IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

AMGEN'S ANSWERING BRIEF IN OPPOSITION TO COHERUS'S MOTION FOR STAY

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I. NATURE AND STAGE OF THE PROCEEDINGS

This case arises under the Biologics Price Competition and Innovation Act (BPCIA) as a result of Coherus Biosciences Inc. ("Coherus")'s submission to FDA of an abbreviated Biologic License Application (the "Coherus aBLA") for a "biosimilar" version of Amgen's Neulasta® under 42 U.S.C. § 262(k)'s abbreviated regulatory approval pathway. D.I. 1 ¶¶ 24–34. Amgen Inc. and Amgen Manufacturing Limited (together, "Amgen") filed their Complaint in this action after the parties agreed that Amgen should file a patent infringement action asserting U.S. Patent No. 8,273,707 (the "'707 Patent") under 42 U.S.C. § 262(*l*)(6). *Id.* ¶¶ 37–38. Coherus responded to the Complaint by moving to dismiss on the ground that Coherus does not infringe. D.I. 9–10. Amgen opposes Coherus's motion to dismiss, which is tantamount to an early summary judgment motion and should be denied on the merits. D.I. 17–18. That motion remains pending.

On July 18, 2017, the Court ordered the parties to meet and confer and, within 30 days, jointly file Chief Judge Stark's Case Management Checklist; a proposed scheduling order; and a letter containing a case description, the parties' positions on scheduling disputes, and a list of topics discussed during the parties' meet and confer(s). One week later, Coherus brought the present motion to stay discovery and this Court's July 18 Order pending resolution of Coherus's motion to dismiss. D.I. 24–26. On July 28, 2017, the Court ordered the parties to comply with the Court's July 18, 2017 oral order, and that it would hear argument on the motion to stay as well as discuss the proposed scheduling order at a Case Management Conference to be scheduled. Accordingly, Amgen sent Coherus a proposed schedule and Amgen's availability to discuss the items of the Court's July 18, 2017 oral order. *See* Ex. 1 (Amgen's Proposed Schedule).

II. SUMMARY OF THE ARGUMENT

The filing of this Complaint, and the attendant costs of resolving patent disputes through litigation, came as no surprise to Coherus. Three years ago, Coherus told its investors that patent litigation was an expected cost of doing business in pursuing FDA approval and market entry under the new abbreviated regulatory pathway for "biosimilars." *See* Ex. 2 at 63 (Coherus, Quarterly Report (Form 10-Q) (Dec. 15, 2014)). Coherus's business model is to return profit by bringing a competitive biological product to market at a lower cost. *See, e.g.*, Ex. 3 (Coherus News Release (Apr. 25, 2017)).[1] Coherus intends to do this by taking advantage of the substantial savings in time and money afforded by the abbreviated regulatory pathway to conduct only limited clinical trials or, as Coherus attempts here, no Phase II and Phase III clinical trials[2]—by relying on the innovator's biological license and its supporting clinical data to establishing safety and efficacy. *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1670 (2017). As Coherus anticipated, the parties identified patent disputes through the information-exchange process prescribed by the BPCIA "Patent" provisions. And, with Coherus's agreement, this lawsuit was filed. *See* D.I. 1 ¶¶ 37–38; Ex. 4 (April 11, 2017 Letter from Coherus).

Coherus's motion, which would effectively stay the patent infringement action that Coherus agreed Amgen should bring as to the '707 Patent, and which Coherus told the world it was "well prepared" to defend, should be denied. Ex. 3. Whatever may have led to Coherus's alleged financial hardship—over-optimism, mismanagement of its capital, or loss of confidence of its partners—it does not justify delaying discovery of information relevant to prepare this case for trial. Notably, during the requested stay, Coherus intends to press full-steam ahead with its

[1] *Available at* http://investors.coherus.com/phoenix.zhtml?c=253655&p=irol-newsArticle&ID=2264425.

[2] *See* https://clinicaltrials.gov, identifier nos. NCT02385851, NCT02418104, NCT02650973.

plan to gain FDA approval and market entry during the term of Amgen's patent. *See, e.g.*, D.I. 25 at 1–2, 8. A stay under these circumstances would unduly prejudice Amgen and present a clear tactical advantage to Coherus by impeding Amgen's ability to enforce its patent rights on a full and developed record. A stay is also contrary to one of the purposes of the BPCIA: to facilitate litigation prior to FDA approval "so that the parties do not have to wait until commercial marketing to resolve their patent disputes." *Sandoz Inc.*, 137 S. Ct. at 1670.

The FDA's rejection of Coherus's aBLA does not justify granting a stay. Coherus asserts that the FDA rejection has resulted in a delay of approval until mid-2018, and also that the rejection imposes financial hardship on Coherus in continuing discovery in this case. D.I. 25 at 1–2, 6, 8. It makes no sense to slow down the case now, only to speed it up next year before the anticipated launch date of mid-2018. Indeed, a stay of discovery would unduly prejudice Amgen by depriving it of the benefit of conducting discovery over this next year in advance of Coherus's anticipated launch. A stay would only provide Coherus with a clear and unfair tactical advantage by effectively preventing Amgen from preparing its case for trial while Coherus pursues FDA approval for a product that is intended to directly compete with Amgen's product. Furthermore, a stay would not simplify the issues at trial or serve the interests of the Court if the Court denies Coherus's motion to dismiss, an outcome that the Court considers in determining whether to grant a stay but which Coherus ignores in its motion. *See, e.g.*, *Yodlee, Inc. v. Plaid Tech. Inc.*, C.A. No. 14–01445–LPS–CJB (July 31, 2015), D.I. 57, at 4 (attached hereto as Ex. 5). There are no efficiencies to be gained from delaying discovery now only to cause the parties and the Court to have to race to resolve the case prior to the anticipated launch in mid-2018. This is particularly true where, as here, the parties have already engaged in "extensive" exchanges mandated by the BPCIA prior to this litigation. *See* D.I. 22 at 2.

Further, Coherus's desire to avoid litigation expenses does not justify granting a stay. *See* D.I. 25 at 1, 8. There is no evidence supporting Coherus's arguments that it will suffer financial hardship from continuing with discovery in this case, and Coherus's present assertion is contrary to its statement four months ago that it is well prepared to defend this action. Moreover, Coherus's claims that it does not have the financial resources to litigate this case are belied by Coherus's own actions, taken after filing this motion to stay. Coherus filed its motion to stay on July 25, 2017, claiming financial hardship. D.I. 24–25. Ten days later, Coherus filed a 79-page petition requesting that the Patent Office institute an *inter partes* review (IPR) on an Amgen patent involving a different product than is at issue here, and announcing that Coherus intended to file another IPR petition "in the near future" directed at a related Amgen patent. *See* Ex. 6 (*Coherus Biosciences, Inc. v. Hoffmann-LaRoche Inc.*, IPR 2017–010916, Pap. No. 1 (PTAB August 4, 2017)); Ex. 7 (Coherus News Release (Aug. 7, 2017)).[3] Surely, Coherus cannot complain about its legal expenses in this case if it is simultaneously filing petitions seeking to commence additional and costly legal proceedings against Amgen. Coherus's decision to spend its legal budget on other matters, such as IPR petitions against Amgen, does not excuse it from its discovery obligations in this action. And, even if Coherus could show financial hardship, it is well established that litigation costs are not an undue hardship or inequity that justify a stay. *See, e.g.*, *Yodlee, Inc.*, C.A. No. 14–01445–LPS–CJB, D.I. 57, at 15 n.10; *ImageVision.Net, Inc. v. Internet Payment Exch., Inc.*, C.A. No. 12–054–GMS–MPT, 2013 WL 663535, at *6 (D. Del. Feb. 25, 2013), *report and recommendation adopted by*, C.A. No. 12–054–GMS–MPT, 2013 WL 1743854 (D. Del. Apr. 22, 2013).

[3] *Available at* http://investors.coherus.com/phoenix.zhtml?c=253655&p=irol-newsArticle&ID=2292206.

In addition, Coherus attempts to justify a stay by arguing that Amgen's case on the merits is "exceptionally weak," or amenable to resolution as a matter of law based on the pleadings without further discovery. *See* D.I. 25 at 1. This is incorrect, but the Court need not consider the relative strengths and weaknesses of Amgen's patent infringement case in resolving this motion to stay. *See, e.g.*, *Kaavo Inc. v. Cognizant Tech. Sols. Corp.*, C.A. No. 14–1192–LPS–CJB, 2015 WL 1737476, at *2 n.4 (D. Del. Apr. 9, 2015).

Accordingly, Amgen respectfully requests that Coherus's motion for a stay be denied. In the alternative, if the Court is inclined to grant a stay, Amgen requests that any stay be structured to protect Amgen's interests and to avoid the need for expedited proceedings if and when Coherus obtains FDA approval. The asserted bases for the stay are circumstances for which Coherus is solely responsible. It would not be appropriate for Coherus to benefit from the fact that it no longer wishes to proceed immediately with the lawsuit it precipitated. Therefore, Amgen respectfully requests that if the Court were to grant a stay, it should leave Amgen in no worse a position after the stay is lifted than it is now. The Court could accomplish this by conditioning a stay on an agreement by Coherus that it will not launch its biosimilar product while the stay is in effect or for a period of at least six months thereafter.[4]

III. STATEMENT OF FACTS

A. The BPCIA

This case relates to Coherus's efforts to make and gain approval to market a "biosimilar" version of Amgen's Neulasta® (pegfilgrastim) biologic product. Until recently, the FDA licensed biological products only under the traditional regulatory pathway of 42 U.S.C. § 262(a)—where the entity seeking approval, an innovator, must establish through clinical trials and other data that the biological products are "safe, pure and potent" in order to obtain an FDA

[4] This agreement would cease to apply if the case were resolved by settlement or otherwise.

license. *See* § 262(a)(2)(C)(i)(I); *Sandoz Inc.*, 137 S. Ct. at 1670. In 2010, the BPCIA introduced a new, abbreviated regulatory pathway, codified in § 262(k), allowing for the licensure of a biological product as "biosimilar to" a "reference product," i.e., the innovator product licensed by the FDA under the traditional regulatory pathway. *See Sandoz Inc.*, 137 S. Ct. at 1670. A biosimilar applicant may piggyback on the showing made by the manufacturer of the reference product, i.e., the reference product sponsor, if the biosimilar applicant can demonstrate that the proposed biosimilar is "highly similar" to the reference product. *See* § 262(k)(2)(A); *Sandoz Inc.*, 137 S. Ct. at 1670.

The BPCIA also facilitates litigation during the period preceding FDA approval, setting forth a "carefully calibrated scheme for preparing to adjudicate, and then adjudicating, claims of infringement." *Sandoz Inc.*, 137 S. Ct. at 1670. When the FDA accepts a biosimilar application for review, it notifies the applicant, who within 20 days "shall provide" to the reference product sponsor a copy of the application and information about how the biosimilar is manufactured. § 262(*l*)(2)(A). The parties then exchange information to identify relevant patents and to flesh out the legal arguments that they might raise in future litigation. § 262(*l*)(3); *Sandoz Inc.*, 137 S. Ct. at 1671. Under § 262(*l*)(4), the applicant and the sponsor must negotiate to determine which patents included in the exchanges will be litigated immediately. *Sandoz Inc.*, 137 S. Ct. at 1671. If they cannot agree, then they must engage in another list exchange per § 262(*l*)(5). *Id.* The sponsor shall bring an action in court within 30 days of the date of the agreement, if the parties agree on which patents to immediately litigate, or within 30 days of the simultaneous list exchange, if the parties do not agree. § 262(*l*)(6); *Sandoz Inc.*, 137 S. Ct. at 1671–72.

B. Coherus Seeks a License to Market a Pegfilgrastim Product Under the BPCIA's Abbreviated § 262(k) Pathway

Three years ago, Coherus stated that submitting an aBLA could result in patent litigation prior to FDA approval: "A significant legal risk in pursuing regulatory approval under the [abbreviated § 262(k)] regulatory approval route" is that the "patent exchange process established by the BPCIA could result in the initiation of patent infringement litigation prior to FDA approval of a [§ 262(k)] application, and such litigation could result in blocking the market entry of our products." Ex. 2 at 63 (emphasis added).[5] Coherus balanced that risk with the benefit afforded to it under the abbreviated § 262(k) pathway—less "development time and costs." *Id.* Coherus also stated that if it did file an aBLA under the § 262(k) pathway, Coherus "may consider it necessary or advisable to adopt the strategy of selecting one or more patents of the originator to litigate in the above described BPCIA process." *Id.* at 64.

Coherus ultimately decided to submit an aBLA under the BPCIA's abbreviated pathway, seeking a license to market its pegfilgrastim product. On October 6, 2016, the FDA accepted that filing for review. *See* D.I. 25, Coherus Ex. 1.

C. The Parties Participate in the BPCIA's Information Exchange

The parties then participated in the BPCIA's pre-litigation information exchanges. At the conclusion of the exchanges, Coherus agreed under § 262(*l*)(4) that the '707 Patent should be the subject of an immediate patent infringement action pursuant to § 262(*l*)(6). This agreement is memorialized in an April 11, 2017 letter from Coherus's counsel to Amgen's counsel stating that the '707 Patent "will be included in the patent infringement under 42 U.S.C. § 262(*l*)(6)," to be

[5] *See, e.g.*, Coherus, Quarterly Reports (Forms 10-Q) for May 11, 2015 at 58, Aug. 10, 2015 at 60, Nov. 10, 2015 at 60, May 9, 2016 at 59, Aug. 9, 2016 at 63, Nov. 9, 2016 at 64, May 8, 2017 at 63, *all available at* http://investors.coherus.com (stating that a consequence of engaging in the BPCIA patent exchanges is that the process "could result in the initiation of patent infringement litigation prior to FDA approval of a [§ 262(k)] application").

filed "within 30 days." Ex. 4. At that time, Coherus publicly announced: "We are well prepared for the possibility that Amgen may decide to assert the '707 patent against us and will defend any such suit vigorously." Ex. 3.

D. This Action

Amgen then timely sued Coherus asserting that the manufacture of Coherus's biosimilar pegfilgrastim infringed the '707 Patent. Coherus then moved to dismiss the complaint on June 1, 2017. D.I. 9–10. As explained in Amgen's answering brief, Coherus's motion is nothing more than a premature summary judgment motion because it improperly relies on documents outside the Complaint and ignores what is said in the Complaint in seeking to dismiss Amgen's claim without any discovery and without any claim construction. D.I. 17. After filing its motion to dismiss, Coherus received a Complete Response Letter (CRL) from FDA, which is FDA's response to an applicant's BLA if the agency determines that it will not approve the BLA in its current form. *See* 21 CFR § 314.110. Coherus's motion to stay now follows.

IV. ARGUMENT

Whether to grant a stay is within the Court's discretion. *See, e.g.*, *Cooper Notification, Inc. v. Twitter, Inc.*, C.A. No. 09–865–LPS, 2010 WL 5149351, at *1 (D. Del. Dec. 13, 2010). Courts consider three factors in deciding whether to grant a motion to stay: (1) whether a stay would unduly prejudice or present a clear tactical disadvantage to the non-moving party; (2) whether a stay will simplify the issues and trial of the case; and (3) whether discovery is complete and a trial date has been set. *Id.* (citation omitted). Furthermore, Coherus, as the party seeking a stay, should make out a "clear case of hardship or inequity" in being required to go forward, if there is even a fair possibility that the requested stay will work damage to Amgen or someone else. *See St. Clair Intellectual Prop. Consultants, Inc. v. Fujifilm Holding Corp.*, C.A. No. 08–373–JJF–LPS, 2009 WL 192457, at *1 (D. Del. Jan. 27, 2009); *Personalized User*

Model, L.L.P. v. Google, Inc., C.A. No. 09–525–LPS, 2012 WL 5379106, at *1 (D. Del. Oct. 31, 2012) ("Courts may also consider whether the moving party would face undue hardship or inequity in the absence of a stay."). Here, each of these factors militates against a stay.

A. A Stay Would Unduly Prejudice Amgen and Would Provide Coherus with a Clear and Unfair Tactical Advantage

Four months ago, Coherus agreed that Amgen should bring a patent infringement action on the '707 Patent, and announced to the world that Coherus was "well prepared" to defend against such an action. *See* Ex. 3; Ex. 4. Specifically, Coherus agreed that Amgen should sue Coherus for infringement of the '707 Patent, and that infringement should be adjudicated as part of an "immediate patent infringement action," pursuant to 42 U.S.C. § 262(*l*)(6). During a telephone conference on April 11, 2017, Amgen and Coherus engaged in good-faith negotiations, per 42 U.S.C. § 262(*l*)(4)(A), and Coherus agreed that the '707 Patent should be included in the immediate patent infringement action under 42 U.S.C. § 262(*l*)(6). Coherus's counsel confirmed this agreement the same day. *See* Ex. 4.

Coherus now seeks to stay this action—an action that it agreed Amgen should bring—on the basis that the FDA's rejection of the Coherus aBLA has delayed anticipated launch by a year until mid-2018 and also imposes financial hardship on Coherus to proceed with discovery. This does not justify a stay.

1. Coherus's Anticipated Mid-2018 Launch Confirms the Case Should Go Forward Now

Coherus has made clear that it intends to launch in mid-2018, despite the FDA rejection. D.I. 25 at 8. This demonstrates the pressing need to continue with discovery now, before Coherus's anticipated launch. 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. And any delay would prejudice Amgen by depriving Amgen of time to conduct discovery that it would otherwise have absent a stay, thereby impeding Amgen's ability to enforce its patent rights on full and developed record. Further, Coherus acknowledges that there is nothing indicating that Coherus will make "changes to the process steps involved in this case" as a result of the FDA rejection. D.I. 22 at 4. Rather, the only asserted effect of the FDA rejection is that Coherus will not be able to launch its product until mid-2018. This militates in favor of moving forward now so that these assertions may be confirmed in fact and the parties can have an orderly discovery process prior to FDA approval and launch.

