

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

Natco Pharma Ltd.,

Plaintiff,

v.

Gilead Sciences, Inc., and Express Scripts
Holding Co.

Defendants.

COMPLAINT

Civil No.: 14-cv-3247

Plaintiff, Natco Pharma Ltd. (“Natco”), by and through its undersigned counsel, files the following complaint against Defendant Gilead Sciences, Inc. (“Gilead”) and Defendant Express Scripts Holding Co. (“Express Scripts”) seeking relief under Sections 1 and 2 of the Sherman Act and under state law for harm resulting from the Defendants’ anticompetitive conduct in the market for ambrisentan.

Natco alleges as follows on information and belief:

INTRODUCTION

1. Gilead is a monopolist who currently controls 100% of the commercial market for the pharmaceutical ambrisentan, which Gilead markets as Letairis[®]. Gilead refuses to permit Natco access to Letairis[®], an essential facility necessary for Natco to conduct the testing required by the FDA to obtain approval for a generic form of Letairis[®]. Express Scripts is a distributor of Letairis[®].

2. Although ambrisentan is a known human teratogen (causing birth defects), it is effective in the treatment of pulmonary hypertension.

3. Due to the known dangers associated with ambrisentan, the FDA has conditioned its approval for use in human females on a restricted method of distribution. As a result, Gilead developed the Letairis[®] Risk Evaluation and Mitigation Strategy Program (“REMS”), and the safeguards included in the REMS program were a condition for FDA approval for the marketing of Letairis[®] to females.

4. Natco intends to seek FDA approval to market a generic ambrisentan product. One requirement for Natco to obtain FDA approval is to conduct bioequivalence testing in males to ensure that its generic ambrisentan product is the bioequivalent of the FDA approved, branded Letairis[®] product marketed by Gilead. Without access to the Letairis[®] samples, Natco cannot conduct bioequivalence testing and thus cannot bring a generic ambrisentan product to the market.

5. Despite its best efforts, Natco has been unable to obtain Letairis[®] samples from Gilead or Express Scripts. As a result, Natco is unable to bring its generic ambrisentan product to market, thereby causing (1) Natco irreparable harm and injury to its business and (2) consumer harm in the form of supra-competitive prices for Letairis[®].

PARTIES

6. Plaintiff Natco is a corporation organized and existing under the laws of India and has a principal place of business at Natco House, Road No. 2, Banjara Hills, Hyderabad - 500 034, India.

7. Defendant Gilead is a corporation organized and existing under the laws of Delaware and has a principal place of business at 333 Lakeside Drive, Foster City, CA 94404.

8. Defendant Express Scripts is a corporation organized and existing under the laws of Delaware and has a principal place of business at One Express Way, St. Louis, MO 63121.

JURISDICTION & VENUE

9. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1337(a), and 15 U.S.C. §§ 15 and 26. This Court has supplemental jurisdiction over the Minnesota state law claims pursuant to 28 U.S.C. § 1367(a).

10. Venue is proper in this Court pursuant to the provisions of 28 U.S.C. §1391(b)(1) and (2), in that Gilead was subject to personal jurisdiction in this district at the time this action was commenced, and thus resides in this district pursuant to 28 U.S.C. § 1391(b)(1). Further, this is the judicial district where a substantial part of the events or omissions giving rise to the claim occurred.

STATUTORY AND REGULATORY BACKGROUND

FDA Approval of New Drug Application

11. Before marketing a new drug in the United States, a manufacturer must obtain FDA approval for its new drug application (“NDA”). Once approved, new drugs generally are referred to as brand-name drugs because they are marketed under a trade

name or trademark for the drug product rather than under the chemical name of the drug product's active ingredient.

12. Among other things, an NDA must contain technical data on the composition of the drug product, including its active ingredient, the means for its manufacture, and a statement of its proposed uses. The FDA approves a new drug only if it determines, based on evidence submitted by the manufacturer, that the drug is safe and effective for its proposed use(s).

