

**UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION**

EVOLVE BIOSYSTEMS, INC.; AND THE	)	
REGENTS OF THE UNIVERSITY OF	)	
CALIFORNIA, a corporation,	)	
	)	Civil Action No. 19-cv-5859
Plaintiffs,	)	
	)	Hon. Judge John Z. Lee
v.	)	Hon. Magistrate Judge Sidney I. Schenkier
	)	
ABBOTT LABORATORIES,	)	
	)	<b>JURY TRIAL DEMANDED</b>
Defendant.	)	

**AMENDED COMPLAINT**

Plaintiffs Evolve BioSystems, Inc. (“Evolve”) and the Regents of the University of California (“the University”) file this Amended Complaint against Defendant Abbott Laboratories (“Abbott”) and allege as follows:

**NATURE OF THE ACTION**

1. This is an action arising under the patent laws of the United States codified at 35 U.S.C. §§ 1, *et seq.*, over which this Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a) for infringement of U.S. Patent Nos. 8,197,872 (“the ’872 patent”) and 9,200,091 (“the ’091 patent”). This action arises out of the imminent manufacture, use, importation, offer for sale, and/or sale by Abbott of a probiotic product that, when combined with other prebiotic products, infringes Plaintiffs’ patent rights. Plaintiffs file this lawsuit to stop Abbott’s infringing activity and to obtain other appropriate relief.

### **THE PARTIES**

2. Plaintiff Evolve BioSystems, Inc. is a Delaware Corporation with its principal place of business at 2121 2nd Street, Suite C108, Davis, CA, 95618.

3. Plaintiff the Regents of the University of California is a California Constitutional Corporation authorized and empowered to administer the public trust known as the University of California, with full powers of organization and government thereof.

4. Defendant Abbott Laboratories is an Illinois Corporation with its principal place of business at 100 Abbott Park Road, Abbott Park, IL, 60064.

### **JURISDICTION AND VENUE**

5. This Court has original jurisdiction over the asserted federal law claims under 28 U.S.C. §§ 1331, 1338(a), 2201(a), and 2202.

6. Abbott is subject to personal jurisdiction in this judicial District because Abbott is incorporated in the State of Illinois and has its principal place of business in this District.

7. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and 1400(b) because Abbott is incorporated in Illinois and has its principal place of business in this District. On information and belief, certain acts complained of herein also occurred within this District and significant evidence of these acts is located within this District.

### **FACTUAL BACKGROUND**

8. Evolve is an innovator and leader in correcting newborn gut dysbiosis—an imbalance of beneficial bacteria that can lead to immune and metabolic dysfunction and disease. While scientists have long appreciated that the composition of microbes—or the microbiome—in the infant gut can impact infant health, not much was known about which microbes were necessary for a healthy gut and what substances promoted their growth. Newborn gut dysbiosis is becoming increasingly prevalent; possible causes include increased delivery by C-sections, formula feeding,

and antibiotic use. Premature infants, in particular, are susceptible to gut dysbiosis. In a healthy infant gut, beneficial bacteria promote health in numerous ways, including reducing enteric inflammation, improving stool patterns, increasing vitamin production, and promoting nutrient absorption. In contrast, infant gut dysbiosis can cause severe health conditions such as enteric infections, necrotizing enterocolitis (NEC), and gastroenteritis. Enteric infections can lead to sepsis, and premature infants with sepsis have significantly higher mortality rates. NEC is also one of the leading causes of premature infant mortality. For the last several decades, scientists and doctors have struggled to identify the cause of and treatments for NEC.

9. Evolve is an early-stage company that was formed to investigate and to address infant gut dysbiosis. Its founders hail from the University's Davis campus, where they performed fundamental research on infant gut dysbiosis, and the bacteria strains needed to establish a healthy gut microbiome. Through their research, Evolve's founders uncovered the crucial role of the bacterium *Bifidobacterium longum* subsp. *infantis* ("*B. infantis*") in newborn gut health. But this was only one piece of the puzzle. Inoculating infants with *B. infantis* without a proper prebiotic environment has little effect. Evolve's founders further discovered that specific oligosaccharides—essentially, long chains of complex sugars—were a selective food source for *B. infantis* and that without these oligosaccharides, *B. infantis* cannot establish a dominant presence in the infant gut. Interestingly, these oligosaccharides make up roughly 15% of the macronutrients of human milk, and without the help of bacteria, they would be indigestible by a human infant. Research performed by Evolve's founders shows that these human milk oligosaccharides (HMOs) serve as prebiotics that promote *B. infantis* growth.

