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Case No. 2023-0617-SG

IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE

ABBVIE INC. and ABBVIE BIOTECHNOLOGY LTD, Plaintiffs, v. COHERUS BIOSCIENCES, INC., Defendant.	)	C.A. No. 2023-0617-SG PUBLIC VERSION filed June 16, 2023

VERIFIED COMPLAINT

Plaintiffs AbbVie Inc. and AbbVie Biotechnology Ltd (collectively, "AbbVie" or "Plaintiffs"), by and through their undersigned attorneys, bring this Verified Complaint against Defendant Coherus BioSciences, Inc. ("Coherus" or "Defendant") and state as follows:

NATURE OF ACTION

1. This is an action arising from Coherus's breach of a [redacted] ("Agreement") with Plaintiffs AbbVie Inc. and AbbVie Biotechnology Ltd related to Coherus's adalimumab biosimilar product YUSIMRY™. Although AbbVie and Coherus agreed that Coherus would not begin to [redacted] YUSIMRY™ in the United States until on or after [redacted]3, Coherus jumped the gun. Specifically, on June 1, 2023, Coherus issued two press releases—the first announced its agreement with a third party to supply YUSIMRY™ with particular pricing and other key contractual terms, and the second

announced a price for and the availability of YUSIMRY™. Coherus also launched its website for YUSIMRY™, which includes prescription and other information for the product and references cost. Coherus thus [redacted] YUSMIRY™ in advance of [redacted] and thereby breached the contract, which, as Coherus [redacted]. AbbVie seeks relief, including an injunction, to prevent Coherus's disregard of its contractual obligations.

2. HUMIRA® is the result of decades of innovation and investment by AbbVie. HUMIRA® has been approved by the United States Food and Drug Administration ("FDA") to treat eleven different diseases, and since its initial approval in 2002, it has been used to treat over one million patients. In recognition of AbbVie's innovation, the United States Patent and Trademark Office ("PTO") issued over 100 patents concerning the HUMIRA® product. HUMIRA®'s patents have withstood numerous validity challenges. For example, biosimilar developers, including Coherus, repeatedly challenged AbbVie's patents by asking the Patent Trial and Appeal Board ("PTAB") to reconsider whether claims are patentable through a process known as *inter partes* review, and AbbVie prevailed on nine patents in thirteen different proceedings (five filed by Coherus).

3. In view of this innovation and HUMIRA®'s unparalleled success at improving patients' lives, 10 companies, including Coherus, have sought approval from the FDA to market biosimilar versions of HUMIRA® (adalimumab) under the

abbreviated regulatory pathway of the Biologics Price Competition and Innovation Act, 42 U.S.C. § 262 ("BPCIA").

4. The BPCIA represents a balancing between the intellectual property rights of innovators like AbbVie and access to an abbreviated regulatory pathway for others to develop biosimilars. Consistent with the goals of the BPCIA, AbbVie reached separate early entry settlement and license agreements with each of 10 companies, granting each a non-exclusive license to AbbVie's patents related to adalimumab. These agreements allow biosimilar developers to bring adalimumab biosimilars to the U.S. market on certain dates in 2023, about a decade before AbbVie's last adalimumab-related patents expire. These early entry settlement and license agreements reflect AbbVie's commitment to protect investment in innovation while also providing access to biosimilars, which play an important role in the U.S. healthcare system.

5. In accordance with AbbVie's early entry settlement and license agreements, one biosimilar adalimumab product has already been launched in the U.S. before expiration of AbbVie's adalimumab patents. Amgen launched the first HUMIRA® biosimilar in the U.S., AMJEVITA™ (adalimumab-atto), on January 31, 2023. And pursuant to other early entry settlement and license agreements, additional biosimilar adalimumab products are expected to be launched in the U.S. on or after [redacted]