The Hatch-Waxman Amendments and Generic Drugs

13. Congress enacted the Drug Price Competition & Patent Term Restoration Act, commonly known as the Hatch-Waxman Amendments ("the Hatch-Waxman Act"), to increase the availability of low-cost generic drugs by expediting the FDA approval process. In recognition of the competing interests to brand-name manufacturers, the Hatch-Waxman Act provided that brand-name manufacturers are entitled to five years of exclusivity for new drugs and they are given the ability to apply to extend the patent protection for their drugs by an additional five years. *See* 21 U.S.C. § 355(c)(3)(E)(ii); 35 U.S.C. § 156.

14. A generic drug is a version of a brand-name drug that contains the same active ingredient as the brand-name drug but typically sells at a lower cost than the brand-name drug.

15. Generic drugs are frequently prescribed in an effort to control healthcare costs and represent an increasing portion of the medicines used in the United States. The introduction of a generic drug as an alternative to a brand-name drug typically results in a

dramatic reduction in the brand-name drug's market share, particularly within the first six months.

16. The Generic Pharmaceutical Association estimates that from 2001 through 2010, the nation's health care system saved \$931 billion from the use of generic drugs.

17. Before marketing a generic drug in the United States, a manufacturer must obtain FDA approval for its ANDA. To obtain FDA approval, an ANDA applicant must show that its generic drug is as safe and effective as the approved brand-name drug, known as the "reference listed drug" or "RLD," in part by demonstrating that the generic drug is bioequivalent to the RLD. *See* 21 U.S.C. § 355U)(2)(A). The two drug products are considered bioequivalent if the rate and extent of absorption of the generic drug does not differ significantly from the rate and extent of absorption of the brand-name drug. The FDA has established regulations and scientific guidance on how an applicant can demonstrate bioequivalence.

18. Under the Hatch-Waxman Act, brand companies are required to list the patents that correspond to each approved drug. These FDA-listed patents are disclosed in the agency's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the "Orange Book."

19. A generic drug manufacturer is free to perform bioequivalence testing and other research and drug development activities without fear of infringing the patents claimed by the RLD that are listed in the Orange Book. The Patent Act expressly provides that such research activities shall not constitute an act of infringement. *See* 35 U.S.C. § 271(e)(1).

20. A generic applicant must identify as part of its ANDA any patents listed in the Orange Book for the RLD and must certify as to each listed patent (i) that no patent information has been filed with the FDA; (ii) that the claimed patent has expired; (iii) the date on which the filed patent will expire; or (iv) that the filed patent is invalid, unenforceable, or will not be infringed by the generic drug for which approval is sought. 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV).

21. As an incentive for generic applicants to challenge invalid, unenforceable, or non-infringed brand-company patents, the Hatch-Waxman Act awards 180 days of marketing exclusivity to the generic applicant that is first to file with, or as an amendment to, its ANDA a Paragraph IV certification with respect to any patent that the brand company asserts covers the RLD. *See* 21 U.S.C. § 355(j)(5)(B)(iv). The exclusivity recipient is known as the “first filer.”

Risk Evaluation and Mitigation Strategies

22. Under the Food and Drug Administration Amendments Act of 2007, the FDA has the authority to require REMS from manufacturers to ensure that the benefits of a drug or biological product outweigh its risks. A REMS can include a medication guide, a patient package insert, or potential restrictions on the distribution of the drug (e.g., by requiring practitioners, pharmacies or healthcare settings to obtain special certifications in order to dispense the drug).

23. In enacting the REMS framework, Congress anticipated that brand-name drug manufacturers like Gilead might use REMS programs as a basis for withholding samples of brand-name drugs from generic drug manufacturers like Natco. Accordingly,

Congress enacted Section 505-1(f)(8) of the FDCA (codified at 21 U.S.C. § 355-1(f)(8)), which prohibits a brand-name drug manufacturer from using a REMS “to block or delay approval of” an ANDA.

FACTUAL BACKGROUND

Ambrisentan

24. The FDA lists Gilead as the holder of NDA No. 22-081 for ambrisentan tablets, which Gilead markets as Letairis[®]. According to the FDA website, the FDA approved NDA No. 22-081 on June 15, 2007.

