

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

CHROMADEx, INC. and TRUSTEES OF	)	
DARTMOUTH COLLEGE,	)	
	)	
Plaintiffs,	)	
	)	C.A. No. 18-1434-CFC
v.	)	
	)	<b>JURY TRIAL DEMANDED</b>
ELYSIUM HEALTH, INC.,	)	
	)	
Defendant.	)	

**DEFENDANT ELYSIUM HEALTH INC.’S FIRST AMENDED ANSWER TO  
PLAINTIFFS’ COMPLAINT FOR PATENT INFRINGEMENT**

Defendant Elysium Health, Inc. (“Elysium”) answers the Complaint for Patent Infringement (“Complaint”) of Plaintiffs ChromaDex, Inc. (“ChromaDex”) and Trustees of Dartmouth College (“Dartmouth”) (collectively, “Plaintiffs”) as follows:

**RESPONSE TO SPECIFIC ALLEGATIONS**

**Nature of the Action**

1. Elysium admits that the Complaint purports to initiate an action for patent infringement. Elysium denies the remaining allegations in paragraph 1 of the Complaint.
2. Elysium admits that a copy of a document that appears to be U.S. Patent No. 8,197,807 (“the ’807 patent”) is attached to the Complaint as Exhibit A.
3. Elysium admits that a copy of a document that appears to be U.S. Patent No. 8,383,086 (“the ’086 patent”) is attached to the Complaint as Exhibit B.
4. Elysium is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 4 of the Complaint and therefore denies them.
5. Elysium denies the allegations in paragraph 5 of the Complaint.

### The Parties

6. Elysium is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 6 of the Complaint and therefore denies them.

7. Elysium is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 7 of the Complaint and therefore denies them.

8. Elysium is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 8 of the Complaint and therefore denies them.

9. Elysium is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 9 of the Complaint and therefore denies them.

10. Elysium is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 10 of the Complaint and therefore denies them.

11. Elysium admits that it is a corporation organized under the laws of Delaware. Except as expressly admitted, Elysium denies the remaining allegations in paragraph 11 of the Complaint.

12. Elysium admits that it makes or has made, offers for sale or has offered for sale, and sells or has sold the supplement BASIS® through the internet to customers nationwide, including to residents of Delaware. The second sentence of paragraph 12 of the Complaint, which recites claim language from the asserted patents that has not been construed by the Court, contains legal conclusions as to which no response is required. Except as expressly admitted, Elysium denies the remaining allegations in paragraph 12 of the Complaint.

### **Jurisdiction and Venue**

13. Paragraph 13 of the Complaint contains legal conclusions as to which no response is required. If a response is deemed necessary, Elysium admits the Complaint purports to state a cause of action under the patent laws of the United States.

14. Paragraph 14 of the Complaint contains legal conclusions as to which no response is required. If a response is deemed necessary, Elysium admits the Complaint purports to state a cause of action over which this Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338.

15. Paragraph 15 of the Complaint contains legal conclusions as to which no response is required. If a response is deemed necessary, Elysium does not contest that this Court has personal jurisdiction over Elysium in this case.

16. Elysium admits that 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. The remaining allegations in paragraph 16 of the Complaint contain legal conclusions as to which no response is required. If a response is deemed necessary, Elysium does not contest that this Court has personal jurisdiction over Elysium in this case.

17. Paragraph 17 of the Complaint contains legal conclusions as to which no response is required. If a response is deemed necessary, Elysium does not contest that venue is proper in this District in this case.

### **Background**

18. Elysium is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 18 of the Complaint and therefore denies them.

19. Elysium is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 19 of the Complaint and therefore denies them.

20. Elysium admits that, under a Supply Agreement that was amended in 2016 (the “Supply Agreement”), ChromaDex provided Elysium nicotinamide riboside (“NR”) for the purpose of developing dietary supplements containing NR. Elysium admits that it marketed its supplement under the trademark BASIS®. Except as expressly admitted, Elysium denies the remaining allegations in paragraph 20 of the Complaint.

21. Elysium admits that it entered into a Trademark License and Royalty Agreement with ChromaDex. Elysium refers to the Trademark License and Royalty Agreement itself for the terms, conditions and provisions of the Agreement. Elysium denies any paraphrasing, summarizing, or characterization of the Trademark License and Royalty Agreement and any factual inferences or legal conclusions made by ChromaDex based on the Trademark License and Royalty Agreement. Elysium admits that the numbers of the ’086 and ’807 patents were printed on jars of its BASIS® product as required by ChromaDex in the Supply Agreement. Except as expressly admitted, Elysium denies the remaining allegations in paragraph 21 of the Complaint.

