IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AUROMEDICS PHARMA LLC, and SCIDOSE LLC, Plaintiffs, v. INGENUS PHARMACEUTICALS, LLC, Defendant.	C.A. No. _____ **DEMAND FOR JURY TRIAL**

COMPLAINT

Plaintiffs AuroMedics Pharma LLC ("AuroMedics") and SciDose LLC ("SciDose") (together "Plaintiffs") for their Complaint against Ingenus Pharmaceuticals, LLC ("Ingenus" or "Defendant"), herein allege as follows:

NATURE OF ACTION

1. This is a civil action for patent infringement, trade secret misappropriation, and unjust enrichment. In this Complaint, Plaintiff SciDose alleges that Defendant has misappropriated SciDose's trade secrets relating to SciDose's development of novel stable liquid cyclophosphamide formulations to improve chemotherapy for cancer patients. SciDose's trade secrets were the product of substantial investment and were treated confidentially by SciDose and Defendant at the time they were disclosed. The trade secrets were of considerable value to Defendant in Defendant's efforts to develop and obtain regulatory approval for a liquid cyclophosphamide product that will compete directly with Plaintiffs' cyclophosphamide product following FDA approval.

2. This patent infringement action arises under the Patent Laws of the United States, Title 35, United States Code.

3. This trade secret action arises under the Delaware Uniform Trade Secrets Act ("DUTSA"), 6 *Del. C.* § 2001, *et seq*.

PARTIES

4. Plaintiff AuroMedics is a limited liability company formed under the laws of the State of Delaware, and its principal place of business is located at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520.

5. Plaintiff SciDose is a limited liability company formed under the laws of the State of Delaware, and its principal place of business is located at 6 University Drive, Amherst, Massachusetts 01002.

6. On information and belief, Defendant Ingenus is a limited liability company formed under the laws of the State of Delaware, and its principal place of business is located at 4190 Millenia Boulevard, Orlando, Florida 32839.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1367, 1338(a), 2201, and 2202.

8. This Court has personal jurisdiction over Ingenus. On information and belief, Ingenus is formed under the laws of the State of Delaware. On information and belief, Ingenus maintains a registered agent for service of process at 1209 Orange Street, Wilmington, Delaware 19801.

9. Venue is proper in this District under 28 U.S.C. §§ 1391(a)-(c) and 1400(b). On information and belief, Ingenus is formed under the laws of the State of Delaware and therefore resides in this District.

THE PATENT-IN-SUIT

10. United States Patent No. 9,662,342 ("the '342 patent"), titled "Formulations of Cyclophosphamide Liquid Concentrate," was duly and legally issued by the United States Patent and Trademark Office ("PTO") on May 30, 2017 to AuroMedics. Plaintiffs own and have exclusive rights to the '342 patent, including the rights to sue for infringement thereof.

11. A true and correct copy of the '342 patent is attached hereto as Exhibit A.

12. The '342 patent is directed to improved cyclophosphamide formulations. Cyclophosphamide is a widely used antineoplastic drug that has been commercially available since the 1960s in a sterile dry mixture of cyclophosphamide monohydrate. For decades, parenteral dosage formulations of cyclophosphamide consisted of sterile packaged dry powder fill of cyclophosphamide monohydrate, which must be dissolved in water or normal saline prior to administration. The sterile dry powder can require as long as 30-minute constitution time, and the prepared solution must be administered promptly or within several hours after preparation. Moreover, the dry powder formulation can deteriorate during processing and/or storage, acquiring a glassy and/or sticky nature, leading to prolonged dissolution times and decreased potency. Unlike the prior dry powder cyclophosphamide products, the inventive liquid cyclophosphamide-containing compositions of the '342 patent do not require prolonged constitution time, and can be diluted directly in a vial or into an infusion bag.

13. The ’342 patent describes inventive liquid cyclophosphamide-containing compositions. For example, the claims of the ’342 patent are directed to cyclophosphamide-containing compositions comprising cyclophosphamide, ethanol, and an ethanol soluble acidifying agent. The compositions may also include an anti-oxidizing agent. The inventive liquid cyclophosphamide-containing compositions of the ’342 patent have improved solubility characteristics and enhanced appearance, while maintaining a potency appropriate for pharmaceutical dosage forms. The inventive cyclophosphamide-containing compositions also have extended stability.

