IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

COHERUS BIOSCIENCES, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 19-139 (RGA)
	)	
AMGEN INC.,	)	
	)	
Defendant.	)	

AMGEN INC.'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS

Defendant Amgen Inc. ("Amgen") hereby submits its Answer, Affirmative Defenses, and Counterclaims to the First Amended Complaint ("Amended Complaint") filed by Plaintiff Coherus Biosciences, Inc. ("Coherus"), on March 5, 2019.

Under Fed. R. Civ. P. 8(b)(3), Amgen denies each and every allegation in the Amended Complaint, whether express or implied, except those specifically and expressly admitted below. Any factual allegation admitted below is admitted only as to the specific admitted facts, not as to any purported conclusion, characterization, implication, or speculation that may arguably follow from the admitted facts. To the extent any allegation in the Amended Complaint is vague and/or ambiguous, Amgen denies such allegations. Amgen denies that Plaintiff is entitled to the relief requested or any other relief.

The headings and subheadings in Amgen's Answer are used solely for purposes of convenience and organization to mirror those appearing in the Amended Complaint; to the extent that any headings or other non-numbered statements in the Amended Complaint contain or imply any allegations, Amgen denies each and every allegation therein. Each of the numbered paragraphs in the Answer below corresponds to the same-numbered paragraphs in the Amended Complaint.

ANSWER TO THE AMENDED COMPLAINT

NATURE OF ACTION

1. Amgen admits that Coherus has brought an action alleging infringement of United States Patent Nos. 10,155,039 ("the '039 patent"), 10,159,732 ("the '732 patent"), 10,159,733 ("the '733 patent"), and 10,207,000 ("the '000 patent") under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*. Amgen denies that Coherus is entitled to any such relief, requested or otherwise. Amgen denies the remaining allegations of paragraph 1.

THE PARTIES

2. Upon information and belief, Amgen admits the allegations of paragraph 2.

3. Amgen admits the allegations of paragraph 3.

JURISDICTION AND VENUE

4. The allegations of paragraph 4 are legal conclusions that require no response, and on that basis Amgen denies them.

5. Amgen admits that it is incorporated in the State of Delaware. The remaining allegations of paragraph 5 contain legal conclusions that require no response, and on that basis Amgen denies them.

6. Amgen admits that it is registered to do business in Delaware. The remaining allegations of paragraph 6 contain legal conclusions that require no response, and on that basis Amgen denies them.

7. The allegations of paragraph 7 are legal conclusions that require no response, and on that basis Amgen denies them.

FACTUAL BACKGROUND

8. Amgen admits that the ’039 patent is entitled “Stable Aqueous Formulations of Adalimumab,” issued on December 18, 2018, and names Mark Manning and Robert W. Payne as inventors. Amgen admits that Exhibit A to the Amended Complaint appears to be a copy of the ’039 patent. Amgen lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 8, and on that basis denies them.

9. Amgen admits that claim 1 of the ’039 patent recites “[a] stable aqueous pharmaceutical composition comprising: a) adalimumab; b) a buffer; c) polysorbate 80; and d) a sugar, wherein the composition is free of i) mannitol, ii) citrate and phosphate buffers, and iii) sodium chloride and wherein the composition has a pH of about 5 to about 6.” Amgen lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 9, and on that basis denies them.

10. Amgen admits that the ’732 patent is entitled “Stable Aqueous Formulations of Adalimumab,” issued on December 25, 2018, and names Mark Manning and Robert W. Payne as inventors. Amgen admits that Exhibit B to the Amended Complaint appears to be a copy of the ’732 patent. Amgen lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 10, and on that basis denies them.

11. Amgen admits that claim 1 of the ’732 patent recites “[a] stable aqueous pharmaceutical composition comprising: i) adalimumab; ii) a buffer; and iii) a stabilizer; wherein the composition is free of mannitol and has a pH of about 5 to about 6.” Amgen lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 11, and on that basis denies them.

12. Amgen admits that the '733 patent is entitled "Stable Aqueous Formulations of Adalimumab," issued on December 25, 2018, and names Mark Manning and Robert W. Payne as inventors. Amgen admits that Exhibit C to the Amended Complaint appears to be a copy of the '733 patent. Amgen lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 12, and on that basis denies them.

13. Amgen admits that the '733 patent claims recite "[a] stable aqueous pharmaceutical composition comprising: i) adalimumab; ii) a single buffer; iii) a surfactant; and iv) a sugar, wherein the composition is free of mannitol and has a pH of about 5 to about 6." Amgen lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 13, and on that basis denies them.

14. Amgen admits that the '000 patent is entitled "Stable Aqueous Formulations of Adalimumab," issued on February 19, 2019, and names Mark Manning and Robert W. Payne as inventors. Amgen admits that Exhibit D to the Amended Complaint appears to be a copy of the '000 patent. Amgen lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 14, and on that basis denies them.

15. Amgen admits that the '000 patent claims recite "[a] stable aqueous pharmaceutical composition comprising: i) adalimumab; ii) a single buffer; iii) a surfactant; and iv) a tonicity modifier, wherein the composition is free of mannitol and has a pH of about 5 to about 6." Amgen lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 15, and on that basis denies them.

16. Amgen lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 16, and on that basis denies them.

17. Amgen denies that on October 15, 2016, it announced that it would launch AMGEVITA™ (adalimumab) in markets across Europe beginning on October 16, 2018. Amgen admits that on October 15, 2018, it issued a press release, which stated that "AMGEVITA™, a biosimilar to adalimumab, will launch in markets across Europe beginning on October 16, 2018." Amgen denies the remaining allegations of paragraph 17.

18. Amgen admits that AMGEVITA is approved by the European Commission and is authorized for the treatment of inflammatory diseases in adults, including moderate-to-severe rheumatoid arthritis; psoriatic arthritis; severe active ankylosing spondylitis ("AS"); severe axial spondyloarthritis without radiographic evidence of AS; moderate-to-severe chronic plaque psoriasis; moderate-to-severe Crohn's disease; and moderate-to-severe ulcerative colitis. AMGEVITA is also authorized for the treatment of pediatric inflammatory diseases, including moderate-to-severe Crohn's disease (ages six and older), severe chronic plaque psoriasis (ages four and older), enthesitis-related arthritis (ages six and older), and polyarticular juvenile idiopathic arthritis (ages two and older). D.I. 7-7. Amgen denies the remaining allegations of paragraph 18.

19. Amgen admits that one or more Amgen affiliates are offering for sale and selling AMGEVITA in Europe. The remaining allegations of paragraph 19 are legal conclusions that require no response, and on that basis Amgen denies them.

20. Amgen admits that Amgen manufactures AMGEVITA in the United States. Amgen admits that the European Medicine Agency's ("EMA") Assessment Report on AMGEVITA states that "Amgen Thousand Oaks (ATO), USA, is responsible for active substance manufacture." Amgen further admits that Annex I to the EMA Assessment Report (which was not filed with the Amended Complaint as Exhibit F) lists the name and address of the

manufacturer of the biological active substance as Amgen Inc., One Amgen Center Drive, Thousand Oaks, California 91320, United States. Amgen denies the remaining allegations of paragraph 20.

21. Amgen admits that the EMA Assessment Report states that "[t]he active substance and finished product have an identical formulation. The formulation is not modified during finished product manufacturing." Amgen further admits that the EMA Assessment Report states that "[t]he finished product has the same formulation and concentration as the active substance. Therefore, no dilution is required for finished product manufacturing and the concentrations of active and excipients remain the same." Amgen denies the remaining allegations of paragraph 21.

22. Amgen admits that it manufactures adalimumab in the United States, and AMGEVITA is sold in Europe. Amgen denies the remaining allegations of paragraph 22.

23. Amgen admits that the active ingredient in AMGEVITA is adalimumab. Amgen admits that excipients in AMGEVITA include glacial acetic acid, sucrose, polysorbate 80, and water for injection; sodium hydroxide is used for pH adjustment. Amgen denies the remaining allegations of paragraph 23.

24. Amgen admits that one of the constituent ions of glacial acetic acid functions as a buffer in the AMGEVITA formulation. Amgen admits that sucrose is a sugar and can function as a stabilizer and/or a tonicity modifier in certain formulations. Amgen admits that polysorbate 80 can function as a surfactant in certain formulations. Amgen further admits that the Annex I to the EMA Assessment Report lists "Sodium hydroxide (for pH adjustment)" as an excipient of AMGEVITA. Amgen admits that Annex I to the EMA Assessment Report does not identify mannitol, citrate or phosphate buffers, or sodium chloride as components in the AMGEVITA

formulation. Amgen admits that the pH of the AMGEVITA formulation is between 5 and 6. Amgen denies the remaining allegations of paragraph 24.

25. Amgen admits that Coherus has brought this action alleging infringement of the '039, '732, '733, and '000 patents with respect to AMGEVITA, and to recover alleged damages. Amgen denies infringement and denies that Coherus is entitled to any relief for the manufacture and use of AMGEVITA in the United States, as requested or otherwise. Amgen lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 25, and on that basis denies them.

COUNT I
Alleged Infringement of the '039 Patent Under 35 U.S.C. § 271(a) by Amgen's AMGEVITA Product

26. Amgen incorporates each of its responses to the preceding paragraphs as if fully set forth herein.

27. Amgen admits that on October 15, 2018, it issued a press release, which stated that "AMGEVITA™, a biosimilar to adalimumab, will launch in markets across Europe beginning on Oct. 16, 2018." Amgen further admits that one or more Amgen affiliates are offering for sale and selling AMGEVITA in Europe. The remaining allegations of paragraph 27 are legal conclusions that require no response, and on that basis Amgen denies them.

