

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY

AMAG PHARMACEUTICALS, INC.

Plaintiff,

v.

SANDOZ INC.,

Defendant.

C.A. No. \_\_\_\_\_

**COMPLAINT**

Plaintiff AMAG Pharmaceuticals, Inc. (“Plaintiff” or “AMAG”) brings this action for patent infringement and declaratory judgment against Defendant Sandoz Inc. (“Sandoz”).

**NATURE OF THE ACTION**

1. This is an action by AMAG for infringement of United States Patent No. 6,599,498 (“the ’498 patent”), United States Patent No. 7,553,479 (“the ’479 patent”), United States Patent No. 7,871,597 (“the ’597 patent”), United States Patent No. 8,501,158 (“the ’158 patent”), United States Patent No. 8,591,864 (“the ’864 patent”), and United States Patent No. 8,926,947 (“the ’947 patent”). This action arises out of the filing of an Abbreviated New Drug Application (“ANDA”) by Sandoz seeking approval by the United States Food and Drug Administration (“FDA”) to sell generic versions of FERAHEME<sup>®</sup>, AMAG’s innovative iron-replacement product approved for the treatment of iron deficiency anemia in adult patients with chronic kidney disease, prior to the expiration of the ’498, ’479, ’597, ’158, ’864, and ’947 patents.

## THE PARTIES

### AMAG

2. AMAG Pharmaceuticals, Inc. is a Delaware corporation with its principal place of business at 1100 Winter Street, Waltham, MA 02451. AMAG Pharmaceuticals, Inc. is a specialty pharmaceutical company primarily engaged in the business of research, development, manufacture, and sale of pharmaceutical products, including nanoparticle iron therapeutic products.

### SANDOZ

3. Upon information and belief, Sandoz Inc. is a corporation organized and existing under the laws of Colorado, having a principal place of business at 100 College Road West, Princeton, New Jersey 08540.

## JURISDICTION AND VENUE

### SUBJECT MATTER JURISDICTION

4. This action for patent infringement arises under 35 U.S.C. § 271.

5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

### VENUE

6. Venue is proper in this Judicial District under 28 U.S.C. § 1400(b) and § 1391.

### PERSONAL JURISDICTION

7. This Court has personal jurisdiction over Sandoz because, *inter alia*, Sandoz's principle place of business is in this District.

8. Upon information and belief, Sandoz markets, distributes and/or sells generic drugs throughout the United States and within the State of New Jersey. Upon information and belief, Sandoz has regular and continuous commercial business dealings with representatives,

agents, distributors, and customers located in New Jersey. Upon information and belief, Sandoz enjoys substantial income from sales in the State of New Jersey.

9. Upon information and belief, Sandoz is registered as a Manufacturer and Wholesaler in the State of New Jersey. Upon information and belief, Sandoz also is registered to do business in New Jersey.

10. Upon information and belief, Sandoz has engaged in and maintained systematic and continuous business contacts within the State of New Jersey and has purposefully availed itself of the benefits and protections of the laws of New Jersey. In addition, Sandoz has availed itself of this Court by asserting counterclaims against plaintiffs in this Judicial District and by consenting to this Court's jurisdiction in numerous legal proceedings. *See, e.g.,* Sandoz's Answer, Defenses, and Counterclaims, *Otsuka Pharmaceutical Co., Ltd. v. Sandoz, Inc., et al.*, Civil Action No. 15-1716 (JBS)(KMW) (D.N.J. April 13, 2015), Dkt. No. 54; Sandoz's Answer, Defenses, and Counterclaims, *United Therapeutics Corp. v. Sandoz Inc.*, Civil Action No. 14-5499 (PGS)(LHG) (D.N.J. November 12, 2014), Dkt. No. 13; Sandoz's Answer, Defenses, and Counterclaims, *Astrazeneca Pharm. LP, et al. v. Sandoz Inc., et al.*, Civil Action No. 14-3547 (RMB)(KMW) (D.N.J. July 29, 2014), Dkt. No. 21.

11. Upon information and belief, Defendant Sandoz has also committed, or aided, abetted, contributed to and/or participated in the commission of the tortious action of patent infringement that has led to foreseeable harm and injury to AMAG, which has FERAHEME® manufactured for sale and use throughout the United States, including the State of New Jersey.

## **BACKGROUND**

### **THE '498 PATENT**

12. The '498 patent, entitled "Heat Stable Colloidal Iron Oxides Coated with Reduced Carbohydrates and Carbohydrate Derivatives," was duly and legally issued on July 29, 2003.

13. Ernest V. Groman, Kenneth G. Paul, Timothy B. Frigo, Howard Bengeler, and Jerome M. Lewis are the named inventors of the '498 patent.

14. AMAG is the sole owner by assignment of all rights, title and interest in the '498 patent.

15. The '498 patent is listed in the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly referred to as "the Orange Book" ("Orange Book"), with respect to FERAHEME®.

16. A true and correct copy of the '498 patent is attached as Exhibit A.

**THE '479 PATENT**

17. The '479 patent, entitled "Heat Stable Colloidal Iron Oxides Coated with Reduced Carbohydrates and Uses Thereof," was duly and legally issued on June 30, 2009.

18. Ernest V. Groman, Kenneth G. Paul, Timothy B. Frigo, Howard Bengeler, and Jerome M. Lewis are the named inventors of the '479 patent.

19. AMAG is the sole owner by assignment of all rights, title and interest in the '479 patent.

20. The '479 patent is listed in the Orange Book with respect to FERAHEME®.

21. A true and correct copy of the '479 patent is attached as Exhibit B.

**THE '597 PATENT**

22. The '597 patent, entitled "Polyol and Polyether Iron Oxide Complexes as Pharmacological and/or MRI Contrast Agents," was duly and legally issued on January 18, 2011.

