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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Proceeding	91226322
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

LUPIN PHARMACEUTICALS, INC.,

Opposer/Petitioner,

v.

Proceeding No. 91226322
Application Serial No. 86/509184
Mark: LuPPiN

AMPEL, LLC,

Applicant/Respondent.

APPLICANT'S BRIEF IN OPPOSITION TO
OPPOSER'S MOTION FOR SUMMARY JUDGMENT

Applicant/Respondent Ampel, LLC ("Applicant" or "Ampel"), by counsel, respectfully submits this Brief in Opposition to the Motion for Summary Judgment filed by Opposer/Petitioner Lupin Pharmaceuticals, Inc. ("Opposer" or "Lupin").

Introduction

Opposer seeks a monopoly on the word "lupin," covering any activity relating to the medical field, no matter how tangential to Opposer's use of its mark for the manufacture of generic pharmaceuticals. Opposer claims it can prohibit Applicant's use of the mark "LuPPiN" for patient education and support groups specific to the disease Lupus simply because Opposer manufactures generic pharmaceuticals that *may* be used to treat common Lupus symptoms, including headache, fatigue, and joint pain. If Opposer's position is correct, then it has a monopoly on the word "lupin" within the medical field because such common symptoms relate to nearly every medical issue. This is not the law, and Opposer's position does not reflect an accurate representation of the facts underlying this matter.

Statement of Facts

Contrary to Opposer's argument, material facts remain in dispute, which precludes entry of summary judgment for Opposer. Moreover, Opposer expands the import of the undisputed facts beyond their fair reading. The facts underlying this matter reveal that Opposer has no connection to Lupus, to Lupus education or support groups, or any other activity that would result in a likelihood of confusion between its marks and the Applicant's mark.

I. Opposer's "Lupin" marks for the manufacture and distribution of pharmaceuticals

Opposer holds United States Trademark Registration No. 4024405 for the word mark "LUPIN," which is a "house mark for full line of pharmaceuticals for medical purposes" in Class 5, Pharmaceutical Products. (*See* Declaration of Thomas H. Curtin at Exh. B).[1] Opposer also holds United States Trademark Registration No. 4874579 for the "word 'Lupin' and a flower shaped design." (*See* Curtin Decl. at Exh. C). Like the word mark "LUPIN," this mark also is limited to pharmaceuticals (including antibiotics and antidepressants), and covers:

> Pharmaceutical preparations for the treatment of infectious and parasitic diseases; antibiotics; pharmaceutical preparations for the treatment of diseases and disorders of the endocrine and metabolic systems; pharmaceutical preparations for the treatment of mental and behavioral conditions and disorders; antidepressants; pharmaceutical preparations for the treatment of diseases and disorders of the nervous system; pharmaceutical preparations for the treatment of diseases and disorders of the eye and adnexa; pharmaceutical preparations for the treatment of diseases and disorders of the ear and mastoid process; pharmaceutical preparations for the treatment of diseases and disorders of the circulatory system; antihypertensives; pharmaceutical preparations for the treatment of diseases and disorders of the respiratory system; pharmaceutical preparations for the treatment of diseases and disorders of the digestive system; pharmaceutical preparations for the treatment of diseases and disorders of the skin and subcutaneous tissue; pharmaceutical preparations for the treatment of diseases and disorders of the musculoskeletal system and connective tissue; pharmaceutical preparations for the treatment of diseases and conditions of the genitourinary system; and pharmaceutical preparations for the treatment of diseases and disorders associated

[1] Hereinafter "Curtin Decl. at __." The Declarations and Affidavits of Thomas H. Curtin, Dave Berthold, and Jay Liska were submitted as part of the record with Opposer's Motion for Summary Judgment.

> with pregnancy, childbirth and the peurperium, namely, contraceptives; oral contraceptives; oral hormonal contraceptives; contraceptive preparations and substances; hormone replacement therapies; hormonal agents for treating disorders and conditions related to women's health, namely, symptoms and conditions associated with menopause, pre-menstruation syndrome and other symptoms and conditions associated with menstruation, in Class 5.

(Id.).

Consistent with these registrations, Opposer manufactures and distributes pharmaceuticals. (*See* Affidavit of Dave Berthold at ¶¶ 5-12).[2]

II. The commercial impression of Opposer's "Lupin" marks

Opposer's mark appears in commerce with its flower design, as follows:

Opposer's consistent and routine use of its mark in conjunction with this flower design can be seen on the labelling of its pharmaceutical bottles, advertisements, website, and approved logos. (*See* Exh. B to Declaration of Patrick C. Asplin).[3] When the public encounters Opposer's marks, it encounters the flower design.

Additionally, Opposer's use of its marks is secondary on these products to the pharmaceuticals actual brand name, as seen on the exhibits Opposer attaches to its motion. (*See* documents forming Exh. A & C, attached to Affidavit of Jay Liska; *see also* Asplin Decl. Exh. B).[4] The inclusion of the "Lupin" mark on these products is for identification, not marketing purposes. The marks that receive the primary emphasis of these advertisements are "Alinia," "InspiraChamber," "InspiraMask," "SootherMask," "Methylphenidate HCI Chewable Tablets," "Allernaze," and "Antara 90." (Id.). These third-party marks are the "public-facing front" of

[2] Hereinafter "Berthold Aff. at __."
[3] Hereinafter "Asplin Decl. at __."
[4] Hereinafter "Liska Aff. at __."

these materials. In contrast, the "Lupin" mark can be found in the "fine print" of these advertisements, which emphasize the primary brand name familiar to the public and not "Lupin," the generic manufacturer. (Id.).

Outside of these materials, Opposer markets its products to industry insiders through "medical journals, pharmaceutical trade journals, pharmaceutical bulletins, and specialty consumer medical publications," and sponsorship of seminars and meetings of medical groups. (Mot. for Summary Judgment by Opposer at p. 5).[5]

III. Opposer's trade channels

"[T]he purchasers of Opposer's products and services are wholesale pharmaceutical distributors…and federal agencies and programs." (Opposer's Response to Interrogatory No. 18).[6] Indeed, "Opposer sells its products through wholesalers including AmeriSource Bergen, Cardinal, and McKesson, *which are the three largest pharmaceutical wholesalers in the United States*." (Mot. for Summary Judgment by Opposer, at p. 4) (emphasis added). These wholesalers in turn distribute Opposer's products to "major retail chains" and grocery chains, including Walmart, CVS, Walgreens, Harris Teeter, Publix, and Kroger. (Id.). "Opposer's pharmaceuticals are also widely prescribed at hospitals throughout the United States" and "offered and sold to various federal government agencies and programs." (Id.). Opposer also has agreements "with pharmaceutical and biopharmaceutical companies," specifically major companies. (Id.).

IV. Opposer's absence from the "Lupus" space

[5] Opposer's claim that "consumers are accustomed to seeing the LUPIN Mark" on packaging and advertising (*See* Mot. for Summary Judgment by Opposer at p. 20) is based on self-serving hearsay and speculation and should be disregarded. Likewise, Opposer's claim that "[c]onsumers are used to seeing pharmaceuticals and related educational and support group services emanating from the same source" (See Mot. for Summary Judgment by Opposer at p. 21) should be disregarded for the same reason. Opposer offers no consumer studies or surveys, or any other evidence beyond the speculation of its own counsel and principals that would support these claims.

[6] Opposer's Amended Responses to Applicant's Interrogatories and Opposer's Responses to Applicant's Requests for Admission are attached as Exhibit A to the Declaration of Patrick C. Asplin.

Opposer offers and sells non-steroidal anti-inflammatory drugs, commonly referred to as "NSAIDs." (Mot. for Summary Judgment by Opposer at p. 13). Well-known examples of NSAIDs include Aspirin and Ibuprofen. These drugs are used to treat a variety of common symptoms, like headache, fatigue, and joint pain. (Mot. for Summary Judgment by Opposer at p. 3; Berthold Aff. at ¶ 16). Like nearly every other disease or illness, symptoms of Lupus may include these run-of-the-mill symptoms as well. Opposer has no specific connection to the Lupus disease aside from the extremely attenuated relationship between these common symptoms and Opposer's manufacture and distribution of NSAIDs, which are used for general pain relief.

Indeed, Opposer admits the following:

- "Opposer has not and does not manufacture, sell or license a pharmaceutical product or any other 'product or good' that is intended solely for the treatment of Lupus or otherwise 'related to' Lupus only." (Opposer's Response to Interrogatory No. 8).

- "Opposer does not provide educational, counseling and support services intended for Lupus patients, or which directly or only relates to Lupus or the treatment of Lupus or clinical trials relating only to Lupus." (Opposer's Response to Interrogatory No. 9).

- Opposer has not used the "LUPIN" word or design marks in connection with a pharmaceutical product intended solely for the treatment of Lupus; educational seminars or mentoring, in the field of Lupus or Lupus treatment options; training Lupus patients to teach other Lupus patients about the nature of Lupus or available treatments for Lupus; organizing or conducting clinical trials for treatments for Lupus; or organizing or conducting support groups for Lupus patients or their caregivers. (Opposer's Response to Request for Admission Nos. 1-16).

- With respect to both the "LUPIN" word and design marks, "Opposer does not: provide pharmaceutical products specifically intended for the treatment of Lupus; offer and/or conduct educational seminars specifically in the field of Lupus and/or for Lupus treatment options; conduct mentoring specifically in the field of Lupus and/or Lupus treatment options; train Lupus patients to teach other Lupus patients about the nature of Lupus; train Lupus patients to teach other Lupus patients about available treatments for Lupus; organize and/or conduct clinical trials specifically intended for treatments for Lupus; organize and/or conduct

> support groups specifically intended for Lupus patients and/or the caregivers of Lupus patients." (Opposer's Response to Interrogatory Nos. 31 & 33).

Opposer's admitted lack of any real connection to the Lupus disease or to patient education and support groups, particularly when coupled with Opposer's primary business of the manufacture of generic pharmaceuticals and its sales to sophisticated industry wholesalers and major retail chains, reveals an unmistakable distinction from Applicant's services.

V. Applicant's "LuPPiN" mark for education and patient support groups

Applicant has filed for registration of the service mark "LuPPiN." (Affidavit of Peter Lipsky, M.D., at ¶ 9)[7]. The word "LuPPiN" has capitalized letters "L," "P," "P," and "N," and is rendered in stylized form as follows:

LuPPiN

(Id.).

Applicant seeks to register the mark in Class 41, for "[e]ducation services, namely, providing seminars and one-on one mentoring in the fields of Lupus, Lupus treatment options and the importance of clinical trials; training Lupus patients to teach other Lupus patients about the nature of Lupus, available treatments and the importance of clinical trials." (Id.). Applicant also seeks to register the mark in Class 45, for "organizing and conducting support groups for Lupus patients who are undergoing treatment and clinical trials, and for the caregivers of Lupus patients who are undergoing treatment and clinical trials." (Id.). The trademark examiner approved the "LuPPiN" mark for publication, and the mark was published on August 18, 2015.

[7] Hereinafter "Lipsky Aff. at __."

Applicant's LuPPiN mark is part of a series of marks used by Applicant and containing a "Lu" beginning, to indicate a specific relationship to Lupus-oriented services, such as "LuCIN, LuCIT, LuPro and LuPPiN," as well as "LuCIN-STAT" and "LuSEC." (Lipsky Aff. at ¶4; Lipsky Depo. 15:23-16:5; Grammer Depo. 42:1-13).[8] "LuPPiN" is an acronym for "Lupus Patient Partner Integrator Network." (Lipsky 30(b)(6) Depo. 13:17-25). The capital "Ps" are intended to emphasize Applicant's services under the LuPPiN mark, specifically, patient/partner services designed to provide education and support to Lupus patients. (Lipsky Aff. at ¶11; Lipsky 30(b)(6) Depo. 16:1-8).

This patient-centric program is designed to provide (1) support groups for Lupus patients who are undergoing treatment and clinical trials and for the caregivers of such patients; and (2) seminars and mentoring to educate Lupus patients about treatment options and available clinical trials, and to train Lupus patients so to educate other Lupus patients. (Lipsky Aff. at ¶9). Through enlarging participation in clinical trials, Applicant hopes to find a cure for Lupus. (Lipsky Depo. 44:19-48:17, 50:11-51:13, 142:4-16). Applicant intends to have LuPPiN representatives on-site at academic institutions where clinical trials may be conducted to educate Lupus patients about its services. (Lipsky 30(b)(6) Depo. 87:7-90:1).

Applicant works with a network of 59 academic centers in the United States and Canada through LuCIN, which refers to Ampel's "Lupus Clinical Investigators Network." (Lipsky Aff. at ¶ 11; Lipsky 30(b)(6) Depo. 14:3-15:20). These academic centers host clinical trials in order to find a more effective treatment for Lupus, primarily through the repurposing of existing drugs for the treatment of Lupus. (Id.; Lipsky Depo. 38:18-39:12). Through the LuPPiN patient partner

[8] Relevant portions of the deposition transcripts of Drs. Lipsky and Grammer are attached as Exh. C, D, & E to the Declaration of Patrick C. Asplin.

program, Lupus patients would receive education, information, and support concerning the disease and the clinical trials. (Id.; Lipsky 30(b)(6) Depo. 80:6-19; Lipsky Depo. 44:19-48:17).

Unlike the Opposer, Applicant does not manufacture, distribute, sell or offer for sale pharmaceuticals. (Lipsky Aff. at ¶ 16). Applicant also does not work directly with the manufacturer of generic pharmaceuticals. (Id.; Lipsky Depo. 42:18-19). Applicant does work with pharmaceutical companies as part of its clinical trial work. Typically, Applicant analyzes potential drugs that could be useful in treating Lupus and approaches the manufacturer about participating in further study through clinical trials conducted through "LuCIN." (Lipsky Aff. at ¶ 7). That outreach is not performed through the "LuPPiN" program, which is patient focused and clearly identified as a standalone "patient partner" network of patient education and support. (Lipsky Aff. at ¶ 13; Lipsky 30(b)(6) Depo. 14:11-21, 70:16-71:17; Lipsky Depo. 44:19-48:17).

VI. Applicant's marketing of "LuPPin" and its consumer base

Applicant does not use traditional advertising channels. Instead, Applicant markets its services primarily through presentations and the personal contacts of its principals. (Lipsky Aff. at ¶ 6; Lipsky 30(b)(6) Depo. 61:9-14, 63:6-9). Applicant also maintains a website which bears the LuPPiN mark and has brochures available. (Lipsky Aff. at ¶ 6; Lipsky 30(b)(6) Depo. 60:11-22, 61:23-24). The primary marketing of the LuPPiN program is through personal, face-to-face contact with actual patients and by word-of-mouth. (Lipsky Aff. at ¶ 6; Lipsky 30(b)(6) Depo. 89:12-90:1). Applicant intends to have LuPPiN representatives on-site at academic institutions to educate prospective patients about its services and to enroll them in the LuPPiN program. (Lipsky 30(b)(6) Depo. 87:7-90:1).

Applicant has also promoted the LuPPiN program at medical conferences and seminars, including with parties highly sophisticated in the medical field generally and with Lupus,

specifically, and has placed a particular emphasis on the patient partner aspect of the program during these presentations. (Lipsky 30(b)(6) Depo. 46:14-18; Lipsky Depo. 135:7-136:9, 142:4-16, 147:13-22, Grammer Depo. 49:16-50:2, 69:1-11, 73:8-17,78:18-79:12). As Opposer notes, Applicant also meets with pharmaceutical companies to discuss the potential repositioning of existing drugs for the treatment of Lupus, but this is done through the personal contacts of Applicant's principals in connection with the separate "LuCIN" initiative, which is responsible for conducting the clinical trials. (Lipsky Aff. at ¶ 7). Applicant does not actively market or promote the LuPPiN program to pharmaceutical companies when marketing its clinical trial services to pharmaceutical companies. (Id. at ¶ 13).

There have been no instances of confusion or mistake arising between Applicant's "LuPPiN" mark for education and patient support services and Opposer's "Lupin" marks for pharmaceutical manufacturing. (Lipsky Aff. at ¶ 15; Lipsky 30(b)(6) Depo. 79:4-16). Indeed, Applicant was not even familiar with Opposer prior to its opposition being filed in this proceeding. (Lipsky Aff. at ¶ 15; Lipsky 30(b)(6) Depo. 31:4-14).[9]

Standard of Review

Summary judgment may be granted only "if the movant shows that there is no genuine dispute as to any material fact." TBMP § 528; Fed. R. Civ. P. 56(a). "A party moving for summary judgment has the burden of demonstrating the absence of any genuine dispute of material fact, and that it is entitled to judgment as a matter of law. This burden is greater than the evidentiary burden at trial…. A factual dispute is genuine if sufficient evidence is presented such that a reasonable fact finder could decide the question in favor of the nonmoving party." TBMP § 528.01.

[9] Opposer's claim that the "consuming public is accustomed to encountering pharmaceutical companies providing or funding educational support groups" (Mot. for Summary Judgment by Opposer at p. 16) should be disregarded, as it is based on the speculative declaration of its own counsel and hearsay from third-parties.

"The nonmoving party must be given the benefit of all reasonable doubt as to whether genuine disputes of material fact exist; and the evidentiary record on summary judgment, and all inferences to be drawn from the undisputed facts, must be viewed in the light most favorable to the nonmoving party." *Id.*; *see also Opryland USA Inc. v. Great Am. Music Show, Inc.*, 970 F.2d 847, 850 (Fed. Cir. 1992) ("The evidence submitted by the non-movant, in opposition to a motion for summary judgment, is to be believed, and all justifiable inferences are to be drawn in its favor.").

Argument

Here, on summary judgment, the Board must review the facts in the light most favorable to Applicant, and resolve all reasonable doubts in its favor. Under this standard, it cannot be said that Applicant's mark will create a likelihood of confusion in the minds of relevant consumers with respect to Opposer's marks. Opposer's claim that Applicant's use of LuPPiN for patient support and education is likely to confuse the purchasers of its LUPIN branded pharmaceuticals – the largest drug wholesalers and retail chains in the United States – is unsupported by bedrock principles of trademark law and the facts of this proceeding. Opposer does not own a monopoly on "Lupin" within the medical field. The parties' marks are sufficiently distinct, their goods and services occupy discrete submarkets, and their channels of advertising and trade do not overlap. Opposer has failed to show that there is no genuine dispute over these material facts, and therefore, its motion for summary judgment should be denied.

I. Opposer's insinuations of nonuse are a "red herring"

Opposer states several times that Applicant has not sufficiently used its mark. Opposer, however, did not raise nonuse in its opposition. The bases for the opposition were specifically limited to whether Applicant's use of the LuPPiN mark is likely to confuse consumers as to the

source of its goods and services. (*See* Notice of Opposition at ¶¶ 10-14). Opposer cannot rely on a nonuse argument now, and Applicant objects to the portion of Opposer's motion regarding alleged nonuse. *See* TMBP § 314 ("A party may not obtain summary judgment on an unpleaded claim."); TMBP § 528.07(a) ("A party may not obtain summary judgment on an issue that has not been pleaded."). "Indeed, the Board has long recognized that summary judgment is not appropriate on an unpleaded issue." *Am. Express Mktg. & Dev. Corp.*, 94 U.S.P.Q.2d 1294 (T.T.A.B. Mar. 15, 2010).

II. Opposer has not shown that registration of Applicant's mark would create a likelihood of confusion

The true focus of Opposer's motion is the "likelihood of confusion" analysis. There is at least a disputed issue of fact that consumers are likely to be confused by registration of Applicant's "LuPPiN" mark.

Opposer claims that simply because it manufacturers generic drugs that can be used to treat common symptoms of Lupus, as well as many other illnesses and diseases, participants in the patient partner "LuPPiN" program may be confused as to the source of that program. Opposer makes this argument despite always using its mark in connection with its flower logo, dealing with the most sophisticated industry insiders in the pharmaceutical field, and not providing the same services as Applicant.

Contrary to Opposer's position, in applying the *DuPont* factors, the "relevant application is made *in the marketplace*." *E.I. DuPont DeNemours & Co.*, 476 F.2d 1357, 1360 (C.C.P.A. 1976) (emphasis added). This does "not refer to a mental exercise, but to all of the known circumstances surrounding use of the mark." *Id.* at 1360-61. The test is inherently factual, and must be based "upon consideration of *all* the evidence." *Id.* at 1361, 1362 (emphasis in original).

"The fact that the goods of one party '*could* be used' in the field of the other is too conjectural and too widely applicable to form the sole basis of decision…." *Id.* at 1363 (emphasis added).

Instead, a "likelihood of confusion exists if the defendant's *actual* practice is likely to produce confusion in the minds of consumers about the origin of the goods or services in question." *George & Co. LLC v. Imagination Entertainment Ltd.*, 575 F.3d 383, 393 (4th Cir. 2009) (emphasis added). Under this proper standard, the Board should "look to how the two parties *actually* use their marks in the marketplace to determine whether the defendant's use is likely to cause confusion." *CareFirst of Md., Inc. v. First Care P.C.*, 434 F.3d 263, 267 (4th Cir. 2006) (emphasis added).

A. Opposer's registrations do not give it a monopoly on the word "lupin"

Opposer's registrations for its "Lupin" marks are expressly limited to the sale of pharmaceuticals and pharmaceutical preparations in Class 5. Applicant does not sell or offer for sale pharmaceuticals or any other good, but instead simply offers a service of education and support specifically for Lupus patients. Opposer's registrations and even use of its "Lupin" marks for the sale of pharmaceuticals does not entitle it to prohibit Applicant's use of the mark "LuPPiN" for its services.

Moreover, the extent of a trademark is defined by customer perception. *McCarthy on Trademarks and Unfair Competition* § 2:11 (5th ed.). Opposer's use of "Lupin" is always in conjunction with its flower design, including in its public-facing materials, *i.e.*, the labelling of its pharmaceutical bottles, advertisements, website, and approved logos. (*See* Asplin Decl. at Exh. B; *see* also Liska Aff. Exh. A, B, & C). Opposer's use of "Lupin" also is always and clearly in connection with the sale of pharmaceuticals. (Liska Aff. at Exh. A & C). The materials submitted by Opposer in support of summary judgment do not reflect the perspective of

Opposer's consumers or Opposer's trademark use as the use of "Lupin" alone or even broadly within the medical field, because each identifies "Lupin" with the flower design and in connection with the sale of pharmaceuticals. *See The N. Face Apparel Corp. v. Sanyan Industry Co., Ltd.*, 116 U.S.P.Q. 2d 1217, *5 (T.T.A.B. Sept. 18, 2015) (opposer's consistent use of design mark in connection with word mark indicated how consumers viewed the mark, due to opposer's "promotion of the design in conjunction with the words").

Opposer *claims* the consuming public recognizes "Lupin" as a maker of generic pharmaceuticals and other goods, but Opposer offers no consumer studies or surveys, or any other evidence beyond the inadmissible speculation and hearsay statements of its own counsel and principals to support this claim. As the exhibits attached to Opposer's own motion indicate, Opposer's mark is buried in the fine print on its public-facing materials, while the primary "brand" – "Alinia," "InspiraChamber," "SootherMask," "Allernaze" – is pushed to the forefront for purposes of public perception. (Liska Aff. at Exh. A & C). Opposer has provided no evidence that consumers view "Lupin" as the brand for these products, and these exhibits actually undermine Opposer's arguments.

Indeed, Opposer has produced no evidence at all as to how its consumers view the *word* "lupin," which Opposer seeks to prohibit Applicant from using, particularly when Opposer's marks are ordinarily part of *generic* drug sales and distribution and their use is secondary to the goods' *actual* brand name. *See*, *e.g.*, *Braun Inc. v. Dynamics Corp. of Am.*, 975 F.2d 815, 826 (Fed. Cir. 1992) (limited evidence as to advertising, sales and media attention was not sufficient to demonstrate that the consuming public identified the product with its maker); *Wag'N Enterprises, LLC v. United Animal Nations*, 2012 WL 1633410, at *5 (E.D. Va. May 9, 2012) (commercial strength of mark was considered weak when no studies were offered to show

consumers associated mark with source). Under these circumstances, whether Opposer may prohibit Applicant from using its "LuPPiN" mark for Lupus patient education and support is at least a question of material fact that cannot be decided on summary judgment.

B. <u>The parties' marks are sufficiently distinct and dissimilar</u>

Opposer claims that, simply because "Lupin" and "LuPPiN" are word marks which are pronounced the same, Opposer can prohibit Applicant's registration. (Mot. for Summary Judgment by Opposer at p. 18). This argument does not reflect a true view of the evidence or a considered application of the law.

A mark must be considered as a whole. *Juice Generation, Inc. v. GS Enterprises LLC*, 794 F.3d 1334, 1341 (Fed. Cir. 2015) (Ordering TTAB to consider PEACE LOVE AND JUICE in its entirety in likelihood of confusion analysis even though JUICE was generic and disclaimed); *Ferrotec (USA) Corp. & Ferrotec Corp.*, 2009 WL 273256, at *7-8 (TTAB Jan. 29, 2009) (marks both beginning with descriptive term "Ferro" dissimilar even though associated with same goods and shared same consumers). "Both parties' entire presentation of the word mark as seen by buyers should be considered. If defendant has used plaintiff's word mark in the same lettering style, color, format or with a similar background design, then the likelihood of confusion is increased, whereas if the lettering style is dissimilar, confusion is less likely." McCarthy on Trademarks and Unfair Competition § 23:52 (5th ed.). "We do not consider these factors in isolation. Instead, we must examine them in the context of the marks as a whole as they are encountered by consumers in the marketplace." *King of the Mountain Sports, Inc. v. Chrysler Corp.*, 185 F.3d 1084, 1090 (10th Cir. 1999) (quotation omitted).

As Opposer must concede, the parties' marks appear in different lettering, "Lupin" and "LuPPiN," and as actually used, Opposer's marks always appear in connection with an

additional logo, its flower design, thus further differentiating the marks. Applicant's LuPPiN mark is further distinguished by being part of a series of marks used by Applicant and containing a "Lu" beginning, to indicate a relationship to Lupus-oriented services, such as "LuCIN, LuCIT, LuPro and LuPPiN," as well as "LuCIN-STAT" and "LuSEC." (Lipsky Depo. 15:23-16:5, Grammer Depo. 42:1-13). These distinguishing characteristics make the marks sufficiently dissimilar. *See Progressive Distribution Servs., Inc. v. United Parcel Serv., Inc.*, 856 F.3d 416, 432-33 (6th Cir. 2017) (Defendant's use of its well-known house mark "UPS" in its mark "UPS ORDERLINK" in different colors contributed to a finding of no infringement of plaintiff's mark ORDERLINK. "The respective marks are displayed in different colors and fonts and depicted with distinct design elements."); *Starbucks Corp. v. Wolfe's Borough Coffee, Inc.*, 588 F.3d 97, 106 (2d Cir. 2009) (No likely confusion was created by defendant's MISTER CHARBUCKS coffee in comparison with plaintiff's STARBUCKS coffee. The defendant's word mark was presented on packages that were different in imagery, color, and format from plaintiff's packages and advertising.) *In re Hartz Hotel Services, Inc.*, 2012 WL 1193704, *4-5 (P.T.O. March 19, 2012) (geographic term used with GRAND HOTEL sufficient to distinguish marks); *see also George & Co.*, 575 F.3d at 396 courts analyze "similarity in sight, sound, and meaning which would result in confusion"); *McCarthy on Trademarks and Unfair Competition* § 23:52 (5th ed.) (consideration should be given to "not only the similarity of the accused word marks, but also the similarity of the lettering style, color and format and any accompanying background matter").

Opposer's registration of "Lupin" as a word mark "does not change this rule." *McCarthy on Trademarks and Unfair Competition* § 23:52 (5th ed.). "'A standard character registration does not override the requirement that likelihood of confusion be measured by the perceptions of consumers in the marketplace, including the effect of packaging.'" *Id.* (quoting *Hornady Mfg.*

Co., Inc. v. Doubletap, Inc., 746 F.3d 995, 1002 n.2 (10th Cir. 2014) ("The court must consider the effect of marketplace presentation, including lettering styles, logos and coloring schemes …. [T]he packaging on which the parties display their marks differs greatly in color scheme and layout." Affirmed summary finding of no likelihood of confusion.)).

Here, the marks are sufficiently distinct, and the simple fact that they share a like pronunciation does not outweigh the substantial differences in the marks in the eyes of consumers. Indeed, "because there are significant differences in the design of two marks," particularly when viewed from the consumer's perspective, any "finding of similarity is a less important factor in establishing a likelihood of confusion than it would be if the two marks had been identical in design or nearly indistinguishable to a casual observer." *In re Coors Brewing Co.*, 343 F.3d 1340, 1344 (Fed. Cir. 2003).

C. The parties offer different services, target different consumers, and use different channels of trade

Again, Opposer's arguments regarding these factors are overly simplistic. Opposer claims it can prohibit Applicant's registration of "LuPPin" for Lupus patient support and education services simply because Opposer makes a line of generic drugs that can be used to treat headaches, fatigue, joint pain, and other common symptoms of Lupus and virtually every other medical condition. (Mot. for Summary Judgment by Opposer at pp. 19-21). Opposer's argument is untenable in light of the actual record before the Board.

1. The parties' services are different

The Board is required "to look to the registration to determine the scope of the goods/services covered by the contested mark." *Cunningham v. Laser Golf Corp.*, 222 F.3d 943, 948 (Fed. Cir. 2000) (citations omitted). "Accordingly, the identification of goods/services statements in the registration…frames the issue." *Id.*; *see also Mattel Inc. v. FunLine*

Merchandise Co., 81 U.S.P.Q. 2d 1372, 1374 (TTAB 2006) (key considerations are similarities between the marks and goods as recited in the parties' registrations).