DEFENDANT’S INFRINGING NDA PRODUCT

14. On information and belief, Defendant submitted New Drug Application No. 21-2501 (“Defendant’s NDA”) to the FDA, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(b)), seeking approval to engage in the commercial manufacture, use, sale or offer for sale, and/or importation of cyclophosphamide injection 200 mg/mL (500 mg/2.5 mL and 1 g/5 mL) in a multiple-dose vial (“Defendant’s NDA Product”), prior to the expiration of the ’342 patent.

15. On information and belief, Defendant’s NDA received FDA approval on July 30, 2020. A true and correct copy of the approved label for Defendant’s NDA Product (Defendant’s Label”), downloaded from https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/212501s000lbl.pdf, is attached hereto as Exhibit B.

16. Defendant’s Label states that Defendant’s NDA Product is a 200 mg/mL sterile clear colorless solution available as 500 mg and 1 g strength vials. *See, e.g.*, Ex. B at § 11.

17. Defendant's Label states that Defendant's NDA Product is available in the following presentations: 500 mg/2.5 mL and 1 g/5 mL. *See, e.g.*, Ex. B at § 3.

18. Defendant's Label states that the 500 mg vial contains 534.5 mg cyclophosphamide monohydrate equivalent to 500 mg cyclophosphamide, 1.55 g Ethanol, 0.085 g Propylene Glycol, 0.085 g Polyethylene glycol 400 and 0.345 mg Monothioglycerol. *See, e.g.*, Ex. B at § 11.

19. Defendant's Label states that the 1 g vial contains 1069.0 mg cyclophosphamide monohydrate equivalent to 1 g cyclophosphamide, 3.1 g Ethanol, 0.17 g Propylene Glycol, 0.17 g Polyethylene glycol 400 and 0.69 mg Monothioglycerol. *See, e.g.*, Ex. B at § 11.

20. On information and belief, Defendant has been, is, and/or will imminently be involved, directly and/or indirectly, in the manufacture, use, sale, offer for sale, and/or importation of Defendant's NDA Product, without authorization from Plaintiffs.

21. Defendant's NDA Product has NDC Number 50742-519-02 for the 500 mg/2.5 mL strength and NDC Number 50742-520-05 for the 1 g/5 mL strength. *See, e.g.*, Ex. B at § 16. Defendant's website lists Defendant's NDA Product with the same NDC/SKU numbers. *See* https://www.ingenus.com/cyclophosphamide-injection/ (last visited September 15, 2020). Defendant's website also lists wholesale numbers 051902 (ABC), 5660816 (Cardinal), 1559921 (McKesson) for the 500 mg/2.5 mL strength and wholesale numbers 052005 (ABC), 5660808 (Cardinal), and 1559954 (McKesson) for the 1 g/5 mL strength. *See id.*

DEFENDANT'S INFRINGEMENT OF THE '342 PATENT

22. Plaintiffs reallege and incorporate each of the preceding paragraphs as if fully set forth herein.

23. Each claim element of at least one claim of the ’342 patent, including at a minimum claim 1, is literally present in Defendant’s NDA Product or such element is present under the doctrine of equivalents.

24. The allegations provided below are exemplary and without prejudice to Plaintiffs’ infringement contentions that will be provided pursuant to the Court’s scheduling order and local civil rules, including after discovery as provided under the Federal Rules of Civil Procedure. In providing these allegations, Plaintiffs do not convey or imply any particular claim constructions or the precise scope of the claims of the ’342 patent. Plaintiffs’ proposed claim constructions will be provided pursuant to the Court’s scheduling order and local civil rules.

25. On information and belief, Defendant’s NDA Product is a cyclophosphamide containing, substantially non-aqueous liquid composition having extended stability. *See, e.g.*, Ex. B at § 11, 16.