6. In [redacted], Coherus agreed with AbbVie to the Agreement (Ex. 1). Coherus [redacted]. Before the Agreement, Coherus had unsuccessfully sought to invalidate AbbVie patents in multiple proceedings before the PTO. Even though Coherus had yet to file an abbreviated regulatory filing with the FDA for its adalimumab biosimilar or engage in BPCIA litigation like other biosimilar companies that settled with AbbVie, Coherus [redacted]

7. The Agreement [redacted] its biosimilar product before the agreed-upon [redacted] license date. This, however, was apparently not good enough for Coherus. In the face of competition from other biosimilar developers, and instead of waiting until the agreed date of [redacted] Coherus announced on June 1, 2023—[redacted]—that it had entered into an agreement to supply its product, YUSIMRY™, to Cost Plus Drug Company ("Cost Plus Drugs"), which is, among other things, an online pharmacy. Coherus also announced that YUSIMRY™ would be distributed to Cost Plus Drugs customers at a certain price. On that date, Coherus separately announced that it intended to sell YUSIMRY™ at "a list price of $995 per carton."

Coherus's [redacted] of product to Cost Plus Drugs, its agreement with Cost Plus Drugs, and its press releases that detail the list price of YUSIMRY™ collectively and/or independently breach at least Coherus's obligations under the Agreement not to [redacted] YUSIMRY™ before [redacted].

8. The effects of the breach are substantial and immediate. Coherus itself agreed that any [redacted]. And in practice, Coherus's breach threatens AbbVie's contractual relationships with other biosimilar companies related to adalimumab, may impact negotiations within the adalimumab market, including by the other licensed biosimilars that are [redacted] and improperly benefits Coherus. In addition, AbbVie's stock price dropped significantly in the days following Coherus's announcement, disrupting a positive trend. At the same time, Coherus's stock price increased by more than 28 percent.

9. Settlements of the type entered into between AbbVie and Coherus are procompetitive. *See, e.g., Federal Trade Commission v. Actavis, Inc.*, 570 U.S. 136, 154 (2013) (recognizing that "settlement on terms permitting the patent challenger to enter the market before the patent expires would … bring about competition … to the consumer's benefit"). Enforcement of these early entry settlement terms is therefore critical to preserve parties' incentives to resolve litigation in this way. *See*

D.R. by M.R. v. East Brunswick Bd. of Educ., 109 F.3d 896, 901 (3d Cir. 1997) (enforcing settlement and holding "settlement agreements are encouraged as a matter of public policy because they promote the amicable resolution of disputes and lighten the increasing load of litigation faced by courts.").

10. In seeking approval for YUSIMRY™, Coherus sought to benefit from AbbVie's substantial innovation and investment in HUMIRA®. In signing the Agreement, Coherus, like other biosimilar companies, [redacted], the vast majority of which are still in force. Coherus also [redacted] Coherus's decision to breach that Agreement, upending AbbVie's expectations and disrupting the adalimumab biosimilar market, unfairly undermines that bargain. AbbVie seeks appropriate relief for Coherus's breach, including an injunction to prevent any ongoing or further breach by Coherus and an extension of the application of the restrictions in the Agreement to give AbbVie the full benefit of its bargain.

PARTIES

11. Plaintiff AbbVie Inc. is a corporation organized and existing under the laws of Delaware with its corporate headquarters at 1 North Waukegan Road, North

Chicago, Illinois 60064. AbbVie Inc. is engaged in the development, sale, and distribution of a broad range of pharmaceutical and biological drugs.

12. Plaintiff AbbVie Biotechnology Ltd is an exempted company limited by shares organized and existing under the laws of Bermuda, with a place of business at Thistle House 4 Burnaby Street Hamilton HM 11 Bermuda. Through intermediate entities, Plaintiff AbbVie Inc. indirectly owns Plaintiff AbbVie Biotechnology Ltd.

13. On information and belief, Defendant Coherus Biosciences, Inc. is a corporation organized and existing under the laws of Delaware, having a place of business at 333 Twin Dolphin Drive, Suite 600, Redwood City, CA 94065.

