

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK**

ALTAIRE PHARMACEUTICALS, INC., and)	
ASSAD SAWAYA,)	
)	
Plaintiffs,)	
)	
v.)	
)	Case No.
PARAGON BIOTECK, INC.,)	
)	
Defendant.)	
)	

COMPLAINT AND JURY DEMAND

Plaintiffs Altaire Pharmaceuticals, Inc. (“Altaire”) and Assad Sawaya (collectively, “Plaintiffs”), by and through their attorneys, bring this action against Defendant Paragon BioTeck, Inc. (“Paragon”), for a declaration of invalidity of U.S. Patent No. 8,859,623 (“the ’623 patent”) under 35 U.S.C. § 101 for failure to name an inventor (Count I); a declaration of invalidity of the ’623 patent under 35 U.S.C. § 102 and/or § 103 because the claimed invention was described in a printed publication, in public use, or on sale before the filing of the ’623 patent application, or, at a minimum, would have been obvious to one of ordinary skill in the art (Count II); a declaration of unenforceability of the ’623 patent for inequitable conduct (Count III); or, alternatively, correction of inventorship of the ’623 patent pursuant to 35 U.S.C. § 256 (Count IV).

PARTIES

1. Altaire is a New York corporation with its principal place of business at 311 West Lane, Aquebogue, New York 11931. All of Altaire's employees, shareholders, officers, and directors are located in New York.

2. Assad (Al) Sawaya, an individual, is President of Altaire and a resident and citizen of New York.

3. On information and belief, Paragon is a Nevada corporation with its principal place of business at 4640 SW Macadam Avenue, Suite 80, Portland, Oregon 97239.

JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a), because the claims in this suit arise under Federal Law, specifically the Patent Laws of the United States.

5. Paragon has directed the actions that are the subject of this Complaint against an individual resident of New York (Mr. Assad Sawaya) and a New York corporation (Altaire). Patrick Witham (“Witham”), President and CEO of Paragon, purposefully reached out and entered into a contractual relationship with Altaire (“the Agreement”) wherein Altaire would supply Paragon with confidential technical information and with phenylephrine products manufactured at Altaire’s facilities, which are exclusively located in New York. Witham entered New York to negotiate the Agreement with Altaire. The Agreement thus cemented a business relationship between Paragon and New York residents, and contemplated continuing and wide-reaching contacts between Paragon and the state of New York. Paragon has caused reputational and commercial injury to Altaire and reputational injury to Assad Sawaya by failing to name him as an inventor of the ’623 patent, despite Paragon’s knowledge that Assad Sawaya, and not Paragon employees, was the rightful inventor or at least a co-inventor of the subject matter disclosed and claimed in the ’623 patent. Paragon has also caused financial and reputational injury to Altaire by improperly disclosing Altaire’s confidential phenylephrine formulation in the publicly-available patent application that issued as the ’623 patent, and by making wrongful acts

and/or omissions during prosecution of the '623 patent application. Paragon's acts have caused Altaire to reasonably believe that it will be charged by Paragon with infringing the '623 patent if a New York court terminates the Agreement as Paragon seeks in the current E.D.N.Y. action. Accordingly, this Court's personal jurisdiction over Paragon arises from the affiliation and contacts that Paragon itself has created with New York, and which form the basis for this Complaint.

6. Moreover, this Court may exercise personal jurisdiction over Paragon at least because: (1) Paragon has transacted business within New York; (2) Paragon has committed a tortious act within New York, and/or (3) Paragon has committed a tortious act outside New York, and: has engaged in a persistent course of conduct, or derives substantial revenue from goods used or consumed or services rendered, in New York; and/or expects or should reasonably expect its acts to have consequences in New York and derives substantial revenue from interstate commerce. N.Y. C.P.L.R. 302.

7. Moreover, Paragon acquiesced to this Court's personal jurisdiction in a pending suit between the parties, styled *Altaire Pharms., Inc. v. Paragon BioTeck, Inc.*, No. 2:15-cv-02416, and filed counterclaims in that litigation.

8. Venue is proper in this District under 28 U.S.C. § 1391(b)(1), because Paragon should be deemed a New York resident. Paragon is a resident of New York because, under 28 U.S.C. § 1391(c), this Court has personal jurisdiction over Paragon. Venue is proper in this District under 28 U.S.C. § 1391(b)(2) because a substantial part of the events or omissions giving rise to the claims asserted in this Complaint occurred in this District, and because Paragon acquiesced to venue in this District in the pending litigation between the parties in this Court.

FACTUAL BACKGROUND

The Phenylephrine Products

9. Altaire is a pharmaceutical company specializing in research and development and manufacturing of high-quality prescription (a.k.a., Rx), diagnostic, and over-the-counter pharmaceutical products. Altaire manufactures (including compounding, filling and packaging) and sells multiple pharmaceutical products, including products containing phenylephrine.

10. Phenylephrine is a drug commonly used by physicians and optometrists to dilate the pupil of the eye during eye examinations. Phenylephrine occurs in one of two chemical forms: an R isomer (“R-phenylephrine”) or an S isomer (“S-phenylephrine”) (also known as “enantiomers”). The ratio of R-phenylephrine to S-phenylephrine may be referred to as “chiral purity.” The Food and Drug Administration (“FDA”) has categorized phenylephrine as a medically necessary drug.

11. Before November 14, 2013, it was known that the R-phenylephrine isomer, but not the S-phenylephrine isomer, was effective to dilate the pupil of the eye. For example, U.S. Patent No. 3,966,749 explains at column 1, lines 29-33 that “a racemic mixture”—that is, a mixture that includes both the R- and S- enantiomers—is “a mixture containing both the biologically active and the biologically non-active isomer,” and adds that the “R isomer is the only isomer exhibiting therapeutic activity.”

12. Altaire manufactures two phenylephrine hydrochloride ophthalmic solutions (collectively, “Phenylephrine Products”), which are described in the package insert for Altaire’s Phenylephrine Products (“Insert”). *See* Insert at 1 (**Exhibit A**) (revised 2010).

13. Altaire has manufactured and sold the Phenylephrine Products at least since 2000. *See also* Declaration of Assad Sawaya (“Sawaya Decl.”), at 1 ¶1 & n.1 (May 7, 2015) (**Exhibit B**).

14. Altaire’s Insert is a printed publication that is prior art to the ’623 patent. (Ex. A.)

15. As the Insert states, one of the Phenylephrine Products contains 2.5% phenylephrine hydrochloride by weight, and the other contains 10% phenylephrine hydrochloride by weight. *E.g.*, Insert at 1 (Ex. A). The Phenylephrine Products are aqueous solutions. *Id.* (solutions include water). The Insert also states that only the R-phenylephrine—*i.e.*, “(—)-*m*-Hydroxy- α -[(methylamino)methyl] benzyl alcohol hydrochloride”—is present in the product. The Insert does not list S-phenylephrine as an ingredient, nor does it otherwise indicate that a mixture of the two stereoisomers is present. A skilled artisan would interpret the Insert to expressly disclose that the Phenylephrine Products’ initial chiral purity was 100%.

16. Altaire’s Phenylephrine Products were publicly available and on sale before November 14, 2013.

17. As reflected in the Insert, Altaire’s Phenylephrine Products’ instructions for use direct consumers to store the Phenylephrine Products at temperatures between 2° C and 8° C. Insert at 2 (Ex. A).

18. On information and belief, the Altaire Phenylephrine Products sold and/or used publicly before November 14, 2013 were stored in cold storage (*e.g.*, at temperatures between -10° and 10° C) prior to being administered.

19. As stated on the Insert, the Phenylephrine Products are ophthalmic compositions to be used for pupil dilation. Insert at 1. Drops of these products are to be placed in the eye of a person in need thereof. *See id.* at 2 (Ex. A).

