IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UNITED THERAPEUTICS CORPORATION,	)	
Plaintiff,	)	
v.	)	C.A. No. 20-755 (RGA)
LIQUIDIA TECHNOLOGIES, INC.,	)	
Defendant.	)	

FIRST AMENDED COMPLAINT

Plaintiff United Therapeutics Corporation ("UTC"), by its undersigned attorneys, for its First Amended Complaint against Liquidia Technologies, Inc. ("Liquidia"), alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, Sections 100 *et seq.*, involving United States Patent Nos. 9,593,066 ("the '066 patent") (attached as Exhibit A hereto), 9,604,901 ("the '901 patent") (attached as Exhibit B hereto), and 10,716,793 ("the '793 patent") (attached as Exhibit C hereto) (collectively, the "Patents-in-Suit").

2. This action arises out of Liquidia's submission of New Drug Application No. 213005 under § 505(b)(2) of the Federal Food, Drug and Cosmetic Act ("Liquidia's 505(b)(2) Application") to the United States Food and Drug Administration ("FDA") seeking approval, prior to the expiration of the '066 patent, the '901 patent, and the '793 patent, to manufacture, market, and sell a generic copy of UTC's TYVASO® (treprostinil) Inhalation Solution, 0.6 mg/ml that is approved by FDA for treatment of pulmonary arterial hypertension ("Liquidia's Proposed Generic Product").

THE PARTIES

3. UTC is a corporation organized and existing under the laws of the State of Delaware and having a place of business at 1040 Spring Street, Silver Spring, Maryland 20910. UTC is a biotech company focused on the development and commercialization of products designed to address the needs of patients with chronic and life-threatening conditions. UTC continues to research and develop treatments for cardiovascular and pulmonary diseases, pediatric cancers, and other orphan diseases.

4. Upon information and belief, Liquidia is a corporation organized and existing under the laws of the State of Delaware, with a registered office at 51 Little Falls Drive, Wilmington, Delaware 19808, and a principal place of business at 419 Davis Drive, Suite 100, Morrisville, North Carolina 27560.

5. Upon information and belief, to manufacture Liquidia's Proposed Generic Product, Liquidia purchases the treprostinil sodium active pharmaceutical ingredient ("API") from third-party manufacturer Yonsung Fine Chemicals Co., LTD ("Yonsung"), operating out of South Korea. Upon information and belief, Liquidia will import treprostinil sodium API from Yonsung into the United States.

6. Upon information and belief, Liquidia's Proposed Generic Product delivers treprostinil through a dry powder inhaler ("DPI") that is manufactured by Plastiape SpA ("Plastiape"). Upon information and belief, Plastiape has a principal place of business at Via Primo Maggio, 8 Osnago, 23875 Italy. Upon information and belief, Plastiape is a wholly-owned subsidiary of Berry Global Group, Inc. Upon information and belief, Berry Global Group, Inc. has a principal place of business at 101 Oakley Street, Evansville, Indiana 47710.

JURISDICTION AND VENUE

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

8. Venue is proper in this Court under 28 U.S.C. § 1400(b).

9. Upon information and belief, this Court has personal jurisdiction over Liquidia because it is a corporation organized and existing under the laws of the State of Delaware with a registered agent in the State of Delaware. Further, upon information and belief, Liquidia has publicly stated its intent to engage in commercializing Liquidia's Proposed Generic Product throughout the United States without any limitation. Upon information and belief, Liquidia will manufacture, market, distribute, and/or sell Liquidia's Proposed Generic Product throughout the United States, including in Delaware, and will derive substantial revenue therefrom. Upon information and belief, upon approval of Liquidia's 505(b)(2) Application, Liquidia will place Liquidia's Proposed Generic Product into the stream of commerce with the reasonable expectation or knowledge and the intent that such products will ultimately be purchased and used by consumers in Delaware.

BACKGROUND

10. UTC holds New Drug Application No. 022387, which has been approved for TYVASO® (treprostinil) Inhalation Solution, 0.6 mg/ml, which UTC markets and sells under the registered trademark TYVASO®.

11. TYVASO® is a pharmaceutical product initially approved by FDA in the United States in July 2009 and is indicated for the treatment of pulmonary arterial hypertension. Pulmonary arterial hypertension is a rare disease affecting the pulmonary vasculature and results

in high pressure in the pulmonary arteries, which increases strain on the right ventricle of the heart, thereby leading to heart failure and death.

