UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND

ADDISON HEMPEL, CASSIDY HEMPEL, CHRISTINE HEMPEL, and HUGH HEMPEL, Plaintiffs, v. CYDAN DEVELOPMENT, INC., CYDAN II, INC., VTESSE, INC., SUCAMPO PHARMACEUTICALS, INC., and MALLINCKRODT PLC, Defendants.	Case No. 18-cv-03404-PX **AMENDED COMPLAINT** **DEMAND FOR JURY**

Addison Hempel, Cassidy Hempel, Christine Hempel, and Hugh Hempel (collectively, the "Hempels"), by their attorneys, and for their amended complaint against Defendants Cydan Development, Inc. ("Cydan"), Cydan II, Inc. ("Cydan II"), Vtesse, Inc. ("Vtesse"), Sucampo Pharmaceuticals, Inc. ("Sucampo"), and Mallinckrodt plc ("Mallinckrodt") (collectively, "Defendants"), allege as follows:

1. This dispute arises out of Defendants' breach of a confidentiality agreement with the Hempels, their misappropriation of the Hempels' confidential business plans, medical research, and clinical data, their unfair competition with the Hempels, their tortious interference with the Hempels' agreements with the National Institutes of Health, and their unjust enrichment.

2. The Hempels dedicated their lives and spent millions of dollars of their own capital and community donated funds to develop medical treatments for an ultra-rare, genetic disease known as Niemann-Pick disease, Type C ("NPC") that afflicts their identical twin daughters. The Hempels planned to commercialize those treatments, and pour the proceeds back into the NPC community, so that those affected by NPC disease could control the treatments, the development, and the pricing. Instead, Defendants swooped in to misappropriate the Hempels' confidential in-

formation and trade secrets, developed a directly competitive treatment, and sold it to an international pharmaceutical company for hundreds of millions of dollars. Defendants' misconduct robbed the Hempels and the NPC community of their power to fund and control future developments in NPC treatments. Defendants' ill-gotten gains must be disgorged.

3. Addison and Cassidy Hempel (the "Hempel twins") were born on January 23, 2004. In 2007, they were diagnosed with NPC. NPC is an ultra-rare and fatal progressive neurological disease. Currently, there are approximately 500 known cases worldwide, and 100 known cases in the United States. Addison and Cassidy Hempel are the only known identical twins in the world living with NPC, making their medical information highly valuable. In all cases, the condition is fatal and responsible for severe disability and premature death.

4. Spurred by their daughters' diagnosis, the Hempels both left their employment and invested approximately $3 million of their personal time and wealth, along with millions of dollars in donations they raised and pro bono work they elicited from world-class physicians around the world, to develop their own, privately-funded treatment for NPC.

5. The Hempels' innovative translational drug research program met with immediate success, resulting in unprecedented treatment approvals by the United States Food and Drug Administration ("FDA") in 2009 and 2010 for the clinical use of 2-hydroxypropyl-β-cyclodextrin ("HPβCD" or "cyclodextrin"), in treating NPC. These events drew international recognition, and attention from the National Institutes of Health ("NIH"), as the Hempels and their team of physicians were approved by the FDA to begin treating their twin daughters with this promising new therapeutic drug. In May 2010, the FDA granted "Orphan Drug Status" to the cyclodextrin molecule being developed by the Hempels, 2HPβCD, indicating its utility in treating humans and the small patient population with NPC.

6. Treatments developed by the Hempels for NPC focused on three different drug delivery pathways: intravenous injections (*i.e.*, bloodstream), intrathecal injections (*i.e.*, lower spinal cord), and intracerebral injections (*i.e.* directly into the brain). Beginning in 2011, the NIH

funded research and a clinical trial into intracerebral injections in NPC patients, while the Hempels pursued the intravenous and intrathecal methods.

7. Over the years, the NIH requested access to the Hempels' confidential information and trade secrets to support its own studies. But each time it requested the Hempels' data, the NIH assured them that it would not use the Hempels' data for any competing commercial purpose.

8. By the spring of 2013, the NIH's Institutional Review Board ("NIH IRB") and the FDA placed the NIH's intracerebral clinical trial on "clinical hold" because it was unsuccessful due to brain infections in patients. Meanwhile, the FDA permitted the Hempels to continue pursuing both the intravenous and intrathecal methods, which showed continuing success.

9. In late June 2013, with several more years of treatment data funded and collected by the Hempels, Cydan—a venture capital-backed drug development incubator—approached the Hempels about forming a joint venture to develop and commercialize a cyclodextrin treatment based on the Hempels' private research. This opportunity was particularly attractive for Cydan. The Hempels had years of uniquely successful medical research related to NPC, and had developed a detailed business plan to commercialize all their research and development. Moreover, because NPC is an ultra-rare pediatric disease, successful development of a therapeutic drug treatment for NPC would entitle the developer to a "Priority Review Voucher" from the FDA. A Priority Review Voucher is transferable, and may be used to expedite the FDA review of any other drug, particularly those with wider indications of use, effectively accelerating the FDA approval process by two to three years. Priority Review Vouchers have sold for as much as $350 million.

10. In September 2013, the Hempels entered into a confidentiality agreement with Cydan that prohibited Cydan from using the Hempels' confidential information for any purpose other than consideration of a possible joint venture. Pursuant to that confidentiality agreement, the Hempels shared with Cydan virtually everything they had developed over the previous four years: among other things, their confidential commercialization plan, their confidential medical

research, treatment results and patient data, their confidential FDA submissions, which detailed the progress of the Hempels' studies, and the goodwill they had garnered. For months thereafter, the Hempels and Cydan developed their joint venture.

11. In the spring of 2014, Cydan suddenly broke off its communications with the Hempels. Without the Hempels' knowledge, Cydan formed an affiliate, Vtesse, which was dedicated to developing intrathecal cyclodextrin injections for NPC—the very treatment path the Hempels had been pursuing for several years. Upon information and belief, Cydan used the Hempels' confidential information and trade secrets when deciding to form and launch Vtesse, and disclosed the Hempels' confidential information and trade secrets to Vtesse for its research and commercial efforts. Cydan placed its executives—the same executives who had negotiated and signed the confidentiality agreement with the Hempels—on Vtesse's board of directors. Thereafter, Vtesse enlisted the intramural and extramural the NIH researchers who had obtained the right to reference the Hempels' confidential drug development information and medical data in their own studies by making promises of non-competition. And Vtesse worked with those NIH researchers to develop the identical treatment the Hempels had been developing.

12. On January 6, 2016, Vtesse announced that the FDA had granted "Breakthrough Therapy" status to Vtesse's cyclodextrin drug, VTS-270, which is a 2HPβCD molecule virtually identical to the molecule the Hempels had been developing. Breakthrough Therapy status enables the FDA to grant priority review for drug candidates, where preliminary clinical trials indicate that the therapy may offer substantial treatment advantages over existing options for patients with serious or life-threatening diseases. Upon information and belief, Vtesse would not have obtained Breakthrough Therapy status for its drug, VTS-270, without the Hempels' confidential business, patient, and research and development data.