28. Amgen incorporates its response to paragraph 27 as if fully set forth herein. Amgen further admits that it began commercial manufacture of adalimumab at a facility it operates in Thousand Oaks, California since at least October 16, 2018. The remaining allegations of paragraph 28 are legal conclusions that require no response, and on that basis Amgen denies them.

29. Amgen admits that AMGEVITA is an aqueous composition containing adalimumab, glacial acetic acid, sucrose, polysorbate 80, and water for injection at a pH between

about 5 and about 6; sodium hydroxide is used for pH adjustment. Amgen denies the remaining allegations of paragraph 29.

30. Amgen specifically denies that it has infringed or will infringe any valid and enforceable claim of the ’039 patent. Amgen denies the remaining allegations of paragraph 30.

31. Amgen admits that it became aware of the ’039 patent no later than January 24, 2019. Amgen denies the remaining allegations of paragraph 31.

32. Amgen denies the allegations of paragraph 32.

33. Amgen denies the allegations of paragraph 33.

34. Amgen denies the allegations of paragraph 34.

35. Amgen denies the allegations of paragraph 35.

COUNT II
Alleged Infringement of the ’732 Patent Under 35 U.S.C. § 271(a) by Amgen’s AMGEVITA Product

36. Amgen incorporates each of its responses to the preceding paragraphs as if fully set forth herein.

37. Amgen admits that on October 15, 2018, it issued a press release, which stated that “AMGEVITA™, a biosimilar to adalimumab, will launch in markets across Europe beginning on Oct. 16, 2018.” Amgen further admits that one or more Amgen affiliates are offering for sale and selling AMGEVITA in Europe. The remaining allegations of paragraph 37 are legal conclusions that require no response, and on that basis Amgen denies them.

38. Amgen incorporates its response to paragraph 37 as if fully set forth herein. Amgen further admits that it began commercial manufacture of adalimumab at a facility it operates in Thousand Oaks, California since at least October 16, 2018. The remaining allegations of paragraph 38 are legal conclusions that require no response, and on that basis Amgen denies them.

39. Amgen admits that AMGEVITA is an aqueous composition containing adalimumab, glacial acetic acid, sucrose, polysorbate 80, and water for injection at a pH between about 5 and about 6; sodium hydroxide is used for pH adjustment. Amgen denies the remaining allegations of paragraph 39.

40. Amgen specifically denies that it has infringed or will infringe any valid and enforceable claim of the ’732 patent. Amgen denies the allegations of paragraph 40.

41. Amgen admits that it became aware of the ’732 patent no later than January 24, 2019. Amgen denies the remaining allegations of paragraph 41.

42. Amgen denies the allegations of paragraph 42.

43. Amgen denies the allegations of paragraph 43.

44. Amgen denies the allegations of paragraph 44.

45. Amgen denies the allegations of paragraph 45.

COUNT III
Alleged Infringement of the ’733 Patent Under 35 U.S.C. § 271(a) by Amgen’s AMGEVITA Product

46. Amgen incorporates each of its responses to the preceding paragraphs as if fully set forth herein.

47. Amgen admits that on October 15, 2018, it issued a press release, which stated that “AMGEVITA™, a biosimilar to adalimumab, will launch in markets across Europe beginning on Oct. 16, 2018.” Amgen further admits that one or more Amgen affiliates are offering for sale and selling AMGEVITA in Europe. The remaining allegations of paragraph 47 are legal conclusions that require no response, and on that basis Amgen denies them.

48. Amgen incorporates its response to paragraph 47 as if fully set forth herein. Amgen further admits that it began commercial manufacture of adalimumab at a facility it operates in Thousand Oaks, California since at least October 16, 2018. The remaining

allegations of paragraph 48 are legal conclusions that require no response, and on that basis Amgen denies them.

49. Amgen admits that AMGEVITA is an aqueous composition containing adalimumab, glacial acetic acid, sucrose, polysorbate 80, and water for injection at a pH between about 5 and about 6; sodium hydroxide is used for pH adjustment. Amgen denies the remaining allegations of paragraph 49.

50. Amgen specifically denies that it has infringed or will infringe any valid or enforceable claim of the ’733 patent. Amgen denies the allegations of paragraph 50.

51. Amgen admits that it became aware of the ’733 patent no later than January 24, 2019. Amgen denies the remaining allegations of paragraph 51.

52. Amgen denies the allegations of paragraph 52.

53. Amgen denies the allegations of paragraph 53.

54. Amgen denies the allegations of paragraph 54.

55. Amgen denies the allegations of paragraph 55.

COUNT IV
Alleged Infringement of the ’000 Patent Under 35 U.S.C. § 271(a) by Amgen’s AMGEVITA Product

56. Amgen incorporates each of its responses to the preceding paragraphs as if fully set forth herein.

57. Amgen admits that on October 15, 2018, it issued a press release, which stated that “AMGEVITA™, a biosimilar to adalimumab, will launch in markets across Europe beginning on Oct. 16, 2018.” Amgen further admits that one or more Amgen affiliates are offering for sale and selling AMGEVITA in Europe. The remaining allegations of paragraph 57 are legal conclusions that require no response, and on that basis Amgen denies them.

58. Amgen incorporates its response to paragraph 57 as if fully set forth herein. Amgen further admits that it began commercial manufacture of adalimumab at a facility it operates in Thousand Oaks, California since at least October 16, 2018. The remaining allegations of paragraph 58 are legal conclusions that require no response, and on that basis Amgen denies them.

59. Amgen admits that AMGEVITA is an aqueous composition containing adalimumab, glacial acetic acid, sucrose, polysorbate 80, and water for injection at a pH between about 5 and about 6; sodium hydroxide is used for pH adjustment. Amgen denies the remaining allegations of paragraph 59.

60. Amgen specifically denies that it has infringed or will infringe any valid or enforceable claim of the ’000 patent. Amgen denies the allegations of paragraph 60.

61. Amgen admits that it became aware of the ’000 patent no earlier than February 19, 2019. Amgen denies the remaining allegations of paragraph 61.

62. Amgen denies the allegations of paragraph 62.

63. Amgen denies the allegations of paragraph 63.

64. Amgen denies the allegations of paragraph 64.

65. Amgen denies the allegations of paragraph 65.

JURY TRIAL DEMAND

No response is required to Coherus’ demand for a trial by jury in this case.

PRAYER FOR RELIEF

Coherus’ prayer for relief does not require a response. To the extent a response is required, Amgen denies that Coherus is entitled to any remedy or relief.

AFFIRMATIVE DEFENSES

Without admitting or implying that Amgen bears the burden of proof or burden of persuasion as to any of them, Amgen, on information and belief, asserts the following defenses:

FIRST AFFIRMATIVE DEFENSE
(Invalidity)

66. The '039, '732, '733 and '000 patents (collectively, the "Asserted Patents"), and each of the claims thereof, are invalid for failure to comply with one or more requirements set forth in 35 U.S.C. § 1 *et seq.*, including, but not limited to, one or more provisions of 35 U.S.C. §§ 102, 103, and/or 112, and/or under other judicially created bases for invalidity and/or unenforceability.

SECOND AFFIRMATIVE DEFENSE
(No Infringement)

67. Amgen has not infringed, does not infringe, and will not infringe, either literally or under the doctrine of equivalents, any claim of the Asserted Patents.

THIRD AFFIRMATIVE DEFENSE
(No Willfulness)

68. Amgen has not willfully infringed, and is not willfully infringing, any claim of the Asserted Patents.

FOURTH AFFIRMATIVE DEFENSE
(Exceptional Case)

69. Amgen's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

FIFTH AFFIRMATIVE DEFENSE
(No Equitable Relief)

70. Coherus is not entitled to any equitable relief.

SIXTH AFFIRMATIVE DEFENSE
(Prior Commercial Use)

71. As noted above, Amgen denies any infringement, but in the event it is found that every element of any asserted claim is met by AMGEVITA, Amgen is entitled to a complete defense under 35 U.S.C. § 273 based on Amgen's prior commercial use.

SEVENTH AFFIRMATIVE DEFENSE
(Inequitable Conduct)

72. The claims of the Asserted Patents are unenforceable due to Coherus' inequitable conduct.

73. In order to obtain the Asserted Patents with claims to anticipated and obvious variants of adalimumab formulations, Coherus had to deceive the United States Patent and Trademark Office ("Patent Office"). Specifically, to procure the Asserted Patents, the Asserted Patents' inventor Mark Manning, Coherus' patent attorney Tiffany Reiter, and anyone working in concert with them, withheld material prior art and other information from the Patent Office and made affirmative misstatements of material fact with the intention of deceiving the Patent Office and procuring the Asserted Patents on the basis of an incomplete and/or misleading record. As an inventor on the Asserted Patents and an attorney prosecuting the application, respectively, Manning and Reiter had a duty to disclose information material to patentability under 37 C.F.R. § 1.56. Manning is an inventor on many patents and Reiter is a highly experienced patent lawyer, and thus both were well aware that the information they failed to disclose or misrepresented would have been material to the Examiner.

74. Below are exemplary instances of inequitable conduct by Coherus, acting through Manning and Reiter, any one of which would be sufficient to render the claims of the Asserted Patents unenforceable.

Failure to Disclose Existence of and Contradictory Statements in Coherus IPR Petitions

75. At the time Manning and Reiter were prosecuting the Asserted Patents, Coherus had filed multiple IPR petitions challenging the claims of AbbVie's adalimumab formulation patents, in which Coherus took positions contrary to positions it knowingly took to procure issuance of the Asserted Patents. *See, e.g.*, IPR Nos. 2016-01018, 2017-00822, -00823, -00826 and -00827. These contrary positions were material to the patentability of the Asserted Patent claims, and at least Manning and Reiter knew this. In particular, Coherus took positions regarding what a POSA would have known and what would have been obvious to a POSA with respect to the creation of stable aqueous formulations of adalimumab as of August 2002, more than ten years before the priority date of the Asserted Patents. Later, during prosecution of the Asserted Patents, when Coherus' legal and financial interests changed, Manning and Reiter knowingly took contradictory positions to procure issuance of the Asserted Patents.