10. Based on these fundamental discoveries, Evolve set about developing a probiotic *B. infantis* product (*B. infantis* EVC001). Because this product would have particular application in

infants, Evolve took safety and efficacy seriously. Evolve conducted and continues to sponsor significant research and clinical trials to demonstrate the safety and effectiveness of *B. infantis* EVC001 in correcting infant gut dysbiosis, in both full-term and premature infant populations, putting significant money, time, and resources on the line.<sup>1</sup> This work allowed Evolve to launch and subsequently promote EVIVO® as a clinically proven *B. infantis* probiotic product for infants.

11. Evolve's EVIVO product has been adopted for use in neonatal intensive care units (NICUs), where ongoing research suggests that its colonization in the infant gut is associated with improved patient outcomes. Under the current standard of care, preterm infants in the NICU often receive processed human milk products synthesized from donor milk combined with a nutritional fortifier of either human or bovine origin, a combination which includes the prebiotic HMOs that Evolve's founders discovered.<sup>2</sup> Evolve instructs care providers to add EVIVO to diets including these synthetic, prebiotic combinations prior to administration, so the HMOs in the combination can establish a healthy gut population of *B. infantis*. NICUs across the country now administer EVIVO to premature infants, with the number of participating NICUs increasing with every quarter.

12. Based in large part on Evolve's path-breaking work, recognition of the importance of *B. infantis* and HMOs to infant gut health has become widespread.<sup>3</sup> The Gates Foundation and Horizon Ventures (a venture arm of the Li Ka Shing Foundation) recently led a consortium of parties that invested \$40 million in Evolve, including to fund research relating to use of EVIVO in

<sup>1</sup> See, e.g., <https://www.evivo.com/scientific-publications>.

<sup>2</sup> Fortified milk is the current standard of care for premature infants in the NICU. See, e.g., <https://www.prolacta.com/knowledge-center/>.

<sup>3</sup> See, e.g., <https://www.nytimes.com/2018/06/17/opinion/babies-bacteria-breastfeeding-formula.html>; <https://www.npr.org/sections/thesalt/2018/04/30/606440075/probiotics-for-babies-and-kids-new-research-explores-good-bacteria>; and <https://www.prnewswire.com/news-releases/top-medical-professionals-gather-to-tackle-infant-gut-dysbiosis-300861207.html>.

promoting the health of children and infants in developed and developing countries. And even Abbott has come to recognize the importance of the scientific contributions by Evolve's founders. Abbott now touts the importance of a healthy microbiome and the role of HMOs as a prebiotic in promoting gut health; Abbott recently began adding HMOs to some of its Similac® infant care products.<sup>4</sup> Its own literature recognizes the significant contributions of combinations involving *B. infantis* and synthetic, prebiotic products including HMOs to the field, and has referenced work by Dr. David Mills—one of Evolve's founders and an inventor of the technology.<sup>5</sup>

13. While substantial research supports the role of HMOs in a healthy infant microbiome, Evolve's founders also discovered that certain bovine milk oligosaccharides (BMOs) can support the growth of *B. infantis* in the human gut. These BMOs can be incorporated into infant formula or nutritional fortifier products comprising bovine milk, including formula and fortifier products used in the NICU.

14. It comes as no surprise, then, that Abbott was interested in partnering with Evolve. Abbott has been following the work of Evolve's founders for years, and beginning in 2018, entered in discussions regarding shared business opportunities between the two companies, whereby Abbott might co-promote Evolve's EVIVO along with Abbott's Similac line of infant care products. Discussions ensued for more than a year and seemed cordial, but rumors began developing that Abbott was preparing to launch its own competing product to Evolve's. An important potential customer of Evolve, with whom discussions had advanced to their final stages, informed Evolve that they were putting discussions about using Evolve's EVIVO in their NICUs on hold, so they could