23. Ernest V. Groman, Kenneth G. Paul, Timothy B. Frigo, Howard Bengeler, and Jerome M. Lewis are the named inventors of the '597 patent.

24. AMAG is the sole owner by assignment of all rights, title and interest in the '597 patent.

25. The '597 patent is listed in the Orange Book with respect to FERAHEME®.

26. A true and correct copy of the '597 patent is attached as Exhibit C.

**THE '158 PATENT**

27. The '158 patent, entitled "Polyol and Polyether Iron Oxide Complexes as Pharmacological and/or MRI Contrast Agents," was duly and legally issued on August 6, 2013.

28. Ernest V. Groman, Kenneth G. Paul, Timothy B. Frigo, Howard Bengeler, and Jerome M. Lewis are the named inventors of the '158 patent.

29. AMAG is the sole owner by assignment of all rights, title and interest in the '158 patent.

30. The '158 patent is listed in the Orange Book with respect to FERAHEME®.

31. A true and correct copy of the '158 patent is attached as Exhibit D.

**THE '864 PATENT**

32. The '864 patent, entitled "Polyol and Polyether Iron Oxide Complexes as Pharmacological and/or MRI Contrast Agents," was duly and legally issued on November 26, 2013.

33. Ernest V. Groman, Kenneth G. Paul, Timothy B. Frigo, Howard Bengeler, and Jerome M. Lewis are the named inventors of the '864 patent.

34. AMAG is the sole owner by assignment of all rights, title and interest in the '864 patent.

35. The '864 patent is listed in the Orange Book with respect to FERAHEME®.

36. A true and correct copy of the '864 patent is attached as Exhibit E.

**THE '947 PATENT**

37. The '947 patent, entitled "Polyol and Polyether Iron Oxide Complexes as Pharmacological and/or MRI Contrast Agents," was duly and legally issued on January 6, 2015.

38. Ernest V. Groman, Kenneth G. Paul, Timothy B. Frigo, Howard Bengeler, and Jerome M. Lewis are the named inventors of the '947 patent.

39. AMAG is the sole owner by assignment of all rights, title and interest in the '947 patent.

40. The '947 patent is listed in the Orange Book with respect to FERAHEME®.

41. A true and correct copy of the '947 patent is attached as Exhibit F.

**AMAG'S FERAHEME® PRODUCT**

42. AMAG researched, developed, applied for, and obtained FDA approval to manufacture, sell, promote, and/or market a ferumoxytol product known as FERAHEME®.

43. AMAG has been selling, promoting, distributing, and marketing FERAHEME® in the United States since 2009.

44. AMAG is the holder of New Drug Application ("NDA") number 02-2180, approved by FDA for the use of ferumoxytol, marketed as FERAHEME®, for the treatment of iron deficiency anemia in adult patients with chronic kidney disease.

45. AMAG's innovative FERAHEME® product is supplied as a single-dose prefilled vial containing 17 mL of 30 mg/mL ferumoxytol for intravenous injection, manufactured for AMAG, and marketed and sold in the United States by AMAG.

**THE SANDOZ ANDA**

46. Sandoz filed an ANDA under 21 U.S.C. § 355(j) seeking FDA approval to manufacture, use, offer for sale, sell in and import into the United States a generic version of

FERAHEME® 30 mg/mL, 17 mL single-use vials, for intravenous injection (“Sandoz’s Ferumoxytol Product”) prior to the expiration of the ’498, ’479, ’597, ’158, ’864, and ’947 patents.

47. FDA assigned the ANDA for Sandoz’s Ferumoxytol Product the number 206604.

48. Sandoz also filed with the FDA a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the claims of the ’498, ’479, ’597, ’158, ’864, and ’947 patents are invalid, unenforceable, and/or will not be infringed.

49. In a letter dated February 4, 2016, Sandoz notified AMAG that Sandoz had filed ANDA No. 206604 and is seeking approval to market Sandoz’s Ferumoxytol Product in the United States prior to the expiration of the ’498, ’479, ’597, ’158, ’864, and ’947 patents (“Sandoz Notice Letter”). Sandoz’s Detailed Statement, which accompanied the Sandoz Notice Letter, contained no non-infringement assertions regarding the ’498, ’479, ’597, ’158, ’864, and ’947 patents.

50. Upon receiving the Sandoz Notice Letter, AMAG began negotiating with Sandoz an Offer of Confidential Access under which Sandoz would provide AMAG a copy of ANDA No. 206604. Sandoz failed to reasonably engage in negotiations concerning the terms of the Offer of Confidential Access and thus refused to produce to AMAG any portions of ANDA No. 206604. In light of the pending expiration of the 45-day window to institute suit pursuant to 21 U.S.C. § 355(c)(3)(C), AMAG therefore files this suit now.

51. This Action is being commenced before the expiration of forty-five days from the date of receipt of the Sandoz Notice Letter.

**COUNT I FOR INFRINGEMENT OF U.S. PATENT NO. 6,599,498 BY SANDOZ**

52. The allegations of the proceeding paragraphs 1–51 are re-alleged and incorporated herein by reference.

53. Sandoz’s Ferumoxytol Product is covered by one or more claims of the ’498 patent.

54. The commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Sandoz’s Ferumoxytol Product would infringe one or more claims of the ’498 patent.

55. Under 35 U.S.C. § 271(e)(2)(A), Sandoz’s submission to FDA of Sandoz’s ANDA to obtain approval for Sandoz’s Ferumoxytol Product with a Paragraph IV Certification related thereto before the expiration of the ’498 patent constitutes an act of infringement, and if approved, the commercial manufacture, use, offer to sell, sale, or importation of Sandoz’s Ferumoxytol Product would infringe one or more claims of the ’498 patent.