A stay would present a tactical advantage to Coherus by forcing Amgen and the Court to consider the disputed issues on an expedited basis before anticipated launch in mid-2018, while at the same time allowing Coherus to pursue FDA approval for a product that is intended to directly compete with Amgen's product. There can be no dispute that Coherus and Amgen would be direct competitors if Coherus launches the proposed biosimilar that is the subject of the Coherus aBLA. By Coherus's own admissions, the very purpose of the stay is so that Coherus can focus its resources to continue to seek FDA licensure to compete with Amgen. *See* D.I. 25 at 8. And, if Coherus launches in mid-2018, Amgen and Coherus would be the only two competitors in the United States pegfilgrastim market. This militates against granting a stay because it is well established that courts are generally "reluctant to stay proceedings where the parties are direct competitors." *Cooper Notification, Inc.*, 2010 WL 5149351, at *5; *ImageVision.Net, Inc.*, 2013 WL 663535, at *6. This is particularly true where, as here, Coherus admits that it has had "hundreds if not thousands" of client meetings about its proposed biosimilar product, specifically targeting Amgen's customers. Ex. 8 at 11 (Coherus's Mot. for

Stay, *Amgen Inc. v. Coherus Biosciences, Inc.*, C.A. No. 56–2017–00493553 (Cal. Super. Ct. July 6, 2017)). Indeed, Coherus has announced that the increase in its general and administrative expenses to $42.3 million for the 6 months ended June 30, 2017 as compared to $22.7 million over the same period in 2016 was "mainly attributable to legal and other professional fees to support intellectual property strategy and personnel-related costs to support [Coherus's proposed biosimilar] precommercial activities in the first 6 months of 2017." Ex. 9 (Coherus Q2 2017 Earnings Call (August 7, 2017)). Amgen would be greatly prejudiced by delaying discovery—and Coherus would obtain a tactical advantage—if a stay were granted simply so that Coherus can press forward with its commercial marketing and regulatory efforts for its proposed biosimilar product.

Coherus suggests, without legal support, that a stay is appropriate because, if the Court grants a six-month stay pending resolution of Coherus's motion to dismiss, Amgen "will still have about six months of discovery before Coherus can likely launch." D.I. 25 at 9. This misses the point. More than six months are needed to conduct orderly discovery so that Amgen can fully understand Coherus's manufacturing process, including details that are not included in Coherus's aBLA, and also for the parties to identify claim construction disputes to be resolved by the Court. *See* Ex. 1. Coherus cannot unilaterally decide that less time is needed for discovery and claim construction. And even if Coherus is correct that the parties could finish discovery and also resolve the merits of this case in six months, that supports proceeding now and resolving the issues on a reasonable, rather than expedited, basis before launch in mid-2018.

Coherus incorrectly accuses Amgen of "dilatory behavior" during the information exchanges, while simultaneously touting Coherus's promptness in completing those exchanges prior to statutory deadlines, and filing its motion to dismiss when it was due. D.I. 25 at 4–5.

Amgen did not engage in dilatory behavior during the BPCIA exchanges: Amgen provided Coherus with the information by the deadlines set forth in the BPCIA statute, and seeks a timely, organized resolution of its patent claims. To find otherwise would mean that a party has "delayed" on a filing when it makes a submission on the due date. Delay means taking action after the deadline, not within the statutory time period. Further, the fact that Coherus completed its BPCIA exchanges earlier than the statutory deadline does not impose upon Amgen an obligation to do the same. Nor does Coherus's choice not to seek an extension to respond to Amgen's Complaint, or its decision to file a motion to dismiss that is tantamount to a premature summary judgment motion of non-infringement (*see* D.I. 17 at 3), support a stay here. Coherus voluntarily accelerated the schedule when acceleration suited it; that does not justify a delay in the case simply because Coherus now wishes to focus its resources on FDA regulatory issues.

2. Coherus's Unsubstantiated Financial Hardship Claims Do Not Justify a Stay

Coherus argues without citing to legal authority that financial hardship justifies a stay of discovery. D.I. 25 at 8. This fails as a matter of law. It is well established that the movant's added litigation costs are not an undue hardship or inequity considered by courts when deciding whether to permit a stay. *See, e.g.*, *Yodlee, Inc.*, C.A. No. 14–01445–LPS–CJB, D.I. 57, at 15 n.10 ("Our Court has found that added litigation cost that would be incurred if a stay is denied does not amount to the kind of 'undue' hardship or inequity that is referenced in the case law."); *ImageVision.Net, Inc.*, 2013 WL 663535, at *6 ("[D]efendant contends it will suffer financial hardship through unnecessary litigation if a stay is denied, but fails to cite any legal basis that litigation alone constitutes hardship or inequity."); *Personalized User Model, L.L.P.*, 2012 WL 5379106, at *2; *Cooper Notification, Inc.*, 2010 WL 5149351, at *2.

Even if financial hardship did qualify as a reason to stay discovery, Coherus has not substantiated its claim here. Coherus's own public statements in April 2017 that it is "well prepared" to defend this action are contrary to its present claims of financial hardship. *See* Ex. 3. Coherus now says that the FDA rejection means that Coherus has "to stretch its limited resources over an additional 12-month period." D.I. 25 at 8. But, ten days after Coherus filed this motion to stay, Coherus filed a 79-page petition requesting that the Patent Office institute an IPR on an Amgen patent involving a different product than is at issue here. *See* Ex. 6. Coherus also announced its intention to file an additional IPR petition against a related Amgen patent in the "near future." Ex. 7. It cannot be the case that Coherus lacks the financial resources to continue discovery in this case when, at the same time, Coherus is filing (and preparing to file) petitions seeking to commence additional and costly legal proceedings against Amgen on another product. At the very least, Coherus could have chosen to devote its "limited resources" to providing discovery to Amgen in this action, rather than spending money preparing and filing IPR petitions against Amgen.

Further, even if Coherus were facing financial pressures generally, this does not support the specific assertion that Coherus will suffer financial hardship as a result of continuing with discovery in this litigation. The only evidence that Coherus submits as to financial hardship is the statement that, "As a consequence of the [FDA rejection], Coherus has laid off approximately one-third of its workforce, including approximately half of its commercial launch team." D.I. 26 ¶ 7. But the fact that Coherus had layoffs does not mean that Coherus cannot litigate this case. Coherus's decision to shift funds from its commercial launch team to the FDA regulatory team is not evidence of Coherus's inability to pay its litigation expenses but rather, for example, a strategic business decision. Coherus has also submitted no evidence as to what litigation

expenses Coherus expects to incur in the next year—such as its retention agreement with its litigation counsel, and projected budget for litigation costs—let alone whether such expenses impose financial hardship on Coherus in continuing with discovery.

Coherus incorrectly asserts that Amgen is trying to "bankrupt" Coherus with "unnecessary litigation expenses before Coherus can launch." D.I. 25 at 1. As an initial matter, if Coherus is going to be bankrupted by this litigation, that provides an additional reason why the case should proceed now: so Amgen can seek relief from Coherus for patent infringement before it enters bankruptcy. Further, even if financial hardship is considered to justify a stay (which it is not under the law), Coherus cannot be heard to complain that its litigation expenses are "unnecessary" or impute bad faith on Amgen's part as to Coherus's financial situation. The litigation expenses that Coherus is bearing are a direct result of Coherus's agreement that Amgen should sue Coherus on the '707 Patent under 42 U.S.C. § 262(*l*)(6). *See* Ex. 4. Indeed, litigating "one or more patents of the originator" under 42 U.S.C. § 262(*l*)(6) was always part of Coherus's "strategy," if it took advantage of the § 262(k) abbreviated biosimilars pathway. Ex. 2 at 64. Coherus fully recognized that financial hardship that it is now experiencing could be expected given that Coherus' organization is a "biosimilar startup with no revenues." D.I. 25 at 6. It is not a result of any action by Amgen, nor could it be. The only reason that Coherus cannot launch sooner than mid-2018 is because it does not yet have FDA approval.

B. A Stay Will Not Simplify the Issues

The Court prefers that discovery not be stayed, even in the face of a pending potentially dispositive motions to dismiss. *See* Honorable Leonard P. Stark, Revised Procedures for Managing Patent Cases, at 6 (June 18, 2014), *available at* http://www.ded.uscourts.gov/sites/default/files/Chambers/LPS/PatentProcs/LPS-PatentProcedures.pdf; *see also Toshiba Samsung Storage Tech. Korea Corp. v. LG Elecs., Inc.*, C.A. No. 15–691–LPS–CJB, 2015 WL 7824098,

at *2 (D. Del. Dec. 3, 2015) ("The Court reads [Judge Stark's revised] procedure as expressing the District Court's preference that, in the main, cases filed by a plaintiff should move forward."). This makes sense in view of the costs involved with a stay if the motion to dismiss is later denied. *See Yodlee, Inc.*, C.A. No. 14–01445–LPS–CJB, D.I. 57, at 6 n.3.

Here, a stay will not simplify or narrow the issues, and will impose additional costs on both parties and the Court as well as prejudicing Amgen if the motion to dismiss is denied. Specifically, if the Court denies Coherus's motion to dismiss or finds that factual development or claim construction is needed before deciding the motion, a stay would not have simplified the issues or trial of the case at all. All a stay will have done in that circumstance is unnecessarily delay the case while forcing the parties and the Court to consider the disputed patent issues on an expedited basis in the limited time before Coherus's anticipated launch in mid-2018.

Nevertheless, Coherus asserts without support that a stay will "narrow" the issues for discovery and that a stay would preserve the Court's resources. D.I. 25 at 7. This is contrary to precedent that, in determining whether a stay will simplify the issues and trial of the case, the Court considers all of the possible outcomes of the motion to dismiss would affect the prospects for simplification and not just the potential outcome most favorable to Coherus. *See Yodlee, Inc.*, C.A. No. 14–01445–LPS–CJB, D.I. 57, at 4 ("[T]he Court cannot solely focus on the potential outcome most favorable to the party seeking the stay; instead, it must assess 'all of the possible outcomes of the proceeding or inquiry that the case would be stayed in favor of.'"). In addition, Coherus ignores that its motion to dismiss addresses only two claim elements of the asserted claims. However, discovery and claim construction may be required on more than just those two elements. For example, Coherus's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) makes non-infringement arguments for other claim elements as well as asserting

invalidity and inequitable conduct defenses. *See* D.I. 10 at 4–8. If the case is stayed pending resolution of the motion to dismiss, no progress would be made on any of these other issues. *See, e.g.*, *Personalized User Model, L.L.P.*, 2012 WL 5379106, at *1 (explaining that a stay pending a reexamination proceeding is not favored when infringement, validity under 35 U.S.C. § 112, or other issues outside the purview of reexamination remain to be tried).

Further, Coherus's attack of the merits of Amgen's infringement theories—which are the same as the ones it makes in the motion to dismiss—does not justify a stay. *See* D.I. 25 at 1–2. Amgen disagrees with the non-infringement arguments made in Coherus's motion to dismiss. *See* D.I. 17. But, for the purposes of deciding the present motion for a stay, the legal merits of the motion to dismiss do not matter: the Court's "job is to take known factors (e.g., the scope of the motion as it relates to the claims and issues in the cases) and assess how they might weigh in favor or against simplification." *Kaavo Inc.*, 2015 WL 1737476, at *2 n.4. Otherwise, the Court's resolution of the motion to stay would depend on its resolution of the motion to dismiss. If the Court does consider the merits of the motion to dismiss in deciding whether to grant the stay, Coherus's motion to dismiss should be denied because it prematurely seeks summary judgment of non-infringement in the absence of either a full factual record or construction of any terms of the asserted claims. D.I. 17 at 9. That Coherus's motion to dismiss relies on documents not cited in the complaint and seeks resolution of disputes that are intensely factual in nature and that involve claim construction, supports the denial of both Coherus's motion to dismiss and the present motion for a stay.

Finally, Coherus's reliance on the *Levey* decision is misplaced. In *Levey*, the district court dismissed the plaintiff's complaint for failure to adequately allege copyright infringement. *Levey v. Brownstone Inv. Grp., LLC*, 590 F. App'x 132, 135 (3d Cir. 2014) (non-precedential).

On appeal, the plaintiff argued that the district court abused its discretion in denying his motion to lift a stay before granting the defendants' motion to dismiss, because, according to him, had he been permitted to take discovery he would have been able to adequately allege copyright infringement. *Id.* at 137. The Third Circuit concluded that the plaintiff cannot use discovery to cure his failure to adequately state a claim in his complaint. *Id.* *Levy* does not stand for the proposition that discovery should be stayed pending resolution of motions to dismiss.

C. The Status of the Litigation Disfavors a Stay

Although this litigation is in its early stages, the timing of this case does not favor a stay. Unlike at the outset of other patent cases, *see, e.g.*, *Kaavo Inc.*, 2015 WL 1737476, at *3, the parties here already invested substantial time and resources addressing the merits of the litigation before Amgen filed its complaint here. In Coherus's words, the parties engaged in "extensive exchanges mandated by the BPCIA," prior to starting the litigation. *See* D.I. 22 at 2 ("In October 2016, Coherus produced over 300,000 pages to Amgen, including a detailed description of the accused purification step. Amgen digested that information and provided infringement contentions in March 2017."); D.I. 10 at 4 ("[T]he parties exchanged detailed infringement and validity contentions, with Coherus's running to nearly 500 pages of narrative and claim charts."). Accordingly, in this particular case, the "economies that might otherwise flow from granting a stay early in a case are somewhat offset by the substantial resources already incurred by both the parties." *See, e.g.*, *SoftView LLC v. Apple Inc.*, C.A. No. 10–389–LPS, 2012 WL 3061027, at *4 (D. Del. July 26, 2012).

D. A Stay Frustrates the Purpose of the BPCIA

A stay is contrary to the purpose of the BPCIA to "facilitate[ ] litigation during the period preceding FDA approval so that the parties do not have to wait until commercial marketing to resolve their patent disputes." *Sandoz*, 137 S. Ct. at 1670 (emphasis added); *see* Ex. 10

(Biologics and Biosimilars: Balancing Incentives for Innovation, Hearing Before the Subcomm. on Courts and Competition Policy of the H. Comm. on the Judiciary, 111th Cong. 9 (2009) (Testimony of Representative Anna G. Eshoo) (the purpose of the BPCIA is to "ensure that litigation surrounding relevant patents will be resolved expeditiously and prior to the launch of the biosimilar product.")).[6] Unlike the filing of an ANDA lawsuit, the filing of a patent infringement action under 42 U.S.C. § 262(*l*)(6) of the BPCIA does not trigger a stay of FDA approval of the proposed biological product. Thus, in order for Amgen to obtain patent resolution prior to FDA approval and anticipated launch in mid-2018, it is necessary to press forward with the case now.

Here, Coherus elected to file its aBLA in August 2016. D.I. 1 ¶ 10. Coherus then engaged in the BPCIA information exchange process, at the end of which Coherus agreed that Amgen should bring an infringement action asserting the '707 Patent. D.I. 1 ¶¶ 35–38; Ex. 4. Coherus did so, fully cognizant that the benefit afforded to it under the § 262(k) pathway of less "development time and costs" is balanced by the "the countervailing risk" that "the complex patent exchange process mandated by the BPCIA could ultimately prevent or substantially delay us from launching our products in the United States." Ex. 2 at 63. Recognizing these tradeoffs, Coherus chose to submit its aBLA under § 262(k) relying on Amgen's demonstration that Neulasta® is "safe, pure, and potent," rather than submitting an application under § 262(a) which has traditionally required proof of safety and efficacy through a series of phased clinical trials (and which Amgen conducted in obtaining FDA approval for Neulasta®). Coherus also engaged in the information exchange procedures of the BPCIA following FDA acceptance of the Coherus aBLA

[6] In enacting the BPCIA, Congress revised 35 U.S.C. § 271(e) to limit the reference product sponsor's remedies in a patent infringement action that is not brought within the statutory deadline. *See* 35 U.S.C. § 271(e)(6)(A)(ii)(II) and (C). This supports Congress's intent for the reference product sponsor and the aBLA applicant to resolve their patent disputes expeditiously.

in August 2016, and agreed that the '707 Patent should be the subject of this patent infringement action. D.I. 1 ¶¶ 35–38; Ex. 4. Having made these choices, Coherus cannot now complain that it would be unfair for this case to go forward. Indeed, the BPCIA says nothing about suspending patent infringement actions brought pursuant to its provisions if the biosimilar applicant faces regulatory difficulties or a rejection, or financial hardship.

Coherus argues that this case is different than typical drug cases because the timing for Coherus's launch has been delayed by at least a year due to the CRL. D.I. 25 at 1. But Coherus fails to explain why a year is too much time prior to launch to litigate a complex patent case. And the ANDA case that Coherus cites, *Novartis Corp. v. Dr. Reddy's Labs., Ltd.*, No. 04 Civ.0757 SAS, 2004 WL 2368007 (S.D.N.Y. Oct. 21, 2004), makes clear that delaying litigation while the FDA is considering approval would be prejudicial to the patent holder. D.I. 25 at 7. In *Novartis*, FDA was prohibited under 21 U.S.C. § 355(c)(3)(C) from approving the drug for thirty months to allow the parties to resolve their patent dispute, and the defendants agreed to toll that period during the stay. This fact was dispositive, as the court found that a stay would otherwise be unduly prejudicial. *See Novartis Corp.*, 2004 WL 2368007, at *3. That is not the case here, where the BPCIA does not impose a stay of regulatory approval after a patent infringement action is filed. Because Coherus asserts that it intends to launch its product by mid-2018, the case should proceed now rather than forcing the parties and the Court to engage in expedited proceedings next year.

E. If a Stay is Granted, Certain Conditions Should Apply During and After the Stay to Minimize Prejudice to Amgen

Amgen believes that the case should not be stayed. In the alternative, if the Court is inclined to grant a stay, Amgen requests that any stay be structured to protect Amgen's interests and to avoid the need for expedited proceedings if and when Coherus obtains FDA approval.

Should the Court grant a stay, it should leave Amgen in no worse a position after the stay is lifted than it is now. The Court could accomplish this by conditioning a stay on an agreement by Coherus that it will not launch its biosimilar product while the stay is in effect or for a period of at least six months thereafter.

If the stay is granted, Amgen also requests that, during the stay, Coherus be ordered to immediately produce any correspondence with FDA regarding the proposed biosimilar because such information may be highly relevant to the disputed patent issues, and there is minimal burden associated with Coherus giving to Amgen what it is sending to the FDA. This allows Amgen to continue developing the patent issues, even if discovery has been stayed. In addition, Amgen requests that Coherus be prohibited from communicating with any potential customers about the proposed biosimilar pegfilgrastim product. It would be unfair for Coherus to take advantage of the stay to prepare for launch in mid-2018 while depriving Amgen of its ability to prepare the case for trial. Of course, if the case were resolved by settlement or otherwise, this agreement not to launch would cease to apply.

V. CONCLUSION

For all the foregoing reasons, Amgen respectfully requests that the Court deny Coherus's motion for a stay pending resolution of Coherus's motion to dismiss.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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August 8, 2017

CERTIFICATE OF SERVICE

I hereby certify that on August 8, 2017, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on August 8, 2017, upon the following in the manner indicated:

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/s/ Jack B. Blumenfeld

Jack B. Blumenfeld (#1014)

EXHIBIT 1

From: Maniscalco, Stephen
Sent: Tuesday, August 08, 2017 4:40 PM
To: 'Lyerla, Bradford P.'; 'Fogel, Louis E.'; 'Dorsney, Kenneth L.'; 'rherrmann@morrisjames.com'
Cc: GRP-Amgen-Coherus; 'Blumenfeld, Jack'; 'Noreika, Maryellen'
Subject: Amgen v. Coherus, Case No. 17-cv-546 - Proposed Scheduling Order
Attachments: DRAFT Proposed Scheduling Order.DOC

Counsel,

Per the Court's July 18, 2017 oral order, please find attached a draft proposed scheduling order. We are available to discuss on Monday, August 14. Please let us know if that will work for you.

