IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
CHARLESTON DIVISION

Louis C. Sanfilippo, M.D., an individual, Plaintiff, v. **Timothy David Brewerton, M.D.**, an individual, Defendant.	Case No. 2:17-CV-183-RMG-BM **LOUIS C. SANFILIPPO, M.D.'S *PRO SE* COMPLAINT** **(DEMAND FOR JURY TRIAL)**

The Plaintiff, Louis C. Sanfilippo, M.D. ("Plaintiff"), herein files this Complaint against Defendant Timothy David Brewerton, M.D. ("Brewerton"), and would allege and show as follows:

JURISDICTION AND VENUE

1. This Court has subject matter jurisdiction over the claims herein under 28 U.S.C. § 1332(a)(1), which provides for "original jurisdiction of all civil actions where the matter in controversy exceeds the sum or value of $75,000 . . . and is between . . . citizens of different States." Here, the amount in controversy is at least $300,000,000 ($300 Million) as explained further herein.

2. This Court has personal jurisdiction because Defendant Brewerton resides in South Carolina, and has incurred the liability complained of herein in South Carolina.

3. Venue is proper in this Judicial District under 28 U.S.C. § 1391(b).

PARTIES

4. Plaintiff resides in and is a citizen of the State of New Jersey.

5. Upon information and belief, Defendant Brewerton resides in and is a citizen of the State of South Carolina.

GENERAL ALLEGATIONS

6. U.S. Patent 8,318,813 (see Exhibit 1 attached hereto), which claims an invention priority date of September 13, 2007 and was issued by the United States Patent and Trademark Office on November 27, 2012, claims methods for the treatment of Binge Eating Disorder as defined in the DSM-IV-TR with the drug lisdexamfetamine dimesylate (*i.e.*, Vyvanse®). The patent's lone inventor is the Plaintiff.

7. On May 9, 2014, a Petition for an *Inter Partes Review* for U.S. Patent 8,318,813 Under 35 U.S.C. §§ 311-319 and 37 C.F.R. §§ 42.1-.80, 42.100-.123 (see Exhibit 2 attached hereto), made by Shire Development LLC, was provided to the patent's then-owner LCS Group, LLC by serving the law firm Cantor Colburn LLP (see page 71, last page, of Exhibit 2).

8. Shire's *Inter Partes Review* Petition relied completely and exclusively on a Declaration by Defendant Brewerton, which he signed on May 8, 2014 (see Exhibit 3 attached hereto; signature line on page 101).

9. Four highly substantiated, evidence-based documents (see Exhibits 4, 5, 6 and 7 attached hereto) contextualize and representationally profile Defendant Brewerton's Declaration, and thereby the Petition which exclusively relied on it, in view of the medical literature on eating disorders, obesity and stimulant drugs, including profiling Defendant Brewerton's Declaration representations against his own published work related to the diagnosis and treatment of eating disorders. Each of these four evidence-based documents discloses and explains the Defendant's extensive use of misleading statements and egregious misrepresentations of the medical literature (including for their "line of reasoning"), as well as characterizes and explains the

Defendant's extensive omission of materially relevant and important information (including from his own publications), in concluding that all the claims of U.S. Patent No. 8,318,813 would have been "obvious" to a Person of Ordinary Skill in the Art as of September 13, 2007 and therefore should all be invalid. One particularly focused contextualization and profile of the Defendant Brewerton and his Declaration can be found on pages 46-171 of Exhibit 4 in the section titled "EXAMPLE 7: 'Profiling the Declarant and his Declaration.'"

10. Two published medical articles immediately preceding U.S. Patent No. 8,318,813's priority date of September 13, 2007 (see Exhibits 8 and 9 attached hereto, respectively, Surman et. al. published March 2006 and Biederman et. al. published in August 2007) demonstrate that Defendant Brewerton egregiously misrepresented key case studies (for their proper medical context and implications) on which the Patent Trial & Appeal Board relied to institute, and to proceed with, a trial regarding the patent (see pages 19-26 of Patent Board's Decision, in particular pages 20-21, of Exhibit 10 attached hereto). The specific nature by which Defendant misrepresented the proper medical context of these studies and their implications, in direct contradiction to their actual significance, context and implications, is extensively characterized in Exhibit 4 (see pages 13-20, 84-89, 102-105, 164-165), as well as in Exhibit 6 (see pages 10-16) and Exhibit 7 (see pages 17-18 or 12-13 of the "Supplemental Information," Point No. 2; see pages 22-23 or 17-18 of the "Supplemental Information," Point No. 2; see pages 32-35 or 27-30 of the "Supplemental Information"; see page 46 or 41 of the "Supplemental Information"; see pages 49-50 or 44-45 of the "Supplemental Information"). As characterized in those Exhibits and further below in paragraph 17, Defendant Brewerton appears to have "plagiarized" these cases from Surman's 2006 study, except that he misrepresented their proper context, significance and implications to the Patent Board, and omitted materially important and relevant information from his own published work that would have cast proper light on them.

