

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

W. R. Grace & Co.-Conn.,

C.A. No.

Plaintiff,

v.

JURY TRIAL DEMANDED

Elysium Health, Inc.,

Defendant.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff W. R. Grace & Co.-Conn. (“Grace” or “Plaintiff”), by and through its undersigned counsel, files this Complaint against Elysium Health, Inc. (“Elysium” or “Defendant”), and alleges as follows:

NATURE OF THE ACTION

1. Grace brings this action to compel Elysium to: (i) cease infringement of U.S. Patent No. 10,233,207 (“the ’207 Patent”), U.S. Patent No. 10,323,058 (“the ’058 Patent”); and U.S. Patent No. 10,189,872 (“the ’872 Patent”) based on Elysium’s unauthorized commercial manufacture, use, offer for sale, sale, and/or importation of its dietary supplement BASIS® containing crystalline Form I and/or Form II of nicotinamide riboside chloride (“NRCI”) in the United States; and (ii) compensate Grace for Elysium’s infringement and willful infringement of those patents and Grace’s provisional rights in those patents.

2. A true and correct copy of the ’207 Patent is attached as Exhibit A.

3. A true and correct copy of the ’058 Patent is attached as Exhibit B.

4. A true and correct copy of the ’872 Patent is attached as Exhibit C.

5. Grace is the owner of all right, title, and interest in and to the '207, '058, and '872 Patents, with full right to bring suit to enforce the Patents, including the right to sue for past, present, and future infringement.

THE PARTIES

6. Grace is a corporation organized under the laws of the State of Connecticut with its principal place of business at 7500 Grace Drive, Columbia, MD 21044.

7. Upon information and belief, Elysium is a corporation organized under the laws of the State of Delaware and having a principal place of business located at 934 Broadway, Floor 2, New York, NY, 10013.

8. Upon information and belief, Elysium makes or has made, uses or has used, offers for sale or has offered for sale, and sells or has sold the dietary supplement BASIS® containing Form I and/or Form II NRCl to customers nationwide, including to residents of Delaware.

JURISDICTION AND VENUE

9. This is an action arising under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, including but not limited to 35 U.S.C. §§ 154, 271 and 281–85.

10. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338.

11. This Court has personal jurisdiction over Elysium consistent with the Due Process Clause of the U.S. Constitution and the Delaware Long-Arm Statute.

12. This Court has personal jurisdiction over Elysium because it is a corporation organized under the laws of the State of Delaware with a registered agent for service of process in the State of Delaware: Corporation Service Company, 251 Little Falls Drive, Wilmington,

Delaware, 19808. Therefore, Elysium resides within, and has consented to, personal jurisdiction within this District.

13. This Court has personal jurisdiction over Elysium because it has systematic and continuous contacts with this judicial district, and, on information and belief, has committed acts of patent infringement giving rise to this action within this judicial district, including by placing its BASIS® product containing Form I and/or Form II NRCl into the stream of commerce in this district, such that Elysium reasonably should have anticipated being subject to suit in this judicial district.

14. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400(b), at least because Elysium resides in this district by virtue of its organization under the laws of the State of Delaware.

THE PATENTS-IN-SUIT

15. The '207 Patent, entitled "Crystalline Form of Nicotinamide Riboside," was duly and legally issued by the United States Patent and Trademark Office on March 19, 2019, and names Erik Carlson, Michael Standen, and Westin Morrill as inventors. Messrs. Carlson, Standen, and Morrill assigned their inventions as disclosed in the '207 Patent to Grace. The '207 Patent is valid and enforceable. The '207 Patent claims, *inter alia*, crystalline Form I NRCl, methods for increasing nicotinamide adenine dinucleotide ("NAD") concentration by administering crystalline Form I NRCl, and a method for supplementing the diet by administering crystalline Form I NRCl.

16. The '058 Patent, entitled "Crystalline Form of Nicotinamide Riboside," was duly and legally issued by the United States Patent and Trademark Office on June 18, 2019, and

names Erik Carlson, Michael Standen, and Westin Morrill as inventors. Messrs. Carlson, Standen, and Morrill assigned their inventions as disclosed in the '058 Patent to Grace. The '058 Patent is valid and enforceable. The '058 Patent claims, *inter alia*, crystalline Form I NRCl, methods for increasing NAD concentration by administering crystalline Form I NRCl, and a method for supplementing the diet by administering crystalline Form I NRCl.

17. The '872 Patent, entitled "Crystalline Form of Nicotinamide Riboside," was duly and legally issued by the United States Patent and Trademark Office on January 29, 2019, and names Erik Carlson and Jose Osuna as inventors. Messrs. Carlson and Osuna assigned their inventions as disclosed in the '872 Patent to Grace. The '872 Patent is valid and enforceable. The '872 Patent claims, *inter alia*, crystalline Form II NRCl and pharmaceutical compositions thereof, methods of making crystalline Form II NRCl, and a method of administering crystalline Form II NRCl.

18. On March 29, 2018, United States Patent Application Publication No. US 2018/0086783 ("the '783 Publication") was published. The application of the '783 Publication resulted in the '207 Patent. A true and correct copy of the '783 Publication is attached as Exhibit D.

19. On July 27, 2017, United States Patent Application Publication No. US 2017/0210774 ("the '774 Publication") was published. The application of the '774 Publication resulted in the '058 Patent. A true and correct copy of the '774 Publication is attached as Exhibit E.

20. On February 1, 2018, United States Patent Application Publication No. US 2018/0030079 ("the '079 Publication") was published. The application of the '079 Publication

resulted in the '872 Patent. A true and correct copy of the '079 Publication is attached as Exhibit F.

21. On information and belief, Elysium has known of the existence of the '207, '058, and '872 Patents, and the existence of the '783, '774, and '079 Publications. For example, on March 27, 2019, a deposition of Elysium's Chief Executive Officer, Eric Marcotulli, was taken in the lawsuit *ChromaDex, Inc. v. Elysium Health, Inc.*, No. 8:16-cv-02277 (C.D. Cal.), which involves breach of contract allegations relating to Elysium's BASIS®, and was later filed in that case at Dkt. 285-2 ("Elysium's Deposition Testimony"). During the deposition, in response to the question "[d]o you remember any patents from Grace?" Mr. Marcotulli testified: "I do believe, at some point, we were made aware that there is a – and I don't know the specifics – some form of either manufacturing process patent or possibly a crystalline structure patent, I'm not sure which. But I'm aware there was an application at one point that was brought to our attention with respect to Grace." *Id.* at 329:22-330:5.

22. In addition, the filing of this Complaint provides actual notice to Elysium of the '207, '058, and '872 Patents under 35 U.S.C. § 287.

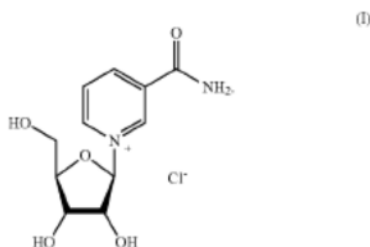
FACTUAL BACKGROUND

23. Elysium markets BASIS® as a daily supplement containing crystalline nicotinamide riboside that promotes a healthy cellular aging process. For example, Elysium instructs its customers, as a "suggested use" of BASIS®, to "take two (2) capsules every morning with or without food." Elysium represents that BASIS® is "clinically proven to increase NAD+ levels by an average of 40%, safely and sustainably."

A. The '207 Patent Claims

24. Claim 1 of the '207 Patent recites:

A crystalline Form I of nicotinamide riboside chloride according to formula I



that is characterized by a powder X-ray diffraction pattern having peaks at 5.1, 15.7, and 21.7 degrees two theta \pm 0.2 degrees two theta.

25. Claim 20 of the '207 Patent recites:

A method for increasing nicotinamide adenine dinucleotide (NAD) concentration in a subject in need thereof comprising administering to the subject a pharmaceutically acceptable amount of the crystalline Form I according to claim 1.

26. Claim 23 of the '207 Patent recites:

A method for supplementing the diet of a subject comprising administering to the subject a pharmaceutically acceptable amount of the crystalline Form I according to claim 1.

27. Additional dependent claims of the '207 Patent specify further limitations, for example, a "powder X-ray diffraction pattern substantially as shown in FIG. 1" (claim 2); a "powder X-ray diffraction pattern having peaks substantially as shown in Table 1 \pm 0.2 degrees two theta" (claim 3); administering the crystalline Form I "in a composition that further comprises a pharmaceutically acceptable excipient" (claim 21); and a method wherein "said administration provides increased insulin sensitivity, enhancement of sirtuin function, improved mitochondrial health or function, increased production of mitochondria, or neuroprotection" (claim 22).

28. On information and belief, BASIS® or its use satisfies each and every limitation of at least claims 1-3 and 20-23 of the '207 Patent either literally or under the doctrine of equivalents.

29. Elysium obtains the NRCI that it uses in BASIS® from unauthorized sources who do not have any ownership or license rights to the '207 Patent.