26. On information and belief, Defendant’s NDA Product contains about 100 to about 600 mg/ml of cyclophosphamide. *See, e.g.*, Ex. B. at § 11.

27. On information and belief, Defendant’s NDA Product contains an ethanolic solvent system consisting of ethanol. On information and belief, at least ethanol in Defendant’s NDA Product is an ethanolic solvent system consisting of ethanol. *See, e.g.*, Ex. B at § 11.

28. On information and belief, Defendant’s NDA Product contains an ethanol soluble acidifying agent. On information and belief, one or more ingredients in Defendant’s NDA Product, including at least Polyethylene glycol 400 and/or monothioglycerol, constitutes an ethanol soluble acidifying agent. *See, e.g.*, Ex. B at § 11.

29. On information and belief, Defendant's NDA Product contains the cyclophosphamide and the ethanol soluble acidifying agent solubilized in the ethanol, and cyclophosphamide is the only pharmaceutically active ingredient. *See, e.g.*, Ex. B at § 11.

30. Further, Defendant's NDA Product meets each and every limitation of additional claims of the '342 patent, including but not limited to claims 11-13, either literally and/or under the doctrine of equivalents. On information and belief, Defendant's NDA Product contains an anti-oxidizing agent. On information and belief, at least monothioglycerol in Defendant's NDA Product is an anti-oxidizing agent.

31. Thus, Defendant's manufacture, use, offer to sell, or sale of Defendant's NDA Product in the United States, and/or import of Defendant's NDA Product into the United States without authority, infringes one or more claims of the '342 patent, including but not limited to claims 1 and 11-13, literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a).

DEFENDANT'S MISAPPROPRIATION OF PLAINTIFF SCIDOSE'S TRADE SECRETS

32. Plaintiffs reallege and incorporate each of the preceding paragraphs as if fully set forth herein.

33. In March 2012, SciDose and Defendant began collaborating to develop a lyophilized (powdered) injectable formulation of cyclophosphamide. Pursuant to the collaboration effort, SciDose was to provide formulation and development of a lyophilized injectable cyclophosphamide product to Defendant, and Defendant was to prepare and submit a drug application with FDA for the product, and commercialize the product upon FDA approval.

34. In or around June to September 2012, Defendant communicated its view to SciDose that a lyophilized cyclophosphamide product may not be commercially viable. In response, SciDose confidentially disclosed to Defendant the idea for liquid cyclophosphamide formulations, which SciDose explained would have advantages over a lyophilized product.

35. SciDose confidentially disclosed to Defendant trade secrets and other proprietary or confidential information relating to SciDose's development of new liquid formulations of cyclophosphamide, including but not limited to formulations, method validation, testing protocols, and stability data. SciDose disclosed information in documents marked "Confidential," and SciDose instructed Defendant to treat the information as confidential.

36. SciDose took reasonable measures to protect and maintain the secrecy of its proprietary information, including, but not limited to, requiring confidentiality and/or nondisclosure agreements to be signed by any party granted access to SciDose's trade secrets.

37. SciDose required Defendant to maintain in confidence SciDose materials disclosed or provided to Defendant, including by entering into confidentiality agreements with Defendant. SciDose also required that Defendant not use or copy any of SciDose's confidential information, and that Defendant not use any of SciDose's confidential information in applying for patents or securing other intellectual property rights.

38. Defendant and SciDose agreed to jointly consider the feasibility of SciDose's new liquid cyclophosphamide formulations.

39. On information and belief, unbeknownst to SciDose, Defendant used and disclosed SciDose's trade secrets and proprietary and confidential information, to separately prepare and file an NDA with FDA for a liquid formulation of cyclophosphamide.

40. In or around January 2014, Defendant informed SciDose that it no longer wanted to develop a lyophilized or liquid cyclophosphamide product with SciDose, and sought to terminate the collaboration between the parties.

41. In or around January 2014, SciDose and Defendant terminated the agreement to collaborate, but SciDose and Defendant expressly provided that the confidentiality provisions remained in force.