FIRST CLAIM FOR RELIEF--FRAUD

11. Plaintiff re-alleges all prior paragraphs of this Complaint and incorporates them herein by reference.

12. Defendant made numerous false representations regarding relevant and important teachings in the medical literature related to the validity of the Plaintiff's invention, including at least the following: (a) that a Person of Ordinary Skill in the Art ("POSA," as defined in Defendant's Declaration, see Exhibit 3, page 19, Paragraphs 27 and 28) "as of September 2007" would have regarded it acceptable to treat Bulimia Nervosa (or its symptom of binge eating thereof) with a psychostimulant drug (as used to treat Attention Deficit Hyperactivity Disorder), such as lisdexamfetamine dimesylate, as explained for its falsity in Exhibits 4,5, 6 and 7 though particularly in the Exhibits and their referenced pages aforementioned in paragraph 10 above, including Exhibits 8 and 9; (b) that a Person of Ordinary Skill in the Art "as of September 2007" would have regarded stimulant drugs (as used to treat Attention Deficit Hyperactivity Disorder), such as lisdexamfetamine dimesylate, to have a reasonable expectation of success (including safety) in treating Bulimia Nervosa, such that it would have been obvious to use a stimulant drug such as lisdexamfetamine dimesylate for the treatment of Bulimia Nervosa with a reasonable expectation of success, as explained for its falsity in Exhibits 4, 5, 6 and 7 though particularly in the Exhibits and their referenced pages aforementioned in paragraph 10 above, including Exhibits 8 and 9; (c) that a Person of Ordinary Skill in the Art "as of September 2007" would have regarded it acceptable to treat Obesity with a psychostimulant drug (as used to treat Attention Deficit Hyperactivity Disorder), especially lisdexamfetamine dimesylate, as explained for its falsity in Exhibits 4, 5, 6 and 7 though particularly in Exhibit 4 (see pages 10-13), Exhibit 5 (see pages 1-20), Exhibit 6 (see pages 1-10), Exhibit 7 (see page 6 or page 1 of the "Supplemental Information"; see page 17 or page 12 of the "Supplemental

Information," Point No. 1; see pages 21-22 or pages 16-17 of the "Supplemental Information," Point No. 1); (d) that a Person of Ordinary Skill in the Art "as of September 2007" would have regarded stimulant drugs (as used to treat Attention Deficit Hyperactivity Disorder), especially lisdexamfetamine dimesylate, to have a reasonable expectation of success (including safety) in treating Obesity, such that it would have been obvious to use a stimulant drug (especially lisdexamfetamine dimesylate) for the treatment of Obesity with a reasonable expectation of success, as explained for its falsity in Exhibits 4, 5, 6 and 7 though particularly in Exhibit 4 (see pages 10-13), Exhibit 5 (see pages 1-20), Exhibit 6 (see pages 1-10), Exhibit 7 (see page 6 or page 1 of the "Supplemental Information"; see page 17 or page 12 of the "Supplemental Information," Point No. 1; see pages 21-22 or pages 16-17 of the "Supplemental Information," Point No. 1); (e) that a Person of Ordinary Skill in the Art "as of September 2007" would have regarded lisdexamfetamine dimesylate as an acceptable "anti-obesity agent," as to regard the use of lisdexamfetamine dimesylate for the treatment of Obesity as an acceptable medical treatment, as explained for its falsity in Exhibits 4, 5, 6 and 7 though particularly in Exhibit 4 (see pages 10-13), Exhibit 5 (see pages 1-20), Exhibit 6 (see pages 1-10), Exhibit 7 (see page 6 or page 1 of the "Supplemental Information"; see page 17 or page 12 of the "Supplemental Information," Point No. 1; see pages 21-22 or pages 16-17 of the "Supplemental Information," Point No. 1); (f) that the invention which claims methods to treat Binge Eating Disorder as defined in the DSM IV-TR with the drug lisdexamfetamine dimesylate would have been obvious to a Person of Ordinary Skill in the Art "as of September 2007," as characterized for its falsity in Exhibits 4, 5, 6 and 7, though particularly on pages 17-27 of Exhibit 6; and (g) that the invention which claims methods to treat Binge Eating Disorder as defined in the DSM IV-TR with the drug lisdexamfetamine dimesylate would have been regarded to have a reasonable expectation of success (including safety) to a Person of Ordinary Skill in the Art "as of

September 2007," such that it would have been obvious to use a stimulant drug (such as lisdexamfetamine dimesylate) for the treatment of Binge Eating Disorder as defined in the DSM-IV-TR with a reasonable expectation of success, as characterized for its falsity in Exhibits 4, 5, 6 and 7, though particularly on pages 17-27 of Exhibit 6.

13. Defendant made numerous false representations regarding the "line of reasoning" of a POSA as of September 13, 2007 in his three core arguments to allege the obviousness of the patent's three independent claims (claim Nos. 1,8 and 13; see p. 15 of Exhibit 1 attached hereto). These three core arguments are referred to, in both the Petition and Declaration, as the Grounds 1, 4 and 7 arguments (for Petition, see Exhibit 2 - Ground 1 on pages 23-28, Ground 4 on pages 36-42, Ground 7 on pages 49-54; for Declaration see Exhibit 3 - Ground 1 on pages 39-42, Ground 4 on pages 49-55, Ground 7 on pages 62-67). The nature and extent of these false representations are more specifically characterized below (*i.e.,* paragraphs 14, 15, 16 and 17). Importantly, the Patent Board dismissed Defendant's Ground 1 line of reasoning but accepted his Ground 4 and Ground 7 line of reasoning to support its decision to institute the *Inter Partes Review* trial that led to the invalidation of all the patent's claims.