56. Sandoz was aware of the ’498 patent when engaging in these knowing and purposeful activities and was aware that filing Sandoz’s ANDA with Sandoz’s Paragraph IV Certification with respect to the ’498 patent constituted an act of infringement of the ’498 patent.

57. Upon information and belief, if Sandoz’s ANDA is approved by the FDA, the FDA will have determined that Sandoz’s Ferumoxytol Product contains the same reduced carboxyalkylated polysaccharide iron oxide complex recited in one or more claims of the ’498 patent.

58. Upon information and belief, Sandoz seeks approval from FDA to manufacture, use, offer for sale, sell in and import into the United States Sandoz’s Ferumoxytol Product, which will be indicated for the treatment of iron deficiency anemia in adult patients with chronic



kidney disease. Upon information and belief, Sandoz's Ferumoxytol Product will be administered via intravenous injection.

59. Upon information and belief, Sandoz plans and intends to, and will, infringe the '498 patent immediately and imminently upon approval of Sandoz's ANDA.

60. Upon information and belief, immediately and imminently upon approval of Sandoz's ANDA, there will be direct infringement of the claims of the '498 patent under 35 U.S.C. § 271(a).

61. Upon information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '498 patent under 35 U.S.C. § 271(b) when Sandoz's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

62. Upon information and belief, Sandoz knows that Sandoz's Ferumoxytol Product is especially made or adapted for use in infringing the '498 patent and that Sandoz's Ferumoxytol Product is not suitable for substantial non-infringing uses.

63. Upon information and belief, Sandoz, under 35 U.S.C. § 271(c), plans and intends to, and will, contribute to the infringement of the '498 patent immediately and imminently upon approval of the Sandoz's ANDA.

64. The foregoing actions by Sandoz constitute and/or would constitute infringement of the '498 patent, active inducement of infringement of the '498 patent and/or contribution to the infringement by others of the '498 patent.

65. Upon information and belief, Sandoz acted without a reasonable basis for believing that it would not be liable for infringing the '498 patent, actively inducing infringement of the '498 patent and/or contributing to the infringement by others of the '498 patent.

66. AMAG will be substantially and irreparably harmed by Sandoz's infringing activities unless the Court enjoins those activities. AMAG will have no adequate remedy at law if Sandoz is not enjoined from the commercial manufacture, use, offer to sell, sale in and importation into the United States of Sandoz's Ferumoxytol Product.

67. Sandoz's activities render this case an exceptional one, and AMAG is entitled to an award of its reasonable attorney's fees under 35 U.S.C. § 285.

**COUNT II FOR DECLARATORY JUDGMENT OF  
INFRINGEMENT OF U.S. PATENT NO. 6,599,498 BY SANDOZ**

68. The allegations of the proceeding paragraphs 1–67 are re-alleged and incorporated herein by reference.

69. Upon information and belief, Sandoz plans to begin manufacturing, marketing, selling, offering to sell and/or importing Sandoz's Ferumoxytol Product soon after FDA approval of Sandoz's ANDA.

70. Such conduct will constitute direct infringement of one or more claims on the '498 patent under 35 U.S.C. § 271(a), inducement of infringement of the '498 patent under 35 U.S.C. § 271(b), and/or contributory infringement of the '498 patent under 35 U.S.C. § 271(c).

71. Upon information and belief, Sandoz knows that Sandoz's Ferumoxytol Product is especially made or adapted for use in infringing the '498 patent and that Sandoz's Ferumoxytol Product is not suitable for substantial non-infringing uses.

72. Upon information and belief, Sandoz is without a reasonable basis for believing that it would not be liable for infringing the '498 patent, actively inducing infringement of the '498 patent, and/or contributing to the infringement by others of the '498 patent.

73. Sandoz's infringing patent activity complained of herein is imminent and will begin following FDA approval of Sandoz's ANDA.

74. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between AMAG and Sandoz as to liability for the infringement of the '498 patent. Sandoz's actions have created in AMAG a reasonable apprehension of irreparable harm and loss resulting from Sandoz's threatened imminent actions.

75. Upon information and belief, Sandoz will knowingly and willfully infringe the '498 patent.

76. AMAG will be substantially and irreparably harmed if Sandoz is not enjoined from infringing the '498 patent. AMAG will have no adequate remedy at law if Sandoz is not enjoined from the commercial manufacture, use, offer to sell, sale in and importation into the United States of Sandoz's Ferumoxytol Product.

**COUNT III FOR INFRINGEMENT OF U.S. PATENT NO. 7,553,479 BY SANDOZ**

77. The allegations of the proceeding paragraphs 1–76 are re-alleged and incorporated herein by reference.

78. Sandoz's Ferumoxytol Product is covered by one or more claims of the '479 patent.

79. The commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Sandoz's Ferumoxytol Product would infringe one or more claims of the '479 patent.

80. Under 35 U.S.C. § 271(e)(2)(A), Sandoz's submission to FDA of Sandoz's ANDA to obtain approval for Sandoz's Ferumoxytol Product with a Paragraph IV Certification related thereto before the expiration of the '479 patent constitutes an act of infringement, and if approved, the commercial manufacture, use, offer to sell, sale, or importation of Sandoz's Ferumoxytol Product would infringe one or more claims of the '479 patent.

81. Sandoz was aware of the '479 patent when engaging in these knowing and purposeful activities and was aware that filing Sandoz's ANDA with Sandoz's Paragraph IV Certification with respect to the '479 patent constituted an act of infringement of the '479 patent.