Thanks,
Stephen

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REVISED June 2014

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

REVISED PATENT FORM SCHEDULING ORDER

This _____ day of _____, 2017, the Court having conducted a Case Management Conference/Rule 16 scheduling and planning conference pursuant to Local Rule 16.2(a) and Judge Stark's Revised Procedures for Managing Patent Cases (which is posted at http://www.ded.uscourts.gov; see Chambers, Judge Leonard P. Stark, Patent Cases) on _____, 201__, and the parties having determined after discussion that the matter cannot be resolved at this juncture by settlement, voluntary mediation, or binding arbitration;

IT IS HEREBY ORDERED that:

1. Rule 26(a)(l) Initial Disclosures and E-Discovery Default Standard. Unless otherwise agreed to by the parties, the parties shall make their initial disclosures pursuant to Federal Rule of Civil Procedure 26(a)(l) within five (5) days of the date of this Order. If they have not already done so, the parties are to review the Court's Default Standard for Discovery, Including Discovery of Electronically Stored Information ("ESI") (which is posted at http://www.ded.uscourts.gov.; see Other Resources, Default Standards for Discovery, and is incorporated herein by reference).

2. Joinder of Other Parties and Amendment of Pleadings. All motions to join other parties, and to amend or supplement the pleadings, shall be filed on or before June 20, 2018.

3. Application to Court for Protective Order. Should counsel find it will be necessary to apply to the Court for a protective order specifying terms and conditions for the disclosure of confidential information, counsel should confer and attempt to reach an agreement on a proposed form of order and submit it to the Court within ten (10) days from the date of this Order. Should counsel be unable to reach an agreement on a proposed form of order, counsel must follow the provisions of Paragraph 8(g) below.

Any proposed protective order must include the following paragraph:

> Other Proceedings. By entering this order and limiting the disclosure of information in this case, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any person or party subject to this order who becomes subject to a motion to disclose another party's information designated "confidential" [the parties should list any other level of designation, such as "highly confidential," which may be provided for in the protective order] pursuant to this order shall promptly notify that party of the motion so that the party may have an opportunity to appear and be heard on whether that information should be disclosed.

4. Papers Filed Under Seal. In accordance with section G of the Administrative Procedures Governing Filing and Service by Electronic Means, a redacted version of any sealed document shall be filed electronically within seven (7) days of the filing of the sealed document.

Should any party intend to request to seal or redact all or any portion of a transcript of a court proceeding (including a teleconference), such party should expressly note that intent at the start of the court proceeding. Should the party subsequently choose to make a request for sealing or redaction, it must, promptly after the completion of the transcript, file with the Court a motion

for sealing/redaction, and include as attachments (1) a copy of the complete transcript highlighted so the Court can easily identify and read the text proposed to be sealed/redacted, and (2) a copy of the proposed redacted/sealed transcript. With their request, the party seeking redactions must demonstrate why there is good cause for the redactions and why disclosure of the redacted material would work a clearly defined and serious injury to the party seeking redaction.

5. Courtesy Copies. Other than with respect to "discovery matters," which are governed by paragraph 8(g), and the final pretrial order, which is governed by paragraph 20, the parties shall provide to the Court two (2) courtesy copies of all briefs and one (1) courtesy copy of any other document filed in support of any briefs (i.e., appendices, exhibits, declarations, affidavits etc.). This provision also applies to papers filed under seal.

6. ADR Process. This matter is referred to a magistrate judge to explore the possibility of alternative dispute resolution.

7. Disclosures. Absent agreement among the parties, and approval of the Court:

a. By December 20, 2017, Plaintiff shall identify the accused product(s), including accused methods and systems; its damages model; the asserted patent(s) that the accused product(s) allegedly infringe(s); and an initial claim chart relating each known accused product to the asserted claims each such product allegedly infringes. Plaintiff shall also produce the file history for each asserted patent.

b. By January 24, 2018, Defendant shall produce its initial invalidity contentions for each asserted claim, as well as the known related invalidating references.

c. By August 17, 2018, Plaintiff shall provide final infringement contentions, and Defendant shall provide final invalidity contentions.

8. Discovery. Unless otherwise ordered by the Court, the limitations on discovery set forth in Local Rule 26.1 shall be strictly observed.

a. Discovery Cut Off. All discovery in this case shall be initiated so that it will be completed on or before September 21, 2018.

b. Document Production. Document production shall be substantially complete by June 13, 2018.

c. Requests for Admission. A maximum of 40 requests for admission are permitted for each side, not including requests for admission seeking to authenticate documents.

d. Interrogatories.

i. A maximum of 25 interrogatories, including contention interrogatories, are permitted for each side.

ii. The Court encourages the parties to serve and respond to contention interrogatories early in the case. In the absence of agreement among the parties, contention interrogatories, if filed, shall first be addressed by the party with the burden of proof. The adequacy of all interrogatory answers shall be judged by the level of detail each party provides; i.e., the more detail a party provides, the more detail a party shall receive.

e. Depositions.

i. Limitation on Hours for Deposition Discovery. Each side is limited to a total of 70 hours of taking testimony by deposition upon oral examination. Each deposition is limited to no more than 7 hours. For depositions taken pursuant to Fed. R. Civ. P.

30(b)(6), the 7-hour limit applies per each individual witness designated to testify on behalf of a party.

i. Location of Depositions. The parties agree to take depositions of Amgen and Coherus witnesses who are located within the Unites States at a location in the United States near the place where each witness is employed.

f. Electronic Discovery. The parties have initiated discussions concerning the extent, scope and handling of electronic discovery and will continue to negotiate an appropriate e-discovery stipulation that will be filed with the Court. The parties agree that they will not follow the Delaware Default Standard except as provided herein or in any e-discovery stipulation. The parties agree to produce documents (both digital information and hard copy) as text searchable image files in Group IV single-page TIFF files (Tagged Image File Format), black and white, at 300 x 300 dpi resolution and 8.5 x 11 inch page size, except for documents requiring different resolution or page size to make them readable. An image load file should accompany all images produced in standard IPRO (* .LFP) and Opticon (*.LOG) formats that should reflect the logical document breaks and parent/child relationship between documents. Also to be produced will be a data load file in Concordance delimited (*.DAT) format which shall include the field names for all information to be produced (e.g. production number fields) in the first line of the DAT file and indicate (at a minimum) appropriate unitization of the documents, including beginning and ending production numbers for (a) each document, and (b) each attachment to each document. Document level text files (. TXT) will be provided for each document containing the extracted text from ESI and OCR for paper documents. The text files are to be named per the Production Number Begin value of the document. The parties may

negotiate a separate production form (including native format) for any documents that are not reasonably producible as standard image files (such as audio files and certain Excel spreadsheets) but expect that the default production form for such documents will be their native formats. The parties are only obligated to provide the following metadata for all ESI produced, to the extent such metadata exists: Custodian, Email Subject, From, To, CC, BCC, Date Sent, Filename, Author, Date Created, MD5 Hash; File Extension, Production Number Begin, Production Number End, Attachment Range, Attachment Begin, and Attachment End (or the equivalent thereof).

g. Privilege Logs. Privilege Logs shall be substantially completed and served by each party by June 27, 2018. The parties agree that no documents generated after Amgen's receipt of Coherus's aBLA shall be required to be logged.

h. Disclosure of Expert Testimony.

i. Expert Reports. For the party who has the initial burden of proof on the subject matter, the initial Federal Rule 26(a)(2) disclosure of expert testimony is due on or before October 19, 2018. The supplemental disclosure to contradict or rebut evidence on the same matter identified by another party is due on or before November 16, 2018. Reply expert reports from the party with the initial burden of proof are due on or before December 14, 2018. No other expert reports will be permitted without either the consent of all parties or leave of the Court. Along with the submissions of the expert reports, the parties shall advise of the dates and times of

their experts' availability for deposition. Expert depositions are to be completed by January 18, 2019.

ii. Expert Report Supplementation. The parties agree they will permit expert declarations to be filed in connection with motions briefing (including case-dispositive motions).

iii. Objections to Expert Testimony. To the extent any objection to expert testimony is made pursuant to the principles announced in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), as incorporated in Federal Rule of Evidence 702, it shall be made by motion no later than the deadline for dispositive motions set forth herein, unless otherwise ordered by the Court. Briefing on such motions is subject to the page limits set out in connection with briefing of case dispositive motions.

i. Discovery Matters and Disputes Relating to Protective Orders.

i. Any discovery motion filed without first complying with the following procedures will be denied without prejudice to renew pursuant to these procedures.

ii. Should counsel find, after good faith efforts – including ***verbal*** communication among Delaware and Lead Counsel for all parties to the dispute – that they are unable to resolve a discovery matter or a dispute relating to a protective order, the parties involved in the discovery matter or protective order dispute shall submit a joint letter in substantially the following form:

Dear Judge Stark:

The parties in the above- referenced matter write to request the scheduling of a discovery teleconference.

The following attorneys, including at least one Delaware Counsel and at least one Lead Counsel per party, participated in a verbal meet-and-confer (in person and/or by telephone) on the following date(s):

_____

Delaware Counsel: _____

Lead Counsel: _____

The disputes requiring judicial attention are listed below:

[provide here a non-argumentative list of disputes requiring judicial attention]

iii. On a date to be set by separate order, generally not less than forty-eight (48) hours prior to the conference, the party seeking relief shall file with the Court a letter, not to exceed three (3) pages, outlining the issues in dispute and its position on those issues. On a date to be set by separate order, but generally not less than twenty-four (24) hours prior to the conference, any party opposing the application for relief may file a letter, not to exceed three (3) pages, outlining that party's reasons for its opposition.

iv. Each party shall submit two (2) courtesy copies of its discovery letter and any attachments.

v. Should the Court find further briefing necessary upon conclusion of the telephone conference, the Court will order it. Alternatively,

the Court may choose to resolve the dispute prior to the telephone conference and will, in that event, cancel the conference.

9. Motions to Amend.

a. Any motion to amend (including a motion for leave to amend) a pleading shall ***NOT*** be accompanied by an opening brief but shall, instead, be accompanied by a letter, not to exceed three (3) pages, describing the basis for the requested relief, and shall attach the proposed amended pleading as well as a "blackline" comparison to the prior pleading.

b. Within seven (7) days after the filing of a motion in compliance with this Order, any party opposing such a motion shall file a responsive letter, not to exceed five (5) pages.

c. Within three (3) days thereafter, the moving party may file a reply letter, not to exceed two (2) pages, and, by this same date, the parties shall file a letter requesting a teleconference to address the motion to amend.

10. Motions to Strike.

a. Any motion to strike any pleading or other document shall ***NOT*** be accompanied by an opening brief but shall, instead, be accompanied by a letter, not to exceed three (3) pages, describing the basis for the requested relief, and shall attach the document to be stricken.

b. Within seven (7) days after the filing of a motion in compliance with this Order, any party opposing such a motion shall file a responsive letter, not to exceed five (5) pages.

c. Within three (3) days thereafter, the moving party may file a reply letter, not to exceed two (2) pages, and, by this same date, the parties shall file a letter requesting a teleconference to address the motion to strike.

11. Tutorial Describing the Technology and Matters in Issue. Unless otherwise ordered by the Court, the parties shall provide the Court, no later than the date on which their opening claim construction briefs are due, a tutorial on the technology at issue. In that regard, the parties may separately or jointly submit a DVD of not more than thirty (30) minutes. The tutorial should focus on the technology in issue and should not be used for argument. The parties may choose to file their tutorial(s) under seal, subject to any protective order in effect. Each party may comment, in writing (in no more than five (5) pages) on the opposing party's tutorial. Any such comment shall be filed no later than the date on which the answering claim construction briefs are due. As to the format selected, the parties should confirm the Court's technical abilities to access the information contained in the tutorial (currently best are "mpeg" or "quicktime").

12. Claim Construction Issue Identification. On April 11, 2018, the parties shall exchange a list of those claim term(s)/phrase(s) that they believe need construction and their proposed claim construction of those term(s)/phrase(s). This document will not be filed with the Court. Subsequent to exchanging that list, the parties will meet and confer to prepare a Joint Claim Construction Chart to be submitted on April 18, 2018. The parties' Joint Claim Construction Chart should identify for the Court the term(s)/phrase(s) of the claim(s)in issue, and should include each party's proposed construction of the disputed claim language with citation(s) only to the intrinsic evidence in support of their respective proposed constructions. A copy of the patent(s) in issue as well as those portions of the intrinsic record relied upon shall be

submitted with this Joint Claim Construction Chart. In this joint submission, the parties shall not provide argument.

13. Claim Construction Briefing. The parties shall contemporaneously submit initial briefs on claim construction issues on May 9, 2018. The parties' answering/responsive briefs shall be contemporaneously submitted on May 23, 2018. No reply briefs or supplemental papers on claim construction shall be submitted without leave of the Court. Local Rule 7.1.3(4) shall control the page limitations for initial (opening) and responsive (answering) briefs.

14. Hearing on Claim Construction. Beginning at _____ __.m. on June 20, 2018, the Court will hear argument on claim construction. The parties shall notify the Court, by joint letter submission, no later than the date on which their answering claim construction briefs are due: (i) whether they request leave to present testimony at the hearing; and (ii) the amount of time they are requesting be allocated to them for the hearing.

Provided that the parties comply with all portions of this Scheduling Order, and any other orders of the Court, the parties should anticipate that the Court will issue its claim construction order within sixty (60) days of the conclusion of the claim construction hearing. If the Court is unable to meet this goal, it will advise the parties no later than sixty (60) days after the conclusion of the claim construction hearing.

15. Interim Status Report. On July 20, 2018, counsel shall submit a joint letter to the Court with an interim report on the nature of the matters in issue and the progress of discovery to date. Thereafter, if the Court deems it necessary, it will schedule a status conference.

16. Supplementation. Absent agreement among the parties, and approval of the Court, no later than August 17, 2018 the parties must finally supplement, *inter alia*, the identification of all accused products and of all invalidity references.

17. Case Dispositive Motions. All case dispositive motions, an opening brief, and affidavits, if any, in support of the motion shall be served and filed on or before February 22, 2019. Briefing will be presented pursuant to the Court's Local Rules, as modified by this Order.

a. No early motions without leave. No case dispositive motion under Rule 56 may be filed more than ten (10) days before the above date without leave of the Court.

b. Page limits combined with Daubert motion page limits. Each party is permitted to file as many case dispositive motions as desired; provided, however, that each ***SIDE*** will be limited to a combined total of 40 pages for all opening briefs, a combined total of 40 pages for all answering briefs, and a combined total of 20 pages for all reply briefs regardless of the number of case dispositive motions that are filed. In the event that a party files, in addition to a case dispositive motion, a Daubert motion to exclude or preclude all or any portion of an expert's testimony, the total amount of pages permitted for all case dispositive and Daubert motions shall be increased to 50 pages for all opening briefs, 50 pages for all answering briefs, and 25 pages for all reply briefs for each ***SIDE***.[1]

c. Hearing. The Court will hear argument on all pending case dispositive and Daubert motions on May 1, 2019 beginning at _____. Subject to further order of the Court, each side will be allocated a total of forty-five (45) minutes to present its argument on all pending motions.

18. Applications by Motion. Except as otherwise specified herein, any application to the Court shall be by written motion filed with the Clerk. Any non-dispositive motion should contain the statement required by Local Rule 7.1.1.

[1] The parties must work together to ensure that the Court receives no more than a ***total*** of ***250 pages*** (i.e., 50 + 50 + 25 regarding one side's motions, and 50 + 50 + 25 regarding the other side's motions) of briefing on all case dispositive motions and Daubert motions that are covered by this scheduling order and any other scheduling order entered in any related case that is proceeding on a consolidated or coordinated pretrial schedule.

19. Pretrial Conference. On August 14, 2019, the Court will hold a pretrial conference in Court with counsel beginning at _____ __.m. Unless otherwise ordered by the Court, the parties should assume that filing the pretrial order satisfies the pretrial disclosure requirement of Federal Rule of Civil Procedure 26(a)(3). The parties shall file with the Court the joint proposed final pretrial order with the information required by the form of Revised Final Pretrial Order - Patent, which can be found on the Court's website (www.ded.uscourts.gov), on or before July 31, 2019. Unless otherwise ordered by the Court, the parties shall comply with the timeframes set forth in Local Rule 16.3(d)(l)-(3) for the preparation of the joint proposed final pretrial order.

The parties shall provide the Court two (2) courtesy copies of the joint proposed final pretrial order and all attachments.

As noted in the Revised Final Pretrial Order – Patent, the parties shall include in their joint proposed final pretrial order, among other things:

a. a request for a specific number of ***hours*** for their trial presentations, as well as a requested number of days, based on the assumption that in a typical jury trial day (in which there is not jury selection, jury instruction, or deliberations), there will be 5 ½ to 6 ½ hours of trial time, and in a typical bench trial day there will be 6 to 7 hours of trial time;

b. their position as to whether the Court should allow objections to efforts to impeach a witness with prior testimony, including objections based on lack of completeness and/or lack of inconsistency;

c. their position as to whether the Court should rule at trial on objections to expert testimony as beyond the scope of prior expert disclosures, taking time from the parties' trial presentation to argue and decide such objections, or defer ruling on all such objections

unless renewed in writing following trial, subject to the proviso that a party prevailing on such a post-trial objection will be entitled to have all of its costs associated with a new trial paid for by the party that elicited the improper expert testimony at the earlier trial; and

d. their position as to how to make motions for judgment as a matter of law, whether it be immediately at the appropriate point during trial or at a subsequent break, whether the jury should be in or out of the courtroom, and whether such motions may be supplemented in writing.

20. Motions *in Limine*. Motions *in limine* shall not be separately filed. All *in limine* requests and responses thereto shall be set forth in the proposed pretrial order. Each ***SIDE*** shall be limited to three (3) *in limine* requests, unless otherwise permitted by the Court. The *in limine* request and any response shall contain the authorities relied upon; each *in limine* request may be supported by a maximum of three (3) pages of argument and may be opposed by a maximum of three (3) pages of argument, and the side making the *in limine* request may add a maximum of one (1) additional page in reply in support of its request. If more than one party is supporting or opposing an *in limine* request, such support or opposition shall be combined in a single three (3) page submission (and, if the moving party, a single one (1) page reply), unless otherwise ordered by the Court. No separate briefing shall be submitted on *in limine* requests, unless otherwise permitted by the Court.