76. Upon information and belief, during prosecution of the Asserted Patents, Manning and Reiter knew of but did not disclose to the Patent Office the existence of Coherus' IPR petitions challenging patents in the very same field (i.e., stable formulations of adalimumab), nor did they disclose the contradictory positions Coherus took therein, despite having a duty to do so. *See* MPEP § 2001.06(c).

77. Had the Examiner been aware of the contradictory positions Coherus took in its IPR petitions regarding what a POSA would have known and what would have been obvious to a POSA with respect to the creation of stable aqueous formulations of adalimumab as of August 2002, the Examiner would not have allowed any of the Asserted Patent claims to issue. Examples of Coherus' contradictory positions are set forth below.

78. During prosecution of the Asserted Patents, Manning and Reiter told the Patent Office that a POSA in 2012 would not have had a reasonable expectation of success in arriving

at the claimed stable adalimumab formulations due to the unpredictability in formulating proteins. In its IPR petitions, however, Coherus told the Patent Office that a POSA in 2002 would have had a reasonable expectation of success in arriving at similar stable liquid adalimumab formulations because combining prior art references in this field entails nothing more than the predictable use of prior art elements.

79. Specifically, during prosecution of the Asserted Patents, Manning and Reiter argued that "[t]he Office ***has not demonstrated that those skilled in the art [as of 2012] would have had a reasonable expectation of success*** in arriving at the claimed invention" in view of prior art discussing stable formulations containing IgG1 or IgG1-derived antibodies (Lam) combined with a reference disclosing formulations comprising adalimumab (Salfeld), citing, among other things, "the ***unpredictability*** in formulating proteins." *See, e.g.*, Appl. No. 15/799,851, 9/18/2018 Response to Final Rejection at 8–9 (emphases added). By contrast, in its May 9, 2016 petition in IPR No. 2016-01018, Coherus took the position that a "POSA [in 2002] ***would have had a reasonable expectation of success***" arriving at the claimed stable adalimumab formulations based on a reference discussing stable formulations of IgG1 antibodies combined with a reference disclosing adalimumab formulations, because the combination of these references, "i.e., exchanging one IgG1 antibody for another in known stable formulations," involves nothing more than "'the ***predictable*** use of prior art elements according to their established functions' and is therefore obvious." IPR2016-01018 (Petition) at 33, 49–50 (quoting *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007)) (emphases added). Had the Examiner been aware of Coherus' IPR arguments regarding reasonable expectation of success and predictability, the Examiner would have rejected Manning's and Reiter's prosecution

arguments that there was no reasonable expectation of success in this unpredictable field and found one or more claims of the Asserted Patents obvious.

80. As another example, during prosecution of the Asserted Patents, Manning and Reiter told the Patent Office that as of 2012, a POSA would not have been able to predict the stability of a recombinant antibody based on data generated using a different IgG1 antibody. Yet, in its IPR petition, Coherus told the Patent Office that as of 2002, prior art discussing formulations containing an IgG1 antibody would be expected to apply to formulations containing another IgG1 antibody.

81. Specifically, during prosecution of the Asserted Patents, Manning and Reiter argued that a POSA in 2012 "would not have been able to reasonably predict the stability of a recombinant antibody based on data generated using a different [IgG1] antibody" (*see, e.g.*, Appl. No. 15/799,851, 9/18/2018 Response to Final Rejection at 8–9), and that "[t]he stability of a protein in a pharmaceutical formulation depends on both the ***specific protein***, as well ***as each additive*** that is present in the formulation" (*id.* at 8) (emphasis in original). By contrast, in its May 9, 2016 petition in IPR No. 2016-01018, Coherus took the position that as of 2002, prior art references discussing IgG1 antibodies were relevant to patentability as "guidepost[s] to formulate the protein of interest," because, among other reasons, "D2E7 [adalimumab] behaves like a typical IgG1 antibody and there is nothing unexpected about its formulations." IPR2016-01018 (Petition) at 3–4, 12. Had the Examiner been aware of Coherus' IPR statements that prior art regarding IgG1 antibody formulations would be expected to apply to formulations containing another IgG1 antibody, the Examiner would have rejected Manning's and Reiter's contrary prosecution arguments that prior art directed to a different IgG1 antibody did not apply and found one or more claims of the Asserted Patents obvious.

82. As another example, in order to procure the Asserted Patents, Manning and Reiter told the Patent Office that as of 2012, extensive experimentation was required to formulate stable proteins, but in its IPR petition, Coherus told the Patent Office that the science of designing stable liquid protein formulations was well established by August 2002, and that formulators knew how to address challenges associated with the development of stable proteins.

83. Specifically, during prosecution of the Asserted Patents, Manning and Reiter took the position that as of 2012, "there is still no[] single pathway to follow in formulating proteins due to their structural diversities and complexities," and that "[t]here are several stages that require careful consideration and ***extensive experimentation*** in formulating a stable protein product." *See, e.g.*, Appl. No. 15/799,851, 9/18/2018 Response to Final Rejection at 9 (emphasis in original) (quoting Wang et al., Int. J Pharmaceutics 185: 129-188, 1999). By contrast, in its May 9, 2016 petition in IPR No. 2016-01018, Coherus took the position that the "science of rationally designing stable, liquid protein formulations was well-established by August 2002," that the literature (including Manning's own publications) "revealed both a rational approach to follow and specific example formulations of IgG1 antibodies," and that "formulators knew how to address" "stability challenges" associated with the "development of stable proteins." IPR2016-01018 (Petition) at 12–13, 32; Ex. A (Declaration of Mark C. Manning, Ph.D. (hereinafter, "Manning Decl.")) ¶¶ 85–90. Had the Examiner been aware of Coherus' IPR statements that there was a rational, well-established approach to developing stable liquid protein formulations of IgG1 antibodies as early as 2002, the Examiner would have rejected Manning's and Reiter's contrary prosecution arguments that in 2012 extensive experimentation was required to develop stable formulations of adalimumab and found one or more claims of the Asserted Patents obvious.

Failure to Disclose the Existence and Content of the Declaration of Mark C. Manning

84. To support its petition IPR No. 2016-01018, Coherus procured, relied on, and submitted sworn testimony from Dr. Mark Manning, one of the two named inventors of the Asserted Patents. In his sworn testimony, Manning provided numerous statements material to the patentability of the Asserted Patent claims, including statements about what a POSA would have known and what would have been obvious to a POSA with respect to the creation of stable aqueous formulations of adalimumab as of August 2002, more than ten years before the priority date of the Asserted Patents. *See* Ex. A (Manning Decl.). Upon information and belief, Manning and Reiter did not disclose Manning's material statements or even the existence of Manning's declaration challenging patents in the same field (stable formulations of adalimumab) to the Patent Office during prosecution of the Asserted Patents, despite having a duty to do so. *See supra* ¶ 73. Had Manning and Reiter disclosed this material information to the Patent Office, one or more claims of the Asserted Patents would not have proceeded to allowance.

85. For example, the claims of the Asserted Patents are all directed to stable aqueous pharmaceutical compositions comprising the IgG1 antibody adalimumab. In his sworn declaration, Manning testified that:

> ***Making stable protein formulations was a mature art field by the early 2000s.*** (*See, e.g.*, EX1024; EX1025; EX1060; EX1052.) In order to develop a new liquid antibody formulation, a POSA would have looked for guidance in the published literature, and particularly for liquid formulations of antibodies belonging to the same subclass. In this case, ***the literature revealed both a rational approach to follow and specific example formulations of IgG1 antibodies***. (D2E7 belongs to the IgG1 subclass.) ***A POSA would have followed the rational approach and used the similar formulations*** as guideposts along the way.

Ex. A (Manning Decl.) ¶ 85 (emphasis added). Manning also took the position that "[i]t is true that development of stable liquid formulations presented certain stability challenges, but formulators knew how to address them." *Id.* ¶ 86. Had the Examiner been aware of Coherus'

statements regarding the development of stable protein formulations, one or more claims of the Asserted Patents would not have issued.

86. For example, claims 2, 4, 6, 8, 10, and 12 of the ’039 patent (D.I. 7-3), claims 4, 7, 10, and 13 of the ’732 patent (D.I. 7-4), claim 8 of the ’733 patent (D.I. 7-5), and claims 5, 7, 9, and 11 of the ’000 patent (D.I. 7-6) require that the claimed composition “has osmolality of about 180 to 420 mOsM.” In his sworn declaration, Manning took the position that as early as “August 16, 2002, the skilled person would have understood that a subcutaneous formulation should have an osmolality matching that of the patient’s cells (*e.g.*, 250–350 mOsM) to minimize or prevent tissue damage at the injection site and minimize pain at the injection site.” Ex. A (Manning Decl.) ¶ 110. As another example, claims 9 through 12 of the ’039 patent (D.I. 7-3) and claims 3, 6, and 9 of the ’733 patent (D.I. 7-5) require an “acetate buffer.” In his sworn declaration, Manning stated that “[c]ommercially available protein and antibody formulations as of August 16, 2002 illustrate that citrate and ***acetate*** were two of the most commonly used buffers, both of which buffer well in the acidic pH range.” Ex. A (Manning Decl.) ¶ 108 (emphasis added). Had the Examiner been aware of these statements, one or more claims of the Asserted Patents requiring an osmolality of about 180 to 420 mOsM and/or an acetate buffer would not have issued.