30. On information and belief, BASIS® comprises crystalline Form I NRCI.

31. Elysium represents on its product label that BASIS® comprises a crystalline nicotinamide riboside material.

32. Elysium represents on its product label that BASIS® comprises other ingredients including microcrystalline cellulose, hypromellose, vegetable magnesium stearate, and silica. On information and belief, the microcrystalline cellulose, hypromellose, vegetable magnesium stearate, and silica in BASIS® are pharmaceutically acceptable excipients.

33. Elysium represents to the public that BASIS® increases NAD+ levels in the body upon oral administration.

34. Elysium represents to the public that administration of BASIS® activates sirtuins, supports cellular energy and metabolism, promotes healthy cellular aging process, and helps maintain healthy DNA.

35. On information and belief, BASIS® contains a crystalline Form I of NRCI according to formula I identified in claim 1 of the '207 Patent that is characterized by a powder X-ray diffraction pattern having peaks at 5.1, 15.7, and 21.7 degrees two theta ± 0.2 degrees two theta, and therefore meets each and every limitation of claim 1 of the '207 Patent.

36. On information and belief, BASIS® contains a crystalline Form I according to claim 1 of the '207 Patent that is characterized by a powder X-ray diffraction pattern

substantially as shown in FIG. 1 of the '207 Patent, and therefore meets each and every limitation of claim 2 of the '207 Patent.

37. On information and belief, BASIS® contains a crystalline Form I according to claim 1 of the '207 Patent that is characterized by a powder X-ray diffraction pattern having peaks substantially as shown in Table 1 ± 0.2 degrees two theta, and therefore meets each and every limitation of claim 3 of the '207 Patent.

38. On information and belief, administering BASIS® is a method for increasing NAD concentration in a subject in need thereof comprising administering to the subject a pharmaceutically acceptable amount of the crystalline Form I according to claim 1 of the '207 Patent, and administering BASIS® therefore meets each and every limitation of claim 20 of the '207 Patent.

39. On information and belief, as specified in claim 21 of the '207 Patent, BASIS® contains “a pharmaceutically acceptable excipient,” including, for example, microcrystalline cellulose, hypromellose, vegetable magnesium stearate, or silica, and administering BASIS® therefore meets each and every limitation of claim 21 of the '207 Patent.

40. On information and belief, as specified in claim 22 of the '207 Patent, administration of BASIS® “provides increased insulin sensitivity, enhancement of sirtuin function, improved mitochondrial health or function, increased production of mitochondria, or neuroprotection,” and administering BASIS® therefore meets each and every limitation of claim 22 of the '207 Patent.

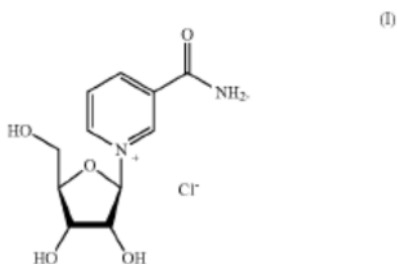
41. On information and belief, administering BASIS® is a method for supplementing the diet of a subject comprising administering to the subject a pharmaceutically acceptable

amount of the crystalline Form I according to claim 1, and administering BASIS® therefore meets each and every limitation of claim 23 of the '207 Patent.

B. The '058 Patent Claims

42. Claim 1 of the '058 Patent recites:

A crystalline Form I of nicotinamide riboside chloride according to formula I



43. Claim 20 of the '058 Patent recites:

A method for increasing nicotinamide adenine dinucleotide (NAD) concentration in a subject in need thereof comprising administering to the subject a pharmaceutically acceptable amount of the crystalline Form I according to claim 1.

44. Claim 23 of the '058 Patent recites:

A method for supplementing the diet of a subject comprising administering to the subject a pharmaceutically acceptable amount of the crystalline Form I according to claim 1.

45. Additional dependent claims of the '058 Patent specify further limitations, for example, a “powder X-ray diffraction pattern substantially as shown in FIG. 1” (claim 2); a “powder X-ray diffraction pattern having peaks substantially as shown in Table 1 ± 0.2 degrees two theta” (claim 3); administering the crystalline Form I “in a composition that further comprises a pharmaceutically acceptable excipient” (claim 21); and a method wherein “said administration provides increased insulin sensitivity, enhancement of sirtuin function, improved

mitochondrial health or function, increased production of mitochondria, or neuroprotection” (claim 22).

46. On information and belief, BASIS® or its use satisfies each and every limitation of at least claims 1-3 and 20-23 of the '058 Patent either literally or under the doctrine of equivalents.

47. Elysium obtains the NRCl that it uses in BASIS® from unauthorized sources who do not have any ownership or license rights to the '058 Patent.

48. On information and belief, BASIS® comprises crystalline Form I NRCl.

49. Elysium represents on its product label that BASIS® comprises a crystalline nicotinamide riboside material.

50. Elysium represents on its product label that BASIS® comprises other ingredients, including microcrystalline cellulose, hypromellose, vegetable magnesium stearate, and silica. On information and belief, the microcrystalline cellulose, hypromellose, vegetable magnesium stearate, and silica in BASIS® are pharmaceutically acceptable excipients.

51. Elysium represents to the public that BASIS® increases NAD⁺ levels in the body upon oral administration.

52. Elysium represents to the public that administration of BASIS® activates sirtuins, supports cellular energy and metabolism, promotes healthy cellular aging process, and helps maintain healthy DNA.

53. On information and belief, BASIS® contains a crystalline Form I of NRCl according to formula I identified in claim 1 of the '058 Patent, and therefore meets each and every limitation of claim 1 of the '058 Patent.

54. On information and belief, BASIS® contains a crystalline Form I according to claim 1 of the '058 Patent that is characterized by a powder X-ray diffraction pattern substantially as shown in FIG. 1 of the '058 Patent, and therefore meets each and every limitation of claim 2 of the '058 Patent.

55. On information and belief, BASIS® contains a crystalline Form I according to claim 1 of the '058 Patent that is characterized by a powder X-ray diffraction pattern having peaks substantially as shown in Table 1 ± 0.2 degrees two theta, and therefore meets each and every limitation of claim 3 of the '058 Patent.

56. On information and belief, administering BASIS® is a method for increasing NAD concentration in a subject in need thereof comprising administering to the subject a pharmaceutically acceptable amount of the crystalline Form I according to claim 1 of the '058 Patent, and administering BASIS® therefore meets each and every limitation of claim 20 of the '058 Patent.

57. On information and belief, as specified in claim 21 of the '058 Patent, BASIS® contains “a pharmaceutically acceptable excipient,” including, for example, microcrystalline cellulose, hypromellose, vegetable magnesium stearate, or silica, and administering BASIS® therefore meets each and every limitation of claim 21 of the '058 Patent.

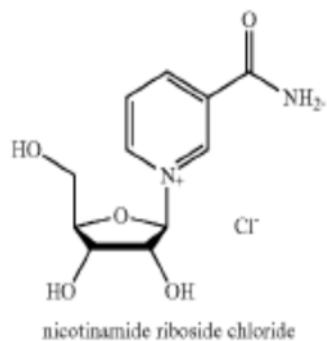
58. On information and belief, as specified in claim 22 of the '058 Patent, administration of BASIS® “provides increased insulin sensitivity, enhancement of sirtuin function, improved mitochondrial health or function, increased production of mitochondria, or neuroprotection,” and administering BASIS® therefore meets each and every limitation of claim 22 of the '058 Patent.

59. On information and belief, orally administering BASIS® is a method for supplementing the diet of a subject comprising administering to the subject a pharmaceutically acceptable amount of the crystalline Form I according to claim 1, and administering BASIS® therefore meets each and every limitation of claim 23 of the '058 Patent.

C. The '872 Patent Claims

60. Claim 1 of the '872 Patent recites:

A crystalline Form II of nicotinamide riboside chloride



61. Claim 15 of the '872 Patent recites:

A pharmaceutical composition comprising the crystalline Form II according to claim 1 and a pharmaceutically acceptable excipient.

62. Claim 16 of the '872 Patent recites:

A method of producing a pharmaceutical composition comprising combining the crystalline Form II according to claim 1 with a pharmaceutically acceptable excipient.

63. Claim 17 of the '872 Patent recites:

A method comprising administering to a subject the crystalline Form II according to claim 1 or the pharmaceutical composition of Claim 15.

64. Additional dependent claims of the '872 Patent specify further limitations, for example, a “powder X-ray diffraction pattern having peaks at 21.9, 22.1, and 24.7 degrees two

theta±0.2 degrees two theta” (claim 2); a “powder X-ray diffraction pattern having peaks at 21.2, 21.9, 22.1, 24.7, and 33.8 degrees two theta±0.2 degrees two theta” (claim 3); a “powder X-ray diffraction pattern having peaks at 21.2, 21.9, 22.1, 23.9, 24.7, 29.6, and 33.8 degrees two theta±0.2 degrees two theta” (claim 4); a “powder X-ray diffraction pattern having peaks at 10.2, 10.7, 13.8, 21.2, 21.9, 22.1, 23.2, 23.9, 24.7, 29.6, and 33.8 degrees two theta±0.2 degrees two theta” (claim 5); a “powder X-ray diffraction pattern substantially as shown in FIG. 1” (claim 6); a “powder X-ray diffraction pattern having peaks substantially as shown in Table 1±0.2 degrees two theta” (claim 7).