21. Jury Instructions, Voir Dire, and Special Verdict Forms. Where a case is to be tried to a jury, pursuant to Local Rules 47 and 51 the parties should file (i) proposed voir dire, (ii) preliminary jury instructions, (iii) final jury instructions, and (iv) special verdict forms three (3) business days before the final pretrial conference. This submission shall be accompanied by

a courtesy copy containing electronic files of these documents, in WordPerfect or Microsoft Word format, which may be submitted by e-mail to Judge Stark's staff.

22. Trial. This matter is scheduled for a 3-5 day jury trial beginning at 9:30 a.m. on September 16, 2019, with the subsequent trial days beginning at 9:00 a.m. Until the case is submitted to the jury for deliberations, the jury will be excused each day at 4:30 p.m. The trial will be timed, as counsel will be allocated a total number of hours in which to present their respective cases.

23. Judgment on Verdict and Post-Trial Status Report. Within seven (7) days after a jury returns a verdict in any portion of a jury trial, the parties shall jointly submit a form of order to enter judgment on the verdict. At the same time, the parties shall submit a joint status report, indicating among other things how the case should proceed and listing any post-trial motions each party intends to file.

24. Post-Trial Motions. Unless otherwise ordered by the Court, all ***SIDES*** are limited to a maximum of 20 pages of opening briefs, 20 pages of answering briefs, and 10 pages of reply briefs relating to any post-trial motions filed by that side, no matter how many such motions are filed.

_____

UNITED STATES DISTRICT JUDGE OR
UNITED STATES MAGISTRATE JUDGE

Exhibit A

Description	Proposed Date
Submission of Joint Scheduling Order	August 17, 2017
Rule 16 Conference	September or October __, 2017
Rule 26(a)(1) Initial Disclosures and E-Discovery Default Standard	Within 5 days of the date of the Scheduling Order
Application to Court for Protective Order	[already entered or within 10 days of Scheduling Order]
Plaintiffs' Identification of Accused Products and Asserted Patents, Damages Model, and Initial Infringement Contentions	December 20, 2017
Initial Invalidity Contentions	January 24, 2018
Claim Construction Exchange of Terms and Proposed Constructions	April 11, 2018
Joint Claim Construction Chart	April 18, 2018
Opening Claim Construction Briefs / Technology Tutorial	May 9, 2018
Responsive Claim Construction Briefs	May 23, 2018
Document Production Substantially Complete	June 13, 2018
Joinder of Other Parties and Amendment of Pleadings	June 20, 2018
Markman Hearing	June 20, 2018, or at the Court's earliest convenience
Privilege Logs	June 27, 2018
Interim Status Report	July 20, 2018
Final Infringement Contentions, Final Invalidity Contentions, and Parties must finally supplement, *inter alia*, the identification of all accused products and of all invalidity references.	August 17, 2018

Description	Proposed Date
Fact Discovery Cut Off	September 21, 2018
Opening Expert Reports	October 19, 2018
Responsive Expert Reports	November 16, 2018
Reply Expert Reports	December 14, 2018
Expert Depositions Complete	January 18, 2019
Case Dispositive / Daubert Motions: Opening Briefs	February 22, 2019
Case Dispositive / Daubert Motions: Responsive Briefs	March 22, 2019
Case Dispositive / Daubert Motions: Reply Briefs	April 5, 2019
Case Dispositive / Daubert Motions: Hearing	May 1, 2019, or at the Court's earliest convenience
Final Pretrial Order	July 31, 2019
Pretrial Conference	August 14, 2019, or at the Court's earliest convenience
Trial	Week of September 16, 2019, or at the Court's earliest convenience

EXHIBIT 2

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2014

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission File Number: 001-36721

Coherus BioSciences, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**27-3615821**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

201 Redwood Shores Parkway, Suite 200,
Redwood City, California 94065
(650) 649-3530

(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☐ No ☒

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a small reporting company. See definition of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated Filer	☐	Accelerated filer	☐
Non-accelerated filer	☒ (Do not check if a smaller reporting company)	Smaller reporting company	☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of November 30, 2014, 33,257,978 shares of the registrant's common stock were outstanding.

We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.

We currently have rights to certain intellectual property, through licenses from third parties and under patent applications that we own, to develop CHS-0214 and CHS-1420. Because we may find that our programs require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights. We may be unable to acquire or in-license compositions, methods of use, processes or other third party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, financial resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment.

If we are unable to successfully obtain rights to required third party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of that program and our business and financial condition could suffer.

Our ability to market our products in the United States may be significantly delayed or prevented by the BPCIA patent dispute resolution mechanism.

The Biologics Price Competition and Innovation Act of 2009, Title VII, Subtitle A of the Patent Protection and Affordable Care Act, Pub.L.No.111-148, 124 Stat.119, Sections 7001-02 signed into law March 23, 2010, or the BPCIA, created an elaborate and complex patent dispute resolution mechanism for biosimilars that could prevent us from launching our product candidates in the United States or could substantially delay such launches. The BPCIA mechanism required for 351(k) biosimilar applicants may pose greater risk that patent infringement litigation will disrupt our activities, as compared to the litigation risk to which we might be exposed under a traditional 351(a) BLA regulatory pathway.

The BPCIA mandates patent disclosure and briefing requirements that are demanding, time-sensitive and, to date, untested. The following is an overview of the patent exchange and patent briefing procedures required by the BPCIA:

1. Disclosure of the Biosimilar Application. Within 20 days after the FDA publishes a notice that its application has been accepted for review, a 351(k) biosimilar applicant must provide a copy of its application to the originator.
2. Identification of Pertinent Patents. Within 60 days of the date of receipt of the application the originator must identify patents owned or controlled by the originator which it believes could be asserted against the biosimilar applicant.
3. Statement by the Biosimilar Applicant. Following the receipt of the originator's patent list, the biosimilar applicant must state either that it will not market its product until the relevant patents have expired or alternatively provide its arguments that the patents are invalid, unenforceable or would not be infringed by the proposed biosimilar product candidate. The biosimilar applicant may also provide the originator with a list of patents it believes the brand-name firm could assert against the reference product.
4. Statement by the Originator. In the event the biosimilar applicant has asserted that the patents are invalid, unenforceable or would not be infringed by the proposed follow-on product, the originator must provide the biosimilar applicant with a response within 60 days. The response must provide the legal and factual basis of the opinion that such patent will be infringed by the commercial marketing of the proposed biosimilar.
5. Patent Resolution Negotiations. If the originator provides its detailed views that the proposed biosimilar would infringe valid and enforceable patents, then the parties are required to engage in good faith negotiations to identify which of the discussed patents will be the subject of a patent infringement action. If the parties agree on the patents to be litigated, the brand-name firm must bring an action for patent infringement within 30 days.
6. Simultaneous Exchange of Patents. If those negotiations do not result in an agreement within 15 days, then the biosimilar applicant must notify the originator of how many patents (but not the identity of those patents) that it wishes to litigate. Within five days, the parties are then required to exchange lists identifying the patents to be litigated. The number of patents identified by the originator may not exceed the number provided by the biosimilar applicant. However, if the biosimilar applicant previously indicated that no patents should be litigated, then the originator may identify one patent.
7. Commencement of Patent Litigation. The originator must then commence patent infringement litigation within 30 days. That litigation will involve all of the patents on the originator's list and all of the patents on the follow-on applicant's list.

The follow-on applicant must then notify the FDA of the litigation. The FDA must then publish a notice of the litigation in the Federal Register.

8. Notice of Commercial Marketing. The BPCIA requires the biosimilar applicant to provide notice to the originator 180 days in advance of its first commercial marketing of its proposed follow-on biologic. The originator is allowed to seek a preliminary injunction blocking such marketing based upon any patents that either party had preliminarily identified, but were not subject to the initial phase of patent litigation. The litigants are required to "reasonably cooperate to expedite such further discovery as is needed" with respect to the preliminary injunction motion.

Biosimilar companies such as ours have the option of applying for U.S. regulatory approval for our products under either a traditional 351(a) BLA approval route, or under the recently enacted streamlined 351(k) approval route established by the BPCIA. The factors underpinning such a decision are extremely complex and involve, among other things, balancing legal risk (in terms of, e.g., the degree and timing of exposure to potential patent litigation by the originator) versus regulatory risks (in terms of, e.g., the development costs and the differing scope of regulatory approval that may be afforded under 351(a) versus 351(k)).

A significant legal risk in pursuing regulatory approval under the 351(k) regulatory approval route is that the above-summarized patent exchange process established by the BPCIA could result in the initiation of patent infringement litigation prior to FDA approval of a 351(k) application, and such litigation could result in blocking the market entry of our products. In particular, while the 351(k) route is more attractive to us (versus 351(a)) for reasons related to development time and costs and the potential broader scope of eventual regulatory approval for our proposed biosimilar candidates, the countervailing risk in such a regulatory choice is that the complex patent exchange process mandated by the BPCIA could ultimately prevent or substantially delay us from launching our products in the United States.

Moreover, the disclosure process required in Step 1 of the process outlined above, which requires the biosimilar applicant to disclose not only the regulatory application but also the applicant's manufacturing process, has the potential to afford originators an easier path than traditional infringement litigation for developing any factual grounds they may require to support allegations of infringement. The rules established in the BPCIA's patent dispute procedures (versus the rules governing traditional patent infringement litigation) place biosimilar firms at a significant disadvantage by affording originators a much easier mechanism for factual discovery, thereby increasing the risk that a biosimilar product could be blocked from the market more quickly than under traditional patent infringement litigation processes.

Preparing for and conducting the patent exchange, briefing and negotiation process outlined above will require extraordinarily sophisticated legal counseling and extensive planning, all under extremely tight deadlines. Moreover, it may be difficult for us to secure such legal support if large, well-funded originators have already entered into engagements with highly qualified law firms or if the most highly qualified law firms choose not to represent biosimilar applicants due to their long standing relationships with originators.

Furthermore, we could be at a serious disadvantage in this process as an originator company, such as Amgen (in the case of CHS-1420 or CHS-0214) or AbbVie (in the case of CHS-1420) may be able to apply substantially greater legal and financial resources to this process than we could.

Although we are not aware that the patent disclosure and dispute resolution mechanisms of the BPCIA patent exchange process have yet been employed by any biosimilar companies, nor legally tested in any court cases, we are aware that some biosimilar companies, namely Sandoz and Celltrion, Inc., or Celltrion, are engaged in legal challenges against originators to establish their right to bring declaratory judgment actions against such originators outside the complex framework of the BPCIA patent exchange rules in order to challenge the validity of the originators' patents prior to the filing of any biosimilar regulatory application. For example, in the Sandoz case against the originator Amgen (relating to Sandoz' proposed etanercept (Enbrel) biosimilar) the Federal District Court ruled that Sandoz did not have the right to bring a declaratory judgment action against Amgen to challenge the validity of certain Amgen-controlled patents directed to Enbrel, but instead determined that Sandoz must use the patent exchange mechanism established in the BPCIA. Sandoz appealed this decision to the United States Court of Appeals for the Federal Circuit, and on December 5, 2014 the Federal Circuit Court ruled that Sandoz did not have the legal right to pursue its declaratory judgment action against Amgen because Sandoz had not yet filed for regulatory approval under the BPCIA (biosimilar) approval pathway. However, the Federal Circuit Court did not address whether the patent resolution mechanism established in the BPCIA would preclude Sandoz from filing its declaratory judgment action against Amgen if and when it files an FDA application under the BCPIA for its etanercept biosimilar.

In October, 2014, Amgen filed suit in federal district court against Sandoz alleging that Sandoz unlawfully refused to follow the patent resolution provisions of the BPCIA in connection with Sandoz' July, 2014 regulatory approval application under 351(k) for its Neupogen (filgrastim) biosimilar, Zarzio. Amgen is seeking declaratory and injunctive relief. In October, 2014, Amgen also filed a Citizen's Petition with the FDA asking that the FDA require biosimilar applicants to comply with the BCPIA by providing to the

reference product sponsor a copy of the biosimilar application accepted for review, together with information that fully describes the manufacture of the proposed biosimilar product, within 20 days after being informed by FDA that the biosimilar application has been accepted for review. The district court and the FDA have not yet reached any decision on these matters.

While the ability to file declaratory judgment actions outside the framework of the BPCIA, or to treat the patent resolution mechanism of this framework as optional, may be attractive to us for addressing and resolving patent infringement risks prior to the expenditure of substantial development and regulatory costs, we see substantial risk that the Federal Appeals Court could uphold the District Court's decision in the Sandoz v. Amgen case. We also believe it is possible that the district court in Amgen's case against Sandoz may decide that the patent resolution framework of the BCPIA is mandatory, and that Sandoz violated this framework by refusing to follow it. These pending court cases may ultimately require biosimilar applicants to test (or defend against) originator patents only in the BPCIA process, after they have filed for regulatory approval under 351(k). We believe this required order of events may expose biosimilar applicants to more patent litigation risk than they might otherwise be exposed to in litigation conducted outside the BPCIA framework, such as (i) under a regulatory application that we might choose to pursue under 351(a), where an originator would not be able to use the BPCIA procedures to potentially block the launch of a biosimilar product candidate; or (ii) under a 351(k) application in which federal court rulings may conclude it is permissible for biosimilar applicants to "opt out" of the BCPIA patent resolution mechanism, as has Sandoz in its 351(k) application for Zarzio.

Whether courts will view the BPCIA process as the sole and mandatory avenue for a biosimilar entity and the originator to identify and potentially litigate such patents remains highly uncertain. We see substantial risk that a final outcome to that effect in the Sandoz and Celltrion cases could increase patent infringement risks for companies, including ours, seeking to introduce biosimilar versions of originator products.

If we file a 351(k) regulatory approval application for one or more of our products, we may consider it necessary or advisable to adopt the strategy of selecting one or more patents of the originator to litigate in the above described BPCIA process (for example in steps 3 and 7, of the process, as outlined above), either to assert our non-infringement of such patents or to challenge their validity; but we may ultimately not be successful in that strategy and could be prevented from marketing the product in the United States.

Under the complex, untested and uncertain rules of the BPCIA patent provisions, coupled with the inherent uncertainty surrounding the legal interpretation of any originator patents that might be asserted against us in this new process, we see substantial risk that the BPCIA process may significantly delay or defeat our ability to market our products in the United States.

Risks Related to Our Business Operations

We may not be successful in our efforts to identify, develop or commercialize additional product candidates.

Although a substantial amount of our effort will focus on the continued clinical testing, potential approval and commercialization of our existing product candidates, the success of our business also depends upon our ability to identify, develop and commercialize additional product candidates. Research programs to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful. Our development efforts may fail to yield additional product candidates suitable for clinical development and commercialization for a number of reasons, including but not limited to the following:

- we may not be successful in identifying potential product candidates that pass our strict screening criteria;
- we may not be able to overcome technological hurdles to development or a product candidate may not be capable of producing commercial quantities at an acceptable cost or at all;
- we may not be able to assemble sufficient resources to acquire or discover additional product candidates;
- our product candidates may not succeed in nonclinical or clinical testing;
- our potential product candidates may fail to show sufficient biosimilarity to originator molecules; and
- competitors may develop alternatives that render our product candidates obsolete or less attractive or the market for a product candidate may change such that a product candidate may not justify further development.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs or we may not be able to identify, develop or commercialize additional product candidates, which would have a material adverse effect on our business and could potentially cause us to cease operations.

EXHIBIT 3

NEWS RELEASE

COHERUS BIOSCIENCES COMPLETES PATENT DANCE EXCHANGE WITH AMGEN FOR NEULASTA BIOSIMILAR

REDWOOD CITY, Calif., April 25, 2017 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. (Nasdaq:CHRS), announced today that it completed the initial phases of the Biologics Price Competition and Innovation Act (BPCIA) patent exchange procedure with Amgen for Coherus' Neulasta (pegfilgrastim) biosimilar candidate, CHS-1701. Of the two patents originally listed by Amgen in the process, the parties have reached agreement on a single patent for potential litigation, U.S. patent 8,273,707 (the '707 patent), directed to a method for purifying the product.

Under the provisions of the BPCIA patent dance, Amgen is subject to a 30-day deadline, expiring on May 11, 2017, to file a patent infringement suit against Coherus under the '707 patent. Failure to do so will result in Amgen's loss of injunctive rights under the patent, limiting any potential recovery to monetary damages. Litigation has not yet been initiated.

"We are confident a court will conclude that our CHS-1701 manufacturing process does not infringe the '707 patent," stated Denny Lanfear, President and CEO of Coherus, further adding "*aside from its lack of any relevance to our process, there are also serious questions regarding the validity of this patent. We are well prepared for the possibility that Amgen may decide to assert the '707 patent against us and will defend any such suit vigorously."*

Mr. Lanfear continued*, "Coherus remains committed to its mission of bringing the highest quality biosimilar drugs to the marketplace. We are confident that we will prevail and achieve our goals of increasing patient access and introducing competition by offering biosimilar products at prices competitive with and lower than those maintained by originator companies, thereby delivering savings that are much-needed for new therapies."*

About Coherus BioSciences, Inc.
Coherus is a leading pure-play, global biosimilar company that develops and commercializes high-quality therapeutics for major regulated markets. Biosimilars are intended for use in place of existing, branded biologics to treat a range of chronic and often life-threatening diseases, with the potential to reduce costs and expand patient access. Composed of a team of proven industry veterans with world-class expertise in process science, analytical characterization, protein production, sales & marketing and clinical-regulatory development, Coherus is positioned as a leader in the global biosimilar marketplace. Coherus is advancing three late-stage clinical products towards commercialization, CHS-1701 (pegfilgrastim biosimilar), CHS-0214 (etanercept biosimilar) and CHS-1420 (adalimumab biosimilar), as well as developing a robust pipeline of future products in four therapeutic areas, oncology, immunology (anti-TNF), ophthalmology and multiple sclerosis. For additional information, please visit www.coherus.com.

Forward-Looking Statements

Except for the historical information contained herein, the matters set forth in this press release, including statements regarding Coherus' plans, potential opportunities, expectations, projections, goals, objectives, milestones, strategies, product pipeline, clinical studies, product development, release of data and the potential benefits of its products under development are forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including Coherus' ability to prevail against Amgen's allegations and to commercialize CHS-1701. Such forward-looking statements involve substantial risks and uncertainties that could cause our clinical development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in the clinical drug development process, including the regulatory approval process, the timing of our regulatory filings and other matters that could affect the availability or commercial potential of our biosimilar drug candidates, as well as patent litigation. Coherus undertakes no obligation to update or revise any forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to Coherus' business in general, see Coherus' Quarterly Report on Form 10-K for the year ended December 31, 2016, filed with the Securities and Exchange Commission on March 13, 2017 and its future periodic reports to be filed with the Securities and Exchange Commission.

