IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

CHROMADEX, INC. and TRUSTEES OF DARTMOUTH COLLEGE, Plaintiffs, v. THORNE RESEARCH, INC., Defendant.	**C.A. NO.: _____** **DEMAND FOR JURY TRIAL**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs ChromaDex, Inc. ("ChromaDex") and Trustees of Dartmouth College ("Dartmouth"), by and through their undersigned counsel, file this Complaint against Defendant Thorne Research, Inc. ("Thorne"), and allege with knowledge regarding their own acts and on information and belief as to other matters, as follows:

NATURE OF THE ACTION

1. ChromaDex and Dartmouth bring this action to compel Thorne to (i) cease infringement of U.S. Patent No. 8,197,807 ("the '807 patent") and U.S. Patent No. 8,383,086 ("the '086 patent") and (ii) compensate them for Thorne's willful infringement of those patents.

2. A true and correct copy of the '807 patent is attached as Exhibit A.

3. A true and correct copy of the '086 patent is attached as Exhibit B.

4. ChromaDex is the exclusive licensee under the '807 and '086 patents in various fields, including dietary supplements. Dartmouth is the assignee of all right, title, and interest in the '807 and '086 patents.

5. ChromaDex has been, and continues to be, the industry leader in the science, research, and development of, among other things, isolated nicotinamide riboside ("NR"), a unique form of vitamin B3 for use in oral dietary supplements.

THE PARTIES

6. Plaintiff ChromaDex is a corporation organized under the laws of the State of California and having a principal place of business at 10900 Wilshire Boulevard, Suite 600, Los Angeles, California, 90024.

7. ChromaDex is a global nutraceutical company with products focused on proprietary health, wellness, and nutritional ingredients that address the dietary supplement, functional food, beverage, and skin care markets. ChromaDex protects these products through, *inter alia*, its intellectual property ("IP") portfolio, including patents. ChromaDex has expended, and continues to expend, significant resources to develop, acquire, and license this IP portfolio, which includes the '807 and '086 patents.

8. ChromaDex sells the TRU NIAGEN® dietary supplement directly to consumers.

9. Plaintiff Dartmouth is a non-profit educational research institution existing under the laws of the State of New Hampshire and having a principal place of business at 6066 Development Office, Hanover, New Hampshire, 03755.

10. Dr. Charles M. Brenner, the inventor of the '807 and '086 patents, was an Associate Professor (2003–2007) and Professor (2007–2009) of Genetics and of Biochemistry at the Dartmouth Medical School. Dr. Brenner assigned his inventions as disclosed in the '807 and '086 patents to Dartmouth.

11. Defendant Thorne is a corporation organized under the laws of the South Carolina with manufacturing facilities located at 620 Omni Industrial Boulevard, Summerville, South Carolina, 29486.

12. Thorne has principal corporate headquarters and an established place of business in the Southern District of New York at 152 West 57th Street, 21st Floor, New York City, New York 10019.

13. Thorne makes or has made, uses or has used, sells or has sold, offers for sale or has offered for sale, and imports or has imported the dietary supplement NiaCel® 200 and NiaCel® 400 (collectively, "the accused NiaCel® products"), which are offered for sale and sold through the internet to customers nationwide, including, on information and belief, to residents of the State of New York and the City of New York. The accused NiaCel® products are compositions that comprise isolated NR and are said to increase NAD^+ biosynthesis upon oral administration.

JURISDICTION AND VENUE

14. 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. §§ 271 and 281–85.

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

16. This Court has personal jurisdiction over Thorne consistent with the Due Process Clause of the U.S. Constitution and the New York Long-Arm Statute.

17. Thorne's corporate headquarters are located in New York at 152 West 57th Street, 21st Floor, New York City, New York 10019. Thorne thus has a regular and established place of business in the State of New York and the City of New York. Therefore, Thorne resides within, and has consented to, personal jurisdiction within this District.

18. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400(b), at least because Thorne has a regular and established place of business within this District by virtue of its corporate headquarters located at 152 West 57th Street, 21st Floor, New York City, New York 10019, and Thorne has committed acts of infringement within this District because Thorne sells and offers to sell the accused NiaCel® products through the internet to customers nationwide, including, on information and belief, to residents of this District.