82. Upon information and belief, if Sandoz's ANDA is approved by the FDA, the FDA will have determined that Sandoz's Ferumoxytol Product contains the same reduced carboxymethylated dextran iron oxide complex recited in one or more claims of the '479 patent.

83. Upon information and belief, Sandoz seeks approval from the FDA to manufacture, use, offer for sale, sell in and import into the United States Sandoz's Ferumoxytol Product, which will be indicated for the treatment of iron deficiency anemia in adult patients with chronic kidney disease. Upon information and belief, Sandoz's Ferumoxytol Product will be administered by intravenous injection.

84. Upon information and belief, Sandoz plans and intends to, and will, infringe the '479 patent immediately and imminently upon approval of Sandoz's ANDA.

85. Upon information and belief, immediately and imminently upon approval of Sandoz's ANDA, there will be direct infringement of the claims of the '479 patent under 35 U.S.C. § 271(a).

86. Upon information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '479 patent under 35 U.S.C. § 271(b) when Sandoz's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

87. Upon information and belief, Sandoz knows that Sandoz's Ferumoxytol Product is especially made or adapted for use in infringing the '479 patent and that Sandoz's Ferumoxytol Product is not suitable for substantial non-infringing uses. Upon information and belief, Sandoz, under 35 U.S.C. § 271(c), plans and intends to, and will, contribute to the

infringement of the '479 patent immediately and imminently upon approval of the Sandoz's ANDA.

88. The foregoing actions by Sandoz constitute and/or would constitute infringement of the '479 patent, active inducement of infringement of the '479 patent and/or contribution to the infringement by others of the '479 patent.

89. Upon information and belief, Sandoz acted without a reasonable basis for believing that it would not be liable for infringing the '479 patent, actively inducing infringement of the '479 patent and/or contributing to the infringement by others of the '479 patent.

90. AMAG will be substantially and irreparably harmed by Sandoz's infringing activities unless the Court enjoins those activities. AMAG will have no adequate remedy at law if Sandoz is not enjoined from the commercial manufacture, use, offer to sell, sale in and importation into the United States of Sandoz's Ferumoxytol Product.

91. Sandoz's activities render this case an exceptional one, and AMAG is entitled to an award of its reasonable attorney's fees under 35 U.S.C. § 285.

**COUNT IV FOR DECLARATORY JUDGMENT OF  
INFRINGEMENT OF U.S. PATENT NO. 7,553,479 BY SANDOZ**

92. The allegations of the proceeding paragraphs 1–91 are re-alleged and incorporated herein by reference.

93. Upon information and belief, Sandoz plans to begin manufacturing, marketing, selling, offering to sell and/or importing Sandoz's Ferumoxytol Product soon after FDA approval of Sandoz's ANDA.

94. Such conduct will constitute direct infringement of one or more claims on the '479 patent under 35 U.S.C. § 271(a), inducement of infringement of the '479 patent under 35 U.S.C. § 271(b), and/or contributory infringement of the '479 patent under 35 U.S.C. § 271(c).

95. Upon information and belief, Sandoz knows that Sandoz's Ferumoxytol Product is especially made or adapted for use in infringing the '479 patent and that Sandoz's Ferumoxytol Product is not suitable for substantial non-infringing uses.

96. Upon information and belief, Sandoz is without a reasonable basis for believing that it would not be liable for infringing the '479 patent, actively inducing infringement of the '479 patent and/or contributing to the infringement by others of the '479 patent.

97. Sandoz's infringing patent activity complained of herein is imminent and will begin following FDA approval of Sandoz's ANDA.

98. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between AMAG and Sandoz as to liability for the infringement of the '479 patent. Sandoz's actions have created in AMAG a reasonable apprehension of irreparable harm and loss resulting from Sandoz's threatened imminent actions.

99. Upon information and belief, Sandoz will knowingly and willfully infringe the '479 patent.

100. AMAG will be substantially and irreparably harmed if Sandoz is not enjoined from infringing the '479 patent. AMAG will have no adequate remedy at law if Sandoz is not enjoined from the commercial manufacture, use, offer to sell, sale in and importation into the United States of Sandoz's Ferumoxytol Product.

**COUNT V FOR INFRINGEMENT OF U.S. PATENT NO. 7,871,597 BY SANDOZ**

101. The allegations of the proceeding paragraphs 1–100 are re-alleged and incorporated herein by reference.

102. Sandoz's Ferumoxytol Product is covered by one or more claims of the '597 patent.

103. The commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Sandoz's Ferumoxytol Product would infringe one or more claims of the '597 patent.

104. Under 35 U.S.C. § 271(e)(2)(A), Sandoz's submission to FDA of Sandoz's ANDA to obtain approval for Sandoz's Ferumoxytol Product with a Paragraph IV Certification related thereto before the expiration of the '597 patent constitutes an act of infringement, and if approved, the commercial manufacture, use, offer to sell, sale, or importation of Sandoz's Ferumoxytol Product would infringe one or more claims of the '597 patent.

105. Sandoz was aware of the '597 patent when engaging in these knowing and purposeful activities and was aware that filing Sandoz's ANDA with Sandoz's Paragraph IV Certification with respect to the '597 patent constituted an act of infringement of the '597 patent.

106. Upon information and belief, if Sandoz's ANDA is approved by the FDA, the FDA will have determined that Sandoz's Ferumoxytol Product contains the same reduced carboxymethylated dextran iron oxide complex recited in one or more claims of the '597 patent.

107. Upon information and belief, Sandoz seeks approval from the FDA to manufacture, use, offer for sale, sell in and import into the United States Sandoz's Ferumoxytol Product, which will be indicated for the treatment of iron deficiency anemia in adult patients with chronic kidney disease. Upon information and belief, Sandoz's Ferumoxytol Product, will be administered by intravenous injection.