14. More specifically with respect to the allegations made in Paragraph 13, Defendant Brewerton egregiously misrepresented the line of reasoning of a POSA as of September 13, 2007 for the "Ground 1 line of reasoning," in particular how a POSA would have relied on Mickle's U.S. Patent Application No. 2007/0042955 "Abuse Resistant Amphetamine Prodrugs," most notably on one sentence within its disclosures, to reason that lisdexamfetamine dimesylate was an acceptable and reasonably successful "anti-obesity agent" for clinical use in the pharmacologic treatment of obesity, as to therefore have been regarded by a POSA as of September 13, 2007 to be an acceptable and reasonably successful drug in the treatment of Binge Eating Disorder as defined in the DSM-IV-TR which is a disorder associated (though not clinically defined) with clinical obesity, as represented in his Declaration by the following line of reasoning,

"Because of the success of these [d-fenfluramine and sibutramine] centrally acting anti-obesity agents in the treatment of BED [per Appolinario], a POSA would have had a reasonable expectation of success that other centrally acting anti-obesity agents would similarly reduce binge eating behavior" (Exhibit 3, p. 40-41)….. "As a result, a POSA would have been motivated to identify another centrally acting anti-obesity agent with positive properties, such as LDX-dimesylate as described by Mickle." (Exhibit 3, p. 41)…. "Mickle teaches amphetamine prodrugs, such as LDX-dimesylate, that are indicated for the treatment of certain disorders, including obesity… In fact, obesity is identified as a preferred indication….." (Exhibit 3, p. 41-42)…. "In light of the teachings of Appolinario together with Mickle, a POSA would have diagnosed BED according to the DSM-IV-TR and would have had a reasonable expectation of success in treating BED with LDX-dimesylate." (Exhibit 3., p. 42)…. "Thus, it is my opinion that… claim 1 would have been obvious over the combination of Appolinario and Mickle….claim 8 would have been obvious over the combination of Appolinario and Mickle for the same reasons that Claim 1 would have been obvious….claim 13 would have been obvious over the combination of Appolinario and Mickle for the same reasons that claim 1 would have been obvious over the combination of Appolinario and Mickle." (Exhibit 3, pages 42, 45, 47). An explanation for the extent and egregiousness of this misrepresented "Ground 1 POSA line of reasoning" can be found on pages 10-13 of Exhibit 4, but is also characterized in Exhibit 5 (see pages 1-20), Exhibit 6 (see pages 1-10), and Exhibit 7 (see page 6 or page 1 of the "Supplemental Information"; see page 17 or page 12 of the "Supplemental Information," Point No. 1; see pages 21-22 or pages 16-17 of the "Supplemental Information," Point No. 1).

15. More specifically with respect to the allegations made in Paragraph 13, Defendant Brewerton egregiously misrepresented the line of reasoning of a POSA as of September 13, 2007 for the "Ground 4 line of reasoning," in particular how a POSA as of September 13, 2007 would have relied on a study from 1983 (Ong), which involved a

one-time dose of intravenous (IV) methylamphetamine to experimentally treat patients with Bulimia Nervosa, to reason to the "obviousness" and "reasonable expectation of success" of lisdexamfetamine dimesylate to treat Binge Eating Disorder as defined in the DSM-IV-TR, as represented in his Declaration by the following line of reasoning, "A POSA would have known that the symptom of bulimia as studied in Ong closely resembles the symptom of binge eating described in the DSM-IV-TR for both BN and BED" (Exhibit 4, p. 50) …. "Therefore, a POSA reading Ong and the DSM-IV-TR would have learned to treat BED by diagnosing the patient and administering [a one-time dose of intravenous] methylamphetamine to the patient. And based upon the teachings of Ong and the DSM-IV-TR, a POSA would have had a reasonable expectation of success of treating BED with [a one-time dose of intravenous] methylamphetamine used in Ong." (Exhibit 4, p. 52)… "Yet, a POSA would have also recognized from Ong that 'drugs with stimulant and euphoric effects carry the dangers of drug dependence and drug induced psychosis…' Such a warning would have led and motivated the POSA to seek an alternative stimulant that could provide similar properties as [a one-time dose of intravenous] methylamphetamine given its success as a treatment in Ong." (Exhibit 4, p. 52)…."A POSA would have been motivated to replace [the one-time dose of intravenous] methylamphetamine as disclosed in Ong with [oral] LDX dimesylate of Mickle. As noted above, Ong cautions about the dangers of dependence and drug-induced psychosis for drugs with stimulant and euphoric effects, with LDX dimesylate designed to exhibit reduced euphoric effects associated with abuse. Further, a POSA would have expected that LDX dimesylate would have the same pharmacological effects as [a one-time dose of intravenous] methylamphetamine…." (Exhibit 3, p. 54)…. "Therefore, based on the disclosures of Mickle, a POSA would have had a reasonable expectation of successfully treating BED by replacing [a one-time dose of intravenous] methylamphetamine with LDX dimesylate…." (Exhibit 3, p. 55)…."In light of the teachings of Ong together with

