ESTTA Tracking number: **ESTTA868150**

Filing date: **12/29/2017**

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

Proceeding	91226322
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Submission	Motion for Summary Judgment **Yes**, the Filer previously made its initial disclosures pursuant to Trademark Rule 2.120(a); OR the motion for summary judgment is based on claim or issue preclusion, or lack of jurisdiction. The deadline for pretrial disclosures for the first testimony period as originally set or reset: **01/01/2018**
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Attachments	for public filing - binder_Part1.pdf(5569156 bytes) for public filing - binder_Part2.pdf(5725718 bytes) for public filing - binder_Part3.pdf(5530390 bytes) for public filing - binder_Part4.pdf(2855426 bytes)

IN THE U.S. PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

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LUPIN PHARMACEUTICALS, INC.,

Opposer, Opposition No. 91226322

v.

AMPEL, LLC,

Applicant.
----------x

MOTION FOR SUMMARY JUDGMENT BY OPPOSER LUPIN PHARMACEUTICALS, INC.

I. PRELIMINARY STATEMENT

The undisputed facts demonstrate that the educational and support group services covered by Applicant's application to register the mark LuPPiN are offered to the same or similar consumer groups, in overlapping channels of trade, as Opposer's full line of pharmaceutical products sold under Opposer's federally registered mark LUPIN. Taking the facts in the light most favorable to Applicant Ampel, LLC ("Ampel" or "Applicant"), there is no genuine issue of material fact that a likelihood of confusion will arise from the registration of Applicant's LuPPiN mark. Accordingly, Opposer Lupin Pharmaceuticals, Inc. ("Lupin" or "Opposer") is entitled to summary judgment pursuant to Fed. R. Civ. P. 56 refusing registration of Application Serial No. 86/509,184 under Section 2(d) of the Lanham Act.

II. STATEMENT OF FACTS

A. Opposer's Well-Known LUPIN Brand

1. Origins of Opposer's LUPIN Mark and Entry into the U.S. Market

In 1968, long prior to the actions of the Applicant set forth herein, the predecessor-in-interest of Opposer's ultimate parent company, Lupin Limited, began doing business in India under the name and mark LUPIN. See the Affidavit of Dave Berthold ("Berthold Aff.") at ¶ 3. The mark LUPIN finds its origin from the lupin flower. Id. at ¶ 4. A true and correct copy of a dictionary definition of "lupin" is

attached as Exhibit A to the Declaration of Thomas H. Curtin ("Curtin Decl."). Opposer's mark is pronounced "LOO-pin." Id.; Berthold Aff. at ¶ 3.

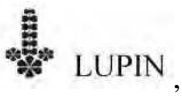
In the 1980s and 1990s, the predecessors-in-interest of Lupin Limited received approval from the United States Food and Drug Administration ("FDA") to allow various manufacturing facilities located in India to manufacture pharmaceutical products intended for distribution and sale to U.S. consumers. Berthold Aff. at ¶ 5. In the early 2000s, Lupin Limited filed its first of many Abbreviated New Drug Applications ("ANDA") with the FDA. Id. at ¶ 6.[1]

On March 28, 2002, Lupin Limited filed an ANDA for the drug ceftriaxone for injection, which was approved by the FDA on September 30, 2003. Id. at ¶ 7. In 2003, Lupin Pharmaceuticals, Inc. was incorporated in the U.S. and began doing business at its headquarters in Baltimore. Id. at ¶ 11. Ceftriaxone for injection eventually became the first drug marketed under the LUPIN trademark in the United States, beginning in July 2005. Id. at ¶ 7-9. Since 2005, Lupin's pharmaceutical products bearing the LUPIN mark have been distributed, offered for sale, and sold continuously throughout the United States. Id. at ¶ 10.

2. Opposer's Valid Federal Registrations for the Mark LUPIN

Opposer is the owner of the following United States Trademark Registrations on the Principal Register of the USPTO:

Reg. No. 4,024,405 for the mark LUPIN, filed on June 24, 2009 and issued on September 13, 2011 covering a "house mark for full line of pharmaceuticals for medical purposes, but excluding dietary supplements and edible flour" in Class 5, claiming a date of first use in United States commerce of July 1, 2005.

Reg. No. 4,874,579 for 

, filed on June 24, 2009 and issued on December 22, 2015

[1] ANDAs are applications for approval by the FDA of a generic version of an existing, FDA-approved drug. Id.

covering:

> 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 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, claiming a date of first use in United States commerce in 2005.

Opposer's registered trademarks are referred to herein collectively as "the LUPIN Mark." Both of the foregoing registrations are valid and subsisting and are in full force and effect, and have been pleaded in this matter. Reg. No. 4,024,405 has become incontestable by operation of law. 15 U.S.C. § 1065. True and correct copies of the foregoing certificates of registration and corresponding TSDR current status printouts are attached as Exhibits B and C, respectively, to the Curtin Decl.

3. Opposer's Sale of a Wide Variety of Pharmaceutical Products

Today, Opposer manufactures, offers for sale, and sells more than 150 types of pharmaceutical products for a wide range of indications including, for the treatment of fever; headache; fatigue; confusion; chest pain; stiffness; shortness of breath; joint or muscle pain; anemia; swelling in the legs, ankles, and feet; joint swelling; and rash, among others. Berthold Aff. at ¶¶ 12, 16. Lupin's products include both branded and generic pharmaceuticals. Id. at ¶ 13. Opposer conducts clinical trials in

conjunction with the development of its drug products. Id. at ¶ 17. Opposer is continually expanding its pharmaceutical product offerings into new therapeutic areas, such as cardiology, diabetes, women's health, and gastroenterology, among others. Id. at ¶ 18; see also Curtin Decl., Ex. Q at LUP-002911.

Both Opposer's branded and generic products are sold in packaging bearing the LUPIN mark. Berthold Aff. at ¶ 14. Some of Opposer's products also bear the LUPIN mark imprinted directly on the drug capsule. Id. at ¶ 15. Among the primary consumers of Opposer's products are women of childbearing age. Id. at ¶ 19.

Opposer sells its products through wholesalers including AmeriSource Bergen, Cardinal, and McKesson, which are the three largest pharmaceutical wholesalers in the United States. Id. at ¶ 20. These wholesalers, in turn, distribute Opposer's LUPIN products to independent pharmacies and pharmacy chains, which distribute the products to the end consumer through an extensive network of retail outlets. Id. Examples of retail outlets where Opposer's LUPIN products are available to consumers are major retail chains such as CVS, Walgreens, and WalMart, as well as grocery store chains such as Giant, Harris Teeter, Publix, and Kroger. Id. at ¶ 21. Opposer's pharmaceuticals are also widely prescribed at hospitals throughout the United States. Id. at ¶ 22. In addition, Lupin's pharmaceutical products are offered and sold to various federal government agencies and programs including, without limitation, the Department of Veterans Affairs (particularly VA Hospitals), federal prisons, and through the Medicare and Medicaid programs. Id. at ¶ 23.

Lupin also has thousands of agreements, [redacted] with pharmaceutical and biopharmaceutical companies [redacted] Id. at ¶ 29.

4. Opposer's Extensive Promotion and Advertising of the LUPIN Mark

Since entering the United States market, Opposer has engaged in extensive and widespread

marketing, promotional, and advertising efforts featuring the LUPIN Mark. Opposer has spent more than [redacted] on those promotional efforts in the past ten years alone. See the Affidavit of Jay Liska ("Liska Aff.") at ¶¶ 3-4.

Opposer advertises its products under the LUPIN Mark through various media including: Opposer's website at lupinpharmaceuticals.com; internet banner ads; internet pop-up ads; infomercials on television networks including *Lifetime* and *Oxygen*; and advertisements in medical journals and pharmaceutical trade journals, pharmaceutical bulletins, and specialty consumer medical publications. Id. at ¶ 5. Examples of the wide range of publications in which Opposer advertises its LUPIN products include *Infectious Disease in Children*; *Clinical Psychiatry Today*; *Pharmacy Times*; *Chain Drug Review*; *Contemporary OB/GYN*; *American Academy of Pediatrics Newsletter; ADDitude Magazine*; *Asthma & Allergy Today*; *Ready Set Grow*; and *Drug Topics*, as well as the online outlets of certain of these publications and other online sources. Id. at ¶ 6 and Ex. A. Some of these publications are available to consumers in doctors' offices as well as directly to subscribers. Id. To the extent it is able to do so under the laws and codes of conduct governing the marketing activities of pharmaceutical companies, Lupin distributes a variety of collateral merchandise that features and promotes the LUPIN Mark, including such goods as mugs, reusable grocery bags, car air fresheners, memo pads, and pens. Id. at ¶ 9 and Ex. B.

Opposer underwrites and sponsors pharmaceutical and medical seminars, such as regional and national meetings of the Society of Maternal Fetal Medicine; American College of Obstetrics & Gynecology; Association of Women's Health, Obstetric and Neonatal Nurses; Society of Obstetrics & Gynecological Hospitalists; Maryland Society of Health System Pharmacists; and New Jersey Obstetrical & Gynecological Society. Id. at ¶ 7. Lupin also provides financial support to educational initiatives, [redacted]

[redacted] Id. at ¶ 8.

Opposer has engaged several advertising agencies and hundreds of vendors in conjunction with the promotion, advertising, and marketing of Opposer's pharmaceutical products under the LUPIN Mark. Id. at ¶ 10.

5. The Resulting Success of the LUPIN Brand

Opposer's efforts to promote and grow the LUPIN Mark have been extraordinarily successful. Since its introduction into the U.S. market, Opposer's business has grown tremendously in both the branded and generic segments. In fiscal year 2017, with a 5.3% market share by prescriptions, Opposer was the fourth largest generic company in the United States. Berthold Aff. at ¶ 27; see also Curtin Decl., Ex. Q at LUP-002933, LUP-002935 and LUP-002941. In fiscal year 2012, the year before Applicant was founded, Opposer recorded U.S. revenues in excess of $500 million. Id. at ¶ 28. By fiscal year 2017, Opposer's revenues had nearly doubled, surpassing the $1 billion mark in the United States. Id. As a result of its remarkable growth, Opposer have often been the subject of favorable press. Curtin Decl., Ex. Q.

B. Applicant's Claimed Mark LuPPiN

On January 21, 2015, Ampel filed an application to register the mark LuPPiN on the Principal Register under Section 1(a) of the Trademark Act, 15 U.S.C. § 1051(a). The application claims that the mark is in special form, and the description of the mark states, *inter alia*, that "[t]he word 'LuPPiN' has capitalized letters 'L', 'P', 'P', and 'N'."

On June 29, 2015, in response to an Office action issued by the assigned Examining Attorney, Applicant amended the application's recitation of services to the following:

> 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, in Class 45, and

Education 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, in Class 41.

Applicant also submitted the following Miscellaneous Statement:

LUPPIN has no meaning or significance in the industry in which the services are provided and is not a "term of art" within applicant's industry. Further, LUPPIN is not the surname of any person known to the applicant and, to applicant's knowledge, has no meaning in any foreign language.

Applicant claimed a date of first use anywhere and in the United States of at least as early as November 17, 2014. Applicant has not asserted any counterclaim for cancellation of Opposer's pleaded registrations, nor has Applicant brought a concurrent use proceeding. Applicant has conceded that Opposer used its LUPIN Mark prior to Applicant's adoption and use of the mark LuPPiN. See Response No. 1 of Ampel LLC's Responses to Opposer's First Requests for Admission attached as Ex. D to the Curtin Decl. Applicant also has admitted that it has no basis to challenge Opposer's claimed first use date. Id. at Nos. 3, 4.

C. Applicant's Claimed "Use" of Its Mark

1. Formation of Applicant Ampel, LLC

Applicant's co-founders Dr. Amrie Grammer and Dr. Peter Lipsky formed the Applicant entity in 2013. See Deposition of Amrie Grammer ("Grammer Depo.") at 35:3-6, attached as Ex. E to Curtin Decl. Applicant's business model consists of obtaining contracts with pharmaceutical companies, as well as obtaining monetary support from voluntary organizations. See Fed. R. Civ. P. 30(b)(6) Deposition of Ampel, by its designee, Peter Lipsky, M.D. ("30(b)(6) Depo.") at 68:12-15, attached as Ex. F to Curtin Decl. Approximately [redacted] of Applicant's funding comes from pharmaceutical companies. Id. at 94:19-95:7. Dr. Lipsky admitted that "[e]verything in our business is eventually supported by the pharmaceutical industry." See Individual Deposition of Peter Lipsky ("Lipsky Depo.") at 75:16-22,

attached as Ex. G to Curtin Decl.

2. "Patient Partner" Programs

While Dr. Lipsky was on the faculty of the University of Texas Southwestern Medical Center about thirty years ago, Dr. Lipsky and a rheumatoid arthritis patient began a "patient partner" program. Lipsky Depo. at 47:7-23, 68:16-23. According to Dr. Lipsky, the patient partner program paired rheumatoid arthritis patients receiving treatment with fellow patients who had been screened and trained, called "patient partners" or "patient educators." Id. The patient partners would communicate with the other patients about subjects related to the disease, including the value of clinical trials. Id.

Eventually, Lipsky partnered with Searle, a pharmaceutical company, which supported training for patient partner programs elsewhere in the United States and around the world. Lipsky Depo. at 69:23-70:4.

3. Inception of the LuPPiN Program and Adoption of the Mark

One of Ampel's chief goals is to offer and provide clinical trial services to pharmaceutical companies and others. 30(b)(6) Depo. at 6:7-25. To that end, Applicant hopes to replicate the prior success of Dr. Lipsky's "patient partner" program in the field of rheumatoid arthritis by establishing a similar network of and for Lupus patients. 30(b)(6) Depo. at 81:20-82:5. One of the services Applicant intends to offer its clients is to train Lupus patients to teach other Lupus patients about clinical trials, and allay some fears and misconceptions that may prevent patients from participating in clinical trials. Lipsky Depo. at 47:24-48:17. Applicant's services to be offered under its claimed LuPPiN mark are to be a "critical aspect" of patient recruitment as part of Applicant's services of planning and providing clinical trials to its pharmaceutical company clients. Lipsky Depo. at 142:4-16; 38:18-39:12. Dr. Lipsky testified "[w]hat we're trying to do is convince the pharma sponsors that by engaging . . . the LuPPiN network it will facilitate enrollment in the [clinical] trial. That's really the strategy." 30(b)(6) Depo. at 87:7-14.

In 2014, Applicant sought to develop a name for its planned patient educator program. Applicant adopted LuPPiN, a coined acronym meaning **Lu**pus **P**atient **P**artner **I**ntegrator **N**etwork. 30(b)(6) Depo. at 13:17-14:2. Dr. Lipsky testified that the word, not the claimed stylization, "was the important aspect." Id. at 52:21-53:13. In any event, Applicant has not made extensive use of its claimed mark. What limited use Applicant has made has been inconsistent. For example, Applicant used the mark with the "I" capitalized in one presentation on November 17, 2014. See, e.g., id. at 35:24-36:7; Curtin Decl., Ex. H[2] In another presentation made on December 9, 2014, the two "P"s are in italics and the "I" is still capitalized. See Curtin Decl., Ex. I.

Applicant's LuPPiN mark is pronounced LOO-pin. 30(b)(6) Depo. at 97:24-98:6; Curtin Decl., Ex. D at No. 36. Applicant's LuPPiN mark is identical to Opposer's LUPIN Mark when spoken or heard. Id. at No. 38; Lipsky Depo. at 163:19-25. Aside from the capitalization, the only difference between the parties' respective marks LUPIN and LuPPiN is the additional "p" in Applicant's mark. 30(b)(6) Depo. at 98:7-12. That additional "p" is not pronounced, but is silent. Curtin Decl., Ex. D at No. 34, 35. Further, the capitalization does not affect the pronunciation of Applicant's mark. Lipsky Depo. at 62:1-5.

4. Claimed "First Use" of the LuPPiN Mark

On November 17, 2014, Dr. Lipsky conducted a presentation during the annual meeting of the American College of Rheumatologists ("ACR"), discussing certain efforts Ampel was undertaking to develop new treatments for Lupus. 30(b)(6) Depo. at 36:11-37:4; 41:13-15; Lipsky Depo. at 140:16-21; Curtin Decl., Ex. H. Lipsky's presentation, held at 6:30 in the morning, was attended by approximately 80 to 120 individuals, mostly rheumatologists as well as trainees and nurses. 30(b)(6) Depo. at 37:17-

[2] Applicant has admitted that all of the documents Bates labeled with the indication "APB" discussed herein are authentic and created and maintained by Applicant in the ordinary course of Applicant's business. Curtin Decl., Ex. D at Nos. 72, 73.