12. TYVASO® is an inhalable product approved for sale in a 0.6 mg/mL concentration.

13. The '066 patent, entitled "Process to prepare treprostinil, the active ingredient in Remodulin®," was duly and legally issued by the United States Patent and Trademark Office on March 14, 2017, and is scheduled to expire on December 15, 2028. The named inventors are Hitesh Batra, Sudersan M. Tuladhar, Raju Penmasta, and David A. Walsh.

14. UTC is the lawful owner of the '066 patent by assignment of all right, title and interest in and to the '066 patent, including the right to bring infringement suits thereon.

15. The '901 patent, entitled "Process to prepare treprostinil, the active ingredient in Remodulin®," was duly and legally issued by the United States Patent and Trademark Office on March 28, 2017, and is scheduled to expire on December 15, 2028. The named inventors are Hitesh Batra, Sudersan M. Tuladhar, Raju Penmasta, and David A. Walsh.

16. UTC is the lawful owner of the '901 patent by assignment of all right, title and interest in and to the '901 patent, including the right to bring infringement suits thereon.

17. The '793 patent, entitled "Treprostinil Administration by Inhalation," was duly and legally issued by the United States Patent and Trademark Office on July 21, 2020, and is scheduled to expire on May 14, 2027. The named inventors are Horst Olschewski, Robert Roscigno, Lewis J. Rubin, Thomas Schmehl, Werner Seeger, Carl Sterritt, and Robert Voswinckel.

18. UTC is the lawful owner of the '793 patent by assignment of all right, title and interest in and to the '793 patent, including the right to bring infringement suits thereon.

19. TYVASO® and its FDA approved manufacture and uses are covered by one or more claims of the '066 patent, the '901 patent, and the '793 patent, which have been listed in connection with TYVASO® in the FDA's *Approved Drug Products with Therapeutic Equivalents* publication (also known as the "Orange Book").

ACTS GIVING RISE TO THIS ACTION

20. Liquidia notified UTC by letter dated April 24, 2020, which was delivered to UTC on or about April 27, 2020 ("Liquidia's Notice Letter"), that it had submitted NDA No. 213005 to the FDA seeking approval to engage in the commercial manufacture, use and/or sale of Liquidia's Proposed Generic Product prior to the expiration of the'066 patent and the '901 patent.

21. Liquidia's Notice Letter included a statement pursuant to 21 U.S.C. § 355(b)(3)(D)(ii) and 21 C.F.R. § 314.52(c)(6) purporting to recite Liquidia's "factual and legal basis" for its opinion that the '066 patent and the '901 patent are invalid, unenforceable, and/or are not, and will not, be infringed by the commercial manufacture, use or sale of Liquidia's Proposed Generic Product. That statement did not include anything beyond conclusory statements as to why the claims of the '066 patent and the '901 patent were allegedly invalid. The statement also did not include anything beyond conclusory statements regarding alleged non-infringement.

22. Upon information and belief, Liquidia submitted Liquidia's 505(b)(2) Application to FDA seeking approval to commercially manufacture, market, use, and sell generic copies of UTC's TYVASO® (treprostinil) Inhalation Solution, 0.6 mg/mL prior to the expiration of the '066 patent and the '901 patent.

23. UTC commenced this action before the expiration of forty-five days from the date it received Liquidia's Notice Letter.

24. Upon information and belief, Liquidia's Proposed Generic Product contains the same active compound, treprostinil, as UTC's approved TYVASO® product.

25. Upon information and belief, Liquidia's 505(b)(2) Application seeks approval from the FDA to market Liquidia's Proposed Generic Product for the same indication as UTC's approved TYVASO® product.

26. Upon information and belief, Liquidia's 505(b)(2) Application refers to and relies upon UTC's NDA No. 022387 for TYVASO® (treprostinil) Inhalation Solution, 0.6 mg/ml.

27. Upon information and belief, Liquidia intends to commercially manufacture, sell, offer for sale, and/or import Liquidia's Proposed Generic Product upon, or in anticipation of, FDA approval.