13. In April 2017, Vtesse announced that it had been acquired by Sucampo Pharmaceuticals for $200 million. Sucampo's valuation of Vtesse was based upon the expected approval of cyclodextrin for the treatment of NPC, and the expected Priority Review Voucher that would be granted to Vtesse.

14. VTS-270 was expected to soon account for more than 40% of Sucampo's revenue.

15. On February 13, 2018, Mallinckrodt announced it had acquired Sucampo for $1.2 billion.

PARTIES

16. Plaintiffs Addison, Cassidy, Christine, and Hugh Hempel are natural persons domiciled in Reno, Nevada.

17. Defendant Cydan is a corporation organized under the laws of the State of Delaware, with its primary place of business at 700 Technology Square, Cambridge, Massachusetts.

18. Defendant Cydan II is a corporation organized under the laws of the State of Delaware, with its primary place of business at 700 Technology Square, Cambridge, Massachusetts. Upon information and belief, Cydan II is an affiliate or successor of Cydan, which was expressly organized to continue Cydan's mission.

19. Defendant Vtesse is a corporation organized under the laws of the State of Delaware, with its primary place of business at 805 King Farm Blvd., Rockville, Maryland. Upon information and belief, Vtesse was wholly owned by Sucampo.

20. Defendant Sucampo is a corporation organized under the laws of the State of Delaware, with its primary place of business at 805 King Farm Blvd., Rockville Maryland. Upon information and belief, Sucampo is wholly owned by Mallinckrodt.

21. Defendant Mallinckrodt is a public liability company organized under the laws of Ireland, with its legal headquarters in Dublin, Ireland, its executive headquarters in Surrey, United Kingdom, and its operational headquarters in St. Louis, Missouri.

JURISDICTION AND VENUE

22. The Court has subject matter jurisdiction over this case pursuant to 28 U.S.C. § 1332(a)(2) because the Hempels are citizens of the State of Nevada, and Defendants are citizens of the states of Delaware, Maryland, Massachusetts, Missouri, Ireland, and the United Kingdom, respectively.

23. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b)(2) because Defendants are domiciled in this District and consented to this Court's jurisdiction.

FACTUAL ALLEGATIONS

A. Background on Niemann-Pick Disease, Type C

24. As described by the National Institutes of Health:

> Niemann-Pick disease (NP) refers to a group of inherited metabolic disorders known as lipid storage diseases. Lipids (fatty materials such as waxes, fatty acids, oils, and cholesterol) and proteins are usually broken down into smaller components to provide energy for the body. In Niemann-Pick disease, harmful quantities of lipids accumulate in the brain, spleen, liver, lungs, and bone marrow. Neurological symptoms may include ataxia (lack of muscle control during voluntary movements such as walking), loss of muscle tone, brain degeneration, increased sensitivity to touch, spasticity (stiff muscles and awkward movement), and slurred speech. Other symptoms may include feeding and swallowing difficulties, eye paralysis, learning problems, and an enlarged liver and spleen. There may be clouding of the cornea and a characteristic cherry-red halo develops around the center of the retina.[1]

25. There are three different variations of Niemann-Pick disease—Types A, B, and C. As it pertains to this action, Niemann-Pick disease, Type C, or NPC, may appear "early in life or develop in the teen or adult years," and is "caused by a lack of the NPC1 or NPC2 proteins." *Id.* "Affected individuals may have extensive brain damage that can cause an inability to look up and down, difficulty in walking and swallowing, and progressive loss of vision and hearing. There may be moderate enlargement of the spleen and liver." And patients frequently experience psychosis, dementia, hearing loss, bipolar disorder, and depression. NPC has often been referred to as "Childhood Alzheimer's."

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[1] https://www.ninds.nih.gov/Disorders/All-Disorders/Niemann-Pick-Disease-Information-Page, *visited* Feb. 14, 2019.

26. The life expectancy of persons with NPC varies. "[S]ome individuals die in childhood while others who appear to be less severely affected can live into adulthood." *Id.* There is, however, currently no cure for NPC. Treatment is supportive. Children usually die from infection or progressive neurological loss.

B. After the Twins are Diagnosed with NPC, The Hempels Dedicate Their Lives to Organizing and Funding Private Research to Develop an Treatment

27. Addison and Cassidy Hempel are identical twin girls. They were born on January 23, 2004.

28. In 2005, the Hempel twins developed what appeared to be a severe case of mononucleosis. After a year and a half of testing at major pediatric medical hospitals including Stanford and UCSF Benioff Children's Hospital Oakland, the Hempel twins were diagnosed with NPC in 2007.

29. With no approved FDA treatments for NPC, the Hempels quickly assumed a role as rare disease advocates and benefactors for NPC research.

30. Following the Hempel twins' diagnoses in 2007, for example, the Hempels met with Dr. Christopher Austin, a senior research director at the National Human Genome Research Institute ("NHGRI") of the NIH, to discuss possibilities for drug investigation. They began raising money for NPC research, and generated millions in research dollars including funds that supported NHGRI. The Hempels built upon organizing efforts with other parents of NPC patients, to collect (for example) human biological samples from NPC children, for use in treatment and research efforts. And the Hempels dedicated significant amounts of their personal wealth, time, and energy to the research effort. Since 2007, they have invested more than $3 million to research efforts, which includes their personal time, and collected millions more in donations and in-kind contributions.

31. As they became immersed in NPC research efforts, the Hempels found a community of medical and research investigators highly interested in NPC, in part because of potential connections between NPC as an ultra-rare genetic disease and its connection to Alzheimer's Dis-

ease and cholesterol diseases, and the hypothesis in the medical science community that successful treatments for NPC could lead to insights and treatments for these more common diseases. In addition, the Hempels later learned of the connection between the NPC1 gene and Ebola and HIV viruses, putting this obscure disease at center stage in numerous medical research fields.

32. In late 2007, Dr. Benny Liu, M.D., et al., published the first research paper suggesting that cyclodextrin, *i.e.*, 2HPβCD, could be used to treat NPC.

33. Upon learning of the Liu publication, the Hempels decided to pursue cyclodextrin treatments for their daughters.

34. The Hempels and their team of doctors, scientists, and advisors developed and published the first human cyclodextrin treatment protocols for intravenous and intrathecal cyclodextrin therapy, which were all approved by the FDA.

35. Beginning in 2008, the center of the Hempels' efforts to develop therapeutic treatment for Addison and Cassidy has been their home in Reno, from which they later promoted a new drug development business, Solution Therapeutics, which they intended to formally incorporate.

36. On November 25, 2008, Dr. Caroline Hastings, UCSF Benioff Children's Hospital Oakland, filed Individual Investigational New Drug Applications ("I-IND") and the first human treatment protocols with the FDA to treat the Hempel twins with intravenous cyclodextrin.