BACKGROUND

19. ChromaDex is an innovator and leader in the field of NR technology. It sells to consumers the TRU NIAGEN® oral dietary supplement. ChromaDex also sells the dietary ingredient NIAGEN® NR to customers in the United States and internationally. Some of those customers formulate the NIAGEN® NR into dietary supplements and sell those supplements to customers in the United States. TRU NIAGEN® and NIAGEN® comprise isolated NR. In November 2015, ChromaDex received its first acknowledgement from the U.S. Food and Drug Administration ("FDA") on ChromaDex's New Dietary Ingredient (NDI) submission for NIAGEN®. It received a second acknowledgement from FDA for ChromaDex's NDA submission for NIAGEN® in March 2018. NIAGEN® was generally recognized as safe by an independent panel of expert toxicologists, and in August 2016, the FDA issued a Generally Recognized As Safe (GRAS) No Objection Letter.

20. ChromaDex has expended, and continues to expend, significant resources to design, conduct, sponsor, fund, and supply the NIAGEN® dietary ingredient products for clinical trials and studies to investigate the benefits of NR on various human structures and functions, cells, organs and tissues, diseases, indications, and conditions. These trials and studies are directed to mild cognitive impairment, epilepsy, neuropathies, neurodegenerative diseases, neurological

injury, obesity, pain, muscular health, aging, metabolic health, mitochondrial myopathies, cardiovascular health, cognitive health, osteoporosis, cancer, intestinal diseases, kidney disease, lactation, and liver function.

21. Beginning in July 2013, ChromaDex provided NIAGEN® to Thorne pursuant to various supply agreements for the purpose of Thorne making and selling dietary supplements containing NIAGEN®, including but not limited to products that Thorne marketed using the names ResveraCel® and NiaCel®.

22. Contemporaneously with the July 2013 Supply Agreement, under a Trademark License and Royalty Agreement, ChromaDex granted Thorne the right to use and display ChromaDex trademarks and logos, and to list ChromaDex patents, patent applications, and other intellectual property and proprietary information on dietary supplements Thorne sold containing NIAGEN®. Thorne marked the accused NiaCel® products, *inter alia*, with the NIAGEN® trademark and with ChromaDex's patent marking website, which identifies the '807 and '086 patents.

23. On September 28, 2020, Thorne informed ChromaDex that it was terminating the operative supply agreement as of December 31, 2020.

24. On information and belief, on March 15, 2021, Thorne began to sell infringing dietary supplements containing isolated NR not supplied by ChromaDex, including the accused NiaCel® products, with full knowledge that such products fall within the claims of the '807 and '086 patents. Despite switching to an alternative source of isolated NR, on information and belief, Thorne continues to promote and market the accused NiaCel® products with reference to the results of clinical trials and studies conducted using ChromaDex-sourced NIAGEN® NR.

THE PATENTS-IN-SUIT

25. Dr. Brenner, the inventor of the ’807 and ’086 patents, discovered that isolated NR is a new and unique form of vitamin B3 that provides an independent and theretofore unknown route (the nicotinamide riboside kinase (“Nrk”) pathway) to the production of oxidized nicotinamide adenine dinucleotide (NAD^+) in humans. NAD^+ is a coenzyme vital to cellular function. NAD^+ is essential for life in all organisms, both as a co-enzyme for oxidoreductases and as a source of ADPribosyl groups used in various reactions and processes in the body, including those that slow aging. NAD^+ is central to energy metabolism, the lack of which may lead to mitochondrial dysfunction, which can affect most cellular systems in the body. NAD^+ levels decrease as people age. NAD^+ levels also decrease as the result of physiological stresses, such as those that result from alcohol consumption, excess nutrients, or sun exposure. NAD^+ deficiency is also implicated in various conditions such as congenital malformations, neuropathies, and diabetes.

26. Although other forms of Vitamin B3—e.g., nicotinamide and nicotinic acid (niacin)—were known, Dr. Brenner discovered that isolated NR could be formulated for oral administration and administered orally in a way that enhances NAD^+ biosynthesis more effectively than other forms of Vitamin B3, while also avoiding their undesirable side effects, such as flushing.

27. The ’807 and ’086 patents are the result of Dr. Brenner’s work and discoveries.

28. The claims of the ’807 patent incorporate Dr. Brenner’s inventions, at least in the context of isolated NR, its formulation into an oral composition, and its use to increase NAD^+ biosynthesis upon oral administration. Individually and together, those inventions were not well understood, routine, or conventional at the time of Dr. Brenner’s inventions.