42. On information and belief, Defendant continued to improperly use and disclose SciDose's trade secrets and confidential information to prepare and file an NDA with FDA for its liquid formulation of cyclophosphamide, and obtain FDA approval for Defendant's NDA Product.

43. On information and belief, by improperly using SciDose's confidential information, Defendant achieved unfair advantages, including at least substantially advancing the timeline for development of Defendant's NDA Product, filing of its NDA with FDA, and receipt of FDA approval in July 2020. On information and belief, by improperly using SciDose's confidential information, Defendant avoided substantial development costs, and significantly shortened its timeline for filing its NDA with FDA and obtaining FDA approval for Defendant's NDA Product.

44. On information and belief, Defendant also improperly used SciDose's confidential information in its involvement with efforts to apply for and/or seek patent protection for its liquid cyclophosphamide formulations.

45. SciDose was not aware that Defendant improperly used and disclosed its confidential trade secret information until July 2020, when Defendant received FDA approval for

Defendant's NDA Product, and the formulation of Defendant's NDA Product was published online at Drugs@FDA.gov. Ex. B.

COUNT ONE
Infringement of the '342 Patent

46. Plaintiffs reallege and incorporate each of the preceding paragraphs as if fully set forth herein.

47. On information and belief, Defendant has infringed, and is infringing, one or more claims of the '342 patent through its manufacture, use, offer to sell, or sale of Defendant's NDA Product in the United States and/or import of Defendant's NDA Product into the United States. Defendant is liable for infringement at least pursuant to 35 U.S.C. § 271(a).

48. On information and belief, Defendant was aware of the disclosures in the '342 patent since at least November 12, 2015, when the '342 patent was first published, and since at least May 30, 2017, when the '342 patent issued, while Defendant was developing Defendant's NDA Product.

49. On information and belief, Defendant is involved with prosecution of U.S. Patent Application No. 15/551,507 ("the '507 application"), entitled "Stable Ready to Use Cyclophosphamide Liquid Formulations," before the U.S. Patent and Trademark Office ("USPTO"). The Image File Wrapper of the '507 application is available from the USPTO website at https://portal.uspto.gov/pair/PublicPair (Application No. 15551507).

50. As described in detail below, the '507 applicants stated to the USPTO during prosecution that a formulation identical to Defendant's NDA Product is a formulation that falls within the pending claims of the '507 application.

51. On information and belief, on or around August 16, 2017, Defendant filed, caused, directed, or participated in filing and/or prosecution of the '507 application in the USPTO.

52. On March 5, 2018, the USPTO examiner of the '507 application rejected the pending claims as anticipated by and obvious over U.S. Patent Publication No. 2015/0320775 ("Palepu publication"), as well as other references. The Palepu publication is the prior publication of the '342 patent, which first published on November 12, 2015. The examiner stated that:

> [The Palepu publication] teaches [] a stable liquid parenteral formulation of cyclophosphamide comprising: (i) cyclophosphamide and (ii) a solvent which is ethanol, or propylene glycol, or polyethylene glycol, which satisfies the limitations of instant claim 1… Palepu teaches [] that the advantage of making a 500 mg/ml solution is that, when diluted to achieve the desired 20 mg/ml solution of cyclophosphamide suitable for intravenous administration, the organic solvent concentration in the mixture is less than 3%, which is a safe level to administer intravenously. Thus, Palepu teaches a stable formulation of cyclophosphamide in concentrated form, as a ready to dilute formulation, as in instant claim 12, as well as a ready to use formulation, as in instant claim 11.

3/5/2018 Non-Final Rejection at 7-8.

53. The examiner also stated that:

> [T]he formulations taught by Palepu that show absolutely no degradation after storage for 1 month at 25 ℃ (Table 6, citric acid 4 mg/ml or 6 mg/ml) anticipate or render obvious the formulation of instant claim 2. Further, the increased stability of cyclophosphamide in the liquid formulation is a property inherent to the composition disclosed by Palepu. "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 UPQ2d 1655, 1658 (Fed. Cir. 1990). *See* [MPEP] 2112.01.

Id. at 11-12.