25. The Orange Book lists U.S. Patent Nos. 5,703,017; 5,840,722; 7,109,205; 7,601,730; 8,349,843; and RE 42,462 (collectively, “Orange Book listed patents) for Letairis[®]. The last Orange Book listed patent will expire on July 29, 2018. Currently there is no generic alternative for Letairis[®].

26. Letairis[®] is subject to an FDA mandated REMS protocol. The FDA gave initial approval of the Letairis[®] REMS in May 2009. The most recent modification to the Letairis[®] REMS was approved in January 2014.

27. Letairis[®] is an extremely profitable drug for Gilead. The average monthly wholesale price of Letairis[®] exceeds \$2,000. In 2013, Gilead’s revenue for Letairis[®] reached roughly \$520 million. Gilead therefore has a strong incentive to maintain its monopoly over ambrisentan, which currently is not set to expire until July 29, 2018.

Natco Identifies and Develops a Generic Version of Letairis®

28. Natco has experience in the development, manufacture, sale, marketing and distribution of pharmaceutical products, including the development and production of pharmaceutical drug products from concept through ANDA approval.

29. As part of its research into promising candidates for generic drugs, Natco identified the opportunity and need for a generic version of Letairis®.

30. Natco then developed a generic drug that it believes is bioequivalent to Letairis®.

31. Before Natco can market its ambrisentan drug in the United States, Natco must submit and obtain FDA approval for its ANDA relating to ambrisentan.

32. Prior to submitting its ANDA, Natco must perform bioequivalence testing to demonstrate that its ambrisentan drug is bioequivalent to Letairis®.

33. To demonstrate bioequivalence, Natco must obtain a sufficient quantity of Letairis® to perform its bioequivalence testing.

34. Letairis® is therefore an essential facility, access to which is wholly controlled by Gilead.

Natco Attempts to Purchase Letairis® for Bioequivalence Testing

35. Natco attempted to purchase samples of Letairis® through normal wholesale distribution channels but was unable to do so.

36. On June 6, 2014, Natco sent Gilead a letter seeking to purchase Letairis® samples for bioequivalence testing.

37. In the June 6, 2014 letter, Natco offered to pay the market rate and shipping for 30 tablets of 5 mg and 500 tablets of 10 mg Letairis[®]. Natco also indicated that the samples would “be used solely for development purposes to meet FDA requirements” and that “[a]ll necessary precautions w[ould] be put in place to limit the access and handling of these samples.” *See* Exhibit A.

38. On June 23, 2014, Gilead responded, indicating that it would not provide samples of Letairis[®] and explained that “Natco should be able to obtain samples of Letairis[®] for male subjects through commercial channels.” *See* Exhibit B.

39. The reference to “male subjects” in Gilead’s response is based on the fact that the FDA guidance for the bioequivalence studies for generic equivalents of Letairis[®] states that such studies must be conducted in male subjects.

40. As a result of receiving Gilead’s letter of June 23, 2014, on July 22, 2014, Natco attempted to purchase samples of Letairis[®] through normal commercial channels. Specifically, Natco requested to purchase samples from Express Scripts, one of Gilead’s approved distributors of the drug. *See* Exhibit C.

41. In so doing, Natco informed Express Scripts that Natco sought to purchase the samples of Letairis[®] solely for the purpose of conducting bioequivalence studies in male subjects.

42. Natco further informed Express Scripts that Natco had been advised by Gilead that Natco should be able to purchase Letairis[®] samples through normal commercial channels, specifically attaching a copy of Gilead’s June 23, 2014 letter to Natco.

43. Express Scripts, however, failed to respond to the July 22, 2014 letter requesting the sale of Letairis[®] samples.

44. Thus, Natco has been unable to obtain Letairis[®] through normal commercial channels.

Relevant Market

45. The relevant product market in this action is the market for FDA-approved ambrisentan drug products.

46. The relevant geographic market in this case is the United States, including the State of Minnesota.

47. Gilead has monopoly power and market power in the market for FDA-approved ambrisentan drug products because it is the only company with FDA approval to market an ambrisentan drug product in the United States. Gilead has sufficient market power to keep prices of FDA-approved ambrisentan drug products artificially high and quantities artificially low.