Neulasta® is a registered trademark of Amgen Inc.

CONTACT:
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Coherus BioSciences, Inc.

EXHIBIT 4

353 N. CLARK STREET CHICAGO, IL 60654-3456

JENNER & BLOCK LLP

April 11, 2017

Louis E. Fogel
Tel +1 312 923 2661
LFogel@jenner.com

CONFIDENTIAL

VIA EMAIL AND FIRST CLASS MAIL

Nick Groombridge, Esq.
Paul, Weiss, Rifkind, Wharton & Garrison LLP
1285 Avenue of the Americas
New York, NY 10019-6064

Re: Coherus BioSciences's Abbreviated Biologics License Application No. 761039

Dear Mr. Groombridge,

I write in regards to today's telephone conference pursuant to 42 U.S.C. § 262(*l*)(4).

This is to confirm that the parties agreed during the call that only U.S. Patent No. 8,273,707 will be included in the action for patent infringement under 42 U.S.C. § 262(*l*)(6), and that this action will be filed within 30 days of today.

Sincerely,

Louis E. Fogel

EXHIBIT 5

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

YODLEE, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 14-1445-LPS-CJB
	)	
PLAID TECHNOLOGIES INC.,	)	
	)	
Defendant.	)	
	)	

MEMORANDUM ORDER

Before the Court is a motion to stay the proceedings in the instant patent infringement case, filed by Defendant Plaid Technologies Inc. ("Defendant" or "Plaid"). (D.I. 30) Defendant seeks a stay pending resolution of its motion to dismiss, filed pursuant to Federal Rule of Civil Procedure 12(b)(6) ("motion to dismiss"). (D.I. 11) The motion to dismiss asserts that all claims of each of the seven patents-in-suit—United States Patent Nos. 6,199,077, 6,317,783, 6,510,451, 7,263,548, 7,424,520, 7,752,535, and 8,266,515 (collectively, the "patents-in-suit")—are patent-ineligible under 35 U.S.C. § 101 ("Section 101"). (D.I. 12 at 1) For the reasons set forth below, the motion to stay is DENIED.

I. BACKGROUND

A. Factual Background

Plaintiff Yodlee, Inc. ("Plaintiff" or "Yodlee") is a Delaware corporation with its principal place of business in Redwood City, California. (D.I. 1 at ¶ 2) Plaintiff is a provider of account aggregation services and personal financial management applications through software it developed. (*Id.* at ¶ 8) Plaintiff has three primary business segments: Data Analytics, Financial Institutions, and Yodlee Interactive. (D.I. 34 at ¶ 4) The Data Analytics segment "gives

businesses the ability to use large amounts of anonymized financial data to better understand and meet their customers' needs." (*Id.* at ¶ 5) The Financial Institutions segment provides services and products to financial institutions (such as banks and wealth management companies), including the Yodlee Platform, which is a "cloud-based platform [that] allows financial institutions to offer services and applications to their customers with functionality such as data aggregation, financial management, money movement, and bank-grade security." (*Id.* at ¶ 6) The third segment, Yodlee Interactive, provides entrepreneurs, partners and developers with access to Plaintiff's platform and Application Programming Interfaces ("APIs"). (*Id.* at ¶ 7) Yodlee Interactive APIs provide these users with "the ability to leverage Yodlee's data collection platform and related capabilities to acquire rich and meaningful data sets from their customers' current bank, credit card, investment, and loan accounts, as well as bills, insurance rewards programs, and other financial and quasi-financial accounts." (*Id.*)

Defendant is a Delaware corporation with its principal place of business in San Francisco, California. (D.I. 1 at ¶ 3) Defendant is alleged to infringe the patents-in-suit by offering "a competing software . . . API . . . that allows users and developers to interact with financial institutions." (*Id.* at ¶ 3; *see also id.* at ¶ 19) Its platform, *inter alia*, enables developers to create an application that: (1) authenticates a user's account information; and (2) retrieves financial account information from a financial institution on behalf of a specific single user. (D.I. 31 at 3 & ex. D)

B. Procedural Background

On December 1, 2014, Plaintiff filed this infringement suit seeking, *inter alia*, monetary relief and a permanent injunction against Defendant for any infringement of the patents-in-suit.

(D.I. 1 at 18-20) On December 4, 2014, Chief Judge Leonard P. Stark referred the case to this Court for certain purposes, including to resolve all motions to dismiss, stay, and/or transfer venue. (D.I. 7) Defendant filed the above-referenced motion to dismiss on January 23, 2015. (D.I. 11) A case management conference was held thereafter, and on May 8, 2015, the Court entered a scheduling order. (D.I. 26) A jury trial is scheduled for March 13, 2017. (*Id.* at ¶ 22)

On May 18, 2015, Defendant filed the motion to stay. (D.I. 30) That motion was fully briefed as of June 8, 2015. (D.I. 39)

II. STANDARD OF REVIEW

A court has discretionary authority to grant a motion to stay. *See Cost Bros., Inc. v. Travelers Indem. Co.*, 760 F.2d 58, 60-61 (3d Cir. 1985); *see also Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1426 (Fed. Cir. 1988) ("Courts have inherent power to manage their dockets and stay proceedings[.]") This Court has typically considered three factors when deciding a motion to stay: (1) whether granting the stay will simplify the issues for trial; (2) the status of the litigation, particularly whether discovery is complete and a trial date has been set; and (3) whether a stay would cause the non-movant to suffer undue prejudice from any delay, or allow the movant to gain a clear tactical advantage. *See, e.g.*, *FMC Corp. v. Summit Agro USA, LLC*, Civil Action No. 14-51-LPS, 2014 WL 3703629, at *2 (D. Del. July 21, 2014); *Cooper Notification, Inc. v. Twitter, Inc.*, Civ. No. 09-865-LPS, 2010 WL 5149351, at *1 (D. Del. Dec. 13, 2010).

III. DISCUSSION

The Court will analyze the three stay factors in turn.

A. Simplification of Issues for Trial

When considering a motion to stay, the Court must assess whether a stay will "simplify

the issues [in question] and trial of this case." *Graphic Props. Holdings, Inc. v. Toshiba Am. Info., Sys., Inc.*, C.A. No. 12-213-LPS, 2014 WL 923314, at *2 (D. Del. Mar. 5, 2014). In assessing that question, our Court has considered how the possible outcomes of the proceeding or inquiry that the case would be stayed in favor of (here, the motion to dismiss) would affect the prospects for simplification. *Kaavo, Inc. v. Cognizant Tech. Solutions Corp.*, Civil Action Nos. 14-1192-LPS-CJB, 14-1193-LPS-CJB, 2015 WL 1737476, at *1 (D. Del. Apr. 9, 2015). In so doing, the Court cannot solely focus on the potential outcome most favorable to the party seeking the stay; instead, it must assess "*all* of the possible outcomes of the proceeding or inquiry that the case would be stayed in favor of[.]" *Kaavo*, 2015 WL 1737476, at *2; *see SenoRx v. Hologic, Inc.*, Civ. Action No. 12-173-LPS-CJB, 2013 WL 144255, at *3 (D. Del. Jan. 11, 2013) (considering how the case would be simplified if any of "three possible outcomes" of a reexamination proceeding occurred, and finding that "[w]hatever outcome occurs, there is the potential for the simplification of issues for trial") (citing *Abbott Diabetes Care, Inc. v. DexCom, Inc.*, C.A. No. 06-514 GMS, 2007 WL 2892707, at *5 (D. Del. Sept. 30, 2007)).

On the one hand, as Defendant points out, "if the Court grants the motion to dismiss [as to all asserted claims of all asserted patents], the case will simply go away and any discovery expense in the meantime will be a pure waste." (D.I. 31 at 6) If one could be sure that the motion to dismiss would be granted in this fashion, that would certainly favor a stay. *Cf. Mann v. Brenner*, 375 F. App'x 232, 239 (3d Cir. 2010) (noting that the Court has the discretion to conclude that it is "appropriate to stay discovery while evaluating a motion to dismiss where, if the motion is granted, discovery would be futile."); *see also Levey v. Brownstone Inv. Grp., LLC*, 590 F. App'x 132, 137 (3d Cir. 2014). At the other extreme, were the motion to dismiss

ultimately to be denied as to all asserted claims and patents, little efficiency gain would be realized. The issue of patent eligibility might be resolved as to some patents or patent claims, but the parties and the Court could potentially face the issue again at the summary judgment stage.[1] Meanwhile, no progress would have been made on any other claim or defense in the case.

In terms of assessing possible or probable outcomes, here the Court finds it particularly relevant that Plaintiff is asserting seven patents, containing 162 claims. The sheer number of asserted patents and asserted claims that will be at issue suggests that it is reasonable to infer that here (as opposed to, for example, a one-patent case involving a handful of challenged claims) there is a greater likelihood[2] that a portion of the case will survive the motion to dismiss. (*See* D.I. 33 at 9) It is true, as Defendants assert, that were even some claims or patents subject to dismissal, that would "narrow the dispute between the parties." (D.I. 31 at 6) But as to the claims and patents that remain, the majority of legal and factual issues will still be pending and

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[1] The patent eligibility question might arise again in the summary judgment context if, for example, the Court were to deny the motion to dismiss on the basis that: (1) issues of fact exist that require further development through discovery; or (2) claim construction is needed before the question of patent eligibility can be definitively resolved. Defendant suggests that if the Court identifies a "claim construction dispute that may be dispositive as to eligibility, the case will narrow to that dispute; there will be no other 'pending and unaddressed' 'legal issue[].'" (D.I. 39 at 2) But that is not the case. Even if the Court were to hold that the claims could be patent ineligible under certain constructions, and Defendant were to offer those constructions during the claim construction process, there is no guarantee that Defendant would prevail. And if it did not prevail on those issues at the *Markman* stage, then any number of "legal issue[s]" relating to those patent claims—as to infringement, invalidity, etc.—would remain squarely on the table in the case.

[2] The Court has previously concluded, after reviewing case law on the subject, that in evaluating a motion to stay, it is not required to decide the legal merits of the pending motion (here the motion to dismiss) that is the impetus for the stay request. *See Kaavo*, 2015 WL 1737476, at *2 n.4 (citing cases). And so, in concluding that there is a real probability that the motion to dismiss will not turn out to be fully dispositive, the Court is not in any way addressing the actual merits of the motion to dismiss.

unaddressed, and a stay will have harmed the efficient progress of that portion of the case, not helped it. *Cf. Ever Win Int'l Corp. v. Radioshack Corp.*, 902 F. Supp. 2d 503, 507 (D. Del. 2012) (noting, in light of the fact that many issues in the district court case would not be raised in an *inter partes* reexamination proceeding, that "if some or all of the claims emerge from reexamination, a not insignificant portion of the case will remain unilluminated by the PTO's review").[3]

Ultimately, in light of the large number of patents involved in this case, the simplification question seems about evenly balanced. The chance that a stay might lead to the total dismissal of the case, or to a very significantly narrowed set of claims or legal issues, seems roughly similar to the chance that it would not. The Court finds this factor to be neutral.

B. Status of Litigation

A motion to stay is most often granted when the case is in the early stages of litigation. *See Abbott Diabetes Care, Inc.*, 2007 WL 2892707, at *5 (staying litigation where no Rule 16 scheduling conference had occurred, a scheduling order had not been entered, discovery had not

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[3] In assessing the "simplification" factor, the Court is also impacted by Chief Judge Stark's "Revised Procedures for Managing Patent Cases." In that document, Chief Judge Stark notes that "[g]enerally, we will not defer the [Case Management Conference] and scheduling process due to the pendency of" a motion to dismiss, transfer or stay. Honorable Leonard P. Stark, Revised Procedures for Managing Patent Cases (June 18, 2014), at 6, *available at* http://www.ded.uscourts.gov/judge/chief-judge-leonard-p-stark (follow "New Patent Procedures" tab; then download "Patent Procedures" document). This procedure certainly 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. But the Court reads it as expressing the District Court's preference that, in the main, cases on its docket should move forward. Put in terms relevant to the simplification factor, this procedure suggests that when 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).

begun, and "little time [had] yet to be invested in the litigation"). Conversely, in the later stages of a case (such as when discovery is complete or nearly complete), a stay is less likely to be granted as "the Court and the parties have already expended significant resources on the litigation, and the principle of maximizing the use of judicial and litigant resources is best served by seeing the case through to its conclusion." *SenoRx*, 2013 WL 144255, at *5.

As of the date when the motion to stay was filed,[4] the Court had (albeit recently) held a Case Management Conference, resolved disputes regarding the proposed Scheduling Order, and heard argument on the motion to dismiss. (D.I. 19, 23-26) The Scheduling Order and a Protective Order had been entered, and discovery had begun. (D.I. 26, 27) Yet despite this, as even Plaintiff acknowledges, the litigation is in its "early stages[.]" (D.I. 33 at 10) The bulk of fact discovery, as well as the entirety of the expert discovery, claim construction and summary judgment processes, will not be implicated for many months. Although the parties may have "expended more than a *de minimis* amount of effort on the litigation thus far[,]" this factor favors a stay. *SenoRx*, 2013 WL 144255, at *6; *see also ImageVision.Net, Inc. v. Internet Payment Exch., Inc.*, C.A. No. 12-054-GMS-MPT, 2012 WL 3866677, at *2 (D. Del. Sept. 4, 2012) (finding that this factor "favor[ed] a stay" where a scheduling order had been entered and a first set of document requests and interrogatories had been served), *report and recommendation*

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[4] *Cf. VirtualAgility Inc. v. Salesforce.com, Inc.*, 759 F. 3d 1307, 1317 (Fed. Cir. 2014) (noting, as to review of a motion to stay filed in favor of a petition for post-grant review submitted as part of the Transitional Program for Covered Business Method Patents, that "[g]enerally, the time of the motion [to stay] is the relevant time to measure the stage of litigation[,]" though acknowledging that there may be circumstances where a district court should consider evidence arising after that date); *see also SenoRx*, 2013 WL 144255, at *6 & n.5. Since the motion to stay was filed, the parties have proceeded forward with discovery, and some discovery disputes have arisen. (D.I. 41, 43, 44, 46, 47) But even were the Court to take these facts into account here, its decision as to the "timing" factor would remain unchanged.

adopted in part, Civil Action No. 12-054-GMS-MPT, 2012 WL 5599338 (D. Del. Nov. 15, 2012); *cf. Kaavo*, 2015 WL 1737476, at *1-4 (finding that this factor strongly favored a stay where a motion to stay had been filed prior to the Court's Case Management Conference, where a scheduling order had not yet been entered, and where discovery had not yet begun at all).

C. Undue Prejudice

The parties make a number of arguments as to the "undue prejudice" factor, which the Court addresses below.

1. Relationship of the Parties

Much of the parties' discussion as to this final factor is focused on assessing the relationship of the parties—a subfactor that is often very important in the stay calculus. (D.I. 31 at 8-10; D.I. 33 at 5-7; D.I. 39 at 3-5) This subfactor typically involves consideration as to whether the parties are direct competitors. *See, e.g.*, *Kaavo*, 2015 WL 1737476, at *3; *SenoRx*, 2013 WL 144255, at *7; *Cooper Notification*, 2010 WL 5149351, at *5.

"It is well established that courts are generally reluctant to stay proceedings where the parties are direct competitors." *ImageVision.Net, Inc. v. Internet Payment Exch., Inc.*, C.A. No. 12-054-GMS-MPT, 2013 WL 663535, at *6 (D. Del. Feb. 25, 2013) (internal quotation marks and citations omitted), *report and recommendation adopted*, 2013 WL 1743854 (D. Del. Apr. 22, 2013). Courts have recognized that when the parties are direct competitors, there is a reasonable chance that delay in adjudicating the alleged infringement will have outsized consequences to the party asserting that infringement has occurred—including the potential for loss of market share and an erosion of goodwill. *See, e.g.*, *Nexans Inc. v. Belden Inc.*, C.A. No. 12-1491-SLR-SRF, 2014 WL 651913, at *3 (D. Del. Feb. 19, 2014); *SenoRx*, 2013 WL 144255, at *7 (citing *Nat'l*

Prods., Inc. v. Gamber-Johnson LLC, No. 2:12-cv-00840, 2012 WL 3527938, at *2-3 (W.D. Wash. Aug. 14, 2012)).

Defendant argues that it and Plaintiff "focus on different markets[,]" with Plaintiff "provid[ing] *end-users* with the ability to aggregate their accounts" while Defendant "markets back-end solutions to *developers*." (D.I. 31 at 8 (emphasis in original)) Plaintiff, however, has put forward significant record evidence demonstrating that it directly competes with Defendant—at least with regard to the Financial Institution and Yodlee Interactive segments of Plaintiff's business.

More specifically, Plaintiff made of record a sworn Declaration submitted by Joseph Polverari, its Chief Strategy and Development Officer, who represents that he has direct involvement with Plaintiff's sales and account management processes. (D.I. 34 at ¶¶ 7, 13) Mr. Polverari represents that Plaintiff's Yodlee Interactive platform is offered to "developers[,]" and that "Plaid competes against Yodlee Interactive APIs and also competes against Yodlee for Financial Institution customers." (*Id.*) In support, Mr. Polverari first lists two specific customers [redacted] Next, he cites by name a company [redacted] Mr. Polverari then goes on to reference by name four large corporations who are currently [redacted] He next cites another specific company [redacted]

[redacted] Next, Mr. Polverari references 11 companies by name that [redacted]

[redacted] Lastly, he lists three specific corporate customers as to which, [redacted]

Plaintiff also cites to an archived webpage, dated April 10, 2015, found on the website

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[5] Some of the arguments that Defendant puts forward to counter the force of Mr. Polverari's declaration fall flat. For example, Defendant relies primarily on *Smarter Agent, LLC v. Mobilerealtyapps.com, LLC*, 889 F. Supp. 2d 673, 676 (D. Del. 2012), to argue that Mr. Polverari's declaration is "self-serving" and thus "'unpersuasive.'" (D.I. 39 at 3) *Smarter Agent*, however, is easily distinguishable. There, this Court found that a declaration submitted by the plaintiff's Chief Executive Officer, offered in order to bolster plaintiff's claims of prejudice were a stay granted, was "largely conclusory" and amounted to "generalized allegations[.]" *Smarter Agent*, 889 F. Supp. 2d at 676. The *Smarter Agent* Court focused on the fact that the CEO's declaration included almost no "names" of persons or entities said to be associated with the allegations set out therein. Here, in contrast, Mr. Polverari has offered specifics. His declaration lists no fewer than 22 specifically-named companies (some of them very large institutions) [redacted] That kind of specificity (at least as to customer identification) is what a court hopes to see when reviewing these kinds of motions, but rarely gets.