54. The ’507 applicants tried to distinguish their pending claims over the Palepu publication, but on September 4, 2018, the examiner again rejected the pending claims of the ’507 application as anticipated by and obvious over the Palepu publication, as well as other references.

55. The ’507 applicants again tried to distinguish their pending claims over the Palepu publication, but on May 7, 2019, the examiner again rejected the pending claims of the ’507 application as anticipated by and obvious over the Palepu publication, as well as other references. The examiner reiterated that:

> Palepu teaches the very formulation of cyclophosphamide as instantly claimed, the property of such a claimed composition will also be anticipated/rendered obvious by the prior art teachings, since the properties are inseparable from its composition. Therefore, if the prior art teaches the composition or renders the composition obvious, then the properties are also taught or rendered obvious by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess or render obvious the same properties as the instantly claimed product.

5/7/2019 Office Action at 3.

56. The ’507 applicants again tried to distinguish their pending claims over the Palepu publication, alleging that “[e]vidence of the superior stability of the claimed formulations vs. exemplary embodiments of the cited art is provided in a Declarations [sic] under 37 CFR § 1.132 (hereinafter ‘Declarations’) filed with this response.” 10/7/2019 Response at 5.

57. The ’507 applicants submitted a “Declaration Under 37 CFR § 1.132” of Banda Nagaraju, a named inventor of the ’507 application, signed on October 1, 2019 (“Nagaraju Declaration”). The declaration states that the “following formulation(s) within the ranges set forth in claim 1 have been made and tested as described below.”

Invention formulation: The invention formulation is prepared in accordance with the procedures described in the instant application with the composition listed in table 1 (below). The formulation has cyclophosphamide, ethanol, polyethylene glycol-400, propylene glycol and monothioglycerol.

Table 1: Composition details

S. No	Ref batch number: 195		
	Ingredients	Qty(mg) /mL	%(w/w)
1	Cyclophosphamide	200.000	22.3
2	Absolute Ethanol	620.000	69.2
3	PEG-400	34	3.8
4	Propylene glycol	34	3.8
5	Mono thoiglycerol	0.138	0.015

Nagaraju Declaration ¶ 9. The "Invention formulation" described in paragraph 9 of the Nagaraju Declaration is the formulation of Defendant's NDA Product. *See* Ex. B at § 11. Both the 500 mg and 1 g strength vials of Defendant's NDA Product are equivalent to 200 mg/mL cyclophosphamide, 620 mg/mL ethanol, 34 mg/mL propylene glycol, 34 mg/mL polyethylene glycol 400 (PEG-400) and 0.14 mg/mL mono thioglycerol, as stated in the Nagaraju Declaration. The Nagaraju Declaration also reports results of stability tests of certain compositions.

58. The '507 applicants submitted a second "Declaration Under 37 CFR § 1.132" of Kocherlakota Chandrashekhar, the other named inventor of the '507 application, signed on October 1, 2019 ("Chandrashekhar Declaration"). The substance of the Chandrashekhar Declaration is the same as the Nagaraju Declaration and contains the same "Invention formulation" identical to Defendant's NDA Product. Chandrashekhar Declaration ¶ 9.

59. On December 31, 2019, the examiner again rejected the pending claims of the '507 application as obvious over the Palepu publication, as well as other references. The

examiner stated that the Nagaraju Declaration "seems to compare the stability of certain compositions taught by [the Palepu publication and other references] and the stability of a formulation of the invention (not disclosed in the original Specification)," *i.e.*, the formulation of Defendant's NDA Product, but that "it is unclear what is being compared and why." 12/31/2019 Final Rejection at 2. The examiner again noted that "Palepu teaches stable liquid parenteral formulations of the very same drug, cyclophosphamide, in the very same solvents, namely ethanol and propylene glycol, as instantly claimed." *Id*. at 13. On April 7, 2020, the '507 applicants initiated an interview with the examiner, and the examiner maintained that the prior art teaches the claimed liquid formulations of cyclophosphamide with ethanol, polyethylene glycol and propylene glycol. 4/7/2020 Interview Summary.