20. On information and belief, Phenylephrine Products sold and/or used publicly before November 14, 2013 were used for pupil dilation, for example via administration to the eye of an individual in need thereof.

21. Before November 14, 2013, Altaire sold the Phenylephrine Products in 5 mL and 15 mL plastic bottles. *E.g.*, Insert at 2 (Ex. A).

22. Before November 14, 2013, Altaire sold the Phenylephrine Products in opaque bottles. *E.g.*, Sawaya Decl. at 2-3 (image of opaque product bottle) (Ex. B).

23. Before November 14, 2013, Altaire developed a proprietary protocol to analyze the chiral purity of its Phenylephrine Products. *See* Analytical Test Method for Chirality (Enantiomeric Purity) Testing of Phenylephrine Hydrochloride in Raw Material and Ophthalmic Solution (2.5% and 10%) (“Chirality Test Method”) (dated May 31, 2013). This method (a.k.a. “TMQC 247-00”) uses high performance liquid chromatography (“HPLC”) to analyze the chiral purity of the Phenylephrine Products. *Id.*

24. The U.S. Patent & Trademark Appeals Board (“PTAB”) found that two lots of phenylephrine hydrochloride ophthalmic solutions manufactured and sold by Altaire are prior art to the ’623 patent. *See* Final Written Decision at 9. *Altaire Pharms., Inc. v. Paragon Biotech, Inc.*, PGR2015-00011 (November 14, 2014) (“PTAB Decision”) (Paper No. 48) (**Exhibit C**).

25. Altaire tested prior art Phenylephrine Products stored in cold storage for longer than 6 months and determined that the products contain no S-phenylephrine. *See* PTAB Decision at 9-10 (Ex. C). Such tests were performed using Altaire’s HPLC method. *See id.* at 10. On information and belief, because the tested products contained no S-phenylephrine, the initial chiral purity of the tested products must have been essentially 100% R-phenylephrine. On

information and belief, the chiral purity of the tested products after at least 6 months' cold storage was at least 95% of the initial chiral purity.

26. On information and belief, the Altaire Phenylephrine Products sold or used publicly before November 14, 2013 were stored in cold storage before administration, and were at least 95% R-phenylephrine when administered after storage to an eye of a person in need thereof.

27. Assad Sawaya has over fifty years of training and involvement in the pharmaceutical industry, including significant experience as a supervisor and manager of multiple pharmaceutical laboratories. Assad Sawaya founded Altaire in 1991. He oversees Altaire's research and development laboratory and the performance of its pharmacists and analytical chemists. Assad Sawaya oversees research methodologies performed at Altaire, including various types of chromatography. He is personally familiar with analyzing and interpreting the results of chromatography experiments.

28. At Altaire, Assad Sawaya conceived, developed, and reduced to practice the chemical formulations of the Phenylephrine Products and conceived and reduced to practice the method of using these products for pupil dilation by administering these solutions into the eye of persons in need of pupil dilation. Assad Sawaya further conceived, developed, and reduced to practice the manufacturing, packaging, testing (including chromatography), and storage conditions of the Phenylephrine Products. His conception and reduction to practice of these inventions is reflected by Altaire's Phenylephrine Products, which have been sold over-the-counter at least since 2000.

The Agreement Between Altaire and Paragon

29. In 2011, Patrick Witham, Paragon's President and CEO, and named co-inventor of the '623 patent, approached Assad Sawaya and proposed a business relationship between Paragon and Altaire to pursue approval of a New Drug Application ("NDA") for Altaire's Phenylephrine Products, and to transition the products to approved status in accordance with the FDA's Unapproved Drug Initiative. Witham entered New York to negotiate the Agreement. The Agreement contains the agreed-on terms of this business relationship.

30. Paragon and Altaire entered into the Agreement on May 30, 2011.

31. As of the date of the filing of this Complaint, the Agreement remains effective and enforceable.

32. The Agreement requires Paragon to keep Altaire's information confidential. *See* Agreement at 3 (**Exhibit D**) ("PARAGON . . . acknowledge[s] and agree[s] that any/all CMC writings, documents, data and/or information disclosed pursuant to the AGREEMENT are the proprietary and confidential information of ALTAIRE . . . and is provided for the Limited purposes of obtaining the NDA approvals contemplated by this AGREEMENT. The ALTAIRE INFORMATION may not be used for any other purpose, nor disclosed to any third party without the written consent of ALTAIRE's principals.").

33. Altaire provided confidential information relating to the Phenylephrine Products to Paragon, including a Chemistry, Manufacturing, and Controls ("CMC") section for inclusion in Paragon's NDA.

34. Altaire developed the 2.5% product formulation disclosed in the CMC on or about July 30, 2011 (A0358). Altaire developed the 10% product formulation disclosed in the CMC on or about July 30, 2011 (A0359).

35. The CMC provided to Paragon contained the confidential quantitative formulations of both of Altaire's prior art Phenylephrine Products, including the active ingredient and excipients. Declaration of Michael Sawaya ("Michael Sawaya Decl.") at ¶10 (**Exhibit E**).

36. On information and belief, Paragon never manufactured, developed or researched ophthalmic compositions containing phenylephrine hydrochloride prior to obtaining Altaire's confidential information relating to the Phenylephrine Products. In fact, Paragon sold the Altaire Phenylephrine Products with Altaire's labeling (a.k.a., trade dress) prior to filing the '623 patent through March 21, 2013, the approval date of NDA 203-510.

37. Paragon filed an NDA (No. 203-510) for the Phenylephrine Products on September 21, 2012.

38. On February 13, 2013, Michael Sawaya, General Counsel of Altaire, communicated with Patrick Witham regarding a chiral HPLC method Altaire was preparing for NDA 203-510. *See* Email from Michael Sawaya to Witham et al. dated February 13, 2013 (**Exhibit F**).

39. NDA 203-510 was approved on March 21, 2013. The '623 patent is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") for NDA 203-510.

40. Upon approval of NDA 203-510, Altaire ceased manufacturing and selling the Phenylephrine Products under its own label or under any other private labels, and manufactured these products exclusively for Paragon.

The '623 Patent

41. On June 12, 2013, attorneys at Wilson Sonsini Goodrich & Rosati (“WSGR”), including Michael Hostetler (“Hostetler”), contacted Altaire regarding a draft amendment to the Agreement that would permit Paragon to file a patent application. *See* WSGR Email at 2 (**Exhibit G**).

42. In part, the draft amendment attached to the WSGR Email stated: “Whereas, Altaire and Paragon entered into an agreement . . . stating that Altaire would be the exclusive manufacturer and supplier of Phenylephrine HCl Ophthalmic Solution, 2.5% and 10% (“Phenylephrine Product”) . . . Whereas, Altaire and Paragon believe that the Phenylephrine Product is an innovation . . . and wish to pursue patent protection . . . Paragon and Altaire will work together to determine inventorship of the Patent Application. . . . Altaire . . . does hereby grant to Paragon . . . a[] . . . license to make, use, sell, and offer for sale the Phenylephrine Product under . . . any patents granted. . .” Draft Amendment dated June 11, 2013 (“Draft Amendment”) at 1 (**Exhibit H**).

43. On information and belief, Hostetler and/or other WSGR attorneys prepared the Draft Amendment upon Witham’s direction. On information and belief, Witham, Hostetler, and/or other WSGR attorneys were aware of the Draft Amendment’s terms.

44. On the same day, June 12, 2013, Michael Sawaya responded “that any such patent application should identify either Al Sawaya or Altaire as the sole inventor. To that end, I would also like to take this opportunity to remind all concerned that the formulation, processes and controls applicable to the Phenylephrine product were developed solely by Al Sawaya and Altaire . . .” WSGR Email at 1 (Ex. G).