Defendant also argues that "the two customers [that] Yodlee asserts Plaid outcompeted it for have earned Plaid only" a modest amount of revenue, especially as compared to the very large amount of revenue that Plaintiff earned in 2014 alone. (D.I. 39 at 3 (citing D.I. 31, exs. A & B)) While the amount of revenue that these two customers brought Defendant is certainly relevant to the prejudice inquiry, it is not the only relevant issue. Also relevant would be the answers to questions such as: (1) How much revenue would these two customers have earned Plaintiff had they not departed for Defendant?; (2) What amount of revenue does Plaintiff stand to lose, were some or all of the customers that Mr. Polverari cites as Plaid targets to actually switch to Plaid?; or (3) What does this evidence suggest about whether Yodlee might lose more customers to Plaid in the future? Mr. Polverari's declaration provides insight into some of these questions. But it also underscores that the amount of revenue Plaid has to date obtained at Yodlee's expense is not the only fact relevant to this inquiry.

www.quora.com. On that webpage, a writer asks "What are some alternatives to Yodlee for accessing bank information?" (D.I. 35, ex. C) One of the posted answers was written by Defendant's co-founder Zach Perret. In it, Mr. Perret advises the questioner to "check out Plaid[.]" (*Id.*; *see also* D.I. 33 at 3) Mr. Perret goes on to explain to another commenter how to get access to Plaid. (D.I. 35, ex. C)[6] Defendant argues that these posts are not relevant to the question of competition, (D.I. 39 at 4), but that argument is weak. One would be hard-pressed to conceive of a better example of "direct competition" evidence than a document in which one defendant's leaders identifies its products or services as an "alternative" to the plaintiff's products or services in the relevant sphere.

Additionally, it is worth noting that Plaintiff and Defendant are not strangers to each other; indeed, the evidence suggests that the two parties have had significant past interactions regarding Plaintiff's technology. In 2012, Defendant's co-founders evaluated Plaintiff's technology, and considered whether to take a license to Plaintiff's aggregation APIs. (D.I. 1 at ¶¶ 10-15; D.I. 31 at 3; D.I. 34 at ¶ 9) This led, in early 2013, to execution of a one-year agreement between the parties (an agreement that was terminated a few months later), in which Defendant was to license certain of Plaintiff's services. (D.I. 1 at ¶¶ 16-18; D.I. 34 at ¶ 10) The fact that Defendant was evaluating Plaintiff's API-related technology further suggests that the parties are participants in the same relevant business area.

For its part, Defendant includes exhibits demonstrating that Plaintiff also competes with various other companies. (D.I. 31, ex. B at 19; *id.*, ex. H); *cf. Neste Oil OYJ v. Dynamic Fuels,*

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[6] According to Plaintiff, a June 1, 2015 printout of the same portion of this website no longer includes Mr. Perret's answer. (D.I. 35, ex. D; *see also* D.I. 33 at 3 n.4)

LLC, Civil Action No. 12-1744-GMS, 2013 WL 3353984, at *3-4 (D. Del. July 2, 2013) ("The presence of multiple active firms in the relevant market . . . may decrease the likelihood of . . . harm befalling the plaintiff.") What is less clear from these documents, however, is how many competitors there are in the particular markets in which Defendant has been shown to compete with Plaintiff. It is at least helpful to Defendant that two of the documents it submits (Yodlee's Form 10-K for the period ending in December 2014, and a May 2015 Yodlee "Company Overview") contain sections specifically relating to competition—and that the competitors listed in those sections do not include Defendant. (D.I. 31, ex. B at 19; *id.*, ex. I at 16) But it is not clear that these documents were intended to be comprehensive lists, nor that they are directed to all of the market segments in which the parties are alleged to compete.[7]

Defendant also asserts that Plaintiff's failure to seek a preliminary injunction against it is evidence of the fact that parties are not competitors. (D.I. 31 at 9) It is true that "[w]here the question of 'direct competition' remains unanswered, courts have sometimes considered whether the plaintiff sought a preliminary injunction." *Neste Oil Oyj v. Dynamic Fuels, LLC*, Civil Action No. 12-662-GMS, 2013 WL 424754, at *3 (D. Del. Jan. 31, 2013). And here, though Plaintiff did seek injunctive relief in its Complaint, (D.I. 1 at 19), it has not moved for a preliminary injunction. That fact amounts to a data point the Court can consider in assessing the question of competition, *see Ever Win*, 902 F. Supp. 2d at 511, though not one that is dispositive,

[7] Indeed, in another portion of the Form 10-K, Plaintiff describes the instant suit in a section relating to alleged intellectual property misappropriation by "our competitors[.]" (D.I. 31, ex. B at 33)

see SenoRx, 2013 WL 144255, at *8.[8]

In sum, it is at least clear from the Complaint that Plaintiff is accusing Defendant's software that "provide[s] account aggregation and personal financial management services to its customers" as infringing the patents-in-suit, (D.I. 1 at ¶ 21), and that some of Defendant's products in that realm compete with Plaintiff's platform and APIs. There is also multi-faceted evidence (particularly from Mr. Polverari's Declaration) that this competition has financially harmed Plaintiff in the past and will likely continue to do so in the future. The scope of these markets and how seriously such competition threatens Plaintiff is, admittedly, less clear. But in the end, Plaintiff's evidence of competition was stronger and more specific than Defendant's evidence to the contrary. In such a circumstance, the Court concludes that Plaintiff has demonstrated the potential for some amount of undue prejudice were a stay granted, due to the likelihood of competitive impact. This subfactor will work against the grant of a stay. *See, e.g.*, *Davol, Inc. v. Atrium Med. Corp.*, Civil Action No. 12-958-GMS, 2013 WL 3013343, at *3-5 (D. Del. June 17, 2013) (holding that this factor "weighs against granting a stay" where Plaintiff "demonstrated that it is a direct competitor of [Defendant] in a limited market."); *ImageVision.Net*, 2012 WL 3866677, at *4 (finding that "direct competition" between the parties as to particular products "strongly favor[ed] denying [the] motion for a stay").

2. Other Subfactors Relating to Undue Prejudice

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[8] Defendant additionally claims that Plaintiff delayed in filing suit subsequent to the issuance of the patents-in-suit, and that this fact further suggests that the parties do not significantly compete. (D.I. 31 at 10) But the evidence is that as of 2013, Defendant was Plaintiff's customer, and did not begin selling infringing products in competition with Plaintiff until thereafter. (D.I. 33 at 7 (citing D.I. 34 at ¶¶ 9-11)) In light of that, the Court does not find any "delay" in filing suit here to be particularly relevant.

Defendant makes several other arguments regarding the "undue prejudice" factor. For example, Defendant argues that there will be only a "short" delay if a stay is granted, because briefing on the motion to dismiss has already been completed and the Court has already heard oral argument. (D.I. 31 at 7) Yet considering the Court's docket, even though that motion is fully briefed and argued, it may still take some months for it to be resolved. While the potential for delay alone "does not, by itself, amount to undue prejudice[,]" *Ever Win*, 902 F. Supp. 2d at 509 (citation omitted), it is a subfactor the Court can consider. The likelihood of some real delay here also favors Plaintiff's position.

Defendant next asserts that because it is a small start-up that lacks its own legal team, it would suffer undue prejudice by having to "interrupt" its operations to handle discovery obligations were the case not stayed. (D.I. 31 at 10) Our Court has at times explicitly considered whether the *moving party* would face undue hardship or inequity in the absence of a stay, explaining that such an inquiry would be relevant to the "prejudice" factor if there is "even a fair possibility that the stay . . . will work damage to [another party]." *ImageVision.Net, Inc.*, 2012 WL 5599338, at *3 (quoting *Landis v. N. Am. Co.*, 299 U.S. 248, 255 (1936)) (additional citations omitted).[9] Where such a "fair possibility" has been established (as here), then the moving party ought to demonstrate that the denial of a stay would result in a "clear case of

[9] *See also Cooper Notification*, 2010 WL 5149351, at *2 (citing *Landis* and noting that "a showing of hardship or inequity is 'generally' needed [to demonstrate] that the balance of equities favors a stay" but also that such a showing is not required, as "circumstances may arise in which the overall balance could be tipped in favor of a stay even if proceeding with the litigation will cause no undue hardship or prejudice to the party seeking a stay").

hardship or inequity." *Landis*, 299 U.S. at 255; *see also SenoRx*, 2013 WL 144255, at *9 n.12.[10] Defendant has failed to make out that case. It cites to no evidence specific to its company (such as an affidavit from one of its employees) in support of its claim that, were it required to go forward and defend the suit, this would severely disrupt its operations. (D.I. 31 at 5-10) In the absence of any such evidence, the Court cannot give weight to Defendant's argument here.

Lastly, Defendant notes that the timing of its motion to stay does not suggest any improper "'dilatory intent'" on its part. (D.I. 31 at 7-8 (citing *Neste Oil*, 2013 WL 3353984, at *2)). Defendant is correct—it made clear its intent to seek a stay from the outset of the litigation, and it filed the stay motion at an early stage. (D.I. 31 at 3-4)

3. Conclusion as to Undue Prejudice

The combination of the real prospect of competitive harm to Plaintiff if a stay is granted, coupled with the delay that such a stay would entail, together indicate that the "undue prejudice" factor should weigh against a stay.

III. CONCLUSION

On balance, the possibility of simplification of the issues is neutral, the status of the litigation weighs squarely in favor of a stay, and the prospect of undue prejudice weighs squarely against a stay. While reasonable minds could disagree as to the right outcome, the Court is ultimately persuaded that the prospect for harm to Plaintiff were a stay granted is the most compelling factor here. Therefore, the motion to stay is DENIED.

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[10] Our Court has found that added litigation cost that would be incurred if a stay is denied does not amount to the kind of "undue" hardship or inequity that is referenced in the case law. *See Personalized User Model, L.L.P. v. Google, Inc.*, C.A. No. 09-525-LPS, 2012 WL 5379106, at *2 (D. Del. Oct. 31, 2012).

Because this Memorandum Order may contain confidential information, it has been released under seal, pending review by the parties to allow them to submit a single, jointly proposed, redacted version (if necessary) of the Memorandum Order . Any such redacted version shall be submitted no later than **July 28, 2015** for review by the Court, along with a clear, factually detailed explanation as to why disclosure of any proposed redacted material would "work a clearly defined and serious injury to the party seeking closure." *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 786 (3d Cir. 1994) (internal quotation marks and citation omitted). The Court will subsequently issue a publicly-available version of its Memorandum Order.

Dated: July 20, 2015

Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE

EXHIBIT 6

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COHERUS BIOSCIENCES, INC.,
Petitioner,

v.

HOFFMANN-LAROCHE INC.,
Patent Owner.

Patent No. 8,163,522

PETITION
to Institute an *Inter Partes* Review of U.S. Patent No. 8,163,522
under 37 C.F.R. § 42.100 et seq.

Mail Stop PATENT BOARD
Patent Trial and Appeal Board
United States Patent and Trademark Office
PO Box 1450
Alexandria, Virginia 22313–1450
Submitted Electronically via the PTAB E2E

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e)(4) and 42.105(a), the undersigned certifies that on August 4, 2017, a complete and entire copy of the foregoing Coherus BioSciences, Inc.'s **Petition to Institute an *Inter Partes* Review of U.S. Patent No. 8,163,522 under 37 C.F.R. § 42.100 *et seq.***, along with **Exhibits 1001-1058** and **Petitioner's Power of Attorney**, were served, via Federal Express overnight courier, on the following counsel of record for Patent Owner:

Amgen Inc.
Law – Patent Operations, M/S 28-2-C
One Amgen Center Drive
Thousand Oaks, CA 91320-1799

Dated: August 4, 2017

/s/ Erik van Leeuwen

Erik van Leeuwen
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EXHIBIT 7

NEWS RELEASE

COHERUS BIOSCIENCES FILES PETITION FOR INTER PARTES REVIEW OF ENBREL® PATENT 8,163,522

REDWOOD CITY, Calif., Aug. 07, 2017 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. (Nasdaq:CHRS), today announced that it has filed a petition for Inter Partes Review ("IPR") in the United States Patent and Trademark Office seeking invalidation of U.S. Patent 8,163,522 (" '522 patent"). The '522 patent, controlled by Amgen, is generally directed to a method for making etanercept, the pharmaceutically active component of ENBREL®. Coherus also announced its intention to file an IPR in the near future seeking invalidation of related U.S. Patent 8,063,182 (" '182 patent"), also controlled by Amgen and generally directed to the etanercept protein.

Dennis M. Lanfear, President and CEO of Coherus noted, "*The '182 and '522 patents do not expire until 2028 and 2029. This could result in over 30 years of patent coverage for Enbrel*." Mr. Lanfear added, "*We believe this is an anti-competitive and unjustified distortion in our patent system that threatens to inflict another dozen years of massive costs on the healthcare system given Amgen's history of substantial price increases for this drug which already total over 400% since launch.*" Mr. Lanfear further added, "*Fortunately, there are compelling grounds why these patents should never have issued, and we are advancing these arguments in both the '522 IPR, filed today, and the '182 IPR which will follow shortly. Biosimilars are an essential drug cost control mechanism for the healthcare system, and challenging these patents in IPR aligns with our decision to refocus the priorities of our etanercept biosimilar program, CHS-0214, on the potential U.S. opportunity, delivering much needed savings.*"

About Coherus BioSciences, Inc.

Coherus is a leading pure-play, global biosimilar company that develops and commercializes high-quality therapeutics for major regulated markets. Biosimilars are intended for use in place of existing, branded biologics to treat a range of chronic and often life-threatening diseases, with the potential to reduce costs and expand patient access. Composed of a team of proven industry veterans with world-class expertise in process science, analytical characterization, protein production, sales & marketing and clinical-regulatory development, Coherus is positioned as a leader in the global biosimilar marketplace. Coherus is advancing three late-stage clinical products towards commercialization, CHS-1701 (pegfilgrastim biosimilar), CHS-0214 (etanercept biosimilar) and CHS-1420 (adalimumab biosimilar), as well as developing a robust pipeline of future products in four therapeutic areas, oncology, immunology (anti-TNF), ophthalmology and multiple sclerosis. For additional information, please visit www.coherus.com.

Forward-Looking Statements

Except for the historical information contained herein, the matters set forth in this press release, including statements regarding Coherus' plans, potential opportunities including market opportunities, goals, objectives, strategies, product pipelineare forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including Coherus' ability to invalidate the '522 or the '182 patents as a result of its IPR petitions. Such forward-looking statements involve substantial risks and uncertainties that could cause our clinical development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in the clinical drug development process, including the regulatory approval process, the timing of our regulatory filings and other matters that could affect the availability or commercial potential of our biosimilar drug candidates, as well as possible patent litigation. Coherus undertakes no obligation to update or revise any forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to Coherus' business in general, see Coherus' Quarterly Report on Form 10-Q for the quarter ended June 30, 2017, filed with the Securities and Exchange Commission on August 7, 2017 and its future periodic reports to be filed with the Securities and Exchange Commission.

ENBREL® is a registered trademark of Immunex Corporation

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EXHIBIT 8

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SUPERIOR COURT OF THE STATE OF CALIFORNIA

IN AND FOR THE COUNTY OF VENTURA

AMGEN INC. and AMGEN USA, INC.,

Plaintiffs,

v.

COHERUS BIOSCIENCES, INC., KBI BIOPHARMA INC., HOWARD WEISER, and DOES 1-20,

Defendants.

Case No. 56-2017-00493553-CU-BT-VTA

DISCOVERY MOTION AND SUPPORTING PAPERS FILED UNDER SEAL AND WITHOUT ANY FURTHER SEALING ORDER REQUIRED (CAL. RULES OF COURT 2.550 AND 2.551)

DEFENDANT COHERUS BIOSCIENCES, INC.'S NOTICE OF MOTION AND MOTION FOR STAY

Date: August 3, 2017
Time: 8:30 a.m.
Dept: 40
Judge: Hon. Mark S. Borrell
RES ID: 2259588
Date Filed: March 3, 2017
Trial Date: Not Assigned

[PUBLICLY FILED REDACTED VERSION]

NOTICE OF MOTION

TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE THAT on August 3, 2017 at 8:30 a.m., or as soon thereafter as this matter may be heard in the above-entitled Court located at 800 s. Victoria Avenue, Ventura, California 93009, Defendant Coherus Biosciences, Inc. will move this Court for a Case Management Order staying this action pending the Food and Drug Administration's decision whether to reconsider Coherus's Biosimilar License Application.

This motion is based upon this Notice, the Memorandum of Points and Authorities in Support thereof, the Declarations of Benjamin Rothstein and Michael Fleming, the complete files and records in this action, and such other evidence as may be allowed at the hearing of this motion.

Dated: July 6, 2017

KEKER, VAN NEST & PETERS LLP

Stuart L Gasner (BDR)

By: John W. Keker
Stuart L. Gasner
Brian L. Farrell
Eric H. MacMichael

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RINCON VENTURE LAW GROUP
K. Andrew Kent

Attorneys for Defendant COHERUS BIOSCIENCES, INC.

[redacted]

In this context, the commercial case is premature at best and should be stayed until the FDA at least indicates it will consider Coherus for a launch in 2018. Yet, following the announcement of the CRL, Amgen pushed forward its commercial discovery efforts. On June 16, it moved to compel a complete response to its Special Interrogatory No. 4, which requests Coherus to narrate *every* "meeting or conversation" between *any* Coherus employee (there are dozens) and *any* "customer or potential customer" (there are hundreds) regarding Neupogen®, Neulasta®, or CHS-1701, occurring at any time since July 1, 2015. It thus encompasses hundreds if not thousands of "meetings and conversations," the subject matter of which dramatically exceeds the scope of Amgen's trade secret disclosure. Amgen claims that this request is relevant "to show the scope and nature of Coherus's misappropriation." Rothstein Dec. Ex. 12 at 10. But even if those conversations were somehow tainted by Amgen's purported trade secret information—they were *not*—the conversations would be completely inconsequential because Coherus has now shut down customer discussions.