Applicant seeks to register its "LuPPiN" mark in Class 41 for "[e]ducation services, namely, providing seminars and one-on one mentoring in the fields of Lupus, Lupus treatment options and the importance of clinical trials; training Lupus patients to teach other Lupus patients about the nature of Lupus, available treatments and the importance of clinical trials." Applicant also seeks to register the mark in Class 45 for "organizing and conducting support groups for Lupus patients who are undergoing treatment and clinical trials, and for the caregivers of Lupus patients who are undergoing treatment and clinical trials." These registrations are very limited, just as Opposer's registrations for pharmaceuticals in Class 5 are very limited. Opposer cannot prohibit use of the word "lupin" for services it does not provide without showing a likelihood of confusion between those services. Viewing the facts and inferences in the light most favorable to Applicant, as the non-movant, Opposer cannot make that showing simply by arguing that it also occupies space in the medical field.

Services which may be "in the same market but in different submarkets do not compete directly and are not in the same relevant [service] market." *Worthington Foods, Inc. v. Kellogg Co.*, 732 F. Supp. 1417, 1438 (S.D. Ohio 1990) (microwaveable meat not related to cereals); *see also The N. Face Apparel Corp. v. Sanyan Industry Co., Ltd.*, 116 U.S.P.Q. 2d 1217, *17 (T.T.A.B. Sept. 18, 2015) (opposer's association with mountain biking and clothing did not create a likelihood of confusion where applicant's mark featured *electric* bicycles); *In re Coors Brewing Co.*, 343 F.3d 1340 (Fed. Cir. 2003) (use of "Blue Moon" for both beer and restaurant services was not confusingly similar even though the two "Blue Moon" marks were similar). The parties' registrations are clear that their services do not overlap, and no one reviewing

Applicant's services could be confused that it may be manufacturing drugs like the Opposer. Indeed, the parties' services are so distinct, consumers are *not* likely to be confused even if Opposer's arguments are simply taken at face value, regardless of the actual services it provides. It is undisputed that Opposer does not provide patient partner support, and that Applicant does not provide pharmaceuticals. Because the parties' respective consumers cannot substitute the parties' services, confusion is not only highly unlikely, but virtually impossible. *See Worthington Foods*, 732 F. Supp. at 1438 (breakfast items were not substitutes because meat alternative item had a specific purpose).

2. <u>The parties' customers are different</u>

Opposer's claim that it targets "Lupus patients" rings hollow. (Mot. for Summary Judgment by Opposer at p. 19). According to Opposer's own motion and supporting testimony, "Opposer sells its products through wholesalers including … *the three largest pharmaceutical wholesalers in the United States*." (Mot. for Summary Judgment by Opposer, at p. 4) (emphasis added). These wholesalers in turn distribute Opposer's products to "major retail chains" and grocery stores. (Id.). "Opposer's pharmaceuticals are also … offered and sold to various federal government agencies and programs." (Id.). Opposer is not targeting Lupus patients, but instead highly sophisticated parties.

In contrast, Applicant's services are offered through in-person contact with actual Lupus patients. (*See* Statement of Facts §§ V & VI, *supra*). To the extent Applicant works with pharmaceutical companies to provide patient/partner services during clinical trials, that work is done through the personal contacts of its principals, and such companies are highly sophisticated, much like the large and sophisticated companies which purchase Opposer's pharmaceuticals. This sophistication merits against a finding of a likelihood of confusion. *See In re N.A.D. Inc.*,

754 F.2d 996, 1000 (Fed. Cir. 1985) (no confusion due to sophistication of consumers in the medical field, who could distinguish between seller of specific anesthesia machine and lessor of general medical equipment); *Nat'l Distillers Products Co., LLC v. Refreshment Brands, Inc.*, 198 F. Supp. 2d 474, 481-82 (S.D.N.Y. 2002) (premium vodka sold to affluent people in bars or liquor stores not related to cheap vodka sold to non-affluent people in supermarkets).

3. <u>The parties' trade channels are different</u>

Opposer cites *In re Pix of America, Inc.*, 225 U.S.P.Q. 691 (TTAB 1985), to argue that "all normal and usual channels of trade and methods of distribution" should be considered, to include the downstream purchasers of its pharmaceuticals for "common symptoms." (Mot. for Summary Judgment by Opposer at p. 19). In that decision, however, the parties both sold apparel (shoes and shirts, respectively), and both parties' apparel could "be found in the same retail outlets." *Id.* It does not provide support for Opposer's argument here.

Here, Applicant offers its "LuPPiN" branded services through in-person solicitation and the business contacts of its principals, and all such contacts are specifically targeted to its work with the Lupus disease. (*See* Statement of Facts §§ V & VI, *supra*). It will pursue these customers primarily through the academic sites at which its affiliated initiative, "LuCIN," operates. At the same time, Opposer works directly with the three largest pharmaceutical wholesalers in the United States, major retail and grocery chains, the federal government, and major pharmaceutical manufacturers, who undoubtedly exercise great care in selecting the pharmaceuticals they sell or provide to third-parties. *See Heartsprings, Inv. v. Heartspring, Inc.*, 143 F.3d 550, 557 (10th Cir. 1998) ("A consumer exercising a high degree of care in selecting a product reduces the likelihood of confusing similar trade names."). Unlike the authority Opposer

relies upon, the parties are not pursuing the general public or using "the same retail outlets" or other confusingly similar channels of trade.

D. Opposer's sales and advertising figures, without context, do not demonstrate strength of its mark

Opposer argues that its mark is strong and entitled to broad protection primarily because it claims significant marketing expenditures and sales. (Mot. for Summary Judgment by Opposer at p. 22). A party must clearly prove the fame of its mark for this factor to weigh in its favor. *The N. Face Apparel Corp.*, 116 U.S.P.Q. 2d at 1225. Sales and advertising figures without context are insufficient to prove fame. *Id.*

For instance, in *The N. Face Apparel Corp.*, the opposer provided annual sales "in the millions of dollars" and substantial advertising figures, but it did not measure itself against other brands or reflect what amounts were for goods Opposer claimed would likely cause confusion. *Id.* Here, Opposer claims its sales of generic drugs for the treatment of Lupus symptoms will cause confusion with Applicant's services, but like the opposer in *The N. Face*, it provides no context beyond its own subjective statements that its sales and advertising, generally, support strength of its mark, and does not tie those figures to sales and advertising of the products *it* claims will result in confusion.

E. Opposer's speculative arguments of "harm" should be ignored

Opposer claims that great care should be taken here because of "the potential harm of confusion in the area of pharmaceuticals." (Mot. for Summary Judgment by Opposer at p. 24). Opposer grounds the risk of confusion, however, in its sale of NSAIDs, which are used to treat headaches, fatigue, joint pain and other common, non-life-threatening issues. Moreover, although Opposer is correct that a "likelihood of confusion takes on additional significance when the goods are pharmaceuticals," *In re Cook Med. Techs., LLC*, 105 U.S.P.Q. 2d 1377 (TTAB

2012), the parties' goods and services do not overlap and there is no threat of mistaken identity as to a pharmaceutical or that a consumer may mistakenly take a drug believing that it is a different drug. Again, Ampel does not manufacture or sell any pharmaceuticals, and no pharmaceuticals, over-the-counter drug or any product is sold by Ampel under the LuPPiN mark. Therefore, this principle does not come into play.

III. Summary judgment should be granted in favor of Applicant on its affirmative defenses

Applicant pleaded as affirmative defenses that the services offered by Applicant under its "LuPPiN" mark are sufficiently distinct and marketed to consumers who will not be confused by any similarity to Opposer's mark, and the marks are not confusingly similar. The record set before the Board on summary judgment satisfies these defenses.

"If the Board concludes that there is no genuine dispute of material fact, but that the *nonmoving* party is the one entitled to judgment as a matter of law, the Board may, after giving notice and a reasonable time to respond, grant summary judgment in favor of the nonmoving party." TBMP § 528.01. If it chooses to enter summary judgment at all, then the Board should enter summary judgment in favor of Applicant.

Conclusion

Opposer has not carried its burden of showing that there are no material facts in dispute as to whether Applicant's registration of its "LuPPiN" mark is likely to confuse consumers of Opposer's goods. This analysis is "inherently factual,"[10] and requires an analysis of consumer perception of the marks as a whole and in light of all relevant circumstances. Opposer's argument that it has shown likely confusion simply because it manufactures drugs that treat

[10] *Swatch AG v. Beehive Wholesale, LLC*, 739 F.3d 150, 155 (4th Cir. 2014); *Clicks Billiards, Inc. v. Sixshooters, Inc.*, 251 F.3d 1252, 1265 (9th Cir. 2001).

common symptoms of Lupus does not satisfy this standard and does not accurately reflect the factual record.

WHEREFORE, Applicant respectfully submits that this Opposition be dismissed with prejudice.

Dated: January 26, 2018

Respectfully Submitted,
AMPEL, LLC
Applicant/Respondent

/s/ Patrick C. Asplin

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Counsel for Applicant/Respondent

CERTIFICATE OF SERVICE

I hereby certify that on January 26, 2018, I electronically filed the foregoing *Applicant's Brief in Opposition to Opposer's Motion for Summary Judgment* using the ESTTA system and also e-mailed and mailed a copy via the United States Postal Service to the Opposer' s attorney at the address listed below:

Diane B. Melnick, Esq.
Robert L. Powley, Esq.
Powley & Gibson, P.C.
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trademarks@powleygibson.com
Counsel for Opposer/Petitioner

/s/ Patrick C. Asplin
Counsel for Applicant/Respondent

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

LUPIN PHARMACEUTICALS, INC.,

Opposer/Petitioner,

v.

AMPEL, LLC,

Applicant/Respondent.

Proceeding No. 91226322
Application Serial No. 86/509184
Mark: LuPPiN

DECLARATION OF PATRICK C. ASPLIN

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

LUPIN PHARMACEUTICALS, INC.,

Opposer/Petitioner,

v.

AMPEL, LLC,

Applicant/Respondent.

Proceeding No. 91226322
Application Serial No. 86/509184
Mark: LuPPiN

DECLARATION OF PATRICK C. ASPLIN

1. I am counsel for Ampel, LLC ("Applicant"), in the above-captioned action pending before the Trademark Trial and Appeal Board.

2. A true and correct copy of the cited portions of Lupin Pharmaceuticals, Inc.'s First Amended Responses to Applicant's First Set of Interrogatories and Lupin Pharmaceuticals, Inc.'s Response to Applicant's First Requests for Admissions is attached hereto as **Exhibit A.**

3. A true and correct copy of relevant documents produced by Lupin Pharmaceuticals, Inc. in this proceeding is attached hereto as **Exhibit B.**

4. A true and correct copy of the cited portions of the Deposition of Peter Lipsky taken in this proceeding is attached as **Exhibit C.**

5. A true and correct copy of the cited portions of the 30(b)(6) Deposition of Applicant, by its designee Peter Lipsky, taken in this proceeding is attached as **Exhibit D.**

6. A true and correct copy of the cited portions of the Deposition of Amrie Grammer taken in this proceeding is attached as **Exhibit E.**

7. I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

January 26, 2018
Date

Patrick C. Asplin

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

LUPIN PHARMACEUTICALS, INC., Opposer, v. AMPEL, LLC, Applicant.	Proceeding No. 91226322 Application Serial No.: 86/509184

OPPOSER'S FIRST AMENDED RESPONSES TO APPLICANT'S FIRST SET OF INTERROGATORIES

Pursuant to Fed. R. Civ. P. 26 and 33, Opposer, Lupin Pharmaceuticals, Inc., ("Opposer"), by and through its undersigned attorneys, hereby submits the following first amended responses to Applicant Ampel, LLC's ("Applicant") First Set of Interrogatories to Opposer ("Interrogatories") as follows. Opposer reserves the right to supplement, amend or correct these responses based upon information that may become known through additional discovery or any other means.

GENERAL RESPONSES AND OBJECTIONS

The following first amended responses hereby incorporate the General Responses and Objections set forth in Opposer's Responses and Objections to Applicant's First Set of Requests for the Production of Documents and Things to Opposer, served concurrently herewith. The individuals identified herein as current employees of Opposer and can be reached through Powley & Gibson, P.C.

EXHIBIT A

- Amlodipine Besylate Tablets, which is intended for the treatment of hypertension and coronary artery disease, with symptoms including, without limitation, headache, fatigue or confusion, chest pain, and shortness of breath;
- Amlodipine, Valsartan and Hydrochlorothiazide Tablets, which is intended for the treatment of hypertension, with symptoms including, without limitation, headache, fatigue or confusion, and chest pain; and
- Abacavir, Lamivudine and Zidovudine Tablets, which is intended, in combination with other antiretroviral agents, for the treatment of HIV-1 infection, with symptoms including, without limitation, fever, headaches, shortness of breath, and confusion.

INTERROGATORY NO. 8: Identify any other product or good that is manufactured, sold or licensed, or has been manufactured, sold or licensed, by Opposer which relates to Lupus.

RESPONSE TO INTERROGATORY NO. 8:

Opposer objects to this Interrogatory as vague, ambiguous, and requiring speculation and subjective judgment as to the meaning of the term "relates to." Subject to and without waiver of the foregoing general and specific objections, Opposer has not and does not manufacture, sell or license a pharmaceutical product or any other "product or good" that is intended only for the treatment of Lupus or otherwise "related to" Lupus only. Opposer affirmatively avers that it manufactures, distributes, advertises, and promotes a number of pharmaceutical products, both branded and generic, all under the Lupin Trademarks, as identified in response to Interrogatory No. 7, that may be used to treat common symptoms of Lupus. In conjunction with the foregoing, Opposer provides various collateral goods.

INTERROGATORY NO. 9: Identify all services (including without limiting, all educational, counseling and support services) that are or have ever been provided by Opposer to Lupus patients and/or which relate to Lupus, the treatment of Lupus and/or clinical trials relating to Lupus.

RESPONSE TO INTERROGATORY NO. 9:

Opposer objects to this Interrogatory as overly broad and not proportional to the needs of this case. Opposer objects to this Interrogatory as vague, ambiguous, and requiring speculation and subjective judgment as to the meaning of the term "relate to" or "relating to." Subject to and

without waiver of the foregoing general and specific objections, Opposer does not provide educational, counseling and support services intended for Lupus patients, or which directly or only relates to Lupus or the treatment of Lupus or clinical trials relating only to Lupus. Opposer however affirmatively avers that Opposer provides ancillary services for certain of its pharmaceutical products identified in response to Interrogatory No. 7 that may be used to treat the symptoms of Lupus. Such educational and support services involve nonsteroidal anti-inflammatory drug (NSAIDs) including celecoxib and anti-malarials.

INTERROGATORY NO. 10: Identify each pharmaceutical and biopharmaceutical company which the Opposer has agreements with or does business with.

RESPONSE TO INTERROGATORY NO. 10:

Opposer objects to this Interrogatory as overly broad, unduly burdensome, oppressive and not proportional to the needs of this case. Opposer further objects to this Interrogatory to the extent it seeks Opposer's confidential and/or trade secret information and that of other companies. Opposer objects to this Interrogatory as vague, ambiguous, and requiring speculation and subjective judgment as to the meaning of the term "does business with." Without waiver of the foregoing general and specific objections, Opposer states that it has thousands of agreements that are technically responsive to this Interrogatory. If Applicant agrees to amend this Interrogatory to narrow its scope, Opposer will re-consider its objections.

INTERROGATORY NO. 11: For each company identified in the answer to Interrogatory No. 10 above, describe the general nature of the business relationship between Opposer and the services, if any, that Opposer provides for such company.

RESPONSE TO INTERROGATORY NO. 11:

Opposer incorporates by reference its objections to Interrogatory No. 10. Opposer further objects to this Interrogatory as overly broad, unduly burdensome, and not proportional to the needs of this case, particularly as it requests Opposer's confidential and/or trade secret

INTERROGATORY NO. 18: Identify and describe with specificity the (i) intended consumers, and (ii) ultimate purchasers of each of Opposer's Products and Services.

RESPONSE TO INTERROGATORY NO. 18:

Opposer objects to this Interrogatory on the grounds it is vague, ambiguous, and requires speculation and subjective judgment as to the meaning of and differences between "intended consumers" and "ultimate purchasers." Opposer further objects to this Interrogatory on the grounds it is overly broad, unduly burdensome, and not proportional to the needs of this case, particularly as it requests the identity of the consumers and purchasers of the hundreds of pharmaceutical products distributed and sold by Opposer, and to the extent it requests confidential information regarding individual and institutional purchasers. Opposer also objects to this Interrogatory to the extent it is not limited to United States commerce. Subject to and without waiver of the foregoing general and specific objections, the purchasers of Opposer's Products and Services are wholesale pharmaceutical distributors (such as AmeriSource Bergen Corporation) and federal agencies and programs such as Medicare, Medicaid, and the Department of Veterans Affairs, among others (see also Response to Interrogatory No. 17). The end consumers of Opposer's pharmaceutical products are individuals who need, or have been prescribed, Opposer's products for a medical ailment or condition. Opposer further incorporates by reference its response to Interrogatory No. 17.

INTERROGATORY NO. 19: List all publications, radio stations, television stations, and other media in the United States where Opposer has advertised Opposer's Products and Services.

RESPONSE TO INTERROGATORY NO. 19:

Opposer objects to this Interrogatory as overly broad, unduly burdensome, and not proportional to the needs of this case. Subject to and without waiver of the foregoing general and specific objections, Opposer advertises and promotes Opposer's Products and Services

INTERROGATORY NO. 30: Identify each person Opposer expects to call as a non-expert witness in this proceeding and state each such person's occupation, residential address, relationship to Opposer, and the subject matter on which such person is expected to testify.

RESPONSE TO INTERROGATORY NO. 30:

Opposer objects to this Interrogatory as premature, as discovery is ongoing. Subject to and without waiver of the foregoing general and specific objections, Opposer will disclose its witnesses in a timely fashion when Opposer has identified same and will amend and supplement its Response to this Interrogatory accordingly.

INTERROGATORY NO. 31: For each of the following products and services, identify with specificity the first date(s) on which Opposer used the word mark LUPIN in connection therewith and any periods of time since such date(s) during which Opposer ceased such use: (a) pharmaceutical products for the treatment of Lupus; (b) educational seminars in the field of Lupus and/or Lupus treatment options; (c) mentoring in the field of Lupus and/or Lupus treatment options; (d) training Lupus patients to teach other Lupus patients about the nature of Lupus; (e) training Lupus patients to teach other Lupus patients about available treatments for Lupus; (f) organizing and/or conducting clinical trials for treatments for Lupus; and (g) organizing and/or conducting support groups for Lupus patients and/or the caregivers of Lupus patients.

RESPONSE TO INTERROGATORY NO. 31:

Opposer objects to this Interrogatory to the extent the term "mentoring" is vague, ambiguous, and requires speculation and subjective judgment as to its meaning. Opposer does not: provide pharmaceutical products specifically intended for the treatment of Lupus; offer and/or conduct educational seminars specifically in the field of Lupus and/or for Lupus treatment options; conduct mentoring specifically in the field of Lupus and/or Lupus treatment options; train Lupus patients to teach other Lupus patients about the nature of Lupus; train Lupus patients to teach other Lupus patients about available treatments for Lupus; organize and/or conduct clinical trials specifically intended for treatments for Lupus; organize and/or conduct support groups specifically intended for Lupus patients and/or the caregivers of Lupus patients. Notwithstanding the foregoing, since at least as early as July 1, 2005, Opposer has offered,

distributed and sold pharmaceutical products under the mark LUPIN in U.S. commerce that, among other things, may be repurposed to treat and alleviate certain common symptoms associated with Lupus, and has not ceased such use since that time.

INTERROGATORY NO. 32: Identify all documents, receipts, purchase orders, invoices, labels, packaging, or any writing whatsoever which Opposer will rely upon to establish the products and services identified in response to Interrogatory No. 31 above and/or to establish the date(s) specified in response to Interrogatory No. 31 above.

RESPONSE TO INTERROGATORY NO. 32:

Opposer objects to this Interrogatory as overly broad, unduly burdensome, and not proportional to the needs of this case, including without limitation as it requests the identity of "*any* writing whatsoever . . .". Opposer objects to this Interrogatory as vague, ambiguous, and requiring speculation and subjective judgment as to the meaning of "establish." Subject to and without waiver of the foregoing general and specific objections, Opposer will produce responsive, extant business records pursuant to Fed. R. Civ. P. 33(d).

INTERROGATORY NO. 33: For each of the following products and services, identify with specificity the first date(s) on which Opposer used the Lupin Design Mark in connection therewith and any periods of time since such date(s) during which Opposer ceased such use: (a) Opposer's Products and Services; (b) pharmaceutical products for the treatment of Lupus; (c) educational seminars in the field of Lupus and/or Lupus treatment options; (d) mentoring in the field of Lupus and/or Lupus treatment options; (e) training Lupus patients to teach other Lupus patients about the nature of Lupus; (f) training Lupus patients to teach other Lupus patients about available treatments for Lupus; (g) organizing and/or conducting clinical trials for treatments for Lupus; (h) organizing and/or conducting support groups for Lupus patients and/or the caregivers of Lupus patients.

RESPONSE TO INTERROGATORY NO. 33:

Opposer objects to this Interrogatory on the ground that it is overly broad, unduly burdensome, and not proportional to the needs of this case. Opposer objects to this Interrogatory to the extent it is duplicative of Interrogatory No. 15 and incorporates by reference the objections and response asserted in response to Interrogatory 15. Opposer objects to this Interrogatory to

the extent the term "mentoring" is vague, ambiguous, and requires speculation and subjective judgment as to its meaning. Opposer does not provide: pharmaceutical products specifically intended for the treatment of Lupus; educational seminars specifically in the field of Lupus and/or for Lupus treatment options; mentoring specifically in the field of Lupus and/or for Lupus treatment options; training to Lupus patients to teach other Lupus patients about the nature of Lupus; training to Lupus patients to teach other Lupus patients about available treatments for Lupus; for organizing and/or conducting clinical trials intended specifically for treatments for Lupus; for organizing and/or conducting support groups specifically intended for Lupus patients and/or the caregivers of Lupus patients. Notwithstanding the foregoing, since at least as early as 2005, Opposer has offered, distributed and sold pharmaceutical products under the Lupin Design Mark in U.S. commerce that, among other things, may be repurposed to treat and alleviate certain common symptoms associated with Lupus, and has not ceased such use since that time.

INTERROGATORY NO. 34: Identify all documents, receipts, purchase orders, invoices, labels, packaging, or any writing whatsoever which Opposer will rely upon to establish the products and services identified in response to Interrogatory No. 33 above and/or to establish the date(s) specified in response to Interrogatory No. 33 above.

RESPONSE TO INTERROGATORY NO. 34:

Opposer objects to this Interrogatory as overly broad, unduly burdensome, and not proportional to the needs of this case, including without limitation as it requests the identity of "*any* writing whatsoever . . .". Opposer objects to this Interrogatory as vague, ambiguous, and requiring speculation and subjective judgment as to the meaning of "establish." Subject to and without waiver of the foregoing general and specific objections, Opposer will produce responsive, extant business records pursuant to Fed. R. Civ. P. 33(d).

As to objections,

Signed this 8th day of March, 2017

POWLEY & GIBSON, P.C.

/s/ Thomas H. Curtin
Robert L. Powley
Thomas H. Curtin
Suzanna M. M. Morales

304 Hudson Street, Suite 202
New York, New York 10013
Telephone: (212) 226-5054
Facsimile: (212) 226-5085

Attorneys for Opposer

CERTIFICATE OF SERVICE

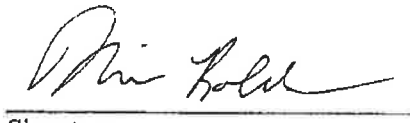
I hereby certify that on this 8th day of March, 2017, a true and correct copy of the foregoing OPPOSER'S FIRST AMENDED RESPONSES TO APPLICANT'S FIRST SET OF INTERROGATORIES was served on counsel of record for the Applicant via email, by agreement of the parties, to the following address:

Patrick Asplin, Esq.
pca@lplaw.com
Lenhart Pettit
530 East Main Street
P.O. Box 2057
Charlottesville, VA 22902

/s/ Thomas H. Curtin
Thomas H. Curtin

VERIFICATION

As to the facts stated herein, I swear that they are true to my personal knowledge or based upon my review of the records of Lupin Pharmaceuticals, Inc.



Signature

Nicholas Bolash
Name

Associate Corporate Counsel
Title

March 8, 2017
Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

LUPIN PHARMACEUTICALS, INC., Opposer, v. AMPEL, LLC, Applicant.	Proceeding No. 91226322 Application Serial No.: 86/509184

OPPOSER'S RESPONSE TO APPLICANT'S FIRST REQUESTS FOR ADMISSIONS

Pursuant to 37 C.F.R. § 2.120 and Rule 36 of the Federal Rules of Civil Procedure ("Fed. R. Civ. P."), Opposer Lupin Pharmaceuticals, Inc. ("Opposer"), by and through its undersigned attorneys, hereby responds to the First Set of Requests for Admissions propounded by Ampel, LLC ("Applicant") dated December 2, 2016 as follows:

REQUEST NO. 1

Admit that Opposer has not used the word mark LUPIN in connection with pharmaceutical products for the treatment of Lupus.

RESPONSE TO REQUEST NO. 1

Admit that Opposer has not used the word mark LUPIN in connection with a pharmaceutical product intended solely for the treatment of Lupus and, except as so admitted, denied.

REQUEST NO. 2

Admit that Opposer has not used the word mark LUPIN in connection with educational seminars in the field of Lupus and/or Lupus treatment options.

RESPONSE TO REQUEST NO. 2

Admitted.

REQUEST NO. 3

Admit that Opposer has not used the word mark LUPIN in connection with mentoring in the field of Lupus and/or Lupus treatment options.

RESPONSE TO REQUEST NO. 3

Opposer objects to this Request to the extent the term "mentoring" is vague, ambiguous and requires speculation and subjective judgment as to its meaning. Opposer further objects to this Request on the grounds it contains multiple Requests. Subject to and without waiver of the foregoing objections and based on Opposer's interpretation of the term "mentoring", admitted.

REQUEST NO. 4

Admit that Opposer has not used the word mark LUPIN in connection with training Lupus patients to teach other Lupus patients about the nature of Lupus.

RESPONSE TO REQUEST NO. 4

Admitted.

REQUEST NO. 5

Admit that Opposer has not used the word mark LUPIN in connection with training Lupus patients to teach other Lupus patients about available treatments for Lupus.

RESPONSE TO REQUEST NO. 5

Admitted.

REQUEST NO. 6

Admit that Opposer has not use [sic] the word mark LUPIN in connection with organizing and/or conducting clinical trials for treatments for Lupus.

RESPONSE TO REQUEST NO. 6

Opposer objects to this Request on the grounds it contains multiple Requests. Subject to and without waiver of the foregoing objection, admitted.

REQUEST NO. 7

Admit that Opposer has not use [sic] the word mark LUPIN in connection with organizing and/or conducting support groups for Lupus patients and/or the caregivers of Lupus patients.

RESPONSE TO REQUEST NO. 7

Opposer objects to this Request on the grounds it contains multiple Requests. Subject to and without waiver of the foregoing objection, admitted.

REQUEST NO. 8

Admit that Opposer has not use [sic] the word mark LUPIN in connection with organizing and/or conducting support groups for the caregivers of Lupus patients.

RESPONSE TO REQUEST NO. 8

Opposer objects to this Request on the grounds it contains multiple Requests. Subject to and without waiver of the foregoing objection, admitted.

REQUEST NO. 9

Admit that Opposer has not used the LUPIN Design Mark in connection with pharmaceutical products for the treatment of Lupus.

RESPONSE TO REQUEST NO. 9

Admit that Opposer has not used the LUPIN Design Mark in connection with a pharmaceutical product intended solely for the treatment of Lupus and, except as so admitted, denied.

REQUEST NO. 10

Admit that Opposer has not used the LUPIN Design Mark in connection with educational seminars in the field of Lupus and/or Lupus treatment options.

RESPONSE TO REQUEST NO. 10

Admitted.

REQUEST NO. 11

Admit that Opposer has not used the LUPIN Design Mark in connection with mentoring in the field of Lupus and/or Lupus treatment options.

RESPONSE TO REQUEST NO. 11

Opposer objects to this Request to the extent the term "mentoring" is vague, ambiguous and requires speculation and subjective judgment as to its meaning. Opposer further objects to this Request on the grounds it contains multiple Requests. Subject to and without waiver of the foregoing objections and based on Opposer's interpretation of the term "mentoring", admitted.

REQUEST NO. 12

Admit that Opposer has not used the LUPIN Design Mark in connection with training Lupus patients to teach other Lupus patients about the nature of Lupus.

RESPONSE TO REQUEST NO. 12

Admitted.

REQUEST NO. 13

Admit that Opposer has not use [sic] the LUPIN Design Mark in connection with training Lupus patients to teach other Lupus patients about available treatments for Lupus.

RESPONSE TO REQUEST NO. 13

Admitted.

REQUEST NO. 14

Admit that Opposer has not use [sic] the LUPIN Design Mark in connection with organizing and/or conducting clinical trials for treatments for Lupus.

RESPONSE TO REQUEST NO. 14

Opposer objects to this Request on the grounds it contains multiple Requests. Subject to and without waiver of the foregoing objection, admitted.

REQUEST NO. 15

Admit that Opposer has not use [sic] the LUPIN Design Mark in connection with organizing and/or conducting support groups for Lupus patients and/or the caregivers of Lupus patients.

RESPONSE TO REQUEST NO. 15

Opposer objects to this Request on the grounds it contains multiple Requests. Subject to and without waiver of the foregoing objection, admitted.

REQUEST NO. 16

Admit that Opposer has not use [sic] the LUPIN Design Mark in connection with organizing and/or conducting support groups for the caregivers of Lupus patients.

RESPONSE TO REQUEST NO. 16

Opposer objects to this Request on the grounds it contains multiple Requests. Subject to and without waiver of the foregoing objections, admitted.

March 6, 2017

POWLEY & GIBSON, P.C.

/s/ Thomas H. Curtin

Robert L. Powley
James M. Gibson
Thomas H. Curtin

304 Hudson Street, Suite 202
New York, New York 10013
Telephone: (212) 226-5054
Facsimile: (212) 226-5085

Attorneys for Opposer
LUPIN PHARMACEUTICALS, INC.