29. The claims of the ’086 patent incorporate Dr. Brenner’s inventions, at least in the context of NR in admixture with a carrier, its formulation into an oral composition, its isolation from a natural or synthetic source, and its use to increase NAD^+ biosynthesis upon oral administration. Individually and together, those inventions were not well understood, routine, or conventional at the time of Dr. Brenner’s inventions.

COMPOSITIONS COMPRISING ISOLATED NR AND PHARMACEUTICAL COMPOSITIONS COMPRISING ISOLATED NR

30. Compositions comprising isolated NR and pharmaceutical compositions comprising isolated NR are not compositions found in nature, nor do they have the inherent properties of any naturally occurring NR composition. Instead, compositions comprising isolated NR and pharmaceutical compositions comprising isolated NR, when formulated in accordance with the teachings of the ’807 and ’086 patents, increase NAD^+ biosynthesis upon oral administration. Isolated NR and pharmaceutical compositions comprising isolated NR do not occur in nature. NR, as it exists in nature (in some foods), is bound to other molecules and is present only in trace amounts. It cannot be isolated in that bound form or formulated into oral or pharmaceutical compositions to be bioavailable, let alone to increase NAD^+ biosynthesis. And even were NR not bound to other molecules, the trace amounts of NR present in some foods have not been shown to increase NAD^+ biosynthesis. Isolated NR and pharmaceutical compositions comprising isolated NR are thus new and non-obvious forms of NR, formulated in new and non-obvious compositions, to achieve new and unexpected benefits that are not possible with the bound form of NR as it exists in nature.

31. Upon information and belief, Thorne promotes and markets the accused NiaCel® products as different in their composition and distinct in their effects from naturally occurring

unisolated NR. Among other things, Thorne promotes and markets the accused NiaCel® products based on the benefits on NAD^+ biosynthesis of orally administering isolated NR.

COUNT I:
(JUDGMENT OF INFRINGEMENT
OF U.S. PATENT NO. 8,197,807 BY THORNE)

32. Plaintiffs reallege and incorporate by reference paragraphs 1–31, inclusive, as if fully set forth herein.

33. The United States Patent and Trademark Office duly and legally issued the '807 patent to Dartmouth on June 12, 2012.

34. On information and belief, the '807 patent is valid, enforceable, and currently in full force and effect.

35. Claim 1 of the '807 patent recites:

> A composition comprising isolated nicotinamide riboside in combination with one or more of tryptophan, nicotinic acid, or nicotinamide, wherein said combination is in admixture with a carrier comprising a sugar, starch, cellulose, powdered tragacanth, malt, gelatin, talc, cocoa butter, suppository wax, oil, glycol, polyol, ester, agar, buffering agent, alginic acid, isotonic saline, Ringer's solution, ethyl alcohol, polyester, polycarbonate, or polyanhydride, wherein said composition is formulated for oral administration and increases NAD+ biosynthesis upon oral administration.

36. On information and belief, the accused NiaCel® products infringe at least claim 1 of the '807 patent.

37. The accused NiaCel® products are made, used, and sold in a capsule form.

38. Each capsule of the accused NiaCel® products contains a composition comprising isolated NR. The isolated NR is in combination with one or more of tryptophan, nicotinic acid, or nicotinamide. In particular, the isolated NR is in combination with at least nicotinamide.

39. Each capsule of the accused NiaCel® products comprises isolated NR in admixture with a carrier as specified in the '807 patent. Thorne represents to the public that each capsule of

the accused NiaCel® products comprises "Hypromellose (derived from cellulose) capsule, Microcrystalline Cellulose, Calcium Laurate, Silicon Dioxide."

40. The accused NiaCel® products are formulated for oral administration.

41. Thorne represents to the public that the accused NiaCel® products increase NAD^+ biosynthesis in the body upon oral administration.

42. On information and belief, Thorne has been, and is still, knowingly and intentionally directly infringing, literally and/or under the doctrine of equivalents, one or more claims of the '807 patent, including at least claim 1, by making, having made, using, having used, selling, having sold, offering to sell, having offered to sell, importing, and/or having imported the accused NiaCel® products in or into the United States, without authority. Thus, Thorne is liable for its infringement of the '807 patent in violation of 35 U.S.C. § 271(a).