38:10, 66:10-17; Lipsky Depo. at 141:8-12. This presentation also marked the launch of Applicant's Lupus Clinical Investigators Network, or LuCIN, a network of approximately 59 clinical investigators at academic medical centers in the United States and Canada. 30(b)(6) Depo. at 15:5-20. This network was organized to conduct clinical trials for Lupus. Id. Applicant intends to establish its patient partner network at these same facilities to aid in recruitment of Lupus patients for clinical trials. Id.

This presentation, on Applicant's claimed first use date, was the first time Applicant displayed the claimed LuPPiN mark, in any form, to the public. 30(b)(6) Depo. at 39:6-10. As noted earlier, rather than the presentation of LuPPiN as covered by the application, the mark was displayed as LuPPIN, with the "i" capitalized in the one and only PowerPoint slide that contained Applicant's Mark. Curtin Decl., Ex. H.

Because the November 17, 2014 presentation was in the "early days" of Applicant's programs, the presentation contained "a lot of aspirational things." 30(b)(6) Depo. at 39:6-21. No actual educational services or support group services for Lupus patients were provided under Applicant's Mark at the time of the November 17, 2014 presentation, nor was Applicant prepared to provide such services at that time. Id. at 40:7-41:1; 54:9-21; Curtin Decl., Ex. D at Nos. 7-13, 27-28. Applicant was not aware of any Lupus patients in attendance. 30(b)(6) Depo. at 66:18-20.

Over four months later, on March 31, 2015, Applicant provided a presentation during a meeting of the Maryland Biotech Forum. The Maryland Biotech Forum was hosted by the pharmaceutical companies MedImmune and AstraZeneca and was sponsored by those and other companies and organizations that are part of the biotech sector in Maryland, Virginia, and the Washington, D.C. area, in the "so-called 270 corridor." Lipsky Depo. at 18:8-22, 148:12-149:25. There were approximately 100 to 200 attendees in the biotech field, mostly scientists or individuals in administrative roles, as well as attendees from pharmaceutical companies. 30(b)(6) Depo. at 67:13-18; Lipsky Depo. at 150:14-19.

LuPPiN was referenced in a single slide of Dr. Lipsky's PowerPoint presentation during this March 2015 meeting. Lipsky Depo. at 150:25-151:6; Curtin Decl., Ex. J. No one began participating in the LuPPiN program as a result of this presentation. Lipsky Depo. at 153:20-24.

Indeed, Applicant admits that it has never provided services under the LuPPiN mark, but merely has developed a draft training manual, which does not even feature the claimed LuPPiN mark. 30(b)(6) Depo. at 59:14-60:10; 58:23-59:2, Depo. Ex. 10, attached as Ex. K to the Curtin Decl. Applicant admits that it has not provided educational seminars, mentoring, training, or support groups under the LuPPiN mark. 30(b)(6) Depo. at 95:11-24. In short, aside from Dr. Lipsky's three PowerPoint slides at professional or fundraising meetings, there has been no use or traditional advertising of the LuPPiN mark.

Since around the time the Notice of Opposition was filed in this matter, Applicant has largely stopped referring to its patient partner program by the mark LuPPiN. Dr. Lipsky testified that, if this matter is resolved in Applicant's favor, "[w]e 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," including clinical trials funded by pharmaceutical companies. Id. at 79:17-80:3.

5. The Market for Applicant's Services

Certain services identified in the application relate specifically to Lupus patients and Lupus caregivers. For example, the application recites "organizing and conducting support groups for Lupus patients who are undergoing treatment and clinical trials." Other services, such as "education services, namely, providing seminars and one-on-one mentoring in the fields of Lupus, Lupus treatment options and the importance of clinical trials," do not specify a particular consumer group. Indeed, even where the services are intended for Lupus patients, the ultimate beneficiaries of these services are the

pharmaceutical companies to whom Applicant offers its network of patients as participants in clinical trials for the pharmaceutical companies' drugs. 30(b)(6) Depo. at 87:7-14.

[redacted] Id. at 83:2-6.

Applicant's active advertising and marketing efforts consist of its website; presentations to rheumatology or biotech professionals; consultations with pharmaceutical companies; and networking using Dr. Lipsky's personal contacts in the pharmaceutical industry. 30(b)(6) Depo. at 61:9-14; 67:24-68:11; Lipsky Depo. at 40:8-25, 154:1-11. However, as noted above, Applicant voluntarily ceased use of the LuPPiN mark around February, 2015 and will not be using the mark until this opposition is resolved.

D. Symptoms and Treatment of Lupus

1. Common Signs and Symptoms of Lupus

Lupus is a chronic autoimmune disease. 30(b)(6) Depo. at 23:24-24:1; Curtin Decl., Ex. D at No. 49. Lupus affects different patients in different ways, and the symptoms can vary among patients and even in the same patient over time. Curtin Decl., Ex. K at APB-00429. Symptoms of Lupus may include extreme fatigue; headache; painful or swollen joints; fever; anemia; pleuritis (inflammation of the membrane surrounding the lungs); rash on the face and other skin rashes; photosensitivity; hair loss; abnormal blood clotting; Raynaud's Phenomenon (constriction of the blood vessels that may cause blanching in the fingers); arthritis; mouth and nose ulcers; kidney involvement; and central and peripheral nervous system involvement such as confusion, stroke, seizures, psychosis, decreased cognitive function, and peripheral neuropathy (inflammation of the nerves causing loss of motor function, loss of sensation, or extreme painful sensation). 30(b)(6) Depo. at 72:3-75:4; Lipsky Depo. at 107:15-108:6; Curtin Decl., Ex L (Respondent's Answers to Opposer's Second Set of Interrogatories),

No. 1. Lupus can affect the musculoskeletal system, including through joint or muscle pain and arthritis. 30(b)(6) Depo. at 74:25-75:4; Curtin Decl., Ex. K at APB-00436; Curtin Decl., Ex. D, Nos. 64-66. It can affect the cardiovascular system, the pulmonary system, and the nervous system, as well as skin and eyes. Curtin Decl., Ex. K at APB-00429 and APB-00437 – APB-00445.

2. Demographics of Lupus Patients

The majority of Lupus patients are women between the ages of 15 and 45. Curtin Decl., Ex. D, No. 48.

3. Current Treatment Options

There is no known cure for Lupus. 30(b)(6) Depo. at 24:5-7. Only one drug has been approved by the FDA specifically for the treatment of Lupus in the past fifty years, and, according to Dr. Lipsky, that has had limited efficacy. Id. at 109:2-5; Curtin Decl., Ex. M at APB-00446 – APB-00448.

Today, Lupus is commonly treated with a combination of drugs. 30(b)(6) Depo. at 26:17-27:5. Most of these drugs are immunosuppressants that have been approved for treatment of other diseases, but not for Lupus. Lipsky Depo. at 37:8-38:1. Because of the variety of manifestations of the disease and the limited options for treatment, the treatment commonly involves taking various drugs to control symptoms and/or prevent or slow the damage to organs. Curtin Decl., Ex. K; 30(b)(6) Depo. at 108:6-12. Drugs that may be used in the treatment of Lupus include non-steroidal anti-inflammatory drugs ("NSAIDs"), acetaminophen (such as Tylenol), corticosteroids, anti-malarial drugs, immunosuppressives, intravenous immunoglobulin, monoclonal antibodies, ACE (Angiotensin-converting enzyme) inhibitors, statins, and anticoagulants. Curtin Decl., Ex. K at APB-00446 – APB-00448; Curtin Decl., Ex. D, Nos. 42-47. For example, celecoxib is a type of NSAID that may be used to treat Lupus, although there are negative side effects. Id., No. 44.

Opposer offers and sells NSAIDs including celecoxib, corticosteroids, anti-malarials, ACE

inhibitors, and other drugs intended for the treatment of arthritis, among numerous types of drugs. Berthold Aff. at ¶ 25.

4. Drug Repurposing

Much of Applicant's work has focused upon the repurposing of existing, FDA-approved drugs for the treatment of Lupus. Repurposing – also called repositioning – is the practice of taking a drug that has been approved by the FDA for treatment of one disease, and using it for the treatment of another, different disease. Lipsky Depo. at 38:18-39:12; 30(b)(6) Depo. at 23:20-23, 27:6-19. Repurposing can be more economical than developing a new drug because the preliminary safety testing has already been conducted. Lipsky Depo. 29:7-30:19. If a drug is identified that already has been approved for another disease, with a known side effect profile, that decreases the potential cost and risk to a pharmaceutical company in bringing a drug to market for Lupus. Id. at 33:20-34:6.

In this case, one goal of repurposing in the field of Lupus is to reposition existing pharmaceuticals to alleviate the symptoms of the disease. Applicant's ultimate goal, however, is to find and repurpose an existing, FDA-approved drug that would lead to remission of the disease. 30(b)(6) Depo. at 24:8-19.

In 2016, Drs. Grammer and Lipsky, along with several other researchers from Ampel and two other researchers, published a paper discussing the results of their research on repurposing drugs for treatment of Lupus. The paper highlighted the process Applicant had used to prepare a list of potential drugs as candidates for repurposing. This included a review of approximately 1,100 currently available FDA-approved drugs as well as other possible treatments such as food supplements. Lipsky Depo. at 97:4-99:1; Curtin Decl., Ex. M. From hundreds of initial candidates, the list was narrowed to 157 potential treatments. 30(b)(6) Depo. at 29:1-3; Lipsky Depo. at 98:9-11.

The narrowed list was then scored by a system Applicant devised. This system provided higher

scores based upon benefits to patients and other positive factors and lower scores based upon adverse side effects, whether the drug induced Lupus, and other negative factors. Curtin Decl., Ex. M at APB-00402 – APB-00403. The objective was to find drugs that scored higher than the current standard of care drugs for Lupus. Lipsky Depo. at 104:6-23. Drugs that already were commonly used to treat Lupus were not scored. Lipsky Depo. 100:12-101:8.

The list of 157 included the drugs abacavir, lamivudine, statins, and zidovudine, each of which are manufactured, either alone or in combination with other pharmaceutical preparations, by Opposer. Berthold Aff. at ¶ 26; Curtin Decl., Ex. M at APB-00403, Table 1. Of the drugs that Lupin has provided, lamivudine and statins received positive scores, though not as high as the current standard of care.

There were approximately 20 to 25 treatments of the 157 that Applicant found to be most promising, and Applicant approached the pharmaceutical companies that held the patents for those drugs about the possibility of conducting clinical trials for repurposing the drugs for treatment of Lupus. 30(b)(6) Depo. at 29:1-9, 10-12, 30:5-14.

Applicant has approached more than [redacted] pharmaceutical companies for this purpose, including [redacted]: "everyone you can think of, we have approached." Id. at 27:20-28:8.[3]

In addition to Applicant's outreach to pharmaceutical companies as potential customers for Applicant's clinical trial services, pharmaceutical companies also have approached Applicant and shared their drug data with Applicant to determine whether that company's data could reveal a drug that may be useful for treating Lupus. Id. at 27:6-19; Lipsky Depo. at 133:7-22.

The article authored by Drs. Lipsky and Grammer states that, "[d]rug repurposing is not a new

[3] Dr. Lipsky testified that he had never heard of Lupin prior to this opposition, although he was familiar with Lupin's main competitors in the field of generic pharmaceuticals, namely, Mylan, Teva, and Sandoz. Lipsky Depo. at 42:21-43:7, 64:3-6; Curtin Decl., Ex. Q at LUP-002941.

concept." Curtin Decl., Ex. M at APB-00400. Indeed, Opposer is aware that certain of its drugs can be and are "repurposed" by third parties to treat multiple symptoms of diseases other than the diseases intended to be treated by such drugs, including Lupus. Berthold Aff. ¶¶ 24-25.

5. Provision of Educational and Support Group Services by Pharmaceutical Companies

The consuming public is accustomed to encountering pharmaceutical companies providing or funding educational services and support groups. Records of use-based trademark registrations as well as internet evidence demonstrating that pharmaceutical products, on the one hand, and related educational and support group services of a type similar to Applicant's services, on the other, are provided by the same companies are attached as Exhibits N and O to the Curtin Decl. Applicant itself has offered to provide patient partner programs, including patient education, physician education, and other communication, on behalf of pharmaceutical companies. 30(b)(6) Depo. at 70:16-71:11. Opposer itself provides information to consumers through its website regarding its products and educational information on the treatment of various conditions. Liska Aff. ¶ 12.

III. LEGAL STANDARD

Summary judgment is appropriate where "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); TBMP § 528.01. "The purpose of the motion is judicial economy, that is, to avoid an unnecessary trial where there is no genuine dispute of material fact and more evidence than is already available in connection with the summary judgment motion could not reasonably be expected to change the result in the case." TBMP § 528.01. The Board is to view the evidence in the light most favorable to the non-moving party and draw all justifiable inferences in the non-movant's favor. Green Spot (Thailand) Ltd. v. Vitasoy Int'l Holdings Ltd., 86 U.S.P.Q.2d 1283 (T.T.A.B. 2008).

IV. ARGUMENT

A. Opposer Has Standing

A party may demonstrate standing by showing that it has a "real interest" in the case – a direct and personal stake in the outcome. Id. at 1285. Here, Opposer has pleaded its registrations for the LUPIN Mark for numerous pharmaceutical products, upon which it has based its allegations of likelihood of confusion. Opposer has standing to oppose.

B. Priority Is Not at Issue

The date of first use claimed in Opposer's registration of the mark LUPIN in standard characters is July 1, 2005, and the claimed date of first use of the mark LUPIN (and design) is at least as early as 2005. Opposer's first use is supported by the testimony and sales records. Berthold Aff. ¶¶ 8-9. Applicant admits that it has no basis to challenge Opposer's claimed first use date, and Applicant has not challenged Opposer's pleaded registrations. Curtin Decl., Ex. D, Nos. 3-5. Applicant claims a date of first use of November 17, 2014, and the filing date of its application is January 21, 2015. Priority, therefore, is not an issue in this case. Central Garden & Pet Co. v. Doskocil Manu. Co., 108 U.S.P.Q.2d 1134, 1139 (T.T.A.B. 2013).

C. Registration of Applicant's Mark LuPPiN Would Create a Likelihood of Confusion

Here, the marks are nearly identical, and the parties' respective goods and services are closely related and offered to overlapping consumers in similar channels of trade. Opposer addresses and analyzes these and other factors as set forth in the seminal case E.I. DuPont de Nemours & Co., 476 F.2d 1357 (C.C.P.A. 1973).

1. The Marks Are Virtually Identical

Applicant's claimed mark is LuPPiN. Opposer's mark is LUPIN. The marks are virtually identical in sight, sound, and meaning.

The so-called stylization claimed in the application consists simply of differences in the

capitalization of the letters. Applicant has not claimed a particular font, design elements, or other stylization. Indeed, the "stylized" elements of the mark merely incorporate characters within the USPTO's standard character set. TMEP §§ 807.03(a), (b).

Moreover, Opposer's Reg. No. 4,024,405 covers the mark LUPIN in standard characters, without limitation for any particular stylization or design element. Therefore, Opposer's registration could cover any form, including LuPiN. In re RSI Sys., LLC, 88 U.S.P.Q.2d 1445, 2008 TTAB LEXIS 64, *6-*7 (T.T.A.B. 2008). Applicant cannot avoid a finding of likelihood of confusion based upon the claimed differences in the stylization of the marks. TMEP 1207.01(c)(iii).

The addition of a single letter "p", which is not pronounced independently from the remainder of the mark, does not comprise a sufficient difference to overcome a likelihood of confusion. See, e.g., Apple Computer v. TVNET.net, Inc., 90 U.S.P.Q.2d 1393, 1396 (T.T.A.B. 2007) ("The dominant, distinctive portions of the parties' marks (ITUNES/VTUNES), differ by only one letter . . . .").

The marks also are phonetically identical, and both are pronounced LOO-pin. Berthold Aff. ¶ 3; 30(b)(6) Depo. at 97:24-98:6; Seacret Spa Int'l v. Lee, 2016 WL 880376, *4 (E.D. Va. Mar. 8, 2016).

The parties' respective marks, as applied to the parties' respective goods and services, are arbitrary. LUPIN has no meaning specific to pharmaceutical goods. Berthold Aff. at ¶ 4. Similarly, as applied to Applicant's educational and support group services, the word LUPPIN is a coined term, and Applicant admitted in its application that the word has no relevant meaning in the industry. See Applicant's June 29, 2016 Response to Office Action.