108. Upon information and belief, Sandoz plans and intends to, and will, infringe the '597 patent immediately and imminently upon approval of Sandoz's ANDA.

109. Upon information and belief, immediately and imminently upon approval of Sandoz's ANDA, there will be direct infringement of the claims of the '597 patent under 35 U.S.C. § 271(a).

110. Upon information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '597 patent under 35 U.S.C. § 271(b) when Sandoz's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

111. Upon information and belief, Sandoz knows that Sandoz's Ferumoxytol Product is especially made or adapted for use in infringing the '597 patent and that Sandoz's Ferumoxytol Product is not suitable for substantial non-infringing uses. Upon information and belief, Sandoz, under 35 U.S.C. § 271(c), plans and intends to, and will, contribute to the infringement of the '597 patent immediately and imminently upon approval of the Sandoz's ANDA.

112. The foregoing actions by Sandoz constitute and/or would constitute infringement of the '597 patent, active inducement of infringement of the '597 patent and/or contribution to the infringement by others of the '597 patent.

113. Upon information and belief, Sandoz acted without a reasonable basis for believing that it would not be liable for infringing the '597 patent, actively inducing infringement of the '597 patent and/or contributing to the infringement by others of the '597 patent.

114. AMAG will be substantially and irreparably harmed by Sandoz's infringing activities unless the Court enjoins those activities. AMAG will have no adequate remedy at law if Sandoz is not enjoined from the commercial manufacture, use, offer to sell, sale in and importation into the United States of Sandoz's Ferumoxytol Product.



115. Sandoz's activities render this case an exceptional one, and AMAG is entitled to an award of its reasonable attorney's fees under 35 U.S.C. § 285.

**COUNT VI FOR DECLARATORY JUDGMENT OF  
INFRINGEMENT OF U.S. PATENT NO. 7,871,597 BY SANDOZ**

116. The allegations of the proceeding paragraphs 1–115 are re-alleged and incorporated herein by reference.

117. Upon information and belief, Sandoz plans to begin manufacturing, marketing, selling, offering to sell and/or importing Sandoz's Ferumoxytol Product soon after FDA approval of Sandoz's ANDA.

118. Such conduct will constitute direct infringement of one or more claims on the '597 patent under 35 U.S.C. § 271(a), inducement of infringement of the '597 patent under 35 U.S.C. § 271(b), and/or contributory infringement of the '597 patent under 35 U.S.C. § 271(c).

119. Upon information and belief, Sandoz knows that Sandoz's Ferumoxytol Product are especially made or adapted for use in infringing the '597 patent and that Sandoz's Ferumoxytol Product is not suitable for substantial non-infringing uses.

120. Upon information and belief, Sandoz is without a reasonable basis for believing that it would not be liable for infringing the '597 patent, actively inducing infringement of the '597 patent and/or contributing to the infringement by others of the '597 patent.

121. Sandoz's infringing patent activity complained of herein is imminent and will begin following FDA approval of Sandoz's ANDA.

122. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between AMAG and Sandoz as to liability for the infringement of the '597 patent. Sandoz's actions have created in AMAG a reasonable apprehension of irreparable harm and loss resulting from Sandoz's threatened imminent actions.

123. Upon information and belief, Sandoz will knowingly and willfully infringe the '597 patent.

124. AMAG will be substantially and irreparably harmed if Sandoz is not enjoined from infringing the '597 patent. AMAG will have no adequate remedy at law if Sandoz is not enjoined from the commercial manufacture, use, offer to sell, sale in and importation into the United States of Sandoz's Ferumoxytol Product.

**COUNT VII FOR INFRINGEMENT OF U.S. PATENT NO. 8,501,158 BY SANDOZ**

125. The allegations of the proceeding paragraphs 1–124 are re-alleged and incorporated herein by reference.

126. The use of Sandoz's Ferumoxytol Product is covered by one or more claims of the '158 patent.

127. The use, offer for sale, sale, marketing, distribution and/or importation of Sandoz's Ferumoxytol Product would infringe one or more claims of the '158 patent.

128. Under 35 U.S.C. § 271(e)(2)(A), Sandoz's submission to FDA of Sandoz's ANDA to obtain approval for Sandoz's Ferumoxytol Product with a Paragraph IV Certification related thereto before the expiration of the '158 patent constitutes an act of infringement, and if approved, the commercial manufacture, use, offer to sell, sale, or importation of Sandoz's Ferumoxytol Product would induce and/or contribute to the infringement of one or more claims of the '158 patent.

129. Sandoz was aware of the '158 patent when engaging in these knowing and purposeful activities and was aware that filing Sandoz's ANDA with Sandoz's Paragraph IV Certification with respect to the '158 patent constituted an act of infringement of the '158 patent.

130. Upon information and belief, if Sandoz's ANDA is approved by the FDA, the FDA will have determined that Sandoz's Ferumoxytol Product contains the same superparamagnetic iron oxide coated with a carboxymethylated reduced dextran recited in one or more claims of the '158 patent.

131. Upon information and belief, Sandoz seeks approval from the FDA to manufacture, use, offer for sale, sell in and import into the United States Sandoz's Ferumoxytol Product, which will be indicated for the treatment of iron deficiency anemia in adult patients with chronic kidney disease. Upon information and belief, Sandoz's Ferumoxytol Product will be administered by intravenous injection.

132. Upon information and belief, Sandoz plans and intends to, and will, induce and/or contribute to the infringement of one or more claims of the '158 patent immediately and imminently upon approval of Sandoz's ANDA.