Intentional and Fraudulent Withholding of Material Prior Art References

87. In order to obtain the Asserted Patents, Manning and Reiter intentionally and fraudulently withheld material prior art references with the specific intent of deceiving the Patent Office. More specifically, Manning and Reiter withheld from the Patent Office the most pertinent prior art patents from AbbVie’s portfolio of adalimumab patents with the inventor Hans-Juergen Krause (the “Krause patent family”), while submitting other patents in the same family with the same priority date that are less relevant.

88. The Krause patent family contains patents with claims to stable liquid aqueous pharmaceutical formulations comprising adalimumab and various excipients. All patents in the family claim priority to an application filed on August 16, 2002, years before the date of the earliest provisional application listed on the face of the Asserted Patents (September 7, 2012). Coherus was aware of the Krause patent family during prosecution of the Asserted Patents, at least because it filed an IPR petition on one of its members, U.S. Patent No. 9,114,166 (the "'166 patent"), and because it selectively disclosed certain Krause family patents to the Patent Office during prosecution of the Asserted Patents. Coherus was also aware that many Krause patents were material to the patentability of the Asserted Patents.

89. During prosecution of the Asserted Patents, Manning and Reiter filed several Information Disclosure Statements ("IDSs") disclosing prior art patents and publications to the Patent Office. Those IDSs included certain patents from AbbVie's Krause patent family (for example, the '166 patent, U.S. Patent No. 8,916,157 (the "'157 patent"), and U.S. Patent No. 8,216,583 (the "'583 patent")). But Manning and Reiter did not disclose patents from the Krause patent family that are most relevant to, and indeed anticipate, the claims of the Asserted Patents, for example, U.S. Patent No. 9,272,041 (the "'041 patent") and U.S. Patent No. 9,738,714 (the "'714 patent"), discussed *infra* at ¶¶ 121–124. The '041 and '714 patents issued on March 1, 2016 and August 22, 2017, respectively, and so were available for Manning and Reiter to disclose to the Patent Office long before the Asserted Patents began issuing on December 18, 2018.

90. For example, the '583 patent that Manning and Reiter did disclose to the Patent Office claims stable liquid aqueous pharmaceutical formulations comprising adalimumab, a surfactant, and ***a buffer system comprising citrate and phosphate***, wherein the formulation has a

pH of about 4 to about 8. But all of the claims of the '039 patent require that the composition be "***free of . . . citrate and phosphate buffers***," and several dependent claims of the other '732, '733, and '000 patents require that the composition is "free of citrate buffer," or that the buffer be acetate buffer. On the other hand, Manning and Reiter ***did not*** disclose the '041 patent, which claims stable liquid aqueous pharmaceutical formulations comprising adalimumab, ***acetate buffer***, polysorbate, trehalose or sucrose at a pH of about 4 to about 8, and anticipates many claims of the Asserted Patents.

91. The single most reasonable inference to be drawn from Manning's and Reiter's selective disclosure of certain, less pertinent or irrelevant Krause family patents is that Manning and Reiter acted with the intention of deceiving the Patent Office and procuring the Asserted Patents on the basis of an incomplete and/or misleading record. Had the Examiner been made aware of the more pertinent Krause family patents, the Asserted Patent claims would not have issued.

Coherus' Misrepresentations and Omissions Regarding the Commercial Formulations of Adalimumab

92. During prosecution of the Asserted Patents, Manning and Reiter made deliberate misrepresentations and omissions regarding prior art to the Asserted Patents, including the commercial adalimumab formulations in public knowledge, knowing that such information would be material to examination of the pending applications, all in an effort to deceive the Patent Office and procure the Asserted Patents on the basis of an incomplete and/or misleading record.

93. For example, during prosecution of the Asserted Patents, Manning and Reiter repeatedly represented to the Patent Office that "the two commercial adalimumab formulations of adalimumab [sic] both ***include mannitol***." *See, e.g.*, Appl. No. 15/799,851, 9/18/2018

Response to Final Rejection at 6 (emphases in original); *see also id.* at 3 ("[W]hile the two commercial formulations of adalimumab vary in several ways, both commercial formulations ***include mannitol***.") (emphasis in original); *id.* at 4 ("[O]ne skilled in the art would have been motivated to generate an adalimumab formulation that ***includes mannitol*** in view of Salfeld and the two commercial formulations of adalimumab[.]") (emphasis in original); *id.* at 7 (discussing two commercial formulations of HUMIRA® that include mannitol). In fact, at the time Manning and Reiter made these representations, both were aware, as was Coherus, that there were at least six different published, commercial formulations of adalimumab, four of which were free of mannitol (AMGEVITA/AMJEVITA/SOLYMBIC™ (adalimumab biosimilar), Cyltezo (U.S. & Europe), Exemptia, and Imraldi).

94. In allowing the claims of the Asserted Patents to issue, the Examiner expressly adopted Manning's and Reiter's argument regarding the commercial formulations of mannitol, demonstrating that the Asserted Patents would not have issued but for Manning's and Reiter's misrepresentations and omissions:

> The following is an examiner's statement of reasons for allowance: the claims are allowable because the most pertinent prior art neither teaches nor suggests any stable antibody formulations without mannitol, citrate/phosphate combination and NaCl.
>
> During the interview conducted on 8/15/18, Applicant has demonstrated that the mannitol is present in the most pertinent art of record (U.S. Pat 6,090,382) ***and the commercial formulation requires mannitol***. As such, the independent claim 1 inherently encompasses polyol even without reciting polyol. The polyol is added to antibody formulations to exhibit stability at room temperature but the claimed invention shows stability without mannitol. Note that the HUMIRA product information requires addition of mannitol.

See, e.g., Appl. No. 15/799,851, 10/18/2018 Notice of Allowance at 2 (emphasis added). *See Apotex Inc. v. UCB, Inc.*, 763 F.3d 1354, 1360–61 (Fed. Cir. 2014) (affirming inequitable conduct where, "[b]ased on the Examiner's reasons for allowance," the "Examiner adopted [the

applicant's] repeated misrepresentations verbatim"); *see also Wyeth Holdings Corp. v. Sandoz, Inc.*, No. 09-955-LPS-CJB, 2012 WL 600715, at *10 (D. Del. Feb. 3, 2012), *report and recommendation adopted*, No. 09-955-LPS, 2012 WL 749378 (D. Del. Mar. 1, 2012) (noting that "the Examiner repeatedly cited the data provided in the [patent applicant's] declaration as the primary reason for his allowance of the patent," and finding that "[t]he clear nexus between the alleged misrepresentations, the circumstances in which they were made, and the resulting impact they had on the Examiner's decision, leads to a reasonable inference of but-for materiality"); *Nycomed U.S. Inc. v. Glenmark Generics, Ltd.*, No. 8-CV-5023 (CBA)(RLM), 2010 WL 1257803, at *14 (E.D.N.Y. Mar. 26, 2010) (finding materiality in part because the examiner "expressly cited [plaintiff's] arguments" concerning the representations at issue). Had the Examiner been aware that there were at least five published commercial formulations of adalimumab that did not include mannitol, the Asserted Patent claims would not have issued.

Coherus' Misrepresentations and Omissions Regarding the Disclosure of the Lam Reference

95. During prosecution of the Asserted Patents, Manning and Reiter made deliberate misrepresentations and omissions regarding the prior art to the Asserted Patents, including U.S. Patent No. 6,171,586 ("Lam"), knowing that such information would be material to examination of the pending application, all in an effort to deceive the Patent Office and procure the Asserted Patents on the basis of an incomplete and/or misleading record.

96. For example, Manning and Reiter asserted that "the arguments presented in the Office Actions dated February 21, 2018 and July 18, 2018 do not establish [that] the art cited in the present obviousness rejection . . . [Lam] . . . teaches the element 'free of mannitol.'" 9/18/2018 Response to Final Rejection at 2. Specifically, Manning and Reiter argued that "the assertion that the claims in Lam teach a formulation 'free of mannitol' . . . is incorrect because

the underlying reasoning does not conform to the M.P.E.P rules or case law on the meaning of claim terms." *Id.* at 5. Manning and Reiter argued that "[t]he transitional term 'comprising' . . . is inclusive or open-ended and ***does not exclude*** additional, unrecited elements or method steps," and therefore that "claims 1, 6, and 8 of Lam do not teach a formulation that is free of mannitol." *Id.* at 5–6 (citations omitted) (emphasis added).

97. At the time Manning and Reiter made these representations, it was well-established that a reference need not state a feature's absence in order to disclose a negative limitation like "free of mannitol." Rather, the "optional inclusion" of a feature is sufficient to anticipate a claim that excludes the feature. *See, e.g.*, *Prolitec, Inc. v. Scentair Techs., Inc.*, 807 F.3d 1353, 1362 (Fed. Cir. 2015) ("[A]n 'optional inclusion' of a feature in the prior art anticipates a claim that excludes the feature."); *Upsher-Smith Laboratories Inc. v. Pamlab, LLC*, 412 F.3d 1319 (Fed. Cir. 2005) (holding that the "'optional inclusion' of antioxidants teaches vitamin supplement compositions that both do and do not contain antioxidants"); *Sud-Chemie, Inc. v. Multisorb Techs. Inc.*, 554 F.3d 1001, 1004–05 (Fed. Cir. 2009) ("Sud-Chemie draws the wrong inference from Komatsu's failure to specifically refer to the films as uncoated. As noted, Komatsu plainly teaches that containers can be made of films that are heat sealed without the use of adhesives, and thus without coatings . . . . The district court was thus correct to characterize Komatsu as teaching the use of uncoated films and not to interpret Komatsu as disclosing only films coated with adhesives.").

