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Case No. 2023-0618-SG

IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE

COHERUS BIOSCIENCES, INC.,	)	
	)	**REDACTED PUBLIC VERSION**
Plaintiff,	)	**E-FILED: June 16, 2023**
	)	
v.	)	C.A. No. 2023-0618-SG
	)	
ABBVIE INC. and ABBVIE BIOTECHNOLOGY LTD.,	)	
	)	
Defendants.	)	

VERIFIED COMPLAINT FOR INJUCTIVE RELIEF AND FOR DECLARATORY JUDGMENT

Plaintiff Coherus BioSciences, Inc. ("Coherus"), by and through its undersigned attorneys, for their Verified Complaint against Defendants AbbVie Inc. and AbbVie Biotechnology Ltd. (collectively "AbbVie"), hereby alleges:

I. NATURE OF THE ACTION

1. This action seeks injunctive, declaratory, and other relief to preserve Coherus's rights to [redacted] a Humira® biosimilar product in the United States starting on July 1, 2023, pursuant to the terms of a Settlement and License Agreement between the parties, which AbbVie has [redacted] based on an insufficient—and meritless—notice of alleged breach.

2. As detailed further below, the alleged breach relates to Coherus's plans to offer its Humira® biosimilar product, called YUSIMRY™, for sale at significant discounts through the Mark Cuban Cost Plus Drug Company pursuant to a [redacted] the date that Coherus will be licensed to launch YUSIMRY™. For the reasons alleged herein, Coherus is entitled, among other forms of relief, to (i) injunctive relief enjoining AbbVie from purporting to terminate the parties' Settlement and License Agreement and (ii) a declaration that Coherus has not breached the Settlement and License Agreement and that AbbVie does not have a contractual right to terminate.

II. PARTIES

A. Plaintiff

3. Coherus is a company organized and existing under the laws of the State of Delaware, with its principal place of business at 333 Twin Dolphin Drive, Suite 600, Redwood City, California 94065.

B. Defendants

4. Upon information and belief, AbbVie Inc. is a corporation organized and existing under the laws of Delaware, with its principal place of business at 1 North Waukegan Road, North Chicago, Illinois 60064.

5. Upon information and belief, AbbVie Biotechnology Ltd. is a corporation organized and existing under the laws of Bermuda, with its principal place of business at Clarendon House, 2 Church Street, Hamilton HM11 Bermuda.

C. Relevant Non-Parties

6. Mark Cuban Cost Plus Drug Company, PBC ("Cost Plus") is a corporation whose mission is to make medications affordable, especially for Americans who are uninsured or underinsured, by offering medications at the lowest possible prices, using a transparent pricing model that involves a markup of just 15% over its costs.

III. JURISDICTION

7. This Court has jurisdiction over this dispute under the Delaware Declaratory Judgments Act, 10 *Del. C.* § 6501, and 10 *Del. C.* § 341 because this Complaint seeks equitable relief.

8. This Court has personal jurisdiction over Defendant AbbVie Inc., including pursuant to 10 *Del. C.* § 3111 because it is a Delaware corporation. In addition, AbbVie Inc. [redacted].

9. The Court has personal jurisdiction over Defendant AbbVie Biotechnology Ltd. because [redacted]

[redacted].

IV. FACTUAL ALLEGATIONS

A. The Market for Biologics and Biosimilars.

10. Many of today's important medications are biological products. Biologic drugs are extracted from, semi-synthesized by, or manufactured in living organisms using recombinant DNA technology, as opposed to small molecule drugs, which are chemically synthesized and represent most pharmaceuticals on the market today. Biologics are complex molecules usually consisting of proteins, carbohydrates, nucleic acids, cells or tissues for transplantation, or a complex composite of these substances.[1]

11. Biological products often represent the cutting-edge of biomedical research and are currently used to treat a range of diseases including cancer, autoimmune diseases, and certain genetic conditions, among others.

12. Biologics are expensive. They comprise only 2% of drugs on the market yet account for 37% of all drug spending in the United States. For example, AbbVie launched Humira® at a price that equates to $13,572 per year and has since raised the price by more than 500%. In fact, "AbbVie has raised the price of

[1] Favour Danladi Makurvet, *Biologics vs. small molecules: Drug costs and patient access*, Medicine in Drug Discovery, Volume 9, 2021, 100075, at https://doi.org/10.1016/j.medidd.2020.100075.