65. On information and belief, BASIS® or its use satisfies each and every limitation of at least claims 1-7 and 15-17 of the '872 Patent either literally or under the doctrine of equivalents.

66. Elysium obtains the NRCI that it uses in BASIS® from unauthorized sources who do not have any ownership or license rights to the '872 Patent.

67. On information and belief, BASIS® comprises crystalline Form II NRCI.

68. Elysium represents on its product label that BASIS® comprises a crystalline nicotinamide riboside material.

69. Elysium represents on its product label that BASIS® comprises other ingredients, including microcrystalline cellulose, hypromellose, vegetable magnesium stearate, and silica. On information and belief, the microcrystalline cellulose, hypromellose, vegetable magnesium stearate, and silica in BASIS® are pharmaceutically acceptable excipients.

70. Elysium encourages its customers to administer BASIS®.

71. On information and belief, BASIS® comprises a pharmaceutical composition.

72. On information and belief, BASIS® contains a crystalline Form II of NRCI identified in claim 1 of the '872 Patent, and therefore meets each and every limitation of claim 1 of the '872 Patent.

73. On information and belief, BASIS® contains a crystalline Form II according to claim 1 of the '872 Patent that is characterized by a powder X-ray diffraction pattern having peaks at 21.9, 22.1, and 24.7 degrees two theta \pm 0.2 degrees two theta, and therefore meets each and every limitation of claim 2 of the '872 Patent.

74. On information and belief, BASIS® contains a crystalline Form II according to claim 1 of the '872 Patent that is characterized by a powder X-ray diffraction pattern having peaks at 21.2, 21.9, 22.1, 24.7, and 33.8 degrees two theta \pm 0.2 degrees two theta, and therefore meets each and every limitation of claim 3 of the '872 Patent.

75. On information and belief, BASIS® contains a crystalline Form II according to claim 1 of the '872 Patent that is characterized by a powder X-ray diffraction pattern having peaks at 21.2, 21.9, 22.1, 23.9, 24.7, 29.6, and 33.8 degrees two theta \pm 0.2 degrees two theta, and therefore meets each and every limitation of claim 4 of the '872 Patent.

76. On information and belief, BASIS® contains a crystalline Form II according to claim 1 of the '872 Patent that is characterized by a powder X-ray diffraction pattern having peaks at 10.2, 10.7, 13.8, 21.2, 21.9, 22.1, 23.2, 23.9, 24.7, 29.6, and 33.8 degrees two theta \pm 0.2 degrees two theta, and therefore meets each and every limitation of claim 5 of the '872 Patent.

77. On information and belief, BASIS® contains a crystalline Form II according to claim 1 of the '872 Patent that is characterized by a powder X-ray diffraction pattern substantially as shown in FIG. 1, and therefore meets each and every limitation of claim 6 of the '872 Patent.

78. On information and belief, BASIS® contains a crystalline Form II according to claim 1 of the '872 Patent that is characterized by a powder X-ray diffraction pattern having peaks substantially as shown in Table 1 ± 0.2 degrees two theta, and therefore meets each and every limitation of claim 7 of the '872 Patent.

79. On information and belief, as specified in claim 15 of the '872 Patent, BASIS® comprises a pharmaceutical composition comprising crystalline Form II according to claim 1 of the '872 Patent and a pharmaceutically acceptable excipient, for example microcrystalline cellulose, hypromellose, vegetable magnesium stearate, or silica, and therefore meets each and every limitation of claim 15 of the '872 Patent.

80. On information and belief, as specified in claim 16 of the '872 Patent, BASIS® is a pharmaceutical composition that is produced by a method comprising combining the crystalline Form II of claim 1 of the '872 Patent with a pharmaceutically acceptable excipient, and therefore meets each and every limitation of claim 16 of the '872 Patent.

81. On information and belief, administering BASIS® is a method comprising administering to a subject the crystalline Form II according to claim 1 or the pharmaceutical composition of claim 15 of the '872 Patent, and administering BASIS® therefore meets each and every limitation of claim 17 of the '872 Patent.

Count I
(Infringement of U.S. Patent No. 10,233,207)

82. Grace re-alleges and incorporates by reference Paragraphs 1-2, 5-15, 18, and 21-41 of its Complaint, as if fully set forth herein.

A. Direct Infringement

83. For the reasons set forth in detail above, on information and belief, Elysium has been, and is still knowingly and intentionally directly infringing, literally and/or under the doctrine of equivalents, one or more claims of the '207 Patent, including at least claims 1-3, by making, having made, using, selling, having sold, offering to sell, and/or importing BASIS® in or into the United States, without authority. Thus, Elysium is liable for its infringement of the '207 Patent in violation of 35 U.S.C. § 271(a).

84. On information and belief, Elysium's customers have been, and are still directly infringing, literally and/or under the doctrine of equivalents, one or more claims of the '207 Patent, including at least claims 1-3 and 20-23, by using BASIS® in the United States, without authority.

B. Induced Infringement

85. For the reasons set forth in detail above, on information and belief, Elysium has had actual knowledge of the '207 Patent.

86. On information and belief, Elysium did possess, and still possesses, actual knowledge that BASIS® infringes one or more claims of the '207 Patent.

87. In addition, the filing of this Complaint provides actual notice to Elysium of the infringement as alleged herein.

88. Despite such actual knowledge, Elysium has been, and continues to make, use, sell, offer for sale, market, and/or import into the United States, its BASIS® product that infringes the '207 Patent. On information and belief, Elysium has been and continues to market BASIS®, including but not limited to on its product packaging, website, and on social media, in a manner to induce others to use BASIS® in the customary and intended manner that infringes

the '207 Patent. For example, Elysium instructs its customers, as a “suggested use” of BASIS®, to “take two (2) capsules every morning with or without food.” Thus, on information and belief, Elysium has been and continues to actively, knowingly, and intentionally induce infringement of the '207 Patent.

89. On information and belief, BASIS® contains a crystalline Form I of NRCl according to formula I identified in claim 1 of the '207 Patent that is characterized by a powder X-ray diffraction pattern having peaks at 5.1, 15.7, and 21.7 degrees two theta ± 0.2 degrees two theta, and therefore infringes claim 1 of the '207 Patent. On information and belief, Elysium has actively, knowingly, and intentionally encouraged and facilitated, and continues to actively, knowingly, and intentionally encourage and facilitate, others to directly infringe claim 1 of the '207 Patent by instructing, directing, and/or advising others how to make, administer, and use BASIS® in a way that induces infringement of claim 1 of the '207 Patent.

90. On information and belief, BASIS® contains a crystalline Form I according to claim 1 that is characterized by a powder X-ray diffraction pattern substantially as shown in FIG. 1 of the '207 Patent, and therefore infringes claim 2 of the '207 Patent. On information and belief, Elysium has actively, knowingly, and intentionally encouraged and facilitated, and continues to actively, knowingly, and intentionally encourage and facilitate, others to directly infringe claim 2 of the '207 Patent by instructing, directing, and/or advising others how to make, administer, and use BASIS® in a way that induces infringement of claim 2 of the '207 Patent.

91. On information and belief, BASIS® contains a crystalline Form I according to claim 1 that is characterized by a powder X-ray diffraction pattern having peaks substantially as shown in Table 1 ± 0.2 degrees two theta, and therefore infringes claim 3 of the '207 Patent. On information and belief, Elysium has actively, knowingly, and intentionally encouraged and

facilitated, and continues to actively, knowingly, and intentionally encourage and facilitate, others to directly infringe claim 3 of the '207 Patent by instructing, directing, and/or advising others how to make, administer, and use BASIS® in a way that induces infringement of claim 3 of the '207 Patent.

92. On information and belief, administering BASIS® is a method for increasing NAD concentration in a subject in need thereof comprising administering to the subject a pharmaceutically acceptable amount of the crystalline Form I according to claim 1 of the '207 Patent, and administering BASIS® therefore infringes claim 20 of the '207 Patent. On information and belief, Elysium has actively, knowingly, and intentionally encouraged and facilitated, and continues to actively, knowingly, and intentionally encourage and facilitate, others to directly infringe claim 20 of the '207 Patent by instructing, directing, and/or advising others how to make, administer, and use BASIS® in a way that induces infringement of claim 20 of the '207 Patent.

