LCS Therapeutics and Lucerne Biosciences to Commercialize '813 Patent for Lisdexamfetamine Dimesylate in the Treatment of Binge Eating Disorder

Dec 26, 2014, 06:00 ET from LCS Group, LLC (http://www.prnewswire.com/news/lcs+group%2C+llc)

NEW HAVEN, Conn., Dec. 26, 2014 /PRNewswire/ -- LCS Therapeutics announced today that it has entered into a strategic collaboration with Lucerne Biosciences, LLC ("Lucerne Biosciences") to commercialize U.S. Patent No. 8,318,813 entitled "Method of Treating Binge Eating Disorder." Patent '813 features claims that encompass the use of the amphetamine prodrug lisdexamfetamine dimesylate (l-lysine-d-amphetamine) alone, or in combination with other pharmacologic therapies, for the treatment of Binge Eating Disorder (BED) according to its current diagnostic criteria in the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V®).*

"This strategic collaboration with Lucerne Biosciences marks an important step forward in bringing much needed public attention to the diagnosis and treatment of BED. BED is a serious eating disorder currently without any FDA-approved medication treatments and for which, unfortunately, there have been many public misconceptions. Developing safe and effective treatments for eating disorders more generally, and for BED in particular, continues to be a critically important unmet need long-recognized in the medical community," said Louis Sanfilippo, M.D., CEO of LCS Therapeutics.

"Recent studies show that between 2 to 3% of the U.S. population will suffer from BED at some point in their lifetime and many of these patients will have a chronic course of symptoms with significant burdens to their emotional and physical health," said Dr. Sanfilippo, who also is a voluntary faculty member at Yale University School of Medicine and teaches psychopharmacology to psychiatry residents.

About LCS Group, LLC (D/B/A LCS Therapeutics) and Lucerne Biosciences, LLC

LCS Therapeutics is a privately-held pharmaceutical development company founded to provide safer, more effective drug treatments for patients suffering from psychiatric disorders by discovering novel uses and reformulations of clinically validated drugs. The company's therapeutic focus has been the treatment of mood and eating disorders with pharmacologic therapies that selectively modulate the brain's reward system. Lucerne Biosciences is a privately-held pharmaceutical development company previously engaged in the development of novel pharmacologic treatments for Major Depressive Disorder.

About BED

BED is a recognized eating disorder in the DSM-V® characterized by eating unusually large amounts of food in a discrete period of time (i.e., within a 2 hour period) and a sense of lack of control over eating during the episode. Binge eating episodes in BED are also associated with at least three (or more) of the following: eating much more rapidly than normal; eating until feeling uncomfortably full; eating large amounts of food when not feeling physically hungry; eating alone because of being embarrassed by how much one is eating; feeling disgusted with oneself, depressed or very guilty after overeating. Marked distress regarding the binge eating is also present and the binge eating occurs, on average, at least once a week for 3 months. In addition, binge eating does not occur exclusively during the course of bulimia nervosa or anorexia nervosa.

About Lisdexamfetamine Dimesylate

Lisdexamfetamine dimesylate (l-lysine-d-amphetamine) is an amphetamine prodrug approved in the United States for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD). Lisdexamfetamine dimesylate is not approved by the Food and Drug Administration (FDA) for the treatment of BED. Based on the Prescription Drug User Fee Act (PDUFA) and the FDA's recent priority review acceptance of a supplemental New Drug Application (sNDA) for the use of lisdexamfetamine dimesylate in the treatment of BED in adults, the FDA is expected to make a decision for this novel use of the drug in February 2015. The use of any prescription medication including lisdexamfetamine dimesylate, alone or in combination with other medications, should be done under close medical supervision.

Inquires/Business Development

Inquiries regarding LCS Therapeutics' intellectual property and/or its strategic collaboration with Lucerne Biosciences, including investment opportunities and/or strategic collaborations regarding the '813 Patent (or pending patent applications), can be emailed to: info@lcsgroupllc.com (http://www.prnewswire.com/news-releases/mailto:info@lcsgroupllc.com). Supplemental information regarding the '813 Patent's claimed methods of treating Binge Eating Disorder with lisdexamfetamine dimesylate and related investment opportunities can be found at: http://www.4shared.com/download/Zq7FJwCAba/Supplemental_Information_US_Pa.pdf?lgfp=3000 (http://www.4shared.com/download/Zq7FJwCAba/Supplemental_Information_US_Pa.pdf?lgfp=3000).

Media Contact:
Louis Sanfilippo, MD
Phone: 203-362-8919

U.S. Patent No. 8,318,813/Method of Treating Binge Eating Disorder

http://www.lcsgroupllc.com (http://www.lcsgroupllc.com/)

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☐ Check the box to include the list of links referenced in the article.

From: "Louis Sanfilippo, MD" <lsanfilippo@lcsgroupllc.com>
Subject: Important Matter Regarding Vyvanse & BED
Date: September 4, 2014 10:00:11 AM EDT
To: fornskov@shire.com
Cc: tmay@us.shire.com, tmay@shire.com, jharrington@shire.com

Dear Dr. Ornskov,

By way of introduction, I am a psychiatrist in New Haven, CT, and also a voluntary faculty member at the Yale School of Medicine. My company, LCS Group LLC, owns US Patent No. 8,318,813, which claims methods for the use of LDX dimesylate in the treatment of Binge Eating Disorder. The '813 Patent currently is the subject of an *inter partes* review petition that Shire Development filed on May 9, 2014 with the Patent Trial and Appeal Board.

The reason for my email is to bring to your attention serious problems with representations made on the public record by Shire's outside counsel and its declarant, Dr. Timothy Brewerton. I believe that it is your fiduciary responsibility as the company's CEO to know about these problems and promptly address them, as they are highly relevant to the interests of Shire's shareholders, its affiliates and even, potentially, its prospective business partners and/or acquirers. As this matter has broad legal implications, I have copied Shire's General Counsel and Chief IP Counsel on this email.

Let me provide you several representative examples of the problems with the representations made by Shire's outside counsel and its declarant and you can judge for yourself.

One such problem involves the representation that LDX dimesylate is an acceptable "anti-obesity agent." Shire, through its outside counsel and declarant, has taken the position that a psychiatrist/MD in 2007 would have regarded an amphetamine-based drug like LDX dimesylate as an acceptable "anti-obesity agent." Specifically, Shire's declarant has represented that a psychiatrist/MD "would have been motivated to identify another centrally acting anti-obesity agent with positive properties, such as LDX dimesylate*"* (Decl, p. 36). Because you are an M.D., I don't have to tell you the problem here. It's been nearly forty years since any competent M.D. would have regarded ***any amphetamine, or any psychostimulant drug*** *for that matter,* as a legitimate pharmacologic treatment of obesity, for self-evident reasons. Shire is now on the public record supporting a view that the medical community would find abhorrent, namely, pharmacologically managing obesity as it would have been in the several decades between the 1940s-1960s, when amphetamines were widely prescribed for such purpose while also ignoring all the relevant medical advancements and regulatory guidance (from the FDA) for treating obesity and its medical comorbidities over that time. As a practicing physician/psychiatrist, it is virtually impossible to believe that such a position was actually argued by another physician and adopted by a pharmaceutical company having expertise in the development and marketing of "stimulant amphetamine drugs."

A somewhat related problem is that Dr. Brewerton's statements in his declaration regarding the use of psychostimulants contradict his prior statements of which the Patent Office was not informed. Dr. Brewerton published a 1997 review on "Binge Eating Disorder" in which he stated that "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**." You probably know that this situation did not change in the 10 years between his publication and the filing of the '813' Patent – for obvious reasons. No reasonable medical practitioner familiar with BED, its psychiatric/medical comorbidities and its treatment would have reasoned to use a stimulant for its treatment, which is why there were still

no published reports on the use of psychostimulants in the treatment of BED until the '813 Patent. Compounding this problem is that Shire's outside counsel did not disclose Dr. Brewerton's prior statements to the Patent Office so that the office could properly evaluate his declaration testimony and Shire's reliance on it.

Another problem is that Dr. Brewerton takes the position that there was no unmet medical need in BED. He writes, "In sum, I disagree that in 2007 there was a long-felt and unmet need for the claimed treatment of BED." (Decl, p. 94). However, you yourself, Dr. Ornskov, highlighted the unmet medical need in BED in a Shire press release on November 5, 2013: "BED is a condition for which there is no currently approved pharmacologic treatment and yet there is significant unmet patient need, as was demonstrated with the faster than expected enrollment of participants in our clinical trial." The same sentiment can also be found in many other places publicly, including from Dr. Susan McElroy in the same November 5, 2013, Shire Press Release. As you know, Dr. McElroy headed up Shire's Phase III LDX/BED program, which is why Shire's representations in its IPR petition are particularly troubling. Clearly, those representations are directly at odds with what you and Dr. McElroy, and the medical community, have long recognized as an accepted understanding of unmet medical need in BED.

The above-noted problems with Shire's representations to the Patent Office (which, as noted above, are only representative of other, similar problems in Shire's filings) highlight the surprising nature of the inventions claimed in the '813 Patent. Many of these problems and their implications for the '813 Patent are addressed in LCS Group's preliminary response to Shire's IPR petition. But I am happy to provide you a more extensive analysis. Taken together with the preliminary response, my additional analysis highlights the extent and scope of the problems in the representations made by Shire's outside counsel and its declarant. Notably, it addresses the particular relevance of two references that are identified in my preliminary response (i.e., Exhibit 2014 - Surman 2006; Exhibit 2015 - Biederman 2007). I believe that it is very important for you and your in-house counsel to understand the significance of these references because they provide the important context for one of the most important representations made by Shire's outside counsel in the IPR petition.

There are many ways for me to optimize the value of the '813 Patent and any that follow. I plan to make a decision very soon on how I shall proceed, as my wife is quite ill with metastatic breast cancer and it is important that I end one chapter of this now seven-year IP project before she passes. If you/Shire are interested in acquiring rights in the patent and any that may follow, please let me know as soon as possible. Should you or others at Shire still have doubts about '813 Patent's uniqueness and value in view of my preliminary response and this email, I am confident that my additional analysis of the IPR petition/declaration filed by Shire's outside counsel will resolve them. I am happy to forward the analysis to you. Further, please know that transparency and accountability are extremely important to me. But please appreciate that given my prior experience with Shire, which includes reaching out to the company in 2008, 2010, 2012, 2013 – and now in 2014 - I would request that ***all communications*** to me (at least initially) be in writing via email and involve only Shire in-house people. I would regard this as a good faith gesture of moving forward in the spirit of trust and cooperation on a matter, it would now seem, involves our shared mutual business interests for the novel treatment of Binge Eating Disorder with LDX dimesylate.

Sincerely,
Louis Sanfilippo, M.D.

CEO, LCS Group, LLC
291 Whitney Avenue, Suite 306
New Haven, CT 06511

From: "Lucci, Joseph" <JLucci@bakerlaw.com>
Subject: FW: Dr. Sanfilippo
Date: September 4, 2014 1:00:39 PM EDT
To: "'Louis Sanfilippo, MD'" <Louiscsan@aol.com>
Cc: "Farsiou, David" <DFarsiou@bakerlaw.com>

Louis

Please see below. Let me know if you would like to discuss.

Thanks,

Joe

Begin forwarded message:

> **From:** Kuzmich, Sandra [mailto:SKuzmich@flhlaw.com]
> **Sent:** Thursday, September 04, 2014 12:56 PM
> **To:** Lucci, Joseph
> **Subject:** Dr. Sanfilippo
>
> Dear Joe,
>
> Good afternoon. I hope you are well and that you had a good summer.
>
> We have been informed by Shire that Dr. Sanfilippo has again (apparently today) contacted Shire management and Shire in-house counsel directly regarding issues related to Vyvanse, BED, and US Patent No. 8,318,813, as well as the related inter partes review petition. Shire understands that Dr. Sanfilippo is represented by you in these matters. Please inform Dr. Sanfilippo that all negotiations with Shire will involve in-house and outside counsel representing Shire. As such, please ask Dr. Sanfilippo to communicate through you with Frommer Lawrence & Haug (Ed Haug or me) or David Banchik, Esq. (Vice President - Intellectual Property, Shire).
>
> Thank you.
>
> Sincerely,
>
> Sandy

From: "Louis Sanfilippo, MD" <lsanfilippo@lcsgroupllc.com>
Subject: Follow-up on Patent '813 and IPR petition
Date: September 12, 2014 1:12:26 PM EDT
To: fornskov@shire.com
Cc: tmay@us.shire.com, tmay@shire.com, jharrington@shire.com, dbanchik@shire.com

Dear Dr. Ornskov,

Further to the email I sent you on September 4, I've been informed that Shire's outside counsel of Frommer, Lawrence & Haug (FLH) contacted attorney Joseph Lucci of Baker Hostetler. As indicated in my email, I believe that all communications should be made to me and involve only Shire in-house people (at least initially). This is appropriate at least because FLH made the problematic representations on the public record to the Patent Trial and Appeal Board. I don't believe it is in the interests of Shire's shareholders, its affiliates and even, potentially, its prospective business partners and/or acquirers to have FLH involved. Moreover, I am the one responsible for making all business decisions at LCS Group, so Shire should communicate directly with me. There is no need for anyone to contact Mr. Lucci at this time; if I need his input, I will contact him myself.

As Shire's CEO, Dr. Ornskov, I believe it is incumbent on you to promptly address the serious problems involving the representations that have been made on the company's behalf, and upon which the Board could mistakenly rely in evaluating the '813 Patent. As previously indicated, these problems go beyond what I have addressed in LCS Group's preliminary response and I am happy to provide you a more extensive analysis to assist you in evaluating Shire's problematic representations. However, given the absence of any response to my prior email by you or anyone else at Shire, along with recently learning that my wife's condition has taken an unsettling and somewhat unexpected turn for the worse, I am actively evaluating available options and plan to make some important decisions imminently to optimize the value of my patent and any that follow. It is now even more important for me to bring this longstanding seven-year IP project of mine to a close.

Sincerely,
Louis Sanfilippo, M.D.

CEO, LCS Group, LLC
291 Whitney Avenue, Suite 306
New Haven, CT 06511

From: "Louis Sanfilippo, MD" <lsanfilippo@lcsgroupllc.com>
Subject: '813 Patent/IPR petition and FLH
Date: September 17, 2014 1:13:33 PM EDT
To: fornskov@shire.com
Cc: tmay@us.shire.com, tmay@shire.com, jharrington@shire.com, dbanchik@shire.com

Dear Dr. Ornskov,

On Monday September 15, I received the email below from Shire's outside counsel of FLH. I take this to mean that you and your in-house counsel at Shire support the representations that FLH publicly made to the Patent Trial and Appeal Board in Shire's IPR petition.

My wife's medical situation has taken a significant turn for the worse and it's now become very important to me that she know the status of this project before she passes. As a result, I expect to make a final decision on how to best commercialize the '813 Patent by October 1, 2014. My wife has sacrificed a lot in the seven-year span it took to prosecute the '813 Patent, and she believes in its value as much as I do. Unfortunately, she did not see much of me this summer because I felt it imperative to clarify the scope and extent of problematic IPR/declaration representations (on BED, BN, and obesity, among others), which took time and resources. These are serious psychiatric/medical disorders; thus, from the outset of my reading the IPR petition and declaration I considered it my fiduciary obligation as a physician to clarify the serious problems in the representations that FLH and Dr. Brewerton made regarding them.

I sincerely hope that my efforts help you and Shire appreciate that the public representations that FLH and Dr. Brewerton made in the IPR Petition are a liability to the interests of Shire's various stakeholders. Further, I believe that Shire and LCS Group have the same mutual business interests deriving from the '813 Patent, a belief I have held for some time though especially now that the FDA has accepted for priority review Shire's sNDA for LDX dimesylate in the treatment of BED. But I will let you, Dr. Ornskov, be the judge of that.

Again, please know that I fully expect to make a final decision on how to best commercialize my IP by October 1. I would be doing a great disservice to my wife if I did not. As I've indicated before, I believe it best that all communications be made to me and involve only Shire in-house people.

Sincerely,

Louis Sanfilippo, M.D.
CEO, LCS Group, LLC
291 Whitney Avenue, Suite 306
New Haven, CT 06511

Begin forwarded message:

> **From:** "Kuzmich, Sandra" <SKuzmich@flhlaw.com>
> **Subject: Contact Information**
> **Date:** September 15, 2014 5:42:48 PM EDT
> **To:** <lsanfilippo@lcsgroupllc.com>
> **Cc:** "Haug, Ed" <EHaug@flhlaw.com>, "Banchik, David" <dbanchik@shire.com>, <jlucci@bakerlaw.com>
>
> Dear Dr. Sanfilippo,

We have been informed by Shire that you have again directly contacted Shire management and Shire in-house counsel regarding issues concerning Vyvanse, BED, and US Patent No. 8,318,813, as well as the related inter partes review petition. Shire has engaged Frommer Lawrence & Haug LLP (FLH) to handle all aspects of the above-referenced matters on its behalf, and has indicated that all your communications concerning the same should be through FLH (and not Shire management). As such, please direct all of your future communications regarding these matters to Ed Haug or me.

Thank you very much for your anticipated cooperation.

Sincerely,

Sandra Kuzmich, Ph.D., Esq.
Partner, Frommer Lawrence & Haug LLP

From: "Louis Sanfilippo, MD" <lsanfilippo@lcsgroupllc.com>
Subject: Decision regarding the '813 Patent & Shire interests
Date: September 22, 2014 1:07:11 PM EDT
To: fornskov@shire.com
Cc: tmay@us.shire.com, tmay@shire.com, jharrington@shire.com, dbanchik@shire.com

Dear Dr. Ornskov,

I have not heard back from you or anyone else at Shire since first writing to you on September 4 to inform you/Shire about the problematic representations in Shire's IPR petition/declaration made by FLH/Dr. Brewerton. Shire's silence on this matter, in connection with its decision to initiate the IPR review in the first place and to then have FLH respond when I expressed serious concern about that firm's representations to the Patent Trial and Appeal Board, lead me to conclude that you/Shire support the representations FLH/Dr. Brewerton made. These developments also lead me to conclude that you/Shire have no interest in acquiring rights in the '813 Patent because you/Shire believe '813's claims would have been obvious to a "Person of Ordinary Skill in the Art."

As a result, I am informing you, your senior management team, your in-house counsel, and Shire's Board of Directors that the decision I plan to make on/by October 1 can be expected to have a serious material bearing on the interests of these various stakeholders. I say this in the spirit of transparency and accountability, because everything that I have written to you has been for a specific objective. As Shire's CEO you should know that objective, which is to make those parties responsible for making and perpetuating the problematic representations in the IPR petition accountable for their actions, especially now that I have made three attempts to bring them to your attention for prompt resolution. Please know, Dr. Ornskov, that I have sincerely made these attempts to make you aware of the scope and seriousness of this problem along with its implications, which extend far beyond what is addressed in LCS Group's preliminary response. In this way, my wife can see first hand before she passes that everything we've both sacrificed considerably for over the last seven years (though particularly over this past summer as I attended to this IPR matter) was not in vain but laid the foundation to bring much needed public attention to serious psychiatric/medical disorders such as BED, BN and obesity.

I take matters of accountability very seriously. In this respect, you/Shire should know that I extensively vetted the many problematic representations made in Shire's IPR petition and Dr. Brewerton's declaration for their truthfulness and implications, including through the use of ***many*** references authored and/or edited by Dr. Brewerton himself but which he/FLH did not submit with the IPR petition. And I can assure you that no stone was left unturned in determining their relevance for the value of the '813 Patent.

In this light, I am providing Shire 48 hours notice that I am terminating the CDA Mr. Harrington executed for Shire on October 29, 2013 (per Section 9). The purpose of the CDA was to discuss a potential business opportunity involving the '813 Patent and related patent applications, but based on Shire's behavior since that time it would appear Shire has no such business interest. As Shire's in-house counsel knows, there has been no exchange of confidential materials; thus, there is none to return or destroy.

Sincerely,

Louis Sanfilippo, M.D.
CEO, LCS Group, LLC
291 Whitney Avenue, Suite 306
New Haven, CT 06511

From: "Louis Sanfilippo, MD" <lsanfilippo@lcsgroupllc.com>
Subject: '813/Serious new matter involving Shire's in-house counsel
Date: September 26, 2014 3:33:29 PM EDT
To: fornskov@shire.com

Dear Dr. Ornskov,

I am writing to you, exclusively, to inform you of a very serious problem that goes beyond FLH's representations to the Patent Trial and Appeal Board. I believe it is imperative for you to promptly resolve this problem before it becomes a massive liability for Shire's various stakeholders.

As forwarded below, I received an email from David Banchik of Shire (on September 23) that requested I "communicate with FLH on these matters." However, Mr. Banchik's request that I communicate with FLH to address FLH's own problematic representations in Shire's IPR petition raises serious conflict of interest issues. Moreover, it improperly places me in the middle of a potentially serious problem between Shire and FLH involving the representations that FLH made on the company's behalf. To use a simple analogy, requesting that I communicate with FLH is like telling a "whistleblower" to blow his whistle amidst those whom he seeks to expose but leaving no one else around to hear the whistle. I am not interested in making FLH's representations to the Patent Board my problem rather than Shire's. That is why I am bringing this issue to you as Shire's CEO and the person ultimately accountable for how this matter is handled.