98. Furthermore, Manning's and Reiter's argument that the claimed formulations do not specifically exclude mannitol completely ignores that the ***specification*** of Lam explicitly discloses compositions free of mannitol. And although Manning and Reiter emphasized that claim 1 of Lam recites "a polyol" (9/18/2018 Response to Final Rejection at 6), the specification

makes clear that mannitol is not even the preferred polyol of the claim, stating that "[n]onreducing sugars such as sucrose and trehalose are the preferred polyols herein." U.S. Patent No. 6,171,586 (Lam) at 6:57–60; *see also id.* at 22:36–37 ("In preferred embodiments, the polyol is a nonreducing sugar, such as sucrose or trehalose."). Moreover, Lam contains a number of exemplary formulations that do not include mannitol, including formulations F1, F2, F3, and F5, which Lam characterizes as "stable aqueous pharmaceutical formulation[s]" of the invention, as shown in Table 1 below. *Id.* at 26:28–45. Manning and Reiter never pointed out these aspects of the specification of Lam to the Examiner, despite their direct relevance to the disputed issue of whether Lam disclosed compositions free of mannitol. Had the Examiner known that the specification of Lam disclosed compositions free of mannitol, the Examiner would have rejected Manning's and Reiter's arguments that the claims of the Asserted Patents are patentable because the exclusion of mannitol was unobvious, and the Asserted Patent claims would not have issued.

TABLE 1

Matrix of formulations prepared for this study.

Formulation	Buffer	pH	TWEEN 20 ™ (0.01% v/v)	NaCl (140 mM)	Mannitol (4% w/v)	Trehalose (8% w/v)
F1	10 mM Acetate	5.0	+	+		
F2	10 mM Acetate	5.0	+			+
F3	10 mM Histidine	6.0	+	+		
F4	10 mM Histidine	6.0	+		+	
F5	10 mM Histidine	6.0	+			+

99. In view of all the circumstances set forth above, the single most reasonable inference to be drawn from the many omissions, misrepresentations, contradictions, and inconsistencies is that Manning and Reiter, acting on behalf of Coherus, withheld the material information and made the inconsistent factual statements identified above with the specific intent to deceive the Patent Office and procure the Asserted Patents. *Aventis Pharma S.A. v. Hospira, Inc.*, 675 F.3d 1324, 1335 (Fed. Cir. 2012) (finding inequitable conduct where intent to deceive the Patent Office was the "single most reasonable inference that could be drawn" where party submitted reference disclosing "problem" but did not submit reference disclosing the chosen "solution"); *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011); *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008).

OTHER AFFIRMATIVE DEFENSES RESERVED

As Amgen's investigation is ongoing and discovery has not yet started, Amgen is without complete information regarding the existence or nonexistence of other facts or acts that would constitute a defense to the purported causes of action in Coherus' Amended Complaint. Accordingly, Amgen reserves the right to assert any other defenses that discovery may reveal.

COUNTERCLAIMS

Amgen asserts the following counterclaims against Plaintiff Coherus Biosciences, Inc.

THE PARTIES

100. Counterclaim-Plaintiff Amgen is a company organized and existing under the laws of the State of Delaware with its corporate headquarters at One Amgen Center Drive, Thousand Oaks, California 91320.

101. As alleged in Coherus' Amended Complaint, Coherus Biosciences, Inc. 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.

JURISDICTION AND VENUE

102. Amgen's Counterclaims arise under the patent laws of the United States, Title 35 of the United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201–2202. This Court has subject matter jurisdiction over Amgen's Counterclaims under 28 U.S.C. §§ 1331 and 1338.

103. Venue in this case is proper in this District because Coherus is a Delaware corporation, and by virtue of Coherus having filed the Amended Complaint in this District, which gave rise to these Counterclaims. Coherus contends in its Amended Complaint that venue is proper in this District.

FACTUAL BACKGROUND

104. Amgen has been a biotechnology pioneer since the 1980s, discovering, developing, manufacturing, and delivering innovative and important human therapeutic products. Since its inception, Amgen has focused on the development of biologic drugs. Unlike most traditional drugs, which are synthesized chemically and have a known structure, biologic drugs are "complex mixtures that are not easily identified or characterized" and represent "the cutting-edge of biomedical research." FDA, What are "Biologics" Questions and Answers (Feb. 6, 2018), https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cber/ucm133077.htm. Because of their complexity, biologic drugs require substantially more effort, monetary resources, and technical expertise to develop than traditional drugs that are synthesized chemically.

105. Over the last nearly 40 years and still today, Amgen's unparalleled experience and expertise in biologics research, development, and manufacture have enabled it to develop biologic drugs to treat serious illnesses where there had previously been unmet medical needs

and limited treatment options. These medicines have dramatically changed the treatment of disease and the lives of patients with these life-altering and life-threatening diseases. Since its inception, Amgen has developed a number of biologic medicines that have changed the standard of care, two of which have been named Product of the Year by Fortune Magazine and many of which have received scientific and industry awards in recognition of Amgen's innovation. Over the last twenty years alone, Amgen received FDA approval for at least thirteen drugs that have addressed serious illnesses of patients.

106. This action relates to AMGEVITA, Amgen's adalimumab biosimilar. In the United States, this product is known under the trade name AMJEVITA. The active ingredient in AMGEVITA is adalimumab, a recombinant human monoclonal antibody.

107. Amgen finalized the formulation of AMGEVITA as it is currently marketed and internally approved that formulation before September 7, 2011. Also before September 7, 2011, Amgen presented the formulation of AMGEVITA as it is currently marketed to the U.S. Food and Drug Administration ("FDA").

108. Subsequently, Amgen requested and obtained a positive formal scientific opinion by the EMA for its AMGEVITA formulation, as currently marketed—then still under the code name ABP 501.

109. On September 23, 2016, Amgen announced that FDA had approved AMJEVITA across all eligible indications of the reference product, HUMIRA. AMJEVITA was the first adalimumab biosimilar approved by FDA, and it was approved for the treatment of seven inflammatory diseases, including moderate-to-severe rheumatoid arthritis, moderate-to-severe polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, moderate-to-severe chronic plaque psoriasis, adult moderate-to-severe Crohn's disease, and moderate-to-

severe ulcerative colitis. AMJEVITA is Amgen's first biosimilar to receive regulatory approval. Amgen, "FDA Approves Amgen's AMJEVITA™ (Adalimumab-Atto) For Treatment Of Seven Inflammatory Diseases" (Sept. 23, 2016), https://www.amgen.com/media/news-releases/2016/09/fda-approves-amgens-amjevita-adalimumabatto-for-treatment-of-seven-inflammatory-diseases/.

110. Effective March 21, 2017, the European Commission granted a marketing authorization for AMGEVITA valid throughout the European Union (Marketing Authorization No. EU/1/16/1164). European Medicines Agency, "Amgevita," https://www.ema.europa.eu/en/medicines/human/EPAR/amgevita.

111. On October 15, 2018, Amgen issued a press release, which stated that "AMGEVITA™, a biosimilar to adalimumab, will launch in markets across Europe beginning on October 16, 2018." D.I. 7-7. AMGEVITA was the first adalimumab to be approved by the European Commission (EC). *Id.* AMGEVITA is authorized for the treatment of inflammatory diseases in adults, including moderate-to-severe rheumatoid arthritis, psoriatic arthritis; severe active ankylosing spondylitis ("AS"); severe axial spondyloarthritis without radiographic evidence of AS; moderate-to-severe chronic plaque psoriasis; moderate-to-severe hidradenitis suppurativa; non-infectious intermediate, posterior and panuveitis; moderate-to-severe Crohn's disease; and moderate-to-severe ulcerative colitis. *Id.* AMGEVITA is also authorized for the treatment of pediatric inflammatory diseases, including moderate-to-severe Crohn's disease (ages six and older), severe chronic plaque psoriasis (ages four and older), enthesitis-related arthritis (ages six and older), and polyarticular juvenile idiopathic arthritis (ages two and older). *Id.*

THE PATENTS-IN-SUIT

112. U.S. Patent No. 10,155,039 ("the '039 patent"), titled "Stable Aqueous Formulations of Adalimumab," issued on December 18, 2018.

113. U.S. Patent No. 10,159,732 ("the '732 patent"), titled "Stable Aqueous Formulations of Adalimumab," issued on December 25, 2018.

114. U.S. Patent No. 10,159,733 ("the '733 patent"), titled "Stable Aqueous Formulations of Adalimumab," issued on December 25, 2018.

115. U.S. Patent No. 10,207,000 ("the '000 patent"), titled "Stable Aqueous Formulations of Adalimumab," issued on February 19, 2019.

116. Coherus alleges that as assignee, it owns the entire right, title and interest in the '039, '732, '733, and '000 patents. D.I. 7-2 (Amended Complaint), ¶ 16.

COUNT 1
Non-Infringement and Invalidity of U.S. Patent No. 10,155,039

117. Amgen restates and incorporates by reference the allegations in the preceding paragraphs as if fully set forth herein.

118. Coherus alleges that it is the owner of the '039 patent.

119. A case or controversy exists because Coherus alleges that Amgen has infringed and will infringe one or more claims of the '039 patent. D.I. 7-2 (Amended Complaint), ¶¶ 26–35.

120. Amgen has not infringed, and will not infringe, any valid and enforceable claim of the '039 patent. Alternatively, in the event it is found that every element of any asserted claim of the '039 patent is met by AMGEVITA, Amgen is entitled to a complete defense under 35 U.S.C. § 273 based on Amgen's prior commercial use.