37. On March 18, 2009, the FDA approved I-IND treatment of cyclodextrin for the Hempel twins.

38. On May 16, 2010, the FDA granted "Orphan Drug Status" to 2HPβCD for the treatment of NPC. The designation was assigned to Dr. Caroline Hastings, the physician sponsor of the Hempel twins' I-INDs.

39. On September 23, 2010, UCSF Benioff Children's Hospital Oakland announced that the FDA granted clearance to administer intrathecal cyclodextrin into the Hempel twins' spinal cords. This was the first time intrathecal cyclodextrin was delivered directly to the brain of any human patient—via the spinal cord—in an attempt to arrest a progressive and fatal neurolog-

ical condition. At that time, the Hempel twins began a "combination treatment" regime of weekly intravenous injections and semi-monthly intrathecal cyclodextrin treatments.

40. Over the course of 2011, the NIH began its own clinical trials of cyclodextrin treatments, through its National Center for Advancing Translational Sciences ("NCATS") and National Institute of Child Health and Human Development divisions ("NICHD"). The Hempels fully cooperated with NIH efforts per their requests because NIH assured them that its studies were not in competition with the Hempels' own research and clinical development efforts.

41. Indeed, whereas the Hempels and their medical research team were focused on intravenous and intrathecal treatments with cyclodextrin, the NIH focused on intracerebral treatments, *i.e.*, delivery of cyclodextrin directly into the brain through the scalp.

42. At various times, NIH researchers asked the Hempels' permission to reference their confidential data in connection with the NIH's submissions to the FDA regarding the NIH's intracerebral treatment study. Because the NIH researchers promised that they were not pursuing a treatment that would compete with the Hempels' and the Hempels' commercial interests, the Hempels granted the NIH's request.

43. The NIH's intracerebral clinical trial was terminated by both the NIH NICHD division and the FDA in or about April or May 2013 because the NIH's protocol caused brain infections. Meanwhile, the Hempels' intravenous and intrathecal cyclodextrin treatment program met with great success.

C. Cydan Misappropriates the Hempels' Business Plan and Confidential Information in Breach of a Confidentiality Agreement

44. With the success of their intrathecal cyclodextrin injections, the Hempels continued to develop the business ideas underlying Solution Therapeutics. The Hempels' concept was to use the data from their daughters' treatments to obtain FDA approval for their intravenous and intrathecal cyclodextrin treatments, and ultimately receive a Priority Review Voucher that they could sell to a pharmaceutical company. They intended to use the money they earned from the

sales of the treatment and the Priority Review Voucher to fund future research in NPC and ensure that NPC treatments were reasonably priced for those in the community.

45. During that time period, the Hempels sometimes received requests for access to the medical data they had compiled to facilitate compassionate use of cyclodextrin on NPC children. The Hempels always agreed to help, providing their safety data under the auspices of express and implied agreements that the disclosure was for compassionate use purposes only, and not for commercial use.

46. The Hempels meticulously developed the Solution Therapeutics plan from 2011 to 2013: they worked closely with former Genentech executive, Stephen Dilly; they employed researchers; they compiled a library of medical data on their daughters, which was wholly unique; they made confidential FDA filings; and they built industry relationships. They only needed a financial partner to push the concept over the finish line.

47. The Hempels met with several potential investors regarding Solution Therapeutics, including Medtronic, Genzyme, and Johnson and Johnson.

48. On June 28, 2013, Chris Adams, Cydan's Chief Business Officer, contacted Hugh Hempel through LinkedIn to discuss a potential collaboration regarding the Hempels' efforts to commercialize an intrathecal injection of cyclodextrin to treat NPC.

49. In their correspondence, Hugh expressed his reciprocal interest in a collaboration.

50. After several emails back and forth, and telephone conversations, Mr. Adams invited Hugh to meet with his Cydan team.

51. By virtue of the correspondence and conversations, the parties developed a special relationship of trust and confidence as they pursued a joint venture.

52. In furtherance of that special relationship, on September 12, 2013, the Hempels disclosed their confidential business plan for Solution Therapeutics (the "Business Plan") to Cydan. The Business Plan included a soup to nuts proposal for Solution Therapeutics, describing in detail a business model predicated on the Hempels' five years of successful medical research

of cyclodextrin and how that business model could and would culminate in receipt of a Priority Review Voucher.

53. The Hempels' Business Plan gave Cydan an accelerated, clear, and risk-reduced path forward.

54. The Business Plan included confidential information developed by the Hempels, including data summaries of "Early Human Clinical Efficacy," which was data demonstrating the efficacy of the intrathecal cyclodextrin on the Hempel twins.

55. The Business Plan suggested that the proceeds from Solution Therapeutics should be distributed 50% to investors and 50% to non-profit efforts to fund additional treatments for the disease and to support families impacted by NPC.

56. The cover of the Business Plan was marked "Confidential."

57. In response to the Business Plan, the then-CEO of Cydan, Cristina Csimma, wrote by email: "the work you have done is truly amazing."

58. On September 13, 2013, Hugh Hempel met with Cydan for an in-person meeting at Cydan's offices in Boston, Massachusetts, to discuss Solution Therapeutics, cyclodextrin, and NPC.

59. The meeting was attended by Chris Adams, Deborah ("Deb") Geraghty, who was the Vice President of Cydan for Project & Portfolio Development, and others. They discussed the Hempels' successes to date, and the commercial opportunities presented by the development of cyclodextrin. During the meeting, which lasted more than two hours, Hugh walked Cydan through the Business Plan, and answered questions about the Hempels' plans to seek FDA approval to commercialize their cyclodextrin treatment for NPC, to pursue a Priority Review Voucher to be sold to a major pharmaceutical company, and then to invest the proceeds back into the NPC community to fund future research and treatment.

60. After the meeting, Ms. Geraghty told Hugh that Cydan wanted to enter into a non-disclosure agreement with the Hempels to facilitate further negotiations regarding the Hempels'

concept for Solution Therapeutics and commercializing the Hempels' intrathecal cyclodextrin treatments for NPC.

61. To that end, the next day Ms. Geraghty sent a follow-up email to the Hempels, requesting a non-disclosure agreement for execution, and "access to your 'server' where you have data and other background available for our review," along with help from the Hempels in "[f]acilitating an introduction to [Dr.] Daniel Ory at [Washington University School of Medicine in St. Louis]."

62. In response, Hugh Hempel sent Cydan the "Agreement for Mutual Exchange of Confidential Information." Hugh drafted the agreement as between Solution Therapeutics and Cydan (the "Confidentiality Agreement"). With the proposed Confidentiality Agreement, Hugh sent a link to an on-line database compiled by the Hempels that contained all of the medical research and data the Hempels had compiled since the twins' diagnosis.