93. On information and belief, as specified in claim 21 of the '207 Patent, BASIS® contains “a pharmaceutically acceptable excipient,” and administering BASIS® therefore infringes claim 21 of the '207 Patent. On information and belief, Elysium has actively, knowingly, and intentionally encouraged and facilitated, and continues to actively, knowingly, and intentionally encourage and facilitate, others to directly infringe claim 21 of the '207 Patent by instructing, directing, and/or advising others how to make, administer, and use BASIS® in a way that induces infringement of claim 21 of the '207 Patent.

94. On information and belief, as specified in claim 22 of the '207 Patent, administration of BASIS® “provides increased insulin sensitivity, enhancement of sirtuin function, improved mitochondrial health or function, increased production of mitochondria, or

neuroprotection,” and administering BASIS® therefore infringes claim 22 of the ’207 Patent. On information and belief, Elysium has actively, knowingly, and intentionally encouraged and facilitated, and continues to actively, knowingly, and intentionally encourage and facilitate, others to directly infringe claim 22 of the ’207 Patent by instructing, directing, and/or advising others how to make, administer, and use BASIS® in a way that induces infringement of claim 22 of the ’207 Patent.

95. On information and belief, administering BASIS® is a method for supplementing the diet of a subject comprising administering to the subject a pharmaceutically acceptable amount of the crystalline Form I according to claim 1, and administering BASIS® therefore infringes claim 23 of the ’207 Patent. On information and belief, Elysium has actively, knowingly, and intentionally encouraged and facilitated, and continues to actively, knowingly, and intentionally encourage and facilitate, others to directly infringe claim 23 of the ’207 Patent by instructing, directing, and/or advising others how to make, administer, and use BASIS® in a way that induces infringement of claim 23 of the ’207 Patent.

96. For the reasons set forth in detail above, on information and belief, Elysium has been, and is still, actively, knowingly, and intentionally inducing infringement, literally and/or under the doctrine of equivalents, of one or more claims of the ’207 Patent, including at least claims 1-3 and 20-23, by actively encouraging others to make, have made, use, offer for sale, sell, have sold, and/or import BASIS® in or into the United States, without authority. Thus, Elysium is liable as an active inducer of infringement of the ’207 Patent in violation of 35 U.S.C. § 271(b).

C. Contributory Infringement

97. For the reasons set forth in detail above, on information and belief, Elysium has had actual knowledge of the '207 Patent.

98. In addition, the filing of this Complaint provides actual notice to Elysium of the infringement as alleged here.

99. Despite such actual knowledge, Elysium has been and continues to actively, knowingly, and intentionally contribute to its customers' infringement of the '207 Patent, literally or by the doctrine of equivalents, by selling BASIS® to customers for use in a manner that infringes one or more claims of the '207 Patent. For example, Elysium instructs its customers, as a "suggested use" of BASIS®, to "take two (2) capsules every morning with or without food."

100. On information and belief, Elysium did possess, and still possesses, knowledge and awareness that BASIS® is especially made or adapted for use in an infringement of the '207 Patent claims, and that BASIS® includes a material component for use in practicing the '207 Patent claims. On information and belief, BASIS® is not a staple article or commodity of commerce suitable for substantial non-infringing use.

101. On information and belief, BASIS® contains a material component for use in practicing claim 1 of the '207 Patent, i.e., a crystalline Form I of NRCl according to formula I identified in claim 1 of the '207 Patent that is characterized by a powder X-ray diffraction pattern having peaks at 5.1, 15.7, and 21.7 degrees two theta ± 0.2 degrees two theta. On information and belief, Elysium did possess, and still possesses, knowledge and awareness that BASIS® includes such a material component for use in practicing claim 1 of the '207 Patent, and that BASIS® is especially made or adapted for use in an infringement of claim 1 of the '207 Patent. On

information and belief, BASIS® is not a staple article or commodity of commerce suitable for substantial non-infringing use of claim 1 of the '207 Patent.

102. On information and belief, BASIS® contains a material component for use in practicing claim 2 of the '207 Patent, i.e., a crystalline Form I according to claim 1 that is characterized by a powder X-ray diffraction pattern substantially as shown in FIG. 1 of the '207 Patent. On information and belief, Elysium did possess, and still possesses, knowledge and awareness that BASIS® includes such a material component for use in practicing claim 2 of the '207 Patent, and that BASIS® is especially made or adapted for use in an infringement of claim 2 of the '207 Patent. On information and belief, BASIS® is not a staple article or commodity of commerce suitable for substantial non-infringing use of claim 2 of the '207 Patent.

103. On information and belief, BASIS® contains a material component for use in practicing claim 3 of the '207 Patent, i.e., a crystalline Form I according to claim 1 that is characterized by a powder X-ray diffraction pattern having peaks substantially as shown in Table 1 ± 0.2 degrees two theta. On information and belief, Elysium did possess, and still possesses, knowledge and awareness that BASIS® includes such a material component for use in practicing claim 3 of the '207 Patent, and that BASIS® is especially made or adapted for use in an infringement of claim 3 of the '207 Patent. On information and belief, BASIS® is not a staple article or commodity of commerce suitable for substantial non-infringing use of claim 3 of the '207 Patent.

104. On information and belief, BASIS® contains a material component for use in practicing claim 20 of the '207 Patent, i.e., a pharmaceutically acceptable amount of the crystalline Form I according to claim 1 of the '207 Patent that increases NAD concentration in a subject upon administration. On information and belief, Elysium did possess, and still possesses,

knowledge and awareness that BASIS® includes such a material component for use in practicing claim 20 of the '207 Patent, and that BASIS® is especially made or adapted for use in an infringement of claim 20 of the '207 Patent. On information and belief, BASIS® is not a staple article or commodity of commerce suitable for substantial non-infringing use of claim 20 of the '207 Patent.

105. On information and belief, BASIS® contains a material component for use in practicing claim 21 of the '207 Patent, i.e., a pharmaceutically acceptable amount of the crystalline Form I according to claim 1 of the '207 Patent in a composition that further comprises a pharmaceutically acceptable excipient, and that increases NAD concentration in a subject upon administration. On information and belief, Elysium did possess, and still possesses, knowledge and awareness that BASIS® includes such a material component for use in practicing claim 21 of the '207 Patent, and that BASIS® is especially made or adapted for use in an infringement of claim 21 of the '207 Patent. On information and belief, BASIS® is not a staple article or commodity of commerce suitable for substantial non-infringing use of claim 21 of the '207 Patent.

106. On information and belief, BASIS® contains a material component for use in practicing claim 22 of the '207 Patent, i.e., a pharmaceutically acceptable amount of the crystalline Form I according to claim 1 of the '207 Patent that increases NAD concentration in a subject upon administration and that provides increased insulin sensitivity, enhancement of sirtuin function, improved mitochondrial health or function, increased production of mitochondria, or neuroprotection. On information and belief, Elysium did possess, and still possesses, knowledge and awareness that BASIS® includes such a material component for use in practicing claim 22 of the '207 Patent, and that BASIS® is especially made or adapted for use in

an infringement of claim 22 of the '207 Patent. On information and belief, BASIS® is not a staple article or commodity of commerce suitable for substantial non-infringing use of claim 22 of the '207 Patent.

107. On information and belief, BASIS® contains a material component for use in practicing claim 23 of the '207 Patent, i.e., a pharmaceutically acceptable amount of the crystalline Form I according to claim 1 of the '207 Patent that is used to supplement the diet of a subject. On information and belief, Elysium did possess, and still possesses, knowledge and awareness that BASIS® includes such a material component for use in practicing claim 23 of the '207 Patent, and that BASIS® is especially made or adapted for use in an infringement of claim 23 of the '207 Patent. On information and belief, BASIS® is not a staple article or commodity of commerce suitable for substantial non-infringing use of claim 23 of the '207 Patent.

108. For the reasons set forth above in detail, on information and belief, Elysium has been, and is still, knowingly, and intentionally contributorily infringing, literally and/or under the doctrine of equivalents, one or more claims of the '207 Patent, including at least claims 1-3 and 20-23, by making, having made, having sold, using, selling, offering to sell, and/or importing BASIS® in or into the United States, without authority, and with knowledge and awareness that BASIS® is especially made or adapted for use in an infringement of the '207 Patent, that BASIS® includes a material component for use in practicing the '207 Patent, and that BASIS® is not a staple article or commodity of commerce suitable for substantial non-infringing use. Thus, Elysium is liable for its infringement of the '207 Patent in violation of 35 U.S.C. § 271(c).

D. Willful Infringement

109. On information and belief, Elysium's infringement of the '207 Patent has been willful, intentional, and deliberate. For the reasons set forth in detail above, on information and

belief, Elysium has had actual knowledge of the '207 Patent, and actual knowledge that BASIS® infringes one or more claims of the '207 Patent. Elysium knew or should have known of the '207 Patent and its infringement of one or more claims thereof at least based on the Elysium Deposition Testimony. In addition, the filing of this Complaint provides actual notice to Elysium of the '207 Patent under 35 U.S.C. § 287 and the infringement as alleged here.

110. Grace has been damaged by the infringing acts of Elysium and will continue to be damaged unless Elysium is enjoined from infringing the '207 Patent.