28. According to Liquidia's Notice Letter, Liquidia's 505(b)(2) Application contained a "Paragraph IV" certification pursuant to 21 U.S.C. § 355(b)(2)(A)(iv) stating that in Liquidia's opinion the '066 and the '901 patents are invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use or sale of Liquidia's Proposed Generic Product.

29. Upon information and belief, as of the date of Liquidia's Notice Letter, Liquidia was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(b)(3)(D)(ii) and 21 C.F.R. § 314.52(c)(6).

30. In Liquidia's Notice Letter, Liquidia offered confidential access to certain information regarding Liquidia's 505(b)(2) Application on the terms and conditions set forth in that letter ("Liquidia's Offer of Confidential Access"). Liquidia requested that UTC accept Liquidia's Offer of Confidential Access before receiving access to information regarding Liquidia's 505(b)(2) Application. Liquidia's Offer of Confidential Access contained sweeping, unreasonable restrictions that differ materially from restrictions found under protective orders.

For example, Liquidia's Offer of Confidential Access required that UTC's outside counsel "do not engage, either formally or informally, in any patent prosecution for UTC and/or are involved in the subject matter related to treprostinil, and/or provide any FDA counseling, litigation or other work before or involving FDA."

31. Under 21 U.S.C. § 355(c)(3)(D)(i)(III), an "offer of confidential access shall contain such restrictions . . . on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information."

32. UTC attempted to negotiate with Liquidia to obtain relevant information from Liquidia's 505(b)(2) Application under restrictions "as would apply had a protective order been issued." Those negotiations were unsuccessful. For example, Liquidia continued to insist that attorneys representing UTC and in-house counsel and the staff of such counsel agree not to be engaged in the drafting of submissions related to compositions, treatment methods, or formulations containing treprostinil to the FDA or to provide any FDA counseling related to such matters, though such restrictions have not been present in any prior protective order relating to any other UTC treprostinil-containing product, such as REMODULIN® (treprostinil) Injection. *See United Therapeutics Corp. v. Sandoz, Inc.*, 3:12-cv-01617-PGS-LHG, Protective Order, Docket No. 32 (D.N.J. Sept. 12, 2012); *United Therapeutics Corp. v. Teva Pharmaceuticals USA, Inc.*, 3:14-cv-05498-PGS-LHG, Protective Order, Docket No. 24, Discovery Confidentiality Order (D.N.J. Nov. 25, 2014); *United Therapeutics Corp. v. Sandoz, Inc.*, 3:14-cv-05499-PGS-LHG, Stipulated Protective Order and Cross Use Agreement (D.N.J. Jan. 15, 2015.). UTC objected to this provision of Liquidia's Offer of Confidential Access as unreasonable and in violation of 21 U.S.C. § 355(j)(5)(C)(i)(III).

33. UTC is not aware of any other means of obtaining information regarding Liquidia's Proposed Generic Product within the 45-day statutory period. Without such information, UTC will use the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, such information as is required to confirm its allegations of infringement and to present to the Court evidence that Liquidia's Proposed Generic Product falls within the scope of one or more claims of the '066 and '901 patents.

34. Upon information and belief, Liquidia's Proposed Generic Product is intended to deliver treprostinil through a DPI utilizing capsules in amounts from 26.5-106 mcgs of treprostinil, and doses from 26.5-212 mcgs of treprostinil. Upon information and belief, the contents of each capsule of Liquidia's Proposed Generic Product "can be inhaled in 1-2 breaths."

COUNT 1: INFRINGEMENT OF THE '066 PATENT
UNDER 35 U.S.C. § 271(e)

35. UTC repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

36. Upon information and belief, Liquidia's Proposed Generic Product or an intermediate in its manufacture is covered by one or more claims of the '066 patent.

37. Liquidia had knowledge of the '066 patent when it submitted Liquidia's 505(b)(2) Application.

38. Liquidia's submission of Liquidia's 505(b)(2) Application for the purpose of obtaining approval to engage in the commercial manufacture, use and/or sale of Liquidia's Proposed Generic Product was an act of infringement of the '066 patent under 35 U.S.C. § 271(e)(2).

39. Upon information and belief, the commercial manufacture, use, offer for sale, sale and/or importation of Liquidia's Proposed Generic Product would infringe one or more claims of the '066 patent.