121. The claims of the ’039 patent are invalid for failure to comply with one or more conditions of patentability set forth in one or more provisions of 35 U.S.C. §§ 102, 103, and/or 112, or under other judicially created bases for invalidation and/or unenforceability. For example, the claims of the ’039 patent are invalid under 35 U.S.C. §§ 102 and/or 103 over AbbVie’s ’714 patent, which Coherus deliberately withheld from the Patent Office. The ’714 patent claims priority to an application filed August 16, 2002, years before the date of the earliest provisional application listed on the face of the ’039 patent (September 7, 2012), making the ’714 patent prior art to the ’039 patent under at least 35 U.S.C. § 102(e)(2).

122. An exemplary chart showing the invalidity of claim 1 of the ’039 patent in view of claim 16 of the ’714 patent appears below.

’039 Patent, Claim 1	**’714 Patent, Claim 16 (depends from claims 1, 4, 6, 7, 13, 15)**
A stable aqueous pharmaceutical composition comprising:	“A stable liquid aqueous pharmaceutical formulation comprising …” (cl. 1)
a) adalimumab;	“a human IgG1 anti-human Tumor Necrosis Factor alpha (TNFα) antibody … wherein the antibody is D2E7 [adalimumab]” (cl. 1)
b) a buffer;	“a buffer system comprising succinate” (cl. 1)
c) polysorbate 80; and	“wherein the polysorbate is polysorbate 80” (cl. 6)
d) a sugar,	“wherein the polyol is a sugar” (cl. 7) “wherein the polyol is sucrose” (cl. 13)
wherein the composition is free of i) mannitol	Claim 16 does not recite mannitol
ii) citrate and phosphate buffers, and	“a buffer system comprising succinate” (cl. 1) (no recitation of citrate and phosphate buffers)
iii) sodium chloride	Claim 16 does not recite sodium chloride
and wherein the composition has a pH of about 5 to about 6	“wherein the pH is 5.2” (cl. 16)

123. The claims of the ’039 patent are also invalid under 35 U.S.C. §§ 102 and/or 103 over AbbVie’s ’041 patent, which Coherus also deliberately withheld from the Patent Office, as shown for exemplary claim 9 of the ’039 patent in the chart below. The ’041 patent claims priority to an application filed August 16, 2002, making the ’041 patent prior art to the ’039 patent under at least 35 U.S.C. § 102(e)(2).

’039 Patent, Claim 9	**’041 Patent, Claim 18 (depends from claims 1, 16)**
A stable aqueous pharmaceutical composition comprising:	“A stable liquid aqueous pharmaceutical formulation comprising …” (cl. 1)
a) adalimumab;	“a human IgG1 anti-human Tumor Necrosis Factor alpha (TNFα) antibody … wherein the antibody is D2E7 [adalimumab]” (cl. 1)
b) acetate buffer;	“a buffer system comprising acetate” (cl. 1)
c) polysorbate 80; and	“a polysorbate” (cl. 1)
d) sucrose	“The formulation of claim 16, wherein the sugar is trehalose or sucrose” (cl. 18)
wherein the composition is free of i) mannitol	Claim 18 does not recite mannitol
ii) citrate and phosphate buffers, and	“a buffer system comprising acetate” (cl. 1) (no recitation of citrate and phosphate buffers)
iii) sodium chloride	Claim 16 does not recite sodium chloride
and wherein the composition has a pH of about 5 to about 6	“and having a pH of 4 to 8” (cl. 1)

124. To the extent the claims of the ’039 patent are not anticipated under 35 U.S.C. § 102 by the ’714 and/or ’041 patents, they are invalid as obvious under 35 U.S.C. § 103 in view of the ’714 and/or ’041 patents and the knowledge of a person of ordinary skill in the art (as well as other potential prior art combinations yet to be identified). Such knowledge is reflected in, *inter alia*, the declaration of ’039 patent inventor Dr. Mark Manning filed in connection with

Coherus' petition in IPR No. 2016-01018, which Coherus deliberately withheld from the Patent Office during prosecution of the '039 patent. For example, Manning provided sworn testimony that, as of August 2002:

- "Making stable protein formulations was a mature art field by the early 2000s." Ex. A (Manning Decl.) ¶ 85.

- "It is true that development of stable liquid formulations presented certain stability challenges, but formulators knew how to address them." *Id.* ¶ 86.

- "Conducting these routine studies with D2E7 [adalimumab] would have given a POSA important information regarding the optimal pH to use in preparing a stable liquid formulation of D2E7 for subcutaneous injection. Here, in my opinion, a POSA would have conducted the pH-stability study and, through routine experimentation, determined that D2E7 was stable around a pH range of 5 to 6." *Id.* ¶ 94.

- "By August 16, 2002 . . . [t]he skilled artisan would have known that antibody stability could be achieved by optimizing the formulation's pH using a buffer (such as organic acids) and by adding stabilizing agents such as polyols (also termed 'polyhydric alcohols'), amino acids, carbohydrates, chelators, and nonionic surfactants." *Id.* ¶ 105.

- "Carpenter & Manning lists the important formulation variables and components of protein formulations as pH, stabilizers [e.g., "Surfactants, sugars"], solubilizers, buffers [e.g., "acetate, histidine, glutamate"], tonicity modifiers and/or bulking agents [e.g., "sorbitol," "glycine"]." *Id.* ¶ 106.

- "As of August 16, 2002, there were a limited number of buffers that had been FDA-approved for use in pharmaceutical formulations. . . . Commercially available protein and antibody formulations as of August 16, 2002 illustrate that citrate and acetate were two of the most commonly used buffers, both of which buffer well in the acidic pH range." *Id.* ¶ 108.

- "As of August 16, 2002, the skilled person would have understood that a subcutaneous formulation should have an osmolality matching that of the patient's cells (e.g., 250–350 mOsm) to minimize or prevent tissue damage at the injection site and minimize pain at the injection site." *Id.* ¶ 110.

- "Therefore, the POSA likely would have included polysorbate 80 as the surfactant in a new liquid protein formulation, especially one at an antibody concentration of 50 mg/ml." *Id.* ¶ 116.

125. The claims of the '039 patent are invalid under 35 U.S.C. §§ 102 and/or 103 over U.S. Patent No. 6,090,382 (Salfeld), which discloses, for example, pharmaceutical compositions

comprising adalimumab, and U.S. Patent No. 6,171,586 (Lam), which discloses, for example, stable aqueous antibody formulations comprising anti-TNF-α antibody, acetate, polysorbate 80, and trehalose at a pH of 5.0 that are free of mannitol, sodium chloride, and citrate/phosphate buffers. As discussed *supra* ¶¶ 95–99, Manning and Reiter made deliberate misrepresentations and omissions regarding Lam to the Patent Office, in particular with respect to Lam's disclosure of compositions that are free of mannitol.

126. The claims of the '039 patent are also invalid under 35 U.S.C. § 103 over AbbVie's HUMIRA product and its associated documentation, including but not limited to the HUMIRA label and package insert, all of which were publicly available well before September 7, 2012. HUMIRA contains adalimumab, citrate/phosphate buffer, mannitol, polysorbate 80, and sodium chloride at a pH of 5.2. A POSA would have been motivated to replace mannitol with another stabilizer such as sucrose to address the known problem of the long-term stability of compositions containing mannitol, and would have had a reasonable expectation of success in doing so in view of prior art showing that replacing mannitol with sucrose results in improved performance. The obviousness of this change is underscored by the commercial formulations of adalimumab biosimilars that were publicly available during prosecution of the Asserted Patents, none of which contained mannitol. Coherus hid this information from the Examiner, instead representing that "the two commercial formulations of adalimumab . . . include mannitol," as discussed *supra* ¶ 93.

127. One or more claims of the '039 patent are also invalid under 35 U.S.C. § 102(g) because, before Coherus' purported invention of this subject matter, the invention was made by Amgen in the United States, and Amgen did not abandon, suppress, or conceal it. Finally, one or more claims of the '039 patent are invalid under 35 U.S.C. § 112 because, for example, the '039

patent fails to enable and provide adequate written description for "[a] stable aqueous pharmaceutical composition comprising: a) adalimumab; b) a buffer; c) polysorbate 80; and d) a sugar, wherein the composition is free of i) mannitol, ii) citrate and phosphate buffers, and iii) sodium chloride and wherein the composition has a pH of about 5 to about 6."

128. Amgen is entitled to a judgment that the claims of the '039 patent are invalid and/or unenforceable, and that Amgen has not infringed and by the continued manufacture of AMGEVITA in the United States will not infringe any valid and enforceable claim of that patent, for at least the reasons set forth above. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT 2
Non-Infringement and Invalidity of U.S. Patent No. 10,159,732

129. Amgen restates and incorporates by reference the allegations in the preceding paragraphs as if fully set forth herein.

130. Coherus alleges that it is the owner of the '732 patent.

131. A case or controversy exists because Coherus alleges that Amgen has infringed and will infringe one or more claims of the '732 patent. D.I. 7-2 (Amended Complaint), ¶¶ 36–45.

132. Amgen has not infringed, and will not infringe, any valid and enforceable claim of the '732 patent. Alternatively, in the event it is found that every element of any asserted claim of the '732 patent is met by AMGEVITA, Amgen is entitled to a complete defense under 35 U.S.C. § 273 based on Amgen's prior commercial use.

133. The claims of the '732 patent are invalid for failure to comply with one or more conditions of patentability set forth in one or more provisions of 35 U.S.C. §§ 102, 103, and/or 112, or under other judicially created bases for invalidation and/or unenforceability. For

example, the claims of the ’732 patent are invalid under 35 U.S.C. §§ 102 and/or 103 over AbbVie’s ’714 patent, which Coherus deliberately withheld from the Patent Office. The ’714 patent claims priority to an application filed August 16, 2002, years before the date of the earliest provisional application listed on the face of the ’732 patent (September 7, 2012), making the ’714 patent prior art to the ’732 patent under at least 35 U.S.C. § 102(e)(2).