In this light, let me provide you an update on my plans regarding commercialization of the '813 Patent and any that may follow. Attached is a press release which will feature prominently in my final decision that I have now determined to make on October 1. It's been a very long time that I've tried to do business with Shire in the spirit of trust and cooperation, having expended substantial time and resources to this end; regrettably, that sentiment has yet to be reciprocated in good faith.

My email of September 22 gave Shire the required 48 hours notice for terminating the LCS Group/Shire CDA; accordingly, the CDA has now been terminated.

Sincerely,

Louis Sanfilippo, M.D.
CEO, LCS Group, LLC
291 Whitney Avenue, Suite 306
New Haven, CT 06511

Begin forwarded message:

> **From:** "Banchik, David" <dbanchik@shire.com>
> **Subject: RE: Contact Information**
> **Date:** September 23, 2014 11:08:04 AM EDT
> **To:** "Kuzmich, Sandra" <SKuzmich@flhlaw.com>, "lsanfilippo@lcsgroupllc.com" <lsanfilippo@lcsgroupllc.com>
> **Cc:** "Haug, Ed" <EHaug@flhlaw.com>, "jlucci@bakerlaw.com" <jlucci@bakerlaw.com>
>
> Dr. Sanfilippo,
>
> We are in receipt of your email of Sept. 17 (in addition your prior emails of Sept. 4 and

Sept. 12).

As previously expressed to you (below), you are requested to communicate through FLH on these matters.

David Banchik
Vice President - Intellectual Property
Shire
725 Chesterbrook Blvd.
Wayne, PA 19087 USA
Tel. (484) 595-8903
Fax (484) 595-8663
Mobile (484) 347-5939
dbanchik@shire.com
http://www.shire.com

From: Kuzmich, Sandra [mailto:SKuzmich@flhlaw.com]
Sent: Monday, September 15, 2014 5:43 PM
To: lsanfilippo@lcsgroupllc.com
Cc: Haug, Ed; Banchik, David; jlucci@bakerlaw.com
Subject: Contact Information

Dear Dr. Sanfilippo,

We have been informed by Shire that you have again directly contacted Shire management and Shire in-house counsel regarding issues concerning Vyvanse, BED, and US Patent No. 8,318,813, as well as the related inter partes review petition. Shire has engaged Frommer Lawrence & Haug LLP (FLH) to handle all aspects of the above-referenced matters on its behalf, and has indicated that all your communications concerning the same should be through FLH (and not Shire management). As such, please direct all of your future communications regarding these matters to Ed Haug or me.

Thank you very much for your anticipated cooperation.

Sincerely,

Sandra Kuzmich, Ph.D., Esq.
Partner, Frommer Lawrence & Haug LLP

ATTACHMENT: "Press Release.pdf"

LCS Group and Lucerne Biosciences to Commercialize '813 Patent for Lisdexamfetamine Dimesylate in the Treatment of Binge Eating Disorder

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dimesylate (l-lysine-d-amphetamine) alone, or in combination with other pharmacologic therapies, for the treatment of Binge Eating Disorder (BED) according to its current diagnostic criteria in the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V®).*

"This strategic collaboration with Lucerne Biosciences marks an important step forward in bringing much needed public attention to the diagnosis and treatment of BED. BED is a serious eating disorder currently without any FDA-approved medication treatments and for which, unfortunately, there have been many public misconceptions. Developing safe and effective treatments for eating disorders more generally, and for BED in particular, continues to be a critically important unmet need long-recognized in the medical community," said Louis Sanfilippo, M.D., CEO of LCS Group, LLC.

"Recent studies show that between 2 to 3% of the U.S. population will suffer from BED at some point in their lifetime and many of these patients will have a chronic course of symptoms with significant burdens to their emotional and physical health," said Dr. Sanfilippo, who also is a voluntary faculty member at Yale University School of Medicine where he co-teaches a year-long course on psychopharmacology to Yale psychiatry residents.

About LCS Group, LLC and Lucerne Biosciences, LLC

LCS Group is a privately-held pharmaceutical development company founded to provide safer, more effective drug treatments for patients suffering from psychiatric and neurologic disorders by discovering novel uses, reformulations and combinations of clinically validated drugs. The company's therapeutic focus has been the treatment of impulse control disorders, mood disorders, obesity and substance-related disorders with pharmacologic therapies that selectively modulate the brain's reward system. Lucerne Biosciences is a privately-held pharmaceutical development company previously engaged in the development of novel pharmacologic treatments for Major Depressive Disorder.

About BED

BED is a recognized eating disorder in the DSM-V® characterized by eating unusually large amounts of food in a discrete period of time (i.e., within a 2 hour period) and a sense of lack of control over eating during the episode. Binge eating episodes in BED are also associated with at least three (or more) of the following: eating much more rapidly than normal; eating until feeling uncomfortably full; eating large amounts of food when not feeling physically hungry; eating alone because of being embarrassed by how much one is eating; feeling disgusted with oneself, depressed or very guilty after overeating. Marked distress regarding the binge eating is also present and the binge eating occurs, on average, at least once a week for 3

months. In addition, binge eating does not occur exclusively during the course of bulimia nervosa or anorexia nervosa.

About Lisdexamfetamine Dimesylate

Lisdexamfetamine dimesylate (l-lysine-d-amphetamine) is an amphetamine prodrug approved in the United States for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD). Lisdexamfetamine dimesylate is not approved by the Food and Drug Administration (FDA) for the treatment of BED. Based on the Prescription Drug User Fee Act (PDUFA) and the FDA's recent priority review acceptance of a supplemental New Drug Application (sNDA) for the use of lisdexamfetamine dimesylate in the treatment of BED in adults, the FDA is expected to make a decision for this novel use of the drug in February 2015. The use of any prescription medication including lisdexamfetamine dimesylate, alone or in combination with other medications, should be done under close medical supervision.

Inquires/Business Development

For any inquiries regarding LCS Group's intellectual property and/or its strategic collaboration with Lucerne Biosciences, including inquiries related to investment opportunities and/or strategic collaborations regarding the '813 Patent (or pending patent applications), please contact:

Louis Sanfilippo, MD
CEO, LCS Group, LLC
291 Whitney Avenue, Suite 306
New Haven, CT 06511
Telephone: 203-362-8919
Email: info@lcsgroupllc.com
Website: http://www.lcsgroupllc.com

U.S. Patent No. 8,318,813/Method of Treating Binge Eating Disorder

SOURCE: LCS Group, LLC

From: "Sanfilippo, Louis" <louis.sanfilippo@yale.edu>
Subject: Important Shire Matter
Date: October 7, 2014 12:37:29 PM EDT
To: "jsiegel@kingdon.com" <jsiegel@kingdon.com>

Hi Jonathan,

Hope all is well. As I'm sure you know from Shire's Sept. 15 press release, FDA accepted Shire's sNDA for LDX in adult BED with a priority review PDUFA date in 2/15. Also a matter of public record, Shire recently filed an Inter Partes review (IPR) petition on U.S. Patent 8,318,813 with the Patent Trial and Appeal Board, arguing that the patent's claims (as related to LDX for the treatment of BED) would have been "obvious" to a "Person of Ordinary Skill in the Art" (i.e., MD/psychiatrist) "as of September 2007" – a time frame in which you and I are very familiar as Vyvanse had just recently been launched for ADHD then. Given that Patent '813 claims LDX as a treatment of BED according to DSM-IV-TR criteria, it also encompasses the less restrictive "BED by DSM-V criteria." Therefore, public developments re: the '813 Patent are sure to have a serious material bearing on the interests of Shire's shareholders – even, potentially, on AbbVie.

What you (or any prospective/active shareholder in Shire) should know is that Shire's IPR petition makes ***many*** representations to the Patent Board that I believe you (or any of your investment colleagues) would immediately find very troubling and problematic, which is why I am bringing this to your immediate attention. Having closely followed and analyzed Shire's portfolio since they acquired NRP in 2/07, I believe this matter is of great significance to shareholder interests, particularly as Shire's IPR representations are easily located publicly and just as easily appreciated for their serious implications. Some representative examples of Shire's public representations to the Patent Board are found below, which can be referenced in more detail in the petition (and the declaration on which it relies) at https://ptabtrials.uspto.gov/prweb/PRWebLDAP2/HcI5xOSeX_yQRYZAnTXXCg%5B%5B*/!STANDARD?UserIdentifier=searchuser (Shire's IPR petition – Exh. 1002; Declaration – Exh. 1009).

1. Shire has publicly represented to the Patent Board that a "psychiatrist/MD" in Sept. '07 would have regarded LDX as an acceptable "anti-obesity agent," like Meridia (Petition, pp. 15-16). You would know as well as anyone how a "psychiatrist/MD" would have regarded LDX at that point in time and that this position is completely absurd. As you know, LDX was hardly even differentiated from Adderall XR, much less other long-acting stimulants, for the treatment of ADHD in Sept. '07 – even among expert psychiatrists familiar with stimulants/ADHD Rx's. It is highly doubtful that an MD/psychiatrist specializing in adult "eating disorders" like BED would have even appreciated/understood ***anything at all*** about Vyvanse at that time given its (i) newness, (ii) pediatric ADHD indication, and (iii) minimal market penetration (Q3/2007 sales of $10MM, on-line with Daytrana and with Adderall XR sales 24x higher and Concerta 17x higher ***the same quarter!).*** Besides, it's been nearly forty years since any competent M.D. would have regarded any stimulant, much less an amphetamine-based one, as a legitimate obesity Rx.

2. Shire also makes the public representation that stimulants (AMP or MPH based) would have been regarded by a "psychiatrist/MD" in Sept. '07 as an acceptable Rx of "binge eating" in Bulimia Nervosa (apart from ADHD). This is the main premise for 2 of its 3 core obviousness arguments (Petition; pp.26-36 and pp. 39-49), while the other core obviousness argument wholly relies on the above "anti-obesity drug" representation (pp. 13-23). Attached below are two references from MGH/Harvard's Surman (2006) and Biederman (2007) whose publication dates basically correspond to the filing date of the '813 Patent, which makes them highly relevant to determining the "truthfulness" of Shire's IPR public representations. Very troublingly, Surman/Biederman both completely contradict the Shire representations on which their two core obviousness arguments are reasoned, simply by saying what any reasonable medical practitioner would have known "as

of Sept. '07." This is, these publications show that stimulants were not regarded as an acceptable drug treatment of "binge eating" in BN apart from comorbid ADHD -- and stimulants even in BN treatment "with comorbid ADHD" was questionable practice on account of their obvious risks in an eating disorder like BN, which is the basis of Surman's/Biederman's research in the first place.

3. Another ***major*** problem: the Brewerton declaration (on which Shire's petition relies) contradicts his own prior statements of which the Board was not informed. Specifically, Brewerton's 1997 review on "Binge Eating Disorder" stated, *"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****."* This is common knowledge by Shire's own "petition standard" of a "Person of Ordinary Skill," as is the fact that nothing changed in the 10 years between Brewerton's '97 publication and '813' in Sept. '07. Compounding this problem is that Shire's IPR petition did not disclose Brewerton's prior public statements to the Patent Board so they could properly evaluate his declaration testimony and Shire's reliance on it.

4. One of the most disturbing public representations in Shire's IPR petition is that (by its own words) it gives "little or no weight" to what has been widely accepted/known in the medical community for some time, namely, the unmet medical need for effective Rx's for BED (Petition, p. 59). Shire's public representation here directly contradicts its own public representation in their 9/15/14 press release announcing the FDA's sNDA acceptance, *"'The decision from the FDA to accept our filing for priority review not only marks progress in the development of Vyvanse for adults with BED, but* ***underscores this is an area of unmet medical need as there are currently no approved pharmacologic options for these patients****,' said Phil Vickers, PhD, Head of Research and Development, Shire."* Things are the same now in BED Rx as they were in Sept. 07 (or if anything "better" now), so why Shire would make diametrically opposite public representations on this matter of "unmet medical need" has its own self-evident implications. Moreover, Shire's IPR representations to the Patent Board on "unmet medical need" in BED also directly contradict public statements made by F. Ornskov (PR 11/5/13) and the PI of Shire's LDX/BED Phase III program, S. McElory (same PR), among other KOLs in the medical community.

As this is all a matter of the public record, including the preliminary response to Shire's IPR Petition that the owner of the '813 Patent filed (which, in transparent self-disclosure, I should tell you is signed by me), I am happy to walk you through Shire's public representations. I think you'd be shocked. In this light, I believe this public matter is both imminently and highly relevant to shareholder interests. To avoid any conflict of interest, you (or anyone who might be interested) should know in advance that any consults I'd provide on this matter would be gratis. I consider it my fiduciary responsibility as a physician to ensure that all such problematic representations be adequately resolved – really for Shire's best interests as this is bound to bite them if they don't promptly resolve it. Eating disorders are serious conditions and people die from them. Perpetuating problematic perceptions of disorders like BED and BN doesn't do anyone well. So you are aware, I do not consult or write for Gerson Lehrman any more, having since turned my attention to new IP projects.

Lastly, please feel free to pass this email along to relevant parties and simply consider it as dissemination of publicly available information. Therefore, my invitation to consult – gratis – is extended to anyone who might have interest.

Best regards,

Louis

Cell: 203-521-2058

ATTACHMENT: Stripped (“Surman 2006.pdf” and “Biederman 2007.pdf”)

From: "Louis Sanfilippo, MD" <louis.sanfilippo@yale.edu>
Subject: Important Shire Matter
Date: October 10, 2014 11:47:26 PM EDT
To: Walid Abi-Saab <wabisaab@hotmail.com>, wabisaab@shire.com, wabi-saab@shire.com

Hi Walid,

Hope all is well on your end, as it's been nearly a couple years since we last communicated (per my forwarded email below of November 7, 2012, when I emailed you about the '813 Patent involving LDX dimesylate for the treatment of BED).

I'm very happy to see that the FDA accepted Shire's sNDA for Vyvanse in adult BED with an expected decision to be made in February, as reported in Shire's Sept. 15 press release. Clearly, this is an important development milestone for an important unmet medical need, and I would be delighted to see an FDA approval as I've seen first-hand for some years now how LDX dimesylate has significantly helped patients with BED. The Vyvanse story has been a remarkable one thus far and I strongly believe its greatest chapter lies ahead.

I'm also very happy to say that since our last communication I've made a final decision regarding how to best optimize the commercial value of the '813 Patent and any that follow, which I made on October 1 (2014) as circumstances warranted it. Among them, my wife is seriously ill with metastatic breast cancer and she is likely to pass at some point soon. Thus, it was important for me to make a final decision so she could have the opportunity to see my IP validated while she'd still be alive. She was first diagnosed a few months before my email to you back in 2012. While she's been unaware of developments regarding my IP since that time for a host of reasons, she has recognized its value and has loyally supported me through its long history of seven years now.

Yet even as I've already made my final decision regarding the disposition of my LDX dimesylate-related IP, I consider it my fiduciary obligation as a physician and educator to write to you on an important Shire matter that involves medical representations the company has publicly made on important clinical conditions like Binge Eating Disorder, Bulimia Nervosa, psychopharmacology and neurotransmitters, obesity and more. As a VP of Global Clinical Development at Shire (as far as I'm still aware), and particularly with your background in academia, I believe it's important that you are aware of these representations, as further explained below, especially because they are very extensive and deeply problematic. As you know, the public perception of eating disorders, themselves very serious clinical matters that people can die from, can have broad ramifications. With, hopefully, an FDA-approval of LDX for BED, there's sure to be heightened attention broadly on eating disorders, especially BED and BN, and therefore the kinds of things that major companies like Shire are representing about them are very important because of their seminal role in shaping the public consciousness. It is for this reason that I am bringing this matter to your attention. You would understand as well as anyone the nature and implications of Shire's problematic public medical representations. And in you're fiduciary role for Shire, you may be able to bring them to their proper attention from within the company before they unduly influence unsuspecting people who may rely on them and also before they could cause irreparable harm.

So let me explain further. Shire recently (in May) filed an Inter Partes review (IPR) petition on U.S. Patent 8,318,813 with the Patent Trial and Appeal Board, arguing that the patent's claims (as related to LDX for the treatment of BED) would have been "obvious" to a "Person of Ordinary Skill in the Art" (i.e., MD/psychiatrist) "as of September 2007." This is a time frame you'd be familiar with, when Vyvanse had just recently been launched for its pediatric ADHD indication, though massively eclipsed by Adderall XR and Concerta (among other long-acting stimulants like

Focalin XR) and thus was still yet to be differentiated from its "stimulant competition" in the mind of the "ordinary psychiatrist-prescriber." Also, given that Patent '813 claims LDX as a treatment of "BED as defined by DSM-IV-TR criteria," it also encompasses the less restrictive "BED as defined by DSM-V criteria." With LDX dimesylate hopefully soon-to-be FDA-approved for the treatment of BED, in view of an expanded prospective treatment population (on account of the less restrictive DSM-V duration/frequency criteria), Shire's public representations are bound to spread across the public consciousness and have significant repercussions.

What you and Shire's senior medical team should know, because it relates to how the company is representing important medical and psychiatric information regarding a drug in development (which is now poised for a major marketing campaign on its anticipated FDA approval), is that Shire's IPR petition makes ***many*** representations to the Patent Board that I believe you (or any of your Shire MD colleagues) would immediately find very troubling and problematic. However, in fairness to Shire it would appear -- based on a careful and extensive analysis I have undertaken on them (with considerable professional help) -- that the source of the problem is Shire's outside law firm responsible for filing the IPR Petition, as well as the physician who submitted a declaration in support of it. The petition does not identify any Shire personnel, much less someone from Shire with medical experience who would have been able to assess this public matter from a medical representation standpoint. From my analysis, as supported by a very bright team including experienced neuroscience people, it would seem that Shire's senior medical management was likely completely ***unaware*** of the kinds of representations that were made to the Patent Board by outside firm and declarant.

Walid, you should know that I e-mailed Dr. Ornskov on this particular matter of the representations of the law firm and declarant so that prompt actions could be taken to resolve them, as any reasonable person would recognize that prompt resolution could only serve Shire's best interests in both the short run and long run. Their potential to impact not only the public perception of serious eating disorders (and their treatments) but also Shire is not something to be taken lightly, and it would be quite troubling if Shire bore the untoward consequences of its outside counsel's poor judgment, apparently caused by a failure to receive feedback and accountable representation from Shire's own senior medical management before making the submission to the Patent Board. Disappointingly, I never heard back from Dr. Ornskov, but instead was repeatedly referred back to the law firm, the very party seemingly responsible for having made these problematic medical representations in the first place. The absence of any indication that Shire's senior medical management has actually considered the issues that I had raised is why I am reaching out to you now.

Below are some representative examples, though there are many more (less dramatic) you'll easily recognize for their problematic nature if you simply take a couple hours to read through Shire's IPR petition and the Brewerton declaration on which it relies. For someone with your background, it would be a rather easy read. These representations are easily located publicly and therefore just as easily appreciated for their ***very serious*** clinical and medical ramifications – as I'm sure you'll appreciate if you were to take the time to read them at https://ptabtrials.uspto.gov/prweb/PRWebLDAP2/HcI5xOSeX_yQRYZAnTXXCg%5B%5B*/!STANDARD?UserIdentifier=searchuser (Shire's IPR petition – Exhibit 2; Declaration – Exhibit 1009).

1. Shire has publicly represented to the Patent Board that a "psychiatrist/MD" in Sept. '07 would have regarded LDX as an acceptable "anti-obesity agent," like Meridia (Petition, pp. 15-16). First of all, you'd appreciate as well as anyone the accepted standard for an "anti-obesity agent" (like Meridia) in 2007, from both a clinical and regulatory perspective. So how Shire, a reputable pharmaceutical company with a lot of bright MD's responsible for its drug development, can argue this position is just about impossible to understand. Which is why it seems highly doubtful that

this medical representation was vetted with Shire's senior medical people. If this position were argued among our shared colleagues here at Yale, it would raise people's hair (which is why I have thus far kept this matter discreet and located to a small trusted circle). Further, you would know as well as anyone how a "psychiatrist/MD" would have regarded LDX at that point in time and that this position is completely absurd, simply based on LDX's "place" among prescribing clinicians (only about four months into its initial launch for pediatric ADHD). As you know, LDX was hardly even differentiated from Adderall XR, much less other long-acting stimulants, ***for the treatment of ADHD*** in Sept. '07 – even among expert psychiatrists familiar with stimulants/ADHD Rx's (like me). It is highly doubtful that an MD/psychiatrist specializing in adult "eating disorders" like BED (of which obesity was known to be a particularly common feature) and Bulimia Nervosa would have even appreciated/understood ***anything at all*** about Vyvanse at that time given its (i) newness, (ii) pediatric ADHD indication, and (iii) minimal market penetration (Q3/2007 sales of $10MM, on-line with Daytrana and with Adderall XR sales 24x higher and Concerta 17x higher ***the same quarter!) -*** particularly as such psychiatrists (that focus on eating disorders like BED, BN and AN) don't usually have much hands-on experience with the many different kinds of stimulant formulations (i.e., IR, intermediate-acting, XR) in the first place, for obvious reasons. Besides and perhaps most importantly, it's been nearly forty years since any competent M.D. would have regarded any stimulant, much less an amphetamine-based one, as a legitimate obesity Rx. Those seasoned medical clinicians who practiced in the 1970s, many of whom still practice in the Yale community, would recall how the FDA restricted amphetamines as "anti-obesity agents" (in 1979) because of safety and efficacy limitations, which leads me to conclude that this "LDX as an anti-obesity agent" representation must have originated from outside of Shire, perhaps on account of some kind of conflict of interest, simply based on the behavioral evidence. Pharmaceutical companies, especially ones like Shire that are known for their expertise in developing and marketing stimulants, simply wouldn't make public representations like this, at least insofar as they sought any kind of self-preservation as well as dignity in the public eye.