On the technical side of the case, Amgen is pressing for virtually every technical document at Coherus, even though it has more than enough information at this point to know if Coherus's manufacturing process utilizes Amgen's trade secrets (it does not). For example, Amgen has moved to compel responses to its RFP Nos. 2 and 5 that, together, call for all "non-privileged communications" among Coherus's scientists "related to" Coherus's entire manufacturing process, dating back to Coherus's "pilot" stage development of CHS-1701 beginning in September 2011. Coherus has objected to these requests as massively overbroad, because their subject matter is essentially unbounded, and they seek documents dating back to

Respectfully submitted,

Dated: July 6, 2017

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Coherus Biosciences, Inc. NasdaqGM:CHRS

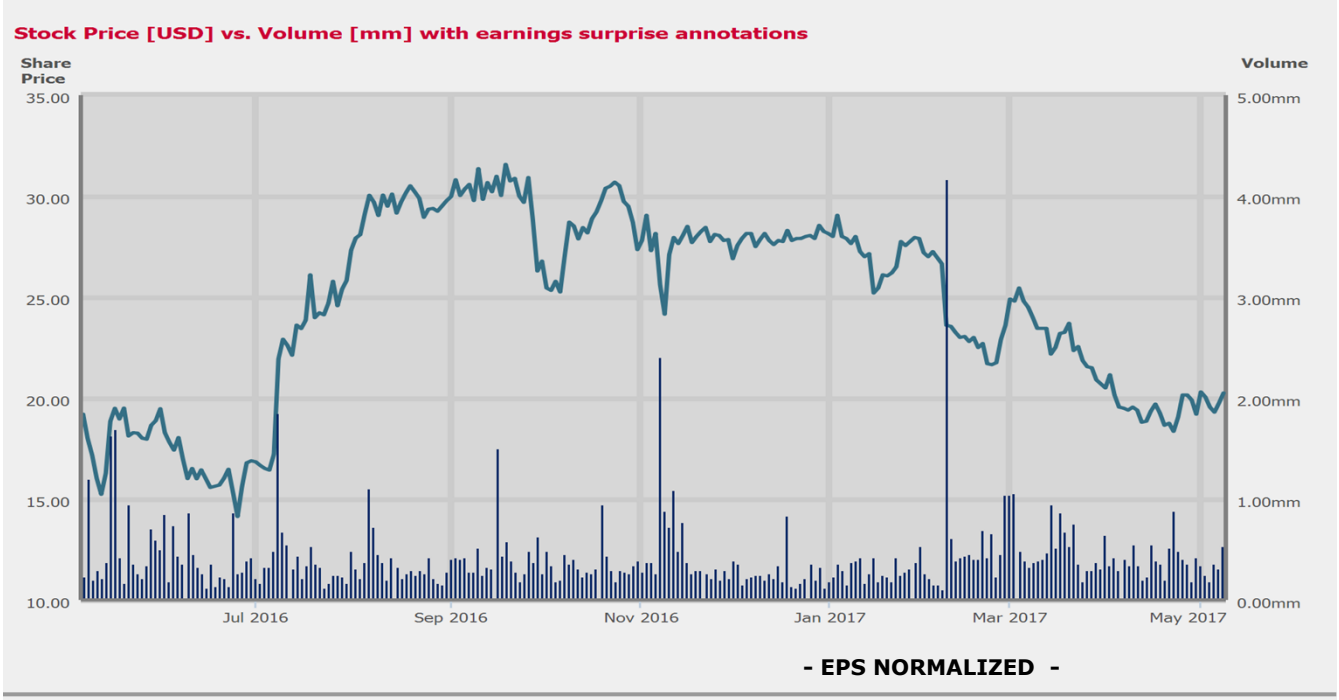
FQ2 2017 Earnings Call Transcripts

Monday, August 07, 2017 8:30 PM GMT

S&P Capital IQ Estimates

	-FQ2 2017-			-FQ3 2017-	-FY 2017-	-FY 2018-
	CONSENSUS	ACTUAL	SURPRISE	CONSENSUS	CONSENSUS	CONSENSUS
EPS Normalized	(1.39)	(1.08)	NM	(0.74)	(4.44)	(2.31)
Revenue (mm)	5.17	1.40	▼ (72.92 %)	14.40	36.91	36.94

Currency: USD
Consensus as of Jun-27-2017 3:25 AM GMT



- EPS NORMALIZED -

	CONSENSUS	ACTUAL	SURPRISE
FQ2 2016	(1.31)	(1.72)	NM
FQ3 2016	(1.57)	1.67	NM
FQ4 2016	(1.34)	(1.71)	NM
FQ1 2017	(1.43)	(1.54)	NM

Call Participants

EXECUTIVES

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Chief Medical Officer

Dennis M. Lanfear
Chairman, Chief Executive Officer and President

Jean-Frédéric Viret
Chief Financial Officer

Matthew R. Hooper
Executive Vice President and General Counsel

Patrick O'Brien
Senior Vice President of Investor Relations

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Presentation

Operator

Ladies and gentlemen, thank you for standing by and welcome to the Coherus BioSciences Second Quarter Earnings Conference Call. My name is Katherine, and I will be your conference operator for today's call. [Operator Instructions] As a reminder, this conference call is being recorded.

I would now like to turn the call over to Patrick O'Brien, Senior Vice President of Investor Relations. Please go ahead.

Patrick O'Brien
Senior Vice President of Investor Relations

Thank you, Katherine, and good afternoon, everyone.

After close of market today, we issued a second quarter financial results press release. This release can be found on the Coherus BioSciences' website.

Joining me for today's call will be Dennis Lanfear, President, CEO and Chairman; Barbara Finck, Chief Medical Officer; Jean Viret, CFO; Matt Hooper, EVP and General Counsel; and Vladimir Vexler, EVP, Analytical and Translational Sciences.

Before we begin our formal remarks, I'd like to remind you that we will be making forward-looking statements with respect to product development plans, all of which involve certain assumptions, risks and uncertainties that are beyond our control and could cause actual results to differ from these statements. A description of these risks can be found in our most recent Form 10-Q on file with the SEC. In addition, Coherus BioSciences does not undertake any obligation to update any forward-looking statements made during this call.

I would now like to turn the call over to Dennis.

Dennis M. Lanfear
Chairman, Chief Executive Officer and President

Thank you, Patrick, and thank you all for joining us today.

Today, we'd like to talk about 3 key areas for you. First of all, we'll talk about our product development update, which, of course, will include an update on the CHS-1701 CRL. Secondarily, we will discuss our we recently filed IPR for Enbrel, and I'll be joined there by Matt Hooper, the company's General Counsel. Lastly, the company has made very good progress towards our financial goals and those will be presented by our CFO, Dr. Jean Viret.

Now, in terms of the CRL and the development of things there, I would point out that we have successfully completed redevelopment of the immunogenicity assay, including with backup capabilities, consistent with the expectations for higher sensitivity per the FDA's request. This assay is performing as required by the agency. The next step is assay validation, followed by the processing of the sample. We continue to anticipate a meeting with the FDA in Q3-Q4 2017 and scheduling is still pending, but timing will be aligned with BLA resubmission by the end of year as previously guided. We're happy to take additional questions during Q&A on this particular aspect of the complete response letter.

As you recall, the second part of the complete response letter addressed certain manufacturing and process-related requests. I'm happy to update you on progress there. Pursuant to those, we have made very good progress, consistent with our expectations and previous guidance, with respect to certain additional manufacturing and release testing reports and information as requested by FDA. As was indicated previously, we are compiling and correlating clinical data as requested and continue to believe this will be completed prior to [the other efforts]. That is to say, this remains off the critical path. We do not foresee and have not been requested to perform additional process qualification lots or other exercises which would exceed our currently planned timing.

Now, in terms of the next steps for the CRL, we will continue to guide to a late Q4 2017 BLA resubmission. We will inform you upon FDA acknowledgment of the resubmission, which should be 30 days after that date. And as you know, normal FDA review timing for this resubmission is 6 months.

Now, in terms of the 1701 MAA and European update, efforts on the EU and the U.S. filings are progressing in parallel. There are a few factors that are impacting the EMA review schedule and the timing for an anticipated positive opinion. First, certain inspections, which comprise the critical path for the review, are now scheduled for late summer and have been subject to EMA availability and their own scheduling constraints. Secondarily, let me point out that EMA and FDA appear to be taking similar approaches with respect to the immunogenicity study and data. Thus, we are currently harmonizing our approach and data sets globally with the regulators.

Secondly, as previously indicated, we anticipate completion of this harmonization by late 2017. We expect to have further discussions with EMA around timing and we'll update you accordingly. This global harmonization with both health authorities may place the EMA positive opinion in roughly the same time frame as the target FDA approval, but guidance is forthcoming.

Now, in terms of CHS-1420, the company's HUMIRA biosimilar, on the legal front, we've had a very good quarter. As you know, we successfully invalidated 3 AbbVie patents, '135, '680, and '987. We've also had some positive developments with the formulation IP portfolio, which I will cover subsequently.

In terms of 1420, we are targeting the BLA filing for late first half of 2018. And in terms of the change of the CMOs, we have now identified an alternative fill-finish facility for CHS-1420 where we have high confidence we'll meet our regulatory expectations. The MAA will occur directly after the U.S. filing. This is primarily because the same drug product CMO is being used to supply both the EU and the U.S. markets. We look forward to the September 12 institution decisions and the Patent Office on our 4 IPR petitions regarding AbbVie's '619 patent covering non-buffered formulations. These decisions are expected to impact ongoing partnering discussions. Also, the PTAB decisions on the '619 IPRs will inform our strategy regarding conduct of an additional human PK study, that is to say which formulation to use in that study.

Let me give you an update on the 1420 formulation. We are successfully advancing complex and robust adalimumab formulation patent portfolio to protect our innovations. We believe our patents will form a competitive advantage against other biosimilars seeking workarounds to the AbbVie patents. Our platform includes both buffered and non-buffered formulations.

In terms of the buffered formulations, we now have 5 issued U.S. patents and 3 more of our patent applications have been allowed and will issue in the coming months. For buffer-free formulations, we now have one issued U.S. patent with 6 additional allowed U.S. patent applications expected to issue soon covering a variety of non-buffered formulations. Four of these allowed applications will issue over the next 3 weeks and are generally directed to various combinations of excipients in a non-buffered adalimumab formulation. All of our published applications and patents are publicly available and can be viewed on the U.S. PTO website.

Now, as previously discussed, the company is prioritizing progress of 1701 and the 1420 filings.

For CHS-0214, the company's Enbrel biosimilar, we are refocusing on the U.S. market and the company's General Counsel, Matt Hooper, will discuss the IPR and that news momentarily. If our overall anti-TNF IP strategy is successful, obviously we could have 2 anti-TNF products in the most attractive market, that is here in the U.S. Let me remind you that clinical program for CHS-0214 has been conducted fully on the auspices of the U.S. FDA.

Now, the company's General Counsel, Matt Hooper, will discuss the Brockhaus IPR news and its implications for 0214. Matt?

Matthew R. Hooper
Executive Vice President and General Counsel

Thank you, Dennis.

On Friday, we filed an IPR against U.S. patent 8,163,522. This patent is owned by Roche, but is controlled exclusively by Amgen.

Before I comment on the IPR, I want to just provide a little bit of brief background. As I think you all know, the etanercept protein is a fusion protein that combines the TNFR receptor with the constant region of an IgG1 antibody. This was a follow-on development based on the original discovery of the TNFR receptor, which was discovered and patented by Smith and Immunex, covering the ability to block TNF alpha. These 2 patents are companion patents that are based on the same specification. The '522 patent is directed to a method of making this fusion protein and the '182 patent, which we expect to file shortly, is directed to the fusion protein itself.

Now, as you know, 2 years ago, Kyle Bass and Hayman Capital, under the entity of Coalition for Affordable Drugs, filed an IPR against the '522 patent. And I think a question that would come up is, what are we doing differently here? What deficiencies have we been able to correct in the Bass IPR?

First, I would point out that even Roche, the owner of the patent, admitted that the Bass IPR took a less than rigorous approach. We certainly agree. At a high level, our view of the deficiencies of the original IPR by Bass is that it did not identify the best prior art, which we believe we have. And the Bass IPR entirely failed to address the patent owner's argument that etanercept somehow achieves unexpected or surprising results.

Now, our IPR is fundamentally different in correcting these deficiencies. First, we rely on 2 prior art publications that CFAD failed to capitalize on. The publications that we use in the IPR demonstrate that it was, in fact, entirely obvious to build a fusion protein, like etanercept, using the exact portion of the IgG constant region as described in the '522 patent. That was a failing that the Board identified in Bass' petition and I think we have thoroughly corrected that. Secondly, there was a deficiency in that the Bass IPR failed to address the argument of the patent owner that there were somehow unexpected results in this fusion protein. We have worked with a renowned expert, who's a declarant in our IPR, Dr. Dennis Burton, who's a professor at Scripps Research Institute. Now, Bass failed to challenge Roche's claim of unexpected results, but Dr. Burton has addressed that very thoroughly and breaks those arguments down. We demonstrate that the vast majority of the results that are achieved with this protein are, in fact, exactly what science has expected and the remainder of the data provided by the patent owner are, in fact, based on highly questionable data. We expect the Board will appreciate these essential differences and will adopt the compelling case that we put together here.

Dennis M. Lanfear
Chairman, Chief Executive Officer and President

Thank you very much, Matt. The company's finances will now be reviewed by Dr. Jean Viret, our Chief Financial Officer. Jean?

Jean-Frédéric Viret
Chief Financial Officer

Thank you, Denny.

Let me give you an update on our financial position and results. Cash, cash equivalents and short-term investments and marketable securities totaled $118.3 million as of June 30, 2017 compared to $174.8 million as of March 31, 2017. Cash used in operation was down 24% to $55.6 million in the second quarter of 2017, as compared to $73.3 million in the first quarter of 2017. We anticipate cash usage of approximately $40 million to $45 million per quarter in the second half of 2017, and $30 million to $35 million per quarter in the first half of 2018 prior to approval.

Total revenue for the second quarter of 2017 was $1.4 million as compared to $14.1 million in the second quarter of 2016. Total revenue for the 6 months ended June 30, 2017 was $1.6 million as compared to $26.4 million for the same period in 2016. Decrease over the same period in 2016 was mainly attributable to the termination of an agreement for CHS-0214 with Shire whereupon Coherus regained rights to CHS-0214 in Europe in the third quarter of 2016.

Research and development expenses for the second quarter of 2017 were $34.5 million compared with $65.5 million over the same period in 2016. R&D expenses for the 6 months ended June 30, 2017 were $88.3 million as compared to $130.9 million over the same period in 2016. Decreases in R&D expenses were mainly attributable to the completion of our Phase III and Phase I clinical studies for CHS-0214 and CHS-1420 in 2016 and a decrease in other development costs for our pipeline products.

General and administrative expenses for the second quarter of 2017 were $23.5 million compared to $11.3 million over the same period in 2016. G&A expenses for the 6 months ended June 30, 2017 were $42.3 million as compared to $22.7 million over the same period in 2016. Changes in G&A expenses were mainly attributable to legal and other professional fees to support intellectual property strategy and personnel-related costs to support our CHS-1701 pre-commercial activities in the first 6 months of 2017.

Net loss attributable to Coherus for the second quarter of 2017 was $55.3 million or $1.08 per share compared to $70 million or $1.72 per share for the same period in 2016.

We will now turn the call to Q&A. Operator, you may open the call to questions.

Dennis M. Lanfear
Chairman, Chief Executive Officer and President
Thank you, Jean.

EXHIBIT 10

BIOLOGICS AND BIOSIMILARS: BALANCING INCENTIVES FOR INNOVATION

HEARING

BEFORE THE

SUBCOMMITTEE ON COURTS AND COMPETITION POLICY

OF THE

COMMITTEE ON THE JUDICIARY
HOUSE OF REPRESENTATIVES

ONE HUNDRED ELEVENTH CONGRESS

FIRST SESSION

JULY 14, 2009

Serial No. 111–73

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BIOLOGICS AND BIOSIMILARS: BALANCING INCENTIVES FOR INNOVATION

TUESDAY, JULY 14, 2009

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON COURTS AND
COMPETITION POLICY
COMMITTEE ON THE JUDICIARY,
Washington, DC.

The Subcommittee met, pursuant to notice, at 2:20 p.m., in room 2141, Rayburn House Office Building, the Honorable Henry C. "Hank" Johnson, Jr. (Chairman of the Subcommittee) presiding.

Present: Representatives Johnson, Gonzalez, Jackson Lee, Watt, Sherman, Issa, Goodlatte, and Coble.

Staff Present: (Majority) Christal Sheppard, Subcommittee Chief Counsel; Eric Garduno, Counsel; Rosalind Jackson, Professional Staff Member; (Minority) and Blaine Merritt, Counsel.

Mr. JOHNSON. This hearing of the Subcommittee on Courts and Competition Policy will now come to order.

Without objection, the Chair will be authorized to declare a recess of the hearing.

Under current law, generic versions of the chemical pharmaceutical products may be introduced through an expedited pathway that allows generic makers to rely on the safety and efficacy test data of an original Food-and-Drug-Administration-approved drug. This dramatically reduces the cost of entry for generics, which has translated into substantial savings to customers. The Congressional Budget Office has estimated that consumers save $8 billion to $10 billion a year, thanks to the price competition from generics.

There is, however, no equivalent statutory pathway for generic versions of biological pharmaceutical products, otherwise known as biosimilars. Congress has explored the creation of a generic pathway for biosimilars for some time, but it wasn't until this Congress that real momentum has built behind such a legislative endeavor. This is in large part due to the effort by Congress and the Obama administration to pass comprehensive health care reform. Many believe that establishing a pathway for biosimilars will contribute to our efforts to reduce the cost of health care.

Creation of a pathway for biosimilars has been a contentious issue. Much of the debate concerning such a pathway revolves around whether the science is perfected enough to determine if a biosimilar that relies on an innovator's test data will have the same health benefits as the innovator drug without additional health risks. Additional concerns center on the intellectual property

protections afforded drug innovators and how the nature of those protections will impact competition, future biotechnology industry investment and the cost of biological pharmaceutical products.

It is, without a doubt, that the development of new biologics is an expensive endeavor. Estimates put average development costs as much as $1.37 billion. It is also without a doubt that the cost of pharmaceutical products, and in particular biologics, is huge. In 2007, pharmaceutical expenditures accounted for $231.3 billion in health care costs, and biologics represented $40.3 billion of this total.

The question before us today is how to frame the intellectual property protections in a pathway for biosimilars that incentivizes the extraordinary investment required to develop new biologics but does not discourage biosimilar introduction.

I look forward to our hearing with the distinguished witnesses that we have on board who will comment on whether there should be a long data exclusivity period that significantly delays biosimilar competition, whether biotechnology patents are broad enough to apply to biosimilar products and processes, and the extent to which other factors provide market-entry barriers that will limit biosimilar entry and thereby protect innovators.

I now recognize my colleague, Mr. Howard Coble, the distinguished Ranking Member of the Subcommittee on Courts and Competition Policy for his opening remarks.

Mr. COBLE. Thank you, Mr. Chairman, and I thank you for having called the hearing which addresses an important health care issue and directly affects subject matter that is a portion of the Judiciary Committee's jurisdiction.

Mr. Chairman, I will try not to be too verbose, but this subject is very detailed and very complex; perhaps not so detailed and complex to the scientifically adept, but I belong to the scientifically inept group, and to me, it is very complex.