Humira®, its top-selling drug, 27 times since its launch" in the early 2000s.[2] The annual cost of Humira® is now $90,000. In 2022, AbbVie reported U.S. net revenues from sales of Humira® of approximately $18.6 billion.[3]

13. Biosimilars, the generic equivalent of biologics, offer significant cost saving opportunities for drug purchasers, insurers, and consumers. The Biologics Price Competition and Innovation Act of 2009 ("BPCIA") created an abbreviated approval pathway for biological products shown to be highly similar to an FDA-licensed reference biological product.

14. FDA approval is required before a biosimilar may be marketed in the United States. Biosimilarity is defined to mean that the proposed biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity and potency of the product.

15. The BPCIA attempts to minimize duplicative testing and thereby lower development costs and increase patient access to affordable treatments. A Federal

[2] AbbVie 2022 Annual Report and 2023 Proxy Statement at Proxy Statement 83, at https://investors.abbvie.com/static-files/e3047152-75b3-44b3-95a8-18e4fa991768.
[3] *Id.* at Annual Report 41.

Trade Commission study found that biosimilars can be as much as 30% less expensive than pioneer biologics.[4]

B. Humira® (adalimumab) and Biosimilar Competition.

16. The active ingredient in Humira® is a monoclonal antibody called adalimumab, which binds to a specific receptor in the body known to cause inflammation. As a result, Humira® (adalimumab) is used to treat numerous inflammatory diseases.

17. Given the size of the market for Humira®, at least ten other pharmaceutical manufacturers have developed, or are in the process of developing, Humira® biosimilars. Most of these companies have received FDA approval to commercially market their products in the United States.[5]

18. In or around 2019, AbbVie brought patent claims against several companies, including Coherus, that were developing biosimilars to Humira®. Each of those companies eventually entered into settlement agreements with AbbVie. On

[4] Federal Trade Comm'n, *Emerging Health Care Issues: Follow-On Biologic Drug Competition*; A Federal Trade Commission Report 47, 53 (June 2009), at https://www.ftc.gov/sites/default/files/documents/reports/emerging-health-care-issues-follow-biologic-drug-competition-federal-trade-commission-report/p083901biologicsreport.pdf.

[5] Cardinal Health – New and Upcoming Biosimilar Launches, Humira (adalimumab) Biosimilars Pipeline (last updated February 20, 2023), at http://www.cardinalhealth.com/content/dam/corp/web/documents/Report/cardinal-health-biosimilar-launches.pdf.

information and belief, each of these settlement agreements included a license and permitted the company to enter the U.S. market on a specific date in 2023.

19. AbbVie's CEO, Richard Gonzalez, indicated in January 2023 that the company is well prepared for these upcoming Humira® biosimilar entrants. "[T]he company rushed to secure broad 2023 formulary access for its aging [Humira®] therapy – despite the impending biosimilar threats."[6] In other words, "[t]he company signed agreements with 'all of the major' U.S. payers, [AbbVie's CEO] Gonzalez said."[7]

20. Amgen's Humira® biosimilar product, Amjevita™, was the first to launch in the United States, on January 31, 2023. Eight other companies, including Coherus, each has a license to launch their biosimilar products on July 1, 2023.[8] These companies are Boehringer Ingelheim, Samsung Bioepis/Organon, Sandoz, Pfizer, Fresenius Kabi, Alvotech/Teva, and Celltrion.[9] And on July 31, 2023, another company, Viatris, will have a license to launch its Humira® biosimilar product in the United States.

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[6] Zoey Becker, *JPM23: Abbvie 'well positioned' for this year's Humira biosimilar showdown, CEO says*, Fierce Pharma, (Jan 11, 2023), at https://www.fiercepharma.com/pharma/jpm23-abbvie-well-positioned-years-humira-biosimilar-attack.
[7] *Id.*
[8] *Id*.
[9] *Id*.