JURISDICTION AND VENUE

14. This Court has jurisdiction over the claims asserted in this Complaint pursuant to 6 Del. C. § 2708 and 10 Del. C. §§ 341-342.

15. This Court has personal jurisdiction over Coherus because Coherus is an entity organized under and subject to the laws of Delaware.

16. This Court also has personal jurisdiction over Coherus [redacted]

17. Venue is likewise proper in this Court pursuant to [redacted] *Id.*

FACTUAL BACKGROUND

I. ABBVIE'S HUMIRA® PRODUCT AND BIOSIMILARS

18. AbbVie Inc. is the holder of Biologic License Application ("BLA") No. 125057 for HUMIRA®, the active pharmaceutical ingredient of which is the antibody adalimumab.

19. HUMIRA® is approved to treat eleven different diseases, including forms of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, plaque psoriasis, juvenile idiopathic arthritis, ulcerative colitis, pediatric Crohn's disease, hidradenitis suppurativa, uveitis, and pediatric ulcerative colitis.

20. AbbVie's investment of hundreds of millions of dollars on scientific studies and clinical trials benefits patients immensely. AbbVie is proud of the fact that HUMIRA® has improved the lives of more than one million patients to date. AbbVie's research and investment have allowed it to provide HUMIRA® in a liquid, high concentration, stable formulation capable of being administered subcutaneously.

21. The PTO has also recognized AbbVie's innovative work by granting it over 100 patents related to HUMIRA®. As noted above, AbbVie's patents have withstood challenges by biosimilar companies, prevailing on nine patents in thirteen different IPR proceedings at the PTO.

22. The BPCIA created an abbreviated pathway for developers to seek regulatory approval of biosimilars of reference biologic drugs. A "biosimilar" must be "highly similar to the reference product" with "no clinically meaningful differences … in terms of the safety, purity, and potency of the product." 42 U.S.C. § 262(i)(2).

23. The BPCIA recognizes, however, that reference products are built on substantial innovation and balances intellectual property rights of innovators with access to that abbreviated regulatory pathway. Congress thus provided a mechanism for reference product sponsors to identify and enforce their intellectual property rights with respect to biosimilar products. *See* 35 U.S.C. § 271(e)(2)(C); *see also* 42 U.S.C. § 262(l).

24. To date, 10 companies have filed biologics license applications ("aBLA"s) with the FDA seeking approval to market biosimilar adalimumab products, and the FDA has approved products from nine companies including Amgen, Boehringer Ingelheim, Celltrion, and Sandoz.

25. Consistent with the goals of the BPCIA, AbbVie reached separate early entry settlement and license agreements with each of those 10 companies that grant non-exclusive licenses to AbbVie's patents related to adalimumab. These early entry settlement and license agreements allow biosimilar developers to bring adalimumab biosimilars to the U.S. on certain dates in 2023, about a decade before

AbbVie's last adalimumab-related patents expire, and reflect AbbVie's commitment to protect investment in innovation while also providing access to biosimilars, which play an important role in the U.S. healthcare system.

26. On January 31, 2023, pursuant to an early entry settlement and license agreement with AbbVie, Amgen launched the first biosimilar adalimumab product in the United States, AMJEVITA™ (adalimumab-atto).

27. The remaining FDA-approved, licensed HUMIRA® biosimilars are expected to launch as early as [redacted] pursuant to the separate early entry settlement and license agreements entered into with those companies.

II. COHERUS'S BIOSIMILAR PRODUCT AND THE EARLY ENTRY SETTLEMENT AND LICENSE AGREEMENT BETWEEN ABBVIE AND COHERUS

28. Prior to filing its aBLA seeking approval to market a biosimilar of HUMIRA®, Coherus sought to invalidate certain of AbbVie's patents in proceedings before the PTO. Among other proceedings, the PTAB rejected five of Coherus's petitions on two patents. Prior to Coherus filing its aBLA, the PTAB also rejected other biosimilar companies' challenges to additional patents that Coherus admitted it would have infringed but for the license granted by AbbVie.

