IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMGEN INC. and AMGEN MANUFACTURING, LIMITED, Plaintiffs, v. COHERUS BIOSCIENCES, INC. Defendant.	)	C.A. No. 17-546 (LPS)(CJB)

COHERUS BIOSCIENCE INC.'S REPLY BRIEF IN SUPPORT OF MOTION FOR STAY PENDING MOTION TO DISMISS

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I. INTRODUCTION AND SUMMARY OF ARGUMENT

Defendant Coherus BioSciences, Inc. ("Coherus") seeks to stay this case only until disposition of its motion to dismiss—a prudent way of ensuring more efficient use of the parties' and the court's resources. After all, the motion to dismiss will completely dispose of the case if granted and, even if denied, will at least simplify the issues. The prospect of avoiding wasteful and unnecessary proceedings, and "dispens[ing] with needless discovery," has prompted the Third Circuit to state that motions to dismiss should "typically 'be resolved before discovery begins.'" *Levey v. Brownstone Inv. Group, LLC*, 590 Fed. Appx. 132, 137 (3d Cir. 2014); *Ghaffari v. Wells Fargo Bank NA*, 621 Fed. Appx. 121, 124 (3rd Cir. 2015).

Amgen's principal complaint is that a stay would force "Amgen and the Court to consider the disputed issues on an expedited basis before anticipated launch in mid-2018." But denying a stay will not prevent that: under Amgen's own proposed schedule, document production will not even be substantially complete until around the time of Coherus's proposed commercial launch next year. Thus, if Amgen decides to seek preliminary relief, the Court will still have to consider the disputed issues on an expedited basis before Coherus's anticipated launch in mid-2018—regardless of whether a stay is granted. In other words, Amgen's purported aversion to expedited proceedings is a strawman that in no way counsels against a stay.

II. ARGUMENT

A. A Stay Would Simplify The Issues.

As argued in Coherus's motion, a stay pending resolution of the motion to dismiss would, at a minimum, simplify the issues for litigation by the parties. In response, Amgen insists that "a stay will not simplify or narrow the issues." (D.I. 27 at 15.) Amgen fails to persuasively explain how that is so. If the Court grants Coherus's motion, the parties will achieve the ultimate in simplification—the case will be over. And even if the Court denies the motion, its decision is likely

to narrow the issues in the case. Only if the Court denies Coherus's motion without comment will there be no simplification or narrowing of the issues.

Amgen is wrong to rely on Judge Stark's case management procedures and the *Yodlee* case as supposedly expressing a preference for denying stays. The *Yodlee* decision instead notes that Judge Stark's procedure "leaves plenty of room for the Court, if appropriate, to stay discovery and defer entry of a schedule if a case dispositive motion to dismiss is pending." *Yodlee, Inc. v. Plaid Tech. Inc.*, C.A. No. 14-01334-LPS-CJB (July 31, 2015), D.I. 57, at 6 n1. *Yodlee* elaborates: "[W]hen balancing the prospects for simplification in a case where a potentially dispositive motion to dismiss has been filed, the Court should be particularly attuned to the costs involved with such a stay (were that motion to dismiss to be later denied or denied in part)." *Id.* That approach *favors* issuance of a stay here. If the motion is denied, the parties will incur the same discovery costs (subject to any reductions due to narrowing of the issues), as if the stay had never been entered. That is because the parties' schedule contemplates that document production will not be substantially complete until June 2018, fact discovery will not be complete until September 2018, and expert discovery will not be complete until February 2019. All of these dates are easily achievable even if the Court grants the stay.

Finally, Amgen misreads the Third Circuit's decision in *Levey*. Amgen argues that "*Lev[e]y* does not stand for the proposition that discovery should be stayed pending resolution of motions to dismiss." Not so. *Levey* holds that motions to dismiss should "typically 'be resolved before discovery begins'" and that the 12(b)(6) procedure "dispenses with needless discovery":

> The Rule 12(b)(6) procedure "streamlines litigation by dispensing with needless discovery and factfinding," and motions to dismiss filed under it should typically "be resolved before discovery begins." Indeed, the purpose of the Rule's plausible inference standard is to ensure that the complaint "raise[s] a reasonable expectation that discovery will reveal evidence of illegal [conduct]."

Levey, 590 F. App'x 132, 137 (citations omitted); *see also Ghaffari,* 621 Fed. Appx. 121, 124 (same). Indeed, the "'purpose of F.R. Civ. P. 12(b)(6) is to enable defendants to challenge the legal sufficiency of complaints without subjecting themselves to discovery.'" *Mann v Brenner*, 375 Fed. Appx. 232, 239 (3rd Cir. 2010) (*quoting Rutman Wine Co. v. E. & J. Gallo Winery*, 829 F.2d 729, 738 (9th Cir. 1987)). These principles apply with full force here.

B. A Stay Will Not Prejudice Amgen.

Amgen argues that a stay would prejudice it by requiring it to engage in "expedited proceedings" in advance of the possible mid-2018 launch of Coherus's product. In fact, under the agreed-upon schedule in this case, with the deadline for the substantial completion of document production not occurring until the anticipated June 2018 timing of Coherus' launch, there will be need for expedited proceedings *regardless* of whether the requested stay is granted. Thus, denying the stay does not spare Amgen the supposed prejudice of "expedited proceedings." Amgen acknowledges that under this schedule, expedited proceedings will be necessary even absent a stay:

> The expected launch date falls well before an expected trial in this case in 2019, ***and even before Amgen's proposed close of fact discovery of September 2018***. See Ex. 1. It makes no sense to wait until 2018 to begin discovery and then ***attempt to resolve the parties' disputed issues in the limited period of time before launch is expected***.