21. Founded in 2014, Coherus is a commercial-stage biopharmaceutical company focused on the research, development, and commercialization of innovative immunotherapies to treat cancer. Coherus's strategy is to build a leading immuno-oncology franchise funded by sales of its diversified portfolio of FDA-approved therapeutics.

22. Coherus's commercial portfolio contains several FDA-approved biologics marketed in the United States, including UDENYCA® (pegfilgrastim-cbqv), a biosimilar of Neulasta®, and CIMERLI™ (ranibizumab-eqrn), a biosimilar of Lucentis®. Coherus's Humira® biosimilar product is called YUSIMRY™.

23. YUSIMRY™ provides therapeutic benefits for treating patients with certain inflammatory diseases characterized by increased production of TNF in the body, including rheumatoid arthritis, psoriatic arthritis, juvenile idiopathic arthritis, ankylosing spondylitis, Crohn's disease, psoriasis, and ulcerative colitis.

C. The License Authorizes Coherus to Sell YUSIMRY™ as of July 1, 2023 in the United States Subject to a Royalty and Certain Pre-Launch Restrictions.

24. The Parties' Settlement and License Agreement, effective January 24, 2019 (the "License," attached as Exhibit A), sets forth the terms by which Coherus may sell YUSIMRY™.

25. Section 5.1 of the License grants Coherus the right to sell YUSIMRY™ in the Territory as of the License Entry Date:

[redacted]

[redacted]

[redacted]

[redacted]

26. [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted] The operative License Entry Date is therefore July 1, 2023.

27. [redacted]

[redacted]

[redacted]

[redacted]

28. [redacted]

[redacted]

[redacted]

[redacted]

29. [redacted]

[redacted]

[redacted]

D. In the Event of a Breach of Section 5.2, the License Requires AbbVie to Provide Notice and a Cure Period Prior to Terminating the License.

30. The License prohibits AbbVie's termination for an alleged violation of Section 5.2 unless it first provides notice of the alleged breach and affords Coherus [redacted]

[redacted]

31. [redacted]

[redacted]

[redacted]

[redacted]

32. [redacted]

E. [redacted]

33. [redacted]

34. [redacted]

35. [redacted]

[redacted]

[redacted]

36. [redacted]

37. A June 5, 2023 article in the Wall Street Journal regarding the agreement between Coherus and Cost Plus opines that Coherus is targeting a market share of just 10% and that its pricing strategy "isn't likely to be popular with many of the pharmacy-benefit managers that control how most Americans get their drugs" because "these gatekeepers don't like it when drugs are priced very cheaply."[10]

38. On information and belief, the other Humira® biosimilar entrants that will be licensed to launch in July 2023 have been engaging in the same kind of preparation as Coherus, including by establishing prospective pricing arrangements [redacted].

F. Coherus and Cost Plus Issue Press Releases.

39. On June 1, 2023, Coherus issued a Press Release announcing

> [P]lans to launch YUSIMRY (adalimumab-aqvh) in July 2023* with a list price of $995 per carton (2 x 40 mg/0.8 mL

[10] David Wainer, *Even Mark Cuban Can't Fix This Broken Drug System*, The Wall Street Journal (June 5, 2023), at https://www.wsj.com/articles/even-mark-cuban-cant-fix-this-broken-drug-system-de914adc.

> autoinjectors), the lowest price announced to date of any adalimumab offering in the United States. With Humira® currently priced at $6,922 per carton of two autoinjectors, the YUSIMRY price will represent about an 85% discount from the originator.

40. The press release includes the following statement: "*No sales will occur, and no purchase orders will be accepted, until July 2023."

41. Recognizing the significant savings this will provide to individual consumers and to the health system overall, the press release quotes the CEO of Coherus, Dennis Lanfear, as saying: "Our YUSIMRY list price is a clear response to the challenges and needs of patients faced with high-cost adalimumab treatments today." He goes on to say:

> We believe there is a large, unmet need for improved access and affordability in the U.S. health care system that YUSIMRY can address with this pricing. Our excellence in manufacturing and supply chain management gives us the ability to deliver safe and effective biosimilar adalimumab at low cost with ensured, reliable supply.