There also is no evidence that consumers recognize Applicant's mark as an acronym, let alone understand the meaning of the acronym. Further, the acronym is not claimed by Applicant in its application, and, therefore, the Board should consider the mark alone, as it appears in the application. See Christian Broad. Network, Inc. v. ABS-CBN Int'l, 84 U.S.P.Q.2d 1560, 1569 (T.T.A.B. 2007); B.V.D. Licensing Corp. v. Rodriguez, 83 U.S.P.Q.2d 1500, 1508 (T.T.A.B. 2007). In any event,

there is scant, if any, evidence that Applicant has even used its mark. Even in the rare instances where the mark was displayed, the mark has not been consistently presented. See Curtin Decl. at Exs. H and I.

Opposer's use and registration of its mark with a design of a highly-stylized Lupin flower also would not significantly differentiate the connotation of Applicant's mark LuPPiN from Opposer's LUPIN Mark because the word portion of Opposer's LUPIN Mark is dominant. B.V.D. Licensing Corp., 83 U.S.P.Q.2d at 1508-1509.

There is no genuine issue that the sight, sound, and commercial impressions of the parties' respective marks are very similar, if not identical.

2. The Established Overlap of the Parties' Trade Channels and Classes of Purchasers

a. The Parties Target the Same Classes of Purchasers

As noted above, Opposer's Reg. No. 4,024,405 covers a "full line" of pharmaceutical products, and Reg. No. 4,874,579 covers a wide range of pharmaceutical products, including for the treatment of diseases and disorders of the nervous system, circulatory system, respiratory system, skin, musculoskeletal system, among various other indications. Opposer's registrations do not contain any limitation as to the channels of trade and classes of purchasers in the specification of goods, and so all normal and usual channels of trade and methods of distribution are to be considered. In re Pix of America, Inc., 225 U.S.P.Q. 691, 691 (T.T.A.B. 1985). This includes consumers purchasing or using a "full line" of pharmaceuticals, which would necessarily include Lupus patients.

Further, the record demonstrates that, since currently there is no known cure for Lupus, Lupus patients are frequently treated with drugs that are not originally intended for the treatment of Lupus, but that are repurposed to alleviate the symptoms of Lupus. Opposer offers for sale and sells pharmaceuticals under the LUPIN Mark that are capable of treating many common symptoms of Lupus. Berthold Aff. ¶ 16; Curtin Decl., Ex. K at APB-00429; Curtin Decl., Ex. D, Nos. 50, 55-57, 63-68. Indeed, Opposer

offers for sale and sells drugs that are commonly used for treatment of Lupus, including NSAIDs (including celecoxib) and corticosteroids. Berthold Aff. ¶ 25: Curtin Decl., Ex. D, Nos. 43-46.

Opposer's Reg. No. 4,874,579 specifically covers pharmaceuticals for the treatment of diseases and disorders of the musculoskeletal, nervous, and respiratory systems and skin, which can be affected by Lupus. Curtin Decl., Ex. D, Nos. 64-68; Curtin Decl., Ex. K at APB-00436 – APB-00445. The trade as well as ordinary consumers are accustomed to seeing the LUPIN Mark both on pharmaceutical packaging and on the drugs themselves as well as in advertising, including in consumer publications. Berthold Aff. ¶¶ 10, 14-15; Liska Decl. ¶¶ 5-6. These same consumers are likely to be confused when encountering Applicant's claimed LuPPiN mark.

Finally, a major portion of Opposer's business is directed toward women of childbearing age, which is the same group predominantly affected by Lupus. Curtin Decl., Ex. D, No. 48; Berthold Aff. ¶ 19. There is no genuine issue of material fact that the parties' respective customers overlap.

b. The Channels of Trade Overlap

Applicant has marketed its services under its LuPPiN mark to pharmaceutical companies, and has expressed an intent to increase such marketing efforts. 30(b)(6) Depo. at 79:17-80:2. One of Applicant's primary goals is to conduct clinical trials for pharmaceutical companies, including offering its LuPPiN program to support such trials. Lipsky Depo. at 142:4-16; 38:18-39:12. To that end, Applicant has approached numerous pharmaceutical companies in its efforts to repurpose existing pharmaceutical products for use in the treatment of Lupus. Id.; 30(b)(6) Depo. at 29:1-9, 29:22-30:14. Opposer is a pharmaceutical company, which also has [redacted] contracts with other pharmaceutical companies, [redacted]. Berthold Aff. ¶ 29. Applicant's services under its claimed LuPPiN mark could be offered to direct competitors and/or business partners of Opposer.

Moreover, Opposer and Applicant operate within the same marketing channels. The principals of

Applicant publish articles in medical journals; Opposer advertises in medical journals. Applicant appears at medical conferences; Opposer provides sponsorship to medical conferences. The same class of potential consumers may encounter the parties' respective marks appearing in the very same or similar channels of trade.

c. The Goods and Services of the Parties Are Closely Related

The parties' respective channels of trade overlap because the goods and services themselves are closely related, such that consumers would expect them to originate from the same source. The goods and services need not be similar or competitive, but must be "related in some manner, and/or . . . the conditions and activities surrounding the marketing of the goods and/or services are such that they would or could be encountered by the same persons under circumstances that could, because of the similarity of the marks, give rise to the mistaken belief that they originate from the same source." Weider Pubs., 109 U.S.P.Q.2d 1347, 1359 (T.T.A.B. 2014) (citations omitted).

Consumers are accustomed to seeing pharmaceuticals and related educational and support group services emanating from the same source. Curtin Decl., Exs. N and O.

Of evidence are third party registrations and websites of pharmaceutical companies that have provided or sponsored the same types of services covered by Applicant's application, including [redacted] Kohler Co. v. Baldwin Hardware Corp., 82 U.S.P.Q.2d 1100, 1110-1111 (T.T.A.B. 2007).

For example:

> "The Patient Partnership Program is a global forum made up of a small group of members from [redacted] teams and patients/carers with personal or professional experience in a given disease are whole goal is to learn from each other and co-create patient centric medicines and solutions throughout drug development." Curtin Decl., Ex. O at LUP-002949 – LUP-002951. (This program includes Lupus patients.)

Indeed, Opposer itself provides written educational resources to consumers, such as brochures providing information for individuals using its products for a particular condition. Liska Aff., Ex. C.

Similarly, Applicant "collaborates" with pharmaceutical companies through contractual arrangements to provide Ampel's services. 30(b)(6) Depo. at 96:15-97:7.

Particularly in view of the virtual identity of the marks, the close relatedness of the parties' respective goods and services weighs heavily in favor of Opposer. See In re Concordia Int'l Forwarding Corp., 222 U.S.P.Q. 355, 355 (T.T.A.B. 1983); Kohler Co., 82 U.S.P.Q.2d at 1110.

3. Opposer's Mark Is Strong and Entitled to a Broad Scope of Protection

Since establishing its business in the United States, Opposer has experienced great sales success and resulting growth of its LUPIN brand in this country. Opposer's marketing expenditures of approximately [redacted] over the past ten years for efforts ranging from sponsorship of medical conferences to advertising in consumer and professional publications have borne fruit as evidenced by Opposer's sales success. Liska Aff. ¶¶ 3-8. From $348 million USD in 2010, to over a billion dollars in fiscal year 2017, Opposer's sales of pharmaceuticals under the LUPIN Mark have increased exponentially. Berthold Aff. ¶ 28.

The inherent strength of Opposer's LUPIN Mark is further established by the arbitrary nature of the mark as applied to Opposer's goods. The word lupin, which refers to a type of flower with no medicinal properties, has no inherent connection with, nor does it immediately describe, pharmaceutical products. Berthold Aff. ¶ 4; Curtin Decl., Ex. A. Accordingly, the arbitrary name and mark LUPIN is entitled to great protection as a strong mark. In re Gina Davia, 110 U.S.P.Q.2d 1810, 1814-1815 (T.T.A.B. 2014).

Applicant's mark, by comparison, has been used inconsistently, has not been used in connection with the recited services, and has no recorded sales or customers to date. 30(b)(6) Depo. at 59:14-60:1; Curtin Decl., Ex. D, Nos. 7-28. Applicant can only benefit from a false association with Opposer's Mark. This duPont factor strongly favors Opposer.

4. There Is No Evidence of Sophistication of the Relevant Consumers

As discussed above, there are multiple relevant consumer groups for the parties' respective goods, including pharmaceutical distributors and pharmacies, pharmaceutical companies, and individual consumers of pharmaceuticals, including Lupus patients. Where there is a range of potential purchasers, "Board precedent requires the decision to be based 'on the least sophisticated potential purchasers.'" Stone Lion Capital Partners, L.P. v. Lion Capital LLP, 746 F.3d 1317, 1325 (Fed. Cir. 2014) (quoting Gen. Mills, Inc. v. Fage Dairy Proc. Indus. S.A., 100 U.S.P.Q.2d 1584, 1600 (T.T.A.B. 2014)).

Here, those least sophisticated purchasers are ordinary consumers of pharmaceuticals and/or Lupus patients. There is no evidence that such consumers are particularly sophisticated. Indeed, one of the stated purposes of Applicant's services is to dispel incorrect information among Lupus patients, indicating that such individuals may be susceptible to such misinformation. Lipsky Depo. at 47:23-48:17.

Although it is possible that consumers will carefully evaluate purchases related to medical treatment, it does not follow that such consumers are particularly sophisticated or are not susceptible to confusion. Cf. Kos Pharms., Inc. v. Andrx Corp., 369 F.3d 700, 717 (3d Cir. 2004) ("There is no reason to believe that medical expertise as to products will obviate confusion as to source or affiliation or other factors affecting goodwill."). Opposer submits that the end consumers of both parties' goods and services are not particularly sophisticated and not able to avoid the likelihood of confusion arising from the concurrent use of virtually identical marks in the pharmaceutical field. This factor favors Opposer.

5. Actual Confusion Is Difficult to Find and Not Required

Opposer is required to demonstrate a likelihood of confusion, not actual confusion. Many courts have observed that evidence of actual confusion is notoriously difficult to come by. Time Warner Enter. Co., LP v. Jones, 65 U.S.P.Q.2D 1650, 2002 WL 1628168 at *10 (T.T.A.B. 2002). Here, Applicant has not actually provided the services covered by its application. Since there has been no concurrent use of

the parties' respective marks, there has been no opportunity for actual confusion to arise. As such, this factor should be given no weight.

6. A Likelihood of Confusion Would Result in Great Harm to the LUPIN Brand

For more than a decade, Opposer has invested a great deal of time, effort, and money in building its LUPIN brand in the United States. Through its efforts, Opposer's LUPIN brand has enjoyed tremendous success as demonstrated by its sales and robust market share for generic prescriptions.

The potential harm to Opposer should Applicant's mark proceed to registration is great. In the past, Dr. Lipsky succeeded with his prior patient partner program, and Applicant has expressed its intent to market its LuPPiN program aggressively. Clinical services and educational programs marketed under a colorable imitation of Opposer's primary mark, supported by a federal trademark registration, would be highly detrimental to Opposer. The danger of confusion is even greater in light of the geographic proximity of Opposer and Applicant, as Applicant has sought to cultivate its reputation in the "270 corridor" in the Baltimore and Washington, D.C. area, in close proximity to the location of Opposer's headquarters. Lipsky Depo. at 18:8-22

In light of the potential harm of confusion in the arena of pharmaceuticals, even greater care should be taken to avoid a likelihood of confusion. In re Cook Med. Tech. LLC, 105 U.S.P.Q.2d 1377, 1381-82 (T.T.A.B. 2012). This factor weighs strongly in Opposer's favor.

D. Applicant's Affirmative Defenses Relate Solely to the Likelihood of Confusion Factors and Summary Judgment Is Appropriate in Opposer's Favor on Those Defenses

In its Answer, Applicant has asserted two "affirmative defenses"[4] but these "affirmative defenses" are merely amplifications of Applicant's denials of Opposer's allegations in the Notice of

[4] The affirmative defenses are: 1) "The goods and/or services offered by Applicant under the Mark and the goods and/or services offered by Opposer under the LUPIN mark are distinct and marketed to different consumers who will not be confused by any alleged similarity between them" and 2) "There is no likelihood of confusion, mistake, or deception because, inter alia, the Mark and the Opposer's marks are not confusing [sic] similar."

Opposition. Humana Inc. v. Humanomics Inc., 3 U.S.P.Q.2d 1696, 1697 n.5 (TTAB 1987). To the extent the Board considers these "affirmative defenses," they are fully addressed in this motion, and do not create any issue of fact for trial.

V. CONCLUSION

Opposer has demonstrated that there is no genuine issue of material fact, and that summary judgment should be granted to Opposer on all issues in this case, and Applicant's application should be refused registration.

Dated: December 29, 2017

By: /Thomas H Curtin/

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Attorneys for Opposer
LUPIN PHARMACEUTICALS, INC.

IN THE U.S. PATENT AND TRADEMARK OFFICE BEFORE THE
TRADEMARK TRIAL AND APPEAL BOARD

----------x
LUPIN PHARMACEUTICALS, INC.,

Opposer, Opposition No. 91226322

v.

AMPEL, LLC,

Applicant.
----------x

AFFIDAVIT OF DAVE BERTHOLD IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT BY OPPOSER LUPIN PHARMACEUTICALS, INC.

STATE OF MARYLAND)
) ss.:
COUNTY OF BALTIMORE)

DAVE BERTHOLD, being duly sworn, deposes and says:

1. I am Senior Vice President of Sales and Operations, U.S. Generics, for Lupin Pharmaceuticals, Inc. (hereinafter "Lupin" or "Opposer"). I make this affidavit in support of the Motion for Summary Judgment brought by Lupin against Applicant Ampel, LLC in the subject action.

2. I have been employed by Lupin since June 2006 and have held the position of Senior Vice President of Sales and Operations, U.S. Generics, since 2015. The facts in this affidavit are based upon my personal knowledge as well as on the records, data, and documents of Lupin that I have reviewed and/or annexed hereto which are kept by Lupin in the ordinary course of its business.

3. In 1968, the predecessor-in-interest of Lupin's ultimate corporate parent, Lupin Limited, began doing business in India under the name and mark LUPIN. The word "LUPIN" is pronounced LOO-pin.

4. The mark LUPIN was named for the lupin flower. The lupin flower and/or seeds are not used by Opposer in the manufacture of its pharmaceutical products.

5. In the 1980s and 1990s, the predecessors-in-interest of Lupin Limited received approval from the United States Food and Drug Administration ("FDA") to allow certain of its manufacturing facilities located in India to manufacture and distribute pharmaceutical products intended for U.S. consumers.

6. In the early 2000s, Lupin Limited filed its first of many Abbreviated New Drug Applications ("ANDA") with the FDA. ANDAs are applications for approval by the FDA of a generic version of an existing, FDA-approved drug.

7. On March 28, 2002, Lupin Limited filed an ANDA for the drug ceftriaxone for injection. That ANDA was approved by the FDA on September 30, 2003 and eventually became the first drug marketed under the LUPIN mark in the United States. Attached hereto as Exhibit A is a true and correct copy of cover letter accompanying the ceftriaxone ANDA.

8. The first sales of pharmaceutical products under the trademark LUPIN ("the LUPIN Mark") in the United States occurred in July 2005.

9. Attached hereto as Exhibit B is a true and correct copy of a quarterly report for the third quarter of 2005 reflecting the market share of sales of ceftriaxone of Lupin in comparison to

other pharmaceutical companies. Exhibit B reflects Opposer's sales of ceftriaxone under the LUPIN Mark in July through September, 2005.

10. Since at least as early as July 2005, pharmaceutical products bearing the LUPIN Mark have been continuously distributed, offered for sale, and sold throughout the United States.

11. In 2003, Lupin Pharmaceuticals, Inc. was incorporated in the U.S. and began doing business at its headquarters in Baltimore.

12. Today, Lupin manufactures, offers for sale, and sells more than 150 types of pharmaceutical products throughout the United States.

13. Lupin's products include both branded and generic pharmaceuticals.

14. All of Lupin's branded and generic products are sold in packaging that bears the LUPIN mark.

15. Some of Lupin's drug products also bear the LUPIN mark imprinted directly on the drug capsule itself.

16. Lupin's pharmaceutical products treat a wide variety of indications, including, without limitation, use for the treatment of fever; headache; fatigue; confusion; chest pain; stiffness; shortness of breath; joint or muscle pain; anemia; swelling in the legs, ankles, and feet; joint swelling; and rash, among other indications.

17. [**CONFIDENTIAL**] [redacted]

[redacted]

18. Since its introduction to the U.S. market, Lupin has continually expanded its pharmaceutical product offerings to new and different therapeutic areas of treatment, such as cardiology, diabetes, women's health, and gastroenterology.