45. On the same day, June 12, 2013, WSGR attorneys, including Hostetler, acknowledged Michael Sawaya's response and replied "look forward to further discussions." WSGR Email at 1 (Ex. G).

46. On information and belief, Paragon employees, including Witham, knew that Michael Sawaya had indicated that Altaire or Al Sawaya should be named as the sole inventor.

47. Altaire never agreed to the Draft Amendment to the Agreement or any amendment to the Agreement to permit Paragon to file a patent application containing Altaire's confidential information, including information regarding the Phenylephrine Products.

48. The Agreement was never amended to permit Paragon to file a patent application containing Altaire's confidential information, including information regarding the Phenylephrine Products.

49. More than 6 months after acknowledging Michael Sawaya's communication (*see* WSGR Email), on November 14, 2013, Paragon filed U.S. Patent Application No. 14/080,771 (the "'771 application"). The '623 patent, entitled "Methods and Compositions of Stable Phenylephrine Formulations," issued on October 14, 2014 from the '771 application. A true and correct copy of the '623 patent is attached to this Complaint as **Exhibit I**.

50. The '623 patent contains one independent claim (claim 1). Claim 1 recites a method of using an ophthalmic composition for pupil dilation, including administering the composition into the eye of an individual in need thereof. The composition recited in claim 1 comprises R-phenylephrine hydrochloride having an initial chiral purity of at least 95% and an aqueous buffer. Claim 1 recites that the composition is stored at temperatures between -10° and 10° C prior to administration, and that the composition comprises R-phenylephrine hydrochloride having a chiral purity of at least 95% when administered after storage. Several

dependent claims recite specific chiral purity percentages of R-phenylephrine hydrochloride either initially or in the composition after 6 months. Other dependent claims recite packaging and storage conditions, including wherein the package identifies storing the composition at a temperature between 2°–8° C. Dependent claim 8 recites a composition comprising 2.5% (w/v) or 10% (w/v) R-phenylephrine hydrochloride by weight. On information and belief, use of the prior art Phenylephrine Products pursuant to the instructions for use that were included with them (e.g., Insert), meets all limitations in the '623 patent claims.

51. The claims of the '623 patent do not require an active step of 6 months' cold storage of the recited composition. *See* PTAB Decision at 6 (Ex. C).

52. The '623 patent specification discloses specific formulations of two ophthalmic compositions—specifically, a 2.5% and a 10% formulation—containing phenylephrine hydrochloride. *See* '623 patent, Table 1; Example 1 (Ex. I).

53. The specific quantitative formulations of the ophthalmic compositions disclosed in Table 1 of the '623 patent are the same as the respective concentration (2.5% or 10%) prior art Phenylephrine Products, as set forth in Altaire's CMC provided to Paragon.

54. On March 25, 2014, prior to issuance of the '623 patent, Paragon employee and named '623 patent inventor Lauren MC Bluett emailed Michael Sawaya requesting information regarding chiral purity of the Phenylephrine Products. *See* Bluett-Sawaya Email dated March 2014 (**Exhibit J**). Michael Sawaya provided a summary of such information on March 27, 2014. *See id.* Such chirality analysis was performed using Altaire's TMQC-247 chromatography method. On March 26, 2014, Michael Sawaya also provided Lauren MC Bluett with Altaire's Method Validation Report for Qualitative Chiral Purity of Phenylephrine HCl in Phenylephrine HCl Ophthalmic Solution, USP (2.5% and 10%) ("STU0346"), the validation study of Altaire's

TMQC-247 chromatography method to analyze chiral purity of the Phenylephrine Products. *See* Sawaya-Bluett Letter (**Exhibit K**). Paragon received that information while the '623 patent application was pending. Yet Paragon and WSGR, including Bluett, Witham, and/or Hostetler, intentionally withheld those documents from the U.S. Patent & Trademark Office ("USPTO").

55. On information and belief, any analysis of chiral purity (of phenylephrine hydrochloride solutions) disclosed in the '623 patent was performed on prior art Phenylephrine Products provided by Altaire.

56. The '623 patent names Patrick H. Witham, Sailaja Machiraju, and Lauren Mackensie-Clark Bluett as co-inventors and Paragon as the sole assignee. On information and belief, Witham, Machiraju, and Bluett are employees of Paragon. Each of their signatures appears on an inventor declaration ("Declaration") under 37 C.F.R. § 1.63 in the prosecution history of the '771 application. *See* 2013-11-14 Transmittal and Oath at 4-5, Partial File History of U.S. Application No. 14/080,771 (**Exhibit L**). In the Declarations, each named inventor stated that "I believe I am the original inventor or . . . joint inventor of a claimed invention in the application." *Id.* Because "[c]onception is the touchstone of inventorship," each joint inventor must generally contribute to the conception of the invention." *Ethicon, Inc. v. United States Surgical Corp.*, 135 F.3d 1456, 1460 (Fed. Cir. 1998) (citations omitted). On information and belief, none of the named inventors contributed to the conception of the claimed invention, or disclosed to the USPTO that any of the subject matter disclosed and claimed in the '771 application was invented by another. On information and belief, before filing the '771 application, each of the inventors knew that the inventions claimed in the '771 application, including the disclosed ophthalmic solution formulations and their intended use, were conceived

of and reduced to practice by Assad Sawaya and/or other Altaire employee(s). On information and belief, the Declarations are false.

57. On information and belief, Witham and/or other named inventors of the '623 patent knew that the information disclosed in the '623 patent relating to specific and/or exemplary formulations of phenylephrine hydrochloride ophthalmic compositions, their storage, chromatography testing, and their packaging, came entirely from confidential information provided by Altaire pursuant to the Agreement, including Altaire's CMC.

58. WSGR attorneys, including at least Hostetler, prosecuted the '771 application. *See, e.g.*, 2013-11-14 Transmittal and Oath at 1 (Ex. L).

59. On information and belief, prior to filing the '771 application, Hostetler, Witham and/or other WSGR attorneys and currently named inventors were aware of the statements made by Michael Sawaya regarding Assad Sawaya's invention of the Phenylephrine Products. *See generally* WSGR Email (Ex. G).

60. On information and belief, prior to filing the '771 application, Hostetler, Witham and/or other WSGR attorneys were aware of the Agreement and that Altaire would and did supply Paragon with confidential information relating to 2.5% and 10% phenylephrine hydrochloride solutions, including information relating to the formulation, storage conditions, chromatography testing, and packaging thereof. *See generally* WSGR Email (Ex. G); *see* Agreement (Ex. D).

61. On information and belief, prior to filing the '771 application, Witham, Hostetler, other named inventors of the '623 patent, and/or other WSGR attorneys, were aware that the Agreement precluded Paragon's disclosure of Altaire's confidential information, including for

use in a patent application, without obtaining an amendment. *See generally* WSGR Email (Ex. G).

62. The Draft Amendment that WSGR attorneys (including Hostetler) sent Altaire acknowledged that Altaire was the exclusive manufacturer of the 2.5% and 10% Phenylephrine Products. The Draft Amendment acknowledged that Paragon believed that Altaire's Phenylephrine Products "is an innovation." The Draft Agreement stated that Altaire would grant to Paragon a license to the Phenylephrine Products "under . . . any patents granted." Draft Amendment at 1 (Ex. H).

63. On information and belief, Witham, Hostetler, other named inventors of the '623 patent, and/or other WSGR attorneys, had a duty to the USPTO to carefully examine the patentability of the '771 application prior to filing, including inventorship thereof. *E.g.*, 37 C.F.R. § 1.56; Manual of Patent Examining Procedure ("MPEP") § 2001. On information and belief, Witham, Hostetler, other named inventors of the '623 patent, and/or other WSGR attorneys, had a duty to the USPTO to disclose all information known to be material to patentability.