63. The Confidentiality Agreement provided that Solution Therapeutics and Cydan "desire to enter into discussions regarding use of cyclodextrin as a therapeutic agent (the 'Agreement') for the treatment of Niemann Pick Type C, Alzheimer's Disease and/or Atherosclerosis (the 'Subject Matter') in order to determine the feasibility of entering into a business relationship between the parties (the 'Stated Purpose')."

64. The Confidentiality Agreement defined the Hempels' "Confidential Information" as "any non-public information of [Solution Therapeutics], including without limitation, that relating to current and planned drug and biologic delivery systems and agents, medical or diagnostic treatments involving such systems and agents, business plans and financial and/or marketing information."

65. The Confidentiality Agreement further stated, "Each party agrees to use the Confidential Information of the other party solely for the Stated Purpose and for no other purpose whatsoever."

66. The term of the Confidentiality Agreement was one year, *i.e.*, until September 2014. Cydan could not use any of the Hempels' Confidential Information for any purpose for an additional year after the term of the Confidentiality Agreement, *i.e.*, until September 2015.

67. On September 17, 2013, Cydan returned a fully-executed copy of the Confidentiality Agreement, signed by Cristina Csimma.

68. Hugh signed the Confidentiality Agreement on behalf of Solution Therapeutics.

69. Thereafter, the Hempels provided Cydan with virtually everything they had developed over the previous five years. Specifically, the Hempels provided Cydan with patient and treatment data, business ideas, technology and intellectual property, and goodwill within the industry.

70. Regarding data and research, Hugh provided Cydan with access to two on-line databases he had created. The first was the NPC Virtual BioTech database, which included all of the confidential medical data collected from the Hempel twins and their treatment with cyclodextrin, confidential medical data they had collected from other NPC patients, and a library of medical research related to NPC and cyclodextrin. The second was the Solution Therapeutics database, which contained confidential information related to the Hempel twins' treatments with cyclodextrin, the Hempels' confidential FDA applications and annual reports, and all other Confidential Information and trade secrets the Hempels had compiled and created in relation to Solution Therapeutics.

71. Regarding patient data, the Hempels supplied Cydan with extensive medical data and results from the intrathecal cyclodextrin treatments on Addison and Cassidy. That data included changes in their hearing, changes in their tau protein levels, pharmacokinetic studies, and urine samples. All of that highly confidential data—which had never been disclosed publicly—established that the intrathecal injections of cyclodextrin were a promising treatment for NPC.

72. Regarding the Hempels' business idea, the Hempels provided a thoroughly researched Business Plan for a biotech start-up founded on cyclodextrin and the NPC patient community. The Business Plan also included the concept of Priority Review Vouchers, which

was relatively misunderstood at the time, even by experienced venture capital and pharma executives at Cydan. The Hempels explained the multiple routes of administration for cyclodextrin—intravenous, intrathecal, and intracerebral—and why the intrathecal method they had championed was promising.

73. The Hempels also explained the potential additional indications for cyclodextrin, from Atherosclerosis to HIV.

74. Regarding technology and intellectual property, the Hempels provided confidential drug formulations, study design elements and other proprietary data the Hempels had developed in conjunction with Johnson & Johnson and their subsidiary Janssen Pharmaceutical. The Hempels had developed an alliance with Johnson & Johnson to enable the production of 2HPβCD, the cyclodextrin molecule used by the Hempels' clinical researchers in the Hempel twins.

75. Regarding goodwill, the Hempels introduced Cydan to the preeminent NPC medical and clinical researchers, including Drs. Daniel Ory, Steven Walkley, Lajos Szente, Caroline Hastings, and Benny Liu, The Hempels also introduced Cydan to key members of Johnson & Johnson and the NIH.

76. Over the subsequent months, Cydan and the Hempels continued to collaborate on their joint venture and advance the Hempels' plan for Solution Therapeutics. Their main point of contact was Ms. Geraghty, with whom they built a strong business relationship and friendship.

77. On January 16, 2014, Ms. Geraghty sent Hugh an email stating that Cydan was "[m]oving forward for sure" with the project and wanted to set up a call with Hugh to discuss next steps.

78. On or about February 14, 2014, Chris Adams of Cydan and Hugh Hempel had a conference call to discuss the next steps.

79. Because of their special relationship with Cydan and assurances that the parties were moving forward, the Hempels ceased all efforts to find a different partner to commercialize an intrathecal cyclodextrin treatment for NPC.

80. Suddenly, in the late spring of 2014, Cydan ceased communicating with the Hempels. Around that same time, Ms. Geraghty abruptly left Cydan with no explanation. At the time, the Hempels believed that Cydan had decided not to proceed with the Hempels' Business Plan and the Solution Therapeutics concept.

81. But, without the Hempels' knowledge, Cydan breached its contractual and fiduciary obligations to the Hempels. misappropriated their Confidential Information and trade secrets, and decided to pursue the Hempels' Business Plan and commercialize an intrathecal cyclodextrin treatment for NPC without granting the Hempels any financial stake. Upon information and belief, Cydan terminated Ms. Geraghty in early 2014 to prevent her from disclosing its misconduct.

82. Indeed, without the Hempels' knowledge, Cydan surreptitiously spun out, formed, and incorporated Vtesse on May 20, 2014, just eight months after signing the Confidentiality Agreement with the Hempels. Vtesse and Cydan were affiliates because they were under control of the same investors. Indeed, Vtesse engaged Cydan to provide due diligence and start-up activities.

83. Vtesse was virtually identical to the Hempels' proposal for Solution Therapeutics. Vtesse was a biotech start-up dedicated to developing intrathecal cyclodextrin injections for NPC patients, the same treatment that the Hempels had pioneered. Vtesse's business model and research focus were precisely what the Hempels had proposed, and Vtesse was founded on the years of intrathecal cyclodextrin treatment data that Cydan had misappropriated from the Hempels.

84. Vtesse had knowledge of the Hempels' Confidential Information and trade secrets because Cristina Csimma and Chris Adams—Cydan executives who had reviewed the Hempels' Business Plan and research and medical data, and who had assured the Hempels that Cydan was going forward with the Solution Therapeutics joint venture—were directors of Vtesse.

85. Just eight months after forming, Vtesse publicly announced on January 7, 2015, that it had been spun out from Cydan and had received financing to conduct a clinical program for VTS-270, a formulation of cyclodextrin that is administered intrathecally, and to discover

and pre-clinically evaluate additional novel drugs for NPC. Cydan touted that it had raised more than $25 million in Series A funding from its investors for Vtesse.

86. It is inconceivable that Cydan's investors would have granted such a sum without significant due diligence about the source and quality of the existing data related to intrathecal treatments for cyclodextrin. As Cydan and its investors knew, the vast majority of that data had been developed by the Hempels. And Cydan had access to that data, which was reviewed by Cristina Csimma and Chris Adams, who were Vtesse executives. In fact, Cydan's promotional materials included photographs of the Hempel twins. And, upon information and belief, Cydan referenced its access to the Hempels' data when courting investors. Thus, the only plausible conclusion is that Cydan and Vtesse improperly used the Hempels' data to form Vtesse and convince Cydan investors to invest in the venture.