133. Upon information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '158 patent under 35 U.S.C. § 271(b) when Sandoz's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

134. Upon information and belief, Sandoz knows that Sandoz's Ferumoxytol Product is especially made or adapted for use in infringing the '158 patent and that Sandoz's Ferumoxytol Product is not suitable for substantial non-infringing uses. Upon information and belief, Sandoz, under 35 U.S.C. § 271(c), plans and intends to, and will, contribute to the infringement of the '158 patent immediately and imminently upon approval of the Sandoz's ANDA.

135. The foregoing actions by Sandoz constitute and/or would constitute active inducement of infringement of the '158 patent and/or contribution to the infringement by others of the '158 patent.

136. Upon information and belief, Sandoz acted without a reasonable basis for believing that it would not be liable for actively inducing infringement of the '158 patent and/or contributing to the infringement by others of the '158 patent.

137. AMAG will be substantially and irreparably harmed by Sandoz's infringing activities unless the Court enjoins those activities. AMAG will have no adequate remedy at law if Sandoz is not enjoined from the commercial manufacture, use, offer to sell, sale in and importation into the United States of Sandoz's Ferumoxytol Product.

138. Sandoz's activities render this case an exceptional one, and AMAG is entitled to an award of its reasonable attorney's fees under 35 U.S.C. § 285.

**COUNT VIII FOR DECLARATORY JUDGMENT OF  
INFRINGEMENT OF U.S. PATENT NO. 8,501,158 BY SANDOZ**

139. The allegations of the proceeding paragraphs 1–138 are re-alleged and incorporated herein by reference.

140. Upon information and belief, Sandoz plans to begin manufacturing, marketing, selling, offering to sell and/or importing Sandoz's Ferumoxytol Product soon after FDA approval of Sandoz's ANDA.

141. Such conduct will constitute inducement of infringement of the '158 patent under 35 U.S.C. § 271(b) and/or contributory infringement of the '158 patent under 35 U.S.C. § 271(c).

142. Upon information and belief, Sandoz knows that Sandoz's Ferumoxytol Product are especially made or adapted for use in infringing the '158 patent and that Sandoz's Ferumoxytol Product is not suitable for substantial non-infringing uses.

143. Upon information and belief, Sandoz is without a reasonable basis for believing that it would not be liable for actively inducing infringement of the '158 patent and/or contributing to the infringement by others of the '158 patent.

144. Sandoz's infringing patent activity complained of herein is imminent and will begin following FDA approval of Sandoz's ANDA.

145. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between AMAG and Sandoz as to liability for the infringement of the '158 patent. Sandoz's actions have created in AMAG a reasonable apprehension of irreparable harm and loss resulting from Sandoz's threatened imminent actions.

146. Upon information and belief, Sandoz will knowingly and willfully induce and contribute to the infringement of the '158 patent.

147. AMAG will be substantially and irreparably harmed if Sandoz is not enjoined from inducing and contributing to the infringement of the '158 patent. AMAG will have no adequate remedy at law if Sandoz is not enjoined from the commercial manufacture, use, offer to sell, sale in and importation into the United States of Sandoz's Ferumoxytol Product.

**COUNT IX FOR INFRINGEMENT OF U.S. PATENT NO. 8,591,864 BY SANDOZ**

148. The allegations of the proceeding paragraphs 1–147 are re-alleged and incorporated herein by reference.

149. Sandoz's Ferumoxytol Product is covered by one or more claims of the '864 patent.

150. The commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Sandoz's Ferumoxytol Product would infringe one or more claims of the '864 patent.

151. Under 35 U.S.C. § 271(e)(2)(A), Sandoz's submission to FDA of Sandoz's ANDA to obtain approval for Sandoz's Ferumoxytol Product with a Paragraph IV Certification related thereto before the expiration of the '864 patent constitutes an act of infringement, and if

approved, the commercial manufacture, use, offer to sell, sale, or importation of Sandoz's Ferumoxytol Product would infringe one or more claims of the '864 patent.

152. Sandoz was aware of the '864 patent when engaging in these knowing and purposeful activities and was aware that filing Sandoz's ANDA with Sandoz's Paragraph IV Certification with respect to the '864 patent constituted an act of infringement of the '864 patent.

153. Upon information and belief, if Sandoz's ANDA is approved by the FDA, the FDA will have determined that Sandoz's Ferumoxytol Product contains the same superparamagnetic iron oxide coated with a carboxymethylated reduced dextran recited in one or more claims of the '864 patent.

154. Upon information and belief, Sandoz seeks approval from the FDA to manufacture, use, offer for sale, sell in and import into the United States Sandoz's Ferumoxytol Product, which will be indicated for the treatment of iron deficiency anemia in adult patients with chronic kidney disease. Upon information and belief, Sandoz's Ferumoxytol Product will be administered by intravenous injection.

155. Upon information and belief, Sandoz plans and intends to, and will, infringe the '864 patent immediately and imminently upon approval of Sandoz's ANDA.

156. Upon information and belief, immediately and imminently upon approval of Sandoz's ANDA, there will be direct infringement of the claims of the '864 patent under 35 U.S.C. § 271(a).

157. Upon information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '864 patent under 35 U.S.C. § 271(b) when Sandoz's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

158. Upon information and belief, Sandoz knows that Sandoz's Ferumoxytol Product is especially made or adapted for use in infringing the '864 patent and that Sandoz's Ferumoxytol Product is not suitable for substantial non-infringing uses. Upon information and belief, Sandoz, under 35 U.S.C. § 271(c), plans and intends to, and will, contribute to the infringement of the '864 patent immediately and imminently upon approval of the Sandoz's ANDA.