22. Elysium admits that it ordered NR from ChromaDex in 2015 and 2016. Elysium admits that ChromaDex purports to have exercised its right to not renew the Supply Agreement effective February 2, 2017 and that the Supply Agreement is now terminated. Elysium admits that it previously used NR supplied by ChromaDex in making its supplement BASIS®. Except as expressly admitted, Elysium denies the remaining allegations in paragraph 22 of the Complaint.

23. Elysium denies the allegations in the first sentence of paragraph 23 of the Complaint. Elysium admits that it refers to clinical trials of its BASIS® product on Elysium's website and elsewhere. Some of these clinical trials were conducted using BASIS® product that was made with NR supplied by ChromaDex and some were conducted using BASIS® product that was made with NR supplied by a different supplier. Elysium admits that its product no longer contains NR supplied by ChromaDex. Except as expressly admitted, Elysium denies the remaining allegations in paragraph 23 of the Complaint.

**The patents-in-suit**

24. Elysium denies the first sentence of paragraph 24 of the Complaint. Elysium admits that NAD<sup>+</sup> is a coenzyme found in living cells. Elysium admits that NAD<sup>+</sup> plays an important role in metabolic processes. Elysium admits that NAD<sup>+</sup> plays a role in energy metabolism and that low levels of NAD<sup>+</sup> are associated with mitochondrial dysfunction. Elysium admits that mitochondrial dysfunction affects most cellular systems in the body. Elysium admits that NAD<sup>+</sup> levels decline with age. Elysium is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in the fifth sentence of paragraph 24 of the Complaint and therefore denies them. Elysium admits the last sentence of paragraph 24 of the Complaint. Except as expressly admitted, Elysium denies the remaining allegations in paragraph 24 of the Complaint.

25. Elysium denies the allegations in paragraph 25 of the Complaint.

26. Elysium is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 26 of the Complaint and therefore denies them.

27. Elysium denies the allegations in paragraph 27 of the Complaint.

28. Elysium denies the allegations in paragraph 28 of the Complaint.

29. The allegations of paragraph 29 of the Complaint, which recite claim language from the asserted patents that has not been construed by the Court, contain legal conclusions as to which no response is required. Except as expressly admitted, Elysium denies the remaining allegations in paragraph 29 of the Complaint.

30. Elysium denies the allegations in paragraph 30 of the Complaint.

31. Elysium admits that it filed petitions for *Inter Partes* Review (“IPR”) proceedings before the Patent Trial and Appeal Board (“PTAB”) of the United States Patent and Trademark Office challenging the ’807 and ’086 patents. Elysium admits that it relied on the testimony of Joseph A. Baur, Ph.D., to support its petitions. Elysium admits that trial was not instituted as to any of the claims of the ’807 patent. Elysium admits that trial was initially instituted as to claims 1 and 3-5, but not claim 2, of the ’086 patent. Elysium admits that the PTAB later issued an Order confirming that the trial would include all challenged claims and all asserted grounds. Elysium admits that the Order did not comment on the likelihood that Elysium would prevail on claim 2. Except as expressly admitted, Elysium denies the remaining allegations in paragraph 31 of the Complaint.

32. Elysium denies paragraph 32 of the Complaint because it mischaracterizes the deposition testimony of Dr. Baur.

### **Count I**

33. Elysium repeats and incorporates its responses to paragraphs 1-2, 4-27 and 29-32 above as if fully set forth herein.

34. Elysium admits that the ’807 patent issued on June 12, 2012. Elysium admits that the ’807 patent lists the Trustees of Dartmouth College as the assignees on the face of the patent.

Elysium denies that the '807 patent was duly and legally issued. Except as expressly admitted, Elysium denies the remaining allegations in paragraph 34 of the Complaint.

35. Elysium denies the allegations in paragraph 35 of the Complaint.

36. Elysium admits the allegation in paragraph 36 of the Complaint.

37. Elysium denies the allegations in paragraph 37 of the Complaint.

38. Paragraph 38 of the Complaint, which recites claim language from the asserted patents that has not been construed by the Court, contains legal conclusions as to which no response is required.

39. Paragraph 39 of the Complaint, which recites claim language from the asserted patents that has not been construed by the Court, contains legal conclusions as to which no response is required.

40. The allegations in the first sentence of paragraph 40 of the Complaint, which recite claim language from the asserted patents that has not been construed by the Court, contain legal conclusions as to which no response is required. Elysium admits that the nutrition label on its BASIS® product lists Microcrystalline Cellulose, Hypromellose, Vegetable Magnesium Stearate and Silica as Other Ingredients. Except as expressly admitted, Elysium denies the remaining allegations in paragraph 40 of the Complaint.