DSM-IV-TR and Mickle, a POSA would have diagnosed BED according to the DSM-IV-TR and would have had a reasonable expectation of success of treating BED with LDX dimesylate."(Exhibit 3, p. 55)...."Thus, ... it is my opinion that....claim 1 would have been obvious over the combination of Ong together with DSM-IV-TR and Mickle .....claim 8 would have been obvious over the combination of Ong, DSM-IV-TR, and Mickle for the same reasons that Claim 1 would have been obvious....claim 13 would have been obvious over the combination of Ong, DSM-IV-TR, and Mickle for the same reasons that claim 1 would have been obvious...." (Exhibit 3, pages 55, 58, 60). An explanation for the extent and egregiousness of this misrepresented "POSA Ground 4 line of reasoning" can be found, in particular, on pages 42-46 of Exhibit 4 in the section titled "EXAMPLE 6. 'Clinical data from a one-time IV injection of an amphetamine-based drug in Bulimia Nervosa patients would lead an MD/psychiatrist to conclude LDX dimesylate's 'reasonable expectation of success' for the treatment of BED patients."

16. More specifically with respect to the allegations made in Paragraph 13, Defendant Brewerton egregiously misrepresented the line of reasoning of a POSA as of September 13, 2007 for the "Ground 7 line of reasoning," in particular how a POSA as of September 13, 2007 would have relied on an experimental study involving co-morbid ADHD and Bulimia Nervosa patients from 2005 (Dukarm) involving the use of d-amphetamine, to reason to the "obviousness" and "reasonable expectation of success" of lisdexamfetamine dimesylate to treat Binge Eating Disorder as defined in the DSM-IV-TR, as represented in his Declaration by the following line of reasoning, "As previously discussed, an essential feature of both BN and BED in DSM-IV-TR is 'recurrent episodes of binge eating'....According to the DSM-IV-TR a 'recurrent episode of binge eating' in BED is the same as a 'recurrent episode of binge eating in BN." (Exhibit 3, p. 63).... "Thus, it would have been clear to a POSA that the characteristics of the binge eating episodes in BED are essentially the same as those in BN." (Exhibit 3, p.

64)….. "Based on the teachings of the DSM-IV-TR, it is my opinion that the binge eating of BN is the same as the binge eating of BED." (Exhibit 3, p. 65)….. "….given the evidence of Dukharm demonstrating that d-amphetamine was successful in eliminating the binge eating in patients with BN, a POSA would have had a reasonable expectation of success in treating with BED with d-amphetamine." (Exhibit 3, p. 65)….. "A POSA would have been motivated to replace d-amphetamine as disclosed in Dukarm [to treat co-morbid ADHD and Bulimia Nervosa patients] with LDX dimesylate for the treatment of BED" (Exhibit 3, p. 66) ….. "In light of the teachings of Dukarm together with the DSM-IV-TR and Mickle, a POSA would have diagnosed BED according to the DSM-IV-TR and would have had a reasonable expectation of success of treating BED with LDX dimesylate." (Exhibit 3, p. 66-67)….. "Thus, … it is my opinion that….claim 1 would have been obvious over the combination of Dukarm together with DSM-IV-TR and Mickle. ….claim 8 would have been obvious over the combination of Dukarm, DSM-IV-TR, and Mickle for the same reasons that Claim 1 would have been obvious…..claim 13 would have been obvious over the combination of Dukarm, DSM-IV-TR, and Mickle for the same reasons that claim 1 would have been obvious…." (Exhibit 3, pages 62, 69-70, 71). An explanation for the extent and egregiousness of this misrepresented "POSA Ground 7 line of reasoning" can be found in Paragraph 10 above.

17. The extent and egregiousness of Defendant's misrepresented "POSA Ground 7 line of reasoning" is also succinctly characterized for its misleading and misrepresented nature in view of Surman's 2006 publication that unambiguously characterizes the state of the art of treating Bulimia Nervosa in 2006 as follows (bold emphasis added), "Considering that **ADHD** and **Bulimia Nervosa respond to different pharmacologic treatments**, diagnosing ADHD in subjects with bulimia nervosa could lead to new therapeutic opportunities to this debilitating and life-threating disorder" (p. 2, Exhibit 8) and "Since **bulimia nervosa** and **ADHD require different pharmacologic**