159. The foregoing actions by Sandoz constitute and/or would constitute infringement of the '864 patent, active inducement of infringement of the '864 patent and/or contribution to the infringement by others of the '864 patent.

160. Upon information and belief, Sandoz acted without a reasonable basis for believing that it would not be liable for infringing the '864 patent, actively inducing infringement of the '864 patent and/or contributing to the infringement by others of the '864 patent.

161. AMAG will be substantially and irreparably harmed by Sandoz's infringing activities unless the Court enjoins those activities. AMAG will have no adequate remedy at law if Sandoz is not enjoined from the commercial manufacture, use, offer to sell, sale in and importation into the United States of Sandoz's Ferumoxytol Product.

162. Sandoz's activities render this case an exceptional one, and AMAG is entitled to an award of its reasonable attorney's fees under 35 U.S.C. § 285.

**COUNT X FOR DECLARATORY JUDGMENT OF  
INFRINGEMENT OF U.S. PATENT NO. 8,591,864 BY SANDOZ**

163. The allegations of the proceeding paragraphs 1–162 are re-alleged and incorporated herein by reference.

164. Upon information and belief, Sandoz plans to begin manufacturing, marketing, selling, offering to sell and/or importing Sandoz's Ferumoxytol Product soon after FDA approval of Sandoz's ANDA.

165. Such conduct will constitute direct infringement of one or more claims on the '864 patent under 35 U.S.C. § 271(a), inducement of infringement of the '864 patent under 35 U.S.C. § 271(b), and/or contributory infringement of the '864 patent under 35 U.S.C. § 271(c).

166. Upon information and belief, Sandoz knows that Sandoz's Ferumoxytol Product is especially made or adapted for use in infringing the '864 patent and that Sandoz's Ferumoxytol Product is not suitable for substantial non-infringing uses.

167. Upon information and belief, Sandoz is without a reasonable basis for believing that it would not be liable for infringing the '864 patent, actively inducing infringement of the '864 patent and/or contributing to the infringement by others of the '864 patent.

168. Sandoz's infringing patent activity complained of herein is imminent and will begin following FDA approval of Sandoz's ANDA.

169. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between AMAG and Sandoz as to liability for the infringement of the '864 patent. Sandoz's actions have created in AMAG a reasonable apprehension of irreparable harm and loss resulting from Sandoz's threatened imminent actions.

170. Upon information and belief, Sandoz will knowingly and willfully infringe the '864 patent.

171. AMAG will be substantially and irreparably harmed if Sandoz is not enjoined from infringing the '864 patent. AMAG will have no adequate remedy at law if Sandoz is not



enjoined from the commercial manufacture, use, offer to sell, sale in and importation into the United States of Sandoz's Ferumoxytol Product.

**COUNT XI FOR INFRINGEMENT OF U.S. PATENT NO. 8,926,947 BY SANDOZ**

172. The allegations of the proceeding paragraphs 1–171 are re-alleged and incorporated herein by reference.

173. Sandoz's Ferumoxytol Product is covered by one or more claims of the '947 patent.

174. The commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Sandoz's Ferumoxytol Product would infringe one or more claims of the '947 patent.

175. Under 35 U.S.C. § 271(e)(2)(A), Sandoz's submission to FDA of Sandoz's ANDA to obtain approval for Sandoz's Ferumoxytol Product with a Paragraph IV Certification related thereto before the expiration of the '947 patent constitutes an act of infringement, and if approved, the commercial manufacture, use, offer to sell, sale, or importation of Sandoz's Ferumoxytol Product would infringe one or more claims of the '947 patent.

176. Sandoz was aware of the '947 patent when engaging in these knowing and purposeful activities and was aware that filing Sandoz's ANDA with Sandoz's Paragraph IV Certification with respect to the '947 patent constituted an act of infringement of the '947 patent.

177. Upon information and belief, if Sandoz's ANDA is approved by the FDA, the FDA will have determined that Sandoz's Ferumoxytol Product contains the same carboxymethylated reduced dextran iron oxide complex recited in one or more claims of the '947 patent.

178. Upon information and belief, Sandoz seeks approval from the FDA to manufacture, use, offer for sale, sell in and import into the United States Sandoz's Ferumoxytol Product, which will be indicated for the treatment of iron deficiency anemia in adult patients with chronic kidney disease. Upon information and belief, Sandoz's Ferumoxytol Product, will be administered by intravenous injection.

179. Upon information and belief, Sandoz plans and intends to, and will, infringe the '947 patent immediately and imminently upon approval of Sandoz's ANDA.

180. Upon information and belief, immediately and imminently upon approval of Sandoz's ANDA, there will be direct infringement of the claims of the '947 patent under 35 U.S.C. § 271(a).

181. Upon information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '947 patent under 35 U.S.C. § 271(b) when Sandoz's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

182. Upon information and belief, Sandoz knows that Sandoz's Ferumoxytol Product is especially made or adapted for use in infringing the '947 patent and that Sandoz's Ferumoxytol Product is not suitable for substantial non-infringing uses. Upon information and belief, Sandoz, under 35 U.S.C. § 271(c), plans and intends to, and will, contribute to the infringement of the '947 patent immediately and imminently upon approval of the Sandoz's ANDA.

183. The foregoing actions by Sandoz constitute and/or would constitute infringement of the '947 patent, active inducement of infringement of the '947 patent and/or contribution to the infringement by others of the '947 patent.

184. Upon information and belief, Sandoz acted without a reasonable basis for believing that it would not be liable for infringing the '947 patent, actively inducing infringement of the '947 patent and/or contributing to the infringement by others of the '947 patent.

185. AMAG will be substantially and irreparably harmed by Sandoz's infringing activities unless the Court enjoins those activities. AMAG will have no adequate remedy at law if Sandoz is not enjoined from the commercial manufacture, use, offer to sell, sale in and importation into the United States of Sandoz's Ferumoxytol Product.