19. A primary demographic of consumers of Opposer's drug products are women of childbearing age.

20. Lupin sells and distributes its products through wholesalers including AmeriSource Bergen, Cardinal, and McKesson, which are the country's three largest pharmaceutical wholesalers. These wholesalers, in turn, distribute Lupin's pharmaceutical products bearing the LUPIN Mark to independent pharmacies, pharmacy chains, and hospitals, which distribute the products to the end consumer through an extensive network of retail outlets.

21. Examples of retail outlets where LUPIN products are available to consumers include major retail chains such as CVS, Walgreens, and WalMart, as well as grocery store chains such as GIANT, Harris Teeter, Publix, and Kroger.

22. Lupin's pharmaceuticals are also prescribed at and distributed through hospitals located throughout the United States.

23. Lupin's pharmaceutical products are also offered and sold to various federal government agencies and programs including, without limitation, the Department of Veterans Affairs (particularly VA Hospitals), federal prisons, and through the Medicare and Medicaid programs.

24. Lupin is aware that certain of its pharmaceutical products can be and are "repurposed" by third parties to treat multiple symptoms of diseases other than the diseases intended to be treated by such drugs.

25. By way of example, Lupin is aware that a number of Opposer's pharmaceutical products are capable of being used, or repurposed, by third parties, to treat certain common symptoms of Lupus, including non-steroidal anti-inflammatory drugs (NSAIDs) such as celecoxib, as well as corticosteroids, anti-malarials, Angiotensin-converting enzyme (ACE) inhibitors, and drugs intended for the treatment of arthritis, among others. It is my understanding that such drugs have some efficacy in alleviating symptoms of Lupus.

26. Lupin also manufactures abacavir (antiretroviral agent), lamivudine (antiviral), statins, and zidovudine (antiretroviral agent), either alone or in combination with other preparations. It is my understanding that the aforementioned drugs also have efficacy in alleviating certain common symptoms of Lupus.

27. In fiscal year 2017, Lupin was the fourth largest generic company in the U.S, with a 5.3% market share by prescriptions.

28. Lupin's sales have grown tremendously since the LUPIN brand was first introduced into the U.S. market in 2005. Since 2010, Lupin has recorded the following sales results (Lupin's fiscal year ends March 31):

2010: $348 million
2011: $441 million
2012: $507 million
2013: $693 million
2014: $803 million
2015: $890 million
2016: $888 million
2017: $1.214 billion

29. **[CONFIDENTIAL]** [redacted]

DAVE BERTHOLD

Sworn to before me this
18th day of December, 2017

NOTARY PUBLIC

CATHERINE M. CARLSON
NOTARY PUBLIC
BALTIMORE COUNTY
MARYLAND
MY COMMISSION EXPIRES SEPT. 28, 2019

IN THE U.S. PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

----------x
LUPIN PHARMACEUTICALS, INC.,

Opposer, Opposition No. 91226322

v.

AMPEL, LLC,

Applicant.
----------x

EXHIBIT A

TO

AFFIDAVIT OF DAVE BERTHOLD IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT BY OPPOSER LUPIN PHARMACEUTICALS, INC.

Exhibit A is a true and correct copy of a cover letter accompanying the Abbreviated New Drug Application ("ANDA") submitted to the Food and Drug Administration for the drug ceftriaxone for injection. Exhibit A is designated as CONFIDENTIAL – FOR ATTORNEYS' EYES ONLY under the Board's Standard Protective Order, and filed under seal.

IN THE U.S. PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

----------x
LUPIN PHARMACEUTICALS, INC.,

Opposer, Opposition No. 91226322

v.

AMPEL, LLC,

Applicant.
----------x

EXHIBIT B

TO

AFFIDAVIT OF DAVE BERTHOLD IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT BY OPPOSER LUPIN PHARMACEUTICALS, INC.

Exhibit B is a true and correct copy of a quarterly report for the third quarter of 2005 reflecting the market share of sales of ceftriaxone. Exhibit B is designated as CONFIDENTIAL – FOR ATTORNEYS' EYES ONLY under the Board's Standard Protective Order, and filed under seal.

IN THE U.S. PATENT AND TRADEMARK OFFICE BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

----------x

LUPIN PHARMACEUTICALS, INC.,

Opposer, Opposition No. 91226322

v.

AMPEL, LLC,

Applicant.

----------x

DECLARATION OF THOMAS H. CURTIN IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT BY OPPOSER LUPIN PHARMACEUTICALS, INC.

I, Thomas H. Curtin, declare the following to be true under penalty of perjury:

1. I am a partner with the firm of Powley & Gibson, P.C. We are the attorneys for Opposer Lupin Pharmaceuticals, Inc. ("Opposer" or "Lupin") in the above-captioned action pending before the Trademark Trial and Appeal Board.

2. I am of legal age, have never been convicted of a felony, have personal knowledge of the facts stated herein, and am otherwise competent to testify to these matters.

3. A true and correct copy of relevant excerpts from Webster's Ninth New Collegiate Dictionary is attached hereto as Exhibit A. The exhibit includes both a pronunciation guide as well as the dictionary's definition for the work "lupin" (found after the first entry for "lupine").

4. A true and correct copy of United States Trademark Registration No. 4,024,405 issued on September 13, 2011 for the mark LUPIN together with the TSDR status printout for

same is attached hereto as Exhibit B.

5. A true and correct copy of United States Trademark Registration No. 4,874,579 issued on December 22, 2015 for the mark LUPIN and Design together with the TSDR status printout for same is attached hereto as Exhibit C.

6. A true and correct copy cited portions of Ampel, LLC's Responses to Opposer's First Requests for Admission is attached hereto as Exhibit D.

7. True and correct copies of cited excerpts from the Deposition of Amrie Grammer ("Grammer Depo.") taken in the above-captioned action are attached hereto as Exhibit E.

8. True and correct copies of cited excerpts from the Fed. R. Civ. P. 30(b)(6) Deposition of Applicant, by its designee, Peter Lipsky, M.D. ("30(b)(6) Depo."), taken in the above-captioned action are attached hereto as Exhibit F.

9. True and correct copies of cited excerpts of the individual Deposition of Peter Lipsky, M.D. ("Lipsky Depo.") taken in the above-captioned action are attached hereto as Exhibit G.

10. True and correct copies of relevant excerpts of Applicant's November 17, 2014 presentation at the American College of Rheumatology annual meeting are attached hereto as Exhibit H. This presentation was produced by Applicant, and introduced as Exhibit 7 during the course of the Lipsky Depo. Lipsky Depo. at 140:3-21, 141:20-25.

11. True and correct copies of relevant excerpts of Applicant's December 9, 2014 presentation at the Alliance for Lupus Research Board of Directors meeting are attached hereto

as Exhibit I. This presentation was produced by Applicant, and introduced as Exhibit 8 during the course of the Lipsky Depo. Lipsky Depo. at 143:5-25.

12. True and correct copies of relevant excerpts of Applicant's March 31, 2015 presentation at the Maryland Biotech Forum are attached hereto as Exhibit J. This presentation was produced by Applicant, and introduced as Exhibit 9 during the course of the Lipsky Depo. Lipsky Depo. at 148:12-149:25.

13. A true and correct copy of Applicant's draft patient educator training manual is attached hereto as Exhibit K. This presentation was produced by Applicant, and introduced as Exhibit 10 during the course of the Lipsky Depo. Lipsky Depo. at 154:12-155:6.

14. A true and correct copy of Respondent's Answers to Opposer's Second Set of Interrogatories, including signed Verification, is attached hereto as Exhibit L.

15. True and correct copies of relevant excerpts of the article *Drug repositioning in SLE: crowd-sourcing, literature-mining and Big Data analysis*, written by "PE Lipsky", "AC Grammer", and others, and published in *Lupus* Volume 25 (2016), pp. 1150-1170 are attached hereto as Exhibit M. This article was produced by Applicant, and introduced as Exhibit 4 during the course of the Lipsky Depo. Lipsky Depo. at 88:9-25.

16. True and correct copies of several USPTO registration certificates and the corresponding TSDR status for same for use-based trademark registrations that cover both pharmaceutical products and educational services are attached hereto as Exhibit N.

17. True and correct copies of internet printouts, bearing the URL and date accessed,

from third party websites that offer pharmaceutical products and educational and support group services are attached hereto as Exhibit O.

18. A true and correct copy of printouts from Applicant's website as produced by Applicant in the above-captioned proceeding which were introduced as Exhibit 3 during the course of the Lipsky Depo. (Lipsky Depo. at 71:15-72:1; Grammer Depo. at 33:18-23) and are attached hereto as Exhibit P.

19. True and correct copies of unsolicited articles, news items and other media mentions that refer to Opposer are attached hereto as Exhibit Q. If obtained from the LexisNexis database, the articles display the publication, date, and page or section number. If obtained from the Internet, the articles display the URL and date accessed.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 22nd day of December, 2017.

THOMAS H. CURTIN

IN THE U.S. PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

----------x
LUPIN PHARMACEUTICALS, INC.,

Opposer, Opposition No. 91226322

v.

AMPEL, LLC,

Applicant.
----------x

EXHIBIT A

TO

DECLARATION OF THOMAS H. CURTIN IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT BY OPPOSER LUPIN PHARMACEUTICALS, INC.

ER'S Ninth New Collegiate Dictionary

A Merriam-Webster®

MERRIAM-WEBSTER INC., *Publishers*
Springfield, Massachusetts, U.S.A.

A GENUINE MERRIAM-WEBSTER

The name *Webster* alone is no guarantee of excellence. It is used by a number of publishers and may serve mainly to mislead an unwary buyer.

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Library of Congress Cataloging in Publication Data
Main entry under title:

Webster's ninth new collegiate dictionary.

Includes index.
1. English language—Dictionaries. I. Merriam-Webster Inc.
PE1628.W5638 1988 423 87-24041
ISBN 0-87779-508-8
ISBN 0-87779-509-6 (indexed)
ISBN 0-87779-510-X (deluxe)

Made in the United States of America

2930RMcN88

Attention is called to the definition of *vocabulary entry* in this book. The term *dictionary entry* includes all vocabulary entries as well as all boldface entries in the separate sections of the back matter headed "Abbreviations and Symbols for Chemical Elements," "Foreign Words and Phrases," "Biographical Names," "Geographical Names," and "Colleges and Universities."

Pronunciation

Pronunciation is indicated between a pair of reversed virgules \ \ following the entry word. The symbols used are listed in the chart printed inside the back cover of this dictionary and on the page facing the first page of the dictionary proper. An abbreviated list appears at the bottom of the second column of each right-hand page of the vocabulary. Explanations of the symbols are given in the Guide to Pronunciation.

SYLLABLES

A hyphen is used in the pronunciation to show syllabic division. These hyphens sometimes coincide with the centered dots in the entry word that indicate end-of-line division; sometimes they do not:

dis·cov·er \dis-'kəv-ər\

[1]met·ric \'me-trik\

STRESS

A high-set mark \ˈ\ indicates primary (strongest) stress or accent; a low-set mark \ˌ\ indicates secondary (medium) stress or accent:

[1]rough·neck \'rəf-ˌnek\

The stress mark stands at the beginning of the syllable that receives the stress.

In some cases the pronunciation of a word or compound shows no primary stress. One such class of words includes those that occur in main entries only as elements of an open compound. The stress shown for these words is the usual stress in the compound and may be less than primary:

clum·ber spaniel \ˌkləm-bər-\

In other contexts the word may have primary stress, as in "Is that spaniel a clumber?"

VARIANT PRONUNCIATIONS

The presence of variant pronunciations indicates that not all educated speakers pronounce words the same way. A second-place variant is not to be regarded as less acceptable than the pronunciation that is given first. It may, in fact, be used by as many educated speakers as the first variant, but the requirements of the printed page are such that one must precede the other:

apri·cot \'ap-rə-ˌkät, 'ā-prə-\

for·eign \'fȯr-ən, 'fär-\

A variant that is appreciably less common than the preceding variant is preceded by the word *also*:

col·league \'käl-ˌēg *also* -ig\

A variant preceded by *sometimes* is infrequent, though it does occur in educated speech:

in·vei·gle \in-'vā-gəl *sometimes* -'vē-\

Sometimes a regional label precedes a variant:

[1]great \'grāt, *Southern also* 'gre(ə)t\

The symbol \÷\ is placed before a pronunciation that occurs in educated speech but that is consid some to be unacceptable:

cu·po·la \'kyü-pə-lə, ÷-ˌlō\

This symbol refers only to the immediately following and not to subsequent variants separated from it by ma or a semicolon.

PARENTHESES IN PRONUNCIATIONS

Symbols enclosed by parentheses represent eleme are present in the pronunciation of some speakers but sent from the pronunciation of other speakers, eleme are present in some but absent from other utterance same speaker, or elements whose presence or absenc certain:

hap·pen . . . *vi* . . . **hap·pen·ing** \'hap-(ə-)niŋ\

sat·is·fac·to·ry \ˌsat-əs-'fak-t(ə-)rē\

re·sponse \ri-'spän(t)s\

Thus, the parentheses at *happening* mean that there who pronounce the \ə\ between \p\ and \n\ an who do not pronounce it.

PARTIAL AND ABSENT PRONUNCIATI

When a main entry has less than a full pronunci missing part is to be supplied from a pronunciation ceding entry or within the same pair of reversed virg

cham·pi·on·ship \-ˌship\

Ma·dei·ra \mə-'dir-ə, -'der-\

The pronunciation of the first three syllables of *cha* is found at the main entry *champion*:

[1]cham·pi·on \'cham-pē-ən\

The hyphens before and after \'der\ in the pronun *Madeira* indicate that both the first and the last pa pronunciation are to be taken from the immediatel ing pronunciation.

Partial pronunciations are usually shown wher more variants have a part in common. When a va stress is involved, a partial pronunciation may be t at the stress mark which stands at the beginning of not shown:

di·verse \dī-'vərs, də-', 'dī-ˌ\

an·cho·vy \'an-ˌchō-vē, an-'\

In general, no pronunciation is indicated for o pounds consisting of two or more English words own-place entry:

kangaroo court *n*

A pronunciation is shown, however, for any elem open compound that does not have entry at its or betical place:

con·ger eel \ˌkäŋ-gər-\

sieve of Er·a·tos·the·nes \-ˌer-ə-'täs-thə-ˌnēz\

Only the first entry in a sequence of number graphs is given a pronunciation if their pronunci the same:

[1]re·ward \ri-'wȯ(ə)rd\

[2]reward

\÷'feb-(y)ə-ˌwer-ē, 'feb-rə-\, even though they are the most frequently heard pronunciations, because some people insist that both *r*'s should be pronounced. The obelus applies only to that portion of the transcription which it immediately precedes and not to any other variants following.

\ə in unstressed syllables as in **banana, collide, abut.** This neutral vowel may be represented orthographically by any of the letters *a, e, i, o, u, y,* and by many combinations of letters. Unstressed \ə\ often intrudes between a stressed vowel and a following \l\ or \r\ though it is not represented in the spelling, as in *eel* \'ē(ə)l\, *wire* \'wī(ə)r\, *corn* \'kȯ(ə)rn\, *sour* \'saù(ə)r\.

\'ə, ˌə in stressed syllables as in **humdrum, abut.**

\ᵊ immediately preceding \l\, \n\, \m\, \ŋ\, as in **battle, cotton,** and one pronunciation of **open** \'ōp-ᵊm\ and of **and** \ᵊŋ\ as in one pronunciation of the phrase *lock and key* \ˌläk-ᵊŋ-'kē\. The symbol \ᵊ\ preceding these consonants does not itself represent a sound. It signifies instead that the following consonant is syllabic; that is, the consonant itself forms the nucleus of a syllable that does not contain a vowel.

In the pronunciation of some French or French-derived words \ᵊ\ is placed immediately after \l\, \m\, \r\ to indicate one nonsyllabic pronunciation of these consonants, as in the French words **table** "table," **prisme** "prism," and **titre** "title," each of which in isolation and in some contexts is a one-syllable word.

\ər as in **further, merger, bird.** (See the section on \r\.) The anglicized pronunciation of the vowel \œ\ is represented in this book as \ə(r)\. (See the section on \œ\.)

\'ər-, 'ə-r as in two different pronunciations of *hurry.* Most U.S. speakers pronounce \'hər-ē\ with the \ər\ representing the same sounds as in *bird* \'bərd\. Usually in metropolitan New York and southern England and frequently in New England and the southeastern U.S. the vowel is much the same as the vowel of *hum* followed by a syllable-initial variety of \r\. This pronunciation of *hurry* is represented as \'hə-rē\ in this book. Both types of pronunciation are shown for words composed of a single meaningful unit (or *morpheme*) as in *current, hurry,* and *worry.* In words such as *furry, stirring,* and *purring* in which a vowel or vowel-initial suffix is added to a word ending in *r* or *rr* (as *fur, stir,* and *purr*), the second type of pronunciation outlined above is heard only occasionally and is not shown in this dictionary.