CERTIFICATE OF SERVICE

I hereby certify that on this 6th day of March, 2017, a true and correct copy of the foregoing OPPOSER'S RESPONSES TO APPLICANT'S FIRST REQUEST FOR ADMISSIONS was served on counsel of record for the Applicant via email, by agreement of the parties, to the following address:

Patrick Asplin, Esq.
pca@lplaw.com
Lenhart Pettit
530 East Main Street
P.O. Box 2057
Charlottesville, VA 22902

/s/ Thomas H. Curtin
Thomas H. Curtin

Approved Lupin Pharmaceuticals, Inc. Logos

1. 

2. 

3. 

4. 

Vinita Gupta, President

5/8/06
Date

EXHIBIT B

LUPIN
PHARMACEUTICALS, INC.

Our mission is to become a transnational pharmaceutical company through the development and introduction of a wide portfolio of branded and generic products in key markets.

About Us

Who We Are

Lupin Pharmaceuticals, Inc. is the U.S. wholly owned subsidiary of Lupin Limited, which is among the top six pharmaceutical companies in India. Through our sales and marketing headquarters in Baltimore, MD, Lupin Pharmaceuticals, Inc. is dedicated to delivering high-quality, branded and generic medications trusted by healthcare professionals and patients across geographies.

Lupin Limited, headquartered in Mumbai, India, is strongly research focused. It has a program for developing New Chemical Entities. The company has a state-of-the-art R&D center in Pune and is a leading global player in Anti-TB, Cephalosporins (anti-infectives) and Cardiovascular drugs (ACE-inhibitors and cholestrol reducing agents) and has a notable presence in the areas of diabetes, anti-inflammatory and respiratory therapy.

We are building on our parent company's strengths of vertical integration in discovery research, process chemistry, active pharmaceutical ingredient production, formulation development and regulatory filings. Lupin Pharmaceuticals, Inc. is committed to achieving its vision and mission of becoming an innovation led transnational pharmaceutical company.

Vinita Gupta, President of Lupin Pharmaceuticals, Inc. says "founded on the strengths of our parent company Lupin Limited, Lupin Pharmaceuticals, Inc. intends to bring a portfolio of generics as well as branded products to the US market."

For the financial year ended March 2008, Lupin Limited's Revenues and Profit after Tax were Rs.27, 730 million (US$ 694 million) and Rs.4, 083 million (US$ 102 million) respectively. Please visit http://www.lupinworld.com for more information about Lupin Limited.

LUPIN
PHARMACEUTICALS, INC.

Our mission is to become a transnational pharmaceutical company through the development and introduction of a wide portfolio of branded and generic products in key markets.

Generics | Specialty | API

Products

API

- Lupin is recognized as a leading manufacturer of cephalosporin API's, with FDA approval to manufacture complex oral and injectable cephalosporins.
- Lupin is fast gaining share in the cardiovascular segment manufacturing a wide range of ACE-inhibitors and cholesterol reducing agents.
- Lupin's capabilities in sterile processing, synthetic process development and fermentation skills coupled with its intellectual property strengths, puts the company in a very strong position to offer a diverse portfolio of niche API's to its customers

For ordering information please call 410-576-2000.

LUPIN
PHARMACEUTICALS, INC.

Our mission is to become a transnational pharmaceutical company through the development and introduction of a wide portfolio of branded and generic products in key markets.

Products

Generics

Lupin Pharmaceuticals, Inc. entered the U.S. generic pharmaceutical market in 2003 with the ANDA approval for cefuroxime axetil. Since then we have received more than a dozen FDA approvals. Six of Lupin's 14 ANDA approvals were the first granted by the US FDA, reinforcing our ability to submit high quality dossiers and gain on time approvals.

We are vertically integrated, from process development of the API to the submission of dossiers for finished dosages. This provides control over the supply chain and the ability to offer quality products at the right time and at competitive prices.

Our integrated manufacturing capability provides a portfolio of the highest quality generic products.

Expanding the product portfolio, Lupin Pharmaceuticals, Inc. is geared to file 15 or more ANDA's per year in some of the following areas:

- Oral and injectable cephalosporins;
- Cardiovascular;
- Controlled release ANDA's,
- Paragraph IV's.

Our oral and injectable cephalosporin facilities, US FDA approved manufacturing sites and the new tablet and capsule facility in Goa, allow us to file and manufacture a wide range of finished products for the US market.

LUPIN
PHARMACEUTICALS, INC.

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Products

Generics

Lupin Pharmaceuticals, Inc. entered the U.S. generic pharmaceutical market in 2003 with the ANDA approval for cefuroxime axetil. Since then we have received more than a dozen FDA approvals.

Specialty

Lupin Pharmaceuticals, Inc., is very pleased to offer Suprax®, an important anti-infective product in pediatric and other physician practices within the United States. Suprax® is now available in tablets and suspension formulations. Lupin Pharmaceuticals, Inc., has an exclusive license in the United States to use the Suprax® trademark.

API

Lupin is recognized as a leading manufacturer of cephalosporin API's, with FDA approval to manufacture complex oral and injectable cephalosporins.

LUPIN
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Newsroom

Lupin is granted USFDA approval for Levetiracetam Tablets	**Jan 16, 2009**
View	
Lupin Receives "Supplier Award of Excellence" from Wal-Mart	**Sept 17, 2008**
View	
Lupin receives USFDA approval for Divalproex Sodium Delayed-Release Tablets	**July 29, 2008**
View	
Lupin appoints New NCE Research Head.	**June 26, 2008**
View	
Lupin Enters Into Marketing Alliance with ASCEND Therapeutics for SUPRAX® 400 mg Tablets in the U.S.	**June 23, 2008**
View	
Lupin receives USFDA approval for Escitalopram Oxalate Tablets	**June 16, 2008**
View	
Lupin launches Ramipril capsules	**June 10, 2008**
View	
Lupin receives USFDA approval for Topiramate Tablets	**May 29, 2008**
View	
Lupin Receives "Best New Manufacturer of the Year" Award from AmerisourceBergen	**July 30, 2007**
View	
Lupin receives final approval for Amlodipine Tablets	**July 12, 2007**
View	

LUPIN
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LUPIN PRODUCTS

GENERICS
Lupin Pharmaceuticals, Inc. entered the U.S. generic pharmaceutical market in 2003 with the ANDA approval for cefuroxime axetil.

SPECIALTY
We are very pleased to be able to bring Suprax® an important anti-infective product in pediatric practice, back to the US market.

API
We are recognized as a leading manufacturer of cephalosporin API's, with FDA approval to manufacture complex oral and injectable cephalosporins.

ABOUT LUPIN

LUPIN
Lupin is amongst the world's largest manufacturers of products in its chosen therapeutic areas.

Click here for

Lupin Somerset **Medical Information**

OUR BRANDS

Methylphenidate HCl®
Chewable Tablets
2.5mg · 5mg · 10mg
The Only Short Acting, IR Chewable Tablet Available!

Methergine

InspiraChamber

NEWS SECTION...

- Lupin Launches Generic Pristiq® Tablets in the US
- Lupin Launches Generic Temovate® Clobetasol Propionate Scalp Application in the US
- Lupin Launches Generic Ortho-Cyclen® 28 Tablets in the US
- Lupin Launches Generic MS Contin® ER Tablets in the US
- Lupin Receives Tentative Approval for Generic Livalo® Tablets
- Lupin Receives Tentative Approval for Generic Giazo® Tablets
- Lupin Receives Tentative Approval for Generic Benicar® Tablets
- Lupin Launches Generic Vfend® Tablets and Vfend® Oral Suspension in the US
- Lupin Receives FDA Approval for Generic Topicort® Ointment, 0.05%
- Lupin Receives FDA Approval for Generic Topicort® Ointment
- Lupin Receives Tentative Approval for Generic Zorvolex® Capsules
- Lupin Receives FDA Approval for Generic Norco® Tablets
- Lupin Receives FDA Approval for Generic Nuvigil® Tablets
- Lupin Receives Tentative Approval for Generic Epzicom® Tablets
- Lupin Launches Generic Activella® Tablets in the US
- Lupin Receives FDA Approval for Generic Ortho-Cyclen® 28 Tablets
- Lupin Receives FDA Approval for Generic Namenda XR® Capsules
- Lupin Receives FDA Approval for Potassium Chloride Extended-Release Capsules
- Lupin Receives FDA Approval for Generic Klor-Con® Extended-Release Tablets
- Lupin Receives Tentative Approval for Generic Lexiva® Tablets, 700 mg from US FDA
- Lupin Launches Generic Ortho Tri-Cyclen® Tablets in the US
- Lupin Receives FDA Approval for Generic ctivella® Tablets

VIEW NEWS ARCHIVES!

- Lupin Receives FDA Approvals for Generic Vfend® Tablets
- Lupin Bolsters US Brands Portfolio with Methergine® Oral Tablets
- Lupin Launches Generic Femhrt® Tablets in the US
- Lupin Launches Generic Intermezzo® Sublingual Tablets in the US
- Lupin Launches Generic Aricept® Tablets in the US
- Lupin Completes its Acquisition of GAVIS in the US
- Lupin Launches Generic Glumetza® HCI ER Tablets in the US
- Lupin Receives FDA Approval for Generic Generess® Tablets
- Lupin Receives FDA Approval for Generic Femhrt® Tablets
- Lupin receives FDA Approval for Generic Aricept® Tablets

LUPIN
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About Us

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Vinita Gupta, CEO of Lupin Pharmaceuticals, Inc. says "founded on the strengths of our parent company Lupin Limited, Lupin Pharmaceuticals, Inc. intends to bring a portfolio of generics as well as branded products to the US market."

For the financial year ended 31st March 2015, Lupin's Consolidated turnover and Profit after Tax were Rs. 125,997 million (USD 2.06 billion) and Rs. 24,032 million (USD 393 million) respectively.Please visit http://www.lupinworld.com for more information.

LUPIN
PHARMACEUTICALS, INC.

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About Us

Mission/Vision

Lupin's mission is to become a transnational pharmaceutical company through the development and introduction of a wide portfolio of branded and generic products in key markets.

Our Vision

Lupin Pharmaceuticals, Inc. is committed to bringing innovative products for the healthcare professional to improve the health and well being of individuals.

Lupin Pharmaceuticals, Inc. is well positioned for growth in the US market. We can capitalize on the strengths of our parent company, Lupin Limited:

- Scientific expertise to develop new and improved products and product line extensions;
- Manufacturing technology, expertise and infrastructure;
- Financial resources.

LUPIN
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About Us

CONTACT LUPIN PHARMACEUTICALS

Still have questions or comments? Feel free to contact us using any of the means listed on this contact page. Take the time to fill out our short contact form if you do have any questions or comments regarding Lupin Pharmaceuticals, our print publication, or any of our products!

LUPIN PHARMACEUTICALS CONTACT INFORMATION

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Baltimore, MD 21202

Phone:
866-587-4617
Fax:
866-587-4627
Email:
customerservice@lupinusa.com (for US marketed products only)
dsrm@lupinworld.com (for products marketed in India)

For employment opportunities, please send your resume to:
careers@lupinusa.com

Patients/Physicians/Pharmacists
Patients and other consumers should contact their physician with questions about prescription products and their indications. For medical information, to report an adverse event or product complaint, please call toll-free: **1-800-399-2561**

CPSA Product Certification
The Consumer Product Safety Act ("CPSA"), at § 14(a) as amended by § 102(a) of the Consumer Product Safety Improvement Act of 2008 ("CPSIA"), Public Law 110-314, requires that, for products manufactured on or after November 12, 2008, manufacturers (including importers) and private labelers of the products certify that the products comply with all applicable CPSA consumer product safety rules and similar rules, bans, standards and regulations under any other laws administered by the Commission by issuing a certificate that accompanies the product and can be furnished to certain parties.

To order a copy of Lupin's Compliance program, call toll-free: 1-800-466-1450

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About Us

Our Logo

LUPIN
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Products

Generics

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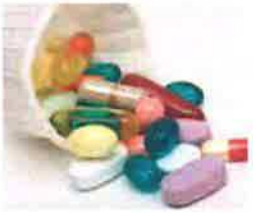
Find out More |

Specialty

Lupin Pharmaceuticals, Inc., is very pleased to offer Suprax®, an important anti-infective product in pediatric and other physician practices within the United States. Suprax® is now available in tablets and suspension formulations. Lupin Pharmaceuticals, Inc., has an exclusive license in the United States to use the Suprax® trademark.

Find out More |

API



Lupin is recognized as a leading manufacturer of cephalosporin API's, with FDA approval to manufacture complex oral and injectable cephalosporins.

Find out More |

LUPIN
PHARMACEUTICALS, INC.

Our mission is to become a transnational pharmaceutical company through the development and introduction of a wide portfolio of branded and generic products in key markets.

Products

Generics

Lupin Pharmaceuticals, Inc. entered the U.S. generic pharmaceutical market in 2003 with the ANDA approval for Cefuroxime Axetil Tablets. Since then we have received more than 75 FDA approvals and have become one of the fastest growing pharmaceutical companies in the US. Our consistent track record of growth is a result of a valuable pipeline, solid customer relationships, and flawless execution.

We are vertically integrated, from process development of the API to the submission of dossiers for finished dosages. This provides control over the supply chain and the ability to offer quality products at the right time and at competitive prices.

Our integrated manufacturing capability provides a portfolio of the highest quality generic products.

Expanding the product portfolio, Lupin Pharmaceuticals, Inc. is geared to file 20 or more ANDA's per year in some of the following areas:

- Oral and injectable cephalosporins;
- Cardiovascular;
- Controlled release ANDA's;
- Paragraph IV's.

Lupin operates a globally integrated network of 11 manufacturing facilities. Our world class facilities are built to manufacture and deliver a wide range of finished products to the US market. All facilities are in constant compliance with quality, safety, environment standards as laid down by governments and leading regulators such as the US FDA.

LUPIN
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Our mission is to become a transnational pharmaceutical company through the development and introduction of a wide portfolio of branded and generic products in key markets.

Compliance

Lupin Code of Conduct Compliance Program
View

Lupin Declaration of Compliance
View

To order a copy of Lupin's Compliance program, call toll-free: 1-800-466-1450

LUPIN PHARMACEUTICALS

Compliance Program

Lupin Pharmaceuticals, Inc. ("LUPIN") is dedicated to conducting its business in a manner consistent with all applicable laws. To that end, LUPIN is committed to establishing and maintaining a compliance program consistent with the "Compliance Program Guidance for Pharmaceutical Manufacturers", published by the Office of Inspector General, US Department of Health and Human Services (hereinafter, "OIG Guidance"); and the Code on Interactions with Healthcare Professionals, published by the Pharmaceutical Research and Manufacturers of America in 2008 (hereinafter, "PHRMA Code").

The LUPIN Compliance Program is designed to meet the requirements set forth in applicable laws and to prevent and detect violations of such laws and company policy. While LUPIN makes efforts to create policies that require proper conduct of all its employees and contractors, LUPIN cannot guarantee that all of its employees and agents will always adhere to same. Therefore, in the event LUPIN becomes aware of any violations or law or policy, it is committed to investigating the matter to determine whether disciplinary action or other corrective action is appropriate in order to prevent such occurrence from happening again in the future. While this Compliance Program is designed to meet the spirit and requirements identified in the OIG Guidance and PHRMA Code of 2008, LUPIN reserves the right to continually assess its program objectives and to continually modify its program without notice.

1. Compliance Leadership

LUPIN has identified a person within its organization who is responsible for the overall commercial compliance of the organization, including but not limited to adherence to this Compliance Program. This person has the ability to make decisions for the company with regard to its compliance and is responsible for developing, monitoring and implementing the Compliance Program. This person also reports up to the President/CEO of LUPIN and has direct access to the Board of Directors, with regard to all compliance concerns.

2. Documented Policies and Procedures

LUPIN has documented policies and procedures that address the company's expectations and management of its employees with regard to adherence to all applicable laws in the Lupin Code of Conduct. The information contained in the Code of Conduct addresses the specific risk areas identified in the OIG Guidance as well as other practice areas specific to LUPIN's business practices.

The OIG Guidance risk areas include (a) data integrity, (b) kickbacks, (c) compliance with drug sampling laws. The PHRMA Code addresses the inappropriate uses of meals, entertainment, and recreation when interacting with healthcare professionals; as well as the appropriate use of speaker programs, educational programs, consulting arrangements, training, and other issues related to interactions with healthcare personnel. In addition, there are various state laws that maintain their own restrictions, disclosures and other requirements with regard to compliance and codes of conduct. LUPIN has adopted policies and procedures designed to meet these requirements and laws.

Pursuant to California Business and Professional Code, section 119402(d)(1), LUPIN has established an annual limit on the amount it may spend on promotional activities directed at healthcare professionals. This limit is not a stated goal, but a maximum that the company sets for itself as a limitation. In most cases, the amounts actually spent are significantly less than the maximum amount set by this limitation. This limitation is also subject to ongoing review and may be changed from time to time at the discretion of the company.

3. Training

LUPIN is dedicated to an ongoing training and education program for its employees with regard to their legal and ethical obligations. LUPIN has specific documented training programs for identified areas of education and employees are required to complete certain programs in accordance with their expected job obligations. These training programs are subject to review, modification and addition from time to time, as deemed appropriate by the company. It is the policy of LUPIN to train all of its employees on the Compliance Program and Code of Conduct.

4. Communication

LUPIN encourages free flow of information, ideas and concerns with regard to its business activitics. To that end, all employees should have a communication channel to express concerns or other information about the company and its practices, especially concerns regarding compliance with the company Compliance Program or Code of Conduct. Retaliation against an employee for expressing a concern or other good faith report of a potential violation of any law or company policy is prohibited. LUPIN also has established a toll free hotline, where employees may express their concerns in an anonymous manner. LUPIN employees are also encouraged to report their concerns to their direct supervisors, Human Resources or the Compliance Department.

5. Auditing & Monitoring

LUPIN has established an audit and monitoring program with regard to its internal review of business activity of LUPIN relating to the Code of Conduct and the Compliance Program. This program includes a random and for-cause element; and is subject to change from time to time.

LUPIN is always assessing its risk of non-compliance and will focus its audits and monitoring in those areas consistent with OIG Guidance, the PHRMA Code and its own internal assessments.

6. Corrective Action

LUPIN has established disciplinary policies for those employees who violate the law or company policy. Based upon the nature of each violation, the company will investigate the matter and consider disciplinary action in accordance with company policy.

In addition, based upon the nature of any transgression or violation, and after proper investigation, the company would consider implementation of corrective action where necessary.

7. CA Spend Limit

LUPIN has established an annual spend limit of $2,000 per healthcare professional. This limitation is set for all activities for the calendar year of 2012, and is subject to change from time to time. LUPIN excludes from its spending limit calculations all items specifically excluded or allowed in the CA law sited herein.

Declaration of Compliance with LUPIN

Comprehensive Compliance Program

Lupin Pharmaceuticals, Inc. ("Lupin") hereby declares, as required by California Health & Safety Code section 119402, that to the best of its knowledge, Lupin is in all material respects, in compliance with its Comprehensive Compliance Program ("CCP").

Lupin has implemented its Comprehensive Compliance Program along with the Lupin Code of Conduct in an effort to define and adhere to those policies and procedures required under California Law and Company policy. While currently documented in the CCP, compliance is a dynamic process, constantly under review and subject to future modification . Lupin, therefore reserves the right to modify or otherwise change its CCP at any time.

In making this declaration, Lupin is not declaring or guaranteeing that all employees, contractors and vendors of the company always comply with CCP or that Lupin can prevent individual violations. That being said, Lupin expects all employees, vendors, contractors and partners to comply with the law and the CCP. The program is reasonably designed to detect and prevent violations of law. Where necessary, CCP provides for disciplinary and corrective action.

In addition, interpretation of policy and regulatory requirements may differ from company to company, and therefore Lupin makes no representation that its interpretations of any law, rule or code is consistent with those expected by the entity that established the relevant laws, rules and codes. That being said, Lupin interpretations are designed to meet the spirit and philosophy of the industry codes it adopts.

As of the date of this Declaration, the systems and processes are in place at Lupin to meet the requirements of the CCP.

Lupin Pharmaceuticals, Inc.

April 1, 2012

LUPIN
PHARMACEUTICALS, INC.

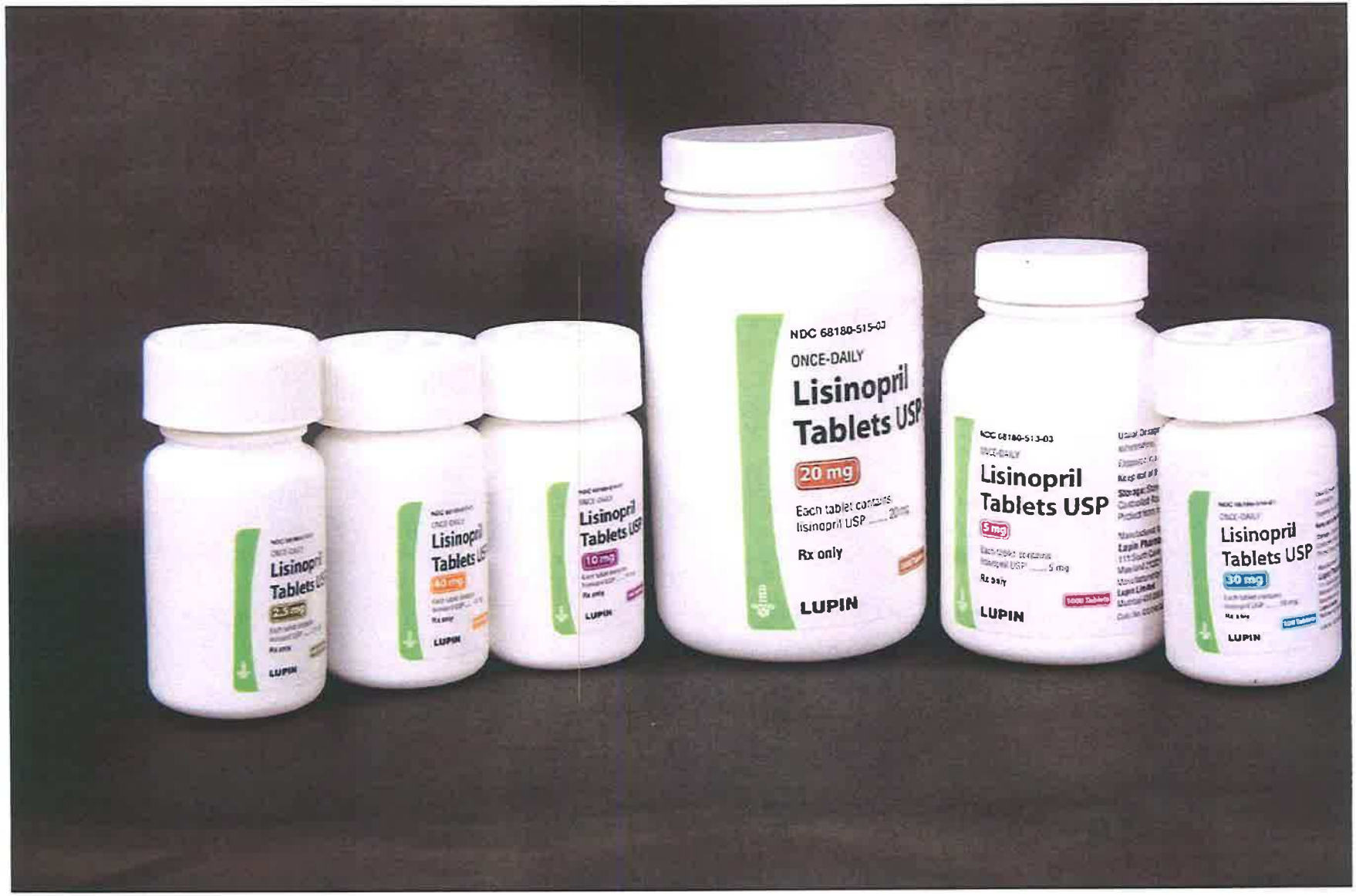
Our mission is to become a transnational pharmaceutical company through the development and introduction of a wide portfolio of branded and generic products in key markets.

Life at Lupin

Welcome to one of the most exciting growth stories in the pharmaceutical industry. At the very heart of Lupin and our phenomenal growth story is our biggest asset - Our People. We are proud of their passion and commitment to the company and the alignment of their aspirations and dreams to our shared vision. Our growth and successes are met equally by even greater steps to ensure that we not only comply but lead in areas of processes and human relations to unleash and harness innovation at every level within the organization. It is the behavior of our leadership team and our people, their shared wisdom, which has gone into creating the business democracy that is Lupin - a Company where entrepreneurship and innovation thrive.

As a closely knit team of over 14000 Lupinytts globally, we have outperformed the Industry over the last 7 years. It is against this backdrop that the Human Resources (HR) assumes a strategic and critical role. HR at Lupin has gone beyond traditional employee engagement programs to ensure that Lupin not only nurtures talent and leadership internally, but also develops platforms that help identify potential talent by creating opportunities to learn, perform and succeed. Innovative Platforms & Programs that makes Lupin amongst the best to place to work within the pharmaceutical and biotechnology industry.


Cefdinir for
Oral Suspension
125 mg/5 mL
FOR ORAL USE ONLY
SHAKE WELL BEFORE USING
LUPIN
NDC 68180-723-10
Cefdinir for
Oral Suspension
250 mg/5 mL
FOR ORAL USE ONLY
SHAKE WELL BEFORE USING
Rx only
100 mL
LUPIN
NDC 68180-711-60
Cefdinir
Capsules
300 mg
Rx only
LUPIN


NDC 68180-515-03
ONCE-DAILY
Lisinopril
Tablets USP
20 mg
Each tablet contains
lisinopril USP
Rx only
LUPIN
Lisinopril
Tablets USP
5 mg
LUPIN
Lisinopril
Tablets USP
30 mg
LUPIN


NDC 68180-611-01
Single Use Vial
Ceftriaxone for Injection USP
250 mg
For Intramuscular or Intravenous Use
Rx only
Each vial contains sterile ceftriaxone sodium USP equivalent to ceftriaxone 250 mg.
LUPIN
Ceftriaxone for Injection USP
250 mg
Rx only
LUPIN

Allergist and immunologist Jay M. Portnoy, MD, prepares for a telehealth appointment from his office at Children's Mercy Hospital in Kansas City.

Telehealth is most practical when it "incorporates data" addressing the patient's current health, symptoms and family health history, Dr. Steven says.

"Jumping online and tossing out a question to a doctor who does not know your medical history, what medications you're taking, what else is going on – that's where problems can occur," he says.

Food Allergy E-Counseling

Fallon Schultz has worked with many food allergy patients and families both in person and online through Food Allergy E-Services, a counseling company she founded in 2014. She also works closely with patients and families affected by Food Protein-Induced Enterocolitis Syndrome (FPIES), an allergic reaction that occurs in the gastrointestinal system, and is president and founder of the International FPIES Association.

"Parents of kids with food allergies often will see the doctor, get instructions on what foods to avoid and what to do in a medical emergency ... but then no one teaches them how to live with a food allergy," she says. "You're completely on your own."

Schultz, who is the mother of a child with FPIES, saw a need to counsel parents and patients on such things as ensuring proper nutrition, avoiding allergens at birthday parties and holidays and navigating a 504 Plan at school.

Through Food Allergy E-Services (*www.foodallergyeservices.com*), Schultz has helped parents cook allergy-free meals in the kitchen and gone food shopping with them – online and in real-time.

"It can be overwhelming to go shopping if you're a parent of a food-allergic child and you don't know what safe foods to look for," she says. "I will connect with you on a mobile phone or tablet and I'll be with you as you walk up and down the aisles, showing you exactly which products to buy."

Telehealth is anything but impersonal, Shultz says.

"If you have a good telehealth program, it's clear, and there's engagement, you can have the same level of connection as an in-person visit," Schultz says. "I actually think

LUP-000967

WELCOME TO

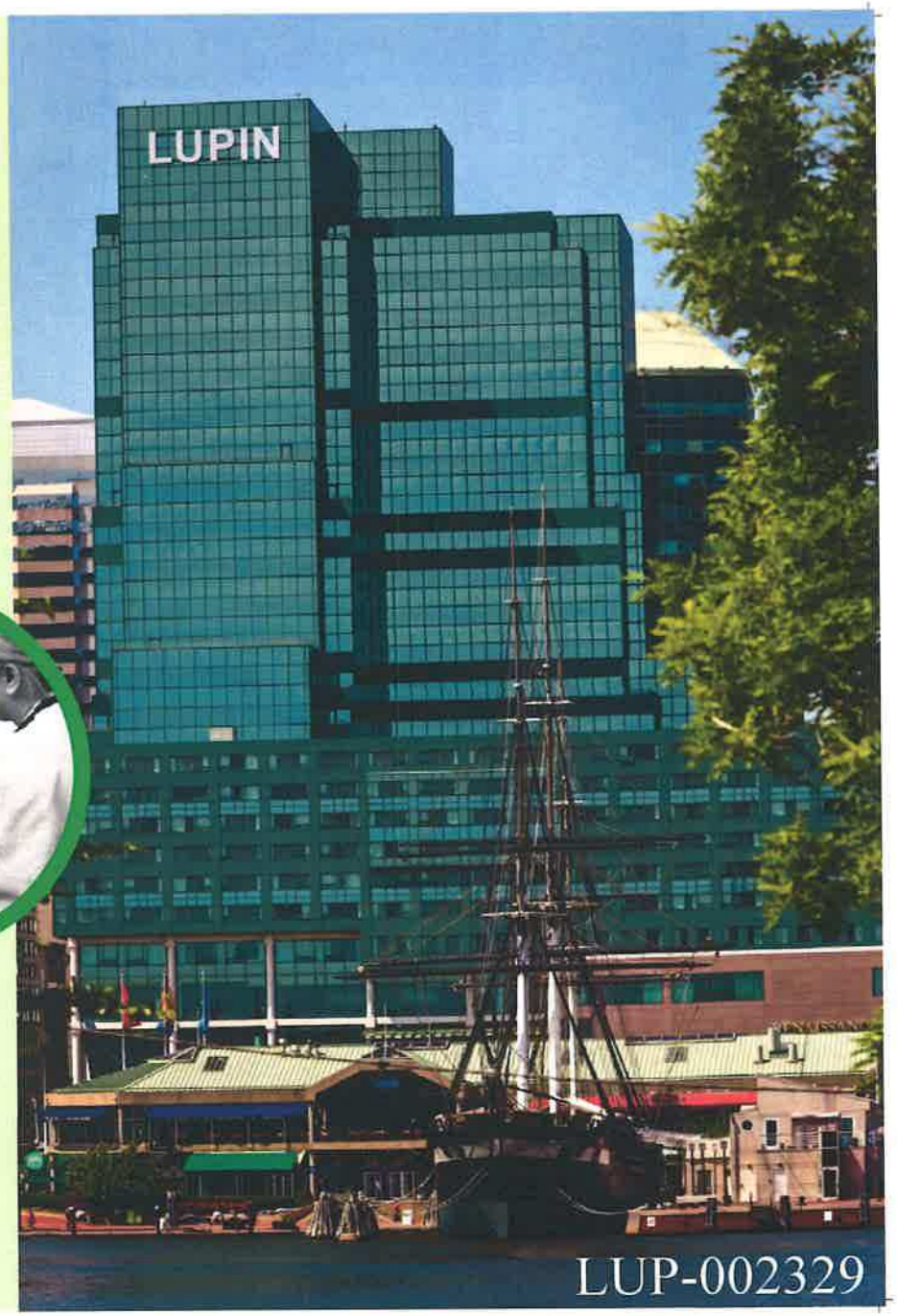
LUPIN

PHARMACEUTICALS, INC.