2. Shire also makes the public representation that stimulants (AMP or MPH based) would have been regarded by an ordinary-skilled "psychiatrist/MD" (with experience in the diagnosis and psychopharmacology of eating disorders) in Sept. '07 as an acceptable Rx of "binge eating" in Bulimia Nervosa (apart from ADHD). This is the main premise for 2 of its 3 core obviousness arguments (Petition; pp.26-36 and pp. 39-49), while the other core obviousness argument wholly relies on the above "LDX as anti-obesity drug" representation (pp. 13-23). Attached below are two references from MGH/Harvard's Surman (2006) and Biederman (2007) whose publication dates basically correspond to the filing date of the '813 Patent, which makes them highly relevant to determining the "truthfulness" of Shire's IPR public representations as an "MD/psychiatrist" would have regarded them. Very troublingly, Surman/Biederman both completely contradict the Shire representations on which their two core obviousness arguments are reasoned, simply by saying what any reasonable medical practitioner would have known "as of Sept. '07," namely, that stimulants were not regarded as an acceptable drug treatment of "binge eating" in BN apart from comorbid ADHD. And even in BN treatment "with comorbid ADHD," the use of stimulants was questionable practice and, as evidenced from the APA's own standard of practice, only to be considered in patients with a "very clear diagnosis of ADHD," as Shire's own IPR reference of the "2006 APA Practice Guidelines for the Treatment of Patients with Eating Disorders" (Exhibit 1031, p. 20) indicates in its guidelines. But these important and obvious clinical teachings ***were not disclosed*** to the Patent Board in Shire's IPR Petition, seemingly because the declaration failed to disclose it and the law firm simply accepted the declaration testimony without any apparent input from Shire's in-house medical team who could have identified the problematic representation. But this is only the beginning of the problem. Most troublingly, the ***very same case report references*** that the petition ***specifically uses*** to support the characterization that stimulants were long regarded as acceptable Rx's of "binge eating" in BN (apart from ADHD) happen also to ***all be found*** in Surman's publication, ***all in one paragraph*** (the third to last in the

"Discussion"), as they are central to his research inquiry involving the clinical implications of "scant reports in the medical literature of adults suffering from both ADHD-like symptoms and BN" (as taken from his introduction, third to last paragraph). And Surman's ***self-evident conclusion*** regarding their clinical treatment significance (for a Person of Ordinary Skill in the Art) "as of 2006" couldn't be any more contradicting of Shire's representations on which their two core obviousness arguments are reasoned. This is yet another compelling reason why it seems highly doubtful that any in-house medical person at Shire, familiar with eating disorders and stimulants, would have been involved in making or vetting these representations and, therefore, that the source of the problem must reside in Shire's outside counsel and the declarant on whom they relied to write the IPR petition on behalf of the company for the Patent Board.

3. Another ***major*** problem that speaks to the outside law firm failing to represent Shire's best interests in this IPR matter is that the declaration contradicts prior statements of the declarant of which the Board was not informed. Specifically, a 1997 review by the declarant on "Binge Eating Disorder" stated, *"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****."* As you'd appreciate, this would have been common knowledge by Shire's own "petition standard" of a "Person of Ordinary Skill," as is the fact that nothing changed in the 10 years between the '97 publication and the '813 patent's filing in Sept. '07 (as there were still no published reports on the use of psychostumulants in the treatment of BED). Compounding this problem is that Shire's IPR petition did not disclose the declarant's prior public statements to the Patent Board so they could properly evaluate his declaration testimony and Shire's reliance on it. Clearly, this failure to disclose ***basic and important teachings*** on the treatment of BED, in this instance from an authority on the topic (who happens to be the declarant himself), would surely have been picked up by a senior medical person like you or someone on your medical/development team.

4. One of the most serious public representations in Shire's IPR petition is that (by its own words) it gives "little or no weight" to what has been widely accepted/known in the medical community for some time, namely, the unmet medical need for effective Rx's for BED (Petition, p. 59). Shire's public representation here directly contradicts its own public representation in their 9/15/14 press release announcing the FDA's sNDA acceptance, *"'The decision from the FDA to accept our filing for priority review not only marks progress in the development of Vyvanse for adults with BED, but* ***underscores this is an area of unmet medical need as there are currently no approved pharmacologic options for these patients****,' said Phil Vickers, PhD, Head of Research and Development, Shire."* As you know, things are the same now in BED Rx as they were in Sept. 07 (or if anything "better" now), so why Shire would make such blatant contradictory statements, particularly when one of them would be universally regarded as correct by any competent psychiatrist (i.e., the one by Dr. Vickers), underscores the behavioral reality that the source of the problem must be in Shire's outside counsel and its declarant, or additionally in a "communication breakdown" between the firm and Shire. Not surprisingly, then, Shire's IPR representations to the Patent Board on "unmet medical need" in BED also directly contradict public statements made by Dr. Ornskov (PR 11/5/13) and the PI of Shire's LDX/BED Phase III program, Dr. Susan McElroy (same PR), among other KOLs in the medical community. With LDX poised for, hopefully, FDA-approval, I imagine many your own colleagues at Shire have expressed the same sentiment as Drs. Vickers, Ornskov and McElroy, which (assuming this is the case among your colleagues) would be further behavioral evidence to identifying the source of this representation problem in Shire's outside counsel and its declarant, and a "communication breakdown" between them and Shire's in-house counsel and its development/medical teams.

5. Lastly – from a psychopharmacology perspective – let me provide you an excerpt from Shire's IPR petition "reasoning as a psychiatrist/M.D." arguably would have in Sept. 07, one with

"clinical experience in the diagnosis and psychopharmacology of eating disorders, specifically BED." Such a person, as Shire's IPR petition argues, "would have known that d-amphetamine increases NE and DA levels in the brain, which is believed to be the main dysfunction in BED, namely, low levels of NTs" (Petition, p. 16). Does this sound like any "MD/psychiatrist" you would have known "as of Sept. '07" (or anytime since or before), particularly one with "clinical experience in the diagnosis and treatment of eating disorders, specifically BED." But unfortunately it gets worse because one of Shire's most important "state of the art" references ***for*** arguing '813's obviousness (in its "anti-obesity drug" line of reasoning) directly contradicts this position, writing what any "MD/psychiatrist" would have appreciated "as of Sept. '07," namely, that "it is important to point out that the mechanism of action of pharmacological agents on BED is unknown" (Exhibit 2010, Appolinario's 2004 "Pharmacological Approaches to the Treatment of Binge Eating Disorder"). The problem, though, is only then amplified considering that the ***only*** neurotransmitter-specific drugs regarded "as successful" for the treatment of BED in Appolinario's "state of the art reference" were clearly ones that ***potentiated serotonin*** (to some degree or another), as any psychiatrist (or psychiatrist-in-training) "as of Sept. 07" would have understood from the publication's teachings (i.e., SSRI's, d-fenfluramine – serotonin release, sibutramine – SNRI). Clearly, Shire's senior medical team would never have allowed such representations to be made to the Patent Trial and Appeal Board, especially when any psychiatrist over the last three decades would readily have understood that d-amphetamine (and therefore LDX) doesn't potentiate serotonin in any notable way and therefore wouldn't have been regarded as an obvious drug candidate to be "successful" in the treatment of BED.

But what you and your medical team should realize is that the declarant himself co-authored a chapter entitled "Neurotransmitter Dysregulation in Anorexia Nervosa, Bulimia Nervosa and Binge Eating Disorder" in a book that he exclusively edited, "Clinical Handbook of Eating Disorders: An Integrated Approach" (2004). And it couldn't offer a more contradictory characterization of the "role of neurotransmitters" ***in BED*** than was represented to the Patent Board. But again, it gets even worse because the declarant's publication ***wasn't submitted*** to the Patent Board to be considered in view of his declaration testimony and Shire's reliance on it. Nor was the chapter in his edited book entitled "Psychopharmacology of Anorexia Nervosa, Bulimia Nervosa, and Binge Eating Disorder" that teaches the same thing as Appolinario does and which concludes, "While emerging data suggest that SSRIs and perhaps, antiobesity agents may provide some benefits, at present there is insufficient information regarding the use of medication for BED." Needless to say, the petition's reasoning to '813's obviousness because an MD/psychiatrist "would have known that d-amphetamine increases NE and DA levels in the brain, which is believed to be the main dysfunction in BED, namely, low levels of NTs," speaks for itself to any psychiatrist with respect to its implications. That is why it's vital that you bring this to the attention of your medical team at Shire so that these medical representations aren't further perpetuated but, rather, promptly resolved for their errors, inconsistences, and flaws in reasoning. The matter of "diagnostic issues" involving "binge eating" in eating disorders (like BED, BN and AN) is yet another major problem in Shire's IPR petition, but that will be easy enough for you and/or any other Shire MD/psychiatrist to recognize for its implications by simply reading through the petition's "Ground 1,4 and 7" arguments (which would take you perhaps an hour including a review of their cited references; Petition, pp. 13-17; 26-30; 39-42).

What I've provided here is really only the "tip of the iceberg." In its totality, this problem of Shire's medical representations apparently made by outside counsel on the basis of the declarant's testimony does get worse. Much worse. The preliminary response to Shire's IPR Petition, which in transparent self-disclosure I should tell you is signed by me, features many more such problematic representations, ones that I am confident would never have been cleared for public representation had you and/or Shire's in-house medical/development team reviewed it. I should also tell you that over the summer I performed an extensive analysis of ***many*** of the declarant's own publications not submitted to the Patent Board, as the Petition wholly relies on his

declaration testimony, including a unique "reasoning analysis" (of the kind you might imagine used in behavioral profiling/intelligence circles) that cross-matched compatible positions in his prior art and then determined the veracity of his declaration's line of reasoning as measured by his own standard. The findings were quite astonishing and consistent with what I've mentioned above about his declaration testimony. Over the summer I also conducted a unique "probability analysis" (based on methods used by institutional investors and hedge funds) to demonstrate, essentially, the virtual impossibility that "Person of Ordinary Skill in the Art" would have concluded the obviousness of '813's claims "as of Sept. '07." But such methods, as used in intelligence/behavioral profiling or investment circles, are hardly necessary when people like you and I – and countless others on Shire's senior/junior medical team – already know how an "MD/psychiatrist" would have regarded a stimulant like LDX and an eating disorder like BED "as of Sept. 07," and can see first-hand themselves how Shire has represented itself to the US Patent Trial and Appeal Board.

What I'd ask of you, Walid, in your role as both a senior medical person in Shire's Global Development and also as a physician/psychiatrist, is to take a look at the IPR petition (and the declaration on which it relies) as well as my preliminary response (Exhibit 6) – and make your own judgments. And once you have, then let Dr. Ornskov know what you think about Shire's representations to the Patent Board, which directly bear on serious, real-life issues. I'm sure your opinion would be respected at Shire.

Best regards,

Louis

ATTACHMENT: Stripped ("Surman 2006.pdf" and "Biederman 2007.pdf")

Begin forwarded message:

> **From:** "Louis Sanfilippo, MD" <louis.sanfilippo@yale.edu>
> **Subject: U.S. Patent for Vyvanse to Treat Binge Eating Disorder**
> **Date:** November 7, 2012 10:46:26 PM EST
> **To:** Walid Abi-Saab <wabisaab@hotmail.com>
>
> Dear Walid,
>
> I hope things are going well on your end. I am writing to see if Shire's executive team would like to license a method patent for the use of lisdexamfetamine dimesylate (Vyvanse) in treating Binge Eating Disorder as defined by DSM-IV-TR criteria (yes, you are reading this correctly). The issue date for this patent, entitled "Method of Treating Binge Eating Disorder" (Patent No. 8,318,813), will be on November 27, 2012. I noticed that Shire recently announced plans to initiate a Phase III program with Vyvanse for this indication and expects to formally announce the start of trials sometime very soon, perhaps even in this calendar year. I am very clear on deal terms that I believe would be equitable to both sides if Shire can close on a transaction on or before the date the patent issues; in this regard, I would be happy to keep news of the patent issuing outside of Shire's interest under the radar. I would appreciate if you could forward this to the right party(ies) at Shire.
>
> Attached is a PDF which includes the patent's claims, which are quite substantial and include both monotherapy and combination treatments with lisdexamfetamine dimesylate

for BED, with additional dependent claims covering the dose ranges Shire plans to use in their Phase III protocol (as posted on clinicaltrials.gov on October 29, 2012). Further, I filed a continuation application last month that has yet to be published but the claims that are covered in a preliminary amendment involve the 'marketing' of lisdexamfetamine dimesylate for Binge Eating Disorder (i.e., informing a user/purchaser, package insert material, other forms of informing/marketing). I am not sure that Shire is even aware of any of these patent developments regarding BED, as I believe the last time I communicated with anyone about this particular indication was an email correspondence I sent Mike Cola a few years back after I initially had filed the IP in the context of seeing BED patients demonstrating notable responses to treatment with Vyvanse. It did not seem that Shire's executive team was interested in following up with me on this matter.

Further, there is another patent application I am prosecuting that I believe Shire may also like to license or collaborate on, regarding the use of lisdexamfetamine dimesylate as an adjunctive therapy to antidepressants for major depressive disorder (yes, you are reading this correctly too). An attorney representing me had previously contacted Shire's general counsel at a point when we were prosecuting a different set of claims but we never had any meaningful follow-up from anyone at Shire for this indication either. Since then, we have filed a continuation application (this summer; claims have yet to be published) that involve a new set of claims that would nicely match Vyvanse's package labeling as an adjunctive therapy for MDD (i.e., claims language involves efficacy in a clinical trial) if the sNDA were approved by the FDA. This new set of claims would provide an opportunity to overcome initial rejections we received from the USPTO and, also, would provide meaningful protection (if granted) to any party seeking to market lisdexamfetamine dimesylate as an adjunct to antidepressants in MDD in accordance with standard package labeling that indicates the drug has shown efficacy in a clinical trial. I think this would be a very attractive opportunity to collaborate with Shire in view of what hopefully will be positive Phase III MDD adjunctive therapy data – and ultimately a new adjunctive treatment option for MDD – something we both know is desperately needed for patients.

Lastly, the IP is entirely my own and assigned to entities fully owned by me; none of this IP is covered under Yale's patent policy as it was filed and developed during the time in which I was fully self-employed through my private practice and had only a voluntary clinical faculty position in which I committed several hours of teaching time a week in exchange for the faculty appointment.

What really began as something of an intellectual exercise upon seeing that patients were having favorable responses to lisdexamfetamine dimesylate for these indications has clearly become something much more – and I am very glad to see that Shire has pursued these platforms with controlled trials. It would be nice to make this a win-win for each of side of the story in Vyvanse's development for these unmet clinical needs.

I look forward to hearing back from you. I am attaching a standard CDA template in order to expedite matters. I want to be very clear to Shire's executive team from the outset that I have given significant consideration to the terms of a license for all this IP but only if both sides can come to an agreement on or before the issue date of the patent which is on November 27, 2012.

Best,

Louis

Louis C. Sanfilippo, MD

Assistant Clinical Professor, Department of Psychiatry,

Yale University School of Medicine

Office: 203-624-2155

Fax: 203-624-2177

Mobile: 203-521-2058

ATTACHMENTS: STRIPPED ("Sanfilippo LSDX-BED US Patent No. 8318813 Issue Notification" and "CDA LCS Group-Shire")

From: "Sanfilippo, Louis" <louis.sanfilippo@yale.edu>
Subject: Important Vyvanse/Shire Matter
Date: November 7, 2014 10:49:09 PM EST
To: "jrenna@shire.com" <jrenna@shire.com>

Dear John,

I hope this email finds you and your family well. Since October 1 (2014), mainly on account of an important decision I made regarding my lisdexamfetamine dimesylate-related intellectual property of which we'd discussed in times past, it's been necessary for me to review our communications between 2008-2011. In so doing, it struck me that it's been awhile since we last spoke and, also, that I've missed our conversations about Vyvanse, particularly our early ones about the drug's unique features as it was making its early entry into the clinical marketplace of ADHD treatment and thus seeking to differentiate itself……..

[EMAIL CONTENTS STRIPPED]

….. I am confident that your opinion would be respected at Shire and by its CEO Dr. Ornskov, particularly as I would expect it to involve you're judgment of me.

Best regards,

Louis

ATTACHMENT: Stripped ("Surman 2006.pdf" and "Biederman 2007.pdf")

Begin forwarded message:

> **From:** <lcs27@pantheon.yale.edu>
> **Subject: Follow-up on phone call**
> **Date:** October 15, 2008 6:49:00 PM EDT
> **To:** <jrenna@shire.com>, <jrenna@us.shire.com>
>
> John,
>
> Thanks very much for your call yesterday. Wednesday November 5 works best - how about 1:45 pm? I have some leeway on either side of that if it will work better for you.
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> Also, as follow-up to our conversation back in August, I am attaching a summary of new potential clinical applications for Vyvanse. I have also emailed Mr. Cola a copy for an evaluation on the business/commercial side.
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> I am still working on a protocol for binge eating disorder/obesity related to binge eating, including some proprietary ideas on patient selection. In addition, I have since had preliminary discussions with a CT based medical group that specializes in obesity treatment that carries their fair share of patients with binge eating problems. It seems they have potential interest in running a pilot.
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> Lastly, after discussing it further with my team at LCS Group, LLC, the consultancy assigned the IP regarding various methods of use for methylphenidate and amphetamine

prodrugs/analogs, including binge eating and depression, I think it would be best if we could put a mutual non-disclosure agreement in place first especially if we plan to discuss these matters. I can provide you with a template if that's fine with you. I look forward to meeting with you to further discuss Vyvanse and also consider its potential value for helping many patients with unmet medical needs.

Best wishes,
Louis

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Assistant Clinical Professor, Department of Psychiatry
Yale University School of Medicine
291 Whitney Avenue, Suite 305
New Haven, CT 06511
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[Attachment stripped: Original attachment type: "application/pdf", name: "VYVANSE New Applications.pdf"]

From: "Sanfilippo, Louis" <louis.sanfilippo@yale.edu>
Subject: Fwd: Important Vyvanse/Shire Matter
Date: November 10, 2014 10:52:25 AM EST
To: "drtimothybrewerton@gmail.com" <drtimothybrewerton@gmail.com>, "tbrewerton1@comcast.net" <tbrewerton1@comcast.net>, Sandra Kuzmich <SKuzmich@flhlaw.com>, Ed Haug <EHaug@flhlaw.com>

FYI – as you should all know.

As for Dr. Brewerton, I can see that no one from FLH or Shire had the foresight to let him know the most important things about me, as I clearly told it to Mr. Haug and Ms. Kuzmich, as well as Shire's senior management when the '813 Patent issued, namely, that I am a very big believer in accountability and transparency -- and, very importantly, I pay attention to ***every detail.*** Or if someone did let Dr. Brewerton know that, then he lost sight of it when he signed his declaration for the U.S. Patent Trial and Appeal Board on which Shire's arguments of "obviousness" rely. But from what I've been able to determine from the way that Dr. Brewerton has reasoned and represented himself in his professional work, including among his peers, it would seem that the failure to be transparent began with FLH.

Louis Sanfilippo, MD, Inventor of the '813 Patent

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Subject: Patent '813/Legal Development
Date: November 13, 2014 11:16:01 AM EST
To: fornskov@shire.com

Dear Dr. Ornskov,

I am writing to let you and Shire know of an important development involving Shire's IPR petition for Patent '813, for which the Patent Board on Nov. 5 decided to institute a trial (with an initial conference call on Dec. 5 at 1 PM EST). As of today, I have instructed attorney Joe Lucci and his law firm, Baker Hostetler, to withdraw their representation of me in, specifically, this *Inter Partes* Review. In the spirit of transparency, as it's consistently been my intention with Shire since I first formally informed the company's senior management about my IP in my email to Michael Cola on Oct. 14, 2008, you should know the reason why.

As I let you know on Sept. 26, I'd determined to make a final decision on Oct. 1 on how to best commercialize Patent '813 and any that follow, on account of Shire's failure to resolve a very troubling and unbelievably extensive "public representation problem" to the Patent Board despite my four good faith efforts until that time to bring this problem to your attention so that it could be resolved discreetly and, importantly, without involvement from the outside law firm responsible for filing the IPR petition. I did, in fact, make that final decision on Oct. 1 and, with hindsight, it was an excellent decision. This is because it directly involved a permanent decision on how I would represent myself in Patent 813's "new chapter" that now includes the Patent Board's decision.

As it's since turned out, the Patent Board ***has now relied on*** Shire's extremely inaccurate declaration testimony ***to make its decision*** that there is a reasonable likelihood Shire would prevail in its obviousness position involving Patent '813's claimed method of treating BED with LDX dimesylate. But even more specifically, the Patent Board has relied on the most egregious "representation problem of them all" to make its determination, the one that I tried to ***warn*** you/Shire about when I first emailed you on Sept. 4 writing, *"I believe it is important for you and your in-house counsel to understand the significance of these references [Biederman and Surman] because they provide the most important context for one the most important representations made by Shire's outside counsel in the IPR petition."* As a result of these ***profoundly troubling developments*** caused and perpetuated by a global pharmaceutical company and its outside law firm in collaboration with an *"eating disorder expert"* who's declaration testimony has been extensively and professionally profiled to reveal highly consistent patterns of ***highly inconsistent and markedly discrepant representation/reasoning behavior*** that any reasonable person would understand for its patent and related behavioral implications, you/Shire should know that I plan to imminently take action outside the *Inter Partes* Review process.