64. On information and belief, prior to filing the '771 application, Witham, Hostetler, other named inventors of the '623 patent, and/or other WSGR attorneys, were aware that Altaire's Phenylephrine Products (including the Insert with its instructions for use) had been publicly available and on sale for more than a year before the '771 application was filed.

65. On information and belief, prior to filing the '771 application, Witham, Hostetler, other named inventors of the '623 patent, and/or other WSGR attorneys, were aware that Altaire's Phenylephrine Products (including instructions for use) had been used to dilate the pupils of eyes for more than a year before the '771 application was filed.

66. The Draft Amendment stated that Paragon would work with Altaire to determine patent inventorship. On information and belief, however, neither Witham, Hostetler, nor any other named inventor of the '623 patent or WSGR attorney, attempted to confirm the inventorship of the subject matter disclosed and claimed in the '771 application or the '623 patent. On information and belief, neither Witham, Hostetler, nor any other named inventor of the '623 patent or WSGR attorney, contacted Assad Sawaya or anyone at Altaire to investigate Michael Sawaya's statements (*e.g.*, WSGR Email) either before or after the filing of the '771 application. On information and belief, neither Witham, Hostetler, nor any other named inventor of the '623 patent or WSGR attorney, communicated to the USPTO the involvement of Assad Sawaya or Altaire with the invention of the subject matter disclosed and claimed in the '771 application or the '623 patent. Moreover, on information and belief, neither Witham, Hostetler, or any other WSGR attorney or named inventor disclosed Michael Sawaya's email to WSGR in which he explained that the sole inventor on any patent application should be Assad Sawaya. On information and belief, that email contained material information that should have been disclosed to the USPTO.

67. On information and belief, Witham, Hostetler, other named inventors of the '623 patent, and/or other WSGR attorneys, knowingly, intentionally, and willfully omitted Assad Sawaya as a sole or joint inventor of the '771 application and '623 patent, despite awareness of the fact that—as found in at least the CMC provided by Altaire and the statements of Michael Sawaya (WSGR Email)—Assad Sawaya and/or others at Altaire had conceived and reduced to practice the inventions disclosed and claimed therein, including the intended use of specific phenylephrine compositions to dilate the pupil, and including packaging, chromatography testing, and storage conditions for such compositions. On information and belief, the same

individuals intentionally failed to disclose to the USPTO these material facts pertaining to the true inventorship of the inventions disclosed and claimed in the '623 patent. On information and belief, such omissions were made in bad faith, at least because, as set forth in the Draft Amendment, Paragon wanted to secure the full ownership interest in the patent, which it would be unable to do if Assad Sawaya were named as the sole inventor or a joint inventor. On information and belief, Paragon further acted in bad faith, because it intends to use its sole ownership interest in the patent to gain leverage in its dealings with Altaire regarding their Exclusive Manufacturing Agreement and potential renewal of that Agreement.

68. On information and belief, despite awareness of the involvement of Assad Sawaya and Altaire in the inventorship of the '771 application and '623 patent, pursuant to the CMC provided by Altaire and the statements of Michael Sawaya, neither Witham, Hostetler, nor any other named inventor of the '623 patent or WSGR attorney, corrected or attempted to correct the '771 application's inventorship to name Assad Sawaya as a sole or joint inventor. On information and belief, the same individuals likewise failed to pursue a correction of inventorship after the '623 patent issued.

69. On information and belief, despite awareness of the information regarding the claimed phenylephrine solutions provided by Altaire, and the necessity of obtaining an amendment to the Agreement for use of such information in a patent application (see WSGR Email), neither Witham, Hostetler, nor any other named inventor of the '623 patent or WSGR attorney, disclosed Altaire's Phenylephrine Products or their instructions for use (e.g., Insert dated 2010) to the USPTO. In fact, Witham submitted a declaration to the Patent Office on March 13, 2014, in which he stated that "current R-Phenylephrine eye products explicitly specify storage at 20 to 25 degree Celsius" and, to support that statement, he included the package insert

from an Akorn product. *See* 2014-03-13 Declaration of Patrick H. Witham (“Witham Declaration”), Partial File History of U.S. Application No. 14/080,771 (**Exhibit M**). Witham’s statements in that declaration are false and, on information and belief, he knew it. On information and belief, Witham intentionally made this false statement to mislead the patent examiner, because his declaration was being used to argue that the pending claims were patentable over the prior art. Indeed, Witham’s declaration also distinguished another reference (Shibini) because it supposedly did not disclose storage at “-10 to 10 degree Celsius,” even though, on information and belief, he knew that Altaire’s product Insert had been instructing such storage for years before the filing of the ’771 patent application. *See, e.g.*, Witham Declaration ¶6. WSGR attorneys, including Hostetler, used these statements to argue for the patentability of the pending claims in a March 19, 2014 response to Office Action. In particular, Hostetler argued that the prior art taught away from storage at -10 to 10 degrees Celsius and stressed that the Akorn label advised that the solution should be stored at 20° to 25 °C, *see id.* ¶9, even though, on information and belief, he knew about Altaire’s product Insert and labeling, which specified that storage should be at 2-8° C. *See* Insert at 2. (Ex. A). Therefore, on information and belief, Hostetler knew that his statements were false and misleading, and they constitute affirmative egregious misconduct.

70. On information and belief, the Witham Declaration also contained further false statements about the Akorn product. For example, Witham attached as an exhibit results from a chiral chromatogram on the Akorn product, which he said was stored at room temperature and which he implied showed a lack of chiral purity because, e.g., it included two unresolved peaks, having retention times of 5.222 minutes and 5.481 minutes, respectively. Witham Declaration at ¶10; Exhibit 3 (Ex. M). Witham’s Exhibit 3 compared the Akorn product to Figure 3 in the ’623

patent, which he said showed over 99% chiral purity for a product stored at 2-8° C after 6 months. *See id.* ¶10. Witham implied that the two unresolved peaks in chromatogram of the Akorn product were the R- and S-isomers of phenylephrine, but, on information and belief, that was false. The '623 patent reports (e.g., in Figure 4) that the retention time applicable to the S-form of phenylephrine is 6.3-6.4 minutes—well after either of the peaks in the chromatogram of the Akorn product. This strongly suggests that the Akorn product did not contain any S-phenylephrine at all, despite its instructions for room temperature storage. Yet Witham's declaration did not direct the examiner to that fact. Instead, on information and belief, the Witham Declaration gave the false impression that the Akorn product had a chiral impurity, while the claimed formulation did not, and that this alleged reason for this difference was cold storage. But, on information and belief, none of that is true.

71. On information and belief, the false statements by Paragon and WSGR, including Witham and Hostetler, had a significant impact on the patent examiner's decision to allow the '623 patent. For example, the examiner relied on their statements about the prior art not teaching storage at the claimed temperature range, cited the Akorn package insert as the closest prior art, and cited the Witham declaration for its assertions about how the claimed invention differed from the Akorn product. *See* 2014-09-03 Notice of Allowance, Partial File History of U.S. Application No. 14/080,771, at 3-4 ("The following is an examiner's statement of reasons for allowance: . . . the closest prior art is Akorn, Inc. (package insert for phenylephrine hydrochloride solution/drops . . . revised 09/2011 . . .). Akorn teaches an ophthalmic solution of (-)-phenylephrine hydrochloride, 2.5%, . . . wherein the composition is to be stored at 20 to 25 degree Celsius (page 3). Akorn does not teach the composition is stored at -10 to 10 degree Celsius, and also does not specify the chiral purity of the solution before or after storage.