48. Gilead has used its market power to foreclose or otherwise adversely affect competition in the market for FDA-approved ambrisentan drug products by causing output to be artificially low, raising competitors' costs and/or keeping the market price for FDA-approved ambrisentan drug products above a competitive level. Gilead has also raised the cost of entry into the market by blocking access to Letairis[®] for the purpose of bioequivalence testing.

COUNT I
**(Violation of Section 1 of The Sherman Act: Contract, Combination or
Conspiracy in Restraint of Trade)**

49. Natco realleges and incorporates by reference paragraphs 1 through 48 as if set forth in full.

50. This Count arises under the Sherman Act, 15 U.S.C. § 1, and the Clayton Act, 15 U.S.C. §§ 15, 26, and seeks a judgment that Gilead has violated Section 1 of the Sherman Act, 15 U.S.C. § 1, by conspiring, combining and/or agreeing to restrain trade in the market for FDA-approved ambrisentan drug products.

51. Through the foregoing acts, Gilead, unlawfully and in violation of Section 1 of the Sherman Act, U.S.C. § 1, has acted pursuant to a contract, combination or conspiracy in order to, and with the likely effect of, unreasonably restraining trade in the market for FDA-approved ambrisentan drug products.

52. Specifically, Gilead has entered into unlawful agreements with Express Scripts and other participants to limit distribution of Letairis[®] to only those entities that Gilead permits. Gilead has also entered into unlawful agreements with each of its approved distributors, under which such participants agree not to supply ambrisentan to any entity without Gilead's approval.

53. By restricting downstream distribution of the drugs only to entities it approves, Gilead is able to effectively foreclose all potential competitors from access to an essential input in the generic drug development process, and thus unlawfully "block or delay approval," 21 U.S.C. § 335-1(f)(8), of a competing generic version of Letairis[®], using its restricted distribution program as pretext.

54. Each of these agreements constitute contracts, combinations and conspiracies that substantially, unreasonably, and unduly restrain trade in the relevant market, and harmed Natco thereby.

55. There is no legitimate, procompetitive business justification for Gilead's agreements with Express Scripts and other participants that outweighs the anticompetitive effect of these agreements. Any purported justification by Gilead is pretextual. Even if there was some business justification, the agreements are broader than necessary to achieve such a purpose.

56. The foregoing acts and practices have harmed consumers and competition.

57. As a result of Gilead's conduct, Natco has suffered and will continue to suffer injury to its business and property, including lost profits, out-of-pocket costs, and lost business opportunities.

58. Gilead's anticompetitive and exclusionary conduct has directly and proximately caused injury to Natco's business and property, as set forth above. Natco's injury is the type that antitrust laws are intended to prohibit and thus constitutes antitrust injury.

59. Gilead's unlawful conduct continues and, unless restrained, will continue. Natco has no adequate remedy at law.

60. Natco is entitled to judgment that Gilead had violated Section 1 of the Sherman Act; to the damages it suffered or may suffer as a result of that violation, to be trebled in accordance with the Clayton Act, 15 U.S.C. § 15, plus interest; to its costs and attorneys' fees; and to an injunction restraining Gilead's continued violations.

COUNT II
(Violation of Section 2 of The Sherman Act – Monopolization, Attempted Monopolization and Conspiracy to Monopolize)

61. Natco realleges and incorporates by reference paragraphs 1 through 60 as if set forth in full.

62. The relevant market for Letairis[®] is the market for ambrisentan in the United States. This market is characterized by significant entry barriers.

63. Gilead possesses monopoly power in the relevant market for Letairis[®]. Gilead controls 100% of the commercial market for ambrisentan.

64. By refusing to sell samples of Letairis[®] at market prices to Natco for the purposes of bioequivalence testing that is necessary in order to submit an ANDA for generic ambrisentan, Gilead has unlawfully and willfully maintained its monopoly power in the relevant market, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

65. Gilead's refusal to sell samples of Letairis[®] at market prices to Natco for bioequivalence testing was intended to, did, and is continuing to thwart the entry to market of competing products, thereby extending Gilead's power in the relevant market.