\a as in **mat, map, mad, gag, snap, patch.** Some variation in this vowel is occasioned by the consonant that follows it; thus, for some speakers *map, mad,* and *gag* have noticeably different vowel sounds. There is a very small number of words otherwise identical in pronunciation that these speakers may distinguish solely by variation of this vowel, as in the two words *can* (put into cans; be able) in the sentence "Let's can what we can." However, this distinction is sufficiently infrequent that the traditional practice of using a single symbol is followed in this book.

\ā as in **day, fade, date, aorta, drape, cape.** In most English speech this is actually a diphthong. In lowland South Carolina, in coastal Georgia an Florida, and occasionally elsewhere \ā\ is pronounce as a monophthong. As a diphthong \ā\ has a first el ment \e\ or monophthongal \ā\ and a second elemer \i\.

\ä as in **bother, cot,** and, with most America speakers, **father, cart.** The symbol \ä\ repre sents the vowel of *cot, cod,* and the stressed vowel of *co lar* in the speech of those who pronounce this vowel dif ferently from the vowel in *caught, cawed,* and *calle* represented by \ȯ\. In U.S. speech \ä\ is pronounce with little or no rounding of the lips, and it is fairly lon in duration, especially before voiced consonants. In south ern England \ä\ is usually accompanied by some li rounding and is relatively short in duration. The vowe \ȯ\ generally has appreciable lip rounding. Some U.S speakers (a perhaps growing minority) do not distinguis between *cot—caught, cod—cawed,* and *collar—caller,* usu ally because they lack or have less lip rounding in th words transcribed with \ȯ\. Though the symbols \ä\ and \ȯ\ are used throughout this book to distinguis the members of the above pairs and similar words, th speakers who rhyme these pairs will automatically repro duce a sound that is consistent with their own speech.

In words such as *card* and *cart* most U.S. speaker have a sequence of sounds that we transcribe as \är\ Most speakers who do not pronounce \r\ before anothe consonant or a pause, however, do not rhyme *card* witl either *cod* or *cawed* and do not rhyme *cart* with either *co* or *caught.* The pronunciation of *card* and *cart* by such speakers, although not shown in this dictionary, would b transcribed as \'kȧd\ and \'kȧt\. Speakers of r-drop ping dialects will automatically substitute \ȧ\ for th transcribed \är\. (See the sections on \ȧ\ and \r\.)

\ȧ as in **father** as pronounced by those who do no rhyme it with *bother.* The pronunciation of thi vowel varies regionally. In eastern New England an southern England it is generally pronounced farther for ward in the mouth than \ä\ but not as far forward a \a\. In New York City and the southeastern U.S. it may have much the same quality as \ä\ but somewhat great er duration.

In areas in which \r\ is not pronounced before anoth er consonant or a pause, \ȧ\ occurs for the sequence transcribed in this book as \är\. (See the sections on \ä\ and \r\.) In these areas \ȧ\ also occurs with varying frequency in a small group of words in which *a* in the spelling is followed by a consonant letter other than and is not preceded by *w* or *wh,* as in *father, calm, palm,* and *tomato* but not in *watch, what,* or *swap* (though \ȧ\ does sometimes occur in *waft*). Especially in southern England and, less consistently, in eastern New England \ȧ\ occurs in certain words in which \a\ is the usual American vowel and in most of which the vowel is followed by \f\, \th\, \s\, or by \n\ and another consonant. The following words and word elements are among the most susceptible to the \ȧ\ pronunciation. Where *a* appears in the spelling more than once, the vowel that may be pronounced \ȧ\ is marked with a dot.

advance, advantage, aft, after, aghast, answer, ask, aunt, avalanche, bask, basket, bath, behalf, blanch, blast, branch, brass, calf, calve, can't, cask, casket, cast, caste, caster, castle, castor, chaff, chance, chancel, chancellor, chancery, chandler, chant, clasp, class, command, dance, demand, fancy, fast, fasten, flabbergast, flask, gasp, ghastly, giraffe, glance, glass, graft, graph, -graph, grass, grasp, half, halve, lance, last, lath, laugh, mask, mast, master, nasty, pass, past, pastor, path, plant, plaster, prance, raft, rafter, rascal, rasp, raspberry, re-

moderately rounded as for the vowel \ù\. This vowel is often anglicized as the \ər\ of *bird* by those who do not "drop their r's" or as the corresponding vowel of *bird* used by those who do (see the section on \r\). Where this anglicization is shown, it is represented as \ə(r)\.

\œ as in French **f**eu "fire," German H**ö**hle "hole." This vowel, which occurs primarily in foreign-derived terms and names, can be approximated by attempting to pronounce a monophthongal vowel \ā\ with the lips fully rounded as for the vowel \ü\. This vowel also occurs in Scots and thus is used in the pronunciation of *guidwillie,* mainly restricted to Scotland.

\ȯi as in c**oi**n, destr**oy**. In some Southern speech, especially before a consonant in the same word, the second element may disappear or be replaced by \ə\. Some utterances of *drawing* and *sawing* have a sequence of vowel sounds identical to that in *coin,* but because *drawing* and *sawing* are analyzed by many as two-syllable words they are transcribed with a parenthesized hyphen: \'drȯ(-)iŋ\, \'sȯ(-)iŋ\.

\p as in **p**epper, li**p**.

\r as in **r**ed, ra**r**ity, ca**r**, bea**rd**. In some dialects, especially those of the southeastern U.S., eastern New England, New York City, and southern England, \r\ is not pronounced when another consonant or a pause follows immediately. This is often, if somewhat misleadingly, referred to as r-dropping. In these dialects *r* is pronounced as a nonsyllabic \ə\ when it occurs in these positions or there may be no sound corresponding to the *r*; thus *beard, corn,* and *assured* may be pronounced as \'biəd\, \'kȯən\, and \'ə-shu̇əd\ or, usually with some lengthening of the vowel sound, as \'bid\, \'kȯn\, and \'ə-shu̇d\. In *car, card,* and *cart* those who do not pronounce \r\ generally have a vowel which we would transcribe as \ȧ\, usually pronounced with some lengthening and without a following \ə\. (See the sections on \ä\ and \ȧ\.) The stressed vowel of *bird* and *hurt* in r-dropping speech is similar to the vowel used by r-keepers in the same words but without the simultaneous raising of the center and/or tip of the tongue. In the U.S. most speakers of r-dropping dialects will pronounce \r\ before consonants in some words or in some contexts. Because it is determined by the phonetic context, r-dropping is not explicitly represented in this dictionary; speakers of r-dropping dialects will automatically substitute the sounds appropriate to their own speech.

\s as in **s**ource, le**ss**.

\sh as in **sh**y, mi**ss**ion, ma**ch**ine, spe**c**ial. Actually this is a single sound, not two. When the two sounds \s\ and \h\ occur in sequence, they are separated by a hyphen in this book, as in *grasshopper* \'gras-ˌhäp-ər\.

\t as in **t**ie, a**tt**ack, la**t**e, la**t**er, la**tt**er. In some contexts, as when a stressed or unstressed vowel precedes and an unstressed vowel or \ᵊl\ follows, the sound represented by *t* or *tt* is pronounced in much American speech the same as the sound represented by *d* or *dd* in similar contexts. Thus, the pairs *ladder* and *latter, leader* and *liter, parody* and *parity* are often homophones. In such instances this dictionary shows \d\ at the end of a syllable for those words spelled with *d* or *dd* (\'lad-ər\, \'lēd-ər\, \'par-əd-ē\) and \t\ at the end of a syllable for those with *t* or *tt* (\'lat-ər\, \'lēt-ər\, \'par-ət-ē\).

\th as in **th**in, e**th**er. Actually, this is a single sound, not two. When the two sounds \t\ and \h\ occur in sequence they are separated by a hyphen in this book, as in *knighthood* \'nīt-ˌhu̇d\.

\th as in **th**en, ei**th**er, **th**is. Actually, this is a single sound, not two. The basic difference between \th\ and \th\ is that the former is pronounced without and the latter with vibration of the vocal cords.

\ü as in r**u**le, y**ou**th, un**i**on \'yün-yən\, few \'fyü\.

\u̇ as in p**u**ll, w**oo**d, b**oo**k, curable \'kyu̇r-ə-bəl\, fury \'fyu̇(ə)r-ē\.

\ue as in German f**ü**llen "to fill," h**ü**bsch "handsome." This vowel, which occurs only in foreign-derived terms and names, can be approximated by attempting to pronounce the vowel \i\ with the lips moderately rounded as for the vowel \u̇\.

\ūe as in French r**ue** "street," German f**ühl**en "to feel." This vowel, which occurs only in foreign-derived terms and names, can be approximated by attempting to pronounce the vowel \ē\ with the lips fully rounded as for the vowel \ü\.

\v as in **v**ivid, in**v**ite.

\w as in **w**e, a**w**ay. In some words having final \(ˌ)ō\, as *follow,* \(ˌ)yü\, as *value,* or \(ˌ)ü\ as *statue,* an unstressed variant \ə\ or \yə\ may occur especially before a consonant or a pause, as in \'fäl-əd\ or \'val-yəd\, and a variant \ə-w\ or \yə-w\ occurs before vowels, as in \'fäl-ə-wiŋ\ or \'val-yə-wiŋ\. These variants are transcribed \ə(-w)\ or \yə(-w)\ at the entry word.

\y as in **y**ard, **y**oung, cue \'kyü\, curable \'kyu̇r-ə-bəl\, few \'fyü\, fury \'fyu̇(ə)r-ē\, union \'yün-yən\. The sequences \lyü\, \syü\, and \zyü\ in the same syllable, as in *lewd, suit,* and *presume,* are common in southern British speech but are rare in American speech and only \lü\, \sü\, and \zü\ are shown in this dictionary.

In English \y\ does not occur at the end of a syllable after a vowel. In a few words of French origin whose pronunciation has not been anglicized, a postvocalic \y\ is transcribed, as in *mille-feuille* \mēl-fœy\ and in *rouille* \'rü-ē, *F* rüy\. The sound represented is the consonantal \y\ of *yard.*

\ʸ indicates that during the articulation of the preceding consonant the tongue has substantially the position it has for the articulation of the \y\ of *yard* as in French *digne* \dēnʸ\ "worthy." Thus \ʸ\ does not itself represent a sound but rather modifies the preceding symbol.

\z as in **z**one, rai**s**e.

\zh as in vi**s**ion, azu**r**e \'azh-ər\. Actually, this is a single sound, not two. When the two sounds \z\ and \h\ occur in sequence, they are separated by a hyphen in this book, as in *hogshead* \'hȯgz-ˌhed, 'hägz-\.

uprooted individuals cut off from the economic and social class with which they might normally be identified ⟨~ proletariat⟩ ⟨~ intellectuals⟩

²lumpen *n, pl* **lumpen** *also* **lumpens** (1941) : a member of the crude and uneducated lowest class of society

lump·er \'ləm-pər\ *n* (1785) : a laborer employed to handle freight or cargo

lump·ish \'ləm-pish\ *adj* (1528) **1** : DULL, SLUGGISH **2** *obs* : low in spirits : DEJECTED **3** : HEAVY, AWKWARD **4** : LUMPY 1a **5** : tediously slow or dull : BORING; *also* : LUMPY 3 — **lump·ish·ly** *adv* — **lump·ish·ness** *n*

lumpy \'ləm-pē\ *adj* **lump·i·er; -est** (1707) **1 a** : filled or covered with lumps **b** : characterized by choppy waves **2** : having a heavy clumsy appearance **3** : uneven and often crude in style — **lump·i·ly** \-pə-lē\ *adv* — **lump·i·ness** \-pē-nəs\ *n*

lumpy jaw *n* (1890) : ACTINOMYCOSIS; *esp* : actinomycosis of the head in cattle

lu·na·cy \'lü-nə-sē\ *n, pl* **-cies** [*lunatic*] (1541) **1** : any of various forms of insanity: as **a** : intermittent insanity once believed to be related to phases of the moon **b** : insanity amounting to lack of capacity or of responsibility in the eyes of the law **2** : wild foolishness : extravagant folly **3** : a foolish act

lu·na moth \'lü-nə-\ *n* [NL *luna* (specific epithet of *Actias luna*), fr. L, moon] (1869) : a large mostly pale green American saturniid moth (*Actias luna*) with long tails on the hind wings

lu·nar \'lü-nər *also* -ˌnär\ *adj* [L *lunaris*, fr. *luna* moon; akin to L *lucēre* to shine — more at LIGHT] (15c) **1** : CRESCENT, LUNATE **2 a** : of or relating to the moon **b** : designed for use on the moon ⟨~ vehicles⟩ **3** : measured by the moon's revolution ⟨~ month⟩

lunar caustic *n* [obs. *luna* silver, fr. ML, fr. L, moon] (1800) : silver nitrate esp. when fused and molded into sticks for use as a caustic

lunar eclipse *n* (ca. 1890) : an eclipse in which the moon near the full phase passes partially or wholly through the umbra of the earth's shadow

lu·nate \'lü-ˌnāt\ *adj* [L *lunatus*, pp. of *lunare* to bend in a crescent, fr. *luna*] (ca. 1777) : shaped like a crescent

lu·na·tic \'lü-nə-ˌtik\ *adj* [ME *lunatik*, fr. OF or LL; OF *lunatique*, fr. LL *lunaticus*, fr. L *luna*; fr. the belief that lunacy fluctuated with the phases of the moon] (13c) **1 a** : affected with lunacy : INSANE **b** : designed for the care of insane persons ⟨~ asylum⟩ **2** : wildly foolish — **lunatic** *n*

lunatic fringe *n* (1913) : the members of a usu. political or social movement espousing extreme, eccentric, or fanatical views

lu·na·tion \ˌlü-'nā-shən\ *n* [ME *lunacioun*, fr. ML *lunation-*, *lunatio*, fr. L *luna*] (14c) : the period of time averaging 29 days, 12 hours, 44 minutes, and 2.8 seconds elapsing between two successive new moons

¹lunch \'lənch\ *n* [prob. short for *luncheon*] (1812) **1** : a light meal; *esp* : one taken in the middle of the day **2** : the food prepared for a lunch — **out to lunch** *slang* : out of touch with reality

²lunch *vi* (1823) : to eat lunch ~ *vt* : to treat to lunch — **lunch·er** *n*

lunch counter *n* (1869) **1** : a long counter at which lunches are sold **2** : LUNCHEONETTE

lun·cheon \'lən-chən\ *n* [perh. alter. of *nuncheon* (light snack)] (1652) : LUNCH; *esp* : a formal usu. midday meal as part of a meeting or for entertaining a guest

lun·cheon·ette \ˌlən-chə-'net\ *n* (1924) : a small restaurant serving light lunches

lunch·room \'lənch-ˌrüm, -ˌrům\ *n* (1830) **1** : LUNCHEONETTE **2** : a room (as in a school) where lunches supplied on the premises or brought from home may be eaten

lunch·time \-ˌtīm\ *n* (1859) : the time at which lunch is usu. eaten : NOON

lune \'lün\ *n* [L *luna* moon — more at LUNAR] (ca. 1704) : the part of a plane surface bounded by two intersecting arcs or of a spherical surface bounded by two great circles

lunes \'lünz\ *n pl* [F, pl. of *lune* crazy whim, fr. MF, moon, crazy whim, fr. L *luna*] (1602) : fits of lunacy

lu·nette \lü-'net\ *n* [F, fr. OF *lunete* small object shaped like the moon, fr. *lune* moon] (1613) **1** : something that has the shape of a crescent or half-moon: as **a** : an opening in a vault esp. for a window **b** : the surface at the upper part of a wall that is partly surrounded by a vault which the wall intersects and that is often filled by windows or by mural painting **c** : a temporary fortification consisting of two faces forming a salient angle and two parallel flanks **d** : a low crescentic mound (as of sand) formed by the wind **2** : the figure or shape of a crescent moon

lung \'ləŋ\ *n* [ME *lunge*, fr. OE *lungen*; akin to OHG *lungun* lung, *līhti* light in weight — more at LIGHT] (bef. 12c) **1 a** : one of the usu. paired compound saccular thoracic organs that constitute the basic respiratory organ of air-breathing vertebrates **b** : any of various respiratory organs of invertebrates **2 a** : a device enabling individuals abandoning a submarine to rise to the surface **b** : a mechanical device for regularly introducing fresh air into and withdrawing stale air from the lung : RESPIRATOR