43. On information and belief, Thorne 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 '807 patent, including at least claim 1, by actively encouraging others to make, have made, use, have used, sell, have sold, offer for sale, have offered for sale, import, and/or have imported the accused NiaCel® products in or into the United States, without authority. For example, on information and belief, Thorne has actively and knowingly encouraged and facilitated, and continues to actively and knowingly encourage and facilitate, others to directly infringe the '807 patent, including at least claim 1, by instructing, directing, and/or advising others how to administer and use the accused NiaCel® products to increase NAD^+ biosynthesis upon oral administration. Thus, Thorne is liable as an active inducer of infringement of the '807 patent in violation of 35 U.S.C. § 271(b).

44. On information and belief, Thorne has been, and is still, knowingly and intentionally contributorily infringing, literally and/or under the doctrine of equivalents, one or more claims of the '807 patent, including at least claim 1, by making, having made, using, having used, selling, having sold, offering to sell, having offered to sell, importing, and/or having imported the accused NiaCel® products in or into the United States, without authority. On information and belief, Thorne did possess, and still possesses, knowledge and awareness that the accused NiaCel® products are especially made or adapted for use in activities that infringe the '807 patent, that the accused NiaCel® products include a material component for use in practicing the '807 patent, and that the accused NiaCel® products are not a staple article or commodity of commerce suitable for substantial non-infringing use. Thus, Thorne is liable for its infringement of the '807 patent in violation of 35 U.S.C. § 271(c).

45. On information and belief, Thorne's infringement of the '807 patent has been willful, intentional, and deliberate. On information and belief, Thorne is and has been aware of the '807 patent and knows that the accused NiaCel® products fall within the claims of the '807 patent. Thorne knew or should have known of the '807 patent at least as early as July 2013. At that time, it entered into a Supply Agreement with ChromaDex, which related to ChromaDex's NIAGEN®, and required Thorne to mark the '807 patent on its products by listing ChromaDexPatents.com, which identified the '807 patent. As recently as March 2021, Thorne continued to mark its dietary supplement products containing NR (other than the accused NiaCel® products) by citing to ChromaDex's patent marking website, showing an awareness that the '807 patent covered the accused NiaCel® products. ChromaDex also provided notice to Thorne of the '807 patent by marking the TRU NIAGEN® dietary supplements pursuant to 35 U.S.C. § 287(a). Third parties, who formulate dietary supplements under their own label using

NIAGEN® NR obtained from ChromaDex, also provide notice to Thorne of the '807 patent by marking those dietary supplements pursuant to 35 U.S.C. § 287(a). In addition, the filing of this Complaint provides actual notice to Thorne of the '807 patent under 35 U.S.C. § 287.

46. Plaintiffs have been damaged by the infringing acts of Thorne and will continue to be damaged unless this Court enjoins Thorne from these actions.

COUNT II:
(JUDGMENT OF INFRINGEMENT
OF U.S. PATENT NO. 8,383,086 BY THORNE)

47. Plaintiffs reallege and incorporate by reference paragraphs 1–31, inclusive, as if fully set forth in this paragraph.

48. The United States Patent and Trademark Office duly and legally issued the '086 patent to Dartmouth on February 26, 2013.

49. On information and belief, claim 2 of the '086 patent is valid, enforceable, and currently in full force and effect.

50. Claim 1 of the '086 patent recites:

> A pharmaceutical composition comprising nicotinamide riboside in admixture with a carrier, wherein said composition is formulated for oral administration.

51. Claim 2 of the '086 patent recites:

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

52. Dependent claim 2 thus incorporates by reference independent claim 1, and includes the additional element "wherein the nicotinamide riboside is isolated from a natural or synthetic source."

53. On information and belief, the accused NiaCel® products infringe claim 2 of the '086 patent.

54. The accused NiaCel® products are made, used, and sold in a capsule form.

55. Each capsule of the accused NiaCel® products is a pharmaceutical composition within the meaning of the claim.

56. Each capsule of the accused NiaCel® products contain a composition comprising isolated NR.

57. Upon information and belief, the NR in each capsule of the accused NiaCel® products is isolated from a natural or synthetic source.

58. Each capsule of the accused NiaCel® products comprises isolated NR in admixture with a carrier as specified in the ’086 patent. Thorne represents to the public that each capsule of the accused NiaCel® products comprises “Hypromellose (derived from cellulose) capsule, Microcrystalline Cellulose, Calcium Laurate, Silicon Dioxide.”