RESEARCH DRIVEN. QUALITY COMMITTED.

CUSTOMER FOCUSED.

AN INNOVATION LED BRANDED AND GENERIC PHARMACEUTICAL COMPANY DEDICATED TO DELIVERING HIGH-QUALITY PRODUCTS TRUSTED BY HEALTHCARE PROFESSIONALS AND PATIENTS.



72in x 48in

NOW AVAILABLE

LUPIN
PHARMACEUTICALS, INC.

BIMATOPROST OPHTHALMIC SOLUTION 0.03%

Size: 17in (W) x 24in (H)

LUP-002330

NOW AVAILABLE

LUPIN
PHARMACEUTICALS, INC.

DULOXETINE DELAYED-RELEASE CAPSULES 40MG

Size: 17in (W) x 24in (H)

LUP-002331

LUPIN
PHARMACEUTICALS, INC.

SIMVASTATIN

SIMVASTATIN ALSO AVAILABLE IN 10MG, 40MG, 80MG

Size: 17in (W) x 24in (H)

LUP-002332

ALINIA® is the only FDA-approved product for the treatment of diarrhea caused by *Giardia lamblia* or *Cryptosporidium parvum* in children 1 year of age and older[1]

Indications

ALINIA® (nitazoxanide) for Oral Suspension (patients 1 year of age and older) is indicated for the treatment of diarrhea caused by *Giardia lamblia* or *Cryptosporidium parvum*. ALINIA for Oral Suspension has not been shown to be superior to placebo for the treatment of diarrhea caused by *Cryptosporidium parvum* in HIV-infected or immunodeficient patients.

Dosing as Easy as 1 strawberry-flavored dose **2** times a day for **3** days[1]

Alinia®
(nitazoxanide) for Oral Suspension 100 mg/5 mL

NOW AVAILABLE:
The ALINIA $25 Co-Pay Savings Program*

- Insured and cash-paying patients are eligible to receive a maximum benefit up to $75, after initial co-pay of $25, for ALINIA for Oral Suspension

IMPORTANT SAFETY INFORMATION

- ALINIA® for Oral Suspension is contraindicated in patients with a prior hypersensitivity to nitazoxanide or any other ingredient in the formulation.
- The pharmacokinetics of nitazoxanide in patients with compromised renal or hepatic function have not been studied. Therefore, nitazoxanide must be administered with caution to patients with hepatic and biliary disease, to patients with renal disease and to patients with combined renal and hepatic disease.
- Diabetic patients and caregivers should be aware that the oral suspension contains 1.48 grams of sucrose per 5 mL.
- Tizoxanide, an active metabolite of nitazoxanide, is highly bound to plasma protein (>99.9%). Therefore, caution should be used when administering nitazoxanide concurrently with other highly plasma protein-bound drugs with narrow therapeutic indices, as competition for binding sites may occur (e.g., warfarin).
- Safety and effectiveness of ALINIA for Oral Suspension in pediatric patients less than 1 year of age have not been studied.
- It is not known whether nitazoxanide is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when nitazoxanide is administered to a nursing woman.
- In clinical studies involving 613 HIV-uninfected pediatric patients receiving ALINIA for Oral Suspension, the most frequent adverse events reported regardless of causality assessment were: abdominal pain (7.8%), diarrhea (2.1%), vomiting (1.1%) and headache (1.1%). These were typically mild and transient in nature. In placebo-controlled clinical trials, the rates of occurrence of these events did not differ significantly from those of the placebo. None of the 613 pediatric patients discontinued therapy because of adverse events.

Please see ALINIA® Brief Summary of Prescribing Information on the adjacent page.

Reference: 1. ALINIA® Prescribing Information

*Terms and conditions apply.

Visit us at www.alinia.com for product information and instant savings cards for your patients.

For seasonal and perennial allergic rhinitis symptoms...[1]

Prescribe AllerNaze™

E-Z on the patient[1,2]

- **Effectively relieves the most common symptom**
  - ›› Significant improvement in SSI at Weeks 1 and 2[2]
  - ›› Significant improvement in individual symptoms of sneezing, rhinorrhea, congestion, pruritis[2]
- **Well tolerated, with a 0.3% discontinuation rate due to nasal irritation[1]**
  - ›› Overall incidence of adverse events was comparable to placebo in clinical trials[1]
  - ›› 200 mcg associated with a lower incidence of epistaxis than placebo[2]
- **Convenient QD dosing**
  - ›› Recommended daily dose is 200 mcg: two 50-mcg sprays per nostril once a day[1]

Rx

AllerNaze™
50mcg
Instill 2 sprays
into each
nostril qd
Refill 3X

The replacement of a systemic corticosteroid with a topical corticosteroid can be accompanied by signs of adrenal insufficiency. Patients taking immunosuppressant drugs are more susceptible to infection than healthy individuals. **Please see IMPORTANT SAFETY INFORMATION on page 3.**

AVAILABLE

AllerNaze™ *E-Z Savings Program*

Offers savings to patients over a 12-month period

AllerNaze™ is indicated for treatment of nasal symptoms of seasonal and perennial allergic rhinitis in adults and children 12 years of age or older.

The maximum dose of AllerNaze™ should not exceed 400 mcg per day. If used, the 400-mcg dose may be given once daily (4 sprays in each nostril), or in 2 divided daily doses (2 sprays in each nostril twice daily). After symptoms are controlled, the dose should be titrated to the minimum effective dose.[1]

Please see accompanying full prescribing information.

References: 1. Allernaze™ Full Prescribing Information.
2. Data on file. Lupin Pharmaceuticals, Inc.

Ahh...
AllerNaze™
E-Z on the nose

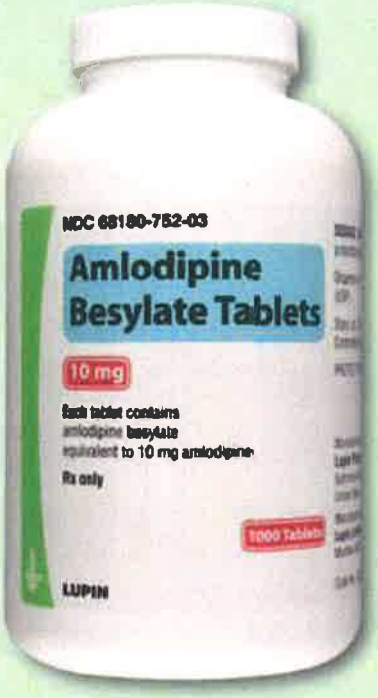
LUPIN PHARMACEUTICALS, INC.

LUP-002334

ANNOUNCING

Amlodipine Besylate Tablets

LUPIN
PHARMACEUTICALS, INC.



Lupin's Amlodipine Besylate tablets are AB-rated and bioequivalent to Norvasc®.*

NDC# 68180-	Lupin Product	Strength	Size
0750-09	Amlodipine Besylate Tablets	2.5mg	90
0751-09	Amlodipine Besylate Tablets	5mg	90
0751-03	Amlodipine Besylate Tablets	5mg	1000
0752-09	Amlodipine Besylate Tablets	10mg	90
0752-03	Amlodipine Besylate Tablets	10mg	1000

Research Driven.
Quality Committed.
Customer Focused.

For more information, contact your Lupin sales representative or call customer service at **(866) 587-4617.**

www.lupinpharmaceuticals.com

*"Norvasc" is a registered trademark of Pfizer, Inc.

AMLO907CDR

LUP-002335

ANNOUNCING

Lisinopril and Hydrochlorothiazide Tablets

LUPIN
PHARMACEUTICALS, INC.

The newest addition to our growing Lisinopril family

Lupin's Lisinopril and Hydrochlorothiazide tablets (Lisinopril/HCTZ) are AB-rated and bioequivalent to Prinzide®* tablets.

NDC# 68180-	Lupin Product	Strength	Size
0518 01	Lisinopril/HCTZ Tablets	10mg/12.5mg	100
0518-02	Lisinopril/HCTZ Tablets	10mg/12.5mg	500
0519-01	Lisinopril/HCTZ Tablets	20mg/12.5mg	100
0519-02	Lisinopril/HCTZ Tablets	20mg/12.5mg	500
0520-01	Lisinopril/HCTZ Tablets	20mg/25mg	100
0520-02	Lisinopril/HCTZ Tablets	20mg/25mg	500

Research Driven.
Quality Committed.
Customer Focused.

For more information, contact your Lupin sales representative or call customer service at **(866) 587-4617**.

www.lupinpharmaceuticals.com

*Prinzide is a registered trademark of Merck & Co., Inc.

LUP-002336

A Small Word for Big Medicine

If You Have High TGs, You May Need A Fibrate (fy' brayt)

If your TGs are too high, changing your lifestyle will help. Your doctor will advise you to eat fewer fatty foods, to exercise, and to make other changes that will improve your health.

Your doctor may also prescribe a fibrate to help lower your TGs. Fibrates can lower TGs by as much as 50%.[1] They can also increase good cholesterol (HDL) and help with bad cholesterol (LDL). Fibrates may be taken safely with some medicines that lower cholesterol. Your doctor will know which medicines can be taken together.

YOU CAN HELP LOWER TGs IF YOU:

- ☑ Improve your diet
- ☑ Eat fewer carbohydrates (breads and starches)
- ☑ Exercise
- ☑ Drink less alcohol
- ☑ Stop smoking
- ☑ Take the medicine your doctor prescribes as directed

Remember...

If you have high TGs, and you have trouble taking your medicine, please ask your doctor for help. Your doctor may suggest a smaller, easy-to-swallow medicine to help you continue taking good care of your heart.

Reference: 1. Miller M, Stone NJ, Ballantyne C, et al. Triglycerides and cardiovascular disease: a scientific statement from the American Heart Association. *Circulation*. 2011;123:2292-333.

Un nombre pequeño para una gran medicina

Si padece de niveles altos de triglicéridos, usted podría necesitar un fibrato.

Si sus niveles de triglicéridos son muy altos, cambiando su estilo de vida le podría ayudar. Su doctor le recomendará que consuma menos alimentos altos en grasa, que se ejercite y que realice otros cambios que mejorarán su salud.

Su doctor también podría recetarle un fibrato para ayudar a disminuir los niveles de triglicéridos. Los fibratos pueden disminuir hasta en un 50% los niveles de triglicéridos.[1] Además pueden aumentar los niveles de colesterol bueno (HDL) y disminuir los de colesterol malo (LDL). Los fibratos pueden se ingeridos sin problema en conjunto con medicamentos para disminuir el colesterol. Su doctor conoce cuales medicamento se pueden ingerir juntos.

USTED PUEDE CONTROLAR LOS NIVELES DE TRIGLICÉRIDOS SI :

- ☑ Mejora su dieta
- ☑ Consuma menos carbohidratos (panes y almidones)
- ☑ Se ejercita
- ☑ Disminuye el consumo de alcohol
- ☑ Deja de fumar
- ☑ Toma los medicamentos recetados por su doctor

Recuerde...

Si usted tiene niveles altos de triglicéridos, y tiene dificultades tomando sus medicamentos, pídale ayuda a su doctor. Él le podría recomendar una píldora de menor tamaño y fácil de tragar, que continue ayudándole a cuidar de su salud cardíaca.

Reference: 1. Miller M, Stone NJ, Ballantyne C, et al. Triglycerides and cardiovascular disease: a scientific statement from the American Heart Association. *Circulation*. 2011;123:2292-333.

LUPIN PHARMACEUTICALS, INC.

Para más información, visite nuestro sitio web www.antararx.com.

Ask for Us by Name

LUPIN
PHARMACEUTICALS, INC.

Lupin Pharmaceuticals, Inc. shares the strengths of our 40-year-old India-based parent company and the generics experience of our U.S.-based sales and marketing team.

Lupin has introduced 9 drugs and received 12 USFDA approvals since launching our generics division in December 2005. These new drugs, and our aggressive goal of more than 20 ANDA filings per year, are supported by sophisticated, vertically integrated operations. Because we control every step—from research to API production and formulation development to manufacturing—we are able to produce high-quality, affordable pharmaceuticals and enhance speed-to-market.

With our rich pipeline and commitment to customer service, Lupin is poised to meet the needs of today's pharmaceutical marketplace for years to come.

Research Driven.
Quality Committed.
Customer Focused.

(866) 587-4617 • www.lupinpharmaceuticals.com

LUP-002338

BIMATOPROST OPHTHALMIC SOLUTION, 0.03%

Currently the Only Generic Bimatoprost Ophth Sol, 0.03% Available†

Same active ingredient, different strength as Lumigan®* (bimatoprost ophthalmic solution) 0.01%

*"Lumigan" is a registered trademark of Allergan

†As of 5/9/2016

LUP-002339

LUPIN PHARMACEUTICALS, INC.

BIMA0300-V3-0516

BIMATOPROST OPHTHALMIC SOLUTION, 0.03%

Currently the Only Generic Bimatoprost Ophth Sol, 0.03% Available†

Same active ingredient, different strength as Lumigan®* (bimatoprost ophthalmic solution) 0.01%

LUPIN
PHARMACEUTICALS, INC.

*Lumigan® is a registered trademark of Allergan

†As of 6/2/2016

BIMATOPROST OPHTHALMIC SOLUTION, 0.03%

Currently the Only Generic Bimatoprost Ophth Sol, 0.03% Available†

Same active ingredient, different strength as Lumigan®* (bimatoprost ophthalmic solution) 0.01%

*Lumigan® is a registered trademark of Allergan

†As of 5/9/2016

BIMA0600-V3-0516

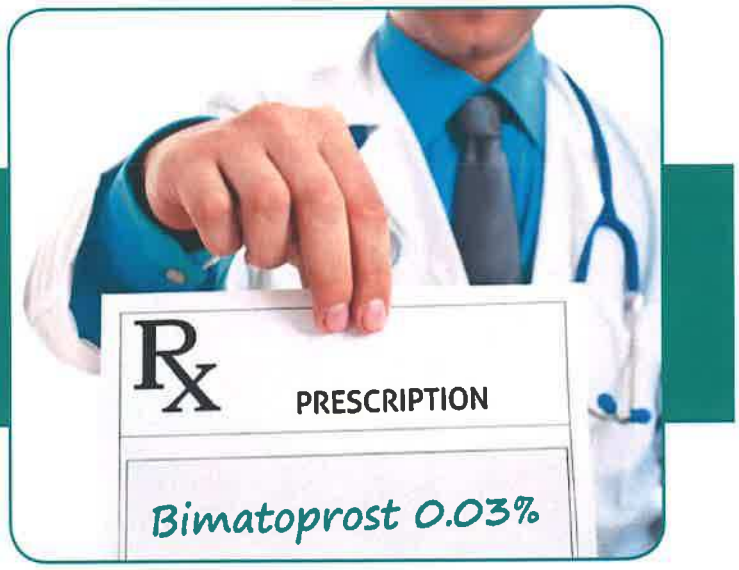
LUP-002341

LUPIN PHARMACEUTICALS, INC.

BIMATOPROST 0.03% OPHTHALMIC SOLUTION

A generic alternative to LUMIGAN®*

Potentially save your patients money on their treatment



Dispense generic Bimatoprost 0.03%

Same active ingredient as LUMIGAN®*

- A generic alternative to LUMIGAN®
- First generic bimatoprost on the market

NDC # 68180-	Size
429-01	2.5mL in a 5mL bottle
429-02	5mL in a 10mL bottle
429-03	7.5mL in a 10mL bottle

Currently the Only Generic Available

Important Safety Information

Bimatoprost ophthalmic solution 0.03% has been reported to cause darkening (pigmentation) of eye color, eyelid skin, and eyelashes as well as increased growth of eyelashes. Pigmentation changes can increase as long as bimatoprost ophthalmic solution 0.03% is used. After stopping bimatoprost ophthalmic solution 0.03%, darkening of eye color is likely to be permanent, while darkening of the eyelid skin and eyelash changes may be reversible. The effects of increased darkening beyond 5 years are not known. When only one eye is treated, there is a possibility of eyelash changes in the eye treated with bimatoprost ophthalmic solution 0.03%. These changes may result in differences between the eyes in eyelash length, thickness, darkness, number of eyelashes, and/or direction of eyelash growth. These changes are usually reversible upon stopping bimatoprost ophthalmic solution 0.03% therapy. Patients should avoid allowing the tip of the dispensing container to contact the eye, surrounding structures, fingers, or any other surface in order to avoid contamination of the solution by common bacteria known to cause ocular infections. Serious damage to the eye and subsequent loss of vision may result from using contaminated solutions. In the event patients develop an intercurrent ocular condition (e.g., trauma or infection), have ocular surgery, or develop any ocular reactions, particularly conjunctivitis and eyelid reactions, they should immediately seek their physician's advice concerning the continued use of bimatoprost ophthalmic solution, 0.03%. Contact lenses should be removed prior to instillation of bimatoprost ophthalmic solution, 0.03% and may be reinserted 15 minutes following its administration. The most common side effects are conjunctival hyperemia, growth of eyelashes, and ocular pruritus.

For additional information and Full Prescribing Information, Please visit www.lupinpharmaceuticals.com

LUPIN PHARMACEUTICALS, INC.

*Bimatoprost 0.03% has the same active ingredient but is a different strength than Lumigan® 0.01%

BIMA06012015UBP

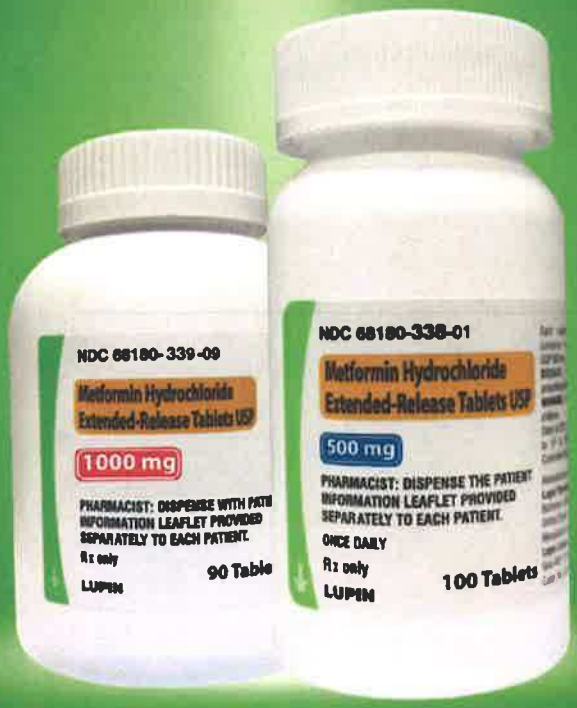
LUP-002342

NOW AVAILABLE

LUPIN
PHARMACEUTICALS, INC.

Metformin Hydrochloride Extended-Release Tablets USP

AB3 Rated to Glumetza®*



NDC #68180-	Molecule	Dosage Form	Strength	Size
0338-01	Metformin Hydrochloride	Extended-Release Tablet	500 mg	100
0339-09	Metformin Hydrochloride	Extended-Release Tablet	1000 mg	90

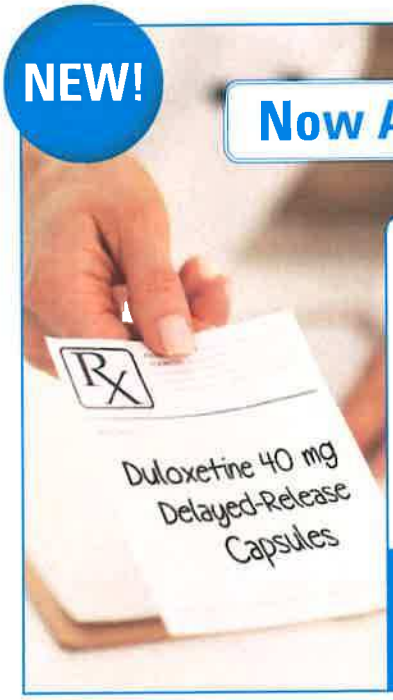
*Glumetza® is a registered trademark of Santarus, Inc.

Grow with us. Call (866) 587-4617 to place your order today.

METFOR041816CDR

NEW!

Now Available!



Generic Duloxetine 40 mg Delayed-Release (DR) Capsules

- The FIRST & ONLY Generic 40 mg Duloxetine DR Capsule formulation on the market
- Same active ingredient as Cymbalta® (duloxetine delayed-release capsules)
- Adds to the available dosing options for greater flexibility of treatment

Prescribe Generic Duloxetine 40 mg Delayed-Release Capsules

✓ If using an EMR system, please make sure to search by molecule name

✓ If writing a script, please note the importance of writing the molecule name and strength to ensure proper dispensing at the pharmacy

See important safety information including BLACK BOX WARNING below
For ordering information, please call: 1-800-399-2561

LUPIN PHARMACEUTICALS, INC.

www.lupinpharmaceuticals.com

Cymbalta® is a registered trademark of Eli Lilly and Co.

IMPORTANT SAFETY INFORMATION

WARNING: SUICIDAL THOUGHTS AND BEHAVIORS

- **Increased risk of suicidal thinking and behavior in children, adolescents, and young adults taking antidepressants.**
- **Monitor for worsening and emergence of suicidal thoughts and behaviors.**

INDICATIONS:

Duloxetine delayed-release (DR) capsules USP are a prescription medication used to treat or manage: Major Depressive Disorder, Generalized Anxiety Disorder, Diabetic Peripheral Neuropathic Pain, Chronic Muscleoskeletal Pain.

SELECT IMPORTANT SAFETY INFORMATION:

Patients should NOT take Duloxetine if:

- They are currently on or have stopped treatment with a monoamine oxidase inhibitor (MAOI) within the last 14 days. Patients should not be treated with an MAOI within 5 days of stopping treatment with duloxetine, as this could cause serious or life-threatening side effects.
- They are currently being treated with linezolid or intravenous methylene blue.
- They are currently being treated with inhibitors of CYP1A2 or thioridazine.

SELECT ADDITIONAL WARNINGS & PRECAUTIONS:

Avoid use in patients with chronic liver disease or cirrhosis as hepatic failure, sometimes fatal, has been reported in patients treated with duloxetine. Duloxetine should be discontinued in patients who develop right, upper abdominal pain, jaundice or other evidence of clinically significant liver dysfunction. Duloxetine should be avoided in patients with severe renal impairment, and should not be prescribed to patients with substantial alcohol use. Cases of orthostatic hypotension, falls and syncope have been reported with duloxetine therapy. Serotonin Syndrome has been reported with SSRIs and SNRIs, including with duloxetine, both when taken alone, but especially when co-administered with other serotonergic agents (including triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, tryptophan, buspirone and St. John's Wort). Patients should be monitored for the emergence of Serotonin Syndrome and if symptoms occur, discontinue duloxetine and initiate supportive treatment. Duloxetine may increase the risk of bleeding events. Patients should be cautioned about the risk of bleeding associated with the concomitant use of duloxetine and NSAIDs, aspirin, or other drugs that affect coagulation. Severe skin reactions can occur with duloxetine. Duloxetine should be discontinued at the first appearance of blisters, peeling rash, mucosal erosions, or any other sign of hypersensitivity if no other etiology can be identified. Discontinuation of duloxetine may result in symptoms, including dizziness, headache, nausea, diarrhea, parasthesia, irritability, vomiting, insomnia, anxiety, hyperhidrosis, and fatigue. Activation of mania or hypomania has occurred in patients treated with duloxetine. Angle-closure glaucoma has occurred in patients with untreated anatomically narrow angles treated with antidepressants. Duloxetine should be prescribed with care in patients with a history of seizure disorder, and blood pressure should be monitored prior to initiating treatment and periodically throughout treatment. Cases of hyponatremia have been reported in patients treated with duloxetine. Duloxetine may worsen glucose control in diabetes. In diabetic peripheral neuropathic pain patients, small increases in fasting blood glucose, and HbA have been observed. The most common adverse reactions include: dry mouth, somnolence, constipation, decreased appetite, and hyperhidrosis. Duloxetine may cause fetal harm, so talk to your patients if they are or plan to become pregnant. Caution should be exercised when duloxetine is administered to nursing mothers.

Click here for Full Prescribing Information including BOXED WARNING and Medication Guide

LUPIN
PHARMACEUTICALS, INC.
Research Driven. Quality Committed. Customer Focused.™

Lupin's Global Team Delivers High-Quality Generics

Lupin is a fully integrated pharmaceutical company with an unrivaled position built on a backbone of cutting-edge research, world-class manufacturing facilities and a truly global supply chain. It is well on its way to becoming a global specialty pharmaceutical company offering a wide portfolio of generic and branded products.

With global revenues surpassing $1.4 billion, Lupin is currently ranked the 14th largest generic pharmaceutical company in the world. Lupin Pharmaceuticals, the company's U.S. subsidiary, has grown to emerge as a $500 million enterprise in just over 8 years. Lupin's focus on flawless execution has enabled it to become the leader in half of the products it markets.

Based on total prescriptions dispensed, Lupin has been the fifth largest and one of the fastest growing generic pharmaceutical players for three consecutive years.

Since the launch of its generics division in December 2005, Lupin has introduced a total of 42 new products in more than 200 dosage strengths and packaging sizes, covering many major therapeutic categories in the U.S. market.

New products

Lupin's sustained growth performance is measured not only in numbers, but also in its ability to continue to enter new segments and launch products that are first to market.

For example, Lupin was the first to introduce an FDA-approved generic equivalent of Shionogi's Fortamet® (metformin HCl extended release tablets).

Lupin introduced 13 new generic products in 2011. Three of them were oral contraceptives, a new category for the company, which now expects approvals for approximately 30 new oral contraceptives over the next few years.

Between January 2011 and July 2012, the company was granted final FDA approval on 15 new products.

In the pipeline

By investing 7.5% of its net sales in R&D, Lupin has created one of the best generic product pipelines in the world. That pipeline is now entering new therapeutic areas, such as dermatologicals and oncology, and new dosage forms, such as ophthalmics and otics.

Lupin continues to maintain its position as one of the Top 10 ANDA filers for the US market. Between January 2011 and June 2012, the company filed 39 ANDAs with the U.S. FDA. The company now has 23 cumulative first-to-file opportunities for the U.S. generics market.

Meeting the growing demand

In order to meet the demand of the U.S. generic pharmaceutical market, Lupin has expanded manufacturing capacities over the last several years at all of its best-in-class manufacturing facilities, and it continues to strengthen its efficient supply chain. It has also taken new technological initiatives in energy conservation and environmental protection. These capital expenditures are focused on meeting the growing demands of Lupin's customers.

The company's focus on technology and differentiation enables it to charter into new areas of business, such as unique therapeutic categories and difficult-to-manufacture drugs. Lupin is prepared with a rich pipeline consisting of niche products, first-to-files, and products that require dedicated facilities or that have high barriers to entry.

Lupin's consistent track record of growth is a direct result of its valuable pipeline, solid customer relationships, and flawless execution.

With a commitment to grow the company with new market entries, exciting new launches, and a series of strategic investments in acquisitions, Lupin Pharmaceuticals, Inc. remains dedicated to exceeding the expectations of its trade partners.

Lupin's Recent Generic Launches	Brand Equivalent
Levonorgestrel and Ethinyl Estradiol Tablets USP	LoSeasonique®
Lamivudine and Zidovudine Tablets USP	Combivir®
Metformin HCl Extended Release Tablets	Fortamet®
Quetiapine Fumarate Tablets	Seroquel®
Ziprasidone HCl Capsules	Geodon®

LUPIN
PHARMACEUTICALS, INC.

BUILT TO GROW—Lupin has now recorded 8 consecutive years of strong growth, making them the 14th largest generic pharmaceutical company in the world by revenue. Lupin is dedicated to delivering high-quality branded and generic medications, trusted by healthcare professionals and patients across the U.S. Lupin is the 5th largest generic manufacturer in the U.S. (by prescriptions) and one of the fastest growing generic pharmaceutical companies in the U.S. This continuous growth can be attributed to a strong pipeline, solid customer relationships, and flawless execution.

SUSTAINED GROWTH—Lupin's sustained growth in revenue stems from a culmination of entities. They have forged a unique growth strategy for the Advanced Markets built around quality niche products, world-class research, manufacturing, and supply chain capabilities. Lupin recognizes the importance of R&D and has invested 7.5% of its FY 2012 net sales in this area. In FY 2013, the U.S. Generics business reported growth of 52% with revenues of $548 million USD, up from $361 million USD in FY 2012.*(unaudited figures)*

SUPPLY CHAIN—As the demands of the U.S. generic pharmaceutical market continue to grow, so does Lupin. Lupin have expanded their manufacturing capabilities over the past several years with additional state-of-the art facilities to exceed customer demands and strengthen their overall supply chain by creating efficiencies that ensure a cutting edge response time, thus creating unrivaled value. Lupin has earned its reputation as a global pharmaceutical company on the back of consistent and reliable delivery of high-quality products. Lupin's customers trust them to act responsibly and deliver safe and effective medications at affordable costs.