Applicant's Declaration . . . provides evidence that the chiral purity of R-phenylephrine is maintained after 6 months of storage at -10 to 10 degree Celsius, but is not maintained when the composition is stored at room temperature (20 to 25 degree Celsius). Therefore, Applicant's Declaration is sufficient for demonstrating nonobviousness of the claimed invention.") (**Exhibit N**). On information and belief, the Examiner would have considered Phenylephrine Products and their instructions for use to be the closest prior art to the '623 patent. *See, e.g.*, Insert dated 2010 (instructing cold storage conditions) (Ex. A). On information and belief, the Phenylephrine Products and their instructions for use are not cumulative over the information of record in the prosecution of the '623 patent, because, e.g., the Insert discloses cold storage conditions that the Examiner cited regarding the non-obviousness of the invention claimed in the '623 patent. Indeed, the Phenylephrine Products and their instructions for use included the very limitation that Witham and Hostetler had falsely insisted was not present in the prior art.

72. On information and belief, the '623 patent is not patentable over the Phenylephrine Products and/or their instructions for use (e.g., Insert dated 2010) (Ex. A).

73. On information and belief, despite awareness that the Phenylephrine Products had been publicly available, sold, and used for the claimed method prior to the filing of the '771 application, neither Witham, Hostetler, nor any other named inventor of the '623 patent or WSGR attorney, identified the prior use or sale of the Phenylephrine Products (including their instructions for use) during prosecution of the application that issued as the '623 patent. On information and belief, despite awareness that the Insert was a printed publication that was prior art to the '771 application, neither Witham, Hostetler, nor any other named inventor of the '623 patent or WSGR attorney, disclosed it during prosecution of the application that issued as the '623 patent. On information and belief, such omissions were made in bad faith.

74. On information and belief, Witham, Hostetler, and/or other named inventors or WSGR attorneys deliberately and deceptively intended to omit Assad Sawaya as an inventor on the '623 patent. On information and belief, the intent of these individuals to deceive the USPTO regarding inventorship of the '771 application and '623 patent is the single most reasonable inference that can be drawn from the circumstances alleged herein. On information and belief, no other reasonable inference can be drawn from the failure of these individuals to investigate or examine Michael Sawaya's representations that Assad Sawaya invented the Phenylephrine Products (described as "an innovation" in the Draft Amendment) and related technical information, particularly because Paragon obtained such confidential information (relating to ophthalmic solution composition, storage conditions, intended use, chromatography testing, and packaging, and which is disclosed in the '623 patent specification) pursuant to the limited terms of the Agreement with Altaire.

75. On information and belief, failure to name Assad Sawaya as an inventor on the '771 application or '623 patent by Witham, Hostetler, and/or other named inventors or WSGR attorneys was not a mistake or oversight, and was not an inadvertent, unintentional, or other error.

76. On information and belief, Witham, Hostetler, and/or other named inventors or WSGR attorneys deliberately and deceptively withheld and/or failed to disclose the Phenylephrine Products and their instructions for use to the USPTO during prosecution of the '771 application. On information and belief, the intent of these individuals to deceive the USPTO regarding patentability of the '771 application and '623 patent is the single most reasonable inference that can be drawn from the circumstances alleged herein. On information and belief, no other reasonable inference can be drawn from the failure of these individuals to

disclose, e.g., the cold storage conditions of Altaire's Phenylephrine Products (described as "an innovation" in the Draft Amendment), as set forth in the publicly-available Insert, particularly given such individuals' knowledge of the Agreement, and particularly given the false statements of Witham and Hostetler in the Witham Declaration and Office Action response discussed above.

77. On information and belief, the failure to disclose the Phenylephrine Products and their instructions for use to the USPTO during prosecution of the '771 application by Witham, Hostetler, and/or other named inventors or WSGR attorneys was not a mistake or oversight, and was not an inadvertent, unintentional, or other error.

78. On information and belief, the intentional and deceptive failure to include Assad Sawaya as a named inventor during prosecution of the '771 application, and/or the failure to correct the '623 patent to name Assad Sawaya as a named inventor, and/or the failure to investigate Michael Sawaya's statements, violated the obligations of Witham, Hostetler, and/or other named inventors or WSGR attorneys to the USPTO. See 37 C.F.R. § 1.56 ("Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section."); MPEP § 2001.

79. On information and belief, the intentional and deceptive failure to identify the Phenylephrine Products and their instructions for use during prosecution of the '771 application violated the obligations that Witham, Hostetler, and/or other named inventors or WSGR attorneys had to the USPTO. See 37 C.F.R. § 1.56; MPEP § 2001.

80. On information and belief, erroneous statements and/or omissions by Witham, Hostetler, and/or other named inventors or WSGR attorneys to the USPTO regarding the named

inventors, including failure to name Assad Sawaya as a sole or joint inventor of the '771 application or '623 patent, are material. Erroneous statements about inventorship have been found material to the patentability of an application before the USPTO. "[T]he Federal Circuit has found that 'falsehoods and omissions . . . calculated to obfuscate the threshold issue of inventorship' are material and support a finding of inequitable conduct." *Fujifilm Corp. v. Motorola Mobility LLC*, No. 12-cv-3587, 2014 WL 2730724, at *3 (N.D. Cal. June 16, 2014) (quoting *PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc.*, 225 F.3d 1315, 1321-22 (Fed. Cir. 2000)).

81. On information and belief, if the USPTO had learned of the intentional and deceptive omissions and/or false statements regarding patent inventorship by Witham, Hostetler, and/or other named inventors or WSGR attorneys during prosecution of the '623 patent application, the USPTO would not have issued the '623 patent. *E.g.*, 35 C.F.R. § 1.56 ("[N]o patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct."). On information and belief, but-for the failure of Witham, Hostetler, and/or other named inventors or WSGR attorneys to disclose to the USPTO the omission of Assad Sawaya as an inventor of the invention claimed in the '623 patent, the USPTO would not have issued the '623 patent. At a minimum, on information and belief, if the USPTO had learned of the intentional and deceptive omissions and/or false statements regarding patent inventorship the USPTO would not have issued the '623 patent to Paragon and the currently named inventors and would have instead required Assad Sawaya to be included as the sole inventor or a co-inventor.

82. On information and belief, erroneous statements and/or omissions by Witham, Hostetler, and/or other named inventors or WSGR attorneys to the USPTO regarding the failure

to disclose the prior art Phenylephrine Products and their instructions for use (e.g., the Insert dated 2010) during prosecution of the '771 application, are material. The Notice of Allowance states that the '771 application is patentable as non-obvious over the prior art Akorn reference because the Akorn reference does not disclose cold storage conditions. Yet Altaire's prior art Insert discloses Phenylephrine Products and use thereof within in the scope of the '623 patent claims, as well as directions to store at cold temperatures.

83. On information and belief, if the USPTO had learned of the intentional and deceptive omissions and/or false statements regarding the prior art Phenylephrine Products by Witham, Hostetler, and/or other named inventors or WSGR attorneys during prosecution of the '623 patent application, the USPTO would not have issued the '623 patent. *E.g.*, 35 C.F.R. § 1.56. On information and belief, but-for the failure of Witham, Hostetler, and/or other named inventors or WSGR attorneys to disclose the Insert to the USPTO, the USPTO would not have issued the '623 patent.

84. On information and belief, the filing of the named inventors' false Declarations constituted affirmative acts of egregious misconduct. *E.g.*, *Auxilium Pharms. v. Watson Labs.*, No. 12-cv-3084, 2014 WL 9859224, at *36 (D.N.J. Dec. 16, 2014) ("Having now determined that the . . . patent was, in fact, derived from Dr. Hsieh's Permeation Studies . . . and thus that Dr. Hsieh was—at a minimum—a co-inventor of the . . . patent, the Court finds that the declarations submitted by Mr. Gyurik to the PTO indicating that he was the "original, first and sole inventor . . . of the subject matter which is claimed" in the . . . patent were false. . . . It follows that Mr. Gyurik's filing of the false affidavits constitutes affirmative acts of egregious misconduct, which are *per se* material to patentability under *Therasense* . . .").