29. AbbVie and Coherus agreed that, in the absence of the Agreement, there would have been litigation under the BPCIA relating to Coherus's infringement of AbbVie's patents based on the filing of Coherus's aBLA.

30. In an effort to avoid litigation, AbbVie and Coherus entered into the Agreement (Ex. 1). The terms of the Agreement are described in relevant part below.

31. AbbVie [redacted]

32. In exchange, the Agreement limited Coherus's ability to [redacted] a HUMIRA® biosimilar prior to an agreed upon date. Specifically, in exchange for, *inter alia*, [redacted]

33. The Parties agreed that the terms and restrictions set forth in the Agreement were necessary to [redacted]

[1] [redacted] Those are not applicable here.

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

34. In the event of a breach of Section 5.2, the Agreement entitles AbbVie to [redacted]. Agreement § 10.1(a).

35. In the Agreement, AbbVie [redacted].

36. On February 17, 2021, Coherus announced that the FDA had accepted for review its aBLA seeking approval to market a biosimilar of HUMIRA®.

37. On December 17, 2021, the FDA approved Coherus's product, YUSIMRY™ (adalimumab-aqvh), for marketing in the United States.

III. COHERUS'S BREACH OF THE SETTLEMENT AND LICENSE AGREEMENT

38. On June 1, 2023, AbbVie learned that Coherus breached the Agreement. On that date, Coherus issued a first press release titled, "Cost Plus Drug Company joins forces with Coherus to make YUSIMRY™, a HUMIRA® biosimilar, available to patients."[2] The press release explained that Coherus entered into an agreement with online pharmacy Cost Plus Drugs to allow Cost Plus Drugs to offer Coherus's HUMIRA® biosimilar, YUSIMRY™. Coherus's press release stated that "Cost Plus Drug Company … and Coherus BioSciences, Inc. … , today

[2] *See* Ex. 2, https://www.globenewswire.com/news-release/2023/06/01/2680351/0/en/Mark-Cuban-Cost-Plus-Drug-Company-joins-forces-with-Coherus-to-make-YUSIMRY-a-HUMIRA-biosimilar-available-to-patients.html (last accessed June 9, 2023).

announced plans to offer … Cost Plus Drug Company customers YUSIMRY (adalimumab-aqvh), a biosimilar of HUMIRA® (adalimumab injection), in July 2023."[3]

39. Coherus went so far as to identify price, availability date, and prescription program information for its HUMIRA® biosimilar: "Cost Plus Drug Company plans to offer YUSIMRY to its customers at a price of $569.27 plus dispensing and shipping fees starting in July 2023. … YUSIMRY will also be included in the … prescription benefit program through participating pharmacies."[4]

40. Also on June 1, 2023, Coherus issued a second press release in which it provided additional launch and list price details regarding its YUSIMRY™ product. That press release, titled, "Coherus Announces Industry-Wide Lowest List Price for Adalimumab Biosimilar YUSIMRY™ (adalimumab-aqvh) Launching in July 2023," "announced that [Coherus] plans to launch YUSIMRY™ (adalimumab-aqvh) in July 2023* with a list price of $995 per carton (2 x 40 mg/0.8 mL autoinjectors)."[5] In a footnote, the press release states, "*No sales will occur, and

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3 *Id.*

4 *Id.*

5 *See* Ex. 3, https://investors.coherus.com/news-releases/news-release-details/coherus-announces-industry-wide-lowest-list-price-adalimumab (last accessed June 9, 2023).

no purchase orders will be accepted, until July 2023."[6] Nonetheless, Coherus's press release advertised YUSIMRY™ and identified list price and availability information.