40. Upon information and belief, Liquidia was and is aware of the existence of the '066 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '066 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

41. UTC will be substantially and irreparably damaged and harmed if Liquidia's infringement of the '066 patent is not enjoined by this Court. UTC does not have an adequate remedy at law.

COUNT 2: INFRINGEMENT OF THE '066 PATENT
UNDER 35 U.S.C. §§ 271(a)-(c) and (g)

42. UTC repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

43. Upon information and belief, upon FDA approval of Liquidia's 505(b)(2) Application, Liquidia will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Liquidia's Proposed Generic Product which will result in infringement of one or more claims of the '066 patent.

44. Liquidia's 505(b)(2) Application and Liquidia's intention to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Liquidia's Proposed Generic Product upon receiving FDA approval prior to the expiration of the '066 patent creates an actual and justiciable controversy with respect to infringement of the '066 patent.

45. Upon information and belief, upon FDA's approval of Liquidia's 505(b)(2) Application, Liquidia's commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Liquidia's Proposed Generic Product will directly infringe one or more

claims of the '066 patent, and will indirectly infringe by actively inducing infringement by others, under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), 35 U.S.C. § 271(c), and/or 35 U.S.C. § 271(g).

46. Upon information and belief, Liquidia's Proposed Generic Product or an intermediate in its manufacture as described in and/or directed by Liquidia's proposed labeling, Liquidia's 505(b)(2) Application, applicable drug master file ("DMF"), and/or other corporate documents for Liquidia's Proposed Generic Product would infringe one or more claims of the '066 patent.

47. Upon information and belief, Liquidia will induce others to infringe one or more claims of the '066 patent under 35 U.S.C. § 271(b) by, among other things, actively and knowingly aiding and abetting others to infringe, including, but not limited to the manufacturer of Liquidia's Proposed Generic Product, or its API, or other subsequent purchasers, distributors, or users thereof, which product or its manufacture constitutes direct infringement of one or more claims of the '066 patent. Upon information and belief, Liquidia's aiding and abetting includes Liquidia's engagement of, contracting of, and/or encouragement of others to engage in the manufacture, use, sale, or importation of infringing products pursuant to Liquidia's 505(b)(2) Application.

48. Upon information and belief, Liquidia will also contributorily infringe one or more claims of the '066 patent under 35 U.S.C. § 271(c) in that Liquidia will make, use, sell, offer to sell, and/or import Liquidia's Proposed Generic Product and/or the API thereof, which Liquidia knows has no substantial non-infringing uses. Upon information and belief, subsequent purchasers, distributors, or users thereof will also directly infringe one or more claims of the '066 patent.

49. Upon information and belief, Liquidia will also infringe one or more claims of the '066 patent under 35 U.S.C. § 271(g) by importing, selling, offering to sell or using Liquidia's Proposed Generic Product or the API or an intermediate thereof which is neither materially changed by subsequent process nor a trivial or non-essential component of another product.

50. Upon information and belief, Liquidia was and is aware of the existence of the '066 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '066 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

51. UTC will be substantially and irreparably damaged and harmed if Liquidia's infringement of the '066 patent is not enjoined by this Court. UTC does not have an adequate remedy at law.

COUNT 3: INFRINGEMENT OF THE '901 PATENT
UNDER 35 U.S.C. § 271(e)

52. UTC repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

53. Upon information and belief, Liquidia's Proposed Generic Product or an intermediate in its manufacture is covered by one or more claims of the '901 patent.

54. Liquidia had knowledge of the '901 patent when it submitted Liquidia's 505(b)(2) Application.

55. Liquidia's submission of Liquidia's 505(b)(2) Application for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, and/or offer for sale of Liquidia's Proposed Generic Product was an act of infringement of the '901 patent under 35 U.S.C. § 271(e)(2).

56. Upon information and belief, the commercial manufacture, use, offer for sale, sale and/or importation of Liquidia's Proposed Generic Product would infringe one or more claims of the '901 patent.

57. Upon information and belief, Liquidia was and is aware of the existence of the '901 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '901 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

58. UTC will be substantially and irreparably damaged and harmed if Liquidia's infringement of the '901 patent is not enjoined by this Court. UTC does not have an adequate remedy at law.