So that you, Dr. Ornskov, are clear about what Shire has publicly represented to the Patent Board in order to invalidate Patent '813, it is that an *"MD/psychiatrist as of Sept. '07 with clinical experience in the diagnosis and psychopharmacology of eating disorders"* would have regarded **the class of stimulant drugs,** as accepted and successful for the treatment of ADHD, as also **acceptable** and **successful for the treatment of Bulimia Nervosa** (and therefore BED because BN and BED have "essentially the same" non-specific symptom of binge eating). The "reasoning" behind this representation made by Shire's declarant is that an MD/physician would have considered it "state of the art" in Sept. '07 to administer stimulant therapy for the non-specific symptom of "binge eating" **without any consideration whatsoever that its diagnostic** (i.e., BN, BED, Anorexia Nervosa-binge eating/purging type) **or comorbid** (i.e., ADHD) **clinical context could have significant therapeutic implications.** After all, that's the only way, as bizarre as it would be to any competent MD/psychiatrist, that anyone could

"diagnostically and therapeutically reason" to the class of stimulants drugs as an acceptable and successful pharmacotherapy approach for the treatment of Bulimia Nervosa (and therefore BED).

That, Dr. Ornskov, is a very deep, extremely basic and blaringly obvious "reasoning and representation problem" made by Shire and its declarant to the Board that has now caused yet another even more serious problem that directly involves Patent 813's claimed methods of treating BED with LDX dimesylate and the public's perception regarding the art of eating disorder diagnosis and psychopharmacology. But that self-evident problem is only amplified when you consider that its source is *"an expert in the field of eating disorders and related comorbidities, including their associated neurobiology and psychopharmacology…since 1987"* who unmistakably made the **exact opposite representation** in his prior published work three years before Sept. 07 that he **failed to disclose** to the Patent Board for its very important diagnostic, therapeutic and Patent '813 implications. That prior representation, in his 2004 chapter on *"Eating Disorders [EDs], Victimization and Comorbidity: Principles of Treatment"* (featured in his exclusively-edited *"Clinical Handbook of Eating Disorders"),* is that EDs such as BN and BED require different pharmacological approaches than ADHD except in such instances that the **ADHD/ED comorbidity** is the reason one would use a stimulant *"to manage the ADHD"* (in which case it may help the "binge eating" in either BN or BED). Of all places, his representation is made in the chapter's section on **ADHD comorbidity with EDs**, and he even applies **the same three published case reports** that Surman, Biederman, and the 2006 APA Practice Guidelines (among others in the art such as his/Shire's key obviousness reference of Dukarm) also apply to make the same "diagnostic/ comorbidity/ therapeutic teaching point" that he **represented in 2004**. **But when he represents these same three published case reports in 2014** to teach the Patent Board and the public-at-large on the use of stimulants for the treatment of BN as it would have been "state of the art" **in Sept. '07** (in view of Patent '813's *Inter Partes* Review), the "ADHD comorbidity/stimulant treatment part of his teaching" is ***entirely missing for its profoundly relevant therapeutic implications.*** Which is the **fundamental reason** for why the Patent Board believes that there is a reasonable likelihood Shire would prevail in its obviousness position involving Patent '813's claimed method of treating BED with LDX dimesylate, as reflected in their comment, *"The numerous publications cited and discussed by Dr. Brewerton in connection with his testimony as to the state of the art prior to September 13, 2007….support the Petitioner's contention that the ordinary artisan would also have been aware of other studies [than Ong's 1983 one] showing the successful use of stimulants to treat the binge eating behavior in BN patients." (p. 21, Paper 8 at the IPR portal).* That is a very serious misunderstanding by the Patent Board at the ***most rudimentary level*** of evaluating, DSM-diagnosing and treating eating disorders that involve the non-specific symptom of binge eating. That misunderstanding in clinical practice, as any MD/psychiatrist would affirm, would be grounds for medical malpractice and/or professional sanctions because of its unmistakably reckless and dangerous reasoning that would necessarily put BN patients at serious risk of harm by administration of stimulant pharmacotherapy when there is no comorbid ADHD to warrant its use.

But the declarant's very deep and blaringly obvious ***IPR-represented misinterpretation of his own very important and clearly stated prior published representation*** is yet further amplified for its very serious implications when you consider that the intended benefactor for a Patent Board invalidity decision on the '813 Patent would be the global pharmaceutical company now imminently awaiting an FDA approval decision so that it can begin marketing Patent '813's claimed method of treating BED with LDX for its own "second chapter Vyvanse life cycle story." And that problem is only further compounded when you consider that I specifically tried to ***warn*** you/Shire by telling ***you exactly where to look in order to understand the massive scope and seriousness of this representation problem,*** which happens now to be nearly all intertwined in how someone interprets those ***"scant reports*** *in the medical literature of adults suffering from both ADHD-like symptoms and bulimia nervosa" (per Surman)* that Shire's

declarant represents to the Patent Board as ***"the extensive data*** *demonstrating the successful use of psychostimulants in the treatment of binge eating [in bulimia nervosa]……" (Decl., p. 84).* But there is an unequivocal consensus opinion that would be obvious to any MD/psychiatrist, as also shared by the declarant himself in his 2004 representation - **and it's just the opposite of what the Patent Board believes to be accurate.** Any reasonable person would understand what all of this means if presented to them in the right way, which leads me to another point that may help you understand why I sent the email (as attached via the 4share link below) to FLH's two partners, Sandra Kuzmich and Ed Haug, as well as Dr. Timothy Brewerton, that walks "any reasonable reader" through the many serious "IPR reasoning and representation problems" vis-à-vis another email that I had sent to former Shire Medical Science Liaison John Renna (who is now a senior MSL at Teva). It's about time FLH and the declarant know what's coming their way, as it's a very important time in the public consciousness to ***accurately teach*** on what's undoubtedly going to be (to my view but many others too) a rather monumental paradigm shift in the art of eating disorder diagnosis and psychopharmacology, at the center of which is Patent '813's claimed method for the treatment of Binge Eating Disorder with LDX dimesylate.

Which brings me to my last point. In the spirit of transparency and accountability, you should know just how seriously I've taken this matter, which I'm confident that Dr. Brewerton will understand (and communicate to you) once he has completely read about how ***the real professional MD/psychiatrist community interprets and represents his -- and Shire's -- collective interpretation and representation of the "art of eating disorder diagnosis and psychopharmacology" and "Patent '813's independent claims" to the Patent Board and the public-at-large.*** But he already knows what the real professional MD/psychiatrist community knows, which was the objective for putting together the professionally-written and extensively-detailed 180-page single-spaced email in the short span of four weeks time since my Oct. 10 email to Shire's Walid Abi-Saab. That email ***accurately establishes*** very important truths (or untruths depending on the perspective) involving eating disorders, their comorbidities and their treatment in a way that any reasonable person would understand for its implications on Shire, its outside counsel, its declarant, and Patent '813. As Dr. Brewerton can assure you, I've obviously brought to bear some rather formidable resources on this "reasoning and representation problem." This is because a "book" accurately representing the truth of Patent '813 and the eating disorder art, while also applying some novel profiling technology on the declarant and his testimony, couldn't have been written in less than one month's time unless with some very good help involved. But as I told you on Sept. 22, Dr. Ornskov, it's been my objective for some time now *"to make those parties responsible for making and perpetuating the problematic representations in the IPR petition accountable for their actions."* And now, on account of my Oct. 1 final decision and having prepared for this moment for nearly six months, my work on all of it is essentially all done, so that now I can leave what remains in its completion to my "Patent '813 team."

There is one last thing that would be particularly important for you to know about me. When you read what's been specifically written to permanently resolve this IPR-related matter, ***as well as*** to prepare the public consciousness for the (expected) use of Vyvanse for the treatment of adult BED, keep in mind that I've consistently made it a point to be *"clear, direct and transparent"* with Shire and its senior management, just as I told a number of Shire's senior management (including your predecessor Angus Russell) in an email on Dec. 10, 2012. In view of today's very "obvious circumstances" involving Patent '813 and just a small measure of hindsight back to that time, it ought to be very clear to you and Shire's in-house counsel by now that any reasonable person would understand ***how and why*** it is that things have come to this point with Patent '813 including, but not limited to, the "problematic representation behavior" of Shire's declarant (as extensively profiled) and its outside law firm. And also ***how and why*** Patent '813 is among the most ***non-obvious patents*** in pharmaceutical history. But so there should be no doubt in your mind, because you are Shire's CEO and my every intention is to be perfectly transparent with you

as Mr. Russell before you, you have the opportunity to understand first-hand ***how and why*** all of that is so through an ***accurate representation*** of Patent '813 and the *"art of eating disorder diagnosis and psychopharmacology, specifically BED."* But of course that choice is yours.

"Important Vyvanse/Shire Matter" email at:

http://www.4shared.com/download/4H91ac5sba/Important_VyvanseShireMatter_e.pdf?lgfp=3000

Louis Sanfilippo, MD
Inventor of the '813 Patent

From: "Louis Sanfilippo, MD" <lsanfilippo@lcsgroupllc.com>
Subject: Fwd: Patent '813/Legal Development
Date: November 14, 2014 5:06:13 PM EST
To: drtimothybrewerton@gmail.com, Sandra Kuzmich <SKuzmich@flhlaw.com>, Ed Haug <EHaug@flhlaw.com>

FYI - As I (re-)informed all of you in my email on Nov. 10, transparency and accountability are very important to me. And so also is the equitable disposition of matters, as I communicated to Mr. Haug and Ms. Kuzmich in emails I sent them regarding Patent '813 on Nov. 16 and Dec. 12, 2012. So in the event that FLH has not let Dr. Brewerton know what's been happening of late, I will, because he ought to be prepared for what's imminently about to happen as it will directly involve him, as well as FLH and Shire. To this effect, forwarded below is the email I sent to Shire's CEO Dr. Fleming Ornskov yesterday; also, as attached in the PDF, are the five emails I sent to Dr. Ornskov and various of Shire's in-house legal counsel since Sept. 4 when I first emailed him/Shire about your collective "representation problem" publicly communicated to the Patent Board on behalf of Shire, the representations of which the Patent Board has now ***relied on*** to make a decision that has caused financial harm to LCS Group, LLC, as any reasonable person would readily appreciate in view of the public written record. This way, Dr. Brewerton won't be surprised by the action I've now planned to take next week outside the IPR venue in order to remedy that and a number of other serious problems caused by your collective "reasoning and representation behavior."

Surely, you must all by now appreciate that the scope and nature of "the problem" is far too large and way too serious to be taken up by the small group of judges comprising the Patent Board. There's clearly too much important teaching here on the art of accurately diagnosing and treating eating disorders to be left quietly disregarded and forgotten in a massive web of inaccurate and self-contradicting representations (as professionally profiled and written-up for its significance in my last email to you), particularly at a most critical juncture in psychiatry as the profession stands poised to help the public-at-large learn more about the DSM-defined disorder known as Binge Eating Disorder.

That said, I've now just about fully completed everything that I've been tasked to do since making a very important and prudent decision on Oct. 1 whose objective was to ensure that the interests of Patent '813 and any others that follow are permanently secured in very good hands. With this email in particular, then, none of you can ever say that I didn't forewarn you, as well Shire before you, that I would not stop until I accomplished my objective of making those parties responsible for making and perpetuating the problematic representations in the IPR petition accountable for their actions. Really ***everything*** -- from my preliminary response, to my emails to Dr. Ornskov, to my "other emails" including the one to Shire's former MSL John Renna (who now works at Teva), to my emails involving all of you -- has been for that one specific objective, because I knew at the beginning how I wanted all of this to finally end - namely, in the truth of the matter. And now that I have brought the problem to the attention of Shire and all of you for a ***collective total of eight times now***, under some rather formidable and very well-reasoned professional guidance, the truth of the matter is unmistakably clear. And, of course, that means it's finally time to publicly disclose it.

Lastly, in the spirit of transparency and accountability, you should know that one hour after the email time-stamp on this email you have received, I will forward this email to Dr. Ornskov so that he/Shire are up-to-speed with what I have communicated to all of you. This way there won't be any surprises when the truth of the matter is represented to all three of you.

Louis Sanfilippo, MD
Inventor of Patent '813

ATTACHMENT: STRIPPED ("LCS Emails.to.FOrnskov.9.4.to.11.13.14.pdf")

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To: fornskov@shire.com

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to institute a trial (with an initial conference call on Dec. 5 at 1 PM EST). As of today, I have instructed attorney Joe Lucci and his law firm, Baker Hostetler, to withdraw their representation of me in, specifically, this *Inter Partes* Review. In the spirit of transparency, as it's consistently been my intention with ……

[EMAIL CONTENTS STRIPPED]

…..But so there should be no doubt in your mind, because you are Shire's CEO and my every intention is to be perfectly transparent with you as Mr. Russell before you, you have the opportunity to understand first-hand ***how and why*** all of that is so through an ***accurate representation*** of Patent '813 and the *"art of eating disorder diagnosis and psychopharmacology, specifically BED."* But of course that choice is yours.

"Important Vyvanse/Shire Matter" email at:

http://www.4shared.com/download/4H91ac5sba/Important_VyvanseShireMatter_e.pdf?lgfp=3000

Louis Sanfilippo, MD
Inventor of the '813 Patent

From: Farsiou, David
Sent: Monday, November 17, 2014 11:30 AM
To: trials@uspto.gov
Cc: shire.ipr.813@flhlaw.com; Lucci, Joseph
Subject: IPR2014-00739: Shire Development LLC v. LCS Group, LLC - Authorization Request

IPR2014-00739 (U.S. Patent No. 8,318,813)
Petitioner: Shire Development LLC
Patent Owner: LCS Group, LLC
Assigned Trial Paralegal: Althea Wilburn
Designated Administrative Patent Judge: Lora Green

Patent Owner respectfully requests a conference call to seek authorization to file a motion for counsel to withdraw from the proceeding pursuant to 37 C.F.R. 42.10.

Regards,

David Farsiou
Attorney for Patent Owner

David Farsiou
BakerHostetler

From: Kuzmich, Sandra [mailto:SKuzmich@flhlaw.com]
Sent: Monday, November 17, 2014 1:11 PM
To: trials@uspto.gov
Cc: shire.ipr.813@flhlaw.com; Lucci, Joseph; Farsiou, David
Subject: RE: IPR2014-00739: Shire Development LLC v. LCS Group, LLC - Authorization Request

Counsel for Petitioner, Shire Development LLC, respectfully requests permission to participate in any call between representatives for Patent Owner and the Patent Trial and Appeal Board regarding IPR2014-00739.

Sincerely,

Sandra Kuzmich
Attorney for Petitioner
Frommer Lawrence & Haug LLP
skuzmich@flhlaw.com

From: "Louis Sanfilippo, MD" <lsanfilippo@lcsgroupllc.com>
Subject: Important Patent '813 IPR Update
Date: November 21, 2014 6:30:24 AM EST
To: <fornskov@shire.com>, <tmay@shire.com>, <tmay@us.shire.com>, <jharrington@shire.com>, <dbanchik@shire.com>, Ed Haug <EHaug@flhlaw.com>, Sandra Kuzmich <SKuzmich@flhlaw.com>, <drtimothybrewerton@gmail.com>

Dear Dr. Ornskov, Ms. May, Mr. Harrington, Mr. Banchik, Mr. Haug, Ms. Kuzmich, & Dr. Brewerton,

On behalf of LCS Group, I have an important update for all of you. On Wednesday I was informed by Joe Lucci of Baker Hostetler that the Patent Board refused to let BH withdraw from their representation of LCS Group in the *Inter Partes* Review, as I requested of BH on Nov. 13 and so informed you individually or through your respective company affiliation last week. In view of the Board's decision, I simply have instructed Mr. Lucci and BH to refrain from any further involvement in the IPR process. This is because I have committed to handling the "IPR matter" on the basis of my Oct. 1 final decision involving my LDX-related IP, the nature of which is characterized in my Nov. 13 email to Dr. Ornskov, so please direct any communications relating to it to me.

Besides "best commercializing Patent '813 and any that follow," my Oct. 1 final decision was itself made to resolve the "massive representation problem" on which the Patent Board has now relied to institute a trial. Its basic rationale is perhaps most specifically communicated on p. 176 of the PDF that I provided Dr. Ornskov on Thursday Nov. 13 and which is still available for download at http://www.4shared.com/download/4H91ac5sba/Important_VyvanseShireMatter_e.pdf?lgfp=3000).

In this light, I have asked Mr. Lucci and BH to refrain from any further involvement whatsoever in the IPR process until such time that this "massive representation problem" is completely resolved. And because this "massive representation problem" that I have collectively brought to your attention a total of ***ten times*** has now unduly burdened the business practice of LCS Group, it has become necessary for me to promptly seek its final resolution through my Oct. 1 final decision.

The Board's decision on Wednesday poses an immediate and serious problem for Shire and its shareholders, FLH and Dr. Brewerton, for reasons that ought to be very obvious to all of you by now. If you should have any doubts about that, then I would encourage you to take another look at the written record since Sept. 4 in view of "today's hindsight" that includes the Patent Board's ***two recent decisions***, as chronologically represented in the attached PDF. You should know in advance that there are a few "new emails" (than were featured in the Nov. 14 PDF'd email transcript) that certain of you may not have seen. One of these I sent on Oct. 7 to the head of healthcare investments at a major NY-based hedge fund who is ***very familiar*** with Vyvanse's "place" among prescribing physicians "as of Sept. '07" and the other I sent on Oct. 10 to an MD/psychiatrist at Shire (and former Ivy-league academic, Yale). Both of these individuals were involved in "Patent '813-related communications" back in 2012 and, based on my Oct. 1 decision, it became important that I re-establish communication with them in this particular way.

Once you read through the PDF'd transcript, I suggest that each of you consider what you ***really think*** about the IPR and Patent '813 at this point in time. Then, think about what's most likely to happen next, as it's all been very well-planned.

Taken together, the story of the IPR and Patent '813 is an unmistakably clear and very compelling real-life story, with all the necessary dramatic behavioral elements. And it's all quite accurately

represented by its own remarkably coherent written narrative for any reasonable person to understand. Truly, the Patent '813 story is a very important real-life story -- far more important than any of you really know, which is why I am writing this email to all seven of you now, ***at this most critical juncture in its own time,*** and also why you are reading it to better understand how the story will finally end one chapter to begin another. I say this in good faith and transparently too -- because I know the final ending of the story and what I have done to make it end that way. And I can assure you of one thing: it's only ***imminently*** about to get much more extraordinary, on account of the final decision I made on Oct. 1 involving my LDX-related IP and the extensive preparations I've made to make sure that everything ends just perfectly.

Sincerely,

Louis Sanfilippo, MD
CEO, LCS Group, LLC

ATTACHMENT: STRIPPED ("LCS.Shire.FLH Public Email Record from Sept. 4 to Nov. 17.version.pdf"

From: "Haug, Ed" <EHaug@flhlaw.com>
Subject: Re: Important Patent '813 IPR Update
Date: November 21, 2014 7:27:47 AM EST
To: "Louis Sanfilippo, MD" <lsanfilippo@lcsgroupllc.com>
Cc: <fornskov@shire.com>, <tmay@shire.com>, <tmay@us.shire.com>, <jharrington@shire.com>, <dbanchik@shire.com>, "Sandra Kuzmich" <SKuzmich@flhlaw.com>, <drtimothybrewerton@gmail.com>

Dear Dr Sanfilippo

I ask you once again to stop communicating directly with our client Shire or any of its officers or employees. All of your communications are being directed to our firm as counsel for Shire. Similarly you should not communicate directly with Dr Brewerton. Your continued threats and attempted intimidation of all recipients on your last email are improper and may well be unlawful. I respectfully suggest you consult with appropriate legal advisors.

Please also advise FLH as to who is now representing LCS in the IPR if Mr Lucci is no longer authorized to speak on behalf of the company.

Sent from my iPhone

From: "Louis Sanfilippo, MD" <lsanfilippo@lcsgroupllc.com>
Subject: Re: Important Patent '813 IPR Update
Date: November 21, 2014 3:33:35 PM EST
To: Ed Haug <EHaug@flhlaw.com>
Cc: fornskov@shire.com, tmay@shire.com, tmay@us.shire.com, jharrington@shire.com, dbanchik@shire.com, Sandra Kuzmich <SKuzmich@flhlaw.com>, drtimothybrewerton@gmail.com

Dear Mr. Haug,

As stated in the email that I sent to you this morning, and in the emails that I had sent you vis-à-vis your client previously, you should direct any communications regarding the IPR to me.

Mr. Haug, let me ask you a question: did you read the extensively detailed email that I sent to you on Nov. 10? Your email today suggests that you haven't. In the spirit of transparency, I should tell you (and everyone else) that its contents are now undergoing some "re-framing" to enhance their narrative coherency for this very important "IPR and Patent '813 story."

As a follow-up question, Mr. Haug, let me ask you if have you received input from any of Shire's "MDs" on the 181-page PDF yet? Surely, based on the number of its downloads that immediately followed my email to Dr. Orsnskov on Nov. 13, I would expect that at least one or two "POSA-type MDs" at Shire would have read it for its extremely serious and far-reaching implications. At this point in time, though, I believe that Dr. Brewerton best understands it all, so I respectfully suggest that you re-consult with him.