66. Gilead does not have a legitimate, pro-competitive business purpose for refusing to sell samples of Letairis[®] at market price to Natco.

67. Gilead's refusal to sell Natco samples of Letairis[®] at market prices, in furtherance of its unlawful monopoly, has had the effect of delaying the entry of a generic competitor for many months, during with time:

- (a) Competition in the manufacture, sale and distribution of ambrisentan is restrained, suppressed and eliminated;

- (b) Gilead has sold and will continue to sell Letairis[®] at artificially high, noncompetitive prices, reaping monopolist's profits in an amount to be determined at trial; and
- (c) Deprived of the benefits of free and open competition in the purchase of ambrisentan, patients who purchase Letairis[®] have been and will continue to be forced to pay artificially high, monopolistic prices for ambrisentan.

68. As a result of Gilead's unlawful conduct, Natco has been injured in its business, in that Gilead's refusal to sell Natco samples of Letairis[®] has prevented and delayed Natco from bringing a competing generic ambrisentan product to market, causing Natco damages in an amount to be determined at trial.

COUNT III
(Violation of Section 2 of The Sherman Act – Essential Facilities)

69. Natco realleges and incorporates by reference paragraphs 1 through 68 as if set forth in full.

70. The relevant market for Letairis[®] is the market for ambrisentan in the United States. This market is characterized by significant entry barriers.

71. It is impossible for a generic manufacturer like Natco to bring a competing ambrisentan product to market without access to Letairis[®] for bioequivalence testing. Letairis[®], the distribution of which is controlled by Gilead, is an essential facility for the production of generic ambrisentan. Gilead is a monopolist with control over this essential facility.

72. By refusing to sell samples of Letairis[®] at market prices to Natco for the purposes of bioequivalence testing that is necessary in order to submit an ANDA for generic ambrisentan, Gilead has controlled an essential facility necessary for the production of ambrisentan, thereby effectively maintaining its monopoly power in the relevant market, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

73. Gilead's refusal to sell samples of Letairis[®] at market prices to Natco for bioequivalence testing was intended to, did, and continues to extend its monopoly in the relevant market.

74. Natco cannot practically or reasonably duplicate samples of Letairis[®] for the purpose of conducting a bioequivalence study that satisfies FDA's requirements. Additionally, Natco cannot obtain samples of the FDA-approved version of Letairis[®] from other sources.

75. It would be feasible for Gilead to sell samples of Letairis[®]. Gilead simply would sell Natco the samples at full market prices, which Natco has offered to pay. In attempting to purchase samples of Letairis[®], Natco has assured Gilead that the samples would not be sold to any patient in the United States, and that the samples would be used only for the purpose of bioequivalence testing on male test subjects.

76. Gilead does not have a legitimate, pro-competitive business purpose for refusing to sell Natco samples of Letairis[®] at market prices.

77. Gilead's refusal to sell Natco samples of Letairis[®] at market prices, in furtherance of its unlawful monopoly, has had the effect of delaying the entry of a generic competitor for many months, during with time:

- (a) Competition in the manufacture, sale and distribution of ambrisentan is restrained, suppressed and eliminated;
- (b) Gilead has sold and will continue to sell Letairis[®] at artificially high, noncompetitive prices, reaping monopolist's profits in an amount to be determined at trial; and
- (c) Deprived of the benefits of free and open competition in the purchase of ambrisentan, patients who purchase Letairis[®] have been and will continue to be forced to pay artificially high, monopolistic prices for ambrisentan.

78. As a result of Gilead's unlawful conduct, Natco has been injured in its business, in that Gilead's refusal to sell Natco samples of Letairis[®] has prevented and delayed Natco from bringing a competing generic ambrisentan product to market, causing Natco damages in an amount to be determined at trial.

COUNT IV
(Violation of the Minnesota Antitrust Act § 325D.52)

79. Natco realleges and incorporates by reference paragraphs 1 through 78 as if set forth in full.

80. Gilead has engaged in a continuing program to establish, maintain, or use monopoly power over its competition in the ambrisentan market for the purpose of affecting competition or controlling, fixing, or maintaining artificially high prices.