approaches, clinical evaluations of women with bulimia nervosa may benefit from systematic identification of ADHD and vice versa" (p. 3, Exhibit 8). In other words, stimulant drugs (as a well-known mainstay treatment for ADHD) clearly would not have been regarded by the psychiatric community (*i.e.,* POSA's, as defined above) to be an acceptable, and thus reasonably successful, pharmacologic treatment of Bulimia Nervosa at the time of the invention's priority date in September 2007. Rather, their use to treat Bulimia Nervosa would have been discouraged, except perhaps in such instances where the stimulant was being used in patients with co-morbid ADHD and Bulimia Nervosa. So when the Defendant represents that (bold emphasis added) "it is my opinion that given the overlapping symptom of binge eating in BN and BED described in the DSM-IV-TR, together with **extensive data** demonstrating the successful use of psychostimulants in the treatment of binge eating described in Dukarm [which featured co-morbid Bulimia Nervosa and ADHD patients], a POSA would have had a reasonable expectation of success in extending the teachings of Dukarm to the treatment of BED [with a stimulant]" (p. 84, Exhibit 3), he is egregiously misrepresenting and miscontextualizing the most critical point of Dukarm's -- and also Surman's -- studies that relate to patients with **co-morbid** Bulimia Nervosa and ADHD or ADHD-like symptoms in which the rationale for using a stimulant is foremost to treat the ADHD symptoms (and without ADHD symptoms, a stimulant to treat Bulimia Nervosa would have been ill-advised and discouraged at the time of the invention). The fraudulent nature of the Defendant's "Ground 7 line of reasoning" is made evident in view of how the same exact cases that the Defendant represents as **"extensive data"** involving the use of stimulants to treat Bulimia Nervosa are represented by Surman, in the peer-reviewed Journal of Clinical Psychiatry, as "**scant reports** in the medial literature of adults suffering from both ADHD-like symptoms and bulimia nervosa" (p. 2, Exhibit 8). Moreover, the significance of these cases is that they show a putative link between ADHD and Bulimia Nervosa which, in fact, Surman found in his study with

"significantly greater rates of bulimia nervosa were identified in women with versus without ADHD (12% vs. 3%)" (p. 1, Exhibit 8, see "Results"). In this respect, Defendant was motivated to use misrepresented context to deceive the Patent Board into perceiving the medical literature one way (*i.e.,* that stimulants were well-regarded as acceptable and reasonably successful treatments of Bulimia Nervosa based on "extensive data") when its true reality in the medical literature was the diametric opposite (*i.e.,* that there were "scant case reports in the medial literature of adults suffering from both ADHD-like symptoms and bulimia nervosa" which showed that stimulants seemed to help not only ADHD symptoms but also Bulimia Nervosa symptoms such as binge eating in these scant reports thus suggesting a possible association/risk between these two disorders). Thus, it would appear that the Defendant plagiarized these case "scant case reports" to allege the obviousness of the patent's claims, except that the act of plagiarism did not involve actually copying them in their proper medical context but, rather, profoundly misrepresenting their context, as if these "scant reports" were long-recognized and well-regarded in the psychiatric community and among POSA's "as extensive data" to support treatment of Bulimia Nervosa with stimulant drugs (as used to treat ADHD). It is not surprising, therefore, that the Defendant did not cite or include Surman's publication in his Declaration, as it would have completely undermined and refuted his Declaration testimony, as well as "sourced" his deceptive testimony.

18. The Defendant repeatedly and egregiously contradicted relevant and important material regarding the treatment of eating disorders from his own published work, but failed to disclose that published work to the Patent Board, as profiled and explained on pages 20-26 of Exhibit 4 in the section titled "Example 3: Self-Contradictory Representations in view of the Declarant's own Prior Representations." The Defendant also negligently failed to disclose materially relevant and important teachings from his own prior work related to the patent's claims, which involve a "therapeutically effective

amount" of lisdexamfetamine dimesylate to treat Binge Eating Disorder as defined in the DSM-IV-TR. For instance, one of the most relevant and important published works in the art of eating disorders that could have helped the Patent Board understand how a POSA as of September 13, 2007 would have regarded the pharmacological treatment of "Binge Eating Disorder as defined in the DSM-IV-TR" (as featured in the patent's claims) would have been an article Defendant Brewerton published in 2004 in "Psychiatry Times" titled "Pharmacotherapy for Patients with Eating Disorders" (see Exhibit 11 attached hereto). The publication identifies acceptable and reasonably successful pharmacologic treatments for Anorexia Nervosa, Bulimia Nervosa and Binge Eating Disorder. The latter section, on BED, would have been directly and materially relevant to how a POSA in September 2007 would have regarded acceptable and reasonable successful pharmacologic treatments of Binge Eating Disorder as defined in the DSM-IV-TR (as featured in the patent's claims). For example, of the numerous studies identified for the appropriate pharmacologic treatment of Binge Eating Disorder (according to DSM-IV/IV-TR criteria) in Defendant Brewerton's 2004 publication, which Defendant concealed from the Patent Board, not a single one of them involved a stimulant (as used to treat ADHD). Nor was a stimulant referenced in any of the studies cited in Defendant Brewerton's 2004 publication to provide evidence that stimulants (as used to treat ADHD) might be an acceptable and reasonably successful treatment class of drugs for Bulimia Nervosa, further supporting the allegation for fraud.

