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

REGENERON PHARMACEUTICALS, INC., Plaintiff, v. MYLAN PHARMACEUTICALS INC., Defendant.	Civil Action No. 1:22-cv-00061-TSK

STIPULATION AND ORDER JOINING
BIOCON BIOLOGICS INC. AS DEFENDANT

WHEREAS, on or about October 29, 2021, Mylan Pharmaceuticals Inc. ("Mylan") submitted Biologics License Application No 761274 (the "BLA") to the U.S. Food and Drug Administration (the "FDA"), seeking licensure to market M710 (or YESAFILI™) for injection (the "BLA Product"), as a biosimilar version of Regeneron Pharmaceuticals, Inc.'s ("Regeneron") EYLEA® product, before expiration of various patents owned by Regeneron;

WHEREAS, on or about August 2, 2022, Regeneron filed this suit against Mylan, alleging that the submission of Mylan's BLA and the commercial manufacture, use, sale, offer for sale and/or importation of the BLA Product are acts of infringement of certain patents (the "Asserted Patents") owned by Regeneron;

WHEREAS, Mylan denies infringement, and has filed counterclaims seeking judicial declarations that the Asserted Patents are invalid, unenforceable and/or not infringed;

WHEREAS, Biocon Biologics Inc. ("BBI") has represented that it is the successor in interest to all of Mylan's rights, title, and interest in and to the BLA and BLA Product;

WHEREAS, the FDA has accepted the transfer of ownership of the BLA from Mylan to BBI, effective as of March 17, 2023;

NOW THEREFORE, the parties hereby stipulate, including pursuant to FED. R. CIV. P. 25(c), and subject to the approval of the Court, that:

1. BBI is hereby joined as a Defendant-Counterclaim Plaintiff to this suit for all purposes, and with respect to all claims, defenses and counterclaims, and rulings of the Court, as successor in interest to all of Mylan's rights, title and interest in and to the BLA and BLA Product. BBI hereby adopts all representations, contentions, admissions, positions, and stipulations made by Mylan in this action to date and agrees to be bound by those representations, contentions, admissions, positions, and stipulations to the same extent as Mylan is or would be bound. Any evidence that supports a finding of infringement as to Mylan will support a finding of infringement as to BBI. Regeneron hereby acknowledges that any representations, contentions, admissions, positions, and stipulations made to Mylan by Regeneron in this action to date shall also apply equally to BBI. For clarity, neither Mylan nor BBI will allege that any finding or judgment as to infringement, validity, enforceability, remedies, or any finding subsidiary thereto, shall not issue or apply on the basis that BBI, rather than Mylan, has any interest in the BLA or BLA Product. For further clarity, any statutory protections afforded Mylan for the actions taken by Mylan and/or Regeneron during the pre-suit exchanges pursuant to Biologics Price Competition and Innovation Act ("BPCIA") shall also equally apply to BBI.

2. The current trial schedule shall be unaffected by this Stipulation and Order.

3. Upon filing of this Stipulation, BBI shall be a party to the Stipulated Protective Order, and may provide a list of no more than three proposed In-House Counsel who it wishes to

have access to Confidential information pursuant to ¶ 6(i) of the Protective Order, on the terms and conditions provided for by the Protective Order.

4. BBI is prepared to produce, via electronic transfer, the entirety of its BLA and regulatory correspondence with the FDA concerning the BLA Product following transfer of ownership to BBI, including any documents reflecting, documenting, or summarizing oral communications with FDA concerning the BLA product, and will produce that material to Regeneron within 2 business days of the parties' filing of this Stipulation with the Court. BBI accepts a continuing obligation to produce such material on an ongoing basis, consistent with FED. R. CIV. P. 26(e). BBI will produce such material in compliance with the terms of the parties' Stipulated Protective Order and will not argue that ¶ 1(m) or other provisions of the Protective Order permit BBI to designate its FDA correspondence "OCEO" on a theory that documents relevant to BBI's prospective product necessarily merit OCEO protection.

5. Neither BBI nor Mylan will use this Stipulation as an admission or basis to seek to have Mylan dismissed from this action. Similarly, nothing in this Stipulation prejudices Regeneron from opposing any request to have Mylan dismissed from this action, and this Stipulation does not constitute a statement by Regeneron that it no longer has claims against Mylan.

6. Neither BBI nor Mylan will seek to dismiss or transfer any portion of this action based on any argument the Court lacks personal jurisdiction over BBI or Mylan or any argument that venue in the Northern District of West Virginia is improper or inconvenient.

7. The Clerk is directed to amend the caption to add BBI as a Defendant-Counterclaim Plaintiff, as noted below.

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Date: June 2, 2023

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