In this light, Mr. Haug, I should say that it's rather striking for you to suggest that I "consult with appropriate legal advisors." The story that I've written (which now includes (i) our email exchange from today, (ii) the attached PDF from this morning, and (iii) the email that I sent you on Nov. 10) should make it abundantly clear that I've already done that **and continue to do that,** to an extent far greater than you could possibly imagine.

Remember, Mr. Haug, from the outset my objective in all of this has been to get at the "truth of the matter," including your own role in it. By the time of what I'd call Patent 813's "final resolution," everything will be completely transparent, because I have made very extensive preparations to make it happen that way -- to an extent far greater than you could possibly imagine. This may help you understand why it is that this very email from me, which cc's your client's CEO and three of its senior legal representatives, is itself ***in direct response to your email.***

Sincerely,

Louis Sanfilippo, MD
CEO, LCS Group, LLC

From: "Louis Sanfilippo, MD" <lsanfilippo@lcsgroupllc.com>
Subject: Re: Important Patent '813 IPR Update
Date: November 26, 2014 11:11:43 AM EST
To: Ed Haug <EHaug@flhlaw.com>
Cc: fornskov@shire.com, tmay@shire.com, tmay@us.shire.com, jharrington@shire.com, dbanchik@shire.com, Sandra Kuzmich <SKuzmich@flhlaw.com>, drtimothybrewerton@gmail.com

Dear Drs. Ornskov and Brewerton,

In light of (i) our newly established "IPR group" (vis-à-vis the reciprocating communication between Mr. Haug and I on Friday Nov. 21), (ii) Mr. Haug's **complete silence** on my two questions asking him if he read the 181-page PDF or received input on it from any Shire "MDs," and (iii) a recent "legal development" that's come to my attention, I'm writing to the "MDs of our group" to address what's clearly some revealing "lawyerly behavior" evidenced in the objections FLH made last week (on behalf of Shire, as attached) to certain LCS Group exhibits. In this respect, there's a "new IPR and Patent '813 story" **rapidly evolving** in public view of the "old one," itself far more troubling than the "old IPR story" ever was -- and it is fast reaching a critical stage. This is because the already **massive and highly obvious misunderstanding** (on which the Patent Board has relied to institute a trial) has now been magnified by what the "lawyers among us" are doing with their time, which is to make (as noted below) that already very serious "massive IPR problem" **even worse**:

> **No. 1: Exhibit 2002.** This is **Shire's own 2011 Phase 2 LDX/BED trial protocol** that quite perfectly teaches on Patent 813's three independent claims 1, 8 and 13 that involve **first establishing a diagnosis of BED (by DSM-IV-TR criteria)** in a patient/subject and **only then administering LDX (vs. placebo)** to that "specifically DSM-diagnosed BED patient" **for treatment of their BED,** with LDX dosing regimens as represented in dependent claims 2, 9, 10 and 12. Why would the "lawyers of our group" object to this exhibit on "relevance" and "confusion of the issues" when there couldn't be any more "relevant," "credible" and "clearly reasoned" piece of medical literature **to specifically teach the Patent Board and the public-at-large on Patent '813's independent and dependent claims involving the treatment of BED (as "DSM-defined") with LDX?** Here, the behavior of the "lawyers of our group" makes them look as if they couldn't care less about properly treating BED patients with LDX, which is particularly concerning now that LDX is (expectedly, to my view and others too) perhaps three months away from its FDA approval for the treatment of adult BED.
>
> **No. 2: Exhibit 2003.** This is Dr. Brewerton's **concisely written, well-referenced** and **highly credible** 2004 *"Pharmacotherapy for Patients with Eating Disorders"* that teaches on acceptable/successful pharmacotherapies for AN, **BN and BED** in the time preceding Patent '813's filing date, which I'm sure is an important reason why *The Psychiatric Times* chose to publish it for its broad "MD/psychiatrist POSA audience." Importantly, it accurately assumes the "reading POSA" would competently apply his/her "ordinary DSM-based diagnostic knowledge and skill" to administer pharmacotherapy for AN, BN or BED in direct view of the **specific** DSM-defined disorder for which a given drug is prescribed, **which is precisely the way that Patent '813's independent claims are written for POSAs to practice** (and also for pharmaceutical companies to represent in their drug label to teach POSAs on how to prescribe it). It's our obligation as physicians to help the "lawyers of our group" see that concealing this most relevant and important "DSM-based diagnostic and pharmacotherapy context" from the Patent Board (and public-at-large) would make it even harder for them to understand how a POSA would have interpreted ("as of Sept.

'07"), or would interpret ("as of today"), Patent '813's independent claims "in the broadest reasonable light of the specification" -- as well as interpret Dukarm's and Ong's publications (on which the Board relied to institute a trial).

No. 3: Exhibit 2008. This is **Shire's own** (vis-à-vis NRP) **2007 Vyvanse package insert**, which any MD knows would have been among the **single most important "Exhibits"** that a "POSA as of Sept. 07" would have relied on in considering administration of LDX pharmacotherapy for a BED patient according to Patent '813's independent and dependent claims. In this light, the behavior of the lawyers raises some serious red flags about what they're trying to persuade the Patent Board (and public-at-large) to believe about a POSA's behavior, particularly as Patent 813's independent claims 1, 8 and 13 **specifically represent the use of LDX** for the treatment of a DSM-defined psychiatric disorder.

No. 4: Exhibit 2010. This is Harold Bays' state of the art 2004 *"Current and Investigational Anti-obesity Agents and Obesity Therapeutic Treatment Targets"* that provides essential context for helping the Patent Board and the public-at-large understand how the medical community as-a-whole would have understood the pharmacologic treatment of obesity "as of Sept. '07." And this, of course, is medically important because obesity goes hand-in-hand with BED; therefore, these "2004 teachings" provide important clinical context for helping the Board (and public) understand how the medical community approaches obesity and its pharmacotherapy today, just a few months before an "ADHD (**non-**anti-obesity) drug" stands poised to be the first ever FDA-approved treatment for adult BED. In this light, the "lawyers among us" are trying to hide very relevant, highly credible, and quite accessible teachings on how a "POSA as of Sept. '07" would have understood the term "anti-obesity agent." Certainly, this behavior doesn't help anyone get to the "Patent '813 truth of the matter," nor resolve this ever-expanding "massive IPR problem."

No. 5: Exhibit 2012. This is the AACAP's *"Practice Parameter for the Assessment and Treatment of Children and Adolescents with ADHD"* that would help the Patent Board (and public-at-large) understand that ADHD is an important disorder and, in particular, its comorbidity with eating disorders (like BN or BED) has important therapeutic implications. The lawyers' behavior to seek its removal from the IPR process raises serious red flags regarding their intent for doing so, as if they're trying to persuade the Patent Board (and the public-at-large) that ADHD comorbidity in eating disorders (and its proper treatment with stimulants) is **completely irrelevant.** The Patent Board has already "bought into" this massive clinical misunderstanding and, to this effect, it's our fiduciary role as MDs to help them see the "clinical truth of the matter" as it would have been in Sept. 2007, in Sept. 2000, or in Sept. 2014.

Nos. 6-7: Exhibits 2014-2015. These are Surman's and Biederman's critically important/relevant publications, the significance of which the three of us surely all understand for their IPR and Patent '813 implications. In this regard, I think it's about time in the "IPR and Patent '813 story" that the three of us, in our **ethical role as physicians,** teach the "lawyers of our group" that their objection to Surman and Biederman on the grounds of "relevance" is a **catastrophic mistake,** because it makes them look as if they are **willfully trying to cover up the most obvious, serious and far-reaching IPR problem of all.** And everyone knows that the "cover-up" is always far worse than the original problem.

That said, Dr. Ornskov and Dr. Brewerton, here's a two-part question for the two of you that I respectfully suggest we collectively answer as the "MDs of the IPR group": what's the purpose of

this IPR and why are there even any lawyers still involved in it at this point in time?

Sincerely,

Louis Sanfilippo, MD
CEO, LCS Group, LLC

ATTACHMENT: STRIPPED ["Petitioner's Objections to Patent Owner's Exhibits (01496219).pdf"]

> **From:** "Louis Sanfilippo, MD" <lsanfilippo@lcsgroupllc.com>
> **Subject: Re: Important Patent '813 IPR Update**
> **Date:** November 21, 2014 3:33:35 PM EST
> **To:** Ed Haug <EHaug@flhlaw.com>
> **Cc:** fornskov@shire.com, tmay@shire.com, tmay@us.shire.com, jharrington@shire.com, dbanchik@shire.com, Sandra Kuzmich <SKuzmich@flhlaw.com>, drtimothybrewerton@gmail.com
>
> Dear Mr. Haug,
>
> As stated in the email that I sent to you this morning, and in the emails that I had sent you vis-à-vis your client previously, you should direct any communications regarding the IPR to me.
>
> Mr. Haug, let me ask you a question: did you read the extensively detailed email that I sent to you on Nov. 10? Your email today suggests that you haven't……
>
> **[EMAIL CONTENTS STRIPPED]**
>
> Remember, Mr. Haug, from the outset my objective in all of this has been to get at the "truth of the matter," including your own role in it. By the time of what I'd call Patent 813's "final resolution," everything will be completely transparent, because I have made very extensive preparations to make it happen that way -- to an extent far greater than you could possibly imagine. This may help you understand why it is that this very email from me, which cc's your client's CEO and three of its senior legal representatives, is itself ***in direct response to your email.***
>
> Sincerely,
>
> Louis Sanfilippo, MD
> CEO, LCS Group, LLC
>
> > **From:** "Haug, Ed" <EHaug@flhlaw.com>
> > **Subject: Re: Important Patent '813 IPR Update**
> > **Date:** November 21, 2014 7:27:47 AM EST
> > **To:** "Louis Sanfilippo, MD" <lsanfilippo@lcsgroupllc.com>
> > **Cc:** <fornskov@shire.com>, <tmay@shire.com>, <tmay@us.shire.com>, <jharrington@shire.com>, <dbanchik@shire.com>, "Sandra Kuzmich" <SKuzmich@flhlaw.com>, <drtimothybrewerton@gmail.com>

Dear Dr Sanfilippo

I ask you once again to stop communicating directly with our client Shire or any of its officers or employees. All of your communications are being directed to our firm as counsel for Shire. Similarly you should not communicate directly with Dr Brewerton. Your continued threats and attempted intimidation of all recipients on your last email are improper and may well be unlawful. I respectfully suggest you consult with appropriate legal advisors.

Please also advise FLH as to who is now representing LCS in the IPR if Mr Lucci is no longer authorized to speak on behalf of the company.

Sent from my iPhone

> On Nov 21, 2014, at 6:31 AM, Louis Sanfilippo, MD <lsanfilippo@lcsgroupllc.com> wrote:
>
> Dear Dr. Ornskov, Ms. May, Mr. Harrington, Mr. Banchik, Mr. Haug, Ms. Kuzmich, & Dr. Brewerton,
>
> On behalf of LCS Group, I have an important update for all of you. On Wednesday I was informed by Joe Lucci of Baker Hostetler that the Patent Board refused to let BH withdraw from their representation of LCS Group in the *Inter Partes* Review, as I requested of BH on Nov. 13 and so informed you individually or through your respective company affiliation last week. In view of the Board's decision, I simply have instructed Mr. Lucci and BH to refrain from any further involvement in the IPR process…….
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> **[EMAIL CONTENTS STRIPPED]**
>
> I say this in good faith and transparently too -- because I know the final ending of the story and what I have done to make it end that way. And I can assure you of one thing: it's only ***imminently*** about to get much more extraordinary, on account of the final decision I made on Oct. 1 involving my LDX-related IP and the extensive preparations I've made to make sure that everything ends just perfectly.
>
> Sincerely,
>
> Louis Sanfilippo, MD
> CEO, LCS Group, LLC
>
> <LCS.Shire.FLH Public Email Record from Sept. 4 to Nov. 17.version 3.pdf>

From: "Louis Sanfilippo, MD" <lsanfilippo@lcsgroupllc.com>
Subject: Re: Important Patent '813 IPR Update
Date: December 1, 2014 10:07:33 AM EST
To: Ed Haug <EHaug@flhlaw.com>
Cc: fornskov@shire.com, tmay@shire.com, tmay@us.shire.com, jharrington@shire.com, dbanchik@shire.com, Sandra Kuzmich <SKuzmich@flhlaw.com>, drtimothybrewerton@gmail.com

Dear Drs. Ornskov and Brewerton,

I am writing to make you both aware of a new "legal reporting development" that itself has broad public implications and speaks to how our "IPR and Patent '813 story" is now getting some very timely national attention. It is the attached Law360 article published on Nov. 26, Thanksgiving eve (later in the day of my last email to both of you). The "lawyers of our IPR group" may have already informed one or both of you of this recent "news development." But because our "IPR and Patent '813 story" is now accelerating **very quickly**, it may be that they aren't even aware that we've collectively made "legal news."

What both of you should know is that the **massive and highly obvious misunderstanding** on which the Patent Board made its decision to institute a trial, which the "lawyers among our group" are self-evidently perpetuating as well as now trying to "cover up," is now causing others (like reporters) to **publicly perpetuate** the Board's **massive and highly obvious misunderstanding too.** You know what this means. It means that this "massive IPR problem" is publically getting much closer to each of you, **personally and individually**, which is why I am bringing this to your immediate attention before it leads to a catastrophic situation for each of you, and particularly for Shire. In this light, it's your fiduciary role as the "MDs of our IPR group" to address it before it spirals totally out-of-control and causes irreparable damage, as it would seem that's the path the "lawyers of our group" would prefer. You should know that this "destructive lawyerly path" is putting the two of you squarely in the middle of the ever-more-troubling wake of this "massive IPR representation problem."

Let me highlight a few examples of how this "news story" only further amplifies the **already magnified, massive IPR problem** (vis-à-vis the recent collective "lawyerly behavior" of our group to "cover up" critically important/relevant evidence from the Patent Board and public-at-large that would shed light on the "truth of the matter").

Reporter Gurrieri writes, *"'Given the complexity and very technical nature of these proceedings, pro se representation carries significant risk,' the PTAB's order said."* You can see the major problem here. Mr. Gurrieri is publicly highlighting that the Board **believes** that Shire's arguments on which the PTAB relied to institute an IPR hearing are **"complex"** and **"very technical."** But as MDs familiar with eating disorders and stimulant drugs (for different reasons), we know that's not the case at all. In fact, those Shire arguments ("Ground 4" and "Ground 7") are **"simple"** and **"very basic,"** and also **"simply wrong"** and **"very basically wrong."** Really, all the Patent Board needs to do in order to understand just how "simply wrong" and "very basically wrong" their decision actually was (to institute a trial) is to understand your respective side's **"very serious and massive misinterpretation of the prior art,"** which could be done by allowing them to simply read Surman's 2006 study in view of Shire's "Ground 4" argument citing Ong and "Ground 7" argument citing Dukarm, as both publications are cited in his study **in their proper context**, with perhaps some "MD guidance" from the two of you. After all, the Board's decision is entirely based on their **erroneous belief** that a competent MD/psychiatrist "as of Sept. '07" with "clinical experience in the diagnosis and psychopharmacology of eating disorders" would have regarded stimulants as acceptable/successful pharmacotherapy for BN **based on extensive data** (just as stimulants were for ADHD).

But here, you can see how the "lawyers of our group" are making an already massive IPR representation problem seriously worse, **because they are trying to conceal Surman's critically important/relevant disclosures from the Patent Board and the public by objecting to it for its lack of "relevance."** You can't get much more of an "obvious cover up" whose purpose is to suppress the "IPR/Patent '813 truth of the matter" than that!

As you ought to recognize by now, the "lawyers of our group" are putting the two of you as the "physicians of our group" in the middle of a problem that's been created by their ever-intensifying poor judgment, as you both know that nothing here is *"complex"* or *"very technical"* for anyone, **insofar as one has access to the "relevant information" --** which the "lawyers among our group" **clearly want to hide** from the Patent Board and public-at-large so that the *"proceedings"* can **appear** *"complex"* and *"very technical."* Any MD would see that, as would any reasonable person in view of the written record, and each would also see that proceeding **any further with the IPR process** would only further unduly burden and financially harm LCS Group while making this "massive IPR problem" even bigger for both of you and especially for Shire. Actually, everything now in this "massive IPR problem" is **so simple** and **so basic** that any reasonable person (without even a science background) would understand it, along with its profound implications for the "Patent '813 truth of the matter."

In this light, take note that Mr. Gurrieri also writes, *"Shire contends that the challenged claims are unpatentable as obvious in light of the prior art."* Surely, you can see the massive problem here, namely, that Shire's "challenge to Patent '813's claims" is **completely based on the company representing a massive and highly obvious misinterpretation of the prior art**. As physicians, you can easily see Shire's "contention" isn't rendered in any **"light** of the prior art" but in a whole lot of **"darkness"** that the company's lawyers have now troublingly cast on the PTAB's three judges who **mistakenly believe** stimulants would have been regarded as an acceptable **and successful treatment of Bulimia Nervosa based on extensive data.** As far as "big pharma legal drama" goes, this is an amazing thing, especially when the pharmaceutical company at the center of this controversy is perhaps two to three months away from marketing Patent '813's claimed method of treating an eating disorder with their own stimulant drug -- but that the eating disorder **isn't even BN.** Consider, too, that the "big pharma legal drama" showcases a pharmaceutical company that's financially supported two Harvard-based MDs, Drs. Biederman and Surman, who have publicly acknowledged that the company's interpretation of the **"relevant prior art"** involving "the stimulant treatment of Bulimia Nervosa" (as in Ong and Dukarm) **couldn't be any more "wrong" for its representation to the Patent Board and the public-at-large.** As you can both see (and as any competent MD would see), Shire's "representation of the prior art" is **diametrically opposite** "the prior art truth of the matter."

The two of you know what this means. It means that Shire couldn't be any more wrong for its "unpatentability challenge" for Patent '813's claimed methods of treating BED with LDX **in light** of the prior art and, therefore, that the "lawyers among us" are making matters **much worse for the two of you and especially for Shire**. So when Mr. Gurrieri also writes, *"The board agreed Nov. 5 to institute the review, saying that Shire established a reasonable likelihood that it would prevail in showing the unpatentability of at least one of the challenged claims,"* doesn't it **personally weigh on your conscience as physicians** (and Dr. Ornskov additionally as Shire's CEO) that the reason for the Board's decision is that it's **entirely based** on something **seriously and fundamentally** "inaccurate and wrong"? And doesn't it weigh on your conscience as physicians that reporters are now informing the public on the basis of those seriously and fundamentally **"inaccurate and wrong representations"?** And, lastly, doesn't it weigh on your conscience that the "lawyers among us" have seized upon the Patent Board's "massive misjudgment," itself based on the massive Shire-represented "misinterpretation of the prior art," to make an already serious, massive IPR problem **much worse** and **publicly extensive** than it originally ever was, which they have done by seeking to conceal the most relevant prior art of all

that sheds light on the "truth of the matter"?

Dr. Ornskov and Dr. Brewerton: just think of the **massive harm** that will be caused if the Patent Board relies on Shire's obviously erroneous challenge, as supported by its obviously erroneous declaration testimony, to declare Patent '813 invalid because it would have been "obvious" that **stimulants were an acceptable/successful treatment of "binge eating in BN" (and therefore, "binge eating in BED").** Then, consider the kind of **massive public attention** that you will each receive, and Shire too, at a most critical juncture in "eating disorder history." That's a serious problem for the two of you to **bear as individuals and physicians, but particularly for you, Dr. Ornskov, as Shire's CEO.** Which leads me to a final point. What do you think will happen in the IPR when LCS fails to allow itself to be put in the middle of this **"massive, ever-expanding and highly obvious IPR problem"** by being complicitous with the very troubling behavior of the "lawyers among us" whose objective, it seems, is increasingly focused on hiding the "IPR/Patent '813 truth of the matter" from the Patent Board and the public-at-large? In this respect, LCS Group has already planned **extensively** to deal with the IPR problem "outside the IPR." Have either of you done the same? If not, I would **strongly advise** that each of you do so **very soon,** because that time of holding "those parties responsible for making and perpetuating the problematic representations in the IPR petition accountable for their actions" **is imminently drawing near.** I know, because I know what I've done to make that **imminently about to happen.**

Sincerely,

Louis Sanfilippo, MD
CEO, LCS Group, LLC

ATTACHMENT: STRIPPED ("PTAB Bars Inventor From Proceeding Pro Se in AIA Review - Law360.pdf")

> **From:** "Louis Sanfilippo, MD" <lsanfilippo@lcsgroupllc.com>
> **Subject: Re: Important Patent '813 IPR Update**
> **Date:** November 26, 2014 11:11:43 AM EST
> **To:** Ed Haug <EHaug@flhlaw.com>
> **Cc:** fornskov@shire.com, tmay@shire.com, tmay@us.shire.com, jharrington@shire.com, dbanchik@shire.com, Sandra Kuzmich <SKuzmich@flhlaw.com>, drtimothybrewerton@gmail.com
>
> Dear Drs. Ornskov and Brewerton,
>
> In light of (i) our newly established "IPR group" (vis-à-vis the reciprocating communication between Mr. Haug and I on Friday Nov. 21), (ii) Mr. Haug's **complete silence** on my two questions asking him if he read the 181-page PDF or received input on it from any Shire "MDs," and (iii) a recent "legal development" that's come to my attention, I'm writing to the "MDs of our group" to address what's clearly some revealing "lawyerly behavior" evidenced in the objections FLH made last week (on behalf of Shire, as attached) to certain LCS Group exhibits. In this respect, there's a "new IPR and Patent '813 story" **rapidly evolving** in public view of the "old one," itself far more troubling than the "old IPR story" ever was -- and it is fast reaching a critical stage….