BY THE NUMBERS

- **58 total generic products**
- **Launched 13 generic products in FY 2013**
- **FY 2013 Revenue of $548 million USD**

API—Lupin's global formulations business is built on the backbone of one of the most efficient API businesses in the world. Lupin is one of the most vertically integrated global generic companies and remains the leader in therapeutic areas such as Cephalosporins, Cardiovasculars, and anti-TB products.

THE LUPIN FLOWER— The company was named after the Lupin flower because of the inherent qualities of the flower and what it personifies and stands for. The Lupin flower is known to nourish the land; the very soil it grows in. The Lupin flower is also known to be tolerant of infertile soils and capable of pioneering change in barren and poor climates.

THE FUTURE—Lupin is a fully integrated pharmaceutical company with a major global presence. This presence was built on its platforms of cutting-edge research, world-class manufacturing facilities, and a truly global supply chain. With these building blocks in place, the future looks even brighter.

www.lupinpharmaceuticals.com

Recent Generic Launches	Brand Equivalent
Fenofibrate Tablets	TriCor®
Valsartan & Hydroclorothiazide Tablets USP	Diovan HCT®
Irbesartan & Hydrochlorothiazide Tablets USP	Avalide®
Levonorgestrel and Ethinyl Estradiol Tablets USP	Lutera®
Daysee™ (Levonorgestrel & Ethinyl Estradiol Tablets USP)	Seasonique®

LUPIN
PHARMACEUTICALS, INC.
Research Driven. Quality Committed. Customer Focused.™

Lupin's Global Integrated Team Focuses on Delivering High-Quality Generics

Lupin Pharmaceuticals, Inc. (LPI), a wholly owned subsidiary of Lupin Ltd., is among the top 4 pharmaceutical companies in India. With its sales and marketing headquarters located in Baltimore, Md., LPI is dedicated to delivering affordable, high-quality generic medications.

Recognized as one of the top 10 fastest-growing generic manufacturers for the third year in succession, LPI's prescribing rate has grown more than 51%. LPI's generics business is ranked 5th in total generic prescriptions dispensed, according to IMS Health's National Prescription Audit (March 2011).

"The U.S. generic business is one of Lupin's primary drivers of value creation," said Bob Hoffman, Senior Vice President, Sales and Marketing, Generics Division. "Lupin continues to increase its market share for most of its marketed products through increased focus on execution, strong relationships with trade partners, and an efficient and responsive supply chain, all supported by a globally integrated team determined to explore better ways to create value."


Bob Hoffman

Of the 30 generic products marketed in the United States, 14 are market leaders in terms of market share. Lupin holds the top 3 positions in 27 of these 30 generic products, and its growth is driven equally by inline as well as new product introductions. "A very lucrative product pipeline, new product launches, deep customer relationships, and world-class intellectual property capabilities have been the key to the success of our U.S. generics business," said Hoffman. "As the fastest growing generic player in the United States, we believe that we have the required momentum in place to accelerate this growth further. The ceiling is far from reached as we are yet to realize the true value of one of the best generic pipelines in the U.S. market."

A Robust Pipeline

Lupin continues to invest in building up its robust pipeline of important new products. During the 2011 fiscal year, the company filed 21 Abbreviated New Drug Applications (ANDAs) with the FDA, including a record 9 which were first-to-file, and received 8 approvals. The cumulative number of ANDA filings made by Lupin now stands at 148, with 48 approvals received to date. Of these, 77 Paragraph IV filings have been made and the cumulative first-to-file opportunities for the U.S. generics market now stands at 20. Lupin continues to maintain its position as one of the top 10 ANDA filers for the U.S. market.

Over the last few years, LPI has made significant investments to expand its product offerings in the United States as well as through strategic partnerships. One major internal initiative is its imminent entry into the oral contraceptive market. Further, LPI continues to seek business development opportunities that are aligned with its strategic vision.

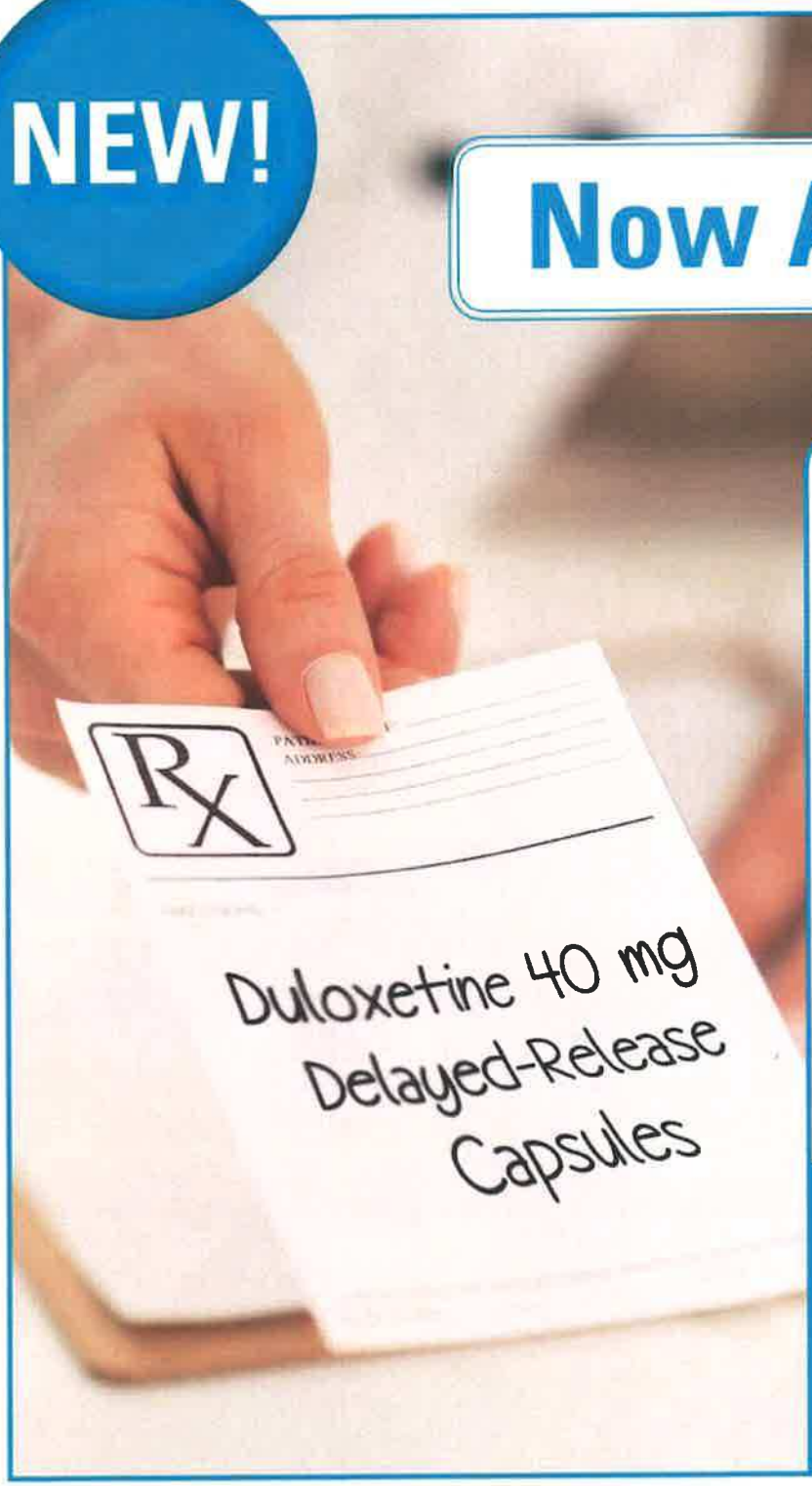
Vertical Integration

Lupin's success rests on its efficient vertically integrated business model. With consistent and continued investments in augmented manufacturing capacities, its capabilities are completely attuned to its growth aspirations. State-of-the-art manufacturing plants support the delivery of quality and scale. Integration of capabilities and capacities ensures delivery of a wide product portfolio catering to the needs of diverse markets. Lupin's manufacturing teams strive to ensure that global standards of best manufacturing practices are implemented at every Lupin facility. Lupin's goal is to deliver the best products all the time, every time. Our customers can depend on Lupin's vigilant compliance and assured quality for their patients' peace of mind.

Our reliability creates peace of mind. Call **866-587-4617** for more information or visit **www.lupinpharmaceuticals.com.**

NEW!

Now Available!



Generic Duloxetine 40 mg Delayed-Release (DR) Capsules

- The FIRST & ONLY Generic 40 mg Duloxetine DR Capsule formulation on the market
- Same active ingredient as Cymbalta® (duloxetine delayed-release capsules)
- Adds to the available dosing options for greater flexibility of treatment

Prescribe Generic Duloxetine 40 mg Delayed-Release Capsules

✓ If using an EMR system, please make sure to search by molecule name

✓ If writing a script, please note the importance of writing the molecule name and strength to ensure proper dispensing at the pharmacy

See Important Safety Information including BLACK BOX WARNING on reverse side

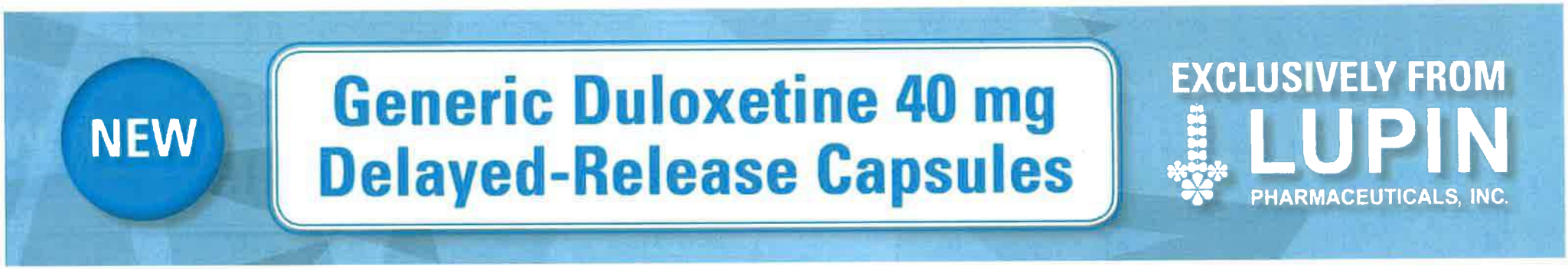
For ordering information, please call: 1-800-399-2561

LUPIN PHARMACEUTICALS, INC.

www.lupinpharmaceuticals.com

Cymbalta® is a registered trademark of Eli Lilly and Co.

LUP-002352


NEW
Generic Duloxetine 40 mg
Delayed-Release Capsules
EXCLUSIVELY FROM
LUPIN
PHARMACEUTICALS, INC.

Launched in December 2005, Lupin Pharmaceuticals, Inc.'s generics division is one of the segment's fastest growing companies. It is ranked fourth in absolute growth for total prescriptions dispensed.* And it is growing aggressively.

We currently have over 20 drugs in the market and countless more in the pipeline. With a goal of 25 to 30 ANDA filings per year, we will continue to leverage the shared strengths of our vertically-integrated India-based parent company along with the generics experience of our U.S.-based sales and marketing team. Together we will bring you and your customers the affordable, high-quality generic solutions you both need.

And that creates an unrivaled opportunity for your generics business.

Research Driven.
Quality Committed.
Customer Focused.

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Grow with us. Call (866) 587-4617 or visit us at www.lupinpharmaceuticals.com

*Source: IMS Health, National Prescription Audit, June 2008.

LUP-002354

AVAILABLE WITHOUT A PRESCRIPTION

BIOEQUIVALENT TO PLAN B ONE-STEP®

An OTC alternative to Plan B One-Step® is now available from Lupin Pharmaceuticals

NDC Number	**68180-853-13**
Quantity	**Each package contains a simple, 1 tablet treatment**
Shelf life	**Store at a controlled room temperature**
Description	**Tablet is white to off-white in color, round, biconvex shaped. Debossed with LU on one side and S25 on the other.**

- ***Fallback Solo™* is bioequivalent to Plan B One-Step®**
- ***Fallback Solo™* is a new generic product from Lupin Pharmaceuticals, Inc.**
- **The sooner *Fallback Solo™* is taken, the more effective it is - within 72 hours of unprotected sex, sexual attack or known or suspected contraceptive failure**
- ***Fallback Solo™* should not be taken as a routine form of birth control**
- **Stocking up on *Fallback Solo™* gives your customers access to the emergency contraception they need, when they need it**

LUPIN
PHARMACEUTICALS, INC.
www.birthcontrolhealth.com

Fallback Solo™ is an FDA-approved emergency contraceptive that can prevent a pregnancy up to 72 hours after unprotected sex, sexual assault or contraceptive failure (for example, if the condom broke or if a birth control pill was missed.)

LUP-002355

LUPIN

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Consistently Exceeding Expectations

Lupin Pharmaceuticals, Inc. (LPI) headquartered in Baltimore, Maryland has a strong record of growth and consistency in its production of delivering high quality, affordable generic medications. Lupin is currently the 6th largest generic pharmaceutical company in the US by prescription and 3rd largest pharmaceutical company in India. It is one of the fastest growing top 10 pharmaceutical corporations in the US; 4.3% market share growing at 9% (market share by prescriptions). With a strong pipeline, reliability and delivery of excellence, Lupin continues to exceed expectations.

Booming Pipeline – Lupin's sustained growth performance has been exceptionally outstanding in not only numbers but in the continued ability to enter new divisions and launch a variety of products. 30 of the 77 generic products marketed by LPI in the US are ranked No. 1 by market share and 55 of these 77 are in the top 3 by Market share (IMS health). During the 2015 fiscal year, the company filed 18 Abbreviated New Drug Applications (ANDAs) with the FDA and now has 99 ANDAs pending for approval and launch, addressing a total market size of over 61 billion USD. Of these, 34 ANDAs are first-to-file addressing a market size of over 8 billion USD. Lupin also has 15 exclusive first-to-file ANDAs addressing a market size of approximately 2.5 billion USD. Lupin continues to maintain its position as one of the top 10 ANDA filers for the U.S. market.

Over the last few years, Lupin has made significant efforts to expand its product offerings in the United States. It has diversified its portfolio and has expanded its platform with the introduction of more oral contraceptives, ophthalmics, transdermals, inhalations, narcotics and more. Additionally, LPI continues to strategically seek more business development opportunities.

Delivering Consistent Quality – Lupin continues to commit to quality and supply. Lupin has implemented a corporate culture of excellence—ensuring all evolving regulatory requirements are met and delivering the highest quality standards in everything that is done from Research and Development (R&D) through commercialization.

Lupin has also restructured its Quality, Operations, and New Product Launch Organizations to meet the increasing healthcare demands. Lupin's Global Supply Chain Organization (GSCO) was set up to ensure that its products not only reach patients and its key customers "on-demand" and "in-time" but to also ensure that it puts in place systems and advanced forecasting tools that enable them to plan and build capacities accordingly. Lupin's supply chain's ability to provide consistency and efficiency has made Lupin a preferred and reliable supplier of generics to the US.

RECENT GENERIC LAUNCHES	BRAND EQUIVALENT
Memantine HCl Tablets USP	Namenda®
Valsartan Tablets USP	Diovan®
Lamivudine Tablets	Epivir®
Amlodipine & Valsartan Tablets	Exforge®
Bimatoprost Ophthalmic Solution, 0.03%	Lumigan®

Thinking Forward – Lupin has historically been aggressive in its approach to research and development. The company has globally invested more than 8% of its FY 2015 net sales in this area and has expanded its R&D team to over 1,200 people. The Company's Pharmaceuticals & API research program has been the primary growth driver in pushing Lupin's rise as a global generics and specialty pharmaceutical company. FY 2015 was also a year where Lupin not only operationalized and ramped up infrastructure and resources at its new inhalation facility in Florida, US, but also added injectable product development capabilities at its global R&D hub near Pune, India. Lupin also further strengthened its existing product development facilities for Dermatology and Inhalation. Lupin's strategic investments indicate its focus to create a highly differentiated global pipeline of complex generic products and continue to remain dedicated to exceeding the expectations of its trade partners.

-
- 77 total generic products


Congratulations
and best wishes
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School of
Medicine's Class
of 2016!
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LUP-002371

Profile

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Lupin Pharmaceuticals, Inc.

Built to Grow

Lupin has now recorded 8 consecutive years of strong growth, making it the 14th largest generic pharmaceutical company in the world by revenue. Lupin is dedicated to delivering high-quality branded and generic medications, trusted by health care professionals and patients across the US, making it the 5th largest generic manufacturer in the US (by prescriptions) and one of the fastest-growing generic pharmaceutical companies in the US. The continuous growth can be attributed to a strong pipeline, solid customer relationships, and flawless execution.

Sustained Growth

Lupin's sustained growth in revenue stems from a culmination of entities. It has forged a unique growth strategy for the Advanced Markets built around quality niche products, world-class research, manufacturing, and supply chain capabilities. Lupin recognizes the importance of R&D and has invested 7.5% of its FY 2012 net sales in this area. In FY 2013, the US Generics business reported growth of 52%, with revenues of $548 million USD, up from $361 million USD in FY 2012 (unaudited figures).

Supply Chain

As the demands of the US generic pharmaceutical market continue to grow, so does Lupin. Lupin has expanded its manufacturing capabilities over the past several years with additional state-of-the art facilities to exceed customer demands and strengthen its overall supply chain by creating efficiencies that ensure a cutting-edge response time, thus creating unrivaled value. Lupin has earned its reputation as a global pharmaceutical company on the back of consistent and reliable delivery of high-quality products. Lupin's customers trust the company to act responsibly and deliver safe and effective medications at affordable costs.

By the Numbers

- **58 total generic products**
- **Launched 13 generic products in FY 2013**
- **FY 2013 revenue of $548 million USD**

RECENT GENERIC LAUNCHES	BRAND EQUIVALENT
Fenofibrate Tablets	TriCor
Valsartan & Hydrochlorothiazide Tablets USP	Diovan HCT
Irbesartan & Hydrochlorothiazide Tablets USP	Avalide
Levonorgestrel and Ethinyl Estradiol Tablets USP	Lutera
Daysee (Levonorgestrel & Ethinyl Estradiol Tablets USP)	Seasonique

API

Lupin's global formulations business is built on the backbone of one of the most efficient API businesses in the world. Lupin is one of the most vertically integrated global generics companies and remains the leader in therapeutic areas such as cephalosporins, cardiovasculars, and anti-TB products.

The Lupin Flower

The company was named after the Lupin flower because of the inherent qualities of the flower and what it personifies and stands for. The Lupin flower is known to nourish the land: the very soil it grows in. The Lupin flower is also known to be tolerant of infertile soils and capable of pioneering change in barren and poor climates.

The Future

Lupin is a fully integrated pharmaceutical company with a major global presence. This presence was built on its platforms of cutting-edge research, world-class manufacturing facilities, and a truly global supply chain. With the building blocks in place, the future looks even brighter. ■

For more information, please visit
www.lupinpharmaceuticals.com

LUP-002373

ORDERING INFORMATION

LUPIN Portfolio of Brands

LUPIN PHARMACEUTICALS, INC.

InspiraChamber
Anti-Static Valved Holding Chamber
with SootherMask™ and InspiraMask™

Product	NDC#	Description
InspiraChamber® Antistatic Valved Holding Chamber with **Small** SootherMask™ and **Small** InspiraMask™	**27437-0025-01**	1 InspiraChamber® Anti-Static Valved Holding Chamber device, 1 SootherMask™ Small mask, 1 InspiraMask™ Small mask for use with a pressurized metered dose inhaler (pMDI)
InspiraChamber® Antistatic Valved Holding Chamber with **Medium** SootherMask™ and **Medium** InspiraMask™	**27437-0026-01**	1 InspiraChamber® Anti-Static Valved Holding Chamber device, 1 SootherMask™ Medium mask,1 InspiraMask™ Medium mask for use with a pressurized metered dose inhaler (pMDI)
InspiraChamber® Antistatic Valved Holding Chamber with **Large** InspiraMask™	**27437-0043-01**	1 InspiraChamber® Anti-Static Valved Holding Chamber device, 1 InspiraMask™ Large mask for use with a pressurized metered dose inhaler (pMDI)
InspiraChamber® Antistatic Valved Holding Chamber	**27437-0024-01**	1 InspiraChamber® Anti-Static Valved Holding Chamber device for use with a pressurized metered dose inhaler (pMDI)

For more product information visit us at **www.inspirachamber.com**

Once-a-day
Suprax®
cefixime

Product	NDC#	Description
SUPRAX® (cefixime) Oral suspension 100 mg/5 mL Bottle of 50 mL	**68180-0202-03**	Off-white to pale yellow colored powder. After reconstitution, each 5 mL of reconstituted suspension contains 100 mg of cefixime as the trihydrate.
SUPRAX® (cefixime) Oral suspension 200 mg/5 mL Bottle of 50 mL Bottle of 75 mL	**27437-0206-03** **27437-0206-02**	Off-white to pale yellow colored powder. After reconstitution, each 5 mL of reconstituted suspension contains 200 mg of cefixime as the trihydrate.
SUPRAX® (cefixime) Chewable Tablets 100 mg Unit Dose Package of 10 (1 blister of 10 tablets)	**27437-0203-11**	Pink, round tablets, debossed with "SUPRAX 100" on one side and "LUPIN" on other side
SUPRAX® (cefixime) Chewable Tablets 200 mg Unit Dose Package of 10 (1 blister of 10 tablets)	**27437-0205-11**	Pink, round tablets, debossed with "SUPRAX 200" on one side and "LUPIN" on other side.
SUPRAX® (cefixime) Capsules 400 mg Unit Dose Package of 10 (1 blister of 10 capsules) Bottle of 50 capsules	**27437-0208-11** **27437-0208-08**	Pink capsules with pink opaque cap and pink opaque body, imprinted with "LU" on cap and "U43" on body in black ink, containing white to yellowish white granular powder containing 400 mg of cefixime as the trihydrate.

For more product information visit us at **www.supraxrx.com**

ORDERING INFORMATION

LUPIN Portfolio of Brands

PHARMACEUTICALS, INC.

Alinia® (nitazoxanide) for Oral Suspension 100 mg/5 mL

Product	NDC#	Description
Alinia® (nitazoxanide) for Oral Suspension 60 mL Bottle	27437-0106-01	Alinia for Oral Suspension is a pink-colored powder formulation that, when reconstituted as directed, contains 100 mg nitazoxanide/5 mL. The reconstituted suspension has a pink color and strawberry flavor.

For more product information visit us at **www.alinia.com**

ANTARA® 90 mg (fenofibrate) capsules & 30 mg

Product	NDC#	Description
ANTARA® (fenofibrate) Capsules, 30 mg 30 Capsule Bottle	27437-0107-06	Size "4" capsules with opaque light green cap and opaque light green body, imprinted with LUPIN logo and "ANTARA" in black ink on body "30" in black ink on cap, containing white to off-white pellets.
ANTARA® (fenofibrate) Capsules, 90 mg 30 Capsule Bottle 90 Capsule Bottle 100 Capsule Bottle	27437-0108-06 27437-0108-09 27437-0108-01	Size "3" capsules with opaque dark green cap and opaque white body, imprinted with LUPIN logo and "ANTARA" in black ink on body "90" in black ink on cap, containing white to off-white pellets.

For more product information visit us at **www.antararx.com**

Methylphenidate HCl® **Chewable** Tablets

The only short-acting, Immediate-Release Chewable Tablet available!

Product	NDC#	Description
Methylphenidate HCl ® Chewable Tablets Bottle of 100 Chewable Tablets - 2.5mg	43386-570-01	Each Methylphenidate Hydrochloride Chewable Tablet 2.5 mg is available as a white colored, grape flavored round, flat faced, beveled edge tablet debossed with "NL" above and "570" below on the one side and plain on the other side.
Bottle of 100 Chewable Tablets - 5mg	43386-571-01	Each Methylphenidate Hydrochloride Chewable Tablet 5 mg is available as a white colored, grape flavored round, flat faced, beveled edge tablet debossed with "NL" above and "571" below on the one side and plain on the other side.
Bottle of 100 Chewable Tablets - 10mg	43386-572-01	Each Methylphenidate Hydrochloride Chewable Tablet 10 mg is available as a white colored, grape flavored round, flat faced, beveled edge tablet debossed with "NL" above the bisect and "572" below the bisect on one side and plain on the other side.

For more product information visit **www.MethylphenidateChewable.com**

LUPIN PHARMACEUTICALS, INC.

 LUP1317-V2-0316

LUPIN

PHARMACEUTICALS, INC.

RESEARCH DRIVEN • QUALITY COMMITTED • CUSTOMER FOCUSED

LUP-002376

Welcome to the world of Lupin Pharmaceuticals

As a wholly owned subsidiary of multinational pharmaceutical company Lupin Limited, Lupin Pharmaceuticals, Inc., shares the strengths of its India-based parent and the expertise of its U.S.-based team.

Lupin Pharmaceuticals has grown rapidly since the launch of our generics division in 2005. We offer generic and branded pharmaceuticals and we anticipate a total of five to 10 introductions a year.

Six of Lupin's 14 ANDA approvals were the first granted by the USFDA, which is a measure of our ability to submit high-quality dossiers and receive on-time approvals. Our established R&D facilities, unique technological breadth and depth and the speed-to-market offered by vertical integration further support our aggressive strategic goal of more than 15 ANDA filings per year.

Lupin's partners appreciate our robust, differentiated pipeline, efficient product launches and customer-focused approach. Health-care providers and patients will come to appreciate the safe, effective, high-quality generic alternatives we provide.

Backed by our vertical integration and global vision, Lupin is poised to meet the needs of today's challenging pharmaceutical environment for years to come.

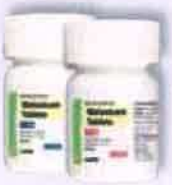
Vinita Gupta

Vinita Gupta

President,

Lupin Pharmaceuticals, Inc.

The lupin plant nourishes the soil wherever it grows, benefiting the environment in the process.

Product	AB Rated To	Therapeutic Category
Cefprozil Oral Suspensions 	Cefzil®*	Cephalosporin, Anti-Infective
Cefprozil Tablets 	Cefzil®*	Cephalosporin, Anti-Infective
Cephalexin Capsules 	Keflex®*	Cephalosporin, Anti-Infective
Cephalexin Oral Suspensions 	Keflex®*	Cephalosporin, Anti-Infective
Lisinopril Tablets 	Zestril®*	Ace Inhibitor
Meloxicam Tablets 	Mobic®*	Non-Steroidal Anti-Inflammatory

*All registered trademarks are the property of their respective owners.

LUP-002378

Vertical Integration

Lupin combines the vertical integration and global vision of our Indian parent company with the expertise of our U.S. sales and marketing team. As our customer, you benefit from the best of both worlds.

Discovery Research

Lupin's research is vertically integrated, starting from API process development to submission of dossiers for finished dosages. We have the proficiency to develop cost-effective and non-infringing technologies that involve complex chemistry.

API Production

Sterile processing, synthetic process development and fermentation capabilities, coupled with intellectual property strengths, position Lupin to offer customers a diverse portfolio of niche APIs. The hallmark of our API business strategy revolves around achieving leadership positions within our chosen market segments.

Formulation Development

Lupin's aggressive strategic goal of more than 15 ANDA filings per year relies upon our scientific expertise in formulation research and development. With a total of over 40 successfully filed ANDAs, our record of meeting approval timelines at or below industry standard is a mark of our ability to submit high-quality dossiers.

World-Class Manufacturing

Lupin's 11 USFDA-approved state-of-the-art manufacturing facilities in India and Thailand include two that received approval with zero observations (483s). Our sophisticated, fully integrated operations enable us to control quality, cost and speed-to-market.

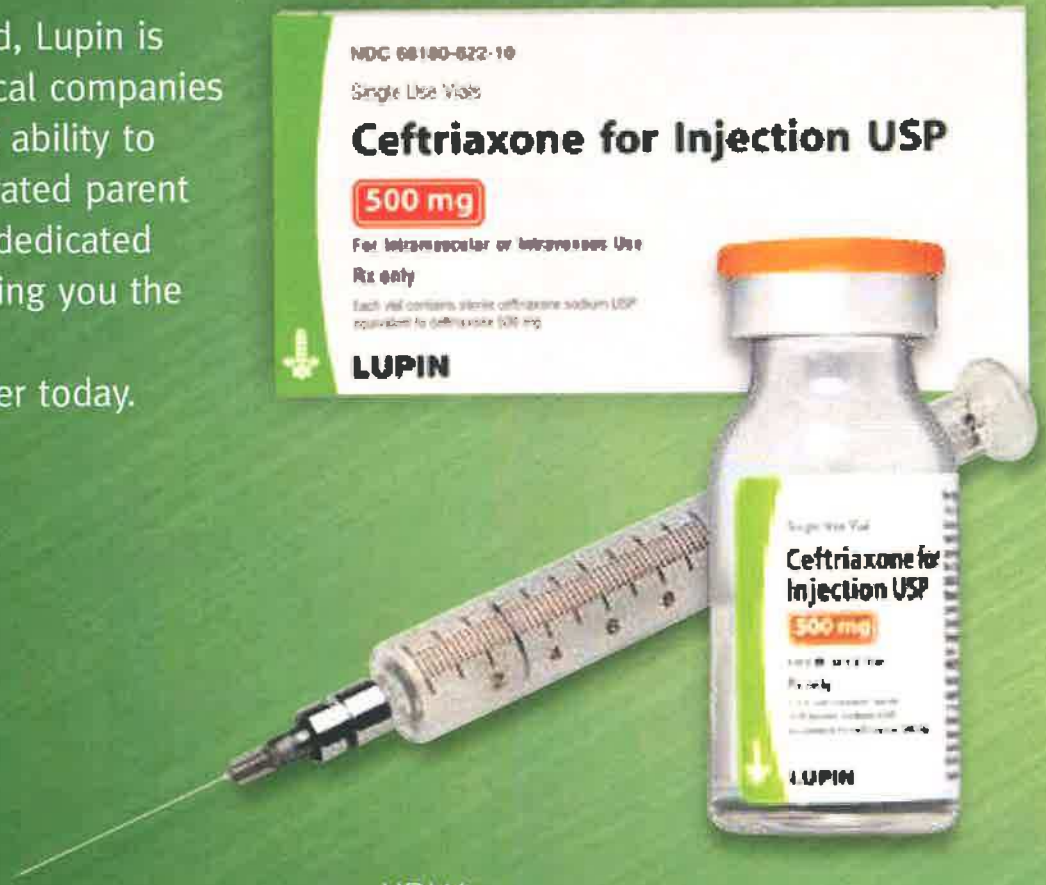
Local Sales and Marketing

With decades of generics market experience, Lupin's U.S.-based team is committed to building its generics business—and long-standing relationships—through personalized service, trust and reliability. Everything from launching products effectively to delivering outstanding service is targeted to meeting our customers' needs.