19. Further, the Defendant failed to cite or include a textbook he exclusively edited, titled "Clinical Handbook of Eating Disorders" published in 2004, that extensively addressed acceptable and successful pharmacotherapies for eating disorders, including Bulimia Nervosa and Binge Eating Disorder (see Exhibit 12 attached hereto for book's table of contents and Chapters 11 and 21). More specifically, Chapter 21 of the Defendant's exclusively edited book, titled "Psychopharmacology of Anorexia Nervosa, Bulimia Nervosa and Binge Eating Disorder" and which nicely captures the

eating disorder "state of the art" shortly before the invention's priority date, nowhere identifies stimulants (as used to treat ADHD) as acceptable or successful pharmacotherapy for any eating disorder (see pp. 30-49 of Exhibit 12). Defendant willfully omitted disclosure of these highly relevant and important 2004 references to the Patent Board because it would have completely belied his testimony alleging the obviousness of the '813 Patent's claims to treat Binge Eating Disorder as defined in the DSM-IV-TR with the stimulant drug lisdexamfetamine dimesylate. Rather, had Defendant disclosed his 2004 publications and their implications to the Patent Board, it would have supported the non-obviousness and validity of the patent, as well as exposed a pervasive pattern of extremely negligent, deceptive and misconextualized representations involving the medical literature in his Declaration.

20. The Defendant's 2004 publication "Pharmacotherapy for Patients with Eating Disorders" and his exclusively edited book "Clinical Handbook of Eating Disorders," which were omitted from his Declaration and therefore concealed from the Patent Board, were also highly relevant and important to his Declaration representations regarding, as stated in his own words (in his Declaration), (i) "the successful use of psychostimulants in the treatment of BN [Bulimia Nervosa]...." (see Exhibit 3, page 83), (ii) "over two decades of prior publications reported on the successful use of psychostimulants in the treatment of bulimic episodes in BN patients...." (see Exhibit 3, page 84), (iii) "At least since the early 1980's, studies have shown psychostimulants to be successful in treating the binge eating symptom of BN" (see page 99, Exhibit 3). This is because in those two 2004 works, there is no evidence whatsoever to support that stimulants (as used to treat ADHD) were acceptable and reasonably successful drugs in treating Bulimia Nervosa or the symptom of binge eating in Bulimia Nervosa (absent their use to treat ADHD for which they are clinically indicated); rather, the Defendant's own published and edited work from 2004 supports the conclusion that stimulants (as used to treat ADHD) would not have been regarded as acceptable and reasonably

successful drugs in treating Bulimia Nervosa or the symptom of binge eating in Bulimia Nervosa (absent their use to treat ADHD for which they are clinically indicated).

21. The Defendant's egregious misrepresentation and miscontextualization of the medical literature is only underscored by the fact that he cited the 2006 APA (American Psychiatric Association) treatment guidelines for Bulimia Nervosa in his Declaration (see Exhibit 3, page 14, Exhibit No. 1031) but he omitted from his Declaration testimony the most materially relevant and important clinical teaching in those guidelines with respect to the use of stimulants in the treatment of Bulimia Nervosa or binge eating in Bulimia Nervosa, namely, that (bold emphasis and parenthetical comments added) "**several case reports** [not extensive data] indicate that methylphenidate [a stimulant as used to treat ADHD] may be helpful for **bulimia nervosa patients with concurrent ADHD"** (see Exhibit 13, page 54) and "Case reports indicate that methylphenidate [a stimulant as used to treat ADHD] may be helpful for bulimia nervosa patients **with concurrent attention-deficit/hyperactivity disorder (ADHD)** [III], **but it should be used only for patients who have a very clear diagnosis of ADHD** [I]" (see Exhibit 13, page 20).

22. In this regard, the Defendant's misrepresentation and miscontextualization on the use of stimulants to treat Bulimia Nervosa based on "extensive data" seriously misled the Patent Board into thinking that stimulants were both a well-accepted and well-studied treatment modality, as well as a reasonably successful one, for Bulimia Nervosa, and therefore would have been "obvious" to use by a POSA as of September 2007 to treat Bulimia Nervosa (not ADHD) in its own right. Thus, when Defendant represents that "Because it was well-established at the time of the invention that the binge eating symptom of BN and BED is the same, a POSA would have had a reasonable expectation of effectively treating the binge eating of BED with a psychostimulant" (Exhibit 3, page 99), he egregiously misrepresents how the medical literature would have been understood by a POSA for its "obviousness" and "reasonable

expectation of success," by his own standard of interpretation and teaching no less which clearly located stimulants for Bulimia Nervosa as irrelevant, non-existent and/or obscure based on his own extensive surveys of the medical literature in 2004, one he exclusively authored and the other he exclusively edited. More than that, he contemptuously disregards the DSM-defined clinical context in which binge eating is clinically present (*i.e.*, BED vs. BN), as if it too is irrelevant, non-existent and/or obscure, even as the patent's claims specifically and unambiguously recite that the use of lisdexamfetamine is for the treatment of **Binge Eating Disorder as defined in the DSM-IV-TR** (not "binge eating" generically).