[EMAIL CONTENTS STRIPPED]

That said, Dr. Ornskov and Dr. Brewerton, here's a two-part question for the two of you that I respectfully suggest we collectively answer as the "MDs of the IPR group": what's the purpose of this IPR and why are there even any lawyers still involved in it at this point in time?

Sincerely,

Louis Sanfilippo, MD
CEO, LCS Group, LLC

ATTACHMENT: STRIPPED ["Petitioner's Objections to Patent Owner's Exhibits (01496219).pdf"]

From: "Louis Sanfilippo, MD" <lsanfilippo@lcsgroupllc.com>
Subject: Re: Important Patent '813 IPR Update
Date: November 21, 2014 3:33:35 PM EST
To: Ed Haug <EHaug@flhlaw.com>
Cc: fornskov@shire.com, tmay@shire.com, tmay@us.shire.com, jharrington@shire.com, dbanchik@shire.com, Sandra Kuzmich <SKuzmich@flhlaw.com>, drtimothybrewerton@gmail.com

Dear Mr. Haug,

As stated in the email that I sent to you this morning, and in the emails that I had sent you vis-à-vis your client previously, you should direct any communications regarding the IPR to me.

Mr. Haug, let me ask you a question: did you read the extensively detailed email that I sent to you on Nov. 10? Your email today suggests that you haven't……

[EMAIL CONTENTS STRIPPED]

Remember, Mr. Haug, from the outset my objective in all of this has been to get at the "truth of the matter," including your own role in it. By the time of what I'd call Patent 813's "final resolution," everything will be completely transparent, because I have made very extensive preparations to make it happen that way -- to an extent far greater than you could possibly imagine. This may help you understand why it is that this very email from me, which cc's your client's CEO and three of its senior legal representatives, is itself ***in direct response to your email.***

Sincerely,

Louis Sanfilippo, MD
CEO, LCS Group, LLC

From: "Haug, Ed" <EHaug@flhlaw.com>

Subject: Re: Important Patent '813 IPR Update
Date: November 21, 2014 7:27:47 AM EST
To: "Louis Sanfilippo, MD" <lsanfilippo@lcsgroupllc.com>
Cc: <fornskov@shire.com>, <tmay@shire.com>, <tmay@us.shire.com>, <jharrington@shire.com>, <dbanchik@shire.com>, "Sandra Kuzmich" <SKuzmich@flhlaw.com>, <drtimothybrewerton@gmail.com>

Dear Dr Sanfilippo

I ask you once again to stop communicating directly with our client Shire or any of its officers or employees. All of your communications are being directed to our firm as counsel for Shire. Similarly you should not communicate directly with Dr Brewerton. Your continued threats and attempted intimidation of all recipients on your last email are improper and may well be unlawful. I respectfully suggest you consult with appropriate legal advisors.

Please also advise FLH as to who is now representing LCS in the IPR if Mr Lucci is no longer authorized to speak on behalf of the company.

Sent from my iPhone

> On Nov 21, 2014, at 6:31 AM, Louis Sanfilippo, MD <lsanfilippo@lcsgroupllc.com> wrote:
>
> Dear Dr. Ornskov, Ms. May, Mr. Harrington, Mr. Banchik, Mr. Haug, Ms. Kuzmich, & Dr. Brewerton,
>
> On behalf of LCS Group, I have an important update for all of you. On Wednesday I was informed by Joe Lucci of Baker Hostetler that the Patent Board refused to let BH withdraw from their representation of LCS Group in the *Inter Partes* Review, as I requested of BH on Nov. 13 and so informed you individually or through your respective company affiliation last week. In view of the Board's decision, I simply have instructed Mr. Lucci and BH to refrain from any further involvement in the IPR process…….
>
> **[EMAIL CONTENTS STRIPPED]**
>
> I say this in good faith and transparently too -- because I know the final ending of the story and what I have done to make it end that way. And I can assure you of one thing: it's only ***imminently*** about to get much more extraordinary, on account of the final decision I made on Oct. 1 involving my LDX-related IP and the extensive preparations I've made to make sure that everything ends just perfectly.
>
> Sincerely,
>
> Louis Sanfilippo, MD

CEO, LCS Group, LLC

<LCS.Shire.FLH Public Email Record from Sept. 4 to Nov. 17.version 3.pdf>

From: "Louis Sanfilippo, MD" <lsanfilippo@lcsgroupllc.com>
Subject: Re: Important Patent '813 IPR Update
Date: December 11, 2014 10:44:53 AM EST
To: Ed Haug <EHaug@flhlaw.com>
Cc: fornskov@shire.com, tmay@shire.com, tmay@us.shire.com, jharrington@shire.com, dbanchik@shire.com, Sandra Kuzmich <SKuzmich@flhlaw.com>, drtimothybrewerton@gmail.com, Joseph Lucci <jlucci@bakerlaw.com>

Dear Dr. Ornskov,

I am writing this email to you "in the presence of" attorney Joe Lucci of BH. The reason for this is that Tuesday's IPR "Order" from the Patent Board, as attached below, "ordered" me to communicate this way in view of Mr. Haug's allegation that I have "attempted to intimidate and threaten Dr. Brewerton and Shire's employees through electronic communications." To the contrary, any reasonable person in view of the **entire email record in its proper narrative context** since I first emailed you on Sept. 4 would see that all I've really been doing is giving you, Shire, FLH and Dr. Brewerton a chance to adapt to what I had determined to do "outside the IPR venue" when I made my Oct. 1 final decision involving the disposition of my LDX-related IP.

This brings me to the reason for this particular email. As you know by now, I'm a big believer in accountability and transparency, so I've written this email to provide you a "choice/decision" on how you wish to handle this **"massive and highly obvious IPR misrepresentation problem."**

As important context for your choice/decision on behalf of Shire and its shareholders, you'll see from Tuesday's "Order" that the first thing the Patent Board wrote is that "counsel for Patent Owner read a statement from Patent Owner, which stated, in essence, that Petitioner had made egregious misrepresentations of the prior art in the Petition…." As Shire's CEO, you should know what that statement to the Board specifically said:

> "Patent Owner would like to inform the Board that its decision to institute a trial was based on Petitioner's massive and egregious misinterpretation of the prior art, and that the Petitioner has explicitly been made aware of this misrepresentation through extensive and detailed communications that have taken place outside the IPR from well before the time the Board made its decision. Further, certain exhibits that the Petitioner has now objected to on grounds of relevance speak to the profound degree of "misinterpretation" represented to the Board and on which the Board relied to make its decision. Because this matter has far-reaching legal, medical and commercial implications, Patent Owner has determined that in order to best protect its interests it is foregoing any further involvement in the IPR process so that it can take the appropriate actions, including legal remedies, to resolve such representations made to the Board that have now caused Patent Owner harm, and so that it can pre-empt further harm from the undue burden of such representations."

Importantly, the Board "ordered" that if I/LCS Group forego further participation in the IPR, I should file a paper to that effect and such a "paper will be viewed as a request for adverse judgment, and judgment will be entered against Patent Owner."

In this light, Dr. Ornskov, it's very easy to see how Shire and its outside counsel continue to, in their attempts, make their massive and egregious misrepresentation problem "my problem." But it isn't "my problem." All I've done is make a good faith effort to represent the truth of the matter so that any reasonable person can understand it in view of the public written record, as any reasonable person would appreciate by simply reading through the most updated transcript of electronic communications (with a few "new lawyer emails", including one from Mr. Lucci) that is

publically available for download at the following 4share link: http://www.4shared.com/download/wfFWmwmvce/LCSShireFLH_Public_Email_Recor.pdf?lgfp=3000. After all, the "Patent '813 Story" is a remarkable one and brings much needed public attention and teaching to the art of eating disorder diagnosis and psychopharmacology -- specifically BED -- at a very important time in eating disorder history. Indeed, even you/Shire yesterday again highlighted "Vyvanse for BED" in the company's press release involving Shire's own self-hosted "R&D Day" for the investment community, including the FDA's PDUFA date of Feb. 1, 2015. I do sincerely hope that it was a productive day for you and Shire in **advancing** the art of eating disorder diagnosis and psychopharmacology, much as I sincerely hope the same between now and Vyvanse's anticipated FDA approval for the treatment of Binge Eating Disorder in adults.

In this context, let me explain the choice/decision that you **imminently** need to make on how you/Shire **finally resolve** the IPR. The choice/decision that you now have to make on behalf of Shire and its shareholders is whether you wish to finally resolve this **"massive and egregious IPR misrepresentation problem"** with or without lots of media and "professional" attention of different kinds (vis-a-vis the complete public email record as available through the 4-share link above, which itself includes the still active link to the 181-page PDF and all its references that I provided you on Nov. 13). And should you need any support in making a good choice/decision that involves Shire's method of treating BED with Vyvanse, then I would highly recommend you directly communicate with Dr. Brewerton, because after me there's no one that knows the "IPR and Patent '813 story" better than Dr. Brewerton does.

You know how to reach me, either directly or through attorney Lucci, to resolve this. But if you choose to stay silent **and** fail to completely withdraw Shire's IPR petition by the time that Mr. Lucci makes his IPR filing tomorrow, on Dec. 12, as requested of him by the Board, then I have asked Mr. Lucci to submit **this very email along with its publically available link of our entire "IPR email communication record"** to the Patent Board as a statement on behalf of LCS Group for the written public record.

Sincerely,

Louis Sanfilippo, MD
CEO, LCS Group, LLC

ATTACHMENTS: STRIPPED
["Order - Conduct of the Proceeding.pdf" (19 KB)]
["Shire Motions.pdf" (107 KB)]

> **From:** "Louis Sanfilippo, MD" <lsanfilippo@lcsgroupllc.com>
> **Subject: Re: Important Patent '813 IPR Update**
> **Date:** December 1, 2014 10:07:33 AM EST
> **To:** Ed Haug <EHaug@flhlaw.com>
> **Cc:** fornskov@shire.com, tmay@shire.com, tmay@us.shire.com, jharrington@shire.com, dbanchik@shire.com, Sandra Kuzmich <SKuzmich@flhlaw.com>, drtimothybrewerton@gmail.com
>
> Dear Drs. Ornskov and Brewerton,
>
> I am writing to make you both aware of a new "legal reporting development" that itself has broad public implications and speaks to how our "IPR and Patent '813 story" is now

getting some very timely national attention. It is …..

[EMAIL AND EMAIL THREAD STRIPPED]

From: "Kuzmich, Sandra" <SKuzmich@flhlaw.com>
Date: Dec 12, 2014 5:08 PM
Subject: IPR2014-00739; Request for Conference Call
To: "trials@uspto.gov" <trials@uspto.gov>
Cc: "Lucci, Joseph" <JLucci@bakerlaw.com>, "Farsiou, David" <DFarsiou@bakerlaw.com>, "shire.ipr.813@flhlaw.com" <shire.ipr.813@flhlaw.com>

IPR2014-00739 (U.S. Patent No. 8,318,813)
Petitioner: Shire Development LLC
Patent Owner: LCS Group, LLC
Assigned Trial Paralegal: Althea Wilburn
Designated Administrative Patent Judge: Lora Green

Petitioner respectfully requests, at the Board's earliest convenience, a conference call to seek authorization to file a motion for sanctions pursuant to 37 C.F.R. § 42.12. In contravention of the Board's order prohibiting Dr. Sanfilippo "from contacting Shire, Shire's employees, the expert retained by Shire for this proceeding, as well as counsel for Petitioner, except through counsel for Patent Owner or in the presence of counsel for Patent Owner" (Paper 11 at 4), Dr. Sanfilippo has once again, on December 11, 2014, sent such prohibited electronic correspondence to Shire's employees, Shire's expert witness, and counsel for Petitioner. Additionally, by including in its December 12, 2014 submission (Paper 12) a link to hundreds of pages of materials that include unfounded allegations, misrepresentations, and threats, Patent Owner has exceeded the Board's authorization, which only provided for the filing of a paper stating that Patent Owner is forgoing any further participation in the proceeding (Paper 11 at 5). For at least these reasons, Petitioner seeks authorization to file a motion for sanctions pursuant to 37 C.F.R. § 42.12.

Respectfully submitted,

Sandra Kuzmich
Counsel for Petitioner

From: Lucci, Joseph
Sent: Monday, December 15, 2014 1:20 PM
To: Haug, Ed (EHaug@flhlaw.com)
Cc: Sandra Kuzmich (SKuzmich@flhlaw.com); Farsiou, David
Subject: FW: [Fwd: IPR2014-00739; Request for Conference Call]

Ed

Dr. Sanfilippo has asked that the communication below be passed along to Dr. Ornskov.

Joe

Begin forwarded message:

> Dear Dr. Ornskov,
>
> **On behalf of Shire shareholder interests,** I am writing to you through your counsel to inform you about a **critically important and serious "legal development"** involving the behavior of Shire's outside counsel, Frommer, Lawrence and Haug.
>
> Let me draw your attention to a very serious and critically important "FLH misrepresentation problem" in Ms. Kuzmich's email to the Patent Board on Dec. 12, as forwarded below. She writes, on behalf of Shire, "Additionally, by including in its December 12, 2014 submission (Paper 12) a link to hundreds of pages of materials that include unfounded allegations, misrepresentations, and threats…." You can see that Ms. Kuzmich is representing, on behalf of Shire, that I've made "misrepresentations" **in the very narrative context** that any reasonable person would recognize as her own **"massive and highly obvious misrepresentation"** to the Patent Board about my own "Dec. 11 email representation" to you that itself was communicated to you "in the presence of counsel for Patent Owner," as the Board requested of me. That's an extraordinary thing. Moreover, my "Patent '813 team" and I are highly confident that **by this point in time** you and your "MD team" at Shire **fully recognize** that there are no "unfounded allegations, misrepresentations, and threats" in the "now-public-IPR-written-record," because (i) all my representations are "founded, accurate, supported and explained," as well as "non-threatening" (unless one is threatened by "truthful representations") and (ii) our unique "profiling technology" (i.e., "temporally weighted analysis," "sequentially expanded analysis," Shire's download activity of my 181-page PDF after I emailed its 4share link to you on Nov. 13, among other kinds of analyses) has determined that you/Shire completely understand this "IPR and Patent '813 story" for its clinical, legal and commercial implications.
>
> In this light, any reasonable person in view of the now-public-written-IPR-record -- as well as any "MD at Shire" in view of the "181-page PDF" -- would also recognize that Ms. Kuzmich's representation to the Patent Board that my representations are "unfounded allegations, misrepresentations, and threats" is itself **completely unfounded.** Thus, it's no surprise that she doesn't offer up even one example to support her representation to the Board. This is in contrast to my own behavior wherein I have provided you/Shire so many detailed accounts of "unfounded representations and outright misrepresentations" in Shire's own IPR petition that it's practically impossible to count them, especially as the basis for so many of them is in an MD/psychiatrist's "basic diagnostic and therapeutic reasoning." And you/Shire still haven't asked me for my two additional versions of "IPR analysis" (from this summer) that I offered to provide you on Sept. 4 and 12 so that you could understand the **full scope and seriousness** of this "IPR representation problem,"

as professionally profiled for its far-reaching implications. I can assure you/Shire my "additional analysis" would provide you yet another remarkable dimension to the "IPR and Patent '813 Story."

In the spirit of transparency, assuming that there is a "conference call" as requested by FLH on behalf of Shire to address "sanctions against me" for simply trying to **truthfully represent** the "IPR and Patent '813 Story," LCS Group does not accept an adverse judgment from the Patent Board because it believes any reasonable person in view of the now-public-written-IPR-record of the "inter partes review outside the IPR" between Patent Owner and Petitioner makes it abundantly clear that Patent '813, in all its claimed methods of treating Binge Eating Disorder with lisdexamfetamine dimesylate, would have been highly non-obvious to a Person of Ordinary Skill in the Art as of September 2007.

Dr. Orsnov, you know what this all means. It means that it's your choice/decision **on behalf of Shire and its shareholders** to determine whether you want the "now-public-written-IPR-record" to begin as it ends -- with "FLH's problematic representations made on behalf of Shire and its shareholders." And, therefore, it's also your choice/decision to determine whether you would like me to **more broadly** "inform the public" of your choice/decision through my "Oct. 1 press release" (that I emailed to you on Sept. 26 when I made my Oct. 1 final decision involving my LDX-related IP), as everything I need to best commercialize Patent '813 (and any that follow) is now quite perfectly represented on the "IPR public record" with, perhaps, one exception -- this email from me to you and the publically available "IPR and Patent '813 Story" as of 12/12/2014 at: http://www.4shared.com/download/07wuISD6ba/LCSShireFLH_Public_Email_Recor.pdf?lgfp=3000.

Sincerely,

Louis Sanfilippo, MD
CEO, LCS Group, LLC

---------- Forwarded message ----------

From: "Kuzmich, Sandra" <SKuzmich@flhlaw.com>
Date: Dec 12, 2014 5:08 PM
Subject: IPR2014-00739; Request for Conference Call
To: "trials@uspto.gov" <trials@uspto.gov>
Cc: "Lucci, Joseph" <JLucci@bakerlaw.com>, "Farsiou, David" <DFarsiou@bakerlaw.com>, "shire.ipr.813@flhlaw.com" <shire.ipr.813@flhlaw.com>

IPR2014-00739 (U.S. Patent No. 8,318,813)
Petitioner: Shire Development LLC
Patent Owner: LCS Group, LLC
Assigned Trial Paralegal: Althea Wilburn
Designated Administrative Patent Judge: Lora Green

Petitioner respectfully requests, at the Board's earliest convenience, a conference call to seek authorization to file a motion for sanctions pursuant to 37 C.F.R. § 42.12. In contravention of the Board's order prohibiting Dr. Sanfilippo "from contacting Shire, Shire's employees, the expert retained by Shire for this proceeding, as well as counsel for Petitioner, except through counsel for Patent Owner or in the presence of counsel for

Patent Owner" (Paper 11 at 4), Dr. Sanfilippo has once again, on December 11, 2014, sent such prohibited electronic correspondence to Shire's employees, Shire's expert witness, and counsel for Petitioner. Additionally, by including in its December 12, 2014 submission (Paper 12) a link to hundreds of pages of materials that include unfounded allegations, misrepresentations, and threats, Patent Owner has exceeded the Board's authorization, which only provided for the filing of a paper stating that Patent Owner is forgoing any further participation in the proceeding (Paper 11 at 5). For at least these reasons, Petitioner seeks authorization to file a motion for sanctions pursuant to 37 C.F.R. § 42.12.

Respectfully submitted,

Sandra Kuzmich
Counsel for Petitioner

From: "Louis Sanfilippo, MD" <lsanfilippo@lcsgroupllc.com>
Subject: Important IPR/Patent '813 Update
Date: December 17, 2014 5:55:31 PM EST
To: lsanfilippo@lcsgroupllc.com

Dear Dr. Ornskov,

I am writing today to more clearly frame the choice/decision that you/Shire now have to make, as it's **very time sensitive.** In this light, I am leaving you with the choice/decision on how you/Shire would like the "IPR and Patent '813 Story" to finally end so that a "new chapter" in the bigger "Patent '813 Story" can finally begin.

But before disclosing more specific details about your choice/decision, Dr. Ornskov, take a look at the most updated version of the "IPR and Patent '813 Story" that now includes my "Dec. 15 counsel to counsel email" to you, "care of" Mr. Lucci and Mr. Haug: http://www.4shared.com/download/odvHRLUmba/LCSShireFLH_Public_Email_Recor.pdf?lgfp=3000. For one, it's striking how difficult your outside law firm of Frommer, Lawrence and Haug has made it for me to directly communicate to you, which is remarkable because any reasonable person in view of the "now public written record" would see that all its "behavioral, business, and legal evidence" make it **very obvious** that Shire and LCS Group each have the same final objective; however, each of our respective companies have different "means" of accomplishing it. Further, you'll also see that since I first emailed you on Sept. 4, I've been writing the "IPR and Patent '813 Story" through its "email correspondence theater" so that its narrative would fit what I've so far written for the bigger and broader "Patent '813 Story" and, of course, to "teach" its reader -- albeit sometimes implicitly -- on "human behavior" and "group dynamics."