LUPIN PHARMACEUTICALS, INC.
Harborplace Tower
111 S. Calvert Street, 21st Floor
Baltimore, MD 21202
(866) 587-4617
www.lupinpharmaceuticals.com

Ceftriaxone for Injection USP

Ranked fifth for total generic prescriptions dispensed, Lupin is consistently one of the fastest growing pharmaceutical companies in the U.S.[1] Our customers have come to rely on our ability to leverage the shared strengths of our vertically integrated parent company coupled with a sales and marketing team dedicated to exceeding customer expectations. Together we bring you the affordable, high-quality generic solutions you need.
Grow with us. Call (866) 587-4617 to place your order today.



Ceftriaxone Injection USP

AB Rated to *Rocephin®

NDC #	Strength	Size
68180-0611-10	250 mg	10 vials
68180-0622-10	500 mg	10 vials
68180-0633-10	1 g	10 vials
68180-0644-10	2 g	10 vials

*Rocephin® is a registered trademark of Hoffmann-La Roche Inc.
[1] Source: IMS Health, National Prescription Audit, June 2011

Reliability for your peace of mind.

HDMA Diana 2011

LUPIN PHARMACEUTICALS, INC.

CEFT012012ANDA

LUP-002380

Here at Lupin, we keep things pretty simple. Our word means something — and when we make a promise, you can be sure we will keep that promise. Our commitment to supplying only the best generic pharmaceuticals means that we run a tight ship — we go the extra mile to ensure each order is shipped on time, every time — no hassle. As we've grown over the last ten years, our customers have trusted us to supply quality products to you and your family. Great voyages start here, so come aboard and experience a partnership based on trust. All hands are on deck for you.

Call (866) 587-4617 or visit www.lupinpharmaceuticals.com

Profile

LUPIN
PHARMACEUTICALS, INC.
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Lupin Pharmaceuticals, Inc.
A Globally Integrated Supply Chain Bringing Affordable Generic Options

Lupin Pharmaceuticals, Inc. is dedicated to delivering high-quality, affordable generic medications. With over $1.4 billion in global revenues, Lupin is currently the 14th largest generic pharmaceutical company in the world. Since the launch of its US generics division in December 2005, Lupin has introduced 42 new products in more than 200 dosage strengths and packaging sizes, covering many major therapeutic categories in the US market.

Lupin's Recent Generic Launches	Brand Equivalent
Levonorgestrel and Ethinyl Estradiol Tablets USP	LoSeasonique®
Lamivudine and Zidovudine Tablets USP	Combivir®
Metformin HCl Extended-Release Tablets	Fortamet®
Quetiapine Fumarate Tablets	Seroquel®
Ziprasidone HCl Capsules	Geodon®

A Market Leader

Lupin is the leader in half of the products it markets, and as many as 35 of these 42 products are in the top 3 ranking by market share. Based on total prescriptions dispensed, Lupin is the 5th largest generic pharmaceutical company, and has been one of the fastest growing pharmaceutical companies for 3 consecutive years in the United States, according to IMS Health's National Prescription Audit (MAT March 2012).

Robust, Growing Pipeline

Lupin's sustained growth performance is not only measured in numbers, but also in its ability to continue to enter new segments and launch products that are first to market. Lupin introduced 13 new generic products in 2011, with 3 of those being oral contraceptives, a new category for the company. The company expects approvals for approximately 30 new oral contraceptives over the next few years. Lupin also introduced the first FDA-approved generic equivalent of Shionogi's Fortamet® (metformin HCl extended-release tablets).

The company was granted final FDA approval on 15 new products from January 2011 to July 2012. Lupin's pipeline is entering into new therapeutic areas, such as dermatologics and oncology, and new dosage forms, such as ophthalmics and otics.

Lupin invested 7.5% of its net sales for R&D, which enables the company to create one of the best generic product pipelines in the world. From January 2011 to June 2012, the company filed 39 ANDAs with the FDA. Lupin continues to maintain its position as one of the top 10 ANDA filers for the US market, with 23 cumulative first-to-file opportunities for the US generics market.

Exceeding Expectations

In order to exceed the demand of the US generic pharmaceutical market, Lupin has expanded manufacturing capacities over the past several years at all of its best-in-class manufacturing facilities and continues to strengthen its efficient supply chain. New technological initiatives were also taken for energy conservation and environmental protection. All of these capital expenditures are focused on meeting the growing demands of Lupin's customers.

The company's focus on technology and differentiation enables it to charter new areas of business, such as unique therapeutic categories and difficult-to-manufacture drugs. Lupin is prepared with a rich pipeline consisting of niche products, first-to-files, and products requiring dedicated facilities or having high barriers to entry.

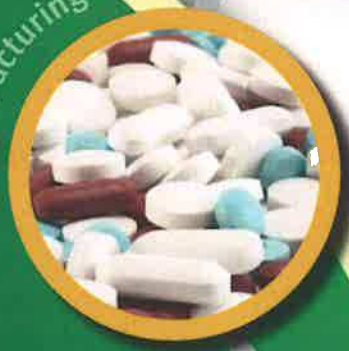
Lupin's consistent track record of growth is a direct result of a valuable pipeline, solid customer relationships, and flawless execution. With a commitment to grow the company with new market entries, exciting new launches, and a series of strategic investments in acquisitions, Lupin Pharmaceuticals, Inc. remains dedicated to exceeding the expectations of its trade partners. ■

For more information, please visit
www.lupinpharmaceuticals.com

LUP-002382

Quality products. Outstanding service.

At Lupin Pharmaceuticals, we're committed to being a leader in high-quality generic medications trusted by healthcare professionals and patients across the world. Our strength in vertical integration enables us to provide you with products and service that you can count on, time and time again.



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Profit from our quality.

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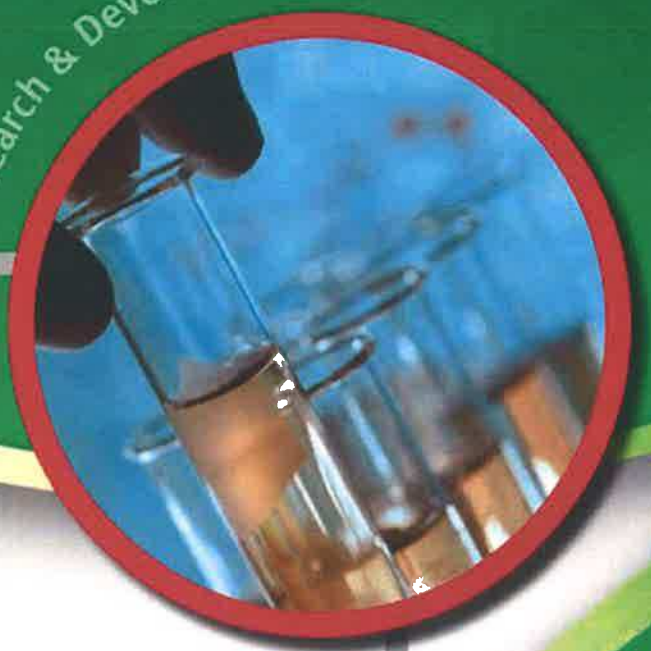
www.lupinpharmaceuticals.com

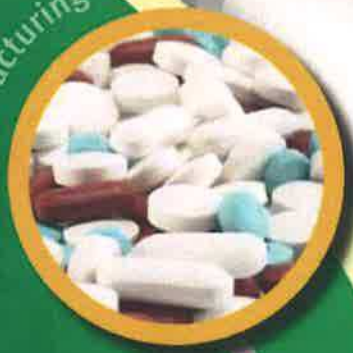
CORP42009CDR

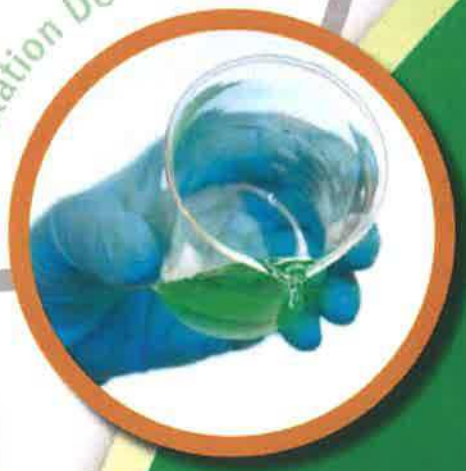
LUP-002383

Quality products. Outstanding service.

At Lupin Pharmaceuticals, we're committed to being a leader in high-quality generic medications trusted by healthcare professionals and patients across the world. Our strength in vertical integration enables us to provide you with products and service that you can count on, time and time again.







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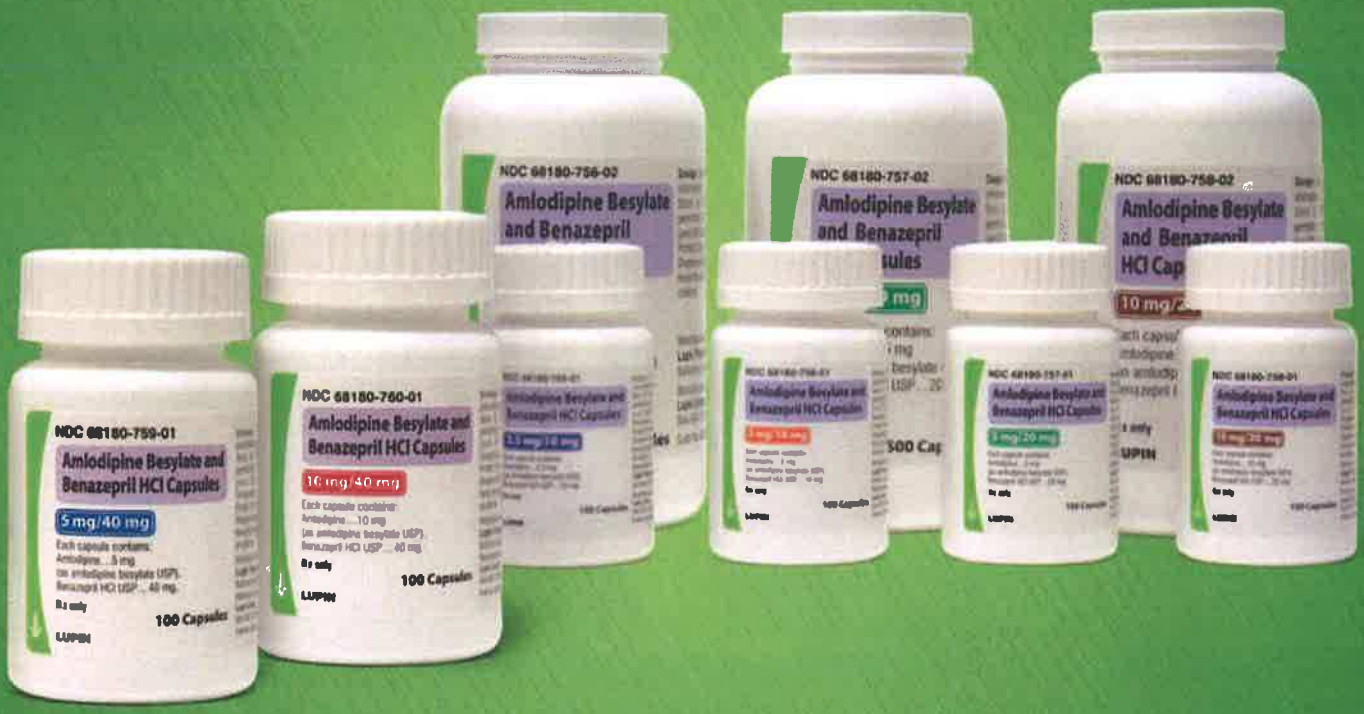

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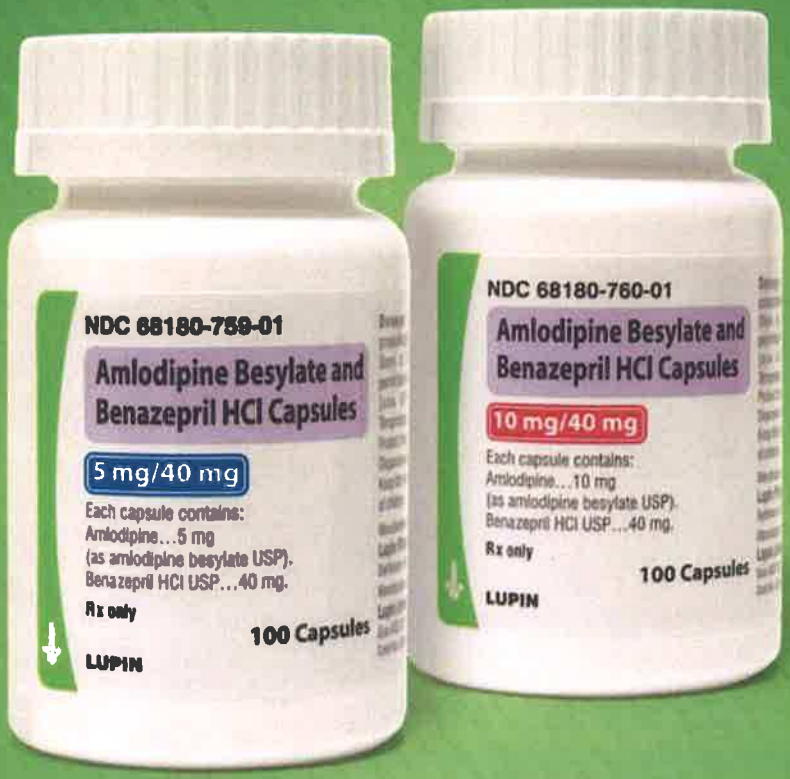

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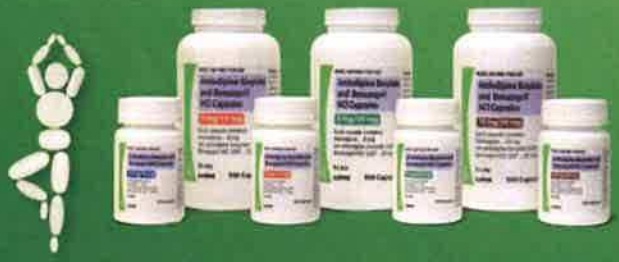

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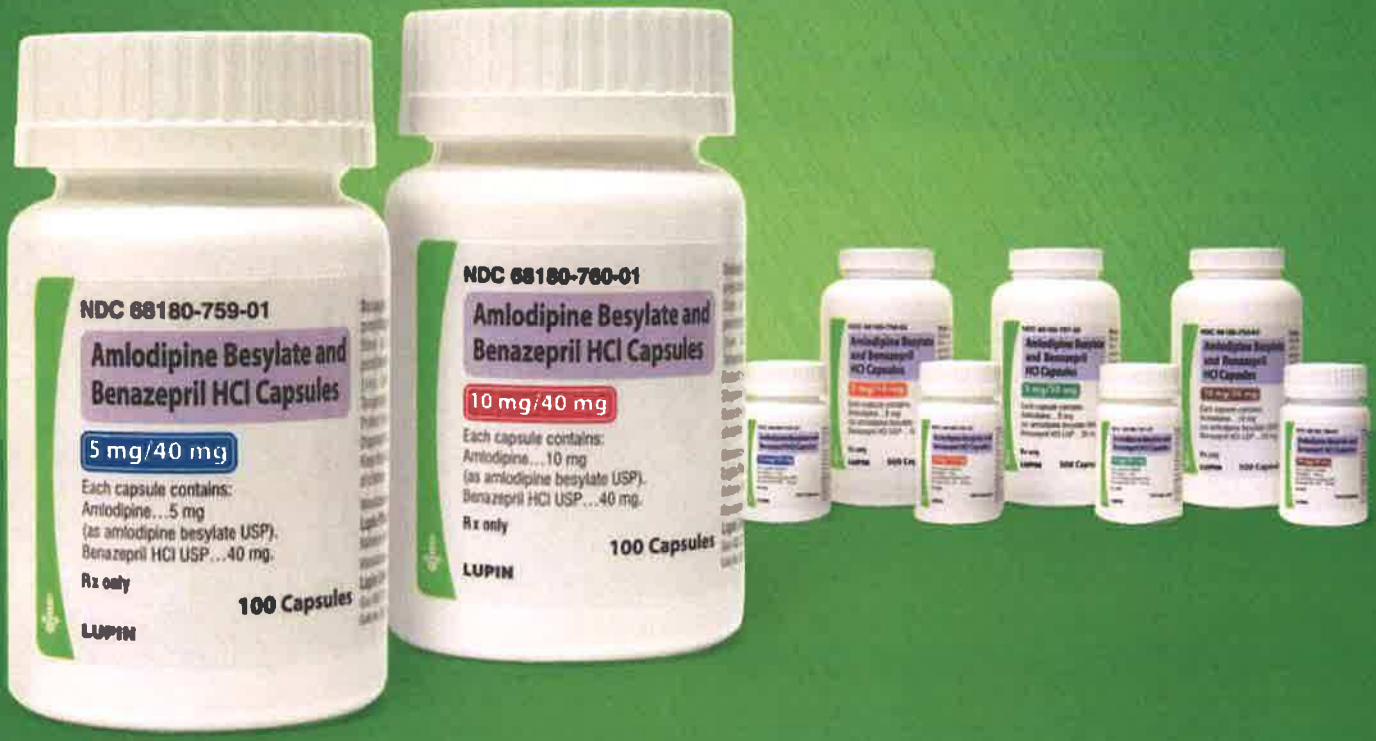

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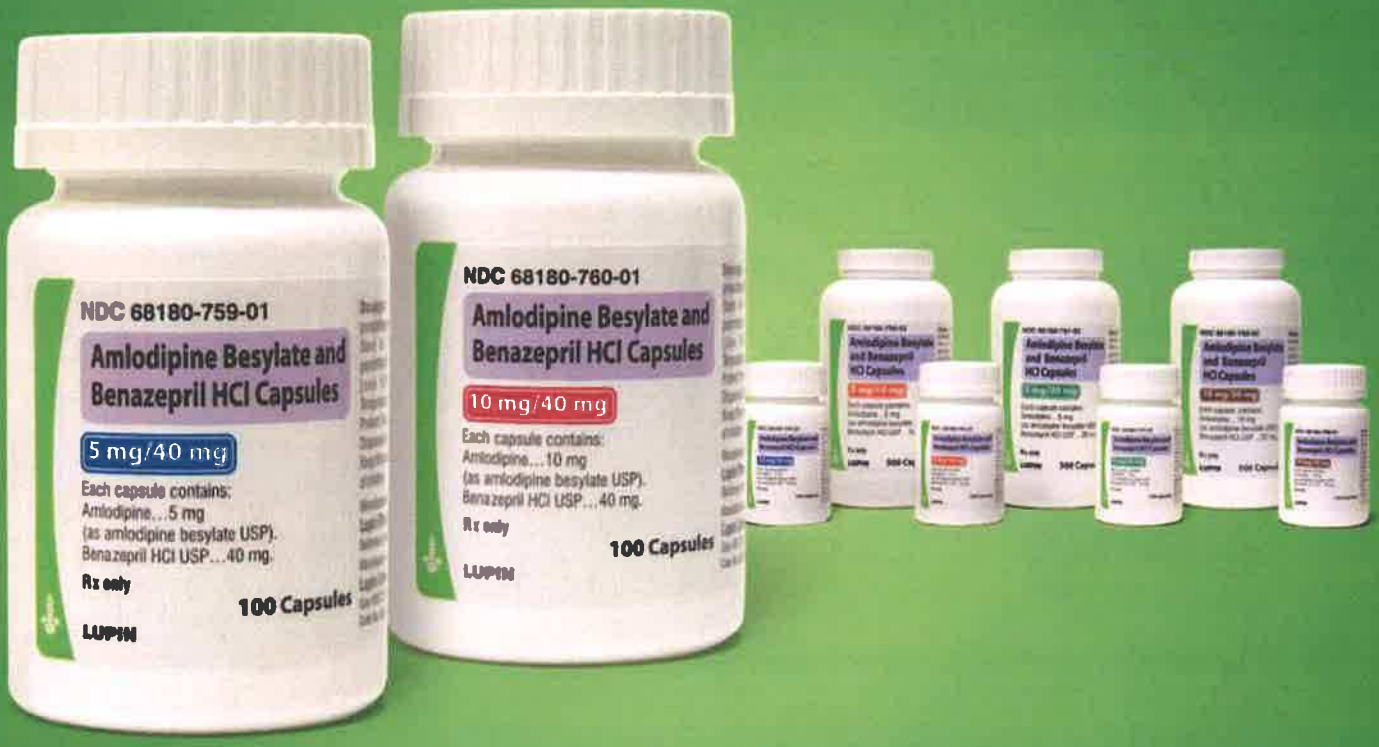

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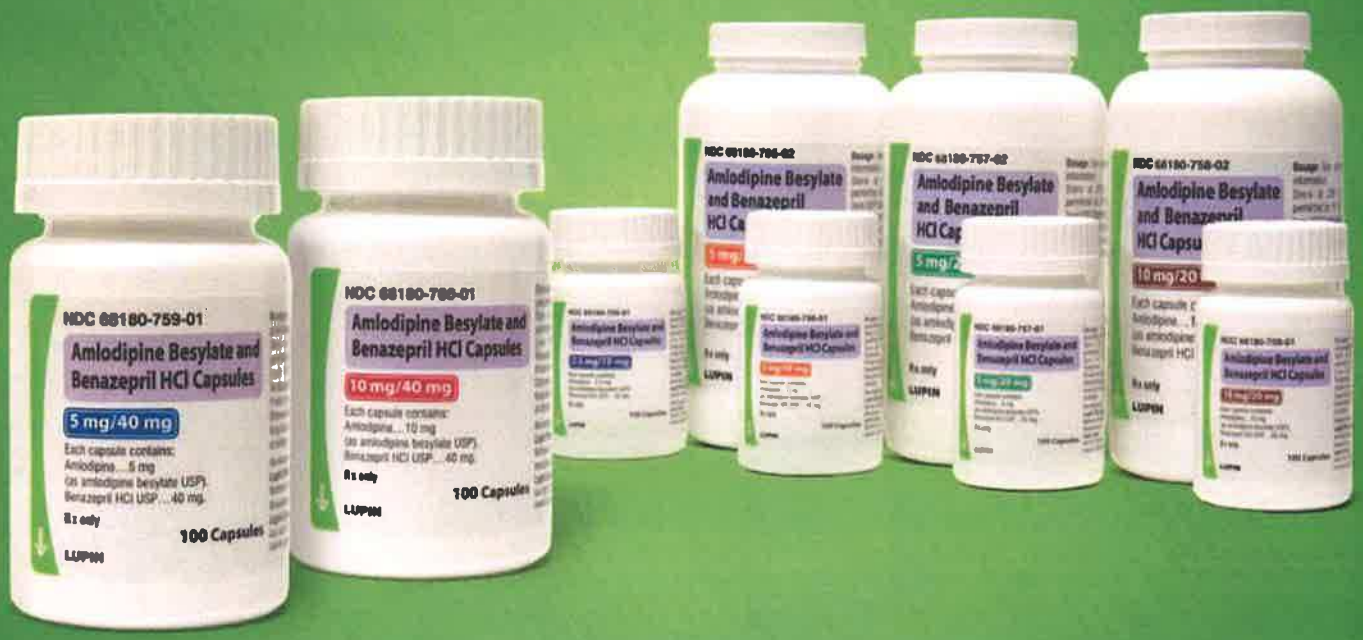

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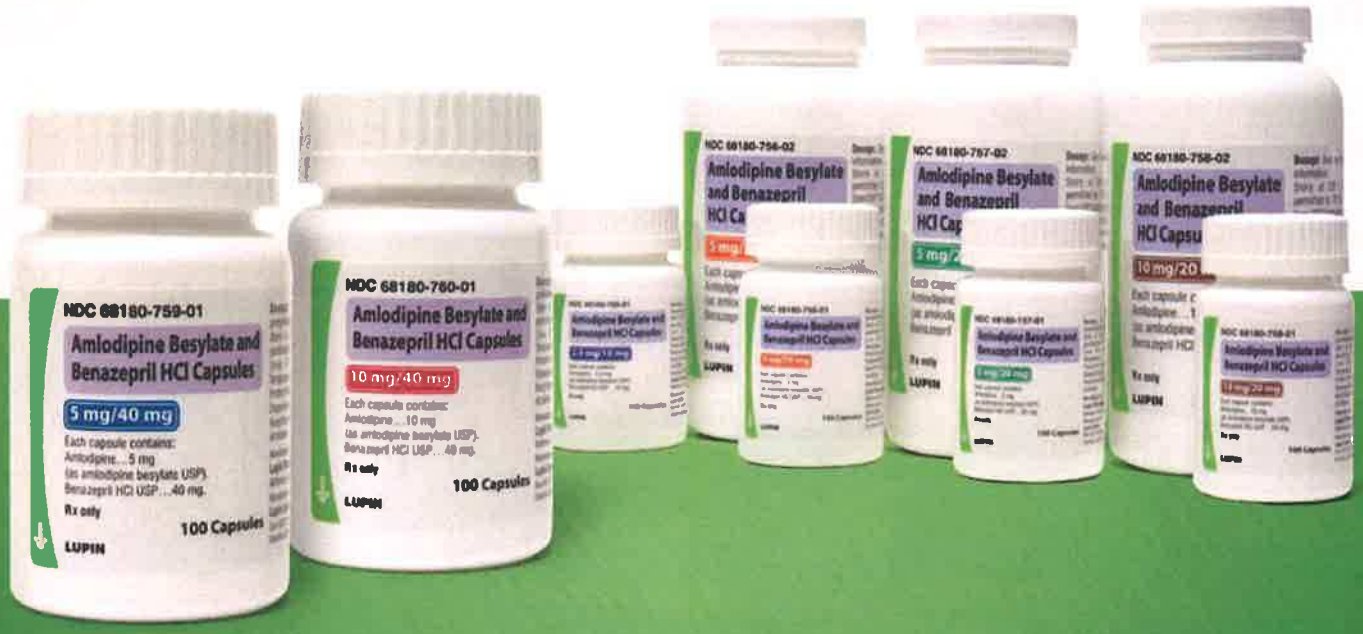

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LUP-002391

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

In the matter of Application Serial No. 86509184
For the Mark: LUPPIN
Published in the Official Gazette on August 18, 2015

LUPIN PHARMACEUTICALS, INC., Opposer,	:	
v.	:	Opposition No. 91226322
AMPEL, LLC, Applicant.	:	

CONFIDENTIAL

DEPOSITION OF PETER LIPSKY, M.D.

TUESDAY, SEPTEMBER 26, 2017

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FILE NO.: AB09E50

EXHIBIT C

Q -- someone like me could --

A Reporting --

Q -- pick it up and --

A You could --

Q -- understand or --

A -- but you would be bored to death, but basically reports of bench research.

Q Okay. I might not. Yeah, I might not pick those up.

A Probably not.

Q Have you written -- you've written articles regarding the repositioning or repurposing of drugs for --

A Correct.

Q -- lupus treatment?

Have you written any articles relating specifically to the LuPPiN program?

A The LuPPiN program? Written articles, no. We have mentioned it in presentations but haven't written articles specifically about that program.

Q Okay. And when -- actually, so you -- how do you pronounce it?

A LuPPiN.

Q LuPPiN. Okay. And the emphasis is on the, I guess, Loo, L-O-O, hyphen P-I-N, with the emphasis on the P-I-N, sort of phonetically?

A We have a series of names of activities, all of which start with capital L, small u, that relate to different activities that we've carried out. So this was one of a series that we have developed acronyms for, all around the L, small u for lupus.

Q Okay. And that includes LuCIN, I think is another one?

A LuCIN, LuCIT, LuPRO and LuPPiN.

Q Okay. What is LuCIT? What is that?

A That's one we use internally. It's a lupus clinical investigator tracker, where we actually track the activities of investigators who we -- are involved in our clinical trials.

Q Okay. So that's --

A It's internal --

Q Does anyone outside of --

A -- not marked at all.

Q Okay. So AMPEL has access to it?

A Correct.

Q And does anyone outside of AMPEL have acces to it?

A No.

Q Okay. All right. So are you involved in any industry organizations?

A Industry organizations?

takes care of most of these patients.

Q And how does someone contract lupus in the first place?

A I don't think you can contract it. It's a genetic component.

Q Okay.

A It's strong.

Q Sure.

A And there's also some sort of environmental stimulus that we don't really understand very well. And the combination seems to make a person more likely to develop lupus. But it's not as though you catch an infection or a cold or a virus. It's some combination of a genetic predisposition and an environmental challenge that we don't understand very well.

Q Okay. Is AMPEL a for-profit company?

A Yes.

Q And what -- in general, what's sort of the business model and how you're making money?

A We have two large components. The first is to take available information, analyze it and generate potential candidate drugs that treat the disease. And that generates us both grants, support from voluntary organizations and, to some level, contracts with pharmaceutical companies about analyzing drugs and finding

drugs that will -- could be useful. That's one whole aspect, involves perhaps eight or nine people and is largely involved in what you might call bioinformatics or big data analysis of available information.