41. Further announcements from third parties relating to YUSIMRY™ have followed Coherus's agreement and press releases. For example, on June 13, 2023, SmithRx, a pharmacy benefits management company, announced that it was "[t]eaming up with … Cost Plus Drug Company" to offer members access to YUSIMRY™ beginning in "early July 2023."[7]

42. [redacted]

43. [redacted]

6 *Id.*

7 *See* Ex. 4, https://www.globenewswire.com/news-release/2023/06/13/2687176/0/en/SmithRx-will-be-First-PBM-to-Offer-YUSIMRY-a-Humira-Biosimilar-for-One-Tenth-the-List-Price-of-Humira.html (last accessed June 13, 2023).

[redacted]

44. Notwithstanding Coherus's assertions that its activities do not breach the Agreement, well before its license date of [redacted], Coherus [redacted] YUSIMRY™ and advertised [redacted] via multiple press releases and its website. That activity, publicization of that activity, and publicization of YUSIMRY™ pricing have had immediate consequences and have harmed AbbVie as described above and below. [redacted]

45. Even after being put on notice, on or around June 13, 2023, Coherus furthered its breach, including by launching a website at www.yusimry.com.[8] The website includes numerous details about YUSIMRY™, including indication and prescribing information and instructions for use, and it advertises YUSIMRY™ as "one of the lowest cost options available."[9]

46. As a result of these activities, Coherus [redacted]

[8] *See* Ex. 9, https://www.yusimry.com (last accessed June 13, 2023).

[9] *Id.*

[redacted] To the extent that Coherus has made any additional [redacted]

IV. IMPACT OF COHERUS'S BREACH OF THE AGREEMENT

47. As discussed in Paragraph 33, [redacted]

48. On information and belief, Coherus's breach has impacted and will continue to significantly impact the market for adalimumab in various ways, at least some of which are not presently quantifiable and/or known due to the complexities of that market.

49. Coherus's breach has also impacted and will continue to impact AbbVie's relationship with its licensees. For example, following Coherus's issuance of its press releases touting its improper agreement with Cost Plus Drugs and launch of YUSIMRY™, [redacted] Coherus's breach of the Agreement may also impact AbbVie's ability to enter into future settlement agreements relating to BPCIA

litigation and/or biosimilar products more broadly. For example, entities may be reluctant to enter into early entry settlement and license agreements in the future on the basis that they may suffer as a result of breaches similar to that committed by Coherus with respect to the Agreement.

50. By jumping the gun, Coherus obtained an unfair head start over other competitors in the market with the same or subsequent license dates, which could give Coherus an unauthorized competitive advantage. For example, other third-party distributors beyond Cost Plus Drugs are already attempting to engage in unauthorized activities with Coherus as a result of Coherus's announcement. In response to Cost Plus Drugs' post on LinkedIn about the sale agreement with Coherus, Scripx Digital Pharmacy commented: "DALLAS!!! Come talk to us. We will carry this for you. Servicing the North Dallas, Plano, Rowlett area!!!" And Coherus engaged with Scripx Digital Pharmacy. In reply, Coherus oncology account manager Jon Briney directed the communication to Coherus executive vice president Karen Kotz by tagging her in the post.[10] Another comment on Cost Plus

[10] *See, e.g.*, Ex. 7 at 2. The post appearing as Ex. 7 was previously accessible at https://www.linkedin.com/feed/update/urn:li:activity:7070034792028766208?commentUrn=urn%3Ali%3Acomment%3A%28activity%3A7070034792028766208%2C7070231251227463681%29&dashCommentUrn=urn%3Ali%3Afsd_comment%3A%287070231251227463681%2Curn%3Ali%3Aactiv

Drugs' LinkedIn announcement tagged Elizabeth Kiernan Pattyn, a vice president at another drug provider, Capital Rx.[11]

51. On June 13, 2023, Coherus also launched a website marketing its product.[12]

52. Any other negotiation or agreements between Coherus and third-party distributors relating to YUSIMRY™ [redacted] that are non-public or otherwise unknown to AbbVie would constitute further breach of the Agreement.

53. Moreover, as explained above, AbbVie's stock price dropped significantly in the days following Coherus's announcements relating to its contracting for and the sale and pricing of YUSIMRY™, while Coherus's stock price increased significantly during that time.