81. Gilead has monopoly power and market power in the market for FDA-approved ambrisentan drug products because it is the only company with FDA approval

to market an ambrisentan drug product in the United States, and therefore the only company with FDA approval to market an ambrisentan drug product in the State of Minnesota. Gilead has sufficient market power to keep prices of FDA-approved ambrisentan drug products artificially high and quantities artificially low.

82. Gilead has used its market power to foreclose or otherwise adversely affect competition in the market for FDA-approved ambrisentan drug products by causing output to be artificially low, raising competitors' costs and/or keeping the market price for FDA-approved ambrisentan drug products above a competitive level. Gilead has also raised the cost of entry into the market by blocking access to Letairis[®] for the purpose of bioequivalence testing.

83. The relevant market for Letairis[®] is the market for ambrisentan in the State of Minnesota. This market is characterized by significant entry barriers.

84. Gilead possesses monopoly power in the relevant market for Letairis[®]. Gilead controls 100% of the commercial market for ambrisentan.

85. By refusing to sell samples of Letairis[®] at market prices to Natco for the purposes of bioequivalence testing that is necessary in order to submit an ANDA for generic ambrisentan, Gilead has unlawfully and willfully maintained its monopoly power in the relevant market, in violation of Section 352D.52 of the Minnesota Antitrust Act.

86. Gilead's refusal to sell samples of Letairis[®] at market prices to Natco for bioequivalence testing was intended to, did, and continues to thwart the entry to market of competing products, thereby extending Gilead's power in the relevant market.

87. Gilead does not have a legitimate, pro-competitive business purpose for refusing to sell samples of Letairis[®] at market price to Natco.

88. Gilead's refusal to sell Natco samples of Letairis[®] at market prices, in furtherance of its unlawful monopoly, has had the effect of delaying the entry of a generic competitor, during with time:

- (a) Competition in the manufacture, sale and distribution of ambrisentan is restrained, suppressed and eliminated;
- (b) Gilead has sold and will continue to sell Letairis[®] at artificially high, noncompetitive prices, reaping monopolist's profits in an amount to be determined at trial; and
- (c) Deprived of the benefits of free and open competition in the purchase of ambrisentan, patients who purchase Letairis[®] in the State of Minnesota have been and will continue to be forced to pay artificially high, monopolistic prices for ambrisentan.

89. As a result of Gilead's unlawful conduct, Natco has been injured in its business, in that Gilead's refusal to sell Natco samples of Letairis[®] has prevented and delayed Natco from bringing a competing generic ambrisentan product to market, causing Natco damages in an amount to be determined at trial.

COUNT V
(Violation of the Minnesota Antitrust Act §§ 325D.51 and 53)

90. Natco realleges and incorporates by reference paragraphs 1 through 89 as if set forth in full.

91. Gilead and its co-conspirators engaged in a continuing agreement, understanding, and conspiracy in restraint of trade and commerce in violation of Minn. Stat. §§ 325D.51 and 325D.53 of the Minnesota Antitrust Act § 325D.49 et seq.

92. In formulating and effectuating the alleged contract, conspiracy or combination, Gilead and its co-conspirators have engaged in anti-competitive activities, the purpose and effect of which has been to artificially raise, fix, maintain, or stabilize the price of ambrisentan in the State of Minnesota. These activities included the following:

- (a) Gilead and its distributors have sold and continue to sell Gilead's ambrisentan product at artificially high, noncompetitive prices, reaping monopolist's profits;
- (b) Gilead and its distributors have colluded or conspired to refuse to sell Letairis[®] to Natco at market prices;
- (c) Natco requires access to Letairis[®] in order to gain FDA approval of its competing generic ambrisentan product;
- (d) By refusing to sell Letairis[®] to Natco, Gilead and its distributors have been able to prevent Natco from bringing a generic ambrisentan product to market; and
- (e) By preventing Natco from developing a generic ambrisentan product and bringing it to market, Gilead and its distributors are able to continue selling Letairis[®] to customers in the United States, including Minnesota, at non-competitive prices.