60. To date, the '507 application still has not been allowed or issued by the USPTO.

61. On information and belief, Defendant therefore had knowledge of the disclosures of the '342 patent at least since November 2015 and/or May 2017, during development of Defendant's NDA Product, and during prosecution of the '507 application. On information and belief, Defendant knew that its conduct constituted infringement of the '342 patent without a good faith belief that the '342 patent is invalid or not infringed. On information and belief, despite this knowledge, Defendant deliberately and intentionally proceeded to obtain FDA approval and sell its infringing NDA product without authorization from Plaintiffs.

62. Plaintiffs have suffered and will suffer damages as a direct and proximate result of Defendant's willful infringement of the '342 patent. Thus, Plaintiffs are entitled to recover damages for such willful infringement pursuant to 35 U.S.C. § 284 in an amount to be proven at trial.

63. Plaintiffs will be irreparably harmed by Defendant's infringing activities unless they are enjoined by this Court. Plaintiffs have no adequate remedy at law.

64. This case is exceptional and Plaintiffs are entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT TWO
Declaratory Judgment of Infringement of the '342 Patent

65. Plaintiffs reallege and incorporate each of the preceding paragraphs as if fully set forth herein.

66. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

67. On information and belief, Defendant will imminently infringe one or more claims of the '342 patent through its manufacture, use, offer to sell, or sale of Defendant's NDA Product in the United States and/or import of Defendant's NDA Product into the United States. Such conduct will infringe one or more claims of the '342 patent at least pursuant to 35 U.S.C. § 271(a).

68. As a result of the foregoing facts, there is an actual case or controversy between Plaintiffs and Defendant regarding whether Defendant's manufacture, use, offer to sell, or sale of Defendant's NDA Product in the United States will directly infringe one or more claims of the '342 patent.

69. Plaintiffs are entitled to a declaratory judgment that Defendant's manufacture, use, offer to sell, or sale of Defendant's NDA Product in the United States before expiration of the '342 patent constitutes infringement under 35 U.S.C. § 271(a).

70. Plaintiffs will be irreparably harmed by Defendant's infringing activities unless they are enjoined by this Court. Plaintiffs have no adequate remedy at law.

71. This case is exceptional and Plaintiffs are entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT THREE
Violation of the Delaware Uniform Trade Secrets Act (6 *Del. C.* §§ 2201, *et seq*.)

72. Plaintiffs reallege and incorporate each of the preceding paragraphs as if fully set forth herein.

73. SciDose is the owner of trade secrets and other proprietary or confidential information relating to stable liquid formulations of cyclophosphamide, which accordingly constitute "trade secrets" under DUTSA, 6 *Del. C*. §§ 2201, *et seq*. This information was not generally known to the public and SciDose derived independent economic value from such information not being known to the general public or to the relevant industry.

74. On information and belief, Defendant misappropriated SciDose's trade secrets by improper means and without authorization, including by using and disclosing SciDose's trade secrets without SciDose's express or implied consent in the preparation for obtaining FDA approval of a competing cyclophosphamide drug product.

75. SciDose took reasonable measures to protect and maintain the secrecy of its proprietary information, including, but not limited to, requiring confidentiality and/or nondisclosure agreements to be signed by any party granted access to SciDose's trade secrets.

76. SciDose entered into confidentiality agreements with Defendant before disclosing SciDose's trade secrets to Defendant.

77. Defendant agreed not to use or disclose SciDose's proprietary information on liquid formulations of cyclophosphamide, which includes trade secrets.

78. SciDose expended significant resources to develop its trade secrets for a liquid formulation of cyclophosphamide. SciDose's trade secrets derived independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, another person who can obtain economic value from the disclosure or use of the information.

79. SciDose's trade secrets were highly valuable to SciDose and to any other person or entity that wanted to enter the market for liquid formulations of cyclophosphamide, and conferred a competitive advantage to SciDose over others in the relevant market.

80. Other than through Defendant's improper use and disclosure of SciDose's trade secrets, the trade secrets were not known to others and were not readily ascertainable by proper means to persons who could derive value from their disclosure or use.