87. The January 7, 2015, announcement was the first time the Hempels had ever heard of Vtesse.

D. Vtesse Misappropriates the Hempels' Data Via the NIH

88. Defendants not only misappropriated the Confidential Information and trade secrets the Hempels disclosed to Cydan, but they also misappropriated the Hempels confidential information and trade secrets by enlisting the same NIH researchers who gained access to the data by making promises of non-commercial use. Vtesse systematically vacuumed up from every possible resource all work based upon the Hempels' data.

89. Cydan misappropriated the Hempels' confidential information and trade secrets through its relationship with Drs. Daniel Ory and Forbes Porter, who were NIH-affiliated researchers.

90. After Hugh met with Cydan on September 13, 2013, Cydan asked Hugh to introduce Cydan to Dr. Ory. Thereafter, upon the formation of Vtesse, Cydan placed Dr. Ory on Vtesse's scientific board of advisors. And Vtesse funded Dr. Ory's study of intrathecal cyclodextrin. But, as explained below, Dr. Ory's study of intrathecal cyclodextrin was only possible because he had gained access to the Hempels' confidential information and trade secrets in connec-

tion with the NIH's assurance of non-competitive use. Thus, upon information and belief, at the prompting of Cydan and Vtesse, Dr. Ory improperly used the Hempels' confidential information and trade secrets for the purpose of advancing Vtesse's VTS-270 clinical trials.

91. As set forth above, beginning in 2011, the Hempels began cooperating with the NIH so that the NIH could develop intracerebral cyclodextrin treatments for NPC, in parallel to the Hempels' development of the intravenous and intrathecal routes of administration.

92. Because the Hempels were several years further along in their research and development than the NIH, the NIH—by Drs. Ory and Porter—requested a right to reference ("ROR") the Hempels' data in its FDA submissions, which the NIH would use to supplement its intracerebral research. The NIH assured the Hempels verbally and in writing that its clinical study was not competing with the Hempels' research and clinical efforts. Based on those assurances, the Hempels granted the ROR to the NIH. But for those assurances, the Hempels would have negotiated different terms with the NIH. For example, they would have sought assurances that they would be included in any competing, commercial venture to protect the NPC community's interests in the future of cyclodextrin research.

93. By the spring of 2013, the NIH's intracerebral trial was placed on clinical hold by both the NIH IRB and FDA because it caused brain infections in the NIH's child-patients.

94. Drs. Porter and Ory was directly involved with the NIH's failed intracerebral clinical trial at the NIH.

95. Because the NPC patient population is tiny, an admission that a clinical trial had failed would be catastrophic because irreplaceable patients would leave the study. As a result, the NIH revised its protocol immediately to conform to the Hempels' proven, intrathecal path of administration. To maintain patient confidence in the study, the NIH needed to begin dosing patients at the higher dosage levels for which the Hempels had been compiling safety data for years, rather than starting from scratch. Otherwise, NPC parents would simply apply for compassionate use of cyclodextrin outside the context of the NIH's study.

96. In an email dated May 7, 2013, Dr. Ory acknowledged that the intracerebral treatment had failed and proposed that the NIH research group—which included Dr. Porter—switch to a clinical trial using intrathecal treatments—in direct competition with the Hempels' efforts. Dr. Ory was concerned, however, that switching from intracerebral to intrathecal treatments would be viewed as a huge setback, and could cause the patient community to lose faith in the NIH. Dr. Ory noted that it would take years to recreate the Hempels' intrathecal medical data, and said he hoped Dr. John McKew, an NIH/NCATS Director, could "engage FDA through back channels" to either accelerate FDA approval of the planned change to intrathecal delivery and/or gain access to the Hempels' Confidential Information and trade secrets related to their intrathecal treatment.

97. Dr. Ory explained to his colleagues at the NIH that the only way for the study to get back on track quickly was if he had access to the Hempels' data. He said he hoped to "capitaliz[e] on the [Hempels'] single use IND experience with [intrathecal] and try to advance the dose selection (200 mg/300 mg/400 mg). While starting at 50 mg would allow us to compare IT and ICV directly, the community—and Jonathan [*i.e.*, a member of the patient community]—will view this as starting the trial over again. If the FDA would allow [us] to start at a higher do[se], based on the single use IND experience, this has two benefits. First, it will likely accelerate the collection of data (positive biochemical response) that are needed to plan the Phase 2 design. This may not satisfy all the families, but it might allow Jonathan and others who are contemplating to justify staying the course. Second, it would show to the community that we are partnering with them by incorporating their experience in the trial design (*i.e.*, FDA allowing us to start at 200 mg rather than 50 mg)."

98. Dr. McKew replied: "Can you summarize the doses the kids have taken so far via IT?"

99. Dr. Porter answered: "The information we had on the [Hempel] twins was initially 175 mg and then increased to 350 mg every two weeks."

100. Upon information and belief, Drs. Porter and Ory and/or the NIH team, successfully accessed those "back channels" at the FDA to gain access to the Hempels' data and/or accelerate FDA approval of the planned change to intrathecal cyclodextrin delivery. The NIH team did not spend years compiling sufficient intrathecal clinical data to justify that dose. Instead, they leveraged, and then utilized, the Hempels data to satisfy the FDA and various hospitals' Internal Review Boards. Consequently, just four months after saying he needed the Hempels data, the NIH launched a study on September 21, 2013, studying intrathecal treatments of NPC1 at higher dosage levels: "Intrathecal 2-hydroxypropyl-β-cyclodextrin decreases neurological disease progression in Niemann-Pick disease, type C1: a non-randomised, open-label, phase 1-2 trial."[2] As he said in his May 7, 2013, email, Dr. Ory was able to dose patients at 50, 200, 300, or 400 mg per month, rather than just 50mg. Upon information and belief, the FDA only permitted Dr. Ory's team to inject patients with 200, 300, and 400 mg per month because Dr. Ory had wrongfully accessed and/or referenced the Hempels' intrathecal data without their permission or consent.

101. The Hempels had no knowledge of Dr. Ory's and the NIH team's use of their intrathecal data. Rather, because the Hempels knew that Dr. Ory shared their common goal of improving treatments for NPC, they introduced him to Cydan at Cydan's request.

102. Defendants then misappropriated Dr. Ory's and the NIH's access to, and knowledge of, the Hempels' intrathecal injection data for their own commercial uses.

103. On October 15, 2017, Dr. Ory was the lead author on a study published in the Lancet detailing the NIHs intrathecal clinical trial. That paper revealed that Vtesse had funded members of the NIH team including Drs. Ory and Berry-Kravis through various grants. Moreover, Dr. Ory and NIH employees, including Dr. Porter, had sat on Vtesse's board of scientific

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[2] https://www.ncbi.nlm.nih.gov/pubmed/28803710, *last visited* Feb. 14, 2019.

advisors the entire time. That is, Vtesse knew or should have known that it was using misappropriated data and funding studies that encouraged the misuse of the Hempels' data.