23. Defendant Brewerton's 2004 publications, made to a community of "Persons of Ordinary Skill in the Art" (one vis-à-vis Psychiatry Times and the other in a "clinical handbook"), makes it evident that he, as well as those POSA's interested in treating the disorder known as "Binge Eating Disorder as defined in the DSM-IV-TR" (as recited in the patent's claims), would have regarded the clinical context of the non-specific symptom of "binge eating" (including its co-morbidity with another disorder, like ADHD) as highly relevant and important in determining an acceptable and reasonably successful pharmacologic treatment, much as Surman does in his analysis (per paragraph 10 above) or as the 2006 APA treatment guidelines for Bulimia Nervosa do (as noted above in paragraph 21). Defendant Brewerton's 2004 publications make self-evident that a POSA would have relied on evidence to support the treatment of non-specific symptoms in their **proper DSM-defined clinical context**, as clearly featured in U.S. Patent No. 8,318,813's thirteen claims that, by method, diagnostically differentiate binge eating in Bulimia Nervosa from binge eating in BED, as well as from binge eating in Anorexia Nervosa. Again, Defendant willfully omitted disclosure of these highly relevant and important 2004 "self-written or self-edited" references to the Patent Board because they would have completely belied his testimony alleging the obviousness of the '813 Patent's claims to treat Binge Eating Disorder as defined in the DSM-IV-TR

with the stimulant drug lisdexamfetamine dimesylate and thus would have exposed the misleading and deceptive nature of his testimony. Its disclosure would also have demonstrated the non-obviousness and validity of the patent's claims.

24. Based on the totality of the evidence above, Defendant Brewerton misrepresented the final statement of his Declaration that states (see p. 100, Exhibit 3, paragraph 191), "I hereby declare that all statements made herein are of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statement and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title of the United States Code." His statements could not be true in view of his own consideration and analysis of the medical literature to his peers through published work which he failed to disclose to the Patent Board, as well as in view of acceptable standards for the treatment of eating disorders laid out by the American Psychiatric Association one year before the invention's priority date (Exhibit 13).

25. Defendant knew and was aware of the falsity of these misrepresentations, or at the very least, had a reckless disregard for their truth or falsity. Defendant intended that the misrepresentations be material and be acted upon by third-parties, and the United States Patent Office's Patent Trial & Appeal Board did rely on the presumed accuracy of Defendant's misrepresentations in granting an *Inter Partes Review* trial, on which it later declared invalid U.S. Patent No. 8,318,813, which claimed exclusive rights to Plaintiff's valuable inventions that were last owned by a company in which Plaintiff is a Manager and Member, Lucerne Biosciences, LLC, and last exclusively licensed by Lucerne Biosciences, LLC to LCS Group, LLC, a company in which Plaintiff is CEO and Member.

26. The United States Patent Office's Patent Trial & Appeal Board was ignorant of the falsity of Defendant's misrepresentations because it possessed

insufficient expertise in the area of eating disorders, obesity and stimulant drugs to reasonably question Defendant's expertise and discover that Defendant's misrepresentations were false and intended to deceive. Because Defendant Brewerton was presented as an expert on the matters at issue, the United States Patent Office had a right to rely on Defendant's misrepresentations.

27. Defendant's misrepresentations have proximately caused substantial damage to Plaintiff, in an amount much greater than $75,000. Specifically, Plaintiff estimates that he has suffered in excess of $300 Million ($300,000,000) in damages, based on the fact that the U.S. patent he solely invented, which was last owned by a company in which he served as Manager and Member (Lucerne Biosciences, LLC) that itself exclusively licensed the patent to a company in which he was CEO and Member (LCS Group, LLC), encompassed method claims (*i.e.,* lisdexamfetamine dimesyslate for the treatment of Binge Eating Disorder as defined in the DSM-IV-TR) for an indication approved by the Food & Drug Administration based on Phase III Clinical Trials in patients with Binge Eating Disorder as defined in the DSM-IV-TR (in January 2015) whose estimated market value to the pharmaceutical company marketing the drug for the indication, Shire US Inc., has been valued in the range of $200-$750 Million in revenues annually. As weighted over the duration of time that the patent would have otherwise been valid and infringed over its lifetime to 2028, this amounts to $2 to $8 Billion, or more, aggregately in revenues to Shire from 2015 to 2028. References alluding to annual revenues expected to Shire, including from Shire's CEO Dr. Flemming Ornskov and "Wall Street analysts," can be found in Exhibits 14,15, and 16 attached hereto.

SECOND CLAIM FOR RELIEF—DEFAMATION

28. Plaintiff re-alleges all prior paragraphs of this Complaint and incorporates them herein by reference.

29. Defendant's misrepresentations alleged herein were false and defamatory statements, published to third parties, and non-privileged.

30. Defendant is at fault because he knew and was aware of the falsity of his misrepresentations, or at the very least, had a reckless disregard for their truth or falsity. Further, he persisted in his efforts to continue supporting his misrepresentations and miscontextualization to invalidate U.S. Patent No. 8,318,813, even when made aware of his misrepresentations and miscontextualization through evidence-based profiling efforts that included his own published work which he concealed from the Patent Board, as characterized in the communications transcript comprising Exhibit 7.