81. On information and belief, Defendant knew, or had reason to know, that it had acquired and/or possessed trade secrets from SciDose through improper means, and used and disclosed SciDose's trade secrets, in direct violation of its confidentiality obligations to SciDose, to develop its own competing liquid formulation of cyclophosphamide.

82. On information and belief, by receiving, improperly using, and further disclosing SciDose's trade secrets, Defendant misappropriated SciDose's trade secrets in violation of DUTSA, 6 *Del. C*. §§ 2201, *et seq*.

83. As a direct and proximate result of Defendant's misappropriation of SciDose's trade secrets, SciDose has suffered and will continue to suffer irreparable harm and other

damages. SciDose is therefore entitled to injunctive relief, monetary damages for its actual losses, and monetary damages for unjust enrichment where damages for its actual losses are not adequately addressed.

84. On information and belief, the misappropriation was willful and malicious, and SciDose is accordingly entitled to exemplary damages, pursuant to DUTSA, 6 *Del. C*. §§ 2201, *et seq*.

85. SciDose is also entitled to an award of attorneys' fees, pursuant to DUTSA, 6 *Del. C*. §§ 2204, *et seq*.

COUNT FOUR
Unjust Enrichment

86. Plaintiffs reallege and incorporate each of the preceding paragraphs as if fully set forth herein.

87. On information and belief, Defendant wrongfully used SciDose's confidential and proprietary information to unlawfully compete with Plaintiffs, by obtaining a head start and/or other unfair advantages on developing and obtaining FDA approval for Defendant's own liquid cyclophosphamide product.

88. On information and belief, Defendant used SciDose's valuable confidential and proprietary information for its own financial benefit, including but not limited to commercializing a competing liquid cyclophosphamide product based on misappropriated SciDose confidential and proprietary information.

89. SciDose was not reimbursed for the value of the scientific and technological knowledge in the confidential and proprietary information wrongly used by Defendant.

Defendant was unjustly enriched by using this information and using it to substantially advance the timeline for development of Defendant's NDA Product, filing of its NDA with FDA, and receipt of FDA approval, without providing any consideration or value in return to SciDose for said information.

90. SciDose has no adequate remedy at law for the injuries suffered. SciDose is entitled to equitable relief against Defendant as alleged herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that Defendant has infringed and is infringing the '342 patent;

B. A declaratory judgment that Defendant's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Defendant's NDA Product would infringe the '342 patent;

C. An order enjoining Defendant, its officers, agents, employees, attorneys, and all other persons or entities acting in concert, participation or in privity with one or more of them, and their successors and assigns, from infringing the '342 patent;

D. A permanent injunction restraining and enjoining Defendant, its officers, agents, employees, attorneys, and all other persons or entities acting in concert, participation or in privity with one or more of them, and their successors and assigns, from engaging in the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Defendant's NDA Product, until the expiration of the '342 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

E. A declaration or order that Defendant's infringement is willful and/or an order increasing damages under 35 U.S.C. § 284;

F. An entry of judgment declaring that this is an exceptional case and judgment awarding Plaintiffs reasonable attorneys' fees and their costs and reimbursements in this action, as provided by 35 U.S.C. § 285;

G. An entry of judgment that Defendant has misappropriated Plaintiffs' trade secrets within the meaning of the Delaware Uniform Trade Secrets Act ("DUTSA");

H. Injunctive relief, monetary damages for actual loss, monetary damages for unjust enrichment, disgorgement of Defendant's profits unjustly obtained, reasonable royalties, exemplary damages, and attorneys' fees for misappropriation of Plaintiff SciDose's trade secrets;

I. A judgment awarding Plaintiffs damages, in an amount to be determined at trial, together with prejudgment and post-judgment interest and costs as fixed by the Court;

J. Any and all other and further relief as the Court deems just and proper.

JURY DEMAND

Plaintiffs demand a trial by jury on all issues so triable in this Complaint.

Dated: September 16, 2020

/s/ Steven J. Fineman

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