**Count II:
(Infringement of Grace's Provisional Rights in the '207 Patent)**

111. Plaintiff realleges and incorporates by reference Paragraphs 1-2, 5-15, 18, 21-41, and 82-110, inclusive, as if fully set forth herein.

112. On information and belief, Elysium had actual notice of the '783 Publication prior to the issuance of the '207 Patent.

113. The '783 Publication includes claims that are substantially identical to the claims of the '207 Patent.

114. On information and belief, Elysium has directly infringed, literally and/or under the doctrine of equivalents, one or more claims of the '207 Patent, including at least claims 1-3, by making, having made, using, selling, having sold, offering to sell, and/or importing BASIS® in or into the United States, without authority. On information and belief, Elysium made, used, sold, offered to sell, and/or imported BASIS® in or into the United States on and/or after the publication of the '783 Publication. Thus, Elysium is liable for its infringement of Grace's provisional rights in the claims of the '207 Patent in violation of 35 U.S.C. § 154(d).

Count III:
(Infringement of U.S. Patent No. 10,323,058)

115. Grace realleges and incorporates by reference Paragraphs 1, 3, 5-14, 16, 19, 21-23, and 42-59 inclusive, as if fully set forth herein.

A. Direct Infringement

116. For the reasons set forth in detail above, on information and belief, Elysium has been, and is still knowingly, and intentionally directly infringing, literally and/or under the doctrine of equivalents, one or more claims of the '058 Patent, including at least claims 1-3, by making, having made, using, selling, having sold, offering to sell, and/or importing BASIS® in or into the United States, without authority. Thus, Elysium is liable for its infringement of the '058 Patent in violation of 35 U.S.C. § 271(a).

117. On information and belief, Elysium's customers have been, and are still directly infringing, literally and/or under the doctrine of equivalents, one or more claims of the '058 Patent, including at least claims 1-3 and 20-23, by using BASIS® in the United States, without authority.

B. Induced Infringement

118. For the reasons set forth in detail above, on information and belief, Elysium has had actual knowledge of the '058 Patent.

119. On information and belief, Elysium did possess, and still possesses, actual knowledge that BASIS® infringes one or more claims of the '058 Patent.

120. In addition, the filing of this Complaint provides actual notice to Elysium of the infringement as alleged here.

121. Despite such actual knowledge, Elysium has been, and continues to make, use, sell, offer for sale, market, and/or import into the United States, its BASIS® product that infringes the '058 Patent. On information and belief, Elysium has been and continues to market BASIS®, including but not limited to on its product packaging, website, and on social media, in a manner to induce others to use BASIS® in the customary and intended manner that infringes the '058 Patent. For example, Elysium instructs its customers, as a “suggested use” of BASIS®, to “take two (2) capsules every morning with or without food.” Thus, on information and belief, Elysium has been and continues to actively, knowingly, and intentionally induce infringement of the '058 Patent.

122. On information and belief, BASIS® contains a crystalline Form I of NRCl according to formula I identified in claim 1 of the '058 Patent, and therefore infringes claim 1 of the '058 Patent. On information and belief, Elysium has actively, knowingly, and intentionally encouraged and facilitated, and continues to actively, knowingly, and intentionally encourage and facilitate, others to directly infringe claim 1 of the '058 Patent by instructing, directing, and/or advising others how to make, administer, and use BASIS® in a way that induces infringement of claim 1 of the '058 Patent.

123. On information and belief, BASIS® contains a crystalline Form I according to claim 1 of the '058 Patent that is characterized by a powder X-ray diffraction pattern substantially as shown in FIG. 1 of the '058 Patent, and therefore infringes claim 2 of the '058 Patent. On information and belief, Elysium has actively, knowingly, and intentionally encouraged and facilitated, and continues to actively, knowingly, and intentionally encourage and facilitate, others to directly infringe claim 2 of the '058 Patent by instructing, directing,

and/or advising others how to make, administer, and use BASIS® in a way that induces infringement of claim 2 of the '058 Patent.

124. On information and belief, BASIS® contains a crystalline Form I according to claim 1 of the '058 Patent that is characterized by a powder X-ray diffraction pattern having peaks substantially as shown in Table 1 ± 0.2 degrees two theta, and therefore infringes claim 3 of the '058 Patent. On information and belief, Elysium has actively, knowingly, and intentionally encouraged and facilitated, and continues to actively, knowingly, and intentionally encourage and facilitate, others to directly infringe claim 3 of the '058 Patent by instructing, directing, and/or advising others how to make, administer, and use BASIS® in a way that induces infringement of claim 3 of the '058 Patent.

125. On information and belief, administering BASIS® is a method for increasing NAD concentration in a subject in need thereof comprising administering to the subject a pharmaceutically acceptable amount of the crystalline Form I according to claim 1 of the '058 Patent, and administering BASIS® therefore infringes claim 20 of the '058 Patent. On information and belief, Elysium has actively, knowingly, and intentionally encouraged and facilitated, and continues to actively, knowingly, and intentionally encourage and facilitate, others to directly infringe claim 20 of the '058 Patent by instructing, directing, and/or advising others how to make, administer, and use BASIS® in a way that induces infringement of claim 20 of the '058 Patent.

126. On information and belief, as specified in claim 21 of the '058 Patent, BASIS® contains “a pharmaceutically acceptable excipient,” and administering BASIS® therefore infringes claim 21 of the '058 Patent. On information and belief, Elysium has actively, knowingly, and intentionally encouraged and facilitated, and continues to actively, knowingly,

and intentionally encourage and facilitate, others to directly infringe claim 21 of the '058 Patent by instructing, directing, and/or advising others how to make, administer, and use BASIS® in a way that induces infringement of claim 21 of the '058 Patent.

127. On information and belief, as specified in claim 22 of the '058 Patent, administration of BASIS® “provides increased insulin sensitivity, enhancement of sirtuin function, improved mitochondrial health or function, increased production of mitochondria, or neuroprotection,” and administering BASIS® therefore infringes claim 22 of the '058 Patent. On information and belief, Elysium has actively, knowingly, and intentionally encouraged and facilitated, and continues to actively, knowingly, and intentionally encourage and facilitate, others to directly infringe claim 22 of the '058 Patent by instructing, directing, and/or advising others how to make, administer, and use BASIS® in a way that induces infringement of claim 22 of the '058 Patent.

128. On information and belief, administering BASIS® is a method for supplementing the diet of a subject comprising administering to the subject a pharmaceutically acceptable amount of the crystalline Form I according to claim 1, and administering BASIS® therefore infringes claim 23 of the '058 Patent. On information and belief, Elysium has actively, knowingly, and intentionally encouraged and facilitated, and continues to actively, knowingly, and intentionally encourage and facilitate, others to directly infringe claim 23 of the '058 Patent by instructing, directing, and/or advising others how to make, administer, and use BASIS® in a way that induces infringement of claim 23 of the '058 Patent.

129. For the reasons set forth in detail above, information and belief, Elysium has been, and is still, knowingly, and intentionally inducing infringement, literally and/or under the doctrine of equivalents, of one or more claims of the '058 Patent, including at least claims 1-3

and 20-23, by actively encouraging others to make, have made, use, offer for sale, sell, have sold, and/or import BASIS® in or into the United States, without authority. Thus, Elysium is liable as an active inducer of infringement of the '058 Patent in violation of 35 U.S.C. § 271(b).

C. Contributory Infringement

130. For the reasons set forth in detail above, on information and belief, Elysium has had actual knowledge of the '058 Patent.

131. In addition, the filing of this Complaint provides actual notice to Elysium of the infringement as alleged here.

132. Despite such actual knowledge, Elysium has been and continues to actively, knowingly, and intentionally contribute to its customers' infringement of the '058 Patent, literally or by the doctrine of equivalents, by selling BASIS® to customers for use in a manner that infringes one or more claims of the '058 Patent. For example, Elysium instructs its customers, as a "suggested use" of BASIS®, to "take two (2) capsules every morning with or without food."

133. On information and belief, Elysium did possess, and still possesses, knowledge and awareness that BASIS® is especially made or adapted for use in an infringement of the '058 Patent claims, and that BASIS® includes a material component for use in practicing the '058 Patent claims. On information and belief, BASIS® is not a staple article or commodity of commerce suitable for substantial non-infringing use.

134. On information and belief, BASIS® contains a material component for use in practicing claim 1 of the '058 Patent, i.e., a crystalline Form I of NRCl according to formula I identified in claim 1 of the '058 Patent. On information and belief, Elysium did possess, and still possesses, knowledge and awareness that BASIS® includes such a material component for use in

practicing claim 1 of the '058 Patent, and that BASIS® is especially made or adapted for use in an infringement of claim 1 of the '058 Patent. On information and belief, BASIS® is not a staple article or commodity of commerce suitable for substantial non-infringing use of claim 1 of the '058 Patent.