Injury to Altaire and Assad Sawaya

85. Assad Sawaya has worked in the field of pharmaceutical research and development for approximately half a century, and conceived of the subject matter disclosed and claimed in the '623 patent. Yet, to the world, Paragon and its employees are the ones responsible for the inventions disclosed and claimed therein, because persons working on behalf of Paragon, including Witham and Hostetler, have deprived Assad Sawaya of the professional credit and benefits associated with patent inventorship. Assad Sawaya thus suffers reputational injury from his omission as a named inventor on the '623 patent, or any future related patents, and his recognition and reputation in his field would be greater if he had been named as an inventor on the '623 patent. *E.g., Shukh v. Seagate Tech., LLC*, 803 F.3d 659, 665 (Fed. Cir. 2015), *cert. denied*, 136 S. Ct. 2512 (2016) (“The evidence supports the conclusion that Dr. Shukh’s reputation as an inventor would have been higher had he been named on the patents.”).

86. Assad Sawaya has assigned to Altaire all of his rights in inventions created in his role as founder and President of Altaire, including the inventions disclosed and claimed in the '623 patent. Accordingly, Altaire suffers financial harm from the omission of Assad Sawaya as a named inventor on the '623 patent, or any future related patents, at least because Altaire cannot license or otherwise exploit the inventions claimed in the '623 patent. Only Paragon has these rights. Altaire’s ability to seek future business opportunities is also diminished, at least because, as owner of the '623 patent, or any future related patents, Paragon possesses superior ability to compete for these opportunities. Altaire is at a disadvantage in the marketplace—in which it has long competed—because Paragon possesses the rights to the inventions claimed in such patent(s). Altaire also suffers reputational harm from the omission of Assad Sawaya as a named inventor on the '623 patent, or any future related patents, because such patent(s) do not reflect

the innovative contributions of Assad Sawaya and Altaire. Altaire is in a very competitive industry, and damage to its reputation is likely to cause significant harm to it in the marketplace.

87. Other litigation is currently pending between the parties: *Altaire Pharms., Inc. v. Paragon BioTeck, Inc.*, No. 2:15-cv-02416 (E.D.N.Y.). Paragon has sought immediate termination of the Agreement in the E.D.N.Y. litigation. *See, e.g.*, Answer, Dkt. No. 22, at 22-23 (August 14, 2015). Trial in that suit is expected in Summer 2017. Accordingly, Altaire is under near immediate threat of termination of the Agreement as a result of the E.D.N.Y. litigation.

88. On information and belief, under the FDA's Unapproved Drug Initiative, the FDA prioritizes enforcement against unapproved drugs that compete with a drug for which an NDA has been approved (such as Altaire's Phenylephrine Products manufactured for Paragon). Thus, upon termination of the Agreement, Altaire intends to file an abbreviated new drug application ("ANDA") to allow it to resume selling its own Phenylephrine Products. *See* Michael Sawaya Decl. at ¶¶16, 18-19 (Ex. E). Absent the relief sought in this Complaint, filing such ANDA will constitute a statutory act of infringement of the '623 patent, which is listed in the Orange Book for Paragon's NDA. *See* 37 U.S.C. § 271(e)(2)(A). Altaire's ANDA will contain a certification that the '623 patent is invalid (a "Paragraph IV certification"). *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV). If Paragon thereafter elects to sue Altaire for infringement of the '623 patent, the FDA will stay approval of Altaire's ANDA—and delay the market entry of Altaire's own Phenylephrine Products—for thirty months. *See* 21 U.S.C. § 355(j)(5)(B)(iii). Thus, even if the Agreement remains in effect, Altaire must file its ANDA well before May 2021 to ensure that it obtains FDA approval to begin selling its own version of the drug in May 2021.

89. In such ANDA, Altaire intends to use a label instructing use of the Phenylephrine Products for pupil dilation, and instructing storage between 2°–8° C consistent with its previous

practices. Altaire's Phenylephrine Products contain R-phenylephrine in an aqueous solution within the recited chiral purity range(s) after cold storage, are provided in 5 and 15 mL opaque bottles, and the Insert instructs storage at 2°–8° C and administration to the eye for pupil dilation. *See generally* Insert (Ex. A). Further, the PTAB was "persuaded that Altaire's Product meets these limitations of claim 1" of the '623 patent. *See* PTAB Decision at 10 (Ex. C). Accordingly, Altaire reasonably anticipates that Paragon will bring a declaratory judgment claim that, if such ANDA is approved, Altaire will indirectly infringe the '623 patent.

90. Under all the circumstances alleged herein, an actual, substantial, and justiciable controversy therefore exists between Plaintiffs and Paragon of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the parties' adverse legal interests with respect to the validity and/or unenforceability of U.S. Patent No. 8,859,623.

91. The Court may and should exercise its broad discretion to adjudicate this action under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02. Such adjudication will serve the underlying purposes of the Declaratory Judgment Act by resolving legal disputes between Plaintiffs and Paragon regarding their respective legal rights to manufacture and sell inventions related to the Phenylephrine Products. This dispute should be resolved efficiently and economically in this action, deciding the controversies between the parties with certainty, completeness, and finality.

COUNT I

Declaration of Invalidity of the '623 Patent (Failure to Name Inventor)

92. Plaintiffs incorporate and re-allege by this reference the allegations of paragraphs 1-91 above.

93. The only named inventors on the '623 patent are Patrick H. Witham, Sailaja Machiraju, and Lauren Mackensie-Clark Bluett.

94. On information and belief, none of the named inventors on the '623 patent contributed to the conception of the claimed invention.

95. Assad Sawaya conceived of the invention claimed in the '623 patent and reduced it to practice before the filing of the '771 application, and, on information and belief, such events occurred no later than 2000. At a minimum, Assad Sawaya contributed significantly to the conception of the invention claimed in the '623 patent, including conception of the Phenylephrine Products' formulation, the use of which falls within the claims of the '623 patent, and/or conceiving of storing that formulation within the claimed temperature range, and packaging thereof.

96. Witham, Hostetler, other named inventors of the '623 patent, and/or WSGR attorneys failed to name Assad Sawaya as an inventor of the application that resulted in the '623 patent.

97. On information and belief, Witham, Hostetler, other named inventors of the '623 patent, and/or WSGR attorneys, acted with deceptive intent in failing to name Assad Sawaya as an inventor of the application that resulted in the '623 patent.

98. On information and belief, the failure to name Assad Sawaya as an inventor on the '771 application or '623 patent by Witham, Hostetler, and/or other named inventors or WSGR attorneys, was not a mistake or oversight, and was not an inadvertent, unintentional, or other error.

99. On information and belief, intentional and deceptive failure to name Assad Sawaya as an inventor of the application that resulted in the '623 patent cannot be corrected pursuant to 35 U.S.C. § 256.

100. Altaire contends that the '623 patent is invalid under 35 U.S.C. § 101 for failing to name the true inventor, Assad Sawaya, or for his nonjoinder as a joint inventor.

101. Altaire anticipates near immediate financial harm because Altaire reasonably believes that it may be sued for infringement of the '623 patent upon filing its ANDA to allow it to resume sales of its Phenylephrine Products. Altaire also suffers ongoing reputational harm from the omission of Assad Sawaya as a named inventor on the '623 patent because the patent does not reflect the innovative contributions of Assad Sawaya and Altaire.

102. Accordingly, an actual, live and justiciable controversy exists between Altaire and Paragon as to whether the '623 patent is valid or invalid, over which this Court has jurisdiction and may make a declaration regarding the rights and legal relations of the parties with the respect to the validity or invalidity of the '623 patent.