The second part involves actually organizing and carrying out clinical trials. So once we identify a candidate drug and persuade a pharmaceutical company that it would be a wise thing to do to test this drug in lupus, we have an entire clinical operations group that can carry out clinical trials in accordance with all FDA regulations. So that's another nine people or so, ten people. And that also generates revenue for carrying out the trials.

Q And so how -- do you propose what the trials would be, or does someone come to you and say we think we want a trial --

A In general, we propose. We're very proactive in going to companies, meeting with companies, explaining to them where their product is -- has a high likelihood of success in lupus and then offering the opportunity to carry out the clinical trials at a cost that's much reduced compared to what a standard research organization could do.

Q Okay. And how do you -- how do you keep the costs more manageable?

A We're really efficient and we're really small.

Q How many people are employed?

phone call. They always want to know what I think about what they want to do, so it's pretty easy to turn the conversation over to what we want to do. And since they know it's -- there's a higher likelihood that we're right than they're right, they frequently listen.

Q Okay.

A So it's a combination of things, really.

Q Okay. Do you send them any kind of written materials?

A Only if solicited. Mostly it's all by phone conversation.

Q Okay.

A And, if they want, we'll make a synopsis of a protocol, things like that. We've done that a number of times for them. But, in general, we don't like to spend a lot of time preparing proposals if there's really no interest.

Q And do you work with any makers of generic pharmaceuticals?

A No, not directly.

Q Okay. Are you familiar with makers of generic pharmaceuticals?

A How can you not be?

Q What are some of the -- some of the ones that you're most familiar with?

Q All right.

A -- and Chief Medical Officer, CMO. And I also wash dishes occasionally.

Q Somebody has to. So what's -- what's the job description of the CEO at AMPEL?

A Keep us financially viable and basically oversee whatever needs to be overseen. We don't have -- we're an LLC. We don't have job descriptions and things of that nature. We do what needs to be done.

Q Okay. And same for the Chief Medical Officer?

A Chief Medical Officer does everything the CEO doesn't do.

Q Such as?

A Well, over -- you know, I have to be medical monitor for the clinical trials. I have to oversee all of the clinical trial work. And that includes submissions to the FDA. It includes protocol design. It includes a variety of different things.

Q And how does the LuPPiN program fit into the whole picture at AMPEL?

A Well, one of the -- one of the big problems -- you might as well learn something about Lu- -- about clinical trials. So clinical trials are a very complicated and expensive business that you may not know very much about, but over the years, clinical -- the pharmaceutical

companies largely backed out of the clinical trial business and they've been replaced by something called contract research organizations. These are large companies that basically run clinical trials. And in many areas the clinical trial work in the United States had just become too expensive to do. And so, as a result, the contract research organizations, those CROs, have moved progressively more and more of this outside of the U.S. and now, more recently, outside of western Europe into areas where it's much cheaper. The difficulty is that when you get the complicated diseases like lupus, there's not much experience in those areas, so many trials have really failed because they're enrolling patients in Moldova. You know, a large trial that Pfizer ran failed because of three deaths in Moldova. Okay? A large trial that was just run by Aurinia basically wound up with an imbalance in deaths, 11 in the active treatment group versus one in the control group, but all of the deaths were in Bangladesh. Now, you may see pictures of Bangladesh and it may indicate to you that lupus isn't their biggest problem, but for financial reasons they've all moved out of the United States and are driven by, really, cost. What we've tried to do is to convince the companies that when you have a disease like lupus, which is complicated and involves a lot of subjectivity on the part of the physician, you need to

really have an expert who understands lupus. And that could only be in places that see a lot of it, which means the United States and western Europe. But then the problems are, it's really expensive to do a trial here. It's really complicated because of all of the rules about patient protection. And if you decide to do it in the place where the most lupus patients are, namely academic centers, then you have to deal with the academic centers' contracting officers and legal team who are, let's just say, complicated. So these are really the challenges in doing clinical trials. How can you actually move a clinical trial into a place where you will get the most reliable information, which in a disease like lupus means fundamentally the United States.

All right. So if you can get past all of that, all right, and you get all of that figured out, which is no mean feat, then you have the problem of the fact that patients are not very inclined to enter clinical trials here. There are a lot of reasons people enter clinical trials, and most of them are absent here. So if you're in a developing country, you get much better health care if you actually enter a clinical trial. There's an incentive to do it. But here you don't. And here there's a tremendous amount of misperception, misconception among the part of the patients about what clinical trials are.

Studies show that 50 percent of patients never even heard of what a -- what a clinical trial is, and then there's a lot of problems in recruiting patients. So how do you go about recruiting patients in the United States, where patients have many choices for health care, they don't necessarily think about a clinical trial and they have misperceptions. So years ago, when we were working in rheumatoid arthritis, we faced the same kinds of problems. And one of the things we discovered was that patients became the best advocates for participation in clinical trials if they understood what they were. So what we did in those days was recruit -- this is almost 30 years ago now -- was recruit a group of individuals with rheumatoid arthritis who had certain characteristics. And we trained them. And we -- they got the name "patient educators" or "patient partners" and we trained them to interact with other patients and to talk about a number of things with the disease but also to talk about the value of clinical trials. And they became very effective because it was peer-to-peer discussion. They understood much better than we did what the pressures a patient was living under. And they could relate much better to all of the misperceptions about clinical trials. So ramp up 30 years and now we're in the problem with lupus. We really need to do these trials in the U.S., but there's this huge amount of

misperception about what a trial is, what the risks are, what the protections are and just, you know, why bother. You know, life is hard. I don't want a -- don't need another clinical trial. So we have developed many, many different programs to try to encourage recruitment into lupus clinical trials because we can't recruit, we can't do trials here. And one of them was to develop a program much like what we had developed in the rheumatoid arthritis space of patients with lupus who would be educated about lupus and would work basically in different academic centers to basically explain what clinical trials were and to try to allay some of the fears that the patients had about trials and to try to deal with some of the misunderstandings and basically to work almost as part of the healthcare team specifically to communicate with patients about the value of clinical trials. And that's really the genesis of the LuPPiN program.

MS. MORALES: We've been going for about an hour. Seems like now might be a good time to take a break.

THE WITNESS: Sure.

MS. MORALES: And if you're --

THE WITNESS: No problem.

MS. MORALES: Again, throughout the whole process, if you're -- you know, need a break at any point, let us know.

A Um-hmm. Sure.

Q Sure. So about midway down the first page, as you are, it says goods and services.

A Um-hmm.

Q Okay. And then there's a section that says class or international class. Do you see where it says -- I think the first one is 41.

A Where am I looking?

Q About midway on the page.

A Okay.

Q All right. Can you just read either -- either aloud or to yourself just the -- what the various services that are next to there?

A Um-hmm. So this basically -- where it says for?

Q Yeah.

A Yeah. Basically, educational services, namely providing seminars and one-on-one mentoring in the field of the lupus, lupus treatment options and the importance of clinical trials, training lupus patients to teach other lupus patients about the nature of lupus, available treatments and the importance of clinical trials.

Q Okay. Then, skipping down a few lines, there's a second --

A Um-hmm.

Q -- international class that should be, I think,

45.

A Um-hmm.

Q And can you --

A Sure.

Q -- take a look at --

A Organizing and conducting support groups for lupus patients who are undergoing treatment and clinical trials and for the caregivers of lupus patients who are undergoing treatment and clinical trials. Yes.

Q Is that a pretty accurate representation of what the company does under the LuPPiN mark?

A It would be what would have been done under the LuPPiN mark if there wasn't this opposition, yes.

Q Were there -- before the opposition, where the -- were these services -- were these services provided with the -- under the LuPPiN mark?

A Well, prior to that, we did hold a large meeting in order to prepare the educational services and to develop ways to identify patients who would participate in this activity. I think you have a copy of the manual that was developed in 2016. So that resulted from quite a bit of work. But since there was uncertainty about the name, we've really kind of not progressed much beyond developing the training manual, which would apply to 41. And then once those people were trained, that would apply to 45.

because that's how we all act, but when you talk to laypeople, especially those with a medical condition, that's the hardest thing to try to educate them about, teach them about, make them understand and be confident because we couldn't have these people representing us and going out and saying crazy stuff to other patients. I mean, so we learned that from the RA space and we wanted to take those learnings and to apply them here. So it took us quite a bit of time to get that organized.

Q And were -- so were there specific individuals that --

A Yeah.

Q -- you were working with? Okay.

A Yes.

Q All right. And how did you communicate with them?

A Mostly by phone, by email, personal contact.

Q Okay. And did -- was that under the name LuPPiN?

A Initially, prior to the opposition, we used that and they liked it. We had that on slides and presentations. People were very enthusiastic. But afterward we just sort of shortened down to patient partners, which really wasn't useful to us because it didn't include the word "lupus," L-U. And also patient

partners is widely used. If you -- if you Google patient partners, you'll find about 40 patient partner programs around the country that do different things. So that wasn't really very helpful for us. But, again, we didn't want to promise something that we couldn't deliver to these people because it's -- they -- they've been disappointed so frequently.

Q So would you have an email from, you know, AMPEL to, you know, Jane Jones lupus patient that said -- that discussed the LuPPiN program?

A I'd have to go back to that period of time. I don't know for sure that I do.

Q Okay.

A I don't know.

Q I would ask that any responsive documents and, you know, emails and so forth that mention LuPPiN would be produced, please.

All right. So then I -- you -- you went through all the component parts, but just to, you know, clarify, so LuPPiN is Lupus Patient Partner Integrator Network?

A Right.

Q Okay. And why is the I not capitalized?

A Looked prettier not being capitalized.

Q And LuCIN, the I is capitalized?

A Right.

Q And have you considered any alternative name since then?

A No. We like LuPPiN. I think it sort of captures what we want to do.

Q Does AMPEL provide or offer any sort of kind of educational services, anything like that, under a different -- any -- any -- pardon me --under any different names?

A Well, we have a 501(c)(3) not-for-profit, which is called the RILITE Foundation. But we do educational activities under that.

Q Okay.

A That's separate, legally separate, completely separate thing, but most of the educational things we do in lupus, including holding meetings and things of that nature, that's done through that because that is supported by unrestricted educational grants from companies.

Q Okay. So RILITE does deal with lupus?

A RILITE deals with lupus and -- but mostly in education. There is some grant that we fund, but the education part is largely through that because that's a not profit -- not-for-profit thing.

Q Okay. Is RILITE an acronym also?

A Um-hmm.

Q Okay. What does that stand for?

source of these patients. All of them may not accept it. Some would, some wouldn't. So at this point we really hadn't gone beyond what you have information about.

Q And were they -- all 60 in the U.S.?

A Fifty-some-odd in the U.S. and the rest in Canada --

Q Okay.

A -- but all North America.

Q Okay. Is there -- is there any specific geographic --

A No.

Q -- concentration?

All right. So, generally in the patient partner programs, patients work in support groups?

A Well, we -- that was not our vision. Basically there would be a support group for the patient partners --

Q Um-hmm.

A -- in other words, so that they didn't get overwhelmed, didn't have -- that they could talk about their experiences because they would be on the front lines. It's not always so pleasant. Patients sometimes are angry, sometime are hostile. They take it quite personally. So the support group was really for the patient partners and working with us so that we would make sure that they felt comfortable.

stakeholders in the LRxL-STAT will have an opportunity to participate in an interactive open meeting, is that one of the meetings that we had spoken with -- spoken about earlier?

A That -- that evolved into the October 2014 meeting.

Q Okay. And what was discussed during that meeting?

A Basically, most of what's on here and the idea of moving forward with clinical trials of some of these compounds.

Q And was the -- was the patient partner program discussed at all during that meeting?

A Yes. You have the slides from that.

Q Okay. And was it -- was it called LuPPiN at that time?

A It was called LuPPiN at that time, yes.

Q And did anyone enroll in the LuPPiN program as a result of that October 2014 meeting?

A We're still in the planning stages. We are working very hard to get it organized, but we weren't ready to enroll patients at that time.

Q And have any other stakeholder meetings taken place since that time?

A Which stakeholders?

Q Well, the stakeholders that are mentioned in the -- this summer all stakeholders in LRxL-STAT.

A Well, there was a subsequent meeting, as I mentioned, some of them in 2015, and there was also the planning meeting that occurred in 2016.

Q Okay. And was the LuPPiN program discussed during the subsequent meetings?

A Yeah. You have the -- I think you have the slides of those.

Q Okay. All right. You can take off your glasses and put this one down.

A I should point out that two of these have -- one of these has finished their clinical trial. One of them is just starting their clinical trial. One of them, we could never find a compound to make. And the other one is still in discussion. So, actually, we were predictive. We had some, actually, success. It's good to see the early work and where we were and where we've gotten to.

Q Sure. Is that the clinical -- are those the ones on the right-hand side or the --

A Yeah, on the right side. For the first one, ustekinumab, the results of that will be reported at the ACR meeting in November.

Q Um-hmm.

A Krill oil starts beginning of 2018. So two out

Q Was your -- was your presentation advertised in any way?

A It was closed. So it was by invitation only.

Q Okay. And the LuPPiN program was discussed during this presentation?

A Yeah, it was. I think there are some slides here somewhere, but yes, it was, because that was going to be an important aspect of this program.

Q And what was discussed about it?

A About how we were going to utilize the LuPPiN network to accentuate trial recruitment. Everybody agrees that trial recruitment is -- patient recruitment is the hardest thing to -- to accomplish in the United States. And we were discussing a number of ways to increase patient recruitment. And LuPPiN was a critical aspect of that, which was embraced by this group.

Q And do you have -- do you have a list of attendees of your presentation?

A You know, I don't know that I can get hold of that. I could try, but I -- honestly, those days, at 6:30 in the morning, we weren't so great at recordkeeping and attendance-keeping and things like that. And it was a long time ago. So I can't guaranty you I could find that group of people.

Q Okay. To the extent that it exists, we ask that

BY MS. MORALES:

Q And what -- what were they going to be funding?

A Well, basically, funding us to continue to look at and scoring drugs. And eventually they funded also that preliminary meeting that I talked to you about in order to develop the LuPPiN training manual.

Q And so this meeting and that funding is how their names got to the top of that poster we just discussed?

A Correct.

Q Okay.

A It's easy to buy a position on a poster.

Q And what was discussed about LuPPiN at this meeting in December --

A Again, it was --

Q -- of 2014?

A -- one of the -- one of the ideas that we were very strongly pushing to them. This was basically a way to -- one way to get some money to get the program started. So we were very much pushing the idea that we would engage patients in this LuPPiN program as a way to facilitate patient enrollment.

Q You mentioned --

A Eventually they embraced it, as I said, and supported that -- that meeting.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

In the matter of Application Serial No. 86509184
For the Mark: LUPPIN
Published in the Official Gazette on August 18, 2015

LUPIN PHARMACEUTICALS, INC., Opposer,	:	
v.	:	Opposition No. 91226322
AMPEL, LLC, Applicant.	:	

CONFIDENTIAL

30(b)(6) DEPOSITION OF PETER LIPSKY, M.D.

THURSDAY, SEPTEMBER 28, 2017

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FILE NO.: AB09E52

EXHIBIT D

Q And to the best of your knowledge, has AMPEL produced every document in its possession, custody and control that are responsive to these --

A Yes.

Q -- document requests?

A Okay. Just for -- for the sake of a clear record, let me finish my question before you answer. Thanks.

Now, turning to mark -- AMPEL's mark LuPPiN, and that's before -- I'll try to clarify when I'm talking about your company's mark and the Lupin mark of the opposer, Lupin Pharmaceuticals. If you get confused, let me know and I'll try to rephrase the question. Who was primarily responsible for coming up with the name LuPPiN for AMPEL?

A I was, with the help from and discussions with Amrie Grammer.

Q Okay. And LuPPiN is an acronym; correct?

A Correct.

Q Okay. And an acronym being the L-U standing for lupus?

A Correct.

Q And the P-P standing for patient partner?

A Correct.

Q The I standing for integrator?

A Correct.

Q And N standing for network?

A Correct.

Q Okay. What is the significance of the term "integrator"?

A Basically, it's a way to imply that the patient partners would function as a go-between, if you would, between other patients and the healthcare group, the healthcare provider group, in a clinical site to try to communicate the importance, value and safety of participating in clinical trials.

Q And why did you also choose the word "network" instead of, say, the word "program"?

A Because we were establishing a group of patient partners in different academic sites. So it was a network, and the idea of network was that they would continue to communicate with the central organizers. Initially they would have -- participate in a training program. They would become educated, but they would still continue to communicate with the central group to provide them support, education, information. So it became really a living network of people.

Q And basically LuPPiN is -- uses a mark by AMPEL to identify a patient partner network; is that it?

A Correct.

Q Okay. Now, you mentioned that the network

itself would have as its loci basic academic centers. Is that --

A Correct.

Q -- correct?

Which academic centers are participating in this network currently?

A We have -- we work with a network of 59 academic centers in the United States and Canada. That network goes under the name of LuCIN, Lupus Clinical Investigators Network. And they -- they're all centered in academic medical centers in the United States or Canada. And the idea is that they've been organized in order to do specific clinical trials in lupus. And such clinical trials are now being carried out in these centers. The idea was that patients would be recruited from these academic sites, would be educated about the purposes of the patient partner program, would learn something about lupus, would learn something about clinical trials and then would be able to function in those academic centers in order to aid in recruitment for clinical trials.

Q Turning back to the mark -- we'll follow up on some of what you talked about later, but I'm trying to focus on the mark now. Who decided -- did you decide on the lower case u and the lower case i in the presentation of the mark?

A The lower case u is the second letter in lupus anyway. And for all of the lupus-related marks that we've come up with, we always use a capital L and a small u as the initiating two letters. We wanted to focus on the patient partner, the reason that the two P's were capitalized. The network seemed like a good thing. And, actually, having the small i just made it look graphically prettier.

Q Okay. But the -- the other parts of the acronym are all capitalized --

A Correct.

Q -- Patient Partner and -- so i is the only one that's not capitalized. You know, it's --

A Right.

Q -- it's -- it has its own word.

A It has its own word, its own meaning, its own importance, but realistically it was just we felt that stylistically it looked prettier with a small i. There was no great scientific strategy there.

Q But, for instance, like for LuCIN --

A Right.

Q -- you have the lower case u, but the I and the C and N --

A Correct.

Q -- are all caps.

drug is not always who's marketing the drug. So it lists who is currently marketing the drug.

Q Okay.

Okay. When did AMPEL first hear about the opposer, Lupin Pharmaceuticals?

A When the opposition was filed and Patrick notified us about it.

Q Okay. So you had never heard of Lupin --

A Correct.

Q -- ever before that?

A Correct.

Q And you were not familiar at all with any of Lupin's pharmaceutical products prior to that?

A Correct.

Q Okay. Now, are you aware -- obviously you now are aware of Lupin Pharmaceuticals, but are you aware of any other third parties, besides AMPEL and the opposer, Lupin Pharmaceuticals, that use the term Lupin, whether with one P or two P's?

A I mean, it means wolf. So it's a common word, right?

Q Well, I mean --

A Refers to a wolf.

Q Well, you're aware -- you're not aware of anyone else in the pharmaceutical --

BY MR. CURTIN:

Q I'm looking specifically at page 114, at the last bullet.

A Um-hmm.

Q So that's an instance where the I was uppercase; is that correct?

A Right.

Q And this is a -- this is the initial launch -- correct? -- in Boston?

A The initial discussion of it, yes.

Q Okay. And this in front -- could you state for the record who this was -- what the meeting was that you -- where you launched --

A This was a meeting of investigators from the LuCIN network, the network that is carrying out clinical trials in lupus.

Q This wasn't held at -- this presentation wasn't made at the American College of Rheumatology?

A Correct.

Q It was or wasn't?

A Yes, it was.

Q It was. Okay. And investigators are part of the American College of Rheumatology?

A Most attend the meeting. The meeting is an open meeting for rheumatologists, and many of the LuCIN

A Correct.

Q And again you have the lower case u, but the P's are in a very distinctive font and -- and there's a capital I. Is there a reason why there was a change between November 17th, 2014, and December 9th, 2014? Or --

A That was just to make it look pretty. I worked hard on the two P's to make it look like it was unique. So I was focused on the two P's and finding all these graphics because these are not -- these are laypeople, and basically the -- the graphic sometimes is more important than the words.

Q Okay. Was this --

A No strategic importance at all.

Q Okay. Is there any -- did you use the distinctive styling for the PP part of LuPPiN anytime after this presentation?

A I think it was just in these slides. We wanted to emphasize the patient partner aspect of this.

Q And, again, I is capitalized there again?

A It is. I don't know why it is.

Q Again, there are about 60 slides here.

A There are.

Q And I only saw one mention of LuPPIN, which is on page 34.

A Correct.

A Correct.

Q -- under the LuPPiN mark?

Have you ever sold anything of -- ever provided those services under the patient partner mark?

A No. As I said, we just developed the training manual --

Q Okay.

A -- and are in a position to initiate identification of patients, but, again, that requires support.

Q Now, turning back to your -- you being AMPEL's -- efforts to promote and advertise the LuPPiN brand, isn't it -- there are no documents, to your knowledge, that would reflect any annual budget for such expenses to promote and advertise the LuPPiN brand?

A It's part of our website. That's basically the way we market all of our services. So there is a budget to support the website, and LuPPiN is on the website, but we don't specifically market ourselves in any other regard. So we don't have a marketing budget. We don't have a marketing department. We have a communications person who maintains our website, and LuPPiN is on the website.

Q And could you just confirm that you've never done any radio ads that featured the LuPPiN mark?

A We don't do any radio ads, we do no advertising

and we don't market any of our services, not specifically LuPPiN but any of our services.

Q Okay. So that -- that includes no television ads and no ads in any --

A No television --

Q -- print magazines?

A -- ads, no internet ads, no ads on billboards. AMPEL does not advertise services.

Q Okay. Your advertising promotion really is basically your presentations before --

A Our presentations, our consulting with pharma and our website. That is basically how the world knows us.

Q Okay. And also through your personal contacts?

A Correct, and my personal contacts.

Q Does AMPEL keep track of the Web traffic on its website?

A We actually do not.

Q Okay. So you have no idea how many people visited your website at any time?

A We do not.

Q Okay. The website you've mentioned is one area where you promote -- strike -- strike that.

You use the LuPPiN mark on your website today; is that correct?

A Still on the website, yes.

booth would hand it out to somebody, largely to give them the contact information.

Q Do you have any idea how many were distributed, total?

A I don't have any idea at all.

Q Okay. Aside from that, the website and the brochure, the presentations we discussed before also mention the LuPPiN mark; correct?

A Correct.

Q Okay. We didn't -- we've talked, obviously, about the launch in Boston, the presentation in New York before the Board of Directors and the biotech forum presentation, but can you tell me a little bit about the 2016 meeting in the District of Columbia?

A The 2016 meeting was the meeting to plan the training brochure.

Q And that wasn't part and parcel of any wider --

A Standalone --

Q -- group meeting --

A -- meeting. A standalone meeting in Washington with seven rheumatologists, seven patients and six other individuals, support people, really to plan the training brochure.

Q Now, when in 2016 was that meeting held?

A March.

useful recruitment strategy for us because, as with all modern universities, have a lot of smart kids with basically no direction.

Q And you have quite a few interns?

A We have intern program and we bring in a lot of interns. And we have a fair number of permanent employees that started out as either interns or recruited for other purposes from the local schools. And UVA is one of the ones that we work with a lot.

Q You get up to Johns Hopkins?

A We haven't been to Hopkins. They're a little bit less open, but we have been to George Mason, GW, VCU. We're going out to Virginia Tech in March. So we've really done a fairly extensive job because we're always looking for talent.

Q Okay. Going back to the contracts you've had with the pharmaceutical companies or the grants you had with pharmaceutical companies, have you ever offered to provide patient partner programs on behalf of these pharmaceutical companies?

A We have.

Q You had four of them, I believe you've testified. Is that correct?

A Yeah. We have a number of companies, as we -- we've done two or three different approaches, which we --

which -- all of which are going on at the moment, but we've not yet wound up with a contract for the patient partner program. But there are some trials that we do with industry where basically we work as a contract research organization. We do everything. That may include holding even the investigated drug application, so the IND. There are others where we take on some part of the program. And that may involve patient education, may involve physician education, may involve communication. And in that context, we've offered the LuPPiN program. And so far we haven't gotten a successful contract, but we continue to try.

Q Now, when you said -- you said LuPPiN program. Have you actually marketed to the pharmaceutical companies under the LuPPiN name for these services you --

A We offer the service, yes, as a patient partner.

Q Oh, as a patient partner. Okay.

A Correct.

Q So anything from basically -- roughly March 2016 forward --

A Right.

Q -- is a patient partner?

A Correct. Pharma companies employ a lot of lawyers. It's a mistake to go there with something which isn't absolutely clear.

Q Okay.

Q Okay. And to the best of your knowledge, those answers are correct?

A Correct.

Q Okay. Turning to the issue of actual confusion, has anyone either internally at AMPEL or any third party ever exhibited any confusion or mistake arising between AMPEL's LuPPiN mark and the Lupin mark of Lupin Pharmaceuticals?

A No.

Q Okay. Has anyone ever remarked about any similarity between the parties' respective marks?

A No.

Q Has anyone ever remarked or inquired about any association or affiliation or sponsorship between AMPEL and Lupin Pharmaceuticals?

A No.

Q Okay. If you're allowed to move forward with use -- registration of LuPPiN, what would be -- what plans do you have if you can start using the mark LuPPiN again?

A We would aggressively market the whole program under the LuPPiN name. We would identify patients and then we would start to train them. And we would start to provide that service to support clinical trials.

Q Okay. And the clinical trials basically would be underwritten or funded by the pharmaceutical companies

that have the compounds that might --

A Some would.

Q -- treat lupus?

A Some would perhaps be supported by grants. Some would be supported by voluntary organizations that are interested in developing new compounds. One of the major problems in -- I think we talked about this two days ago -- in clinical trials is recruiting patients. And there's a real problem with recruiting patients. Patients just are unaware or not interested or afraid to enter into clinical trials. And this becomes a significantly greater problem when one is dealing with minority individuals, either African-American, Hispanic or Asian, in the United States. So the goal is to use the patient partner program, the LuPPiN program in order to demystify clinical trials, both for white patients as well as African-Americans, Hispanics and Asians, and to hopefully increase the enrollment in clinical trials so these trials can get done quickly and patients can be given access to these drugs.

Q You mentioned earlier in your testimony from a couple days ago, but there are about, what, 500 to 1.5 million --

A Somewhere --

Q -- folks afflicted --

A Somewhere --

a position where their cadre of lawyers, which is way bigger than yours, feels comfortable that what we're telling them can actually be done. And they do lots of due diligence. I mean, there's no privacy in this world when you're actually trying to sign a contract with a large pharma company.

Q Now, to get the word out, I mean are you going to be using the LuPPiN mark in terms of, you know, trying to directly target potential participants in these clinical trials?

A What we're trying to do is to convince the pharma sponsors that by engaging the lupus -- the LuPPiN network it will facilitate enrollment in the trial. That's really the strategy.

Q But -- okay. Just back up, then. Who's recruiting for you? Is it the academic sites --

A The academic sites are -- we engage in the academic -- with the academic sites. The academic sites engage -- recruit the patients. In this discipline, unfortunately they're not as active as we would like them to be. We know everything about them. We know how many patients are in their sites. We know how many have lupus, et cetera et cetera. And we know their performance is not as wonderful as they think it is. So we would -- one of our tasks is to increase enrollment because, as I said, you

know, every day costs a certain amount of money. The companies know how much money it costs, and they would very much like to foreshorten the length of these trials so they can get an answer before their management shuts them down.

You know all this stuff. It's not --

Q No, I'm -- I'm more interested -- my -- my question --

A And that's what the -- that's what the role of the LuPPiN program is, to facilitate enrollment in these trials.

Q What I'm trying to get at, inartfully apparently, is how does the target, you know, these -- the LuPPiN -- the lupus sufferers, ever encounter the LuPPiN mark? Do they get it through the -- the investigators --

A No, no, no. Basically, we will have trained LuPPiN members in each of those clinics who will be identified as members of the LuPPiN network.

Q Okay.

A And that network will imply -- training quality will separate it from a concierge, from a support group, from whatever else that particular hospital provides, to service, you know, volunteers, candy stripers. You know, when you're in the hospital, it's impossible to know who you're actually talking to, except you can be certain it's not a doctor. But, you know, when you can have a program

which has this kind of training and this kind of validation and this kind of history and you can then use that to indicate that this is different than what else that -- what -- what -- other people. This person is not wheeling you to the x-ray. This person knows about lupus. So that's the plan.

Q And you're still in the midst of recruiting these folks, right?

A We're still in the midst of finishing up the training program and recruiting them. We need, basically, the financial support to begin to do that.

Q So then, at the end of the day, after you train these people in this cadre, it's basically word of mouth. You're not going to be, you know, putting it on billboards or --

A Oh, no, no, no, no, not billboards. These people are going to be working in a clinic in a university hospital, interacting with other patients. All right? There's no -- no intent here to, you know, put this on buses and say look for your LuPPiN representative.

Q Okay.

A The intent is that it will be a kind of an indication of a quality training in a person who's trustworthy, but that would be just something which is communicated within the clinic space of that academic

institution.

Q Okay. And obviously if, you know, you go where the academic sites are, which could be all 50 states as --

A Right.

Q -- well as Canada? Okay.

A Correct. And all of that would be done after approval by an institutional review board. There's a lot of steps --

Q To get to --

A -- involved in --

Q -- that point.

A -- this. I mean it's not that you can just set up a tent here and hang up a sign and do whatever you want. It all is very much regulated.

Q Now, you -- we talked about academic sites, but then you mentioned hospitals. Are hospitals, you know, part and parcel of the academic sites?

A Each of the sites we're at is a medical school. Some of those medical schools have hospitals that are part of the medical center. Some of them have affiliated hospitals that they work with. But they're all basically the primary teaching facility of a -- of a medical school.

