dkt. No. 1, at 3 (listing the asserted patents)).

(Fed. Cir. 2005) ("[T]here is a significant public policy interest in removing invalid patents from the public arena.") (Gajarsa, J., concurring). Biosimilars have the potential to lower costs for consumers, which expands access to a wider patient population that would benefit from those lower costs in battling their (potentially sight-threatening) ophthalmic disorders. *See, e.g.*, Rebecca Taylor, *Biosimilars in Ophthalmology*, EYENET MAG., Jan. 2021, at 39 ("With biosimilar product development, pharmaceutical companies are able to create drugs similar enough to proven biotherapeutics in safety and efficacy—and they can do so more quickly and at a lower cost.").

In late 2022, Regeneron stood before this Court and explained that the parties already had participated in the "patent dance," thus "facilitating adjudication of remaining disputes," which "advanced the parties' understanding of what will be at issue in this case far beyond what would be achieved through the ordinary filing of a complaint." (Dkt. No. 7, at 2). Indeed, at that point Regeneron proclaimed the parties to be "much of the way down the runway" in terms of discovery. (Dkt. No. 90, at 5:1-12). The Biocon Defendants' request is ripe for expediting for much the same reason, in addition to the fact of having already litigated to judgment on a number of Regeneron's core patent claims. The Biocon Defendants' request also is consistent with the Defendants' prior stated desire to litigate to certainty all 24 asserted patents and be in a position to have that certainty as soon as practicable. (*See* Dkt. No. 26, at 5-6). The Biocon Defendants were forced to wait 18 months to accommodate Regeneron's first wave schedule to allow it to chase its statutory injunction on just a subset of the asserted patents. Given that precedent, Regeneron will not be prejudiced if litigation on the Remaining Patents is expedited, whereas significant prejudice accrues to the Biocon Defendants and the public with each passing day where certainty is lacking.

D. The Pendency of the Motion for Transfer Does not Preclude Setting a Schedule for the Biocon Defendants Now.

The pending motion for transfer and coordinated pre-trial proceedings is not a basis to delay scheduling as to the remaining claims against the Biocon Defendants. It will be some months before there is a resolution of the issue by the JPML, which will not even be heard until March 28, 2024. *In re Aflibercept Patent Litig.*, MDL No. 3103, Dkt. No. 7 (J.P.M.L. Jan. 12, 2024). Even if the JPML elects to order transfer of the additional cases to this Court or another court, that will not make the scheduling, and any progress in this case, moot. A transferee court is not required to place all civil actions on the same "track" in a multi-district litigation. *See In re Bear Creek Techs., Inc., ('722) Patent Litig.*, 858 F. Supp. 2d 1375, 1377 (J.P.M.L. May 2, 2012) ("We refrain from dictating the structure of an MDL's pretrial proceedings…"). In the event that the transfer motion is granted, the Biocon Defendants would seek to have this matter proceed on a track separate from the others, given the proceedings to date and the harm to the Biocon Defendants in being forced to endure delays for the sake of later-filing defendants.

III. CONCLUSION.

Accordingly, the Biocon Defendants respectfully request expedited entry of a schedule for a trial on the Remaining Patents by October 2024. A proposed Scheduling Order for the expedient adjudication of the Remaining Patents, consistent with that afforded Regeneron in the initial phase, is filed with this motion. The Biocon Defendants thank the Court for its attention to this matter.

Date: January 30, 2024

STEPTOE & JOHNSON PLLC

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

Of Counsel (admitted pro hac vice):
William A. Rakoczy
Deanne M. Mazzochi
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
dmmazzochi@rmmslegal.com
hsalmen@rmmslegal.com
ehunt@rmmslegal.com
nmclaughlin@rmmslegal.com
llesko@rmmslegal.com

Attorneys for Defendants Mylan Pharmaceuticals Inc. and Biocon Biologics, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on January 30, 2024, I electronically filed the foregoing with the Clerk of the Court by using the Court's CM/ECF system. Counsel of record for all parties will be served by the Court's CM/ECF system.

Date: January 30, 2024

STEPTOE & JOHNSON PLLC

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

Attorneys for Defendants Mylan Pharmaceuticals Inc. and Biocon Biologics, Inc.

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[PROPOSED] SCHEDULING ORDER

Pursuant to Federal Rules of Civil Procedure 16(b) and 26(f), and the Local Rules of Civil Procedure, it is hereby ORDERED that the below listed dates be adopted to address the Remaining Patents:

	Date
Parties to submit Rule 54(b) Partial Final Judgment with respect to Court's December 27, 2023 trial decision, summary judgment, and any patents Regeneron does not intend to litigate in Phase 2	February 7, 2024
Regeneron to identify remaining patents it intends to litigate in Phase 2	February 9, 2024
Supplemental, limited *Markman*: exchange of proposed terms for construction	February 23, 2024
Supplemental, limited *Markman:* exchange of preliminary constructions and intrinsic support	March 1, 2024
Supplemental, limited *Markman:* File joint claim construction chart. The parties may identify no more than 10 claim terms for construction (5 per side)	March 8, 2024
Supplemental, limited *Markman:* parties file opening claim construction briefs	March 15, 2024
Supplemental, limited *Markman*: parties file responsive claim construction briefs	March 29, 2024

Substantial completion of supplemental document production	April 5, 2024
Markman hearing	April __, 2024
Close of Fact Discovery	May 8, 2024
Deadline to amend pleadings / final infringement and invalidity contentions	May 10, 2024
Opening Expert Reports on Issues for Which the Party Bears the Burden of Proof	May 24, 2024
Responsive/Rebuttal Expert Reports	June 21, 2024
Reply Expert Reports	July 17, 2024
Close of Expert Discovery	August 7, 2024
Regeneron to identify asserted claims it intends to take to trial, dismiss all others	August 9, 2024
Motions *in Limine* / *Daubert*	August 16, 2024
Responses to Motions *in Limine* / *Daubert*	August 23, 2024
Joint Stipulation of Facts	September 6, 2024
Proposed Joint Pretrial Order	September 6, 2024
Final Pretrial and Settlement Conference	September 19, 2024
Trial	**Commencing October 7, 2024, or as soon thereafter as the Court's calendar permits the parties to be heard.**

It is so **ORDERED**.

The Clerk is directed to transmit copies of this Order to all counsel of record herein.

DATED: _____

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THOMAS S. KLEEH, CHIEF JUDGE
NORTHERN DISTRICT OF WEST VIRGINIA