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ity%3A7070034792028766208%29 and was last accessed on June 9, 2023. As of June 12, 2023, the post is no longer available at that link.

11 *See* Ex. 8 at 2, https://www.linkedin.com/feed/update/urn:li:activity:707003479202876620 8?commentUrn=urn%3Ali%3Acomment%3A%28activity%3A7070034792 028766208%2C70700865817174548 48%29&dashCommentUrn=urn%3Ali %3Afsd_comment%3A%28707007086581717454848%2Curn%3Ali%3Aactiv ity%3A7070034792028766208%29 (last accessed June 9, 2023).

12 *See* Ex. 9, https://www.yusimry.com (last accessed June 13, 2023).

54. While some of the injury described above suffered by AbbVie entitles AbbVie to damages in an amount to be proven at trial, at least some of the injury suffered by AbbVie is not quantifiable and has no adequate remedy at law.

COUNT I:
(Breach of Contract)

55. AbbVie repeats and realleges the foregoing paragraphs as if set forth fully here.

56. Coherus entered into the Agreement with AbbVie and agreed that it would not [redacted]

57. As described above, there is adequate consideration supporting the promises to perform by the parties under the Agreement.

58. Therefore, the Agreement is a valid and enforceable contract.

59. AbbVie has performed its obligations under the Agreement.

60. Despite Coherus's contractual obligation to AbbVie not to [redacted] Coherus breached that obligation, no relevant

exception applies, and such breach was material. The facts relevant to Coherus's breach are described in detail above. *See, e.g.*, *supra* at ¶¶ 38-54.

61. Pursuant to at least [redacted] Coherus's breach of Section 5.2 of the Agreement has and will continue to cause irreparable injury to AbbVie, at least a portion of which has no adequate remedy at law. Specifically, [redacted]

62. As a direct and proximate result of Coherus's breach of its contractual obligations under the Agreement, AbbVie has been and will be damaged and irreparably harmed, as described above. On information and belief, Coherus's breach has impacted and will continue to significantly impact the market for adalimumab in various ways, at least some of which are not presently quantifiable and/or known due to the complexities of that market, as explained above.

63. As a result of those harms, AbbVie is entitled to legal and equitable remedies, including damages in an amount to be proven at trial, an injunction against ongoing and future breaches of the Agreement by Coherus, and an extension of the application of the restrictions in Section 5.2 of the Agreement to give AbbVie the full benefit of its bargain.

64. As a result of Coherus's breach of its contractual obligations under the Agreement pursuant to its agreement with Cost Plus Drugs, Coherus should be enjoined from carrying out its rights and obligations under that agreement, and the agreement between Coherus and Cost Plus Drugs should be voided in its entirety.

PRAYER FOR RELIEF

WHEREFORE, AbbVie respectfully requests that the Court enter judgment against Defendant Coherus:

(a) Finding that Coherus materially breached its obligations to AbbVie under the Agreement;

(b) Finding that AbbVie has been irreparably harmed by Coherus's breach;

(c) Awarding AbbVie damages in an amount to be proven at trial for those damages which are quantifiable;

(d) Finding that at least a portion of the injury suffered by AbbVie as a result of Coherus's breach has no adequate remedy at law;

(e) Awarding AbbVie all appropriate equitable relief for those injuries that have no adequate remedy at law;

(f) Enjoining Coherus from carrying out any rights and/or obligations under its agreement with Cost Plus Drugs and otherwise voiding that agreement;

(g) Enjoining Coherus from any ongoing and future breach of the Agreement;

(h) Extending the application of the restrictions in Section 5.2 of the Agreement to give AbbVie the full benefit of its bargain;

(i) Requiring Coherus to pay Plaintiffs' attorneys' fees and expenses;

(j) Awarding pre-judgment and post-judgment interest; and

(k) Granting such other and further relief as the Court deems just and proper.

Dated: June 13, 2023

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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