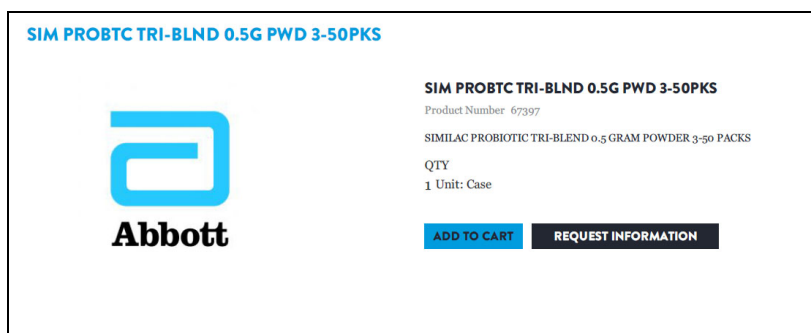
<sup>4</sup> See, e.g., <https://www.abbott.com/corpnewsroom/product-and-innovation/the-role-of-the-microbiome.html>; <https://www.nutritionnews.abbott/pregnancy-childhood/prenatal-breastfeeding/the-power-of-human-milk-oligosaccharides/>; and <https://www.nutritionnews.abbott/pregnancy-childhood/infant-toddler/breakthroughs-in-infant-nutrition/>.

<sup>5</sup> See, e.g., Exhibit 3 (Abbott's 2018 Growth Summit).

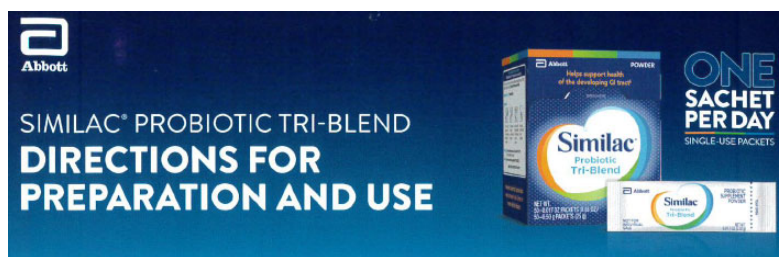
consider Abbott's imminent probiotic offering. Eventually, the product description leaked; Abbott was indeed planning on offering a *B. infantis* product that would directly compete with Evolve's—"Similac Probiotic Tri-blend"—as shown below.



15. On information and belief, Abbott trained its existing sales team and prepared marketing collateral and care provider instructions for, and now plans to launch, its own *B. infantis* product that would compete directly with Evolve's. According to current and potential Evolve customers, this launch is imminent and will occur within the next two months. The product is already listed for sale on Abbott's website, as shown below.



16. On information and belief, Abbott will distribute this product in powder form and instruct care providers to mix it with food products administered to infants in the NICU, including infants being fed synthetic human milk products combined with nutritional fortifiers of human or bovine origin (*e.g.*, Abbott's human milk fortifier) or infant formula (*e.g.*, Abbott's Special Care® line of products). At a recent Advances in Neonatal Nursing conference, Abbott released directions for preparation and use that instruct care providers mix its *B. infantis* product with "human milk or infant formula" products, as shown below.



**USE AS DIRECTED BY A DOCTOR**  
**Directions for Preparation and Use**

Proper hygiene, handling and storage are important when preparing and adding probiotic blend to a feeding. **Follow directions as specified.**

**Suggested Use** | 1 Packet per Day

**Preparation**

1. Pour 3–5 mL of human milk or infant formula into mixing container.
2. To open packet, tear top off completely along perforation.
3. Add 1 packet of Similac Probiotic Tri-Blend powder to mixing container.
4. Gently shake until mixed well and feed immediately.

**Storage** | Store packets unopened at or below 25°C (77°F); Use immediately once opened.

**Warning** | Do not warm feeding beyond 37°C (98.6°F).

**USE BY DATE ON BOTTOM OF CARTON**

Similac Probiotic Tri-Blend should not be prepared at the bedside.

It is recommended the product be prepared in a designated, separate area that is away from the bedside.

A small amount of sediment is normal. Gently shake to resuspend.

17. As detailed below, this combination will infringe patent claims for patents on which Evolve is an exclusive licensee, and Abbott will induce and contribute to that infringement.