(D.I. 27 at 9-10 (emphasis added).) Thus, *whether or not the Court stays discovery*, there will need to be expedited proceedings "to resolve the parties' disputed issues in the limited period of time before launch is expected." (*Id.*)

Indeed, Amgen's actions to date show it does not expect to be able to enjoin Coherus or that it will even try to do so. Amgen delayed bringing this lawsuit, despite Coherus's contrary

urgings, imposing unnecessary delays and completing BPCIA-mandated acts just before the deadlines; and Amgen's proposed schedule makes no mention of a preliminary injunction motion.

Thus, if Amgen intends to seek a preliminary injunction in the first half of 2018, denying a stay will not avoid any expedited proceedings. And if Amgen does not intend to seek a preliminary injunction, there is no reason to jump into discovery now. In either event, any prejudice to Amgen from a stay is illusory.

C. The Status of Litigation Favors a Stay

Next, Amgen argues that the status of litigation disfavors a stay because of the extensive pre-litigation exchanges conducted pursuant to the BPCIA. However, the relevant status of the litigation is "the stage of litigation, including whether discovery is complete and a trial date has been set"—not merely whether extensive exchanges have already taken place. *See, e.g., Softview LLC v. Apple Inc.,* C.A. No. 10-389-LPS, 2012 WL 3061027, at *2 (D. Del. July 26, 2012). Here, under the agreed schedule expert discovery will not be complete until *February 2019* and the proposed trial date is not until mid-September 2019.

With respect to the status of the litigation, the single most important point is that no discovery has been conducted. The point of the requested stay is to spare the parties (and the Court) the burden of conducting discovery on a case that ultimately is dismissed or narrowed. To be sure, Coherus believes that no discovery is necessary and has filed a motion to dismiss on that basis. Amgen, however, has indicated it will take extensive and expensive discovery from Coherus. All of that could be avoided if a stay is granted.[1] In short, a denial of the stay would only

[1] *SoftView LLC v. Apple Inc.* does not support Amgen's view that the BPCIA exchanges militate against a stay here. In that case, "substantial time and resources [had already] been devoted . . . to scheduling and the resolution of discovery disputes." 2012 WL 3061027, at *4. Here, by contrast, discovery has not yet begun and such expenditures have not occurred.

be of consequence to Amgen if it believes—and it clearly does not—that without a stay discovery will be completed before Coherus' anticipated launch in June 2018.

D. The BPCIA Does Not Require Wasting Money On Discovery Pending Dispositive Motions.

Finally, Amgen argues that a stay here is contrary to the BPCIA's purpose because a stay supposedly will prevent resolution of this case before Coherus's launch in mid-2018. Again, Amgen is mistaken. Even if a stay is denied, discovery will not be complete before Coherus is expected to launch. The parties have tentatively agreed on a schedule where fact discovery closes in October 2018, months after Coherus's expected launch date of June 2018. Expert reports are not due until November 2018. Thus, the goal of completing this litigation before FDA approval of Coherus' biosimilar product in no way hinges on the grant or denial of the stay.

The BPCIA does not require courts to conduct wasteful procedures, and certainly does not bar a court from managing its docket in ways that maximize judicial efficiency. Here, Coherus seeks a stay pending a motion to dismiss, because Amgen's patent infringement case is deficient as a matter of law. There is no reason to think that the BPCIA—which was meant to streamline procedures for biosimilars to become commercially available—would compel the parties to pursue discovery during the pendency of a motion such as Coherus's.

E. Amgen's Proposed Conditions Are Unwarranted.

In the alternative, Amgen asks that any stay be accompanied by certain conditions so that, if the stay is lifted, Amgen is no worse a position than if the stay were never in place. Amgen's request that Coherus defer launch until six months after the stay is lifted has no basis in the BPCIA or in case law. Still, to eliminate any argument that Amgen is prejudiced, Coherus agrees that any stay can be lifted upon the resumption of FDA's review of Coherus's aBLA. At present, because of the Complete Response Letter ("CRL") that Coherus received, FDA is not

reviewing Coherus's aBLA. But once Coherus addresses the issues in the CRL and submits new material to FDA, Coherus expects the agency to resume its review. Coherus expects that it will launch four to six months after the FDA review. When Amgen filed this lawsuit in May, Coherus was expecting to launch in June. Thus, the four-to-six-month period of lead time proposed above is more than Amgen had when it filed this lawsuit (after dragging its feet in the patent dance), and certainly is no cause for complaint by Amgen.

Coherus will also agree to produce correspondence with FDA, subject to an agreement that permits Coherus to redact certain testing information and limit that correspondence to outside counsel and in-house counsel who agree to not take part in any regulatory proceedings with the FDA or any other regulatory authority. These restrictions are currently in place in a related litigation between the parties that is pending in a California state court.

Amgen's other conditions, however, are unreasonable. Amgen asks that Coherus be precluded from discussing pegfilgrastim with potential customers. But if a stay were not granted, there would be no prohibition on that activity. Consequently, that condition is not necessary to ensure "Amgen is no worse a position that if the stay were never in place."

III. CONCLUSION

For all the foregoing reasons, Coherus respectfully requests that its motion to stay be granted.

Dated: August 15, 2017

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