¹lunge \'lənj\ *n* [modif. of F *allonge* extension, reach, fr. OF *alonge*, fr. *alongier* to lenghten, fr. (assumed) VL *allongare*, fr. L *ad-* ad- + LL *longare*, fr. L *longus* long] (1748) **1** : a quick thrust or jab (as of a sword) usu. made by leaning or striding forward **2** : a sudden forward rush or reach ⟨made a ~ to catch the ball⟩

²lunge *vb* **lunged; lung·ing** *vi* (1821) : to make a lunge : move with or as if with a lunge ~ *vt* : to thrust or propel (as a blow) in a lunge

lunged \'ləŋd\ *adj* (1693) **1** : having lungs : PULMONATE **2** : having a lung or lungs of a specified kind or number — used in combination ⟨one-*lunged*⟩

¹lung·er \'lən-jər\ *n* (1842) : one that lunges

²lung·er \'ləŋ-ər\ *n* (1893) : one suffering from a chronic disease of the lungs; *esp* : one that is tubercular

lung·fish \'ləŋ-ˌfish\ *n* (1883) : any of various fishes (order Dipneusti or Cladistia) that breathe by a modified air bladder as well as gills

lung·worm \-ˌwərm\ *n* (1882) : any of various nematodes that infest the lungs and air passages of mammals

lung·wort \-ˌwərt, -ˌwȯ(ə)rt\ *n* (bef. 12c) : any of several plants (as a mullein) formerly used in the treatment of respiratory disorders; *esp* : a European herb (*Pulmonaria officinalis*) of the borage family with hispid leaves and bluish flowers

lu·ni·so·lar \ˌlü-ni-'sō-lər *also* -ˌlär\ *adj* [L *luna* moon + E *-i-* + *solar*] (1691) : relating or attributed to the moon and the sun

lu·ni·tid·al \-'tīd-ᵊl\ *adj* [L *luna* + E *-i-* + *tidal*] (1851) : relating to or being tidal movements dependent on the moon

lun·ker \'ləŋ-kər\ *n* [origin unknown] (ca. 1912) : something large of its kind — used esp. of a game fish

lunk·head \'ləŋk-ˌhed\ *n* [prob. alter. of *lump* + *head*] (1852) : a stupid person : DOLT — **lunk·head·ed** \-'hed-əd\ *adj*

lunt \'lənt\ *n* [D *lont*] (1525) **1** *chiefly Scot* : SLOW MATCH **2** *chiefly Scot* : SMOKE

lu·nule \'lü-(ˌ)nyü(ə)l\ *n* [NL *lunula*, fr. L, crescent-shaped ornament, fr. dim. of *luna* moon] (1828) : a crescent-shaped body part or marking (as the whitish mark at the base of a fingernail)

lu·ny \'lü-nē\ *var of* LOONY

lu·pa·nar \lü-'pā-nər, -'pän-ər\ *n* [L, fr. *lupa* prostitute, lit., she-wolf, fem. of *lupus*] (1864) : BROTHEL

Lu·per·ca·lia \ˌlü-pər-'kā-lē-ə, -'kāl-yə\ *n* [L, pl., fr. *Lupercus*, god of flocks] (1600) : an ancient Roman festival celebrated February 15 to ensure fertility for the people, fields, and flocks — **Lu·per·ca·lian** \-'kā-lē-ən, -'kāl-yən\ *adj*

¹lu·pine *also* **lu·pin** \'lü-pən\ *n* [ME, fr. L *lupinus*, *lupinum*, fr. *lupinus*, adj.] (14c) : any of a genus (*Lupinus*) of leguminous herbs some of which are poisonous and others cultivated for green manure, fodder, or their edible seeds; *also* : an edible lupine seed (as of the European *L albus*)

²lu·pine \-ˌpīn\ *adj* [L *lupinus*, fr. *lupus* wolf — more at WOLF] (1660) : WOLFISH

lu·pus \'lü-pəs\ *n* [ML, fr. L, wolf] (15c) : any of several diseases (as systemic lupus erythematosus) characterized by skin lesions

lupus er·y·the·ma·to·sus \-ˌer-ə-ˌthē-mə-'tō-səs\ *n* [NL, lit., erythematous lupus] (1860) : a disorder characterized by skin inflammation; *esp* : SYSTEMIC LUPUS ERYTHEMATOSUS

¹lurch \'lərch\ *vb* [ME *lorchen*, prob. alter. of *lurken* to lurk] *vi, dial chiefly Eng* (15c) : to loiter about a place furtively : PROWL ~ *vt* 1 *obs* : STEAL **2** *archaic* : CHEAT

²lurch *n* [MF *lourche*, adj., defeated by a lurch, deceived] (1598) : a decisive defeat in which an opponent wins a game by more than double the defeated player's score esp. in cribbage — **in the lurch** : in a vulnerable and unsupported position

³lurch *vt* (1651) **1** *archaic* : to leave in the lurch **2** : to defeat by a lurch (as in cribbage)

⁴lurch *n* [origin unknown] (1819) **1** : a sudden roll of a ship to one side **2** : a jerking or swaying movement; *also* : STAGGER 3

⁵lurch *vi* (ca. 1828) : to roll or tip abruptly : PITCH; *also* : STAGGER

lurch·er \'lər-chər\ *n* [³*lurch*] (1528) **1** *archaic* : a petty thief : PILFERER **2** *Brit* : a crossbred dog; *esp* : one that resembles a greyhound **3** : one who lurks; *also* : SPY

lur·dane \'lərd-ᵊn\ *n* [ME *lurdan*, fr. MF *lourdin* dullard, fr. *lourd* dull, stupid, fr. L *luridus* lurid] *archaic* (14c) : a lazy stupid person — **lurdane** *adj*

¹lure \'lü(ə)r\ *n* [ME, fr. MF *loire*, of Gmc origin; akin to MHG *luoder* bait; akin to OE *lathian* to invite, OHG *ladōn*] (14c) **1** : an object usu. of leather or feathers attached to a long cord and used by a falconer to recall a hawk **2 a** : an inducement to pleasure or gain : ENTICEMENT **b** : APPEAL, ATTRACTION **3** : a decoy for attracting animals to capture: as **a** : artificial bait used for catching fish **b** : an often luminous structure on the head of pediculate fishes that is used to attract prey

²lure *vt* **lured; lur·ing** (14c) **1** : to recall (a hawk) by means of a lure **2** : to draw with a hint of pleasure or gain : attract actively and strongly — **lur·er** *n*

syn LURE, ENTICE, INVEIGLE, DECOY, TEMPT, SEDUCE mean to lead astray from one's true course. LURE implies a drawing into danger, evil, or difficulty through attracting and deceiving; ENTICE suggests drawing by artful or adroit means; INVEIGLE implies enticing by cajoling or flattering; DECOY implies a luring into entrapment by artifice; TEMPT implies the presenting of an attraction so strong that it overcomes the restraints of conscience or better judgment; SEDUCE implies a leading astray by persuasion or false promises.

lu·rid \'lůr-əd\ *adj* [L *luridus* pale yellow, sallow] (ca. 1656) **1 a** : wan and ghastly pale in appearance **b** : of any of several light or medium grayish colors ranging in hue from yellow to orange **2** : shining with the red glow of fire seen through smoke or cloud **3 a** : causing horror or revulsion : GRUESOME **b** : MELODRAMATIC, SENSATIONAL; *also* : SHOCKING ⟨paperbacks in the usual ~ covers —T. R. Fyvel⟩ *syn* see GHASTLY — **lu·rid·ly** *adv* — **lu·rid·ness** *n*

lurk \'lərk\ *vi* [ME *lurken*; akin to MHG *lūren* to lie in wait — more at LOWER] (14c) **1 a** : to lie in wait in a place of concealment esp. for an evil purpose **b** : to move furtively or inconspicuously : SNEAK **c** : to persist in staying **2 a** : to be concealed but capable of being discovered; *specif* : to constitute a latent threat **b** : to lie hidden — **lurk·er** *n*

syn LURK, SKULK, SLINK, SNEAK mean to behave so as to escape attention. LURK implies a lying in wait in a place of concealment and often suggests an evil intent; SKULK suggests more strongly cowardice or fear or sinister intent; SLINK implies moving stealthily often merely to escape attention; SNEAK may add an implication of entering or leaving a place or evading a difficulty by furtive, indirect, or underhanded methods.

lus·cious \'ləsh-əs\ *adj* [ME *lucius*, perh. alter. of *licius*, short for *delicious*] (15c) **1 a** : having a delicious taste or smell : SWEET **b** *archaic* : excessively sweet : CLOYING **2** : sexually attractive : SEDUCTIVE, SEXY **3 a** : richly luxurious or appealing to the senses **b** : excessively ornate — **lus·cious·ly** *adv* — **lus·cious·ness** *n*

¹lush \'ləsh\ *adj* [ME *lusch* soft, tender] (1610) **1 a** : growing vigorously esp. with luxuriant foliage ⟨~ grass⟩ **b** : lavishly productive: as (1) : FERTILE (2) : THRIVING (3) : characterized by abundance : PLENTIFUL (4) : PROSPEROUS, PROFITABLE **2 a** : SAVORY, DELICIOUS **b** : appealing to the senses ⟨the ~ sounds of the orchestra⟩ **c** : OPULENT, SUMPTUOUS *syn* see PROFUSE — **lush·ly** *adv* — **lush·ness** *n*

²lush *n* [origin unknown] (ca. 1790) **1** *slang* : intoxicating liquor : DRINK **2** : an habitual heavy drinker : DRUNKARD

³lush *vb, slang* (ca. 1810) : DRINK

Lu·so- *comb form* [Pg, fr. *lusitano* Portuguese, fr. L *lusitanus* of Lusitania (ancient region corresponding approximately to modern

IN THE U.S. PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

----------x
LUPIN PHARMACEUTICALS, INC.,

Opposer, Opposition No. 91226322

v.

AMPEL, LLC,

Applicant.
----------x

EXHIBIT B

TO

DECLARATION OF THOMAS H. CURTIN IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT BY OPPOSER LUPIN PHARMACEUTICALS, INC.

United States of America
United States Patent and Trademark Office

LUPIN

Reg. No. 4,024,405

Registered Sep. 13, 2011

Int. Cl.: 5

TRADEMARK

PRINCIPAL REGISTER

LUPIN PHARMACEUTICALS, INC. (MARYLAND CORPORATION)
HARBORPLACE TOWER
111 SOUTH CALVERT STREET, 21ST FLOOR
BALTIMORE, MD 21202

FOR: HOUSE MARK FOR FULL LINE OF PHARMACEUTICALS FOR MEDICAL PURPOSES, BUT EXCLUDING DIETARY SUPPLEMENTS AND EDIBLE FLOUR, IN CLASS 5 (U.S. CLS. 6, 18, 44, 46, 51 AND 52).

FIRST USE 7-1-2005; IN COMMERCE 7-1-2005.

THE MARK CONSISTS OF STANDARD CHARACTERS WITHOUT CLAIM TO ANY PARTICULAR FONT, STYLE, SIZE, OR COLOR.

SER. NO. 77-766,890, FILED 6-24-2009.

RONALD AIKENS, EXAMINING ATTORNEY

David J. Kappos

Director of the United States Patent and Trademark Office

REQUIREMENTS TO MAINTAIN YOUR FEDERAL TRADEMARK REGISTRATION

WARNING: YOUR REGISTRATION WILL BE CANCELLED IF YOU DO NOT FILE THE DOCUMENTS BELOW DURING THE SPECIFIED TIME PERIODS.

Requirements in the First Ten Years*
What and When to File:

First Filing Deadline: You must file a Declaration of Use (or Excusable Nonuse) between the 5th and 6th years after the registration date. *See* 15 U.S.C. §§1058, 1141k. If the declaration is accepted, the registration will continue in force for the remainder of the ten-year period, calculated from the registration date, unless cancelled by an order of the Commissioner for Trademarks or a federal court.

Second Filing Deadline: You must file a Declaration of Use (or Excusable Nonuse) **and** an Application for Renewal between the 9th and 10th years after the registration date.* *See* 15 U.S.C. §1059.

Requirements in Successive Ten-Year Periods*
What and When to File:

You must file a Declaration of Use (or Excusable Nonuse) **and** an Application for Renewal between every 9th and 10th-year period, calculated from the registration date.*

Grace Period Filings*

The above documents will be accepted as timely if filed within six months after the deadlines listed above with the payment of an additional fee.

The United States Patent and Trademark Office (USPTO) will NOT send you any future notice or reminder of these filing requirements.

***ATTENTION MADRID PROTOCOL REGISTRANTS:** The holder of an international registration with an extension of protection to the United States under the Madrid Protocol must timely file the Declarations of Use (or Excusable Nonuse) referenced above directly with the USPTO. The time periods for filing are based on the U.S. registration date (not the international registration date). The deadlines and grace periods for the Declarations of Use (or Excusable Nonuse) are identical to those for nationally issued registrations. *See* 15 U.S.C. §§1058, 1141k. However, owners of international registrations do not file renewal applications at the USPTO. Instead, the holder must file a renewal of the underlying international registration at the International Bureau of the World Intellectual Property Organization, under Article 7 of the Madrid Protocol, before the expiration of each ten-year term of protection, calculated from the date of the international registration. *See* 15 U.S.C. §1141j. For more information and renewal forms for the international registration, see http://www.wipo.int/madrid/en/.

NOTE: Fees and requirements for maintaining registrations are subject to change. Please check the USPTO website for further information. With the exception of renewal applications for registered extensions of protection, you can file the registration maintenance documents referenced above online at http://www.uspto.gov.

Generated on: This page was generated by TSDR on 2017-12-13 15:05:44 EST

Mark: LUPIN

LUPIN

US Serial Number: 77766890

Application Filing Date: Jun. 24, 2009

US Registration Number: 4024405

Registration Date: Sep. 13, 2011

Register: Principal

Mark Type: Trademark

Status: A Sections 8 and 15 combined declaration has been accepted and acknowledged.

Status Date: Sep. 02, 2017

Publication Date: Jun. 28, 2011

Mark Information

Mark Literal Elements: LUPIN

Standard Character Claim: Yes. The mark consists of standard characters without claim to any particular font style, size, or color.

Mark Drawing Type: 4 - STANDARD CHARACTER MARK

Goods and Services

Note: The following symbols indicate that the registrant/owner has amended the goods/services:

- Brackets [..] indicate deleted goods/services;
- Double parenthesis ((..)) identify any goods/services not claimed in a Section 15 affidavit of incontestability; and
- Asterisks *..* identify additional (new) wording in the goods/services.

For: HOUSE MARK FOR FULL LINE OF PHARMACEUTICALS FOR MEDICAL PURPOSES, BUT EXCLUDING DIETARY SUPPLEMENTS AND EDIBLE FLOUR

International Class(es): 005 - Primary Class

U.S Class(es): 006, 018, 044, 046, 051, 052

Class Status: ACTIVE

Basis: 1(a)

First Use: Jul. 01, 2005

Use in Commerce: Jul. 01, 2005

Basis Information (Case Level)

Filed Use: Yes	**Currently Use:** Yes	**Amended Use:** No
Filed ITU: No	**Currently ITU:** No	**Amended ITU:** No
Filed 44D: No	**Currently 44D:** No	**Amended 44D:** No
Filed 44E: No	**Currently 44E:** No	**Amended 44E:** No
Filed 66A: No	**Currently 66A:** No	
Filed No Basis: No	**Currently No Basis:** No	

Current Owner(s) Information

Owner Name: Lupin Pharmaceuticals, Inc.