18. Abbott is a leading seller in the United States of infant formula under its Similac brand and has significant business relationships with Evolve's current and potential customers. On information and belief, to establish a market for its products, Abbott frequently provides NICUs with its products below cost. On information and belief, Abbott benefits from this, as it establishes recognition for its Similac brand with care providers, and with parents who purchase Abbott's products after infants are discharged from hospital care. Abbott's imminent launch is already damaging Evolve, as even rumors about Abbott's competing product have put discussion with potential Evolve customers on hold. Evolve is a small company with comparatively limited resources, and loss of (or even delays relating to) current or potential customers due to Abbott's market entry will irreparably damage Evolve's business. Plaintiffs therefore bring this suit to stop Abbott's planned infringement.

#### **THE ASSERTED PATENTS**

19. The '872 patent, titled "Human Milk Oligosaccharides to Promote Growth of Beneficial Gut Bacteria," issued on June 12, 2012. A true and correct copy of the '872 patent is attached as Exhibit 1. The '872 patent discloses and claims compositions comprising specific HMOs and methods of producing a synthetic, prebiotic food product or food supplement comprising said HMOs and *B. infantis*.

20. The '091 patent, titled "Bovine Milk Oligosaccharides," issued on December 1, 2015. A true and correct copy of the '091 patent is attached as Exhibit 2. The '091 patent discloses and claims compositions comprising specific BMOs and *B. infantis*, methods of obtaining or modifying said BMOs, and methods of administering compositions comprising said BMOs and *B. infantis* to treat certain conditions.



21. The University owns the '872 and '091 patents. Evolve is exclusively licensed to make, use, sell, offer for sale, and import products, methods, and services that practice the '872 and '091 patents. The University and Evolve together hold the exclusive right to initiate, control, and defend any patent infringement litigation involving the '872 and '091 patents.

### **COUNT I**

#### **DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,197,872**

22. Plaintiffs incorporate by reference as though fully set forth herein the allegations in Paragraphs 1 through 21 of the Complaint.

23. Plaintiffs' claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

24. Abbott's imminent launch of its *B. infantis* product creates an actual, immediate, and real controversy within the purview of the Declaratory Judgment Act that Abbott will directly and/or indirectly infringe one or more valid and enforceable claims of the '872 patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy.

25. On information and belief, Abbott will induce others to infringe and/or will commit acts of contributory infringement of at least claim 15, which depends from claim 12, and claim 18, which depends from claims 1 and 16, of the '872 patent under 35 U.S.C. §§ 271(b) and/or (c).

26. Independent claim 1 recites "[a] synthetic prebiotic composition comprising a first, second and third purified oligosaccharide each of which naturally occur in human breast milk, wherein the first oligosaccharide has a mass/charge (m/z) ratio of about 732.3; the second oligosaccharide has a mass/charge (m/z) ratio of about 1243.4; and the third oligosaccharide has a mass/charge (m/z) ratio of about 1389.5, wherein the m/z ratio is measured by matrix-assisted laser desorption/ionization (MALDI), and wherein the composition is consumed at a higher rate by *Bifidobacterium longum* bv. *infantis* (*B. infantis*) compared to other *Bifidobacterium* strains."

27. Dependent claim 16 recites: “[a] method of producing a synthetic prebiotic food product or food supplement, the method comprising, combining at least one food ingredient with the first and second and third oligosaccharide of claim 1, thereby generating a prebiotic food product or food supplement.”

28. Dependent claim 18 recites: “[t]he method of claim 16, further comprising combining an inoculum of *B. infantis* with the food ingredient and/or first and second and third oligosaccharide.”

29. On information and belief, Abbott intends to supply its *B. infantis* product for use by care providers in the NICU.

30. On information and belief, Abbott will supply this *B. infantis* product to care providers in the United States with the understanding that they will mix the *B. infantis* product with synthetic, prebiotic human milk products. Synthetic, prebiotic human milk products of the type now used in NICUs for premature infants contain the oligosaccharides set forth in claim 1 of the '872 patent. Prior to Evolve's disclosures, it was not conventional to mix live and verified *B. infantis* with the recited HMOs via synthetic, prebiotic human milk products or otherwise. Synthetic, prebiotic human milk products of the type now used in NICUs for premature infants are “prebiotic composition[s]” that qualify as “synthetic prebiotic food products[s] or supplement[s],” as set forth claims 1 and 16 of the '872 patent, when inoculated with *B. infantis*. By combining these synthetic, prebiotic human milk products with an inoculum of *B. infantis*, care providers will thus directly infringe at least claim 18 of the '872 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, unless sublicensed by Evolve.