135. On information and belief, BASIS® contains a material component for use in practicing claim 2 of the '058 Patent, i.e., a crystalline Form I according to claim 1 of the '058 Patent that is characterized by a powder X-ray diffraction pattern substantially as shown in FIG. 1 of the '058 Patent. On information and belief, Elysium did possess, and still possesses, knowledge and awareness that BASIS® includes such a material component for use in practicing claim 2 of the '058 Patent, and that BASIS® is especially made or adapted for use in an infringement of claim 2 of the '058 Patent. On information and belief, BASIS® is not a staple article or commodity of commerce suitable for substantial non-infringing use of claim 2 of the '058 Patent.

136. On information and belief, BASIS® contains a material component for use in practicing claim 3 of the '058 Patent, i.e., a crystalline Form I according to claim 1 of the '058 Patent that is characterized by a powder X-ray diffraction pattern having peaks substantially as shown in Table 1 ± 0.2 degrees two theta. On information and belief, Elysium did possess, and still possesses, knowledge and awareness that BASIS® includes such a material component for use in practicing claim 3 of the '058 Patent, and that BASIS® is especially made or adapted for use in an infringement of claim 3 of the '058 Patent. On information and belief, BASIS® is not a staple article or commodity of commerce suitable for substantial non-infringing use of claim 3 of the '058 Patent.

137. On information and belief, BASIS® contains a material component for use in practicing claim 20 of the '058 Patent, i.e., a pharmaceutically acceptable amount of the crystalline Form I according to claim 1 of the '058 Patent that increases NAD concentration in a subject upon administration. On information and belief, Elysium did possess, and still possesses, knowledge and awareness that BASIS® includes such a material component for use in practicing claim 20 of the '058 Patent, and that BASIS® is especially made or adapted for use in an infringement of claim 20 of the '058 Patent. On information and belief, BASIS® is not a staple article or commodity of commerce suitable for substantial non-infringing use of claim 20 of the '058 Patent.

138. On information and belief, BASIS® contains a material component for use in practicing claim 21 of the '058 Patent, i.e., a pharmaceutically acceptable amount of the crystalline Form I according to claim 1 of the '058 Patent in a composition that further comprises a pharmaceutically acceptable excipient, and that increases NAD concentration in a subject upon administration. On information and belief, Elysium did possess, and still possesses, knowledge and awareness that BASIS® includes such a material component for use in practicing claim 21 of the '058 Patent, and that BASIS® is especially made or adapted for use in an infringement of claim 21 of the '058 Patent. On information and belief, BASIS® is not a staple article or commodity of commerce suitable for substantial non-infringing use of claim 21 of the '058 Patent.

139. On information and belief, BASIS® contains a material component for use in practicing claim 22 of the '058 Patent, i.e., a pharmaceutically acceptable amount of the crystalline Form I according to claim 1 of the '058 Patent that increases NAD concentration in a subject upon administration and that provides increased insulin sensitivity, enhancement of

sirtuin function, improved mitochondrial health or function, increased production of mitochondria, or neuroprotection. On information and belief, Elysium did possess, and still possesses, knowledge and awareness that BASIS® includes such a material component for use in practicing claim 22 of the '058 Patent, and that BASIS® is especially made or adapted for use in an infringement of claim 22 of the '058 Patent. On information and belief, BASIS® is not a staple article or commodity of commerce suitable for substantial non-infringing use of claim 22 of the '058 Patent.

140. On information and belief, BASIS® contains a material component for use in practicing claim 23 of the '058 Patent, i.e., a pharmaceutically acceptable amount of the crystalline Form I according to claim 1 of the '058 Patent that is used to supplement the diet of a subject. On information and belief, Elysium did possess, and still possesses, knowledge and awareness that BASIS® includes such a material component for use in practicing claim 23 of the '058 Patent, and that BASIS® is especially made or adapted for use in an infringement of claim 23 of the '058 Patent. On information and belief, BASIS® is not a staple article or commodity of commerce suitable for substantial non-infringing use of claim 23 of the '058 Patent.

141. For the reasons set forth above in detail, on information and belief, Elysium has been, and is still, knowingly, and intentionally contributorily infringing, literally and/or under the doctrine of equivalents, one or more claims of the '058 Patent, including at least claims 1-3 and 20-23, by making, having made, having sold, using, selling, offering to sell, and/or importing BASIS® in or into the United States, without authority, and with knowledge and awareness that BASIS® is especially made or adapted for use in an infringement of the '058 Patent, that BASIS® includes a material component for use in practicing the '058 Patent, and that BASIS®

is not a staple article or commodity of commerce suitable for substantial non-infringing use.

Thus, Elysium is liable for its infringement of the '058 Patent in violation of 35 U.S.C. § 271(c).

D. Willful Infringement

142. On information and belief, Elysium's infringement of the '058 Patent has been willful, intentional, and deliberate. For the reasons set forth in detail above, on information and belief, Elysium has had actual knowledge of the '058 Patent, and actual knowledge that BASIS® infringes one or more claims of the '058 Patent. Elysium knew or should have known of the '058 Patent and its infringement of one or more claims thereof at least based on the Elysium Deposition Testimony. In addition, the filing of this Complaint provides actual notice to Elysium of the '058 Patent under 35 U.S.C. § 287 and the infringement as alleged here.

143. Grace has been damaged by the infringing acts of Elysium and will continue to be damaged unless Elysium is enjoined from infringing the '058 Patent.

**Count IV:
(Infringement of Grace's Provisional Rights in the '058 Patent)**

144. Plaintiff realleges and incorporates by reference Paragraphs 1, 3, 5-14, 16, 19, 21-23, 42-59, and 115-143 inclusive, as if fully set forth herein.

145. On information and belief, Elysium had actual notice of the '774 Publication prior to the issuance of the '058 Patent.

146. The '774 Publication includes claims that are substantially identical to the claims of the '058 Patent.

147. On information and belief, Elysium has directly infringed, literally and/or under the doctrine of equivalents, one or more claims of the '058 Patent, including at least claims 1-3, by making, having made, using, selling, having sold, offering to sell, and/or importing BASIS®

in or into the United States, without authority. On information and belief, Elysium made, used, sold, offered to sell, and/or imported BASIS® in or into the United States on and/or after the publication of the '774 Publication. Thus, Elysium is liable for its infringement of Grace's provisional rights in the claims of the '058 Patent in violation of 35 U.S.C. § 154(d).

Count V
(Infringement of U.S. Patent No. 10,189,872)

148. Grace re-alleges and incorporates by reference Paragraphs 1, 4-14, 17, 20-23, and 60-81 of its Complaint, as if fully set forth herein.

A. Direct Infringement

149. For the reasons set forth in detail above, on information and belief, Elysium has been, and is still knowingly and intentionally directly infringing, literally and/or under the doctrine of equivalents, one or more claims of the '872 Patent, including at least claims 1-7 and 15-16, by making, having made, using, selling, having sold, offering to sell, and/or importing BASIS® in or into the United States, without authority. Thus, Elysium is liable for its infringement of the '872 Patent in violation of 35 U.S.C. § 271(a).

150. On information and belief, Elysium's customers have been, and are still directly infringing, literally and/or under the doctrine of equivalents, one or more claims of the '872 Patent, including at least claims 1-7, 15 and 17, by using BASIS® in the United States, without authority.

B. Induced Infringement

151. For the reasons set forth in detail above, on information and belief, Elysium has had actual knowledge of the '872 Patent.

152. On information and belief, Elysium did possess, and still possesses, actual knowledge that BASIS® infringes one or more claims of the '872 Patent.

153. In addition, the filing of this Complaint provides actual notice to Elysium of the infringement as alleged here.

154. Despite such actual knowledge, Elysium has been, and continues to make, use, sell, offer for sale, market, and/or import into the United States, its BASIS® product that infringes the '872 Patent. On information and belief, Elysium has been and continues to market BASIS®, including but not limited to on its product packaging, website, and on social media, in a manner to induce others to use BASIS® in the customary and intended manner that infringes the '872 Patent. For example, Elysium instructs its customers, as a “suggested use” of BASIS®, to “take two (2) capsules every morning with or without food.” Thus, on information and belief, Elysium has been and continues to actively, knowingly, and intentionally induce infringement of the '872 Patent.

155. On information and belief, BASIS® contains a crystalline Form II of NRCI identified in claim 1 of the '872 Patent, and therefore infringes claim 1 of the '872 Patent. On information and belief, Elysium has actively, knowingly, and intentionally encouraged and facilitated, and continues to actively, knowingly, and intentionally encourage and facilitate, others to directly infringe claim 1 of the '872 Patent by instructing, directing, and/or advising others how to make, administer, and use BASIS® in a way that induces infringement of claim 1 of the '872 Patent.