The Hatch-Waxman Act, which is almost a quarter century old, gave birth to the generic chemical drug industry, as we all know. By most accounts, it has worked well by balancing the interests of brand manufacturers, generic companies, and patients. It has generated greater price competition in the pharmaceutical industry without destroying the incentive for brands to conduct further research and roll out new products that benefit patients worldwide.

In recent years, Mr. Chairman, legislators and other health care experts have contemplated the creation of a similar legislative pathway for a generic biologics industry. This discussion not only resurrects some of the same issues confronting Congress during consideration of Hatch-Waxman, it also invites debate over the wisdom of using Hatch-Waxman as an appropriate template for biosimilars.

As I said at the outset, I am no expert in the fields of biology, chemistry, or recombinant DNA, but I do understand the basic difference between chemical pharmaceuticals and biologics.

Chemical drugs are usually produced in pill form. They are chemically synthesized and comprised of small molecules. Compared to biologics, chemical pharmaceuticals are far easier to manufacture and replicate.

Biologics are made, as we know, from living organisms. They are normally comprised of protein and are increasingly a part of recombinant DNA research and production. Their characteristic properties include a high molecular weight, varying levels of hard-to-remove biological impurities, and a high degree of sensitivity to environmental conditions. The manufacturing process is therefore critical to the final product. This complexity means one cannot guarantee that reproduction of a biological drug results in an exact duplicate.

This is not the case for chemical pharmaceuticals regulated under Hatch-Waxman since it is chemically identical to the innovator drug. That is why the term generic biologic is technically inaccurate, it seems to me. Biosimilar or follow-on biologic would be preferred.

In our quest to develop a legislative pathway for biosimilars, we must keep these differences in mind. While the Judiciary Committee's jurisdiction does not include public health and related safety issues, all Members, whatever their Committee assignments, cannot discharge the importance of protecting patients. Any bill we end up supporting cannot sacrifice public safety on the alter of potential cost savings.

I have some more to say, Mr. Chairman, but in the interest of time, I would ask unanimous consent to have my entire statement put into the record, and we hope that we will have a balanced and talented roster of witnesses, which we will have, who will add to our understanding of this complex subject.

I look forward to participating and thank you again, Mr. Chairman, for having called the hearing.

Mr. JOHNSON. Without objection, that will be done, Mr. Coble.

I thank the gentleman for his statement.

[The prepared statement of Mr. Coble follows:]

PREPARED STATEMENT OF THE HONORABLE HOWARD COBLE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NORTH CAROLINA, AND RANKING MEMBER, SUBCOMMITTEE ON COURTS AND COMPETITION POLICY

HEARING STATEMENT OF THE HONORABLE HOWARD COBLE
SUBCOMMITTEE ON COURTS AND COMPETITION POLICY
"BIOLOGICS AND BIOSIMILARS:
BALANCING INCENTIVES FOR INNOVATORS"
JULY 14, 2009

Thank you Mr. Chairman. I appreciate your calling this hearing today, which addresses an important healthcare issue and directly affects subject matter that is part of the Judiciary Committee's jurisdiction.

The Hatch-Waxman Act, which is almost a quarter-century old, gave birth to the generic chemical drug industry. By most accounts, it has worked well by balancing the interests of brand manufacturers, generic companies, and patients. It has generated greater price competition in the pharmaceutical industry without destroying the incentive for brands to conduct further research and roll-out new products that benefit patients worldwide.

In recent years, legislators and other healthcare experts have contemplated the creation of a similar legislative pathway for a "generic" biologics industry. This discussion not only resurrects some of the same issues confronting Congress during consideration of Hatch-Waxman, it also invites debate over the wisdom of using Hatch-Waxman as an appropriate template for biosimilars.

Mr. Chairman, law school was created for non-scientists such as yours truly. And while I am no expert in the fields of biology, chemistry, or recombinant DNA, I understand the basic difference between chemical pharmaceuticals and biologics. Chemical drugs are usually produced in pill form. They are chemically-synthesized and comprised of small molecules. Compared to biologics, chemical pharmaceuticals are far easier to manufacture and replicate.

Biologics are made from living organisms. They are normally composed of protein, and are increasingly a part of recombinant DNA research and production. Their characteristic properties include a high molecular weight, varying levels of hard-to-remove biological impurities, and a high degree of sensitivity to environmental conditions. The manufacturing process is therefore critical to the final product.

This complexity means one cannot guarantee that reproduction of a biological drug results in an exact duplicate. This isn't the case for a chemical pharmaceutical regulated under Hatch-Waxman, since it is chemically identical to the innovator drug. That's why the term "generic" biologic is technically inaccurate; "biosimilar" or "follow-on biologic" is preferred.

In our quest to develop a legislative pathway for biosimilars, we must keep these differences in mind. While the Judiciary Committee's jurisdiction does not include public health and related safety issues, all Members – whatever their Committee assignments – cannot disregard the importance of protecting patients. Any bill we end up supporting cannot sacrifice public safety on the altar of potential cost savings.

Nor can we disregard the importance of creating and maintaining appropriate incentives for innovator companies to do their jobs. As much as it costs a chemical pharmaceutical company to bring a state-of-the-art drug to market – about $800 million, give or take – it costs even more for a biotech firm to do the same – in excess of a billion dollars.

Our Committee retains jurisdiction over the Patent Act, which provides the greatest incentive available for pharmaceutical companies to raise capital, immerse themselves in R&D, and produce drugs – chemical and biological – that enable patients to enjoy longer and healthier lives. It is imperative that any legislation creating a biosimilar pathway contain reasonable patent and exclusivity protections. Without these incentives, the core research and development won't get done. This would cripple the industry and produce an even worse outcome for patients awaiting the next generation of biological therapeutics.

That concludes my statement, Mr. Chairman. We have a balanced and talented roster of witnesses who will add to our understanding of this complex subject. I look forward to participating, and thank you again for calling the hearing.

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Mr. JOHNSON. Without objection, other Members' opening statements as well will be included in the record.

I am now pleased to introduce the witness for the first panel of today's hearing. Our first panel will feature Congresswoman Anna Eshoo.

Representative Eshoo, you are the top dog on this panel, there is no question about it.

Ms. ESHOO. Wait until I tell my children.

Mr. JOHNSON. You may want to put this in the new book that you are coming out with also.

Representative Eshoo has served in Congress since 1993 and represents California's 14th Congressional District, which includes large portions of Silicon Valley. She serves on the House Energy and Commerce Committee and on the House Permanent Select Committee on Intelligence. In addition, Representative Eshoo co-chairs the Congressional High-Tech Caucus and the House Medical Technology Caucus and serves as Vice Chair of the 21st Century Health Care Caucus.

Representative Eshoo, please proceed with your testimony.

TESTIMONY OF THE HONORABLE ANNA G. ESHOO, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Ms. ESHOO. Good afternoon, Mr. Chairman, and thank you very much for allowing me to be here today to give testimony on the issue of biosimilars before this distinguished Subcommittee.

Ranking Member, Mr. Coble, a good and long-time friend, to my friends Congressman Gonzales and Congressman Watt, thank you for being here.

This is a very important, yet complex, discussion, to develop a regulatory pathway for biosimilars that, as Mr. Coble and others have said, protects patients—protects patients, that must be our number one goal—while balancing incentives for innovation.

The field of biotechnology is the future of medicine. We are just beginning to scratch the service of the potential to harness the extraordinary power of biology and the astounding natural processes which occur in the human body, in animals, and in other living organisms to advance breakthrough medical discoveries and treatments.

This vital future, in my view and I am sure yours, must advance. But the cost of biologic treatments are very expensive, and I think the time has come to develop a pathway, as the Congress did many years ago and was mentioned by the Ranking Member, to develop a pathway for biosimilar products in our country the way we did for pharmaceutical compounds.

Now, what exactly do I mean when I say develop a pathway for biosimilars? In 1984, the Drug Price Competition and Patent Term Restoration Act, better known as the Hatch-Waxman Act, ushered in a new era of competition and cheaper drugs for traditional pharmaceuticals, called compounds. It is now appropriate for us to create a pathway for follow-on versions of biologics.

But biologics and traditional drugs are fundamentally different, and they require different legal and scientific frameworks. First,

we need to understand the differences between biologics and traditional drugs.

Many of us take a prescription or an over-the-counter drug frequently. Each time we reach for a pill, we expect the same safety and efficacy, whether we are using a brand name or a generic drug.

Small molecule chemical compounds of traditional drugs are ideal for replication as generics. These products have well-defined structures that can be thoroughly characterized and copied, and generic drugs are chemically identical, chemically identical, to the brand name products they copy. Doctors and patients can expect the generics will have the same properties, the same efficacy and the same safety characteristics as the product that they copied.

Biological products are fundamentally different. A biologic is a large complex molecule which is grown in living cells, in living systems, such as a microorganism, a plant, or an animal cell. The resulting protein is unique to the cell lines and the specific processes that are used to produce it, and even slight differences, even the slightest differences, in the manufacturing of a biologic can alter its nature. And that will have an effect on the patient.

As a result, biologics are difficult and sometimes impossible to characterize, and laboratory analysis of the finished product is insufficient to ensure its safety and efficacy.

I brought a chart. They say a picture is worth a thousand words. You see on the stand here the chart. These are both breast cancer treatments. The top is Tamoxifen. That is a small-molecule compound. You can see its simplicity. The picture says it all.

Below it is Herceptin, and that is a biologic. Look at the complexity of that biologic.

Even if a biosimilar is proven to be safe and effective, it will likely still have different properties than the original innovative product. There may be differences in dosing, different side effects or safety profiles, and differences in effectiveness for certain diseases or for different patient groups.

Biologics are expensive, and they are risky to develop. A recently released study sponsored by the National Venture Capital Association analyzed the relative cost for investors in biotechnology and found that the cost of capital for startup biotech companies is more than double the costs that other companies must pay. These costs stem from long developmental timelines of typically 10 years or more and extraordinary levels of risk.

Fewer than 1 percent of biologics make it to the market. Imagine that. Fewer than 1 percent. And the large amounts of capital required to support this development are at the other end of the scale.

So, to preserve the existing incentives for investment and innovation, the Pathway for Biosimilars Act provides a data-exclusivity period equivalent to patent protections for small molecules. The Congressional Budget Office has determined that 11.5 years is the average length of time that drugs are marketed under patent. In other words, innovative drugs and biologics typically stay on the market for about 12 years before facing competition. My legislation maintains this level of protection for biologics.

Now, today innovators are assured that the costly clinical trial results and data that they develop during their approval process

cannot be used by competitors to secure approval and enter the market even if their patents do not prevent entry. In effect, innovators today have infinite data protection, which allows for competition but doesn't permit free-riding on their data.

I am proposing to allow competitors access to their data and a shortcut into the market, but we preserve through the legislation the existing incentives for innovators by maintaining a 12-year period of exclusivity of concurrent data protection as a backstop to existing patent protections.

In order to protect the rights of all parties and ensure that all patent disputes involving a biosimilar are resolved before, and I emphasis the word before, the expiration of the data-exclusivity period, H.R. 1548 also establishes a simple, streamlined patent resolution process.

This process would take place within a short window of time, roughly 6 to 8 months after the biosimilar application has been filed with the FDA. It will help ensure that litigation surrounding relevant patents will be resolved expeditiously and prior to the launch of the biosimilar product, providing certainty to the applicant, the reference product manufacturer, and the public at large.

Unlike any other proposal, our legislation also preserves the ability of third-party patent holders, such as universities and medical centers, to defend their patents.

Once a biosimilar application is accepted by the FDA, the agency will publish a notice identifying the reference product and a designated agent for the biosimilar applicant. After an exchange of information to identify the relevant patents at issue, the applicant can decide to challenge any patents' validity or applicability. All information exchanged as part of this procedure will be maintained in strict confidence and used solely for the purpose of identifying patents relevant to the biosimilar product. The patent owner will then have 2 months to decide whether to enforce the patent, and if the patent owner's case is successful in court, the final approval of the application will be deferred until the patent expires.

So this legislation I think sets forth a straightforward, scientifically-based process for an expedited approval of new biologics based on innovative products already on the market, with patient safety coming first. This new pathway will promote competition and lower prices and, most importantly again, protect patients and give them the safe and the effective treatments and I might say the hope that this represents to really conquer the most dreaded diseases that still plague humankind, and all through the scrutiny and testing by the FDA.

The legislation enjoys today 130 bipartisan cosponsors, many on this Committee, the House Judiciary Committee, and it is known as the Kennedy Bill in the Senate. Last evening, the Health Subcommittee in the Senate voted the bill out 16-7, which I think is really quite a victory for the legislation. After all, it is complicated and enormously complex, as well as enormously important.

I also want to note that the bill is endorsed by the Association of American Universities, the National Venture Capital Association, the Biotechnology Industry Organization, the Governors of four States, and a wide array of patient and industry groups.

Mr. Chairman and distinguished Members of the Subcommittee, I appreciate being welcomed here today. It is an honor to testify before my House colleagues.

I thank you, and I stand willing to answer questions, should you have any.

[The prepared statement of Ms. Eshoo follows:]

PREPARED STATEMENT OF THE HONORABLE ANNA G. ESHOO,
A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Statement of Congresswoman Anna G. Eshoo
House Committee on the Judiciary
Subcommittee on Courts and Competition Policy
Hearing on "Biologics and Biosimilars: Balancing Incentives for Innovation
July 14, 2009

Thank you Mr. Chairman. I'm pleased to be here today to discuss this important issue – developing a regulatory pathway for biosimilars that protects patients while balancing incentives for innovation.

The field of biotechnology is the future of medicine – we're just beginning to scratch the surface of the potential to harness the extraordinary power of biology and the astounding natural processes which occur in the human body, in animals, and in other living organisms to advance breakthrough medical discoveries and treatments.

This vital future must advance, but the costs of biologic treatments are very high and I believe the time has come to develop a pathway for biosimilar products in our country.

What, exactly, do I mean when I say "develop a pathway" for biosimilars?

In 1984 the *Drug Price Competition and Patent Term Restoration Act*, otherwise known as 'Hatch-Waxman,' ushered in a new era of competition and cheaper drugs for traditional pharmaceuticals – compounds.

It's now appropriate to create a pathway for follow-on versions of biologics. However, biologics and traditional drugs are fundamentally different and require different legal and scientific frameworks.

First, we need to understand the differences between biologics and traditional drugs.

Many of us take a prescription or over-the-counter drug frequently. Each time we reach for a pill, we expect the same safety and effectiveness, whether using a brand name or generic drug.

Small-molecule chemical compounds of traditional drugs are ideal for replication as generics. These products have well-defined structures that can be thoroughly characterized and copied, and generic drugs are chemically identical to the reference products they copy. Doctors and patients can expect that generics will have the same properties, the same efficacy, and the same safety characteristics as the innovative product they copy.

Biological products are fundamentally different. A biologic is a large, complex molecule, which is 'grown' in living systems such as a microorganism, a plant or animal cell. The resulting protein is unique to the cell lines and the specific process used to produce it, and even slight differences in the manufacturing of a biologic can alter its nature. As a result,

biologics are difficult, sometimes impossible to characterize, and laboratory analysis of the finished product is insufficient to ensure its safety and efficacy. *[SEE DISPLAY]*

Even if a biosimilar is proven to be safe and effective, it will likely still have different properties than the original innovative product. There may be differences in dosing, different side effects or safety profiles, and differences in effectiveness for certain diseases or patient groups.

Biologics are expensive and risky to develop. A recently released study sponsored by the National Venture Capital Association analyzed the relative costs for investors in biotechnology and found that the 'cost of capital' for start-up biotech companies is more than double the costs that other companies must pay. These costs stem from long developmental timelines of typically 10 years or more, extraordinary levels of risk (fewer than 1% of biologics make it to market), and the large amounts of capital required to support development.

To preserve existing incentives for investment and innovation the *Pathway for Biosimilars Act* provides a data exclusivity period equivalent to patent protections for small molecules. The Congressional Budget Office has determined that 11.5 years is the average length of time that drugs are marketed under patent. In other words, innovative drugs and biologics typically stay on the market for about 12 years before facing competition. My legislation maintains this level of protection for biologics.

Today innovators are assured that the costly clinical trial results and data that they develop during their approval process cannot be used by competitors to secure approval and enter the market, even if their patents do not prevent entry. In effect innovators now have 'infinite' data protection, which allows for competition but doesn't permit 'free riding' on their data.

I'm proposing to allow competitors access to their data and a shortcut into the market, but also preserving the existing incentives for innovators by maintaining a 12-year period of concurrent data protection as a 'backstop' to existing patent protections.

In order to protect the rights of all parties and ensure that all patent disputes involving a biosimilar are resolved before the expiration of the data exclusivity period, H.R. 1548 also establishes a simple, streamlined patent resolution process.

This process would take place within a short window of time – roughly 6-8 months after the biosimilar application has been filed with the FDA. It will help ensure that litigation surrounding relevant patents will be resolved expeditiously and prior to the launch of the biosimilar product, providing certainty to the applicant, the reference product manufacturer, and the public at large.

Unlike any other proposal, our legislation also preserves the ability of third-party patent holders such as universities and medical centers to defend their patents.

Once a biosimilar application is accepted by the FDA, the agency will publish a notice identifying the reference product and a designated agent for the biosimilar applicant. After an exchange of information to identify the relevant patents at issue, the applicant can decide to challenge any patent's validity or applicability. All information exchanged as part of this procedure must be maintained in strict confidence and used solely for the purpose of identifying patents relevant to the biosimilar product.

The patent owner will then have two months to decide whether to enforce the patent. If the patent owner's case is successful in court, the final approval of the application will be deferred until the patent expires.

The *Pathway for Biosimilars Act* sets forth a straightforward, scientifically based process for expedited approval of new biologics based on innovative products already on the market. This new biosimilars approval pathway will promote competition and lower prices, but also ensure that patients are given safe and effective treatments that have been subjected to thorough scrutiny and testing by the FDA.

I'm pleased that Congressmen Inslee, Barton and I have been joined by a diverse group of 125 bipartisan cosponsors in the House.

I also want to note that my bill is the only legislation endorsed by the Association of American Universities, the National Venture Capital Association, the Biotechnology Industry Organization, the governors of 4 states, and a wide array of patient and industry groups.

This broad support is extremely encouraging, and I look forward to working finally addressing this critical issue in the 111th Congress.

Thank you again for inviting me to testify today.

Mr. JOHNSON. Thank you, Madam Congresswoman. It is our pleasure to host you today.

Without objection, your written statement will be placed into the record.

I now call for the second panel to take their seats. Thank you.

I might add here also that Representative Waxman has introduced a similar bill, and he was offered the opportunity to come