41. Paragraph 41 of the Complaint, which recites claim language from the asserted patents that has not been construed by the Court, contains legal conclusions as to which no response is required.

42. Paragraph 42 of the Complaint, which recites claim language from the asserted patents that has not been construed by the Court, contains legal conclusions as to which no response is required.

43. Elysium denies the allegations in paragraph 43 of the Complaint.

44. Elysium denies the allegations in paragraph 44 of the Complaint.

45. Elysium denies the allegations in paragraph 45 of the Complaint.

46. Elysium denies the allegations in the first and second sentence of paragraph 46 of the Complaint. Elysium is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in the third sentence of paragraph 46 of the Complaint and therefore denies them. Elysium admits that it entered into a Supply Agreement and Trademark License and Royalty Agreement with ChromaDex (the “Agreements”). Elysium admits that in 2017, it sold jars of its BASIS® product on which the number of the ’807 patent was printed, as required by ChromaDex in the Supply Agreement. The last three sentences of paragraph 46 of the Complaint contain legal conclusions as to which no response is required. Except as expressly admitted, Elysium denies the remaining allegations in paragraph 46 of the Complaint.

47. Elysium denies the allegations in paragraph 47 of the Complaint.

## **Count II**

48. Elysium repeats and incorporates its responses to paragraphs 1, 3-26, and 28-32 above as if fully set forth herein.

49. Elysium admits that the ’086 patent issued on February 26, 2013. Elysium admits that the ’086 patent lists the Trustees of Dartmouth College as the assignees on the face of the patent. Elysium denies that the ’086 patent was duly and legally issued. Except as expressly admitted, Elysium denies the remaining allegations in paragraph 49 of the Complaint.

50. Elysium denies the allegations in paragraph 50 of the Complaint.

51. Elysium denies the allegation in paragraph 51 of the Complaint. Further answering, Elysium states that claim 2 of the ’086 patent states:

2. The pharmaceutical composition of claim 1, wherein the nicotinamide riboside is isolated from a natural or synthetic source.

52. Elysium denies the allegations in paragraph 52 of the Complaint.

53. Paragraph 53 of the Complaint, which recites claim language from the asserted patents that has not been construed by the Court, contains legal conclusions as to which no response is required.

54. Paragraph 54 of the Complaint, which recites claim language from the asserted patents that has not been construed by the Court, contains legal conclusions as to which no response is required.

55. Paragraph 55 of the Complaint, which recites claim language from the asserted patents that has not been construed by the Court, contains legal conclusions as to which no response is required.

56. The allegations in the first sentence of paragraph 56 of the Complaint, which recite claim language from the asserted patents that has not been construed by the Court, contain legal conclusions as to which no response is required. Elysium admits that the nutrition label on its BASIS® product lists Microcrystalline Cellulose, Hypromellose, Vegetable Magnesium Stearate and Silica as Other Ingredients. Except as expressly admitted, Elysium denies the remaining allegations in paragraph 56 of the Complaint.

57. Paragraph 57 of the Complaint, which recites claim language from the asserted patents that has not been construed by the Court, contains legal conclusions as to which no response is required.

58. Elysium denies the allegations in paragraph 58 of the Complaint.

59. Elysium denies the allegations in paragraph 59 of the Complaint.

60. Elysium denies the allegations in paragraph 60 of the Complaint.

61. Elysium denies the allegations in the first and second sentence of paragraph 61 of the Complaint. Elysium is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in the third sentence of paragraph 61 of the Complaint and therefore denies them. Elysium admits that it entered into a Supply Agreement and Trademark License and Royalty Agreement with ChromaDex (the “Agreements”). Elysium admits that in 2017, it sold jars of its BASIS® product on which the number of the ’086 patent was printed, as required by ChromaDex in the Supply Agreement. The last three sentences of paragraph 61 of the Complaint contain legal conclusions as to which no response is required. Except as expressly admitted, Elysium denies the remaining allegations in paragraph 61 of the Complaint.

62. Elysium denies the allegations in paragraph 62 of the Complaint.

Elysium further denies that Plaintiffs are entitled to the judgment sought and set forth in paragraphs (a)-(f) on pages 14-15 of the Complaint.

### **AFFIRMATIVE AND OTHER DEFENSES**

#### **FIRST DEFENSE – FAILURE TO STATE A CLAIM**

The Complaint fails to state a claim upon which relief may be granted.