In view of the now-publically-available "IPR and Patent '813 Story" (as updated through Dec. 15), it's unmistakably in Shire's shareholders interests for you, Dr. Ornskov, to understand that the "behavioral answers" to the following questions would be **highly obvious to any reasonable reader** in view of the "whole story" involving Shire, FLH and Patent '813**:**

> **No. 1: The "Confidentiality Disclosure Agreement - 'CDA.'"** What would have motivated Shire to enter into a "confidentiality disclosure agreement" with LCS Group (with an "effective date" of Oct. 24, 2013) to "facilitate the Parties' discussions regarding a potential business opportunity involving U.S. Patent No. 8,318,813 and related patent applications," and in which there was some meaningful progress between Shire's "in-house counsel" and LCS Group's "outside counsel" with talk of "deal structure," only to then **unexpectedly** publically file an "*Inter Partes* review" on Patent '813 in May 2014 through its "outside counsel" arguing the "obviousness" and, therefore, "invalidity" of its claims? And why would Shire have filed its "**public** IPR petition" representing Patent '813's "obviousness" and "invalidity" while still having a **"private** confidentiality disclosure agreement" in place with LCS Group to discuss "a potential business opportunity involving Patent '813 and related patent applications"?
>
> **No. 2: The "timing" of the IPR.** Considering that Shire's senior management (CEO, CFO, in-house counsel, senior medical director, among others) and FLH (Mr. Haug and Ms. Kuzmich) "as of Nov. 2012" (when Patent '813 was issued) **were made completely aware of Patent '813** (as evidenced in the "first chapter" of the "semi-public" written "Patent '813 Story"), what would have motivated Shire and FLH to file the company's IPR petition **in May 2014** (rather than in 2013, for instance)? In other words, was "the timing" of Shire's IPR filing motivated by something "other" than a legitimate position that Patent '813's claims would have been "obvious" (and therefore "invalid") to an MD/psychiatrist "as of Sept. '07"? And was that "IPR timing decision"

related to Shire's plan to file a "supplemental New Drug Application" ("sNDA") in **Q3 2014** with "FDA-approval" expected some 5-9 months later? After all, Shire's May 1 "First Quarter 2014 Results" involving representations from you, Dr. Ornskov, highlighted Shire's "regulatory plan" for Vyvanse in the treatment of BED, including its expected "Q3 sNDA filing" and "2015 launch." (slide 17).

No. 3: The "IPR Trial Rate." Considering the Patent Trial and Appeal Board was granting "IPR petitions" (for trial) in whole, or in part, at nearly 90% by most "professional determinations," did Shire pursue its IPR petition because it legitimately believed Patent '813's claims would have been "obvious" (and therefore "invalid") as represented in its IPR petition? --or, perhaps, because it believed it could leverage a "likely trial process" against LCS Group while it concurrently pursued its "sNDA filing" and "prospective FDA approval" for Patent '813's claimed method of treating Binge Eating Disorder with Vyvanse? Would Shire have been "additionally motivated" to pursue this "concurrent dual IPR--regulatory strategy" in view of the fact that (i) IPRs are "relatively expensive" and take time and (ii) LCS Group is a **one-man company** with **very limited financial resources** (as compared to Shire that had a market cap of $33.5 Billion the day the IPR petition was filed)?

No. 4: "The Declaration that Looks as if it Were Written by Lawyers." As profiled against Dr. Brewerton's "prior art publications," why did his declaration appear as if written by lawyers? I, and "MD/psychiatrist colleagues" of mine, have provided declarations in patent matters and they look **very different** than Dr. Brewerton's declaration. **Specifically,** who (i.e., which law firm) helped Dr. Brewerton write his 100-page declaration testimony and what was their motivation for doing so?

No. 5: "Ignoring the 'Additional IPR Analysis.'" What would have motivated you, Dr. Ornskov, to "not want to see" the "additional analysis" on the IPR I offered to provide you in my Sept. 4 and Sept. 12 emails when I brought "to your attention serious problems with representations made on the public record by Shire's outside counsel and its declarant…." (Sept. 4 email) and even identified a few of them for you, including the "biggest representation problem of them all" (on which the Board ultimately made its decision to institute a trial) vis-à-vis "Surman and Biederman"? --which, as the "now-public-IPR-written-record" shows, I warned you about.

No. 6: "Re-directing LCS Group/I Back to the Problem, Shire's 'Outside Counsel' of Frommer, Lawrence and Haug." When I brought "to your attention serious problems with representations made on the public record by Shire's outside counsel and its declarant…." on Sept. 4, why did you have Shire's outside counsel of FLH contact me (which they did on Sept. 4 via Ms. Kuzmich contacting attorney Lucci "outside my view")? And when I told you on Sept. 12 that FLH's "contacting me" was a problem "because FLH made the problematic representations on the public record to the Patent Trial and Appeal Board," why did you to have FLH contact me again (via Ms. Kuzmich's email of Sept. 15)?

No. 7: "Complete Silence from You, Shire's CEO, on Shire's own Public (Problematic) Representations." What motivated you, Dr. Ornskov, to stay **so completely silent on your company's own public problematic representations** when I emailed you those fives times before my Oct. 1 final decision? Surely, any reasonable person in view of the written record would see that you showed **no interest at all in trying to understand and investigate** the kinds of "problematic representations" your outside counsel of FLH and declarant Dr. Timothy Brewerton publically made to the Patent Board and public-at-large on behalf of Shire**.** As Shire's

> CEO, why would you seem to have no interest at all on this important matter of the company's "representation," especially with Vyvanse poised to be the "first ever" FDA-approved drug for Binge Eating Disorder according to Patent '813's claims?

Attached you will find a PDF of a revised press release that I have prepared in view of my Oct. 1 final decision involving my LDX-related IP. In the absence of any effort on your part to finally resolve Shire's **massive, highly obvious, and now-public IPR misrepresentation problem,** I will broadly publically issue this press release **on Tuesday, December 23,** which will include a "public access feature" (via web link) to some "new IP" from LCS Group. In this respect, I'm leaving you with the choice/decision as to how you/Shire would like to finally end the "IPR and Patent '813 Story" outside the IPR**.** After all, I've sufficiently developed my "new IP" since having made my final decision on Oct. 1 to best commercialize my "old IP" that is "Patent '813 and any that follow." I'm just leaving you as the "accountable executive" at Shire for making that choice/decision in a way that secures the company's best interests**,** namely, whether or not you would like the "IPR and Patent '813 Story" to finally end "outside the IPR" with lots of media, professional and general public attention**.** Surely, an extraordinary "real-life story" with all the remarkable "key dramatic elements" (including a potential blockbuster drug indication, and some "untoward legal behavior" from a number of lawyers) would certainly be a compelling way to bring much needed public attention to the art of eating disorder diagnosis and psychopharmacology (specifically BED with LDX) at a most critical time in eating disorder -- especially as its all "self-contained and easily accessible" on the internet for any reasonable person to read.

At this point in time, I do sincerely believe that I've provided you more than enough information on **how** to make a good decision on behalf of Shire so that you and Shire can **really** advance the art of treating "Binge Eating Disorder" with "lisdexamfetamine dimesylate" according to Patent '813's claimed methods of treatment.

Sincerely,

Louis Sanfilippo, MD
CEO, LCS Group, LLC

ATTACHMENT: "Press Release Version 2.pdf"

LCS Group and Lucerne Biosciences to Commercialize '813 Patent for Lisdexamfetamine Dimesylate in the Treatment of Binge Eating Disorder

NEW HAVEN, Conn., December 23, 2014/ -- LCS Group, LLC ("LCS Group") announced today that it has entered into a strategic collaboration with Lucerne Biosciences, LLC ("Lucerne Biosciences") to commercialize U.S. Patent No. 8,318,813 entitled "Method of Treating Binge Eating Disorder." Patent '813 features claims that encompass the use of the amphetamine prodrug lisdexamfetamine dimesylate (l-lysine-d-amphetamine) alone, or in combination with other pharmacologic therapies, for the treatment of Binge Eating Disorder (BED) according to its current diagnostic criteria in the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V®).*

"This strategic collaboration with Lucerne Biosciences marks an important step forward in bringing much needed public attention to the diagnosis and treatment of BED. BED is a serious eating disorder currently without any FDA-approved medication treatments and for which, unfortunately, there have been many public misconceptions. Developing safe and effective treatments for eating disorders more generally, and for BED in particular, continues to be a critically important unmet need long-recognized in the medical community," said Louis Sanfilippo, M.D., CEO of LCS Group, LLC.

"Recent studies show that between 2 to 3% of the U.S. population will suffer from BED at some point in their lifetime and many of these patients will have a chronic course of symptoms with significant burdens to their emotional and physical health," said Dr. Sanfilippo, who also is a voluntary faculty member at Yale University School of Medicine where he co-teaches a year-long course on psychopharmacology to Yale psychiatry residents.

About LCS Group, LLC and Lucerne Biosciences, LLC

LCS Group is a privately-held pharmaceutical development company founded to provide safer, more effective drug treatments for patients suffering from psychiatric and neurologic disorders by discovering novel uses, reformulations and combinations of clinically validated drugs. The company's therapeutic focus has been the treatment of impulse control disorders, mood disorders, obesity and substance-related disorders with pharmacologic therapies that selectively modulate the brain's reward system. Lucerne Biosciences is a privately-held pharmaceutical development company previously engaged in the development of novel pharmacologic treatments for Major Depressive Disorder.

About BED

BED is a recognized eating disorder in the DSM-V® characterized by eating unusually large amounts of food in a discrete period of time (i.e., within a 2 hour period) and a sense of lack of control over eating during the episode. Binge eating episodes in BED are also associated with at least three (or more) of the following: eating much more rapidly than normal; eating until feeling uncomfortably full; eating large amounts of food when not feeling physically hungry; eating alone because of being embarrassed by how much one is eating; feeling disgusted with oneself, depressed or very guilty after overeating. Marked distress regarding the binge eating is also present and the binge eating occurs, on average, at least once a week for 3 months. In addition, binge eating does not occur exclusively during the course of bulimia nervosa or anorexia nervosa.

About Lisdexamfetamine Dimesylate

Lisdexamfetamine dimesylate (l-lysine-d-amphetamine) is an amphetamine prodrug approved in the United States for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD). Lisdexamfetamine dimesylate is not approved by the Food and Drug Administration (FDA) for the treatment of BED. Based on the Prescription Drug User Fee Act (PDUFA) and the FDA's recent priority review acceptance of a supplemental New Drug Application (sNDA) for the use of lisdexamfetamine dimesylate in the treatment of BED in adults, the FDA is expected to make a decision for this novel use of the drug in February 2015. The use of any prescription medication including lisdexamfetamine dimesylate, alone or in combination with other medications, should be done under close medical supervision.

Inquires/Business Development

For any inquiries regarding LCS Group's intellectual property and/or its strategic collaboration with Lucerne Biosciences, including inquiries related to investment opportunities and/or strategic collaborations regarding the '813 Patent (or pending patent applications), please contact:

Louis Sanfilippo, MD
CEO, LCS Group, LLC
291 Whitney Avenue, Suite 306
New Haven, CT 06511
Telephone: 203-362-8919
Email: info@lcsgroupllc.com
Website: http://www.lcsgroupllc.com

Supplemental information regarding the '813 Patent's claimed methods of treating Binge Eating Disorder with lisdexamfetamine dimesylate can be found at:
XXXXXXXXXXXXX.

U.S. Patent No. 8,318,813/Method of Treating Binge Eating Disorder

SOURCE: LCS Group, LLC

From: Lucci, Joseph
Sent: Thursday, December 18, 2014 8:12 AM
To: Haug, Ed (EHaug@flhlaw.com)
Cc: Sandra Kuzmich (SKuzmich@flhlaw.com); Farsiou, David
Subject: FW: Important IPR/Patent '813 Update

Ed

Here's another communication that Dr. Sanfilippo has asked to be passed on to Dr. Ornskov.

Joe

Begin forwarded message:

> **From:** "Louis Sanfilippo, MD" <lsanfilippo@lcsgroupllc.com>
> **Subject: Important IPR/Patent '813 Update**
> **Date:** December 17, 2014 5:55:31 PM EST
> **To:** lsanfilippo@lcsgroupllc.com
>
> Dear Dr. Ornskov,
>
> I am writing today to more clearly frame the choice/decision that you/Shire now have to make, as it's **very time sensitive.** In this light, I am leaving you with the choice/decision on how you/Shire would like the "IPR and Patent '813 Story" to finally end so that a "new chapter" in the bigger "Patent '813 Story" can finally begin.
>
> But before disclosing more specific details about your choice/decision, Dr. Ornskov, take a look at the most updated version of the "IPR and Patent '813 Story" that now includes my "Dec. 15 counsel to counsel email" to you, "care of" Mr. Lucci and Mr. Haug: http://www.4shared.com/download/odvHRLUmba/LCSShireFLH_Public_Email_Recor.pdf?lgfp=3000. For one, it's striking how difficult your outside law firm of Frommer, Lawrence and Haug has made it for me to directly communicate to you, which is remarkable because any reasonable person in view of the "now public written record" would see that all its "behavioral, business, and legal evidence" make it **very obvious** that Shire and LCS Group each have the same final objective; however, each of our respective companies have different "means" of accomplishing it. Further, you'll also see that since I first emailed you on Sept. 4, I've been writing the "IPR and Patent '813 Story" through its "email correspondence theater" so that its narrative would fit what I've so far written for the bigger and broader "Patent '813 Story" and, of course, to "teach" its reader -- albeit sometimes implicitly -- on "human behavior" and "group dynamics."
>
> In view of the now-publically-available "IPR and Patent '813 Story" (as updated through Dec. 15), it's unmistakably in Shire's shareholders interests for you, Dr. Ornskov, to understand that the "behavioral answers" to the following questions would be **highly obvious to any reasonable reader** in view of the "whole story" involving Shire, FLH and Patent '813**:**
>
> > **No. 1: The "Confidentiality Disclosure Agreement - 'CDA.'"** What would have motivated Shire to enter into a "confidentiality disclosure agreement" with LCS Group (with an "effective date" of Oct. 24, 2013) to "facilitate the Parties' discussions regarding a potential business opportunity involving U.S. Patent No. 8,318,813 and related patent applications," and in which there was some meaningful progress

between Shire's "in-house counsel" and LCS Group's "outside counsel" with talk of "deal structure," only to then **unexpectedly** publically file an "*Inter Partes* review" on Patent '813 in May 2014 through its "outside counsel" arguing the "obviousness" and, therefore, "invalidity" of its claims? And why would Shire have filed its "**public** IPR petition" representing Patent '813's "obviousness" and "invalidity" while still having a **"private** confidentiality disclosure agreement" in place with LCS Group to discuss "a potential business opportunity involving Patent '813 and related patent applications"?

No. 2: The "timing" of the IPR. Considering that Shire's senior management (CEO, CFO, in-house counsel, senior medical director, among others) and FLH (Mr. Haug and Ms. Kuzmich) "as of Nov. 2012" (when Patent '813 was issued) **were made completely aware of Patent '813** (as evidenced in the "first chapter" of the "semi-public" written "Patent '813 Story"), what would have motivated Shire and FLH to file the company's IPR petition **in May 2014** (rather than in 2013, for instance)? In other words, was "the timing" of Shire's IPR filing motivated by something "other" than a legitimate position that Patent '813's claims would have been "obvious" (and therefore "invalid") to an MD/psychiatrist "as of Sept. '07"? And was that "IPR timing decision" related to Shire's plan to file a "supplemental New Drug Application" ("sNDA") in **Q3 2014** with "FDA-approval" expected some 5-9 months later? After all, Shire's May 1 "First Quarter 2014 Results" involving representations from you, Dr. Ornskov, highlighted Shire's "regulatory plan" for Vyvanse in the treatment of BED, including its expected "Q3 sNDA filing" and "2015 launch." (slide 17).

No. 3: The "IPR Trial Rate." Considering the Patent Trial and Appeal Board was granting "IPR petitions" (for trial) in whole, or in part, at nearly 90% by most "professional determinations," did Shire pursue its IPR petition because it legitimately believed Patent '813's claims would have been "obvious" (and therefore "invalid") as represented in its IPR petition? --or, perhaps, because it believed it could leverage a "likely trial process" against LCS Group while it concurrently pursued its "sNDA filing" and "prospective FDA approval" for Patent '813's claimed method of treating Binge Eating Disorder with Vyvanse? Would Shire have been "additionally motivated" to pursue this "concurrent dual IPR--regulatory strategy" in view of the fact that (i) IPRs are "relatively expensive" and take time and (ii) LCS Group is a **one-man company** with **very limited financial resources** (as compared to Shire that had a market cap of $33.5 Billion the day the IPR petition was filed)?

No. 4: "The Declaration that Looks as if it Were Written by Lawyers." As profiled against Dr. Brewerton's "prior art publications," why did his declaration appear as if written by lawyers? I, and "MD/psychiatrist colleagues" of mine, have provided declarations in patent matters and they look **very different** than Dr. Brewerton's declaration. **Specifically,** who (i.e., which law firm) helped Dr. Brewerton write his 100-page declaration testimony and what was their motivation for doing so?

No. 5: "Ignoring the 'Additional IPR Analysis.'" What would have motivated you, Dr. Ornskov, to "not want to see" the "additional analysis" on the IPR I offered to provide you in my Sept. 4 and Sept. 12 emails when I brought "to your attention serious problems with representations made on the public record by Shire's outside counsel and its declarant…." (Sept. 4 email) and even identified a few of them for you, including the "biggest representation problem of them all" (on which the Board

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Attached you will find a PDF of a revised press release that I have prepared in view of my Oct. 1 final decision involving my LDX-related IP. In the absence of any effort on your part to finally resolve Shire's **massive, highly obvious, and now-public IPR misrepresentation problem,** I will broadly publically issue this press release **on Tuesday, December 23,** which will include a "public access feature" (via web link) to some "new IP" from LCS Group. In this respect, I'm leaving you with the choice/decision as to how you/Shire would like to finally end the "IPR and Patent '813 Story" outside the IPR**.** After all, I've sufficiently developed my "new IP" since having made my final decision on Oct. 1 to best commercialize my "old IP" that is "Patent '813 and any that follow." I'm just leaving you as the "accountable executive" at Shire for making that choice/decision in a way that secures the company's best interests**,** namely, whether or not you would like the "IPR and Patent '813 Story" to finally end "outside the IPR" with lots of media, professional and general public attention**.** Surely, an extraordinary "real-life story" with all the remarkable "key dramatic elements" (including a potential blockbuster drug indication, and some "untoward legal behavior" from a number of lawyers) would certainly be a compelling way to bring much needed public attention to the art of eating disorder diagnosis and psychopharmacology (specifically BED with LDX) at a most critical time in eating disorder -- especially as its all "self-contained and easily accessible" on the internet for any reasonable person to read.

At this point in time, I do sincerely believe that I've provided you more than enough information on **how** to make a good decision on behalf of Shire so that you and Shire can **really** advance the art of treating "Binge Eating Disorder" with "lisdexamfetamine dimesylate" according to Patent '813's claimed methods of treatment.

Sincerely,

Louis Sanfilippo, MD
CEO, LCS Group, LLC

ATTACHMENT: (Stripped) "Press Release Version 2.pdf"

From: "Louis Sanfilippo, MD" <lsanfilippo@lcsgroupllc.com>
Subject: Fwd: Final Decision
Date: December 21, 2014 5:00:00 PM EST
To: lsanfilippo@lcsgroupllc.com

Dear Dr. Ornksov,

In view of my last communication to you, I can see that you made some "effort" to resolve Shire's IPR representation problem by having Mr. Haug request during Thursday's conference call that the Patent Board invalidate Patent '813**.** To this effect, I've decided to hold off on **broadly publically** issuing "Version 2" of the press release on Tuesday Dec. 23. However, let me say that I thought your "effort" wasn't very equitable or well-reasoned, nor did it require five lawyers from "your side" to be present. But nonetheless, it was "behaviorally highly productive," which is why I've decided to issue the press release on Dec. 26 in the absence of a complete and final resolution of the **"IPR problem."**

Let me also say that Shire's "collective counsel" **continues** its obvious misjudgments at a particularly sensitive time, as evidenced in the "Dec. 18 IPR conference call" when Mr. Haug sought to conceal important written evidence from the public-at-large, as evidenced by his request on behalf of Shire to expunge my prior Dec. 11 email to you. Any reasonable person would see this "cover up behavior" from a global pharmaceutical company "implemented by its heavily-manned outside counsel," the implications of which couldn't be any worse for Shire and its shareholders six weeks before Vyvanse's Feb. 1 PDUFA date for the treatment of Binge Eating Disorder.

To this effect, I've **finally decided** that in the absence of Shire **completely and finally resolving** its "massive IPR problem" by **Thursday Dec. 25 at 5:00 AM EST** according to my Oct. 1 "final decision," I will **broadly publically** issue "Version 3" of LCS Group's press release **on Friday December 26.** Surely, whoever's been attentively reading the "IPR and Patent '813 Story" (and looked at "Version 2's" new edits) would understand that "Version 3" would feature a hyperlink to a downloadable PDF of the **most updated version of the "IPR and Patent '813 Story,"** including both this email and the last one I sent you "care of" Mr. Haug. Further, the press release would also establish a "public means and context" through which I could broadly share with other parties my two versions of "additional IPR analysis" that I offered to provide you on Sept. 4 and 12, and which arguably hold "the biggest surprise of them all" in the "IPR and Patent '813 Story" because of their highly unique contents that include, among other things, additional "profiling" and representations made by MD/psychiatrists that support the "IPR and Patent 813-related representations" which I've communicated to you.

This, of course, leads me to disclose the full details of my "final decision." Please see the forwarded email below that I sent to myself at two of my email accounts, as well as to another unnamed party (as referenced in the email), on October 1 when I made my "final decision" involving "Patent '813 and any that follow." The same time-stamped PDF as attached in that Oct. 1 email is also available by a Box.com link (https://app.box.com/s/wpnj13bxonvafobn0210) in the event that the forwarded email attachment is stripped (i.e., for its size, email security reasons, etc…).

My **final decision** was/is very straightforward and speaks for itself. If you/Shire would like to do business with LCS Group and I, then you will need to fill in its self-explanatory blank spaces (as highlighted in gray) with the "Effective Date" **made today ("my time"), Sunday December 21, 2014,** and then return it to me via email in keeping with its clearly stated time-sensitive provisions. Please know that that under no circumstance will I accept any other date as the "Effective Date" for my final decision (as witnessed by the representation I've made in this

email). Also, please know that **this email** has also been bcc'd to the same unnamed party as referenced in the forwarded Oct. 1 "Final Decision" email below, as well as to two "new parties" (at email addresses that represent their respective "institutional/company affiliations").