31. On information and belief, Abbott will imminently manufacture, use, offer for sale, or sell its *B. infantis* product or import its *B. infantis* product into the United States with the intent of causing care providers to infringe the '872 patent. Abbott will imminently induce care providers to

infringe by instructing, directing, and/or requiring them to combine its *B. infantis* product with synthetic, prebiotic human milk products, or by being willfully blind to the standard of care, which will require care providers to do so. On information and belief, Abbott has either already performed these acts or taken substantial steps toward their performance.

32. On information and belief, Abbott has actual knowledge of the '872 patent. For example, Abbott has actual knowledge of EVIVO and the research conducted by Evolve's founders at UC Davis, including that Evolve holds patent rights relating to its EVIVO product. Indeed, over the course of the last year, Abbott and Evolve entered into discussions regarding Evolve's technology and its patents. To the extent Abbott contends that it does not currently have knowledge of the '872 patent, this complaint provides such knowledge. This conduct therefore constitutes active inducement of infringement of at least claim 18 of the '872 patent under 35 U.S.C. § 271(b). Abbott infringes claim 15 for substantially similar reasons.

33. On information and belief, Abbott is or will be supplying its *B. infantis* product only for administration to premature infants in the NICU. Under the current standard of care, premature infants in the NICU are fed fortified milk products, such as synthetic, prebiotic human milk products combined with a fortifier (*e.g.*, Abbott's human milk fortifier) or formula (*e.g.*, Abbott Special Care line of products). As Abbott's *B. infantis* product is intended for administration to premature infants in the NICU, the product must be combined with such synthetic, prebiotic milk products resulting in infringement as explained above. Because Abbott's *B. infantis* product is especially made or especially adapted for use with synthetic, prebiotic human milk products, it is not a staple article or commodity of commerce suitable for substantial noninfringing use. Abbott's manufacture, use, offer for sale, or sale within the United States or importation into the United States of its *B. infantis*

product therefore constitutes contributory infringement for at least claim 18 of the '872 patent under 35 U.S.C. § 271(c). Abbott infringes claim 15 for substantially similar reasons.

34. Plaintiffs seek a declaratory judgment that commercial manufacture, use, sale, offer for sale, and/or importation of Abbott's *B. infantis* product and actions to induce others to infringe or contribute to their infringement constitute indirect infringement the '872 patent. Unless Abbott is enjoined from infringing the '872 patent, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

## **COUNT II**

### **INFRINGEMENT OF U.S. PATENT NO. 8,197,872**

35. Plaintiffs incorporate by reference as though fully set forth herein the allegations in Paragraphs 1 through 34 of the Complaint.

36. On information and belief, Abbott has tested its *B. infantis* product and continues to test its *B. infantis* product by combining it with synthetic, prebiotic human milk products with the recited HMOs, allowing Abbott to evaluate and to prepare its *B. infantis* product for launch. For the reasons stated above, this conduct constitutes direct infringement of at least claims 15 and 18 of the '872 patent under 35 U.S.C. § 271(a).

## **COUNT III**

### **DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,200,091**

37. Plaintiffs incorporate by reference as though fully set forth herein the allegations in Paragraphs 1 through 36 of the Complaint.

38. Plaintiffs' claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

39. Abbott's imminent launch of its *B. infantis* product creates an actual, immediate, and real controversy within the purview of the Declaratory Judgment Act that Abbott will directly and/or

indirectly infringe one or more valid and enforceable claims of the '091 patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy.

40. On information and belief, Abbott will induce others to infringe and/or will commit acts of contributory infringement of at least claim 14, which claims a method of treatment using the composition from claim 1, and claim 15, which depends from claim 14, of the '091 patent under 35 U.S.C. §§ 271(b) and/or (c).