134. An exemplary chart showing the invalidity of claim 1 of the ’732 patent in view of claim 16 of the ’714 patent appears below.

’732 Patent, Claim 1	**’714 Patent, Claim 16 (depends from claims 1, 4, 6, 7, 13, 15)**
A stable aqueous pharmaceutical composition comprising:	“A stable liquid aqueous pharmaceutical formulation comprising …” (cl. 1)
i) adalimumab;	“a human IgG1 anti-human Tumor Necrosis Factor alpha (TNFα) antibody … wherein the antibody is D2E7 [adalimumab]” (cl. 1)
ii) a buffer; and	“a buffer system comprising succinate” (cl. 1)
iii) a stabilizer	“a polyol” (cl. 1)
wherein the composition is free of mannitol	No recitation of mannitol
and has a pH of about 5 to about 6	“wherein the pH is 5.2” (cl. 16)

135. The claims of the ’732 patent are also invalid under 35 U.S.C. §§ 102 and/or 103 over AbbVie’s ’041 patent, which Coherus also deliberately withheld from the Patent Office. The ’714 patent claims priority to an application filed August 16, 2002, making the ’041 patent prior art to the ’732 patent under at least 35 U.S.C. § 102(e)(2).

136. To the extent the claims of the ’732 patent are not anticipated under 35 U.S.C. § 102 by the ’714 and/or ’041 patents, they are invalid as obvious under 35 U.S.C. § 103 in view of the ’714 and/or ’041 patents and the knowledge of a person of ordinary skill in the art (as well

as other potential prior art combinations yet to be identified). Such knowledge is reflected in, *inter alia*, the declaration of '732 patent inventor Dr. Mark Manning, as discussed *supra* ¶ 124.

137. The claims of the '732 patent are also invalid under 35 U.S.C. §§ 102 and/or 103 over U.S. Patent No. 6,090,382 (Salfeld), which discloses, for example, pharmaceutical compositions comprising adalimumab, and U.S. Patent No. 6,171,586 (Lam), which discloses, for example, stable aqueous antibody formulations comprising anti-TNF-α antibody, acetate, polysorbate 80, and trehalose at a pH of 5.0 that are free of mannitol, sodium chloride, and citrate/phosphate buffers. As discussed *supra* ¶¶ 95–99, Manning and Reiter made deliberate misrepresentations and omissions regarding Lam to the Patent Office, in particular with respect to Lam's disclosure of compositions that are free of mannitol.

138. The claims of the '732 patent are invalid under 35 U.S.C. § 103 over AbbVie's HUMIRA product and its associated documentation, including but not limited to the HUMIRA label and package insert, all of which were publicly available well before September 7, 2012. HUMIRA contains adalimumab, citrate/phosphate buffer, mannitol, polysorbate 80, and sodium chloride at a pH of 5.2. A POSA would have been motivated to replace mannitol with another stabilizer such as sucrose to address the known problem of the long-term stability of compositions containing mannitol, and would have had a reasonable expectation of success in doing so in view of prior art showing that replacing mannitol with sucrose results in improved performance. The obviousness of this change is underscored by the commercial formulations of adalimumab biosimilars that were publicly available during prosecution of the Asserted Patents, none of which contained mannitol. Coherus hid this information from the Examiner, instead representing that "the two commercial formulations of adalimumab . . . include mannitol," as discussed *supra* ¶ 93.

139. One or more claims of the ’732 patent are also invalid under 35 U.S.C. § 102(g) because before Coherus’ purported invention of this subject matter, the invention was made by Amgen in the United States, and Amgen did not abandon, suppress, or conceal it. Finally, one or more of the claims of the ’732 patent are invalid under 35 U.S.C. § 112 because, for example, the ’732 patent fails to enable and provide adequate written description for “[a] stable aqueous pharmaceutical composition comprising: i) adalimumab; ii) a buffer; iii) a stabilizer; wherein the composition is free of mannitol and has a pH of about 5 to about 6.”

140. Amgen is entitled to a judgment that the claims of the ’732 patent are invalid and/or unenforceable, and that Amgen has not infringed and by the continued manufacture of AMGEVITA in the United States will not infringe any valid and enforceable claim of that patent, for at least the reasons set forth above. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT 3
Non-Infringement and Invalidity of U.S. Patent No. 10,159,733

141. Amgen restates and incorporates by reference the allegations in the preceding paragraphs as if fully set forth herein.

142. Coherus alleges that it is the owner of the ’733 patent.

143. A case or controversy exists because Coherus alleges that Amgen has infringed and will infringe one or more claims of the ’733 patent. D.I. 7-2 (Amended Complaint), ¶¶ 46–55.

144. Amgen has not infringed, and will not infringe, any valid and enforceable claim of the ’733 patent. Alternatively, in the event it is found that every element of any asserted claim of the ’733 patent is met by AMGEVITA, Amgen is entitled to a complete defense under 35 U.S.C. § 273 based on Amgen’s prior commercial use.

145. The claims of the ’733 patent are invalid for failure to comply with one or more conditions of patentability set forth in one or more provisions of 35 U.S.C. §§ 102, 103, and/or 112, or under other judicially created bases for invalidation and/or unenforceability. For example, the claims of the ’733 patent are invalid under 35 U.S.C. §§ 102 and/or 103 over AbbVie’s ’714 patent, which Coherus deliberately withheld from the Patent Office. The ’714 patent claims priority to an application filed August 16, 2002, years before the date of the earliest provisional application listed on the face of the ’733 patent (September 7, 2012), making the ’714 patent prior art to the ’733 patent under at least 35 U.S.C. § 102(e)(2).

146. An exemplary chart showing the invalidity of claim 1 of the ’733 patent in view of claim 16 of the ’714 patent appears below.

’733 Patent, Claim 1	**’714 Patent, Claim 16 (depends from claims 1, 4, 6, 7, 13, 15)**
A stable aqueous pharmaceutical composition comprising:	“A stable liquid aqueous pharmaceutical formulation comprising …” (cl. 1)
i) adalimumab;	“a human IgG1 anti-human Tumor Necrosis Factor alpha (TNFα) antibody … wherein the antibody is D2E7 [adalimumab]” (cl. 1)
ii) a single buffer;	“a buffer system comprising succinate” (cl. 1) (no other buffers recited)
iii) a surfactant; and	“a polysorbate” (cl. 1) “wherein the polysorbate is polysorbate 80” (cl. 6)
iv) a sugar,	“wherein the polyol is a sugar” (cl. 7) “wherein the polyol is sucrose” (cl. 13)
wherein the composition is free of mannitol	No recitation of mannitol
and has a pH of about 5 to about 6	“wherein the pH is 5.2” (cl. 16)

147. The claims of the ’733 patent are also invalid under 35 U.S.C. §§ 102 and/or 103 over AbbVie’s ’041 patent, which Coherus also deliberately withheld from the Patent Office.

The ’041 patent claims priority to an application filed August 16, 2002, making the ’041 patent prior art to the ’733 patent under at least 35 U.S.C. § 102(e)(2).

148. To the extent the claims of the ’733 patent are not anticipated under 35 U.S.C. § 102 by the ’714 and/or ’041 patents, they are invalid as obvious under 35 U.S.C. § 103 in view of the ’714 and/or ’041 patents and the knowledge of a person of ordinary skill in the art (as well as other potential combinations yet to be identified). Such knowledge is reflected in, *inter alia*, the declaration of ’733 patent inventor Dr. Mark Manning, as discussed *supra* ¶ 124.

149. The claims of the ’733 patent are also invalid under 35 U.S.C. §§ 102 and/or 103 over U.S. Patent No. 6,090,382 (Salfeld), which discloses, for example, pharmaceutical compositions comprising adalimumab, and U.S. Patent No. 6,171,586 (Lam), which discloses, for example, stable aqueous antibody formulations comprising anti-TNF-α antibody, acetate, polysorbate 80, and trehalose at a pH of 5.0 that are free of mannitol, sodium chloride, and citrate/phosphate buffers. As discussed *supra* ¶¶ 95–99, Manning and Reiter made deliberate misrepresentations and omissions regarding Lam to the Patent Office, in particular with respect to Lam’s disclosure of compositions that are free of mannitol.

150. The claims of the ’733 patent are invalid under 35 U.S.C. § 103 over AbbVie’s HUMIRA product and its associated documentation, including but not limited to the HUMIRA label and package insert, all of which were publicly available well before September 7, 2012. HUMIRA contains adalimumab, citrate/phosphate buffer, mannitol, polysorbate 80, and sodium chloride at a pH of 5.2. A POSA would have been motivated to replace mannitol with another stabilizer such as sucrose to address the known problem of the long-term stability of compositions containing mannitol, and would have had a reasonable expectation of success in doing so in view of prior art showing that replacing mannitol with sucrose results in improved

performance. The obviousness of this change is underscored by the commercial formulations of adalimumab biosimilars that were publicly available during prosecution of the Asserted Patents, none of which contained mannitol. Coherus hid this information from the Examiner, instead representing that "the two commercial formulations of adalimumab . . . include mannitol," as discussed *supra* ¶ 93.

151. One or more claims of the '733 patent are also invalid under 35 U.S.C. § 102(g) because before Coherus' purported invention of this subject matter, the invention was made by Amgen in the United States, and Amgen did not abandon, suppress, or conceal it. Additionally, one or more of the claims of the '733 patent are invalid under 35 U.S.C. § 112 because, for example, the '733 patent fails to enable and provide adequate written description for "[a] stable aqueous pharmaceutical composition comprising: i) adalimumab; ii) a single buffer; iii) a surfactant; and iv) a sugar, wherein the composition is free of mannitol and has a pH of about 5 to about 6."