Owner Address: Harborplace Tower
111 South Calvert Street, 21st Floor
Baltimore, MARYLAND 21202
UNITED STATES

Legal Entity Type: CORPORATION

State or Country MARYLAND

Where Organized:

Attorney/Correspondence Information

Attorney of Record

Attorney Name: Robert L. Powley
Docket Number: 190.175(US)
Attorney Primary Email Address: trademarks@powleygibson.com
Attorney Email Authorized: Yes

Correspondent

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UNITED STATES

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Correspondent e-mail Authorized: Yes

Domestic Representative - Not Found

Prosecution History

Date	Description	Proceeding Number
Sep. 02, 2017	NOTICE OF ACCEPTANCE OF SEC. 8 & 15 - E-MAILED	
Sep. 02, 2017	REGISTERED - SEC. 8 (6-YR) ACCEPTED & SEC. 15 ACK.	69615
Sep. 02, 2017	CASE ASSIGNED TO POST REGISTRATION PARALEGAL	69615
Jul. 27, 2017	TEAS SECTION 8 & 15 RECEIVED	
Apr. 17, 2012	COUNTERCLAIM OPP. NO. 999999	201582
Sep. 13, 2011	REGISTERED-PRINCIPAL REGISTER	
Sep. 09, 2011	ATTORNEY/DOM.REP.REVOKED AND/OR APPOINTED	
Sep. 09, 2011	TEAS REVOKE/APP/CHANGE ADDR OF ATTY/DOM REP RECEIVED	
Jun. 28, 2011	PUBLISHED FOR OPPOSITION	
Jun. 08, 2011	NOTICE OF PUBLICATION	
May 25, 2011	LAW OFFICE PUBLICATION REVIEW COMPLETED	66213
May 24, 2011	APPROVED FOR PUB - PRINCIPAL REGISTER	
May 24, 2011	ASSIGNED TO EXAMINER	75589
Jan. 25, 2011	REPORT COMPLETED SUSPENSION CHECK CASE STILL SUSPENDED	66213
Jan. 25, 2011	ASSIGNED TO LIE	66213
Jul. 22, 2010	LETTER OF SUSPENSION MAILED	
Jul. 22, 2010	SUSPENSION LETTER WRITTEN	76137
Mar. 17, 2010	LETTER OF SUSPENSION MAILED	
Mar. 16, 2010	SUSPENSION LETTER WRITTEN	76137
Mar. 11, 2010	TEAS/EMAIL CORRESPONDENCE ENTERED	88889
Mar. 11, 2010	CORRESPONDENCE RECEIVED IN LAW OFFICE	88889
Mar. 11, 2010	TEAS RESPONSE TO OFFICE ACTION RECEIVED	
Sep. 24, 2009	NON-FINAL ACTION MAILED	
Sep. 23, 2009	NON-FINAL ACTION WRITTEN	76137
Sep. 23, 2009	ASSIGNED TO EXAMINER	76137
Jun. 29, 2009	NEW APPLICATION OFFICE SUPPLIED DATA ENTERED IN TRAM	
Jun. 27, 2009	NEW APPLICATION ENTERED IN TRAM	

Maintenance Filings or Post Registration Information

Affidavit of Continued Use: Section 8 - Accepted

Affidavit of Incontestability: Section 15 - Accepted

TM Staff and Location Information

TM Staff Information - None

File Location

Current Location: TMO LAW OFFICE 112 **Date in Location:** Sep. 02, 2017

Proceedings

Summary

Number of Proceedings: 3

Type of Proceeding: Opposition

Proceeding Number: 91226322 **Filing Date:** Feb 16, 2016

Status: Pending **Status Date:** Feb 16, 2016

Interlocutory Attorney: BENJAMIN U OKEKE

Defendant

Name: Ampel, LLC

Correspondent Address: PATRICK C. ASPLIN
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UNITED STATES

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Associated marks

Mark	Application Status	Serial Number	Registration Number
LUPPIN	Opposition Pending	86509184	

Plaintiff(s)

Name: Lupin Pharmaceuticals, Inc.

Correspondent Address: Diane B. Melnick
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Correspondent e-mail: thcurtin@powleygibson.com

Associated marks

Mark	Application Status	Serial Number	Registration Number
LUPIN	Section 8 and 15 - Accepted and Acknowledged	77766890	4024405
LUPIN	Registered	77766816	4874579

Prosecution History

Entry Number	History Text	Date	Due Date
1	FILED AND FEE	Feb 16, 2016	
2	NOTICE AND TRIAL DATES SENT; ANSWER DUE:	Feb 16, 2016	Mar 27, 2016
3	PENDING, INSTITUTED	Feb 16, 2016	
4	ANSWER	Mar 24, 2016	
5	STIP FOR EXT	Sep 23, 2016	
6	EXTENSION OF TIME GRANTED	Sep 23, 2016	
7	STIP FOR EXT	Nov 22, 2016	
8	EXTENSION OF TIME GRANTED	Nov 22, 2016	
9	STIP FOR EXT	Jan 25, 2017	
10	EXTENSION OF TIME GRANTED	Jan 25, 2017	
11	STIP FOR EXT	Mar 31, 2017	
12	EXTENSION OF TIME GRANTED	Mar 31, 2017	

13	STIP FOR EXT	Jun 02, 2017
14	EXTENSION OF TIME GRANTED	Jun 02, 2017
15	STIP FOR EXT	Jul 20, 2017
16	EXTENSION OF TIME GRANTED	Jul 20, 2017
17	STIP FOR EXT	Sep 25, 2017
18	EXTENSION OF TIME GRANTED	Sep 25, 2017

Type of Proceeding: Opposition

Proceeding Number: 91201582 **Filing Date:** Sep 12, 2011

Status: Terminated **Status Date:** Apr 22, 2013

Interlocutory Attorney: ANDREW P BAXLEY

Defendant

Name: Guerlain S.A.

Correspondent Address: DAVID EHRLICH
FROSS ZELNICK LEHRMAN & ZISSU PC
866 UNITED NATIONS PLAZA
NEW YORK NY , 10017-1822
UNITED STATES

Correspondent e-mail: dehrlich@fzlz.com

Associated marks

Mark	Application Status	Serial Number	Registration Number
ARSENE LUPIN	Registered	85161714	4475508

Plaintiff(s)

Name: Lupin Pharmaceuticals, Inc.

Correspondent Address: ROBERT L POWLEY
POWLEY & GIBSON PC
304 HUDSON STREET, 2ND FLOOR
NEW YORK NY , 10013
UNITED STATES

Correspondent e-mail: trademarks@powleygibson.com , dbmelnick@powleygibson.com

Associated marks

Mark	Application Status	Serial Number	Registration Number
LUPIN	Section 8 and 15 - Accepted and Acknowledged	77766890	4024405
LUPIN	Registered	77766816	4874579

Prosecution History

Entry Number	History Text	Date	Due Date
1	FILED AND FEE	Sep 12, 2011	
2	NOTICE AND TRIAL DATES SENT; ANSWER DUE:	Sep 13, 2011	Oct 23, 2011
3	PENDING, INSTITUTED	Sep 13, 2011	
4	D MOT FOR EXT W/ CONSENT	Oct 20, 2011	
5	EXTENSION OF TIME GRANTED	Oct 20, 2011	
6	D MOT FOR EXT W/ CONSENT	Dec 13, 2011	
7	EXTENSION OF TIME GRANTED	Dec 13, 2011	
8	D MOT FOR EXT W/ CONSENT	Jan 04, 2012	
9	EXTENSION OF TIME GRANTED	Jan 04, 2012	
10	D MOT TO SUSP W/ CONSENT PEND SETTL NEGOTIATIONS	Feb 17, 2012	
11	TRIAL DATES RESET	Feb 17, 2012	
12	D MOT FOR EXT W/ CONSENT	Mar 14, 2012	
13	EXTENSION OF TIME GRANTED	Mar 14, 2012	
14	ANSWER AND COUNTERCLAIM (FEE)	Apr 12, 2012	
15	ANSWER TO COUNTERCLAIM DUE 30 DAYS	Apr 16, 2012	
16	ANSWER TO COUNTERCLAIM	May 16, 2012	
17	P MOT FOR EXT W/ CONSENT	Jul 16, 2012	

18	EXTENSION OF TIME GRANTED	Jul 17, 2012
19	P MOT FOR EXT W/ CONSENT	Aug 14, 2012
20	EXTENSION OF TIME GRANTED	Aug 14, 2012
21	W/DRAW OF OPPOSITION	Apr 18, 2013
22	BD DECISION: DISMISSED W/ PREJ	Apr 22, 2013
23	TERMINATED	Apr 22, 2013

Type of Proceeding: Cancellation

Proceeding Number: 92052316 **Filing Date:** Mar 30, 2010

Status: Terminated **Status Date:** Mar 11, 2011

Interlocutory Attorney: ANN LINNEHAN VOGLER

Defendant

Name: Australis Foods Pty Ltd

Correspondent Address: MICHAEL J. MCCUE
LEWIS AND ROCA LLP
3993 HOWARD HUGHES PARKWAY, SUITE 600
LAS VEGAS NV , 3000
UNITED STATES

Associated marks

Mark	Application Status	Serial Number	Registration Number
LUPIN8	Cancelled - Section 8	77707006	3738119

Plaintiff(s)

Name: Lupin Pharmaceuticals, Inc.

Correspondent Address: VASILIOS PEROS
THOMAS & LIBOWITZ, P.A.
100 LIGHT STREET, SUITE 1100
BALTIMORE MD , 21202
UNITED STATES

Correspondent e-mail: vperos@tandllaw.com

Associated marks

Mark	Application Status	Serial Number	Registration Number
LUPIN	Section 8 and 15 - Accepted and Acknowledged	77766890	4024405
LUPIN	Registered	77766816	4874579

Prosecution History

Entry Number	History Text	Date	Due Date
1	FILED AND FEE	Mar 30, 2010	
2	NOTICE AND TRIAL DATES SENT; ANSWER DUE:	Apr 15, 2010	May 25, 2010
3	PENDING, INSTITUTED	Apr 15, 2010	
4	STIPULATION FOR AN EXTENSION OF TIME	May 25, 2010	
5	ANSWER	Jun 08, 2010	
6	EXTENSION OF TIME GRANTED	Jun 21, 2010	
7	P'S MOT TO SUSP PEND SETLMT NEGOTIATIONS	Oct 05, 2010	
8	SUSPENDED	Nov 03, 2010	
9	P'S MOTION TO DISMISS	Dec 06, 2010	
10	RESPONSE DUE 30 DAYS (DUE DATE)	Jan 19, 2011	Feb 18, 2011
11	BOARD'S DECISION: DISMISSED W/ PREJUDICE	Mar 11, 2011	
12	TERMINATED	Mar 11, 2011	

IN THE U.S. PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

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LUPIN PHARMACEUTICALS, INC.,

Opposer, Opposition No. 91226322

v.

AMPEL, LLC,

Applicant.
----------x

EXHIBIT C

TO

DECLARATION OF THOMAS H. CURTIN IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT BY OPPOSER LUPIN PHARMACEUTICALS, INC.

United States of America
United States Patent and Trademark Office

LUPIN

Reg. No. 4,874,579

Registered Dec. 22, 2015

Int. Cl.: 5

TRADEMARK

PRINCIPAL REGISTER

LUPIN PHARMACEUTICALS, INC. (MARYLAND CORPORATION)
HARBORPLACE TOWER
111 SOUTH CALVERT STREET, 21ST FLOOR
BALTIMORE, MD 21202

FOR: 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 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 (U.S. CLS. 6, 18, 44, 46, 51 AND 52).

FIRST USE 0-0-2005; IN COMMERCE 0-0-2005.

THE MARK CONSISTS OF THE WORD "LUPIN" AND A FLOWER SHAPED DESIGN.

Michelle K. Lee

Director of the United States
Patent and Trademark Office

Reg. No. 4,874,579 SN 77-766,816, FILED 6-24-2009.

RONALD AIKENS, EXAMINING ATTORNEY

REQUIREMENTS TO MAINTAIN YOUR FEDERAL TRADEMARK REGISTRATION

WARNING: YOUR REGISTRATION WILL BE CANCELLED IF YOU DO NOT FILE THE DOCUMENTS BELOW DURING THE SPECIFIED TIME PERIODS.

Requirements in the First Ten Years*
What and When to File:

First Filing Deadline: You must file a Declaration of Use (or Excusable Nonuse) between the 5th and 6th years after the registration date. *See* 15 U.S.C. §§1058, 1141k. If the declaration is accepted, the registration will continue in force for the remainder of the ten-year period, calculated from the registration date, unless cancelled by an order of the Commissioner for Trademarks or a federal court.

Second Filing Deadline: You must file a Declaration of Use (or Excusable Nonuse) **and** an Application for Renewal between the 9th and 10th years after the registration date.* *See* 15 U.S.C. §1059.

Requirements in Successive Ten-Year Periods*
What and When to File:

You must file a Declaration of Use (or Excusable Nonuse) **and** an Application for Renewal between every 9th and 10th-year period, calculated from the registration date.*

Grace Period Filings*

The above documents will be accepted as timely if filed within six months after the deadlines listed above with the payment of an additional fee.

***ATTENTION MADRID PROTOCOL REGISTRANTS:** The holder of an international registration with an extension of protection to the United States under the Madrid Protocol must timely file the Declarations of Use (or Excusable Nonuse) referenced above directly with the United States Patent and Trademark Office (USPTO). The time periods for filing are based on the U.S. registration date (not the international registration date). The deadlines and grace periods for the Declarations of Use (or Excusable Nonuse) are identical to those for nationally issued registrations. *See* 15 U.S.C. §§1058, 1141k. However, owners of international registrations do not file renewal applications at the USPTO. Instead, the holder must file a renewal of the underlying international registration at the International Bureau of the World Intellectual Property Organization, under Article 7 of the Madrid Protocol, before the expiration of each ten-year term of protection, calculated from the date of the international registration. *See* 15 U.S.C. §1141j. For more information and renewal forms for the international registration, see http://www.wipo.int/madrid/en/.

NOTE: Fees and requirements for maintaining registrations are subject to change. Please check the USPTO website for further information. With the exception of renewal applications for registered extensions of protection, you can file the registration maintenance documents referenced above online at http://www.uspto.gov.

NOTE: A courtesy e-mail reminder of USPTO maintenance filing deadlines will be sent to trademark owners/holders who authorize e-mail communication and maintain a current e-mail address with the USPTO. To ensure that e-mail is authorized and your address is current, please use the Trademark Electronic Application System (TEAS) Correspondence Address and Change of Owner Address Forms available at http://www.uspto.gov.

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Mark: LUPIN

LUPIN

US Serial Number:	77766816	**Application Filing Date:**	Jun. 24, 2009
US Registration Number:	4874579	**Registration Date:**	Dec. 22, 2015
Register:	Principal		
Mark Type:	Trademark		
Status:	Registered. The registration date is used to determine when post-registration maintenance documents are due.		
Status Date:	Dec. 22, 2015		
Publication Date:	Feb. 28, 2012	**Notice of Allowance Date:**	Apr. 24, 2012

Mark Information

Mark Literal Elements:	LUPIN
Standard Character Claim:	No
Mark Drawing Type:	3 - AN ILLUSTRATION DRAWING WHICH INCLUDES WORD(S)/ LETTER(S)/NUMBER(S)
Description of Mark:	The mark consists of the word "Lupin" and a flower shaped design.
Color(s) Claimed:	Color is not claimed as a feature of the mark.
Design Search Code(s):	05.03.08 - More than one leaf, including scattered leaves, bunches of leaves not attached to branches 05.03.25 - Leaf, single; Other leaves 05.05.25 - Daffodils; Iris (flower); Other flowers

Goods and Services

Note: The following symbols indicate that the registrant/owner has amended the goods/services:

- Brackets [..] indicate deleted goods/services;
- Double parenthesis ((..)) identify any goods/services not claimed in a Section 15 affidavit of incontestability; and
- Asterisks *..* identify additional (new) wording in the goods/services.

For: 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 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

International Class(es):	005 - Primary Class	**U.S Class(es):**	006, 018, 044, 046, 051, 052
Class Status:	ACTIVE		
Basis:	1(a)		
First Use:	2005	**Use in Commerce:**	2005

Basis Information (Case Level)

Filed Use:	Yes	**Currently Use:**	Yes	**Amended Use:**	No
Filed ITU:	No	**Currently ITU:**	No	**Amended ITU:**	No
Filed 44D:	No	**Currently 44D:**	No	**Amended 44D:**	No
Filed 44E:	No	**Currently 44E:**	No	**Amended 44E:**	No
Filed 66A:	No	**Currently 66A:**	No		
Filed No Basis:	No	**Currently No Basis:**	No		

Current Owner(s) Information

Owner Name: Lupin Pharmaceuticals, Inc.