By now, Dr. Ornskov, you ought to understand that it's my "baseline behavior" to always give you/Shire a choice/decision for which you/Shire are made accountable. So please take note that if you/Shire decide to accept my Oct. 1 final decision as represented for its details in the email below (with its PDF attachment/link) and this email too, then you'll need to make another **very critically important time-sensitive choice/decision,** namely, **when** you choose/decide to accept it **within** its "time-bound terms," as "the timing" of your choice/decision will have very serious implications for Shire, its management, its shareholders and, of course, **most specifically for you, Dr. Ornskov.** This is what I've been trying to transparently communicate to you for some time now.

So you know, my wife is very ill. She is dying and it's very important to me that she be made completely aware of how one real-life story finally ends so that another can begin, which I'll regard as my "Patent '813-related" Christmas gift for her. Any reasonable person in view of the real-life narrative I've been writing for some time now would appreciate that this would be a fitting way to finally end the "IPR and Patent '813 Story" so that the "next chapter" of the bigger and broader "Patent '813 Story" can finally begin. And, of course, it would be a most fitting way to reveal the "Patent '813-related truth of the matter."

Sincerely,

Louis Sanfilippo, MD
CEO, LCS Group, LLC

Begin forwarded message:

> **From:** "Louis Sanfilippo, MD" <lsanfilippo@lcsgroupllc.com>
> **Subject: Final Decision**
> **Date:** October 1, 2014 5:00:00 PM EDT
> **To:** lsanfilippo@lcsgroupllc.com
> **Cc:** louiscsan@aol.com
>
> Dear Dr. Ornskov,
>
> I have made my final decision today, October 1, on how to best commercialize the '813 Patent and any that follow, as I had determined to do and so informed you on September 26 that I would. My final decision is attached in the time-stamped PDF below. I should also disclose to you that there is one party bcc'd on this particular email, unnamed here yet very important in helping me accomplish all my objectives since I first emailed you/Shire on September 4.
>
> The rationale for my final decision is simple. I believe that I made Shire a very equitably-valued business proposal for my IP on four separate occasions in 2012, as communicated to various members of Shire's senior management/in-house counsel and/or FLH (i.e., my emails of Nov. 16, Nov.19, Nov. 26, Dec. 10). My initial 2012 business proposal also featured the prospect of "doubling the value" of my IP through a second patent application for the claimed use of LDX dimesylate as an adjunctive

treatment of Major Depressive Disorder, as assigned to Lucerne Biosciences (i.e., my email of Nov. 16 to Ed Haug of FLH, cc'ing Sandra Kuzmich of FLH and Peter Cicala of Shire). In view of key development/regulatory milestones since making my first business proposal to Shire in 2012 (when Shire had yet to even formally launch their Phase III LDX dimesylate/BED registrational program), I am confident that any reasonable healthcare investor/investment analyst would conservatively regard the financial value of my LDX dimesylate-related IP "as of today" to be at least equal to three-fold its proposed value to Shire "as of 2012."

However, I also believe that any reasonable person would value the '813 Patent and any that follow as only 1/3 of my ***"composite IP portfolio as of today."*** Another "third" would be related to FLH's problematic IPR/declaration representations (as extensively characterized and evaluated for their implications). And the "last third" would be related to the problematic behavior of Shire's in-house counsel since I first communicated my invention to Mr. Cola on October 14, 2008, as transparently revealed across many communications over time that tell a very consistent and compelling story any reasonable person would appreciate for its meaning and significance. Collectively taken, this explains my reasoning for what I regard as the equitable financial terms of my final decision.

Of course, as I communicated to Shire and FLH on any number of occasions in 2012, the valuation of my IP could still increase substantially more than its ***"current real-time equitable valuation"*** (herein represented by the terms of my final decision). By very conservative forecasts, its financial value could still stand to increase by a measure of three-fold more over the terms of my final decision in but a very short span of time, which is why I have made every effort to inform you/Shire that the matters involving FLH's problematic IPR representations and the problematic behavior of Shire's in-house counsel are highly relevant to the interests of Shire shareholders and could pose serious risk to such interests, including potentially to the company's business partners and/or prospective acquirers. I have made every effort to be transparent to you about this matter and also be very discreet given its broad implications. And I have made every effort to be very fair in my final decision.

Thus, I have made my final decision on October 1 as I promised you I would. Now it is time for you, Dr. Ornskov, to make your final decision as Shire's CEO and the person ultimately accountable for how this matter is handled.

I do sincerely hope that you/Shire would finally decide to do business with me/LCS Group in the spirit of trust and cooperation. But as I hope you/Shire may by now fully appreciate, I've already made extensive preparations for how I would commercialize my IP in the event that you decide to perpetuate what has been a very longstanding problem involving Shire and my IP.

Sincerely,

Louis Sanfilippo, MD
CEO, LCS Group, LLC
291 Whitney Avenue, Suite 306
New Haven, CT

ATTACHMENT: (Stripped) "Final Decision.pdf"

From: "Louis Sanfilippo, MD" <lsanfilippo@lcsgroupllc.com>
Subject: Fwd: [Fwd: Final Decision]
Date: December 21, 2014 6:00:00 PM EST
To: Joseph Lucci <jlucci@bakerlaw.com>

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> This, of course, leads me to disclose the full details of my "final decision." Please see the forwarded email below that I sent to myself at two of my email accounts, as well as to another unnamed party (as referenced in the email), on October 1 when I made my "final decision" involving "Patent '813 and any that follow." The same time-stamped PDF as

attached in that Oct. 1 email is also available by a Box.com link (https://app.box.com/s/wpnj13bxonvafobn0210) in the event that the forwarded email attachment is stripped (i.e., for its size, email security reasons, etc…).

My **final decision** was/is very straightforward and speaks for itself. If you/Shire would like to do business with LCS Group and I, then you will need to fill in its self-explanatory blank spaces (as highlighted in gray) with the "Effective Date" **made today ("my time"), Sunday December 21, 2014,** and then return it to me via email in keeping with its clearly stated time-sensitive provisions. Please know that that under no circumstance will I accept any other date as the "Effective Date" for my final decision (as witnessed by the representation I've made in this email). Also, please know that **this email** has also been bcc'd to the same unnamed party as referenced in the forwarded Oct. 1 "Final Decision" email below, as well as to two "new parties" (at email addresses that represent their respective "institutional/company affiliations").

By now, Dr. Ornskov, you ought to understand that it's my "baseline behavior" to always give you/Shire a choice/decision for which you/Shire are made accountable. So please take note that if you/Shire decide to accept my Oct. 1 final decision as represented for its details in the email below (with its PDF attachment/link) and this email too, then you'll need to make another **very critically important time-sensitive choice/decision,** namely, **when** you choose/decide to accept it **within** its "time-bound terms," as "the timing" of your choice/decision will have very serious implications for Shire, its management, its shareholders and, of course, **most specifically for you, Dr. Ornskov.** This is what I've been trying to transparently communicate to you for some time now.

So you know, my wife is very ill. She is dying and it's very important to me that she be made completely aware of how one real-life story finally ends so that another can begin, which I'll regard as my "Patent '813-related" Christmas gift for her. Any reasonable person in view of the real-life narrative I've been writing for some time now would appreciate that this would be a fitting way to finally end the "IPR and Patent '813 Story" so that the "next chapter" of the bigger and broader "Patent '813 Story" can finally begin. And, of course, it would be a most fitting way to reveal the "Patent '813-related truth of the matter."

Sincerely,

Louis Sanfilippo, MD
CEO, LCS Group, LLC

Begin forwarded message:

From: "Louis Sanfilippo, MD" <lsanfilippo@lcsgroupllc.com>
Subject: Final Decision
Date: October 1, 2014 5:00:00 PM EDT
To: lsanfilippo@lcsgroupllc.com
Cc: louiscsan@aol.com

Dear Dr. Ornskov,

I have made my final decision today, October 1, on how to best commercialize the '813 Patent and any that follow, as I had determined to do and so informed you on September 26 that I would. My final decision is attached in the time-stamped PDF below. I should also disclose to you that there is one party bcc'd on this particular email, unnamed here yet very important in helping me accomplish all my objectives since I first emailed you/Shire on September 4.

The rationale for my final decision is simple. I believe that I made Shire a very equitably-valued business proposal for my IP on four separate occasions in 2012, as communicated to various members of Shire's senior management/in-house counsel and/or FLH (i.e., my emails of Nov. 16, Nov.19, Nov. 26, Dec. 10). My initial 2012 business proposal also featured the prospect of "doubling the value" of my IP through a second patent application for the claimed use of LDX dimesylate as an adjunctive treatment of Major Depressive Disorder, as assigned to Lucerne Biosciences (i.e., my email of Nov. 16 to Ed Haug of FLH, cc'ing Sandra Kuzmich of FLH and Peter Cicala of Shire). In view of key development/regulatory milestones since making my first business proposal to Shire in 2012 (when Shire had yet to even formally launch their Phase III LDX dimesylate/BED registrational program), I am confident that any reasonable healthcare investor/investment analyst would conservatively regard the financial value of my LDX dimesylate-related IP "as of today" to be at least equal to three-fold its proposed value to Shire "as of 2012."

However, I also believe that any reasonable person would value the '813 Patent and any that follow as only 1/3 of my ***"composite IP portfolio as of today."*** Another "third" would be related to FLH's problematic IPR/declaration representations (as extensively characterized and evaluated for their implications). And the "last third" would be related to the problematic behavior of Shire's in-house counsel since I first communicated my invention to Mr. Cola on October 14, 2008, as transparently revealed across many communications over time that tell a very consistent and compelling story any reasonable person would appreciate for its meaning and significance. Collectively taken, this explains my reasoning for what I regard as the equitable financial terms of my final decision.

Of course, as I communicated to Shire and FLH on any number of occasions in 2012, the valuation of my IP could still increase substantially more than its ***"current real-time equitable valuation"*** (herein represented by the terms of my final decision). By very conservative forecasts, its financial value could still stand to increase by a measure of three-fold more over the terms of my final decision in but a very short span of time, which is why I have made every effort to inform you/Shire that the matters involving FLH's problematic IPR representations and the problematic behavior of Shire's in-house counsel are highly relevant to the interests of Shire shareholders and could pose serious risk to such interests, including potentially to the company's business partners and/or prospective acquirers. I have made every effort to be transparent to you about this matter and also be very discreet given its broad implications. And I have made every effort to be very fair in my final decision.

Thus, I have made my final decision on October 1 as I promised you I would. Now it is time for you, Dr. Ornskov, to make your final decision as Shire's CEO and the person ultimately accountable for how this matter is handled.

I do sincerely hope that you/Shire would finally decide to do business with

me/LCS Group in the spirit of trust and cooperation. But as I hope you/Shire may by now fully appreciate, I've already made extensive preparations for how I would commercialize my IP in the event that you decide to perpetuate what has been a very longstanding problem involving Shire and my IP.

Sincerely,

Louis Sanfilippo, MD
CEO, LCS Group, LLC
291 Whitney Avenue, Suite 306
New Haven, CT

ATTACHMENT: (Stripped) "Final Decision.pdf"

From: Lucci, Joseph
Sent: Monday, December 22, 2014 8:32 AM
To: Haug, Ed (EHaug@flhlaw.com)
Cc: Sandra Kuzmich (SKuzmich@flhlaw.com); Farsiou, David
Subject: FW: [Fwd: Final Decision]

Ed,

Here's a communication that Dr. Sanfilippo has asked be passed on to Dr. Ornskov and Dr. Brewerton, as well as Ms. May, Mr. Harrington, and Mr. Banchik.

Joe

> **From:** "Louis Sanfilippo, MD" <lsanfilippo@lcsgroupllc.com>
> **Subject: Fwd: [Fwd: Final Decision]**
> **Date:** December 21, 2014 6:00:00 PM EST
> **To:** Joseph Lucci <jlucci@bakerlaw.com>
>
> Begin forwarded message:
>
> > **From:** "Louis Sanfilippo, MD" <lsanfilippo@lcsgroupllc.com>
> > **Subject: Fwd: Final Decision**
> > **Date:** December 21, 2014 5:00:00 PM EST
> > **To:** lsanfilippo@lcsgroupllc.com
> >
> > Dear Dr. Ornksov,
> >
> > In view of my last communication to you, I can see that you made some "effort" to resolve Shire's IPR representation problem by having Mr. Haug request during Thursday's conference call that the Patent Board invalidate Patent '813**.** To this effect, I've decided to hold off on **broadly publically** issuing "Version 2" of the press release on Tuesday Dec. 23. However, let me say that I thought your "effort" wasn't very equitable or well-reasoned, nor did it require five lawyers from "your side" to be present. But nonetheless, it was "behaviorally highly productive," which is why I've decided to issue the press release on Dec. 26 in the absence of a complete and final resolution of the **"IPR problem."**
> >
> > Let me also say that Shire's "collective counsel" **continues** its obvious misjudgments at a particularly sensitive time, as evidenced in the "Dec. 18 IPR conference call" when Mr. Haug sought to conceal important written evidence from the public-at-large, as evidenced by his request on behalf of Shire to expunge my prior Dec. 11 email to you. Any reasonable person would see this "cover up behavior" from a global pharmaceutical company "implemented by its heavily-manned outside counsel," the implications of which couldn't be any worse for Shire and its shareholders six weeks before Vyvanse's Feb. 1 PDUFA date for the treatment of Binge Eating Disorder.
> >
> > To this effect, I've **finally decided** that in the absence of Shire **completely and finally resolving** its "massive IPR problem" by **Thursday Dec. 25 at 5:00 AM EST** according to my Oct. 1 "final decision," I will **broadly publically** issue "Version 3" of LCS Group's press release **on Friday December 26.** Surely, whoever's been attentively reading the "IPR and Patent '813 Story" (and looked at "Version 2's" new edits) would understand that "Version 3" would feature a hyperlink to a downloadable

PDF of the **most updated version of the "IPR and Patent '813 Story,"** including both this email and the last one I sent you "care of" Mr. Haug. Further, the press release would also establish a "public means and context" through which I could broadly share with other parties my two versions of "additional IPR analysis" that I offered to provide you on Sept. 4 and 12, and which arguably hold "the biggest surprise of them all" in the "IPR and Patent '813 Story" because of their highly unique contents that include, among other things, additional "profiling" and representations made by MD/psychiatrists that support the "IPR and Patent 813-related representations" which I've communicated to you.

This, of course, leads me to disclose the full details of my "final decision." Please see the forwarded email below that I sent to myself at two of my email accounts, as well as to another unnamed party (as referenced in the email), on October 1 when I made my "final decision" involving "Patent '813 and any that follow." The same time-stamped PDF as attached in that Oct. 1 email is also available by a Box.com link (https://app.box.com/s/wpnj13bxonvafobn0210) in the event that the forwarded email attachment is stripped (i.e., for its size, email security reasons, etc…).

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Sincerely,

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CEO, LCS Group, LLC

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From: "Louis Sanfilippo, MD" <lsanfilippo@lcsgroupllc.com>
Subject: Final Decision
Date: October 1, 2014 5:00:00 PM EDT
To: lsanfilippo@lcsgroupllc.com
Cc: louiscsan@aol.com

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Sincerely,

Louis Sanfilippo, MD
CEO, LCS Group, LLC
291 Whitney Avenue, Suite 306
New Haven, CT

ATTACHMENT: (Stripped) "Final Decision.pdf"

From: Haug, Ed [mailto:EHaug@flhlaw.com]
Sent: Monday, December 22, 2014 12:43 PM
To: Lucci, Joseph
Cc: Kuzmich, Sandra
Subject: FW: [Fwd: Final Decision]

Joe

You have attached an option agreement apparently signed October 1, 2014 by your client and a license agreement. Why are you sending this to me? The PTAB was clear that any further communications must be from you and not your client. Merely being a conduit to pass along a document is not proper and does not comply with the directive form the PTAB. I also do not think it appropriate for me to take instruction from you or your client as to whom I should pass anything to. Ed

From: Lucci, Joseph
Sent: Monday, December 22, 2014 5:36 PM
To: 'Haug, Ed'
Cc: Kuzmich, Sandra; Farsiou, David
Subject: RE: [Fwd: Final Decision]

Ed

I don't believe that what I sent you is in any way inconsistent with the directions that we received from the PTAB.

Also, neither I nor my client gave you any instruction. What I did was send you a business proposition for your client to consider. What you do with it is your decision.

Joe

From: "Haug, Ed" <EHaug@flhlaw.com>
Date: Dec 22, 2014 6:50 PM
Subject: Re: [Fwd: Final Decision]
To: "Lucci, Joseph" <JLucci@bakerlaw.com>
Cc: "Kuzmich, Sandra" <SKuzmich@flhlaw.com>, "Farsiou, David" <DFarsiou@bakerlaw.com>

We believe what you and your client did directly violates the ruling of the PTAB and is sanctionable. What your client sent is preposterous as you well know from when we met before the IPR was filed much less granted. Please request that your client stop trying to communicate with Shire, it's counsel and third party experts. Thank you. Ed

Sent from my iPhone

From: Lucci, Joseph
Sent: Tuesday, December 23, 2014 9:34 AM
To: 'Haug, Ed'
Cc: Kuzmich, Sandra; Farsiou, David
Subject: RE: [Fwd: Final Decision]

Ed,

I communicated to you a settlement proposal for you to communicate to your client. That is entirely consistent with the PTAB ruling.

Dr. Sanfilippo is simply offering Shire consideration of a business opportunity before he broadly publicizes it on Friday with his press release. Regarding your claim that his proposal is "preposterous," he believes his terms for the business opportunity are a bargain for Shire considering all that's been made publically available for prospective investors since he made his final decision on Oct. 1, which now includes the Dec. 11 expunged email and the context it provides.

Joe

From: Arbuiso, Nicole [mailto:NArbuiso@flhlaw.com] **On Behalf Of** Haug, Ed
Sent: Tuesday, December 23, 2014 3:48 PM
To: Lucci, Joseph
Cc: Kuzmich, Sandra
Subject: RE: [Fwd: Final Decision]
Importance: High

Joe,

We disagree that your communication forwarding Dr. Sanfilippo's emails was consistent with the PTAB ruling. We intend to seek sanctions regarding yet another violation of a PTAB order.

Further, from your email of this morning, it appears you are confirming that Dr. Sanfilippo plans to issue a press release this Friday, December 26th, in which he will provide a link to his numerous harassing e-mails to Shire and others. We strongly urge that Dr. Sanfilippo refrain from further publishing these communications, which contain threatening and libelous statements that are tortious when publically disseminated. Please be on notice that FLH, Shire, and Dr. Brewerton are considering all potential options, including legal action against you as well as your client. We consider the actions taken by your client and you as very serious matters.

Ed

From: Kuzmich, Sandra [mailto:SKuzmich@flhlaw.com]
Sent: Tuesday, December 23, 2014 3:56 PM
To: trials@uspto.gov
Cc: Farsiou, David; Lucci, Joseph; shire.ipr.813@flhlaw.com; Haug, Ed
Subject: IPR2014-00739 (U.S. Patent No. 8,318,813)

IPR2014-00739 (U.S. Patent No. 8,318,813)

Petitioner: Shire Development LLC
Patent Owner: LCS Group, LLC
Assigned Trial Paralegal: Althea Wilburn
Designated Administrative Patent Judge: Lora Green

Petitioner respectfully requests authorization or, at the Board's earliest convenience, a conference call to seek authorization to (1) include a discussion of additional misconduct by Patent Owner in Petitioner's Motion for Sanctions to be filed on December 29, 2014, and (2) increase the page limit of the motion to ten pages to accommodate this additional discussion. Patent Owner violated the Board's directive from the December 18, 2014 teleconference that required any communication from Patent Owner to Petitioner or Petitioner's representatives regarding this proceeding to be signed by Patent Owner's counsel of record. This directive was memorialized in the Board's Order entered on December 23, 2014 (Paper 14). In contravention of the Board's instructions, Patent Owner's counsel, Mr. Lucci, merely forwarded email communications from Dr. Sanfilippo that were not signed by Patent Owner's counsel of record as required by the Order. Mr. Lucci forwarded these email communications to Petitioner's counsel of record, with a request that they simply be passed along to Petitioner's employees and expert declarant, Dr. Brewerton. Yet again, these emails from Dr. Sanfilippo are inflammatory, containing unfounded allegations that Mr. Haug, lead counsel for Petitioner, "sought to conceal important written evidence from the public-at-large," and that Petitioner has engaged in "cover up behavior."

We look forward to hearing from the Board at its earliest convenience.

Respectfully submitted,

Sandra Kuzmich
Counsel for Petitioner

From: Lucci, Joseph
Sent: Tuesday, December 23, 2014 5:46 PM
To: trials@uspto.gov
Cc: 'Kuzmich, Sandra'; Haug, Ed; Farsiou, David
Subject: RE: IPR2014-00739 (U.S. Patent No. 8,318,813)

Petitioner's counsel has provided a misleading and self-serving characterization of the settlement email that counsel for Patent Owner recently sent to counsel for Petitioner. Attached hereto is a copy of that email, along with subsequent, related communications between the parties' respective counsel.

Respectfully submitted,

Joseph Lucci
Counsel for Patent Owner

ATTACHMENT: Stripped ("Settlement Email String.pdf")