42. Chris Slavinsky, Coherus's Chief Legal & Business Officer, added:

> We believe YUSIMRY can be an affordable solution for patients who are uninsured, underinsured, or recently separated from Medicaid coverage, who experience the most difficult financial health challenges. We also believe that employers and the employees on their health plans can experience significant savings by selecting YUSIMRY when it becomes available in July.

43. That same day, Coherus and Cost Plus issued a joint press release that "announced plans to offer Mark Cuban Cost Plus Drug Company customers YUSIMRY (adalimumab-aqvh), a biosimilar of HUMIRA®, in July 2023."

44. "Humira is the top-selling medicine of all time, but for those without insurance or who are underinsured, this therapy and other biologic medicines have been out of reach due to price," said Alex Oshmyansky, Co-Founder and CEO of Cost Plus. "Working with Coherus, a pioneer in the field of biosimilars, we are excited to disrupt the high-cost biologic space by offering YUSIMRY, a biosimilar of Humira, one of the highest cost drugs in America."

45. The press release continues:

> Mark Cuban 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 has a state-of-the-art autoinjector presentation and includes Coherus's proprietary non-stinging, citrate-free formulation and a 29-gauge needle. YUSIMRY will also be included in the Team Cuban Card (teamcubancard.com) prescription benefit program through participating pharmacies. The Team Cuban Card provides patients the flexibility to get prescriptions filled at a local independent pharmacy at the same low prices they expect from Cost Plus Drugs. Importantly, the Team Cuban Card also supports the independent pharmacy community with fair dispensing fees and a transparent pricing structure.

46. "Cost Plus Drugs is saving patients hundreds and thousands of dollars a month by pricing our medications fairly at our cost plus 15%," said Mark Cuban, Co-Founder of Cost Plus. "Adding YUSIMRY, a biosimilar of Humira, to Cost Plus

Drugs will extend these savings to biologics. This is just our first step in making biologics affordable for patients."

COUNT I
IMMEDIATE ENTRY OF TEMPORARY RESTRAINING ORDER FOLLOWED BY A PROHIBITORY INJUNCTION

47. Coherus hereby incorporates paragraphs 1 through 46 alleged above, as if fully stated herein.

48. On June 6, 2023, AbbVie sent Coherus a letter purporting to notify Coherus that it had violated Section 5.2 of the License. The letter pointed to language contained in the Coherus/Cost Plus press release announcing "plans to offer Mark Cuban Cost Plus Drug Company customers YUSIMRY . . . in July 2023." AbbVie did not specify which portion of Section 5.2 it believed Coherus had violated, or how. The letter stated that "AbbVie reserves all its rights to take any actions necessary to address Coherus's violation of the [License]." AbbVie also demanded that Coherus provide it [redacted]

49. Coherus responded to AbbVie's letter on June 11, 2023 and provided AbbVie [redacted]. Coherus demanded that AbbVie state specifically what part of Section 5.2 it claims Coherus has violated, and how, to

enable Coherus to assess AbbVie's claim and, if appropriate, take steps to cure. It also demanded that AbbVie withdraw its notice.

50. Despite Coherus's request in response to the notice, AbbVie has neither specified what conduct it believes violated Section 5.2, nor agreed to withdraw the

[redacted]

51. Coherus will be irreparably harmed if AbbVie terminates the License. Coherus has relied on the grant of the license to prepare a major product launch over the past year or more, involving numerous market entities and likely thousands of customers. [redacted] A temporary restraining order ensures that Coherus's long-planned YUSIMRY™ launch will occur without disruption to Coherus, its many partners, and the customers who will gain access to a critical medicine at a much more affordable price.

52. AbbVie, on the other hand, would suffer no harm from a temporary restraining order prohibiting it from terminating the royalty-bearing License pending further action by this Court. In addition to Amgen, which is already selling a generic version of Humira®, at least eight other companies are planning to launch biosimilar versions of Humira® in July 2023. Given Coherus's production capacity and low-

priced business model, its presence in the market poses no risk of harm to AbbVie, which will benefit from the royalties Coherus must pay.

53. Based on the foregoing facts and the terms of the License, Coherus is entitled to a temporary restraining order followed by a prohibitory injunction requiring AbbVie to refrain from terminating or purporting to terminate the License.