31. Defendant defamed the Plaintiff, an inventor, by publicly characterizing the invention he invented as being merely "obvious" and as having a "reasonable expectation of success" at the time of its invention, thus making it uninventive, despite the fact that Defendant Brewerton himself made statements that supported the contrary but which he failed to disclose to the Patent Trial & Appeal Board. In this regard, in addition to the allegations stated above regarding how Defendant Brewerton failed to disclose to the Patent Board materially relevant and important testimony he himself published, he also stated in a publication he authored prior to the invention, titled "Binge Eating Disorder: Recognition, Diagnosis and Treatment," that (bold emphasis added) "**There are no published reports on the use of psychostimulants in the treatment of BED**. Even though acutely administered stimulants suppress binge eating, the risks of addiction and the possible induction of affective and psychotic symptomatology **make this agent class undesirable as a therapeutic tool**" (see pages 20, 38, 45, 165, and 173 of Exhibit 4 for further explanation). Thus, by the Defendant's own published standard by which to treat Binge Eating Disorder, the invention invented by the Plaintiff related to the use of a psychostimulant to treat Binge Eating Disorder was not only inventive, unorthodox and counter-intuitive but even radical and against established medical guidance from eating disorder experts. Yet the Defendant failed to

disclose this publication and statement to the Patent Trial & Appeal Board for consideration of the invention's novel, unorthodox and first-of-its-kind claimed methods of treating Binge Eating Disorder as defined in the DSM-IV-TR (***not*** "binge eating") with a psychostimulant drug approved only, at the time of the invention's priority date of September 13, 2007, for pediatric Attention Deficit Hyperactivity Disorder. Exhibits 4, 5, 6 and 7 collectively demonstrate that, at the time of the invention's priority date, there were still no documented case reports for the treatment of Binge Eating Disorder as defined in the DSM-IV-TR with a psychostimulant, except perhaps in such instances where BED was co-morbid with ADHD and the stimulant was used as a primary treatment for ADHD, despite the fact that the criteria for Binge Eating Disorder as defined in the DSM-IV TR were in research and clinical usage for 13 years prior (as defined by the same criteria in the DSM-IV from 1994-2000; see page 1 of Exhibit 6). In this respect, the Plaintiff's invention stands as one of the most inventive and radical inventions for the treatment of eating disorders in view of the medical literature on treating Binge Eating Disorder, particularly in view Defendant Brewerton's 2004 publication "Pharmacotherapy for Patients with Eating Disorder" and his 2004 edited "Psychopharmacology of Anorexia Nervosa, Bulimia Nervosa and Bing Eating Disorder" which nowhere identify a single stimulant (as used to treat ADHD, like lisdexamfetamine dimesylate) as an acceptable, reasonably successful treatment modality for any eating disorder in which "binge eating" may be a central feature (i.e., Bulimia Nervosa, Binge Eating Disorder, Anorexia Nervosa, binge eating/purging type). However, as characterized above, Defendant failed to disclose these materially important and relevant publications, too, to the Patent Board for consideration of the invention's novel and inventive features, itself a form of misrepresentation by material omission of relevant and important context for addressing the patent's claims that specifically involved administering a therapeutically effective amount of stimulant drug to treat Binge Eating Disorder as defined in the DSM-IV-TR.

32. The publication of Defendant's misrepresentations caused special harm to Plaintiff, in an amount much greater than $75,000, as explained herein.

THIRD CLAIM FOR RELIEF—NEGLIGENCE

33. Plaintiff re-alleges all prior paragraphs of this Complaint and incorporates them herein by reference.

34. Defendant owed the court and this Plaintiff a duty of due care in forming his opinions and submitting materials relevant to whether Defendant's invention, owned by companies in which he served management and membership roles during Shire's *Inter Partes Review* proceeding (LCS Group, LLC first; then Lucerne Biosciences, LLC), was "obvious" and had a "reasonable expectation of success" at the time of its invention.

35. Defendant breached this duty and was negligent, gross negligent, and/or was reckless, willful, and wanton in making the representations alleged herein.

36. Such representations as indicated herein were false and were relied upon by the patent board and others in determining the subject issue at the *Inter Partes Review.*

37. Defendant is at fault, because he knew and was aware of the falsity of his misrepresentations, or at the very least, had a reckless disregard for their truth or falsity. Further, he persisted in his efforts to continue supporting his misrepresentations and miscontextualization to invalidate U.S. Patent No. 8,318,813, even when made aware of his misrepresentations and miscontextualization through evidence-based profiling efforts that included his own published work which he concealed from the Patent Board, as characterized in the communications transcript comprising Exhibit 7.

38. Defendant was not subject to cross examination at the *Inter Partes Review,* and, therefore Plaintiff had no opportunity to directly confront Defendant with the falsity of his representations.

39. Defendant's misrepresentations actually and proximately caused injuries and damages to Plaintiff as set forth herein in the Complaint, for which Defendant is responsible.

PRAYER FOR RELIEF

Therefore, Plaintiff prays for the following relief:

A. A determination that Defendant is liable to Plaintiff for fraud;

B. A determination that Defendant is liable to Plaintiff for defamation;

C. A determination that Defendant is liable to Plaintiff for negligence;

D. An accounting for damages, including but not limited to Plaintiff's losses, exemplary and punitive damages, pre-judgment and post-judgment interest, costs and attorney fees; and

E. Such other and further relief as this Court deems just and proper.

Respectfully submitted,

Dated: January 18, 2017 By: 

Louis C. Sanfilippo, M.D.