104. Indeed, when Vtesse announced it had received financing to conduct a clinical program for cyclodextrin, Vtesse simultaneously announced it had entered into a "Cooperative Research and Development Agreement" ("CRADA") with NIH/NCATS to work together on research and developing intrathecal injections of cyclodextrin. Upon information and belief, Vtesse entered into the CRADA with NIH/NCATS because Vtesse knew the NIH/NCATS had been using the safety data the Hempels had compiled and confidentially disclosed to the FDA and NIH.

105. Separately, in September 2013, Dr. Elizabeth Berry-Kravis of Rush University Medical Center sought an ROR to the Hempels' intrathecal clinical data related to semi-monthly dosing in order to treat one of her patients. On behalf of the Hempels, Dr. Caroline Hastings granted Dr. Berry-Kravis's request. Dr. Berry-Kravis did not disclose any intention to use the data for any commercial purpose. Thereafter, Dr. Berry-Kravis treated her NPC patient with cyclodextrin intrathecally.

106. Three years later, on September 2, 2016, Vtesse announced a breakthrough and that, in the Phase 2/3 part of the VTS-270 clinical trial, the frequency of the dosing was going to change from monthly to semi-monthly. That "breakthrough" was purportedly based on intrathecal research by Dr. Berry-Kravis. But her research was premised on the Hempels' Confidential Information and trade secrets.

107. Thus, Vtesse had only achieved its "breakthrough" by misappropriating the Hempels' data subject to the confidentiality and use restrictions of the ROR applicable to Dr. Berry-Kravis.

E. Defendants Capitalize on their Misappropriation of the Hempels' Confidential Information and Trade Secrets

1. Sucampo Acquires Vtesse and VTS-270 for $200 million

108. On January 6, 2016, Vtesse announced that the FDA had granted Breakthrough Therapy designation status to VTS-270, which is Vtesse's name for its 2HPβCD drug for treat-

ment of NPC. Both the FDA and the European Medicines Agency had previously granted Orphan Drug status to VTS-270.

109. Three months later, on April 3, 2017, Cydan announced "the acquisition of its first rare disease spin-out, Vtesse Inc., by Sucampo Pharmaceuticals, Inc." Cydan noted "Vtesse was launched by Cydan in 2015 to advance its orphan drug candidate, VTS-270," *i.e.*, a cyclodextrin molecule, "for treatment of Niemann-Pick Disease Type C (NPC)."

110. Upon information and belief, Sucampo acquired all of Vtesse's assets and liabilities. Sucampo acquired Vtesse "for an upfront consideration of $200 million," including "the issuance of 2,782,678 shares of Sucampo Class A common stock and $170 million of cash on hand." The proceeds of the transaction went directly to Vtesse's shareholders.

111. As part of the transaction, Cydan shareholders who previously owned Vtesse received a financial stake in VTS-270 if Sucampo received a Priority Review Voucher.

112. Sucampo touted the "[m]echanism and intrathecal route of administration" for VTS-270 and the potential FDA approval and a Priority Review Voucher.

113. Following the acquisition, Sucampo folded Vtesse into its operations. According to Vtesse's press release, the acquisition "provide[d] Sucampo with VTS-270" and "[b]uilt upon Sucampo's capabilities, global development platform and focus on specialized areas of high, unmet medical need," and Vtesse employees were all "expected to join Sucampo."

114. Vtesse moved its operations from Gaithersburg, Maryland to Rockville, Maryland, where Sucampo was located and had the same address as Sucampo. *Id*. At the time of the acquisition, Vtesse had ten total employees. Upon information and belief, each of them became Sucampo employees or contractors afterwards. And upon information and belief, Vtesse ceased to have a functioning board of directors after the acquisition. In fact, Machielse—Vtesse's CEO—was terminated from Vtesse immediately after the acquisition, and became a consultant to Sucampo.

115. Sucampo immediately hollowed out Vtesse and transferred ownership of Vtesse's assets to its own balance sheet. Per its 10-Q, dated August 2, 2017, Sucampo represented, "On

March 31, 2017, the Company entered into an Agreement and Plan of Merger with Vtesse Inc. (Vtesse), a privately-held rare disease company. The Company acquired Vtesse's lead product candidate, known as VTS-270, upon closing the acquisition on April 3, 2017. . . . The Company accounted for the transaction as an asset acquisition and incurred an acquired in-process research and development charge of $186.6 million (and no related current tax benefit) in the second quarter of 2017." Later in its 10-Q, Sucampo represented, "Vtesse did not meet the definition of a business under ASC 805 as substantially all of the fair value of Vtesse was attributable to the VTS-270 IPR&D asset." Sucampo acknowledged that VTS-270 was Vtesse's "only significant asset."

2. Cydan Becomes Cydan II Immediately After Selling Vtesse

116. Just one month after orchestrating the sale of Vtesse to Sucampo for $200 million, Cydan formed Cydan II on May 10, 2017. Cydan publicly stated that Cydan II would be operated by the same "experienced team" that had operated Cydan, that Cydan II would "continu[e] the mission of [Cydan]," and that new funding would "extend [Cydan's] operations for another four years." In short, Cydan II merely supplanted Cydan as the public-facing operating Cydan entity.

117. Cydan II occupied the same address as Cydan.

118. The Cydanco.com website changed references to Cydan to references to Cydan II.

119. Cydan II's investors were essentially the same as Cydan's, including Alexandria Equities, Ludenbeckfond Invest A/S, New Enterprise Associates, and Pfizer, Inc.

120. Cydan ceased operations after the formation of Cydan II. Cydan assigned its assets to Cydan II. And when Cydan II was first capitalized in August 2017, it issued offer letters to former Cydan employees.

3. Mallinckrodt Acquires Sucampo and VTS-270 for $1.2 Billion

121. Less than eight months after Sucampo acquired VTS-270, on December 26, 2017, Mallinckrodt plc, a global specialty pharmaceutical company, announced that it had entered into an agreement to acquire Sucampo, including its two commercial assets and its two development

assets, one of which was VTS-270. A month after this action was originally filed, the transaction closed on February 13, 2018, for a total transaction value of $1.2 billion.

122. Mallinckrodt announced that it had acquired Sucampo, "including its commercial and development assets." After the acquisition, Sucampo ceased to exist as an independent entity.

123. Sucampo shareholders received shares of Mallinckrodt in exchange.

124. After the acquisition, Vtesse became a mere department within Mallinckrodt. Upon information and belief, Vtesse currently has five employees and no functional divisions. Vtesse has no actual or projected revenues or income streams, and is funded entirely by Mallinckrodt. Indeed, Mallinckrodt's website identifies VTS-270 as one of its pipeline products, but does not mention Vtesse.

125. Upon information and belief, all of Sucampo's and Vtesse's records are now maintained by Mallinckrodt as part of its regular course of business.