93. In formulating and effectuating the alleged contract, conspiracy or combination, Gilead and its co-conspirators also illegally refused to deal with Natco. These activities have included the following:

- (a) Gilead has refused to sell Letairis[®] to Natco at market prices;
- (b) Gilead has caused its distributors to refuse to sell Letairis[®] to Natco at market prices; and
- (c) As a result of Gilead and its distributors' refusal to deal, Natco is unable to obtain the Letairis[®] samples it needs to obtain FDA approval of its generic ambrisentan product.

94. Given that Gilead has a monopoly on the sale of ambrisentan in the United States and thus in the State of Minnesota, and that Gilead's distributors benefit from Gilead's monopoly, Gilead and its distributors had a common economic motive to enter into the illegal price fixing and refusal to deal arrangements herein described.

95. Gilead and its co-conspirators have engaged in the activities described above for the purpose of effectuating the unlawful arrangements herein described.

96. The unlawful contract, conspiracy or combination has had the following effects, among others:

- (a) Competition in the manufacture, sale and distribution of ambrisentan is restrained, suppressed and eliminated;
- (b) Gilead has sold and will continue to sell Letairis[®] at artificially high, noncompetitive prices, reaping monopolist's profits in an amount to be determined at trial; and

- (c) Deprived of the benefits of free and open competition in the purchase of ambrisentan, patients who purchase Letairis[®] in the State of Minnesota have been and will continue to be forced to pay artificially high, monopolistic prices for ambrisentan.

97. As a result of Gilead and its co-conspirators' unlawful conduct, Natco has been injured in its business, in that Gilead's refusal to sell Natco samples of Letairis[®] has prevented and delayed Natco from bringing a competing generic ambrisentan product to market, causing Natco damages in an amount to be determined at trial.

COUNT VI
(Declaratory Relief)

98. Natco realleges and incorporates by reference paragraphs 1 through 97 above as if set forth in full.

99. Natco seeks to submit an ANDA to manufacture generic ambrisentan. The FDA has stated that this ANDA must demonstrate bioequivalence based on bioequivalence studies performed using the RLD (i.e., FDA-approved) Letairis[®].

100. Natco has requested that Gilead sell Natco sufficient samples of Letairis[®] to perform bioequivalence testing, and has indicated that it will pay Gilead market prices for these samples, that it will use them only on male patients, and that it will take all reasonably necessary and appropriate precautions in handling the drug.

101. Gilead has refused to sell samples of Letairis[®] to Natco.

102. Thus, a dispute currently exists between Natco and Gilead with respect to

Gilead's obligation to sell Natco samples of Letairis[®] for bioequivalence testing.

103. Natco is therefore entitled, pursuant to the Declaratory Judgments Act, 28 U.S.C. §§ 2201 and 2202, to a declaration of rights and obligations whereby Gilead is obliged to sell Natco sufficient quantities of Letairis[®] at market prices so that Natco can perform the bioequivalence testing necessary to support an ANDA for its generic ambrisentan product.

REQUEST FOR RELIEF

WHEREFORE, Natco respectfully requests that this Court enter a Judgment and Order in its favor and against Defendants as follows:

- a. restraining Defendants from continuing their Sherman Act and state law violations;
- b. restraining Defendants from limiting distribution of Letairis[®] to Natco through use of its REMS and/or restricted distribution programs or otherwise;
- c. awarding Natco three times its actual damages suffered as a result of Defendants' Sherman Act violations plus interest, including costs and attorneys' fees;
- d. awarding Natco three times its actual damages suffered as a result of Defendants' Minnesota Antitrust Act violations plus interest, including costs and attorneys' fees;
- e. awarding Natco its damages suffered as a result of Defendants' common law violations plus interest;

- f. granting Natco a declaration that Defendants' anticompetitive conduct is unlawful; and
- g. awarding Natco any further and additional relief as the Court deems just and proper.

JURY DEMAND

Natco demands a trial by jury on all issues so triable.

Date: August 22, 2014

s/Jeffer Ali
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