186. Sandoz's activities render this case an exceptional one, and AMAG is entitled to an award of its reasonable attorney's fees under 35 U.S.C. § 285.

**COUNT XII FOR DECLARATORY JUDGMENT OF  
INFRINGEMENT OF U.S. PATENT NO. 8,926,947 BY SANDOZ**

187. The allegations of the proceeding paragraphs 1–186 are re-alleged and incorporated herein by reference.

188. Upon information and belief, Sandoz plans to begin manufacturing, marketing, selling, offering to sell and/or importing Sandoz's Ferumoxytol Product soon after FDA approval of Sandoz's ANDA.

189. Such conduct will constitute direct infringement of one or more claims on the '947 patent under 35 U.S.C. § 271(a), inducement of infringement of the '947 patent under 35 U.S.C. § 271(b), and contributory infringement of the '947 patent under 35 U.S.C. § 271(c).

190. Upon information and belief, Sandoz knows that Sandoz's Ferumoxytol Product is especially made or adapted for use in infringing the '947 patent and that Sandoz's Ferumoxytol Product is not suitable for substantial non-infringing uses.

191. Upon information and belief, Sandoz is without a reasonable basis for believing that it would not be liable for infringing the '947 patent, actively inducing infringement of the '947 patent and/or contributing to the infringement by others of the '947 patent.

192. Sandoz's infringing patent activity complained of herein is imminent and will begin following FDA approval of Sandoz's ANDA.

193. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between AMAG and Sandoz as to liability for the infringement of the '947 patent. Sandoz's actions have created in AMAG a reasonable apprehension of irreparable harm and loss resulting from Sandoz's threatened imminent actions.

194. Upon information and belief, Sandoz will knowingly and willfully infringe the '947 patent.

195. AMAG will be substantially and irreparably harmed if Sandoz is not enjoined from infringing the '947 patent. AMAG will have no adequate remedy at law if Sandoz is not enjoined from the commercial manufacture, use, offer to sell, sale in and importation into the United States of Sandoz's Ferumoxytol Product.

#### **PRAYER FOR RELIEF**

WHEREFORE, AMAG respectfully requests the following relief:

(a) a judgment that the '498, '479, '597, '158, '864, and '947 patents are valid and enforceable;

(b) a judgment that Sandoz's submission of the ANDA No. 206604 was an act of infringement of one or more claims of the '498, '479, '597, '158, '864, and '947 patents and that the making, using, offering to sell, selling, marketing, distributing, or importing of Sandoz's Ferumoxytol Product prior to the expiration of the '498, '479, '597, '158, '864, and '947 patents

will infringe, actively induce infringement and/or contribute to the infringement of one or more claims of the '498, '479, '597, '158, '864, and '947 patents;

(c) an Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Sandoz ANDA No. 206604 or any product or compound the use of which infringes the '498, '479, '597, '158, '864, and '947 patents shall be a date that is not earlier than the expiration of the '498, '479, '597, '158, '864, and '947 patents;

(d) an Order pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Sandoz and all persons acting in concert with Sandoz from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Sandoz's Ferumoxytol Product, or any product or compound the use of which infringes the '498, '479, '597, '158, '864, and '947 patents, or inducing or contributing to the infringement of the '498, '479, '597, '158, '864, and '947 patents, until after the expiration of the '498, '479, '597, '158, '864, and '947 patents;

(e) an Order pursuant to 35 U.S.C. § 283 permanently enjoining Sandoz and all persons acting in concert with Sandoz from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Sandoz's Ferumoxytol Product, or any product or compound the use of which infringes the '498, '479, '597, '158, '864, and '947 patents, or inducing or contributing to the infringement of the '498, '479, '597, '158, '864, and '947 patents until after the expiration of the '498, '479, '597, '158, '864, and '947 patents;

(f) an Order enjoining Sandoz and all persons acting in concert with Sandoz from seeking, obtaining, or maintaining approval of the Sandoz ANDA No. 206604 before the expiration of the '498, '479, '597, '158, '864, and '947 patents;

(g) an award of AMAG's damages or other monetary relief to compensate AMAG if Sandoz engages in the commercial manufacture, use, offer to sell, sale or marketing or

distribution in, or importation into the United States of Sandoz's Ferumoxytol Product, or any product or compound the use of which infringes the '498, '479, '597, '158, '864, and '947 patents, or the inducement or contribution of the foregoing, prior to the expiration of the '498, '479, '597, '158, '864, and '947 patents in accordance with 35 U.S.C. § 271(e)(4)(C);

(h) an award of AMAG's damages or other monetary relief to compensate AMAG if Sandoz engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Sandoz's Ferumoxytol Product, or any product or compound the use of which infringes the '498, '479, '597, '158, '864, and '947 patents, or the inducement or contribution of the foregoing, prior to the expiration of the '498, '479, '597, '158, '864, and '947 patents;

(i) a judgment that this is an exceptional case and awarding AMAG its attorneys' fees under 35 U.S.C. § 285;

(j) an award of AMAG's reasonable costs and expenses in this action; and

(k) an award of any further and additional relief to AMAG as this Court deems just and proper.

Respectfully submitted,

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Dated: March 17, 2016

**CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2**

Pursuant to Local Civil Rule 11.2, AMAG Pharmaceuticals, Inc., by its undersigned counsel, hereby certifies to the best of its knowledge and belief that the matter in controversy, including the patents at issue in this action, is not the subject of any other pending action in any court, arbitration or administrative proceeding.

Dated: March 17, 2016

**PATUNAS TARANTINO LLC**

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