126. As a result of these transactions, the NPC community and the Hempels lost all control over the development of a cyclodextrin for their children. Because of their various and repeated violations of confidentiality agreements, misappropriation of the Hempels' confidential information and trade secrets, breach of fiduciary duties, and unethical conduct, Defendants were enriched by hundreds of millions of dollars and obtained exclusive control over a vital treatment for NPC sufferers. Because of Defendants' misconduct, the Hempels and the NPC community not only lost out on their share of the proceeds, which they would have used to finance future NPC research, but they also lost control of the future of cyclodextrin research, and the power to ensure fair product pricing for NPC patients. Because of their unfair acts, Defendants not only misappropriated the Hempels' confidential information and trade secrets, but also the NPC community's autonomy.

FIRST CAUSE OF ACTION
BREACH OF CONTRACT
(AGAINST DEFENDANTS)

127. The Hempels repeat and reallege each and every one of the foregoing allegations as though fully set forth herein.

128. Cydan breached both the Confidentiality Agreement and an implied contract regarding the Hempels' the Business Plan.

129. *First*, Solution Therapeutics and Cydan entered into the Confidentiality Agreement on or about September 13, 2013.

130. As the promoter of Solution Therapeutics, Hugh Hempel signed the Confidentiality Agreement on its behalf.

131. Because Solution Therapeutics was never incorporated, Hugh Hempel has the power to enforce the Confidentiality Agreement.

132. The Confidentiality Agreement prohibited Cydan from using any Confidential Information disclosed by the Hempels for any purpose except for the consideration of a joint venture.

133. Cydan could not use the Confidential Information for the term of one year, plus an additional year. Thus, Cydan could not use the Confidential Information for any purpose other than exploring a joint venture with the Hempels prior to September 15, 2015.

134. The Hempels performed Solution Therapeutics' obligations under the Confidentiality Agreement and, thus, are empowered to enforce the Confidentiality Agreement against Cydan.

135. In breach of the Confidentiality Agreement, Cydan used the Hempels' Confidential Information for its own purpose, using the Hempels' Confidential Information to form Vtesse in May 2014, to negotiate a CRADA with the NIH in January 2015, to gain FDA approval to use of VTS-270, to obtain a rare pediatric disease designa-

tion that put it in line to receive a Priority Review Voucher, and to ultimately sell Vtesse for $200 million to Sucampo.

136. *Second*, Cydan breached an implied contract with the Hempels in connection with the disclosure of the Business Plan.

137. The Business Plan was novel: it proposed the creation of a business dedicated to developing an intrathecal cyclodextrin treatment for NPC, which had never been done before.

138. The Business Plan was concrete: it was a 43-page presentation detailing the business goals and the scientific and medical research data establishing the viability of the enterprise, along with the relevant collaborators and ongoing research to illustrate the flexibility of the enterprise.

139. The Hempels disclosed the Business Plan to Cydan under circumstances that implied confidentiality. It was disclosed in a private email in connection with a proposed meeting to discuss a joint venture. Moreover, the Business Plan was clearly marked "Confidential" on the first page.

140. Cydan breached that implied contract in connection with the Business Plan by executing on it without properly compensating the Hempels. When it formed Vtesse, Cydan followed the blueprint detailed in the Business Plan, creating a biotech company dedicated to developing an intrathecal cyclodextrin treatment for NPC. But Cydan failed to compensate the Hempels in any way for their contribution.

141. Vtesse, Sucampo, and Mallinckrodt are liable for Cydan's breach of contract because they, *inter alia*, knowingly accepted the benefits of Cydan's breach.

142. As a direct and proximate cause of Defendants' breach of the Confidentiality Agreement and implied contract in connection with the Business Plan, the Hempels have been irreparably harmed and Defendants must disgorge their profits.

143. Defendants' breach of the contract was with reckless, willful, or callous disregard for the Hempels' rights and with malice, fraud, or oppression toward them,

thereby entitling the Hempels to an award of punitive damages in accordance with proof at trial.

SECOND CAUSE OF ACTION
COMMON LAW MISAPPROPRIATION AND VIOLATION OF THE MARYLAND UNIFORM TRADE SECRETS ACT (AGAINST ALL DEFENDANTS)

144. The Hempels repeat and reallege each and every one of the foregoing allegations as though fully set forth herein.

145. The Hempels possessed trade secrets, including, but not limited to, their confidential Business Plan, their Confidential Information, the years of confidential medical data they had compiled from the intravenous and intrathecal cyclodextrin treatments on the twins, their compilations of research, and their confidential FDA submissions. Each of these trade secrets derive independent economic value from not being generally known to, and not being readily ascertainable by proper means, by the public or any other persons who can obtain commercial or economic value from their disclosure or use.

146. The Hempels took adequate measures and maintained the foregoing information and technology as trade secrets, the secrecy of which was guarded and not readily available to others.

147. Defendants intentionally, and with reason to believe that their actions would cause injury to the Hempels, misappropriated and exploited the trade secret information through use and disclosure of the Hempels' trade secrets for Defendants' own use and personal gain.

148. The misappropriation is wrongful because it was made in breach of an expressed or implied contract, and because Defendants had a duty not to disclose the Hempels' trade secrets.

149. The Hempels have been damaged in an amount to be determined at trial. Otherwise, Defendants have been unjustly enriched by their misappropriation and must disgorge their ill-gotten profits.

150. Defendants acted with reckless, willful, or callous disregard for the Hempels' rights and with malice, fraud, or oppression toward them, thereby entitling the Hempels to an award of double damages and/or disgorgement and punitive damages in accordance with proof at trial.

THIRD CAUSE OF ACTION
BREACH OF FIDUCIARY DUTY
(AGAINST CYDAN)

151. The Hempels repeat and reallege each and every one of the foregoing allegations as though fully set forth herein.

152. Cydan was the Hempels' joint venturer. The Hempels reposed special trust in and confidence in Cydan. This relationship developed from their first communications with Chris Adams of Cydan (and later Vtesse) in June 2013, through the spring of 2014, as the parties worked together toward a common goal of creating a start-up dedicated to developing cyclodextrin treatments for NPC. The special relationship was initiated by Cydan, and codified in the Confidentiality Agreement, which prohibited Cydan from using the Hempels' Confidential Information for its own benefit. Moreover, by that special relationship, Cydan gained control over the Hempels' Business Plan, Confidential Information, and trade secrets.

153. By creating and fostering this relationship of trust, Cydan had a fiduciary duty of care, loyalty, and good faith to the Hempels.

154. Cydan violated its fiduciary duties when it executed on the parties' mutual business venture without including the Hempels.

155. As the direct and proximate cause of the Cydan's breach of its fiduciary duties, the Hempels have been damaged. Cydan has been unjustly enriched and must disgorge all profits in an amount to be determined at trial.

156. Cydan acted with reckless, willful, or callous disregard for the Hempels' rights and with malice, fraud, or oppression toward the Hempels, thereby entitling the Hempels to an award of punitive damages in accordance with proof at trial.