#### **SECOND DEFENSE – NON-INFRINGEMENT**

Elysium has not directly infringed, induced infringement, or contributed to infringement of any valid and enforceable claim of the ’807 or ’086 patents, either literally or under the doctrine of equivalents, and has not committed any acts in violation of 35 U.S.C. § 271.

### **THIRD DEFENSE – INVALIDITY**

The claims of the '807 and '086 patents are invalid for failure to satisfy one or more of the conditions for patentability specified in Title 35 of the United States Code, including without limitation §§ 101, 102, 103, and 112, and/or any judicially-created doctrine of invalidity.

### **FOURTH DEFENSE – PATENT MISUSE**

The '807 and '086 patents are unenforceable against Elysium under the doctrine of patent misuse. Elysium's patent misuse allegations are set forth in Elysium's pending Third Amended Counterclaims in *ChromaDex, Inc. v. Elysium Health, Inc.*, 16-cv-2277-CJC (S.D. Cal.) (the "California Litigation"), the allegations of which are incorporated by reference in this Answer. *See* California Litigation at Dkt. No. 103. Elysium intends to litigate its patent misuse allegations in the California Litigation, where they are scheduled to be tried beginning on April 2, 2019. Elysium pleads its patent misuse defense in this case to preserve its right to litigate the defense in this case if necessary.

### **FIFTH DEFENSE – NO WILLFULNESS**

Elysium has not willfully infringed any claim of the '807 or '086 patents, and Plaintiffs are not entitled to enhanced damages under 35 U.S.C. § 284.

### **SIXTH DEFENSE – NO EXCEPTIONAL CASE**

Elysium's actions and/or defense of this case do not give rise to an exceptional case finding pursuant to 35 U.S.C. § 285.

### **SEVENTH DEFENSE – NO EQUITABLE RELIEF**

Plaintiffs are not entitled to equitable relief.

**EIGHTH DEFENSE – 35 U.S.C. § 271(e)**

To the extent Plaintiffs assert infringement of any claim of the '807 or '086 patents based on any act of making, using, offering to sell, or selling within the United States, or importing into the United States, any accused product solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products or medical devices, that activity cannot constitute infringement under 35 U.S.C. § 271(e).

**NINTH DEFENSE – EQUITABLE ESTOPPEL**

The '807 and '086 patents are unenforceable, in whole or in part, against Elysium under the doctrine of equitable estoppel.

**TENTH DEFENSE – UNCLEAN HANDS**

Plaintiffs' Complaint is barred, in whole or part, by Plaintiffs' unclean hands.

In the California Litigation, ChromaDex has sought to have Elysium's patent misuse counterclaim dismissed on the grounds that there is no actual controversy between ChromaDex and Elysium related to potential patent infringement litigation. In particular, ChromaDex asserted that it had not accused Elysium of patent infringement, had not taken any actions to imply such a claim, had not made plans to assert that Elysium's BASIS® product infringes ChromaDex's patent rights, and had not taken any affirmative action to enforce its patent rights against Elysium. In view of its representations to a Federal Court in California that it does not accuse Elysium of infringing the asserted patents, ChromaDex cannot seek to enforce the asserted patents against Elysium in this Court.

**ELEVENTH DEFENSE – LICENSE/AUTHORIZATION**

Plaintiffs' claims are barred because Elysium's actions were licensed and/or authorized.

**TWELFTH DEFENSE – WAIVER**

Plaintiffs have waived any rights they may have had for relief from the Court.

**THIRTEENTH DEFENSE – PATENT EXHAUSTION**

Plaintiffs' claims are barred by the doctrine of patent exhaustion.

**PRAYER FOR RELIEF**

WHEREFORE, Elysium respectfully requests entry of judgment as follows:

1. That the Court dismiss with prejudice all claims of Plaintiffs' Complaint, order that Plaintiffs take nothing as a result of the Complaint, and deny all of Plaintiffs' prayers for relief;
2. That the Court enter judgment that Elysium has not directly infringed, induced infringement, or contributed to infringement of any valid and enforceable claim of the '086 or '807 patents, either literally or under the doctrine of equivalents, and has not committed any acts in violation of 35 U.S.C. § 271;
3. That the Court enter judgment declaring that the claims of the '807 and '086 patents are invalid and unenforceable;
4. That the Court determine that this case is exceptional pursuant to 35 U.S.C. § 285 by reason of the misconduct of Plaintiffs, and that Elysium be awarded its reasonable attorneys' fees and costs; and
5. That the Court grant to Elysium such other and further relief as may be deemed just and appropriate.

**JURY DEMAND**

Elysium respectfully requests a jury trial on all issues so triable.

ASHBY & GEDDES

*/s/ Steven J. Balick*

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