41. Independent claim 1 recites “[a] composition comprising an oligosaccharide from bovine milk or milk product and an inoculum of *Bifidobacterium longum* subsp. *infantis* or *B. breve*, wherein the oligosaccharide is selected from the group consisting of: an oligosaccharide consisting of 3 Hexose (Hex) moieties, 4 N-acetyl hexosamine (HexNAc) moieties and 1 fucose (Fuc) moiety; an oligosaccharide consisting of 4 Hex moieties, 4 HexNAc moieties, and 1 Fuc moiety; an oligosaccharide consisting of 5 Hex moieties, 4 HexNAc moieties, and 1 Fuc moiety; an oligosaccharide consisting of 4 Hex moieties, 5 HexNAc moieties, and 1 Fuc moiety; an oligosaccharide consisting of 3 Hex moieties, 6 HexNAc moieties, and 1 Fuc moiety; an oligosaccharide consisting of 3 Hex moieties and 6 HexNAc moieties, an oligosaccharide consisting of 4 Hex moieties and 3 HexNAc moieties; an oligosaccharide consisting of 3 Hex moieties and 4 HexNAc moieties; an oligosaccharide consisting of 6 Hex moieties and 2 HexNAc moieties; an oligosaccharide consisting of 4 Hex moieties and 4 HexNAc moieties; an oligosaccharide consisting of 3 Hex moieties and 5 HexNAc moieties; an oligosaccharide consisting of 5 Hex moieties and 4 HexNAc moieties; an oligosaccharide consisting of 4 Hex moieties and 5 HexNAc moieties; and an oligosaccharide consisting of 3 Hex moieties and 6 HexNAc moieties.”

42. Independent claim 14 recites: “[a] method of treating a condition in an individual comprising administering an amount of the composition of claim 1 to the individual wherein the

condition is selected from the group consisting of diarrhea; necrotizing enterocolitis; irritable bowel syndrome; allergic reaction; Autism Spectrum Disorder (ASD); and presence of *Enterococcus faecalis*, *Clostridium difficile*, *Salmonella enterica*, *Salmonella typhimurium*, *Vibrio cholerae*, *E. coli* O157:H7, *Clostridium perfringens*, *Vibrio cholerae*, *Listeria monocytogenes*, *Yersinia enterocolitis*, *Enterococcus faecalis*, *Eubacteria rectales*, or *Shigella* species in the individual.”

43. Dependent claim 15 recites: “[t]he method of claim 14, wherein the oligosaccharide selectively stimulates the production of a Bifidobacterial secretion that modulates gut health in the individual; improves at least one biomarker of gut health in the individual; or increases gut colonization and persistence of probiotic bacteria.”

44. On information and belief, Abbott intends to supply its *B. infantis* product for use by care providers in the NICU.

45. On information and belief, Abbott will supply this *B. infantis* product to care providers in the United States with the understanding that they will mix the *B. infantis* product with bovine milk products. Bovine milk products of the type now used in NICUs for premature infants, including Abbott’s human milk fortifier and Special Care line of products, contain at least one of the oligosaccharides set forth in claim 1 of the ’091 patent. Care providers will administer the composition to prevent gut dysbiosis, including at least the conditions recited in claim 14 of the ’091 patent. Prior to Evolve’s disclosures, it was not conventional to treat gut dysbiosis by administering a mixture of live and verified *B. infantis* and one or more of the recited BMOs via bovine milk products or otherwise. By administering this composition to treat these conditions, care providers will thus directly infringe at least claim 14 of the ’091 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, unless sublicensed by Evolve.

46. On information and belief, Abbott will imminently manufacture, use, offer for sale, or sell its *B. infantis* product or import its *B. infantis* product into the United States with the intent of causing care providers to infringe the '091 patent. Abbott will imminently induce care providers to infringe by instructing, directing, and/or requiring them to combine its *B. infantis* product with bovine milk products comprising the at least one of the recited BMOs before administering the composition to prevent gut dysbiosis, or by being willfully blind to the standard of care, which will require care providers to do so. On information and belief, Abbott has either already performed these acts or taken substantial steps toward their performance.