COUNT II
DECLARATORY JUDGMENT
(10 *Del. C.* § 6501)

54. Coherus hereby incorporates paragraphs 1 through 53 alleged above, as if fully stated herein.

55. Coherus has a legal interest in whether the License remains in effect. Absent the License, Coherus would be exposed to potential patent infringement claims by AbbVie.

56. AbbVie has an interest in contesting whether it has the right to terminate the License. In particular, absent the License, AbbVie has the right to sue Coherus for patent infringement and to seek to preclude Coherus from selling YUSIMRY™.

57. Coherus and AbbVie have an actual controversy over whether there has been sufficient notice of breach, an actual breach, a failure to cure, and the corresponding right to terminate the License.

58. The determination whether AbbVie has the legal right to terminate the License is ripe because AbbVie is threatening to terminate the License [redacted] AbbVie has taken this action only weeks before Coherus will launch YUSIMRY™.

59. The License permits AbbVie to terminate for a breach of Section 5.2 only upon providing notice of the alleged breach and allowing Coherus [redacted] to cure that breach.

60. The notice that AbbVie has provided does not meet the contract requirements. AbbVie has not identified what Coherus has done that violates Section 5.2 or what portion of that section it claims Coherus has violated. Because AbbVie's notice was insufficiently specific, Coherus cannot assess AbbVie's claim or determine how it might cure the alleged breach. Accordingly, AbbVie has not afforded Coherus its contractual right to cure any alleged breach of Section 5.2. To the extent AbbVie's notice purports to claim that Coherus breached Section 5.2 by issuing the press release quoted in the notice or by [redacted] AbbVie is wrong. Neither the press release nor the [redacted] violates Section 5.2.

61. Based on the foregoing facts and the terms of the License, Coherus is entitled to a declaration that Coherus has not breached the License and that AbbVie does not have a contractual right at this time to terminate the License.

COUNT III
SPECIFIC PERFORMANCE

62. Coherus hereby incorporates paragraphs 1 through 61 alleged above, as if fully stated herein.

63. The License is a valid and enforceable contract.

64. Coherus has performed all of its obligations under the License and has not breached the License.

65. Coherus and AbbVie have an actual controversy over whether there has been sufficient notice of breach, an actual breach, a failure to cure, and the corresponding right to terminate the License.

66. The determination whether AbbVie has the legal right to terminate the License is ripe because AbbVie is threatening to terminate the License [redacted] and refuses to withdraw its June 6, 2023 notice of breach. Moreover, AbbVie has taken this action only weeks before Coherus will launch YUSIMRY™.

67. The License permits AbbVie to terminate for a breach of Section 5.2 only upon providing notice of the alleged breach and allowing Coherus [redacted] to cure that breach.

68. The notice that AbbVie has provided does not meet the contract requirements. AbbVie has not identified what Coherus has done that violates Section 5.2 or what portion of that section it claims Coherus has violated. Because

AbbVie's notice was insufficiently specific, Coherus cannot assess AbbVie's claim or determine how it might cure the alleged breach. Accordingly, AbbVie has not afforded Coherus its contractual right to cure any alleged breach of Section 5.2. To the extent AbbVie's notice purports to claim that Coherus breached Section 5.2 by issuing the press release quoted in the notice or by [redacted] AbbVie is wrong. Neither the press release nor the [redacted] violates Section 5.2.

69. Based on the foregoing facts and the terms of the License, Coherus is entitled to an order of specific performance compelling AbbVie to comply with its obligations under the License.

Prayer for Relief

WHEREFORE, Plaintiff requests that the Court:

A. Enter a temporary restraining order pending further action by this Court with respect the parties' dispute over Section 5.2 and prohibiting AbbVie from terminating the License in the meantime;

B. Declare that Coherus has not been provided adequate notice of a breach of Section 5.2, has not been afforded [redacted] cure period, has not breached Section 5.2 by [redacted] with Cost Plus or by issuing its press releases, and that AbbVie is not entitled to terminate the License;

C. Order specific performance compelling AbbVie to continue to comply with its obligations under the License;

D. Award Coherus its costs and expenses, including attorneys' fees, incurred in connection with this action; and

E. Grant such other relief as the Court may deem just and proper.

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