FOURTH CAUSE OF ACTION
UNFAIR COMPETITION
(AGAINST ALL DEFENDANTS)

157. The Hempels repeat and reallege each and every one of the foregoing allegations as though fully set forth herein.

158. Defendants unfairly usurped the Hempels' competitive advantage by gaining access to the Hempels' Business Plan, confidential information, trade secrets, and goodwill.

159. Specifically, Cydan gained access to the Hempels' Business Plan, Confidential Information, and trade secrets in connection with private meetings and the Confidentiality Agreement, lulled the Hempels' into thinking that they were embarking upon a joint venture, and then appropriated for itself and the other Defendants the business opportunity afforded them by the Hempels.

160. Defendants' intentional misconduct was in bad faith and Defendants deliberately breached the Confidentiality Agreement, knowingly engaged in the misappropriation of the Hempels' trade secrets, and knowingly used the Hempels' confidential information and trade secrets that was in the hands of various NIH-affiliated researchers who, as Defendants knew or should have known, were under confidentiality restrictions.

161. Defendants' misconduct constitutes unfair competition as it is recognized under the common law and established concepts of unfairness.

162. Defendants' misconduct caused substantial injury to the Hempels, who were robbed of their opportunity to commercialize the intrathecal cyclodextrin treatment they had spent years and millions of dollars developing, and to the NPC community at

large, which was robbed of its opportunity to control the development and commercialization of the cyclodextrin treatment.

163. As the direct and proximate cause of Defendants' unfair conduct, the Hempels have been damaged, and Defendants have been unjustly enriched, in an amount to be determined at trial.

FIFTH CAUSE OF ACTION
VIOLATION OF MASS. GEN. LAWS. CH. 93A, § 11
(AGAINST CYDAN)

164. The Hempels repeat and reallege each and every one of the foregoing allegations as though fully set forth herein.

165. Cydan unfairly usurped the Hempels' competitive advantage by gaining access to the Hempels' Business Plan, confidential information, trade secrets, and goodwill.

166. Specifically, Cydan gained access to the Hempels' Business Plan, Confidential Information, and trade secrets in connection with private meetings and the Confidentiality Agreement, lulled the Hempels' into thinking that they were embarking upon a joint venture, and then appropriated for itself and the other Defendants the business opportunity afforded them by the Hempels.

167. Cydan's intentional misconduct was in bad faith and Cydan deliberately breached the Confidentiality Agreement, knowingly engaged in the misappropriation of the Hempels' trade secrets, and knowingly used the Hempels' confidential information and trade secrets that was in the hands of various NIH-affiliated researchers who, as Cydan knew or should have known, were under confidentiality restrictions.

168. Cydan's misconduct, which occurred primarily in Massachusetts, where it was headquartered, constituted an unfair method of competition and an unfair act or practice in violation of Mass. Gen. Laws. ch. 93A, § 11.

169. Cydan's misconduct caused substantial injury to the Hempels, who were robbed of their opportunity to commercialize the intrathecal cyclodextrin treatment they had spent years and millions of dollars developing, and to the NPC community at large, which was robbed of its opportunity to control the development and commercialization of the cyclodextrin treatment.

170. As the direct and proximate cause of Cydan's malfeasance, the Hempels have been damages, and Defendants have been unjustly enriched, in an amount to be determined at trial.

SIXTH CAUSE OF ACTION
UNJUST ENRICHMENT
(AGAINST VTESSE, SUCAMPO, AND MALLINCKRODT)

171. The Hempels repeat and reallege each and every one of the foregoing allegations as though fully set forth herein.

172. Upon information and belief, Sucampo paid approximately $200 million to Vtesse's shareholders to acquire Vtesse.

173. Upon information and belief, Mallinckrodt bought Sucampo for $1.2 billion, a significant portion of which is due to the value of VTS-270, the potential revenue generated thereby, and the potential entitlement to a Priority Review Voucher.

174. The profits realized by Vtesse, Sucampo, and Mallinckrodt relate to their misappropriation of use of the Hempels' confidential information and trade secrets, and their conduct is not governed by the terms of any agreement.

175. Vtesse, Sucampo, and Mallinckrodt inequitably used the Hempels' confidential information and trade secrets.

176. The Hempels' efforts directly enriched Vtesse, Sucampo, and Mallinckrodt to the Hempels' detriment.

177. It would be inequitable to permit Vtesse, Sucampo, and Mallinckrodt to retain the benefits of the Hempels' efforts.

178. As the direct and proximate cause of Vtesse's, Sucampo's, and Mallinckrodt's malfeasance, they have been unjustly enriched in an amount to be determined at trial, and such amount must be disgorged to the Hempels.

SEVENTH CAUSE OF ACTION
TORTIOUS INTERFERENCE
(AGAINST ALL DEFENDANTS)

179. The Hempels repeat and reallege each and every one of the foregoing allegations as though fully set forth herein.

180. The Hempels had implied and express agreements of confidentiality with the NIH and its researchers, pursuant to which the Hempels granted the NIH the right to reference the Hempels' confidential information and trade secrets in connection with its own studies of cyclodextrin on the assurance that the NIH would not pursue a competing project.

181. Defendants knew or should have known about the implied and express confidentiality agreements between the Hempels and the NIH researchers.

182. Defendants intended to interfere the Hempels' confidentiality agreements and economic expectations when they entered into data-sharing agreements with the NIH researchers, knowing that the data the NIH researchers were using the Hempels' confidential information and trade secrets or data derived directly from the Hempels' confidential information and trade secrets for an improper purpose.

183. Defendants interfered with the Hempels' contractual rights and economic expectations by obtaining and misappropriating the Hempels' confidential information and trade secrets from the NIH, to the exclusion of the Hempels' interests.

184. Defendants' interference with the Hempels' interests and economic expectancy was improper, because it was pursued by means of wrongful conduct, *i.e.*, the misappropriation of the Hempels' confidential information and trade secrets.

185. The Hempels have been damaged and irreparably injured as a result of Vtesse's conduct, in an amount to be determined at trial, as a result of Vtesse's interference with the Hempels' contractual rights and economic interests with Cydan.

JURY TRIAL DEMANDED

186. The Hempels hereby demand a trial by jury on all claims and issues to triable.

WHEREFORE, the Hempels respectfully request entry of judgment after a jury trial:

a) awarding the Hempels damages and/or disgorgement in an amount to be determined at trial, but no less than $100,000,000;

b) awarding the Hempel treble damages under Mass. Gen. Laws. ch. 93A, § 11;

c) awarding the Hempels punitive damages in an amount to be determined at trial;

d) awarding the Hempels pre-judgment interest on any recovery;

e) awarding the Hempels their costs and disbursements, including attorney's, accountant's, and expert witness's fees;

f) and granting the Hempels such other and further relief as the Court deems just and proper.

DATED: February 15, 2019

/s/ Jonathan Biran
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