59. The accused NiaCel® products are formulated for oral administration.

60. On information and belief, Thorne has been, and is still, knowingly and intentionally directly infringing, literally and/or under the doctrine of equivalents, claim 2 of the ’086 patent by making, having made, using, having used, selling, having sold, offering to sell, having offered to sell, importing, and/or having imported the accused NiaCel® products in or into the United States, without authority. Thus, Thorne is liable for its infringement of the ’086 patent in violation of 35 U.S.C. § 271(a).

61. On information and belief, Thorne has been, and is still, knowingly and intentionally inducing infringement, literally and/or under the doctrine of equivalents, of claim 2 of the ’086 patent by actively encouraging others to make, have made, use, have used, sell, have sold, offer for sale, have offered for sale, import, and/or have imported the accused NiaCel® products in or into the United States, without authority. For example, on information and belief,

Thorne has actively and knowingly encouraged and facilitated, and continues to actively and knowingly encourage and facilitate, others to directly infringe claim 2 of the '086 patent by instructing, directing, and/or advising others how to administer and use the accused NiaCel® products. Thus, Thorne is liable as an active inducer of infringement of the '086 patent in violation of 35 U.S.C. § 271(b).

62. On information and belief, Thorne has been, and is still, knowingly and intentionally contributorily infringing, literally and/or under the doctrine of equivalents, claim 2 of the '086 patent by making, having made, using, having used, selling, having sold, offering to sell, having offered to sell, importing, and/or having imported the accused NiaCel® products in or into the United States, without authority. On information and belief, Thorne did possess, and still possesses, knowledge and awareness that the accused NiaCel® products are especially made or adapted for use in an infringement of the '086 patent, that the accused NiaCel® products include a material component for use in practicing the '086 patent, and that the accused NiaCel® products are not a staple article or commodity of commerce suitable for substantial non-infringing use. Thus, Thorne is liable for its infringement of the '086 patent in violation of 35 U.S.C. § 271(c).

63. On information and belief, Thorne's infringement of the '086 patent has been willful, intentional, and deliberate. On information and belief, Thorne is and has been aware of the '086 patent and knows that the accused NiaCel® products fall within claim 2 of the '086 patent. Thorne knew or should have known of the '086 patent at least as early as July 2013. At that time, it entered into a Supply Agreement with ChromaDex, which related to ChromaDex's NIAGEN®, and required Thorne to mark the '086 patent on its products by listing ChromaDexPatents.com, which identified the '086 patent. As recently as March 2021, Thorne continued to mark its dietary supplement products containing NR (other than the accused NiaCel® products) by citing to

ChromaDex's patent marking website, showing an awareness that the '086 patent covered the accused NiaCel® products. ChromaDex also provided notice to Thorne of the '086 patent by marking the TRU NIAGEN® dietary supplements pursuant to 35 U.S.C. § 287(a). Third parties, who formulate dietary supplements under their own label using NIAGEN® NR obtained from ChromaDex, also provide notice to Thorne of the '086 patent by marking those dietary supplements pursuant to 35 U.S.C. § 287(a). In addition, the filing of this Complaint provides actual notice to Thorne of the '086 patent under 35 U.S.C. § 287.

64. Plaintiffs have been damaged by the infringing acts of Thorne and will continue to be damaged unless this Court enjoins Thorne from these actions.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request that this Court enter judgment in their favor and against Thorne, granting the following relief:

(a) Declaring that Thorne has directly infringed, contributorily infringed, and induced infringement of, and is continuing to directly infringe, contributorily infringe, and induce infringement of, one or more claims of the '807 and '086 patents;

(b) Permanently enjoining Thorne, 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 '807 and '086 patents;

(c) Awarding Plaintiffs damages adequate to compensate for Thorne'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;

(d) Declaring that Thorne's infringement has been willful, and awarding enhanced damages under 35 U.S.C. § 284;

(e) Finding that this case is exceptional under 35 U.S.C. § 285, and awarding ChromaDex and Dartmouth their attorneys' fees incurred in connection with this action; and

(f) Awarding Plaintiffs such other and further relief as this Court deems just and appropriate.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38, Plaintiffs demand a trial by jury of all issues so triable.

Dated: May 12, 2021

/s/ Jennifer D. Cieluch

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