156. On information and belief, BASIS® contains a crystalline Form II according to claim 1 of the '872 Patent that is characterized by a powder X-ray diffraction pattern having peaks at 21.9, 22.1, and 24.7 degrees two theta±0.2 degrees two theta, and therefore infringes

claim 2 of the '872 Patent. On information and belief, Elysium has actively, knowingly, and intentionally encouraged and facilitated, and continues to actively, knowingly, and intentionally encourage and facilitate, others to directly infringe claim 2 of the '872 Patent by instructing, directing, and/or advising others how to make, administer, and use BASIS® in a way that induces infringement of claim 2 of the '872 Patent.

157. On information and belief, BASIS® contains a crystalline Form II according to claim 1 of the '872 Patent that is characterized by a “powder X-ray diffraction pattern having peaks at 21.2, 21.9, 22.1, 24.7, and 33.8 degrees two theta±0.2 degrees two theta, and therefore infringes claim 3 of the '872 Patent. On information and belief, Elysium has actively, knowingly, and intentionally encouraged and facilitated, and continues to actively, knowingly, and intentionally encourage and facilitate, others to directly infringe claim 3 of the '872 Patent by instructing, directing, and/or advising others how to make, administer, and use BASIS® in a way that induces infringement of claim 3 of the '872 Patent.

158. On information and belief, BASIS® contains a crystalline Form II according to claim 1 of the '872 Patent that is characterized by a powder X-ray diffraction pattern having peaks at 21.2, 21.9, 22.1, 23.9, 24.7, 29.6, and 33.8 degrees two theta±0.2 degrees two theta, and therefore infringes claim 4 of the '872 Patent. On information and belief, Elysium has actively, knowingly, and intentionally encouraged and facilitated, and continues to actively, knowingly, and intentionally encourage and facilitate, others to directly infringe claim 4 of the '872 Patent by instructing, directing, and/or advising others how to make, administer, and use BASIS® in a way that induces infringement of claim 4 of the '872 Patent.

159. On information and belief, BASIS® contains a crystalline Form II according to claim 1 of the '872 Patent that is characterized by a powder X-ray diffraction pattern having

peaks at 10.2, 10.7, 13.8, 21.2, 21.9, 22.1, 23.2, 23.9, 24.7, 29.6, and 33.8 degrees two theta \pm 0.2 degrees two theta, and therefore infringes claim 5 of the '872 Patent. On information and belief, Elysium has actively, knowingly, and intentionally encouraged and facilitated, and continues to actively, knowingly, and intentionally encourage and facilitate, others to directly infringe claim 5 of the '872 Patent by instructing, directing, and/or advising others how to make, administer, and use BASIS® in a way that induces infringement of claim 5 of the '872 Patent.

160. On information and belief, BASIS® contains a crystalline Form II according to claim 1 of the '872 Patent that is characterized by a powder X-ray diffraction pattern substantially as shown in FIG. 1, and therefore infringes claim 6 of the '872 Patent. On information and belief, Elysium has actively, knowingly, and intentionally encouraged and facilitated, and continues to actively, knowingly, and intentionally encourage and facilitate, others to directly infringe claim 6 of the '872 Patent by instructing, directing, and/or advising others how to make, administer, and use BASIS® in a way that induces infringement of claim 6 of the '872 Patent.

161. On information and belief, BASIS® contains a crystalline Form II according to claim 1 of the '872 Patent that is characterized by a powder X-ray diffraction pattern having peaks substantially as shown in Table 1 \pm 0.2 degrees two theta, and therefore infringes claim 7 of the '872 Patent. On information and belief, Elysium has actively, knowingly, and intentionally encouraged and facilitated, and continues to actively, knowingly, and intentionally encourage and facilitate, others to directly infringe claim 7 of the '872 Patent by instructing, directing, and/or advising others how to make, administer, and use BASIS® in a way that induces infringement of claim 7 of the '872 Patent.

162. On information and belief, as specified in claim 15 of the '872 Patent, BASIS® comprises a pharmaceutical composition comprising crystalline Form II according to claim 1 of the '872 Patent and a pharmaceutically acceptable excipient, and therefore infringes claim 15 of the '872 Patent. On information and belief, Elysium has actively, knowingly, and intentionally encouraged and facilitated, and continues to actively, knowingly, and intentionally encourage and facilitate, others to directly infringe claim 15 of the '872 Patent by instructing, directing, and/or advising others how to make, administer, and use BASIS® in a way that induces infringement of claim 15 of the '872 Patent.

163. On information and belief, as specified in claim 16 of the '872 Patent, BASIS® is a pharmaceutical composition that is produced by a method comprising combining the crystalline Form II of claim 1 of the '872 Patent with a pharmaceutically acceptable excipient, and therefore infringes claim 16 of the '872 Patent. On information and belief, Elysium has actively, knowingly, and intentionally encouraged and facilitated, and continues to actively, knowingly, and intentionally encourage and facilitate, others to directly infringe claim 16 of the '872 Patent by instructing, directing, and/or advising others how to make, administer, and use BASIS® in a way that induces infringement of claim 16 of the '872 Patent.

164. On information and belief, administering BASIS® is a method comprising administering to a subject the crystalline Form II according to claim 1 or the pharmaceutical composition of claim 15 of the '872 Patent, and administering BASIS® therefore infringes claim 17 of the '872 Patent. On information and belief, Elysium has actively, knowingly, and intentionally encouraged and facilitated, and continues to actively, knowingly, and intentionally encourage and facilitate, others to directly infringe claim 17 of the '872 Patent by instructing,

directing, and/or advising others how to make, administer, and use BASIS® in a way that induces infringement of claim 17 of the '872 Patent.

165. For the reasons set forth in detail above, on information and belief, Elysium has been, and is still, knowingly, and intentionally inducing infringement, literally and/or under the doctrine of equivalents, of one or more claims of the '872 Patent, including at least claims 1-7 and 15-17, by actively encouraging others to make, have made, use, offer for sale, sell, have sold, and/or import BASIS® in or into the United States, without authority. Thus, Elysium is liable as an active inducer of infringement of the '872 Patent in violation of 35 U.S.C. § 271(b).

C. Contributory Infringement

166. For the reasons set forth in detail above, on information and belief, Elysium has had actual knowledge of the '872 Patent.

167. In addition, the filing of this Complaint provides actual notice to Elysium of the infringement as alleged here.

168. Despite such actual knowledge, Elysium has been and continues to actively, knowingly, and intentionally contribute to its customers' infringement of the '872 Patent, literally or by the doctrine of equivalents, by selling BASIS® to customers for use in a manner that infringes one or more claims of the '872 Patent. For example, Elysium instructs its customers, as a "suggested use" of BASIS®, to "take two (2) capsules every morning with or without food."

169. On information and belief, Elysium did possess, and still possesses, knowledge and awareness that BASIS® is especially made or adapted for use in an infringement of the '872 Patent claims, and that BASIS® includes a material component for use in practicing the '872

Patent claims. On information and belief, BASIS® is not a staple article or commodity of commerce suitable for substantial non-infringing use.

170. On information and belief, BASIS® contains a material component for use in practicing claim 1 of the '872 Patent, i.e., a crystalline Form II of NRCl identified in claim 1 of the '872 Patent. On information and belief, Elysium did possess, and still possesses, knowledge and awareness that BASIS® includes such a material component for use in practicing claim 1 of the '872 Patent, and that BASIS® is especially made or adapted for use in an infringement of claim 1 of the '872 Patent. On information and belief, BASIS® is not a staple article or commodity of commerce suitable for substantial non-infringing use of claim 1 of the '872 Patent.

171. On information and belief, BASIS® contains a material component for use in practicing claim 2 of the '872 Patent, i.e., a crystalline Form II according to claim 1 of the '872 Patent that is characterized by a powder X-ray diffraction pattern having peaks at 21.9, 22.1, and 24.7 degrees two theta \pm 0.2 degrees two theta. On information and belief, Elysium did possess, and still possesses, knowledge and awareness that BASIS® includes such a material component for use in practicing claim 2 of the '872 Patent, and that BASIS® is especially made or adapted for use in an infringement of claim 2 of the '872 Patent. On information and belief, BASIS® is not a staple article or commodity of commerce suitable for substantial non-infringing use of claim 2 of the '872 Patent.

172. On information and belief, BASIS® contains a material component for use in practicing claim 3 of the '872 Patent, i.e., a crystalline Form II according to claim 1 of the '872 Patent that is characterized by a powder X-ray diffraction pattern having peaks at 21.2, 21.9, 22.1, 24.7, and 33.8 degrees two theta \pm 0.2 degrees two theta. On information and belief, Elysium did possess, and still possesses, knowledge and awareness that BASIS® includes such a material

component for use in practicing claim 3 of the '872 Patent, and that BASIS® is especially made or adapted for use in an infringement of claim 3 of the '872 Patent. On information and belief, BASIS® is not a staple article or commodity of commerce suitable for substantial non-infringing use of claim 3 of the '872 Patent.