103. Wherefore Altaire is entitled to a declaratory judgment that the '623 patent is invalid under 35 U.S.C. § 101 for failing to name the true inventor, Assad Sawaya.

COUNT II

Declaration of Invalidity of the '623 Patent Under 35 U.S.C. §§ 102 and/or 103

104. Plaintiffs incorporate and re-allege by this reference the allegations of paragraphs 1-91 above.

105. Altaire's Phenylephrine Products, including the packaging, and including an insert directing cold storage conditions and use of the products for pupil dilation, had been on sale to the public before the '771 application was filed.

106. Altaire's Phenylephrine Products and their instructions for use are prior art to the '623 patent. On information and belief, the initial chiral purity of Altaire's prior art Phenylephrine Products, and the chiral purity of such products after at least 6 months and cold storage, were within the ranges recited in the claims of the '623 patent.

107. On information and belief, Altaire's prior art Phenylephrine Products sold or used publicly before November 14, 2013 were packaged and stored in cold storage before administration as recited in the claims of the '623 patent, and the chiral purity of such products was within the ranges recited in the '623 patent.

108. On information and belief, Altaire's prior art Phenylephrine Products were used publicly to dilate the pupils of eyes before the '771 application was filed.

109. Altaire's Insert is a printed publication that is prior art to the '623 patent. The Insert expressly discloses a phenylephrine product was an initial chiral purity of 100%, because, for example, it states that only the R-phenylephrine—*i.e.*, "(—)-*m*-Hydroxy- α -[(methylamino)methyl] benzyl alcohol hydrochloride"—is present in the product and does not list S-phenylephrine as an ingredient or otherwise indicate that the solution contains a mixture of the two stereoisomers. At a minimum, it would have been obvious to the skilled artisan to modify the product to include 100% R-phenylephrine, because skilled artisans knew that only the R-isomer caused pupil dilation. The Insert states that the product is "for pupil dilation," that it uses an aqueous buffer, and that it should be administered to the eye. The Insert further instructs that the composition should be stored at 2-8 degrees Celsius, as required by the '623 patent claims. Moreover, a skilled artisan knew that the remaining limitation of claim 1 of the '623 patent—that "the composition comprises R-phenylephrine hydrochloride having a chiral purity of at least 95% when administered after storage" for at least 6 months—was inherent based on

the Insert's disclosures, because phenylephrine's chiral purity does not degrade over time, either when stored at room temperature or when stored in a refrigerator, as the Insert instructs. The same is true for the chiral purity limitations in dependent claims 3-7. The Insert discloses that the composition comprises 2.5% w/v or 10% w/v, as required by claim 8. The Insert also discloses storage in 5 mL and 15 mL sterile plastic bottles and instructs to "protect from light" the composition, thus disclosing or, at a minimum rendering obvious, the additional limitations of claims 9, 12, and 13.

110. Altaire thus contends that the '623 patent is invalid under 35 U.S.C. § 102 because the inventions claimed in the '623 patent were described in a printed publication, in public use, on sale, or otherwise available to the public before the effective filing date of the '771 application.

111. Altaire contends that the '623 patent is invalid under 35 U.S.C. § 103 because the invention claimed in the '623 patent would have been obvious based on Altaire's Insert (a printed publication) in light of the knowledge of a skilled artisan.¹

112. Altaire anticipates near immediate financial harm because Altaire reasonably believes that it may be sued for infringement of the '623 patent upon termination of the Agreement, upon filing its ANDA to allow it to resume sales of its Phenylephrine Products. Altaire also suffers ongoing reputational harm from the omission of Assad Sawaya as a named inventor on the '623 patent because the patent does not reflect the innovative contributions of Assad Sawaya and Altaire.

¹ To be clear, Altaire is only asserting obviousness based on a ground that was not instituted in the post-grant review of the '623 patent and is not asserting obviousness under the ground that was the subject of the final written decision. Therefore, 35 U.S.C. § 325(e)(2) does not apply.

113. Accordingly, an actual, live and justiciable controversy exists between Altaire and Paragon as to whether the '623 patent is valid or invalid, over which this Court has jurisdiction and may make a declaration regarding the rights and legal relations of the parties with respect to the validity or invalidity of the '623 patent.

114. Wherefore Altaire is entitled to a declaratory judgment that the '623 patent is invalid under 35 U.S.C. §§ 102 and/or 103 because the invention claimed in the '623 patent was described in a printed publication, on sale, in public use, or otherwise available to the public more than one year before the filing date of the '623 patent application, and, at a minimum, would have been obvious based on Altaire's Insert.

COUNT III

Declaration of Unenforceability of the '623 Patent

115. Plaintiffs incorporate and re-allege by this reference the allegations of paragraphs 1-91 above.

116. On information and belief, the information regarding phenylephrine hydrochloride ophthalmic solutions, cold storage conditions, packaging, and intended use for pupil dilation, as recited in the '623 patent disclosure and claims, was obtained by Paragon entirely from Altaire, including from Altaire's CMC.

117. On information and belief, Witham, Hostetler, other named inventors of the '623 patent, and/or WSGR attorneys, knew that the information regarding phenylephrine hydrochloride ophthalmic solutions, cold storage conditions, packaging, and intended use for pupil dilation, as recited in the '623 patent disclosure and claims, was obtained by Paragon entirely from Altaire, including from Altaire's CMC.

118. On information and belief, Witham, Hostetler, and/or other named inventors of the '623 patent or WSGR attorneys knew that the invention claimed in the '623 patent was not developed by employees of Paragon.

119. On information and belief, Witham, Hostetler, and/or other named inventors of the '623 patent or WSGR attorneys knew that the invention claimed in the '623 patent was conceived of and reduced to practice by employees of Altaire.

120. On information and belief, Witham, Hostetler, other named inventors of the '623 patent, and/or WSGR attorneys, knew of the statements of Michael Sawaya, made prior to the filing of the '771 patent, that that the inventions disclosed and claimed in the '623 patent were conceived of and reduced to practice by Assad Sawaya.

121. On information and belief, Witham, Hostetler, other named inventors of the '623 patent, and/or WSGR attorneys, knew that Assad Sawaya (or other Altaire employees) was the true inventor of the inventions disclosed and claimed in the '623 patent application. On information and belief, such individuals had a duty to the USPTO to examine the true inventorship of the '623 patent application, including the basis for Michael Sawaya's statements, yet intentionally failed to do so.

122. On information and belief, Witham, Hostetler, and/or other named inventors of the '623 patent or WSGR attorneys knowingly, intentionally, and deceptively omitted Assad Sawaya as a named inventor of the '771 application during prosecution.

123. On information and belief, the single most reasonable inference to be drawn from the circumstances alleged herein is that Witham, Hostetler, and/or other named inventors of the '623 patent or WSGR attorneys had specific intent to deceive the USPTO about the true inventorship of the '771 application and '623 patent.

124. On information and belief, no other inference can be drawn from such individuals' failure to examine the inventorship of the '623 patent application, including the basis for Michael Sawaya's statements.

125. On information and belief, the failure to name Assad Sawaya as an inventor on the '771 application or '623 patent by Witham, Hostetler, and/or other named inventors or WSGR attorneys, was not a mistake or oversight, and was not an inadvertent, unintentional, or other error.

126. On information and belief, erroneous statements and/or omissions by Witham, Hostetler, and/or other named inventors or WSGR attorneys to the USPTO regarding the named inventors, including failure to name Assad Sawaya as a sole or joint inventor of the '771 application or '623 patent, are material.

127. On information and belief, but-for the failure of Witham, Hostetler, and/or other named inventors or WSGR attorneys to disclose to the USPTO the omission of Assad Sawaya as an inventor of the invention claimed in the '623 patent, the USPTO would not have issued the '623 patent.