152. Amgen is entitled to a judgment that the claims of the '733 patent are invalid and/or unenforceable, and that Amgen has not infringed and by the continued manufacture of AMGEVITA in the United States will not infringe any valid and enforceable claim of that patent, for at least the reasons set forth above. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT 4
Non-Infringement and Invalidity of U.S. Patent No. 10,207,000

153. Amgen restates and incorporates by reference the allegations in the preceding paragraphs as if fully set forth herein.

154. Coherus alleges that it is the owner of the '000 patent.

155. A case or controversy exists because Coherus alleges that Amgen has infringed and will infringe one or more claims of the '000 patent. D.I. 7-2 (Amended Complaint), ¶¶ 56–65.

156. Amgen has not infringed, and will not infringe, any valid and enforceable claim of the '000 patent. Alternatively, in the event it is found that every element of any asserted claim of the '000 patent is met by AMGEVITA, Amgen is entitled to a complete defense under 35 U.S.C. § 273 based on Amgen's prior commercial use.

157. The claims of the '000 patent are invalid for failure to comply with one or more conditions of patentability set forth in one or more provisions of 35 U.S.C. §§ 102, 103, and/or 112, or under other judicially created bases for invalidation and/or unenforceability. For example, the claims of the '000 patent are invalid under 35 U.S.C. §§ 102 and/or 103 over AbbVie's '714 patent, which Coherus deliberately withheld from the Patent Office. The '714 patent claims priority to an application filed August 16, 2002, years before the date of the earliest provisional application listed on the face of the '000 patent (September 7, 2012), making the '714 patent prior art to the '000 patent under at least 35 U.S.C. § 102(e)(2).

158. An exemplary chart showing the invalidity of claim 1 of the '000 patent in view of claim 16 of the '714 patent appears below.

'000 Patent, Claim 1	**'714 patent, Claim 16 (depends from claims 1, 4, 6, 7, 13, 15)**
A stable aqueous pharmaceutical composition comprising:	"A stable liquid aqueous pharmaceutical formulation comprising …" (cl. 1)
i) adalimumab;	"a human IgG1 anti-human Tumor Necrosis Factor alpha (TNFα) antibody … wherein the antibody is D2E7 [adalimumab]" (cl. 1)
ii) a single buffer;	"a buffer system comprising succinate" (cl. 1) (no other buffers recited)

'000 Patent, Claim 1	**'714 patent, Claim 16 (depends from claims 1, 4, 6, 7, 13, 15)**
iii) a surfactant; and	"a polysorbate" (cl. 1) "wherein the polysorbate is polysorbate 80" (cl. 6)
iv) a tonicity modifier	"wherein the polyol is sucrose" (cl. 13)
wherein the composition is free of mannitol	No recitation of mannitol
and has a pH of about 5 to about 6	"wherein the pH is 5.2" (cl. 16)

159. The claims of the '000 patent are also invalid under 35 U.S.C. §§ 102 and/or 103 over AbbVie's '041 patent, which Coherus also deliberately withheld from the Patent Office. The '041 patent claims priority to an application filed August 16, 2002, making the '041 patent prior art to the '000 patent under at least 35 U.S.C. § 102(e)(2).

160. To the extent the claims of the '733 patent are not anticipated under 35 U.S.C. § 102 by the '714 and/or '041 patents, they are invalid as obvious under 35 U.S.C. § 103 in view of the '714 and/or '041 patents and the knowledge of a person of ordinary skill in the art (as well as other potential prior art combinations yet to be identified). Such knowledge is reflected in, *inter alia*, the declaration of '733 patent inventor Dr. Mark Manning, as discussed *supra* ¶ 124.

161. The claims of the '000 patent are also invalid under 35 U.S.C. §§ 102 and/or 103 over U.S. Patent No. 6,090,382 (Salfeld), which discloses, for example, pharmaceutical compositions comprising adalimumab, and U.S. Patent No. 6,171,586 (Lam), which discloses, for example, stable aqueous antibody formulations comprising anti-TNF-α antibody, acetate, polysorbate 80, and trehalose at a pH of 5.0 that are free of mannitol, sodium chloride, and citrate/phosphate buffers. As discussed *supra* ¶¶ 95–99, Manning and Reiter made deliberate misrepresentations and omissions regarding Lam to the Patent Office, in particular with respect to Lam's disclosure of compositions that are free of mannitol.

162. The claims of the ’000 patent are invalid under 35 U.S.C. § 103 over AbbVie’s HUMIRA product and its associated documentation, including but not limited to the HUMIRA label and package insert, all of which were publicly available well before September 7, 2012. HUMIRA contains adalimumab, citrate/phosphate buffer, mannitol, polysorbate 80, and sodium chloride at a pH of 5.2. A POSA would have been motivated to replace mannitol with another stabilizer such as sucrose to address the known problem of the long-term stability of compositions containing mannitol, and would have had a reasonable expectation of success in doing so in view of prior art showing that replacing mannitol with sucrose results in improved performance. The obviousness of this change is underscored by the commercial formulations of adalimumab biosimilars that were publicly available during prosecution of the Asserted Patents, none of which contained mannitol. Coherus hid this information from the Examiner, instead representing that “the two commercial formulations of adalimumab . . . include mannitol,” as discussed *supra* ¶ 93.

163. One or more claims of the ’000 patent are also invalid under 35 U.S.C. § 102(g) because before Coherus’ purported invention of this subject matter, the invention was made by Amgen in the United States, and Amgen did not abandon, suppress, or conceal it. Additionally, one or more of the claims of the ’000 patent are invalid under 35 U.S.C. § 112 because, for example, the ’000 patent fails to enable and provide adequate written description for “[a] stable aqueous pharmaceutical composition comprising: i) adalimumab; ii) a single buffer; iii) a surfactant; and iv) a tonicity modifier, wherein the composition is free of mannitol and has a pH of about 5 to about 6.”

164. Amgen is entitled to a judgment that the claims of the ’000 patent are invalid and/or unenforceable, and that Amgen has not and will not infringe any valid and enforceable

claim of that patent, for at least the reasons set forth above. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT 5
Inequitable Conduct During Prosecution of the ’039 Patent

165. Amgen restates and incorporates by reference the allegations in the preceding paragraphs as if fully set forth herein.

166. The claims of the ’039 patent are unenforceable due to Coherus’ inequitable conduct.

167. As set forth above, in order to procure the ’039 patent, the ’039 patent inventor Mark Manning and Coherus’ patent attorney Tiffany Reiter, on behalf of Coherus, withheld material information from the Patent Office and made affirmative misstatements of material fact with the intention of deceiving the Patent Office and procuring the ’039 patent on the basis of an incomplete and/or misleading record.

COUNT 6
Inequitable Conduct During Prosecution of the ’732 Patent

168. Amgen restates and incorporates by reference the allegations in the preceding paragraphs as if fully set forth herein.

169. The claims of the ’732 patent are unenforceable due to Coherus’ inequitable conduct.

170. As set forth above, in order to procure the ’732 patent, the ’732 patent inventor Mark Manning and Coherus’ patent attorney Tiffany Reiter, on behalf of Coherus, withheld material information from the Patent Office and made affirmative misstatements of material fact with the intention of deceiving the Patent Office and procuring the ’732 patent on the basis of an incomplete and/or misleading record.

COUNT 7
Inequitable Conduct During Prosecution of the ’733 Patent

171. Amgen restates and incorporates by reference the allegations in the preceding paragraphs as if fully set forth herein.

172. The claims of the ’733 patent are unenforceable due to Coherus’ inequitable conduct.

173. As set forth above, in order to procure the ’733 patent, the ’733 patent inventor Mark Manning and Coherus’ patent attorney Tiffany Reiter, on behalf of Coherus, withheld material information from the Patent Office and made affirmative misstatements of material fact with the intention of deceiving the Patent Office and procuring the ’733 patent on the basis of an incomplete and/or misleading record.

COUNT 8
Inequitable Conduct During Prosecution of the ’000 Patent

174. Amgen restates and incorporates by reference the allegations in the preceding paragraphs as if fully set forth herein.

175. The claims of the ’000 patent are unenforceable due to Coherus’ inequitable conduct.

176. As set forth above, in order to procure the ’000 patent, the ’000 patent inventor Mark Manning and Coherus’ patent attorney Tiffany Reiter, on behalf of Coherus, withheld material information from the Patent Office and made affirmative misstatements of material fact with the intention of deceiving the Patent Office and procuring the ’000 patent on the basis of an incomplete and/or misleading record.

JURY TRIAL DEMAND

177. Under Federal Rule of Civil Procedure 38(b), Amgen hereby requests a trial by jury on all issues so triable in Amgen’s counterclaims and Coherus’ Amended Complaint.

PRAYER FOR RELIEF

WHEREFORE, Amgen respectfully requests that the Court enter Judgment:

A. Adjudging and decreeing that Coherus be denied all forms of relief requested in its Amended Complaint;

B. Dismissing the Amended Complaint in its entirety with prejudice;

C. Declaring that the claims of the Asserted Patents have not been and are not infringed by Amgen;

D. Declaring that the claims of the Asserted Patents are invalid;

E. Declaring that the claims of the Asserted Patents are unenforceable for inequitable conduct;

F. Finding that this is an exceptional case under 35 U.S.C. § 285;

G. Awarding attorneys' fees, costs, and expenses to Amgen; and,

H. Granting such other and further relief as this Court deems just and proper.

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April 18, 2019

CERTIFICATE OF SERVICE

I hereby certify that on April 18, 2019, 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 April 18, 2019, upon the following in the manner indicated:

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