COUNT 4: INFRINGEMENT OF THE '901 PATENT
UNDER 35 U.S.C. §§ 271(a)-(c) and (g)

59. UTC repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

60. Upon information and belief, upon FDA approval, Liquidia will manufacture, market, sell, offer to sell, import, and distribute Liquidia's Proposed Generic Product which will result in infringement of one or more claims of the '901 patent.

61. Liquidia's 505(b)(2) Application and Liquidia's intention to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Liquidia's Proposed Generic Product upon receiving FDA approval of Liquidia's 505(b)(2) Application prior to the expiration of the '901 patent creates an actual and justiciable controversy with respect to infringement of the '901 patent.

62. Upon information and belief, upon FDA's approval of Liquidia's 505(b)(2) Application, Liquidia's commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Liquidia's Proposed Generic Product will directly infringe one or more

claims of the '901 patent, and will indirectly infringe by actively inducing infringement by others, under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), 35 U.S.C. § 271(c), and/or 35 U.S.C. § 271(g).

63. Upon information and belief, Liquidia's Proposed Generic Product or an intermediate in its manufacture as described in and/or directed by Liquidia's proposed labeling, Liquidia's 505(b)(2) Application, applicable DMF, and/or other corporate documents for Liquidia's Proposed Generic Product would infringe one or more claims of the '901 patent.

64. Upon information and belief, Liquidia will induce others to infringe one or more claims of the '901 patent under 35 U.S.C. § 271(b) by, among other things, actively and knowingly aiding and abetting others to infringe, including, but not limited to the manufacturer of Liquidia's Proposed Generic Product, or its API, or other subsequent purchasers, distributors, or users thereof, which product or its manufacture constitutes direct infringement of one or more claims of the '901 patent. Upon information and belief, Liquidia's aiding and abetting includes Liquidia's engagement of, contracting of, and/or encouragement of others to engage in the manufacture, use, sale, or importation of infringing products pursuant to Liquidia's 505(b)(2) Application.

65. Upon information and belief, Liquidia will also contributorily infringe one or more claims of the '901 patent under 35 U.S.C. § 271(c) in that Liquidia will make, use, sell, offer to sell, and/or import Liquidia's Proposed Generic Product and/or the API thereof, which Liquidia knows has no substantial non-infringing uses. Upon information and belief, subsequent purchasers, distributors, or users thereof will also directly infringe one or more claims of the '901 patent.

66. Upon information and belief, Liquidia will also infringe one or more claims of the '901 patent under 35 U.S.C. § 271(g) by importing, selling, offering to sell or using Liquidia's Proposed Generic Product or the API or an intermediate thereof which is neither materially changed by subsequent process nor a trivial or non-essential component of another product.

67. Upon information and belief, Liquidia was and is aware of the existence of the '901 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '901 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

68. UTC will be substantially and irreparably damaged and harmed if Liquidia's infringement of the '901 patent is not enjoined by this Court. UTC does not have an adequate remedy at law.

COUNT 5: INFRINGEMENT OF THE '793 PATENT
UNDER 35 U.S.C. § 271(e)

69. UTC repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

70. Upon information and belief, Liquidia's Proposed Generic Product is covered by one or more claims of the '793 patent.

71. Liquidia's maintenance of Liquidia's 505(b)(2) Application for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, and/or offer for sale of Liquidia's Proposed Generic Product is an act of infringement of the '793 patent under 35 U.S.C. § 271(e)(2).

72. Upon information and belief, the commercial manufacture, use, offer for sale, sale and/or importation of Liquidia's Proposed Generic Product would infringe one or more claims of the '793 patent.

73. Upon information and belief, Liquidia was and is aware of the existence of the '793 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '793 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

74. UTC will be substantially and irreparably damaged and harmed if Liquidia's infringement of the '793 patent is not enjoined by this Court. UTC does not have an adequate remedy at law.

COUNT 6: INFRINGEMENT OF THE '793 PATENT
UNDER 35 U.S.C. §§ 271(a)-(c)

75. UTC repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

76. Upon information and belief, upon FDA approval, Liquidia will manufacture, market, sell, offer to sell, import, and distribute Liquidia's Proposed Generic Product which will result in infringement of one or more claims of the '793 patent.

77. Liquidia's 505(b)(2) Application and Liquidia's intention to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Liquidia's Proposed Generic Product upon receiving FDA approval of Liquidia's 505(b)(2) Application prior to the expiration of the '793 patent creates an actual and justiciable controversy with respect to infringement of the '793 patent.