128. On information and belief, Altaire's prior art Phenylephrine Products and their directions for use (e.g., Insert) are the closest prior art to the '623 patent.

129. On information and belief, Witham, Hostetler, other named inventors of the '623 patent, and/or WSGR attorneys, knew of Altaire's prior art Phenylephrine Products and their directions for use.

130. On information and belief, Witham, Hostetler, other named inventors of the '623 patent, and/or WSGR attorneys, knew that Altaire's prior art Phenylephrine Products and their

directions for use (e.g., Insert) were the closest prior art to the '623 patent, or that the '623 patent was unpatentable over such prior art.

131. On information and belief, Witham, Hostetler, and/or other named inventors of the '623 patent or WSGR attorneys knowingly, intentionally, and deceptively failed to disclose Altaire's prior art Phenylephrine Products and their directions for use to the USPTO during prosecution of the '771 application.

132. On information and belief, the single most reasonable inference to be drawn from the circumstances alleged herein is that Witham, Hostetler, and/or other named inventors of the '623 patent or WSGR attorneys had specific intent to deceive the USPTO about the patentability of the '771 application and '623 patent.

133. On information and belief, no other inference can be drawn from such individuals' failure to disclose such prior art, particularly because of such individuals' awareness that the Agreement protected disclosure of this information and would require amendment. *See* WSGR Email (Ex. G).

134. On information and belief, the failure to disclose the prior art Phenylephrine Products and their instructions for use to the USPTO, by Witham, Hostetler, and/or other named inventors or WSGR attorneys, was not a mistake or oversight, and was not an inadvertent, unintentional, or other error.

135. On information and belief, erroneous statements and/or omissions by Witham, Hostetler, and/or other named inventors or WSGR attorneys to the USPTO regarding the failure to disclose the prior art Phenylephrine Products and their instructions for use during prosecution of the '771 application, are material.

136. On information and belief, but-for the failure of Witham, Hostetler, and/or other named inventors or WSGR attorneys to disclose prior art Phenylephrine Products and their instructions for use to the USPTO, the USPTO would not have issued the '623 patent.

137. On information and belief, the actions of WSGR attorneys, including Hostetler, and the named inventors of the '623 patent, including Witham, violated their respective obligations to the USPTO, including the duty of disclosure. *See* 37 C.F.R. § 1.56.

138. On information and belief, the named inventors' Declarations constituted false affidavits, the filing of which were affirmative acts of egregious misconduct.

139. Altaire anticipates near immediate financial harm because Altaire reasonably believes that it may be sued for infringement of the '623 patent upon termination of the Agreement, upon Altaire filing its ANDA to allow it to resume sales of its Phenylephrine Products. Altaire also suffers ongoing reputational harm from the omission of Assad Sawaya as a named inventor on the '623 patent because the patent does not reflect the innovative contributions of Assad Sawaya and Altaire.

140. Accordingly, an actual, live and justiciable controversy exists between Altaire and Paragon as to whether the '623 patent is valid or invalid, over which this Court has jurisdiction and may make a declaration regarding the rights and legal relations of the parties with the respect to the validity or invalidity of the '623 patent.

141. Wherefore Altaire is entitled to a declaratory judgment that the '623 patent is unenforceable for inequitable conduct.

COUNT IV (PLED IN THE ALTERNATIVE ONLY)

Correction of Inventorship

142. Plaintiffs plead this count in the alternative in light of many of the facts described above.

143. The only named inventors on the '623 patent are Patrick H. Witham, Sailaja Machiraju, and Lauren Mackensie-Clark Bluett.

144. On information and belief, none of the named inventors on the '623 patent contributed to the conception of the claimed invention.

145. Assad Sawaya conceived of the invention claimed in the '623 patent and reduced it to practice before the filing of the '771 application, and, on information and belief, such events occurred no later than 2000. At a minimum, Assad Sawaya contributed significantly to the conception of the invention claimed in the '623 patent, including conception of the Phenylephrine Products' formulation, the use of which falls within the claims of the '623 patent, and/or conceiving of storing that formulation within the claimed temperature range for at least 6 months.

146. Plaintiffs have alleged above that Paragon's failure to name Assad Sawaya as the sole inventor (or, at a minimum, as a joint inventor) of the '623 patent was done with deceptive intent. Nevertheless, Plaintiffs expect that Paragon did not act with deceptive intent. The facts described above show that the inventorship is not correct. So, if one were to assume that Paragon and its lawyers made an honest error or mistake in failing to name Assad Sawaya as the sole inventor (or, at a minimum, as a joint inventor), then the proper remedy would be to correct the inventorship of the '623 patent under 35 U.S.C. § 256 to fix that error. As a result, Plaintiffs have included this Count to seek that remedy as an alternative to the Counts above.

147. Assad Sawaya has suffered and will suffer reputational harm if the inventorship of the '623 patent is not corrected, because his omission as a named inventor on the '623 patent deprives him of the professional credit and benefits associated with patent inventorship and wrongfully confers such advantages exclusively to the named inventors and Paragon.

148. Altaire has an interest in correcting inventorship of the '623 patent to name Assad Sawaya because Assad Sawaya has assigned to Altaire all of his rights in the invention claimed in the '623 patent, yet Altaire cannot license or otherwise exploit the inventions claimed in the '623 patent. Altaire anticipates near immediate financial harm because Altaire reasonably believes that it may be sued for infringement of the '623 patent upon termination of the Agreement, upon Altaire filing its ANDA to allow it to resume sales of its Phenylephrine Products. Altaire also suffers ongoing reputational harm from the omission of Assad Sawaya as a named inventor on the '623 patent because the patent does not reflect the innovative contributions of Assad Sawaya and Altaire.

149. Under 35 U.S.C. § 256, Plaintiffs are entitled to a judgment ordering correction of the '623 patent to add Assad Sawaya as the sole inventor or a joint inventor, and to an order that the Director of the USPTO correct the '623 patent to add Assad Sawaya as named inventor and to remove any inventors who did not, in fact, contribute to the conception of the claimed subject matter.

DEMAND FOR JURY TRIAL

150. Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiffs hereby demand a jury trial on all issues and causes of action triable to a jury. Further, Plaintiffs hereby request that an advisory jury be empaneled pursuant to FED. R. CIV. P. 39(c) on all issues and causes of action not triable to a jury under Rule 38.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request:

- A. A declaration that the '623 patent is invalid under 35 U.S.C. §§ 101, 102, or 103;
- B. A declaration that the '623 patent is unenforceable;
- C. Alternatively, a judgment that Assad Sawaya is the sole inventor or a co-inventor of the '623 patent;
- D. Alternatively, an order pursuant to 35 U.S.C. § 256 to the USPTO to correct the '623 patent to name Assad Sawaya as the sole or joint inventor thereof;
- E. An injunction against Paragon from further filing patent applications related to the '771 application;
- F. An award of attorneys' fees and costs of suit;
- G. Any such further and additional relief as the Court deems appropriate.

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Respectfully submitted,

By: /s/ Michael F. Autuoro
Michael F. Autuoro
FISH & RICHARDSON P.C.
601 Lexington Avenue, 52nd Floor
New York, NY 1002
Telephone: (212) 765-5070
Facsimile: (212) 765-2331

Ahmed J. Davis
Sarah M. Cork
Laura C. Whitworth
FISH & RICHARDSON P.C.
1425 K Street, N.W., 11th Floor
Washington, D.C. 20005
Telephone: (202) 783-5070
Facsimile: (202) 783-2331

Craig E. Countryman
Oliver J. Richards
FISH & RICHARDSON P.C.
12390 El Camino Real
San Diego, CA 92130
Telephone: (858) 678-5070
Facsimile: (858) 678-5099