173. On information and belief, BASIS® contains a material component for use in practicing claim 4 of the '872 Patent, i.e., a crystalline Form II according to claim 1 of the '872 Patent that is characterized by a powder X-ray diffraction pattern having peaks at 21.2, 21.9, 22.1, 23.9, 24.7, 29.6, and 33.8 degrees two theta \pm 0.2 degrees two theta. On information and belief, Elysium did possess, and still possesses, knowledge and awareness that BASIS® includes such a material component for use in practicing claim 4 of the '872 Patent, and that BASIS® is especially made or adapted for use in an infringement of claim 4 of the '872 Patent. On information and belief, BASIS® is not a staple article or commodity of commerce suitable for substantial non-infringing use of claim 4 of the '872 Patent.

174. On information and belief, BASIS® contains a material component for use in practicing claim 5 of the '872 Patent, i.e., a crystalline Form II according to claim 1 of the '872 Patent that is characterized by a powder X-ray diffraction pattern having peaks at 10.2, 10.7, 13.8, 21.2, 21.9, 22.1, 23.2, 23.9, 24.7, 29.6, and 33.8 degrees two theta \pm 0.2 degrees two theta. On information and belief, Elysium did possess, and still possesses, knowledge and awareness that BASIS® includes such a material component for use in practicing claim 5 of the '872 Patent, and that BASIS® is especially made or adapted for use in an infringement of claim 5 of the '872 Patent. On information and belief, BASIS® is not a staple article or commodity of commerce suitable for substantial non-infringing use of claim 5 of the '872 Patent.

175. On information and belief, BASIS® contains a material component for use in practicing claim 6 of the '872 Patent, i.e., a crystalline Form II according to claim 1 of the '872 Patent that is characterized by a powder X-ray diffraction pattern substantially as shown in FIG.

1. On information and belief, Elysium did possess, and still possesses, knowledge and awareness that BASIS® includes such a material component for use in practicing claim 6 of the '872 Patent, and that BASIS® is especially made or adapted for use in an infringement of claim 6 of the '872 Patent. On information and belief, BASIS® is not a staple article or commodity of commerce suitable for substantial non-infringing use of claim 6 of the '872 Patent.

176. On information and belief, BASIS® contains a material component for use in practicing claim 7 of the '872 Patent, i.e., a crystalline Form II according to claim 1 of the '872 Patent that is characterized by a powder X-ray diffraction pattern having peaks substantially as shown in Table 1 ± 0.2 degrees two theta. On information and belief, Elysium did possess, and still possesses, knowledge and awareness that BASIS® includes such a material component for use in practicing claim 7 of the '872 Patent, and that BASIS® is especially made or adapted for use in an infringement of claim 7 of the '872 Patent. On information and belief, BASIS® is not a staple article or commodity of commerce suitable for substantial non-infringing use of claim 7 of the '872 Patent.

177. On information and belief, BASIS® contains a material component for use in practicing claim 15 of the '872 Patent, i.e., a pharmaceutical composition comprising crystalline Form II according to claim 1 of the '872 Patent and a pharmaceutically acceptable excipient. On information and belief, Elysium did possess, and still possesses, knowledge and awareness that BASIS® includes such a material component for use in practicing claim 15 of the '872 Patent, and that BASIS® is especially made or adapted for use in an infringement of claim 15 of the

'872 Patent. On information and belief, BASIS® is not a staple article or commodity of commerce suitable for substantial non-infringing use of claim 15 of the '872 Patent.

178. On information and belief, BASIS® contains a material component for use in practicing claim 16 of the '872 Patent, i.e., the crystalline Form II according to claim 1 of the '872 Patent and a pharmaceutically acceptable excipient. On information and belief, Elysium did possess, and still possesses, knowledge and awareness that BASIS® includes such a material component for use in practicing claim 16 of the '872 Patent, and that BASIS® is especially made or adapted for use in an infringement of claim 16 of the '872 Patent. On information and belief, BASIS® is not a staple article or commodity of commerce suitable for substantial non-infringing use of claim 16 of the '872 Patent.

179. On information and belief, BASIS® contains a material component for use in practicing claim 17 of the '872 Patent, i.e., the crystalline Form II according to claim 1 or the pharmaceutical composition of claim 15 of the '872 Patent. On information and belief, Elysium did possess, and still possesses, knowledge and awareness that BASIS® includes such a material component for use in practicing claim 17 of the '872 Patent, and that BASIS® is especially made or adapted for use in an infringement of claim 17 of the '872 Patent. On information and belief, BASIS® is not a staple article or commodity of commerce suitable for substantial non-infringing use of claim 17 of the '872 Patent.

180. For the reasons set forth above in detail, on information and belief, Elysium has been, and is still, knowingly, and intentionally contributorily infringing, literally and/or under the doctrine of equivalents, one or more claims of the '872 Patent, including at least claims 1-7 and 15-17, by making, having made, having sold, using, selling, offering to sell, and/or importing BASIS® in or into the United States, without authority. On information and belief, Elysium did

possess, and still possesses, knowledge and awareness that BASIS® is especially made or adapted for use in an infringement of the '872 Patent, that BASIS® includes a material component for use in practicing the '872 Patent, and that BASIS® is not a staple article or commodity of commerce suitable for substantial non-infringing use. Thus, Elysium is liable for its infringement of the '872 Patent in violation of 35 U.S.C. § 271(c).

D. Willful Infringement

181. On information and belief, Elysium's infringement of the '872 Patent has been willful, intentional, and deliberate. For the reasons set forth in detail above, on information and belief, Elysium has had actual knowledge of the '872 Patent, and actual knowledge that BASIS® infringes one or more claims of the '872 Patent. Elysium knew or should have known of the '872 Patent and its infringement of one or more claims thereof at least based on the Elysium Deposition Testimony. In addition, the filing of this Complaint provides actual notice to Elysium of the '872 Patent under 35 U.S.C. § 287 and the infringement as alleged here.

182. Grace has been damaged by the infringing acts of Elysium and will continue to be damaged unless Elysium is enjoined from infringing the '872 Patent.

**Count IV:
(Infringement of Grace's Provisional Rights in the '872 Patent)**

183. Plaintiff realleges and incorporates by reference Paragraphs 1, 4-14, 17, 20-23, 60-81, and 148-182 inclusive, as if fully set forth herein.

184. On information and belief, Elysium had actual notice of the '079 Publication prior to the issuance of the '872 Patent.

185. The '079 Publication includes claims that are substantially identical to the claims of the '872 Patent.

186. On information and belief, Elysium has directly infringed, literally and/or under the doctrine of equivalents, one or more claims of the '872 Patent, including at least claims 1–7 and 15–16, by making, having made, using, selling, having sold, offering to sell, and/or importing BASIS® in or into the United States, without authority. On information and belief, Elysium made, used, sold, offered to sell, and/or imported BASIS® in or into the United States on and/or after the publication of the '079 Publication. Thus, Elysium is liable for its infringement of Grace's provisional rights in the claims of the '872 Patent in violation of 35 U.S.C. § 154(d).

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

- (a) A judgment that Elysium has infringed the '207, '058, and '872 Patents;
- (b) A judgment that Elysium has infringed Grace's provisional rights in the claims of the '207, '058, and '872 Patents;
- (c) A judgment and order permanently enjoining Elysium, together with its directors, officers, agents, servants, employees, attorneys, parents, subsidiaries, divisions, affiliates, other related business entities, and all persons in active concert or privity with them, and their successors and assigns, from directly or indirectly infringing the '207, '058, and '872 Patents;
- (d) A judgment that awards Grace a reasonable royalty for Elysium's infringement of Grace's provisional rights in the claims of the '207, '058, and '872 Patents pursuant to 35 U.S.C. § 154(d)(1);
- (e) A judgment that awards Grace damages adequate to compensate for Elysium's infringing activities, including lost profits, but in no event less than a reasonable

royalty, in accordance with 35 U.S.C. § 284, including supplemental damages for any post-verdict infringement up until entry of final judgment with an accounting, as needed, together with pre-judgment and post-judgment interest on the damages awarded;

(f) In the event that a permanent injunction is not granted, damages for any continuing future infringement of the '207, '058, and '872 Patents;

(g) A judgment declaring that Elysium's infringement has been willful and awarding enhanced damages under 35 U.S.C. § 284;

(h) Finding that this case is exceptional under 35 U.S.C. § 285, and awarding Grace its reasonable attorneys' fees incurred in connection with this action;

(i) Awarding Grace its costs and expenses in this action; and

(i) Awarding Grace such other and further relief as this Court deems just and appropriate.

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Of Counsel:

Christopher P. Borello
Natalie D. Lieber
James R. Tyminski
VENABLE LLP
1270 Ave. of the Americas
New York, New York 10020
Tel: (212) 218-2574

VENABLE LLP

/s/ Daniel A. O'Brien
Daniel A. O'Brien (No. 4897)
1201 N. Market Street, Suite 1400
Wilmington, Delaware 19801
Tel: (302) 298-3523
daobrien@venable.com

*Attorneys for Plaintiff W. R. Grace & Co.-
Conn.*