47. On information and belief, Abbott has actual knowledge of the '091 patent. For example, Abbott has actual knowledge of EVIVO and the research conducted by Evolve's founders at UC Davis, including that Evolve holds patent rights relating to its EVIVO product. Indeed, over the course of the last year, Abbott and Evolve entered into discussions regarding Evolve's technology and its patents. To the extent Abbott contends that it does not currently have knowledge of the '091 patent, this complaint provides such knowledge. This conduct therefore constitutes active inducement of infringement of at least claim 14 of the '091 patent under 35 U.S.C. § 271(b). Abbott infringes claim 15 for substantially similar reasons.

48. On information and belief, Abbott is or will be supplying its *B. infantis* product only for administration to premature infants in the NICU. Under the current standard of care, premature infants in the NICU are fed fortified milk products, such as synthetic, prebiotic human milk products combined with a fortifier (*e.g.*, Abbott's human milk fortifier) or formula (*e.g.*, Abbott Special Care line of products). As Abbott's *B. infantis* product is intended for administration to premature infants in the NICU, the product must be combined with such products before administering the composition to treat gut dysbiosis, resulting in infringement as explained above. Because Abbott's *B. infantis*

product is especially made or especially adapted for use with bovine milk products, it is not a staple article or commodity of commerce suitable for substantial noninfringing use. Abbott's manufacture, use, offer for sale, or sale within the United States or importation into the United States of its *B. infantis* product therefore constitutes contributory infringement for at least claim 14 of the '091 patent under 35 U.S.C. § 271(c). Abbott infringes claim 15 for substantially similar reasons.

49. Plaintiffs seek a declaratory judgment that commercial manufacture, use, sale, offer for sale, and/or importation of Abbott's *B. infantis* product and actions to induce others to infringe or contribute to their infringement constitute indirect infringement the '091 patent. Unless Abbott is enjoined from infringing the '091 patent, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

#### **COUNT IV**

#### **INFRINGEMENT OF U.S. PATENT NO. 9,200,091**

50. Plaintiffs incorporate by reference as though fully set forth herein the allegations in Paragraphs 1 through 49 of the Complaint.

51. On information and belief, Abbott has tested its *B. infantis* product and continues to test its *B. infantis* product by combining it with bovine milk products with at least one of the recited BMOs and administering this composition to treat gut dysbiosis, allowing Abbott to evaluate and to prepare its *B. infantis* product for launch. For the reasons stated above, this conduct constitutes direct infringement of at least claims 14 and 15 of the '091 patent under 35 U.S.C. § 271(a).

#### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs request the following relief:

1. Judgment that Abbott's commercial manufacture, use, offer for sale, or sale of its *B. infantis* product infringes one or more claims of the '872 and '091 patents;
2. Judgment awarding Plaintiffs damages resulting from such infringement;



3. A declaration that this is an exceptional case and an award of attorney fees pursuant to 35 U.S.C. § 285;

4. A determination that Abbott's infringement has been willful and that the damages against it be increased up to treble on this basis or for any other basis within the Court's discretion;;

5. Injunctive relief, in the form of an order directing Defendant to cease all infringing acts;

6. Costs of suit; and

7. Any further and additional relief as the Court deems just and proper.

**DEMAND FOR JURY TRIAL**

Plaintiffs demand a trial by jury as to all issues so triable.

Dated: October 7, 2019

By: /s/ Matthew A. Chivvis

Matthew A. Chivvis (admitted *pro hac vice*)

*mchivvis@mofo.com*

Parisa Jorjani (*pro hac vice pending*)

*pjorjani@mofo.com*

Stephanie Blij (*pro hac vice pending*)

*sblij@mofo.com*

**Morrison & Foerster LLP**

425 Market Street

San Francisco, CA 94105

Telephone: 415-268-7000

Facsimile: 415-268-7522

James R. Hancock (*pro hac vice pending*)

*jhancock@mofo.com*

**Morrison & Foerster LLP**

755 Page Mill Road

Palo Alto, CA 94304-1018

Telephone: (650) 813-5600

Facsimile: (650) 494-0792

Todd H. Flaming

*TF@TFLaw.US*

**Todd Flaming LLC**

20 South Clark Street, Suite 2620

Chicago, IL 60603

Telephone: 312-447-7217

*Attorneys for Plaintiffs Evolve BioSystems, Inc.  
and The Regents of the University of California*