78. Upon information and belief, upon FDA's approval of Liquidia's 505(b)(2) Application, Liquidia's commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Liquidia's Proposed Generic Product will directly infringe one or more claims of the '793 patent, and will indirectly infringe by actively inducing infringement by others, under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

79. Upon information and belief, Liquidia's Proposed Generic Product or an intermediate in its manufacture as described in and/or directed by Liquidia's proposed labeling, Liquidia's 505(b)(2) Application, applicable DMF, and/or other corporate documents for Liquidia's Proposed Generic Product would infringe one or more claims of the '793 patent.

80. Upon information and belief, Liquidia will induce others to infringe one or more claims of the '793 patent under 35 U.S.C. § 271(b) by, among other things, actively and knowingly aiding and abetting others to infringe, including, but not limited to the manufacturer of Liquidia's Proposed Generic Product, or its API, or other subsequent purchasers, distributors, or users thereof, which product or its manufacture constitutes direct infringement of one or more claims of the '793 patent. Upon information and belief, Liquidia's aiding and abetting includes Liquidia's engagement of, contracting of, and/or encouragement of others to engage in the manufacture, use, sale, or importation of infringing products pursuant to Liquidia's 505(b)(2) Application.

81. Upon information and belief, Liquidia will also contributorily infringe one or more claims of the '793 patent under 35 U.S.C. § 271(c) in that Liquidia will make, use, sell, offer to sell, and/or import Liquidia's Proposed Generic Product and/or the API thereof, which Liquidia knows has no substantial non-infringing uses. Upon information and belief, subsequent purchasers, distributors, or users thereof will also directly infringe one or more claims of the '793 patent.

82. Upon information and belief, Liquidia was and is aware of the existence of the '793 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '793 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

83. UTC will be substantially and irreparably damaged and harmed if Liquidia's infringement of the '793 patent is not enjoined by this Court. UTC does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, UTC requests the following relief:

1. A judgment that:

A. Liquidia has infringed the '066 patent, the '901 patent, and the '793 patent; and

B. declaring that making, using, selling, offering for sale, or importing into the United States of Liquidia's Proposed Generic Product, or any product or compound that infringes one or more of the '066 patent, the '901 patent, and the '793 patent, prior to the expiration dates of the respective patents, will infringe, actively induce infringement of, and contribute to the infringement by others of the '066 patent, the '901 patent, and the '793 patent;

2. A judgment ordering that the effective date of any FDA approval of Liquidia's NDA No. 213005 permitting Liquidia to commercially manufacture, make, use, offer to sell, sell, market, or import into the United States Liquidia's Proposed Generic Product be not earlier than the latest of the expiration dates of the '066 patent, the '901 patent, and the '793 patent, inclusive of any extension(s) and additional period(s) of exclusivity to which UTC is or may become entitled;

3. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Liquidia, its officer, agents, servants, employees, parents, subsidiaries, affiliate

corporations, other business entities and all other persons acting in concert, participation, or privity with them, their successors, and assigns, from infringing, contributorily infringing, or inducing others to infringe the ’066 patent, the ’901 patent, and the ’793 patent, including engaging in the commercial manufacture, use, sale, offer to sale and/or importation in the United States of the product that is the subject of Liquidia’s 505(b)(2) Application and/or any applicable DMF until the expiration of the ’066 patent, the ’901 patent, and the ’793 patent, inclusive of any extension(s) and additional period(s) of exclusivity to which UTC is or may become entitled;

4. A judgment awarding UTC damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(c) and 284, if Liquidia engages in commercial manufacture, use, sale, offer to sell and/or importation into the United States of any product that is the subject of Liquidia’s 505(b)(2) Application that infringes one or more claims of the ’066 patent, the ’901 patent, and the ’793 patent;

5. A judgment declaring that, pursuant to 35 U.S.C. § 285, this is an exceptional case and awarding UTC its attorney’s fees;

6. An award of costs and expenses in this action to UTC; and

7. Such further and other relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

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July 22, 2020

CERTIFICATE OF SERVICE

I hereby certify that on July 22, 2020, 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 July 22, 2020, upon the following in the manner indicated:

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