Q Okay. Does AMPEL own the trademark LuCIN currently?

A We registered it and we licensed it out.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

In the matter of Application Serial No. 86509184
For the Mark: LUPPIN
Published in the Official Gazette on August 18, 2015

LUPIN PHARMACEUTICALS, INC., Opposer,	:	
v.	:	Opposition No. 91226322
AMPEL, LLC, Applicant.	:	

CONFIDENTIAL

DEPOSITION OF AMRIE GRAMMER, Ph.D.

WEDNESDAY, SEPTEMBER 27, 2017

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REPORTED BY: Cheryl McGrory
FILE NO.: AB09E51

EXHIBIT E

Q Okay. All right. And what -- can you just describe the process of selecting the name?

A Sure. So we -- to give you a little background, one of the first things that we did was focus on repositioning drugs from other diseases into lupus, and so we developed a number of programs to do that, most of which are described in Exhibit 3 that you provided me. And they all started, you know, with L-U, for lupus, and then, you know, the rest of an acronym. And Dr. Lipsky is very good at making up acronyms. So, you know, LuCIN, LuCIN-STAT, you know, LuPPiN. You know, we have LuSEC, LuCIT. We have, you know, many, many things that are in this family of names.

Q I don't think LuSEC was one that I've heard yet. What does that stand for?

A So LuSEC, I -- I don't remember exactly what it stands for, but it's our medical education program for clinical trials.

Q Is that something that you publicized at all?

A It is.

Q Okay. And how -- who have you publicized that to?

A Dr. Lipsky would know the detail about that, but has to do with clinical operations, so --

Q Okay. So, in general, who would be the people

LuPPiN?

A Yes.

Q Okay. So if you -- went today to a conference and mentioned the patient partner program, you -- you would call it LuPPiN?

A That's what I have it in my mind as, so --

Q And are there any written materials that are distributed at any of your speaking engagements?

A No.

Q Is there any slide presentations at those meetings?

A So there are slide presentations, but they're mostly focused on the drugs. Dr. Lipsky is the one that's presented the LuPPiN program in the context of clinical operations.

Q Okay. So is LuPPiN mentioned in those -- in the -- on the slides at all?

A I think he -- you know, he mentioned when we kicked off the LuCIN network, which was at the ACR meeting in, I think, the fall of 2014. And then, you know, he attends the Board of Directors meetings of the Alliance for Lupus Research, which is now the Lupus Research Alliance, you know, to talk about the program. He has talked about it at various other things, like we were invited to the BioHealth Capital Forum. He talked about it then. And

certainly he's talked about it to, you know, patient groups. But he really has a knowledge of all of that.

Q Okay. And what about -- are you -- are you also attending those same -- the conferences that you're speaking of Dr. Lipsky attending?

A The ones that I just mentioned are ones that I was present at. There are many more that he has done that I wasn't present at.

Q Okay. And have you spoken at those -- those particular conferences?

A I have not.

Q Okay. What is BioHealth Capital Forum?

A So BioHealth Capital Forum is a meeting that's actually put on by Maryland Bio.

Q Okay.

A And the goal of that is to collaborate with Virginia Bio, similar to how we are collaborating with Maryland Bio.

Q And do you ever speak with lupus caregivers about the LuPPiN program?

A I do not. That's under clinical operations.

Q Okay. And when you see clinical operations, is Dr. Lipsky in charge of that?

A Correct. He's the Chief Medical Officer. He's in charge of charge of clinical operations.

Q Okay. And you mentioned the kick-off meeting for the LuPPiN program. Can you describe that to us?

A So that was a meeting. I think it was in the spring of 2015 in Washington, D.C. And so, you know, there was a social worker there that was hired as a coordinator, you know, of the patients to act in, you know, a support capacity. And then, you know, there were a lot of patients there. There were physician scientists there. I think I probably was the only Ph.D. there. I was there as a courtesy because I've been involved in the drug repositioning program since the beginning.

Q Okay.

A I remember distinctly because I love the cherry blossoms. It was during the Cherry Blossom Festival. It was in D.C. Hadn't seen them in many years, so...

Q Great time of year. Yeah. And what happened at that meeting?

A So, you know, my recollection is, you know, talked about the drug repositioning program, talked about all of the clinical trials that potentially could be going on, the investigator sites. You know, the LuPPiN program, as I mentioned, a social worker was hired that coordinated -- supposedly interacted with the patients. You know, I was in and out a lot of the day for the meeting, taking calls. As I said, I was there as a

A Right. And I mentioned this before, you know. I periodically give presentations to the funding organizations as well as at these other meetings.

Q All right.

A And the focus of this was all about drug repositioning. I'm sure if you listen to the video you'll see that.

Q Okay. And these -- the -- these slides, are those an accurate representation, to the best of your remembrance, of the portion -- portions of those slides in the presentation?

A Yes. And this slide in particular, I initially presented at that meeting I mentioned in Washington, D.C., right before the lupus caucus. As I've mentioned, I always mention the network when I'm giving presentations. And this looks like almost the exact slide as I presented in D.C. a couple years before.

Q That was -- let's see. We've been speaking about a bunch of -- few different meetings, so --

A So Cherry Blossom Festival, spring. So I guess that would have been spring of 2014, to the best of my knowledge.

Q Okay.

A The Cherry Blossom Festival meeting in D.C. with the lupus caucus.

know, I called it LuPPiN, Lupus Patient Network, you know. I don't remember exactly.

Q And do you still speak at the conferences for lupus patients?

A This is actually, I think, the last one that I spoke directly to the patients at --

Q Okay.

A -- that was sponsored by the ALR and the LRI. They subsequently merged. This meeting has changed dramatically after the merger.

Q Okay. Did you -- so you -- you said that that was the last conference specifically for lupus patients. Were there other conferences that lupus patients may have been in attendance after this time?

A So, to clarify, I said that was the last conference I spoke to patients at that was sponsored by the LRI and the ALR, which is now the Lupus Research Alliance.

Q Okay. Have there been conferences sponsored, you know, of any other -- any other sort that you've spoken to lupus patients?

A So I always speak at the FOCIS meeting, at the Board of Directors meeting. And there are patients there as well as, you know, researchers and physician scientists and physicians.

Q Okay. Is that the -- at the annual conference?

A Correct.

Q Okay. And when was the last time you did that?

A In June.

Q And do you mention the LuPPiN program?

A I always try, you know, to mention it --

Q Um-hmm.

A -- whenever I'm talking about drug repositioning.

Q Sure. And do you mention it by the name LuPPiN?

A I do. And sometimes I mention it -- you know, the lupus patient network or patient partners. They're all interchangeable, in my mind.

Q And do you know whether anyone signs up for -- to be participants in the LuPPiN program as a result of your presentations?

A I don't. You'd have to ask Dr. Lipsky, since he's in charge of clinical operations. If people are interested, I refer them to him.

Q Okay. And do you -- do you recall specifically whether you've had people asking about the program?

A People are always asking me about the program. I always get a mob of people at the end of my talk waiting to talk with me. I usually just try to hand out cards.

Q Um-hmm. And do you know whether any of them have contacted Dr. Lipsky about the LuPPiN program?

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

LUPIN PHARMACEUTICALS, INC.,

Opposer/Petitioner,

v.

AMPEL, LLC,

Applicant/Respondent.

Proceeding No. 91226322
Application Serial No. 86/509184
Mark: LuPPiN

AFFIDAVIT OF DR. PETER LIPSKY

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

LUPIN PHARMACEUTICALS, INC.,

Opposer/Petitioner,

v.

Proceeding No. 91226322
Application Serial No. 86/509184
Mark: LuPPiN

AMPEL, LLC,

Applicant/Respondent.

AFFIDAVIT OF DR. PETER LIPSKY

1. I am the CEO and the Director of Clinical Operations for Ampel, LLC (hereinafter "Ampel"). I make this affidavit in opposition to the Motion for Summary Judgment filed by Lupin Pharmaceuticals, Inc. (hereinafter "Lupin"). The facts in this affidavit are based upon my personal knowledge as well as the records, data, and documents of Ampel that I have reviewed and/or annexed hereto which are kept by Ampel in the ordinary course of business.

2. I graduated from Cornell University in 1965 and from the New York University School of Medicine in 1969. Following completion of residency, I worked at the National Institutes of Health and as a faculty member at the University of Texas (UT) Southwestern Medical Center. Between 2006 and 2013, I worked as an independent consultant.

3. I founded Ampel with Dr. Amrie Grammer in 2013. Ampel is a biomedical research consultation firm, and has a particular focus on projects involving the autoimmune disease Lupus.

4. With respect to Lupus initiatives, Ampel has pursued several projects which are identified by names starting with "Lu," to connote a specific connection to Lupus, including "LuCIN," "LuCIT," "LuPro," "LuCIN-STAT," and "LuSEC." In addition, Ampel has established the "Lupus Patient Partner Integrator Network," which it identifies with the mark "LuPPiN," which is the mark at issue in this proceeding.

5. Ampel's business involves identifying existing drugs and scoring them to assess their potential efficacy in treating Lupus. This is known in the industry as "drug repositioning" or "drug repurposing," whereby an existing drug which is used for a specific therapeutic purpose is used to treat another disease. Ampel has developed a proprietary system to test existing drugs and to assess and score their potential effectiveness in treating Lupus. In scoring drugs, Ampel is not seeking to identify drugs which may be effective in treating common symptoms of Lupus or to develop new drugs. Instead, Ampel's goal is to identify existing drugs which effectively treat Lupus as a disease.

6. Ampel markets its services through its website and the personal contacts of myself and Dr. Grammer, which have been built over many years, and through my work in the medical field for nearly 50 years, through speaking engagements and by simple word of mouth. Except for its website and a few brochures which are produced from time to time, Ampel does not advertise through print or visual media.

7. When Ampel identifies a drug which may be effective in treating Lupus, I use my personal contacts in the pharmaceutical industry to approach pharmaceutical companies who I believe may have interest in conducting a clinical trial to test the efficacy of such drug as a treatment for Lupus. Ampel's experience and expertise in arranging and conducting clinical trials allows it to conduct clinical trials far more efficiently and cost-effectively than many other companies who conduct clinical trials. In marketing Ampel's clinical trial services to pharmaceutical companies, Ampel uses its "LuCIN" trademark, which is an acronym for "Lupus Clinical Investigators Network." LuCIN is the mark under which Ampel conducts clinical trials for Lupus treatments.

8. The LuPPiN program is a patient centric program designed to develop a network of Lupus patients dedicated to assisting and supporting other Lupus patients who are considering participating in clinical trials conducted by Ampel's associated LuCIN network of clinical

investigators. The LuPPiN program has its roots in a similar program that I administered at the UT Southwestern Medical Center in Dallas for Rheumatoid Arthritis patients called "Patient Partners." Patients were trained to help medical students and professionals detect early signs and symptoms of musculoskeletal conditions, thereby facilitating an early diagnosis and therapeutic intervention to improve patient outcomes. Similarly, Lupus patients can be of great help in educating other Lupus patients about available treatment options, demystifying clinical trials to other patients, and helping to explain the nature of clinical trials, the patient protections in such trials and the important contribution patients can make in the development of new treatments.

9. The focus of the LuPPiN program is on the Lupus patient. This patient-centric program is designed to provide (1) support for Lupus patients who are undergoing treatment and clinical trials and for the caregivers of such patients; and (2) seminars and mentoring to educate Lupus patients about treatment options and available clinical trials, and to train Lupus patients so that they can educate other Lupus patients. To that end, Ampel applied to register the LuPPiN mark in furtherance of "[o]rganizing and conducting support groups for Lupus patients who are undergoing treatment and clinical trials, and for the caregivers of Lupus patients who are undergoing treatment and clinical trials," as set forth on the copy of the Ampel's application attached hereto as **Exhibit A**. The mark is an acronym for "Lupus Patient Partner Integrator Network." An example of Ampel's use of the LuPPiN mark can be found on its website, a screenshot of which is attached hereto as **Exhibit B**, and in a representative brochure, a copy of which is attached hereto as **Exhibit C**.

10. In addition to these materials, Ampel has also promoted the LuPPiN program at medical conferences and seminars, specifically, the 2014 Annual Meeting of the American College of Rheumatology, a presentation to the Board of Alliance of Lupus Research, also in 2014, and the Maryland Biotech Forum in 2015.

11. Ampel works with a network of 59 academic medical centers in the United States and Canada through its associated LuCIN network. These academic medical centers host clinical trials for drugs that have been identified by Ampel as potential treatments of Lupus. The LuPPiN program seeks to recruit a small, highly-select number of Lupus patients who are treated at one of these academic medical centers to participate in training so that they can provide support and education to other Lupus patients who are being treated at the same academic medical center and who may be suitable candidates to participate in a clinical trial for a potential Lupus treatment. The Lupus patients who participate in the LuPPiN program will typically have previously participated in a clinical trial for a Lupus treatment and will be well-educated, articulate and fully familiar with all aspects of Lupus and the workings of a clinical trial. As such, they are able to answer a patient's questions and address their understandable fears and concerns about participating in a clinical trial. If a Lupus patient agrees to participate in a clinical trial, her "patient partner" will continue to provide support throughout the trial. Thus, the two capital "P" letters in LuPPiN emphasize the most important aspect of the LuPPiN program – the "patient partner."

12. Accordingly, Ampel's use of the mark "LuPPiN" is primarily and predominately targeted to Lupus patients who are treated at the academic medical centers where clinical trials will be conducted. These patients, who will act as patient partners, have the intelligence, emotional capacity, knowledge and experience to educate Lupus patients about clinical trials and to support them through such trials. At its heart, the LuPPiN program helps to support and promote the clinical trials conducted by the LuCIN network by recruiting patients to participate in clinical trials and supporting such patients, thereby reducing the drop-out rate of such clinical trial.

13. Ampel does not actively market or promote the LuPPiN program to pharmaceutical companies when marketing its clinical trial services to such pharmaceutical companies. As noted, the primary mark that pharmaceutical companies would encounter when considering whether to

engage Ampel to conduct a clinical trial is "LuCIN." In explaining the total package of services that Ampel provides, I may discuss the LuPPiN program with pharmaceutical representatives and explain that this is a program that helps Ampel to recruit Lupus patients to participate in the clinical trial and to support such patients throughout the clinical trial. However, Ampel does not specifically market LuPPiN to pharmaceutical companies as the LuPPiN network is very much secondary to the primary purpose of our discussions with pharmaceutical companies which is to encourage them to support a clinical trial for a drug which Ampel has identified as being a potential treatment for Lupus.

14. When I do discuss the LuPPiN program with representatives of pharmaceutical companies, no representative has ever expressed any confusion that the program is associated with or sponsored by Lupin or questioned whether there is any association with Lupin. In my experience, representatives of pharmaceutical companies who make multi-million dollar decisions as to whether to fund a clinical trial are highly educated, experienced and sophisticated, and it is implausible that such representatives would confuse Ampel's LuPPiN program with a generic drug manufacturer.

15. I have spent my entire career, now spanning almost 50 years, in the medical field. I was not familiar with the opposer, Lupin, until its filed its opposition in this proceeding. I am not aware of any confusion between the LuPPiN program and Lupin, and no one has ever expressed any such confusion to me or anyone else affiliated with Ampel or ever questioned whether there is any affiliation or relationship between the LuPPiN program and Lupin.

16. Based on the information provided by Lupin in this proceeding, I understand that Lupin is a generic drug manufacturer which sells generic drugs through wholesalers. Ampel does not manufacture, market, sell, or distribute any pharmaceuticals. Ampel has no dealings of any nature whatsoever with any wholesalers, distributors or retailers of any pharmaceuticals. Ampel

also does not work directly with any manufacturers of generic pharmaceuticals, like the opposer, Lupin. There is simply no overlap in the channels of trade between Ampel and Lupin.

17. I declare and verify under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

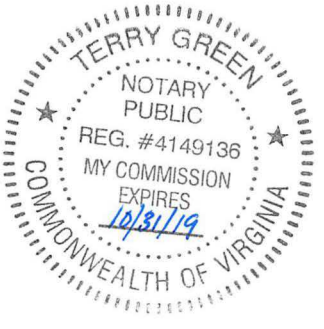
1/26/2018
Date

Peter Lipsky, M.D.

COMMONWEALTH OF VIRGINIA
CITY OF CHARLOTTESVILLE, to-wit:

Subscribed, sworn to and acknowledged before me this 26th day of January 2018 by Peter Lipsky, M.D.

My commission expires: 10/31/2019
Registration Number: 4149136



Notary Public

EXHIBIT A
Affidavit of Dr. Peter Lipsky

Under the Paperwork Reduction Act of 1995 no persons are required to respond to a collection of information unless it displays a valid OMB control number.
PTO Form 1478 (Rev 09/2006)
OMB No. 0651-0009 (Exp 02/28/2018)

Trademark/Service Mark Application, Principal Register

NOTE: Data fields with the * are mandatory. The wording "(if applicable)" appears where the field is only mandatory under the facts of the particular application.

The table below presents the data as entered.

Input Field	Entered
SERIAL NUMBER	N/A
MARK INFORMATION	
***MARK**	MRK7515059213-101455574_._Ampel_-_LuPPiN_Trademark_Logo__CV313442xA26AD_.JPG
SPECIAL FORM	YES
USPTO-GENERATED IMAGE	NO
LITERAL ELEMENT	LuPPiN
COLOR MARK	NO
***DESCRIPTION OF THE MARK (and Color Location, if applicable)**	The mark consists of the word LuPPiN. LuPPiN has capitalized letters L, P, P, and N.
PIXEL COUNT ACCEPTABLE	YES
PIXEL COUNT	727 x 335
APPLICANT INFORMATION	
***OWNER OF MARK**	Ampel, LLC
INTERNAL ADDRESS	Suite 301
***STREET**	1001 Research Park Blvd.
***CITY**	Charlottesville
***STATE** (Required for U.S. applicants)	Virginia
***COUNTRY**	United States
***ZIP/POSTAL CODE** (Required for U.S. applicants)	22911
PHONE	434-296-2675
LEGAL ENTITY INFORMATION	
TYPE	limited liability company

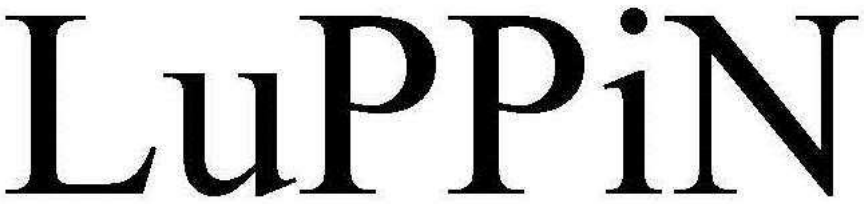
STATE/COUNTRY WHERE LEGALLY ORGANIZED	Virginia
GOODS AND/OR SERVICES AND BASIS INFORMATION	
INTERNATIONAL CLASS	016
***IDENTIFICATION**	Educational materials, namely, training manuals in the field of Lupus to train Lupus patients to assist in recruiting other Lupus patients to participate in clinical trials for Lupus treatments.
FILING BASIS	SECTION 1(b)
INTERNATIONAL CLASS	035
***IDENTIFICATION**	Recruitment of Lupus patients to participate in clinical trials for Lupus treatments.
FILING BASIS	SECTION 1(b)
INTERNATIONAL CLASS	041
***IDENTIFICATION**	Training services, namely, training Lupus patients to assist in recruiting other Lupus patients to participate in clinical trials for Lupus treatments.
FILING BASIS	SECTION 1(b)
ADDITIONAL STATEMENTS SECTION	
MISCELLANEOUS STATEMENT	Applicant claims ownership of pending application Serial No. 86509184.
ATTORNEY INFORMATION	
NAME	Patrick C. Asplin
FIRM NAME	Lenhart Pettit
STREET	530 East Main Street
CITY	Charlottesville
STATE	Virginia
COUNTRY	United States
ZIP/POSTAL CODE	22902
PHONE	434-979-1400
FAX	434-977-5109
EMAIL ADDRESS	pca@lplaw.com
AUTHORIZED TO COMMUNICATE VIA EMAIL	Yes
OTHER APPOINTED ATTORNEY	Andrew B. Stockment

CORRESPONDENCE INFORMATION	
NAME	Patrick C. Asplin
FIRM NAME	Lenhart Pettit
STREET	530 East Main Street
CITY	Charlottesville
STATE	Virginia
COUNTRY	United States
ZIP/POSTAL CODE	22902
PHONE	434-979-1400
FAX	434-977-5109
*EMAIL ADDRESS	pca@lplaw.com;abs@lplaw.com; tlg@lplaw.com
*AUTHORIZED TO COMMUNICATE VIA EMAIL	Yes
FEE INFORMATION	
APPLICATION FILING OPTION	TEAS RF
NUMBER OF CLASSES	3
APPLICATION FOR REGISTRATION PER CLASS	275
*TOTAL FEE DUE	825
*TOTAL FEE PAID	825
SIGNATURE INFORMATION	
SIGNATURE	/patrick asplin/
SIGNATORY'S NAME	Patrick C. Asplin
SIGNATORY'S POSITION	Attorney of Record, Virginia Bar Member
SIGNATORY'S PHONE NUMBER	434-220-6105
DATE SIGNED	10/13/2017

PTO Form 1478 (Rev 09/2006)
OMB No. 0651-0009 (Exp 02/28/2018)

Mark (Applicant-generated image):

MRK7515059213-101455574_._Ampel_-_LuPPiN_Trademark_Logo__CV313442xA26AD_.JPG



Back

EXHIBIT B
Affidavit of Dr. Peter Lipsky

Lupus Projects

WHAT WE HAVE DONE

Researchers

LRxL STAT™ is the ongoing drug repositioning initiative searching for new treatments for persons with lupus.

Clinical Investigators

LuCIN™ is the Lupus Clinical Investigators Network that will carry out clinical trials of the top priority treatment candidates generated by LRxL STAT™.

Patient Partners

LuPPiN™ is the Lupus Patient Partners program that will identify and train lupus patients to help other patients to understand and participate in the clinical trials carried out by LuCIN™.

AMPEL BioSolutions & Lupus (SLE)

AMPEL BioSolutions launched a project in July of 2013 to re-imagine drug discovery in SLE and rapidl bring new precision therapies to patients with this chronic disabling disease.

SLE is a systemic autoimmune disease in which the immune system that normally protects against infectious diseases becomes misdirected and attacks the person's organs and tissues. This disease predominantly affects women of childbearing age and also is more common in many minority groups. Despite intensive research on this disease, there has been only one nev treatment approved in more than half a century, and that new therapy (Benlysta) has been onl modestly effective. The standard process of drug development has not been effective in SLE, stimulating AMPEL BioSolutions to rethink the paradigm.

LRxL STAT

One of AMPEL's most recent LRxL™ projects, LRxL-STAT™ was launched in October of 2013 with the support of New York's Alliance for Lupus Research & the Lupus Research Institute (LRI Effective safe treatments for Lupus are sorely lacking, with only one drug approved for Lupus i the last 50 years. Frustrated by the slow-paced translation of basic science discoveries into new treatments for Lupus, the ALR & LRI commissioned AMPEL BioSolutions to carry out an in-dept analysis of all drugs & biologics approved for human use in the United States.

After six month of extensive research of the human & mouse literature, AMPEL has compiled the Lupus Treatment List (LRxL™) in consultation with members of the community which wer then vetted by an expert committee in April of 2014. Take a look at the LRxL-STAT™ LinkedIn site to view the poster presented at the American College of Rheumatology meeting in November of 2014. The next step is conducting SLE Treatment Acceleration Trials (STAT) with our Lupus Clinical Investigators Network (LuCIN™) & Patient Partner Integrator Network (LuPPiN™).

LRxL

Through its ground-breaking LRxL™ program, AMPEL has made a significant advance on the p
AMPEL conducted extensive research to compile valuable information relating to the potential
component of this information is the development of what is simply referred to as LRxL™, an
the treatment of Lupus. Under its LRxL™ program, AMPEL will continue its research efforts an
The LRxL™ will be utilized by LuCIN™ to conduct research and trials, including LuCIN-STAT™

LuCIN

AMPEL is in process of identifying highly qualified and experienced research sites to participate
Lupus Drug Repositioning Initiative. This Lupus Clinical Investigators Network (LuCIN™) is
composed of clinical sites throughout the United States with exceptional research capabilities
and experience in Lupus.

With the administrative and technical support of AMPEL, LuCIN™ sites will conduct science-ric
trials on the novel and interesting agents of the Lupus Treatment List that have a high likelihoo
of success. We have identified over 60 sites with interest in carrying out science-rich trials of
novel and interesting agents that have a high likelihood of success. In addition, we plan that all
investigators will have access to all data and publication of trial results will be encouraged. The
members of LuCIN™ had their first meeting at the American College of Rheumatology summi
in November of 2014.

LuCIN STAT

An initial core initiative of LuCIN™ is LuCIN STAT,™ ground-breaking research and clinical tria
therapies. Under the LUCIN STAT™ program, LuCIN™ will focus on SLE treatment and accele
to the LRxL™.

LuPPiN

LuPPiN™, or the Lupus Patient Partner Integrator Network, is AMPEL's patient centric program
patient advocates dedicated to assisting and supporting Lupus patients. LuPPiN™ has its root

program at the UT Southwestern Medical Center in Dallas for Rheumatoid Arthritis patients called Patient Partners. Patients were trained to help medical students and professionals detec early signs and symptoms of musculoskeletal conditions, thereby facilitating an early diagnosis and therapeutic intervention to improve patient outcomes. These “Patient Partners” were a milestone in patient empowerment with “Centers of Excellence” established worldwide and more than 600 Patients Partners trained over a four-year period.

Today, AMPEL BioSolutions aims to expand this program to SLE clinical research through LuPPiN™. Because of the difficulty of diagnosis and the lack of clear communication of symptoms, AMPEL believes that developing a patient training program will facilitate better communication between patients and doctors. In addition, patient partners—whether they be Lupus patients or dedicated patient advocates—can be of great help in educating Lupus patients about available treatment options, demystifying clinical trials to other patients, and helping to explain the nature of clinical trials, the patient protections in such trials and the impo development of new treatments. Working together with Lupus advocacy organizations and ind pushing the boundaries of clinical research and developing ways of improving the clinical trial e

CoLTs

AMPEL BioSolutions has developed a unique and proprietary system for assessing the efficacy enables potential Lupus therapies to be scored and ranked based on defined criteria. As part o analysis of Lupus therapies to its partners who are testing existing Lupus therapies and/or here interested in utilizing CoLTs™ should contact AMPEL.

Lupus Drug Candidates

- Kadmon, KD025 ROCK2 inhibitor
- Janssen, Stelara IL-12/23 inhibitor

AMPEL BIOSOLUTIONS & LUPUS (SLE)

AMPEL BioSolutions launched a project in July of 2013 to re-imagine drug discovery in SLE and rapidly bring new precision therapies to patients with this chronic disabling disease.

SLE is a systemic autoimmune disease in which the immune system that normally protects against infectious diseases becomes misdirected and attacks the person's organs and tissues. This disease predominantly affects women of childbearing age and also is more common in many minority groups. Despite intensive research on this disease, there has been only one new treatment approved in more than half a century, and that new therapy (Benlysta) has been only modestly effective. The standard process of drug development has not been effective in SLE, stimulating AMPEL BioSolutions to rethink the paradigm.

WHAT WE HAVE DONE

Community Networks
Researchers, LRxL-STAT™
Clinical Investigators, LuCIN™
Patient Partners, LuPPIN™

Drug Repositioning
Literature Mining
Crowd Sourcing
Big Data Mining
CoLTs™ scoring system

Lupus Drug Candidates
Kadmon KD025 ROCK2 inhibitor
Janssen Stelara IL-12/23 inhibitor

AMPEL BIO SOLUTIONS LLC

CONTACT

AMPEL BioSolutions, LLC
1001 Research Park Blvd, Suite 301
Charlottesville, Virginia 22911
(434) 296-AMPL (2675)
(434) 964-9586 (fax)
info@ampel.org

ampelbiosolutions.com

EXHIBIT C
Affidavit of Dr. Peter Lipsky

AMPEL BIO SOLUTIONS LLC

Catalyzing the identification and development of new autoimmune and inflammatory treatments

REIMAGINING TREATMENT OF AUTOIMMUNE DISEASES

AMPEL BioSolutions is focused on transforming the process of target identification and drug discovery in autoimmune/inflammatory diseases, such as systemic lupus erythematosus (SLE), and hastening the development of new treatments for these chronic conditions.

OUR PRINCIPALS

The Principals of AMPEL BioSolutions are Dr. Peter Lipsky, the former director of the intramural research program at the National Institute of Arthritis Musculoskeletal and Skin Diseases at NIH and Dr. Amrie Grammer, former chief of the B Cell Biology Group at NIAMS, NIH. Together they bring more than 50 years experience in basic and translational research as well as expertise in clinical trial design and bioinformatics.

Peter Lipsky, MD
CEO & CMO

Amrie Grammer, PhD
COO & CSO

CONCEPTUALIZE DISEASE

A comprehensive approach aimed at understanding pathways disease causation.

CONCEPTUALIZE DISEASE

The first involves a comprehensive approach aimed at repositioning approved drugs.

MINE DATA & IDENTIFY TARGETS

A comprehensive approach involving Literature mining and bioinformatic analysis of large data sets. Using uniquely developed iterative big data analysis tools, specific disease signatures emerge that will permit cross-referencing to drug action and perturbagen data sets. The anticipated outcome is the identification of novel pathways and targets.

DESIGN & OPERATIONALIZE CLINICAL TRIALS

To solve the final piece of the drug development puzzle, AMPEL BioSolutions has managed the creation of a clinical network, developed novel clinical trial design strategies, identified unique biomarker panels and established a dialog with biotech/pharma and regulatory agencies that will permit the rapid assessment of drugs in well controlled proof-of-concept trials.

AMPEL BioSolutions is transforming the drug development process and stimulating rapid development of new therapies for SLE and other autoimmune disease.

FIND OUT MORE AT
ampelbiosolutions.com

APB-00012