Owner Address: Harborplace Tower
111 South Calvert Street, 21st Floor
Baltimore, MARYLAND 21202
UNITED STATES

Legal Entity Type: CORPORATION

State or Country Where Organized: MARYLAND

Attorney/Correspondence Information

Attorney of Record

Attorney Name: Robert L. Powley

Docket Number: 190.176(US)

Attorney Primary Email Address: trademarks@powleygibson.com

Attorney Email Authorized: Yes

Correspondent

Correspondent Name/Address: Robert L. Powley
Powley & Gibson, P.C.
304 Hudson Street, 2nd Floor
New York, NEW YORK 10013
UNITED STATES

Phone: 212-226-5054

Fax: 212-226-5085

Correspondent e-mail: trademarks@powleygibson.com

Correspondent e-mail Authorized: Yes

Domestic Representative - Not Found

Prosecution History

Date	Description	Proceeding Number
Dec. 22, 2015	REGISTERED-PRINCIPAL REGISTER	
Nov. 19, 2015	NOTICE OF ACCEPTANCE OF STATEMENT OF USE E-MAILED	
Nov. 18, 2015	ALLOWED PRINCIPAL REGISTER - SOU ACCEPTED	
Nov. 18, 2015	DATA MODIFICATION COMPLETED	77312
Nov. 14, 2015	TEAS/EMAIL CORRESPONDENCE ENTERED	88889
Nov. 13, 2015	CORRESPONDENCE RECEIVED IN LAW OFFICE	88889
Nov. 13, 2015	TEAS RESPONSE TO OFFICE ACTION RECEIVED	
Jun. 01, 2015	NOTIFICATION OF NON-FINAL ACTION E-MAILED	
Jun. 01, 2015	NON-FINAL ACTION E-MAILED	
Jun. 01, 2015	SU - NON-FINAL ACTION - WRITTEN	75589
May 02, 2015	STATEMENT OF USE PROCESSING COMPLETE	66530
Apr. 23, 2015	USE AMENDMENT FILED	66530
Apr. 23, 2015	TEAS STATEMENT OF USE RECEIVED	
Oct. 22, 2014	NOTICE OF APPROVAL OF EXTENSION REQUEST E-MAILED	
Oct. 21, 2014	EXTENSION 5 GRANTED	66530
Oct. 16, 2014	EXTENSION 5 FILED	66530
Oct. 16, 2014	TEAS EXTENSION RECEIVED	
Apr. 26, 2014	NOTICE OF APPROVAL OF EXTENSION REQUEST E-MAILED	

Apr. 25, 2014	EXTENSION 4 GRANTED	66530
Apr. 21, 2014	EXTENSION 4 FILED	66530
Apr. 21, 2014	TEAS EXTENSION RECEIVED	
Oct. 24, 2013	NOTICE OF APPROVAL OF EXTENSION REQUEST E-MAILED	
Oct. 23, 2013	EXTENSION 3 GRANTED	66530
Oct. 16, 2013	EXTENSION 3 FILED	66530
Oct. 16, 2013	TEAS EXTENSION RECEIVED	
Apr. 26, 2013	NOTICE OF APPROVAL OF EXTENSION REQUEST E-MAILED	
Apr. 25, 2013	EXTENSION 2 GRANTED	66530
Apr. 23, 2013	EXTENSION 2 FILED	66530
Apr. 23, 2013	TEAS EXTENSION RECEIVED	
Nov. 03, 2012	NOTICE OF APPROVAL OF EXTENSION REQUEST MAILED	
Oct. 30, 2012	NOTICE OF APPROVAL OF EXTENSION REQUEST E-MAILED	
Oct. 29, 2012	EXTENSION 1 GRANTED	66530
Oct. 24, 2012	EXTENSION 1 FILED	66530
Oct. 29, 2012	CASE ASSIGNED TO INTENT TO USE PARALEGAL	66530
Oct. 24, 2012	TEAS EXTENSION RECEIVED	
Apr. 24, 2012	NOA E-MAILED - SOU REQUIRED FROM APPLICANT	
Feb. 28, 2012	OFFICIAL GAZETTE PUBLICATION CONFIRMATION E-MAILED	
Feb. 28, 2012	PUBLISHED FOR OPPOSITION	
Feb. 08, 2012	NOTIFICATION OF NOTICE OF PUBLICATION E-MAILED	
Jan. 26, 2012	LAW OFFICE PUBLICATION REVIEW COMPLETED	77312
Jan. 24, 2012	APPROVED FOR PUB - PRINCIPAL REGISTER	
Jan. 23, 2012	AMENDMENT FROM APPLICANT ENTERED	77312
Jan. 23, 2012	CORRESPONDENCE RECEIVED IN LAW OFFICE	77312
Jan. 17, 2012	PAPER RECEIVED	
Sep. 09, 2011	ATTORNEY/DOM.REP.REVOKED AND/OR APPOINTED	
Sep. 09, 2011	TEAS REVOKE/APP/CHANGE ADDR OF ATTY/DOM REP RECEIVED	
Jul. 12, 2011	NON-FINAL ACTION MAILED	
Jul. 12, 2011	NON-FINAL ACTION WRITTEN	75589
Jul. 12, 2011	PREVIOUS ALLOWANCE COUNT WITHDRAWN	
Jun. 13, 2011	WITHDRAWN FROM PUB - OG REVIEW QUERY	76621
Jun. 01, 2011	LAW OFFICE PUBLICATION REVIEW COMPLETED	77312
May 31, 2011	ASSIGNED TO LIE	77312
May 24, 2011	APPROVED FOR PUB - PRINCIPAL REGISTER	
May 24, 2011	ASSIGNED TO EXAMINER	75589
Jan. 07, 2011	REPORT COMPLETED SUSPENSION CHECK CASE STILL SUSPENDED	
Dec. 20, 2010	TEAS/EMAIL CORRESPONDENCE ENTERED	88889
Dec. 20, 2010	CORRESPONDENCE RECEIVED IN LAW OFFICE	88889
Dec. 20, 2010	TEAS RESPONSE TO SUSPENSION INQUIRY RECEIVED	
Jul. 07, 2010	LETTER OF SUSPENSION MAILED	
Jul. 06, 2010	SUSPENSION LETTER WRITTEN	76137
Jan. 14, 2010	NON-FINAL ACTION MAILED	
Jan. 14, 2010	NON-FINAL ACTION WRITTEN	76137
Dec. 21, 2009	TEAS/EMAIL CORRESPONDENCE ENTERED	88889
Dec. 21, 2009	CORRESPONDENCE RECEIVED IN LAW OFFICE	88889
Dec. 21, 2009	TEAS RESPONSE TO OFFICE ACTION RECEIVED	
Sep. 24, 2009	NON-FINAL ACTION MAILED	
Sep. 23, 2009	NON-FINAL ACTION WRITTEN	76137
Sep. 23, 2009	ASSIGNED TO EXAMINER	76137
Jun. 30, 2009	NOTICE OF DESIGN SEARCH CODE MAILED	
Jun. 29, 2009	NEW APPLICATION OFFICE SUPPLIED DATA ENTERED IN TRAM	
Jun. 27, 2009	NEW APPLICATION ENTERED IN TRAM	

TM Staff and Location Information

TM Staff Information - None

File Location

Current Location: PUBLICATION AND ISSUE SECTION **Date in Location:** Nov. 18, 2015

Proceedings

Summary

Number of Proceedings: 3

Type of Proceeding: Opposition

Proceeding Number: 91226322 **Filing Date:** Feb 16, 2016

Status: Pending **Status Date:** Feb 16, 2016

Interlocutory Attorney: BENJAMIN U OKEKE

Defendant

Name: Ampel, LLC

Correspondent Address: PATRICK C. ASPLIN
Lenhart Pettit
530 E MAIN ST, PO BOX 2057
CHARLOTTESVILLE VA , 22902-5336
UNITED STATES

Correspondent e-mail: pca@lplaw.com , tlg@lplaw.com

Associated marks

Mark	Application Status	Serial Number	Registration Number
LUPPIN	Opposition Pending	86509184	

Plaintiff(s)

Name: Lupin Pharmaceuticals, Inc.

Correspondent Address: Diane B. Melnick
Powley & Gibson P.C.
304 HUDSON ST. SUITE 202
NEW YORK NY , 10075
UNITED STATES

Correspondent e-mail: thcurtin@powleygibson.com

Associated marks

Mark	Application Status	Serial Number	Registration Number
LUPIN	Section 8 and 15 - Accepted and Acknowledged	77766890	4024405
LUPIN	Registered	77766816	4874579

Prosecution History

Entry Number	History Text	Date	Due Date
1	FILED AND FEE	Feb 16, 2016	
2	NOTICE AND TRIAL DATES SENT; ANSWER DUE:	Feb 16, 2016	Mar 27, 2016
3	PENDING, INSTITUTED	Feb 16, 2016	
4	ANSWER	Mar 24, 2016	
5	STIP FOR EXT	Sep 23, 2016	
6	EXTENSION OF TIME GRANTED	Sep 23, 2016	
7	STIP FOR EXT	Nov 22, 2016	
8	EXTENSION OF TIME GRANTED	Nov 22, 2016	
9	STIP FOR EXT	Jan 25, 2017	
10	EXTENSION OF TIME GRANTED	Jan 25, 2017	
11	STIP FOR EXT	Mar 31, 2017	
12	EXTENSION OF TIME GRANTED	Mar 31, 2017	
13	STIP FOR EXT	Jun 02, 2017	
14	EXTENSION OF TIME GRANTED	Jun 02, 2017	

15	STIP FOR EXT	Jul 20, 2017
16	EXTENSION OF TIME GRANTED	Jul 20, 2017
17	STIP FOR EXT	Sep 25, 2017
18	EXTENSION OF TIME GRANTED	Sep 25, 2017

Type of Proceeding: Opposition

Proceeding Number: 91201582 **Filing Date:** Sep 12, 2011

Status: Terminated **Status Date:** Apr 22, 2013

Interlocutory Attorney: ANDREW P BAXLEY

Defendant

Name: Guerlain S.A.

Correspondent Address: DAVID EHRLICH
FROSS ZELNICK LEHRMAN & ZISSU PC
866 UNITED NATIONS PLAZA
NEW YORK NY , 10017-1822
UNITED STATES

Correspondent e-mail: dehrlich@fzlz.com

Associated marks

Mark	Application Status	Serial Number	Registration Number
ARSENE LUPIN	Registered	85161714	4475508

Plaintiff(s)

Name: Lupin Pharmaceuticals, Inc.

Correspondent Address: ROBERT L POWLEY
POWLEY & GIBSON PC
304 HUDSON STREET, 2ND FLOOR
NEW YORK NY , 10013
UNITED STATES

Correspondent e-mail: trademarks@powleygibson.com , dbmelnick@powleygibson.com

Associated marks

Mark	Application Status	Serial Number	Registration Number
LUPIN	Section 8 and 15 - Accepted and Acknowledged	77766890	4024405
LUPIN	Registered	77766816	4874579

Prosecution History

Entry Number	History Text	Date	Due Date
1	FILED AND FEE	Sep 12, 2011	
2	NOTICE AND TRIAL DATES SENT; ANSWER DUE:	Sep 13, 2011	Oct 23, 2011
3	PENDING, INSTITUTED	Sep 13, 2011	
4	D MOT FOR EXT W/ CONSENT	Oct 20, 2011	
5	EXTENSION OF TIME GRANTED	Oct 20, 2011	
6	D MOT FOR EXT W/ CONSENT	Dec 13, 2011	
7	EXTENSION OF TIME GRANTED	Dec 13, 2011	
8	D MOT FOR EXT W/ CONSENT	Jan 04, 2012	
9	EXTENSION OF TIME GRANTED	Jan 04, 2012	
10	D MOT TO SUSP W/ CONSENT PEND SETTL NEGOTIATIONS	Feb 17, 2012	
11	TRIAL DATES RESET	Feb 17, 2012	
12	D MOT FOR EXT W/ CONSENT	Mar 14, 2012	
13	EXTENSION OF TIME GRANTED	Mar 14, 2012	
14	ANSWER AND COUNTERCLAIM (FEE)	Apr 12, 2012	
15	ANSWER TO COUNTERCLAIM DUE 30 DAYS	Apr 16, 2012	
16	ANSWER TO COUNTERCLAIM	May 16, 2012	
17	P MOT FOR EXT W/ CONSENT	Jul 16, 2012	
18	EXTENSION OF TIME GRANTED	Jul 17, 2012	
19	P MOT FOR EXT W/ CONSENT	Aug 14, 2012	

20	EXTENSION OF TIME GRANTED	Aug 14, 2012
21	W/DRAW OF OPPOSITION	Apr 18, 2013
22	BD DECISION: DISMISSED W/ PREJ	Apr 22, 2013
23	TERMINATED	Apr 22, 2013

Type of Proceeding: Cancellation

Proceeding Number: 92052316 **Filing Date:** Mar 30, 2010

Status: Terminated **Status Date:** Mar 11, 2011

Interlocutory Attorney: ANN LINNEHAN VOGLER

Defendant

Name: Australis Foods Pty Ltd

Correspondent Address: MICHAEL J. MCCUE
LEWIS AND ROCA LLP
3993 HOWARD HUGHES PARKWAY, SUITE 600
LAS VEGAS NV , 3000
UNITED STATES

Associated marks

Mark	Application Status	Serial Number	Registration Number
LUPIN8	Cancelled - Section 8	77707006	3738119

Plaintiff(s)

Name: Lupin Pharmaceuticals, Inc.

Correspondent Address: VASILIOS PEROS
THOMAS & LIBOWITZ, P.A.
100 LIGHT STREET, SUITE 1100
BALTIMORE MD , 21202
UNITED STATES

Correspondent e-mail: vperos@tandllaw.com

Associated marks

Mark	Application Status	Serial Number	Registration Number
LUPIN	Section 8 and 15 - Accepted and Acknowledged	77766890	4024405
LUPIN	Registered	77766816	4874579

Prosecution History

Entry Number	History Text	Date	Due Date
1	FILED AND FEE	Mar 30, 2010	
2	NOTICE AND TRIAL DATES SENT; ANSWER DUE:	Apr 15, 2010	May 25, 2010
3	PENDING, INSTITUTED	Apr 15, 2010	
4	STIPULATION FOR AN EXTENSION OF TIME	May 25, 2010	
5	ANSWER	Jun 08, 2010	
6	EXTENSION OF TIME GRANTED	Jun 21, 2010	
7	P'S MOT TO SUSP PEND SETLMT NEGOTIATIONS	Oct 05, 2010	
8	SUSPENDED	Nov 03, 2010	
9	P'S MOTION TO DISMISS	Dec 06, 2010	
10	RESPONSE DUE 30 DAYS (DUE DATE)	Jan 19, 2011	Feb 18, 2011
11	BOARD'S DECISION: DISMISSED W/ PREJUDICE	Mar 11, 2011	
12	TERMINATED	Mar 11, 2011	

IN THE U.S. PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

----------x
LUPIN PHARMACEUTICALS, INC.,

Opposer, Opposition No. 91226322

v.

AMPEL, LLC,

Applicant.
----------x

EXHIBIT D

TO

DECLARATION OF THOMAS H. CURTIN IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT BY OPPOSER LUPIN PHARMACEUTICALS, INC.

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

LUPIN PHARMACEUTICALS, INC.,

Opposer,

v.

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

AMPEL, LLC,

Respondent.

AMPEL LLC'S RESPONSES TO OPPOSER'S FIRST SET OF REQUESTS FOR ADMISSION

Respondent/Applicant, Ampel, LLC ("Ampel"), by counsel and pursuant to the applicable provisions of 37 C.F.R. 2.120 and Rules 33, 34 and 36 of the Federal Rules of Civil Procedure ("FRCP"), hereby responds as follows to Opposer Lupin Pharmaceutical, Inc.'s ("Lupin") First Set of Requests for Admission:

GENERAL OBJECTIONS

1. Ampel objects to all Requests for Admission to the extent that they seek information or documents prepared in anticipation of litigation.

2. Ampel objects to all Requests for Admission to the extent that they seek information protected by the attorney-client privilege and/or any other applicable privilege or doctrine, including the work product doctrine and the privilege extending to work undertaken and information obtained in anticipation of litigation. These objections also encompass all privileged communications, including related and associated documents and other information, between and among Ampel's attorneys and any investigators, consultants, experts, agents or other representatives of Ampel relating to, or pertaining in, any way to this proceeding.

3. Ampel objects to all Requests for Admission to the extent that they seek materials and documents that are not in its possession, custody or control.

4. Ampel objects to all Requests for Admission to the extent that they seek information, documents and materials that are equally or more easily available to, or accessible by, Lupin.

5. Ampel objects to all Requests for Admission to the extent that they seek information that is irrelevant, immaterial and not reasonably calculated to lead to the discovery of admissible evidence.

6. Ampel objects to all Requests for Admission to the extent that they are overly broad, vague, ambiguous, subject to multiple interpretations, oppressive, unduly burdensome, harassing and/or beyond the scope of permissible discovery under the applicable provisions of the Rules of Practice in Trademark Cases (37 C.F.R. §§ 2.1-2.209) and the Federal Rules of Civil Procedure (collectively, the "Rules").

7. Ampel objects to all Requests for Admission to the extent that its investigation and analysis of the matters in dispute are continuing. Ampel reserves its right to supplement its responses and answers to any of the Requests for Admission.

Subject to the foregoing objections, which are incorporated into each specific answer, and without waiver thereof, Ampel specifically objects and responds to Lupin's First Set of Requests for Admission in correspondingly-numbered paragraphs as set forth below.

SPECIFIC OBJECTIONS AND RESPONSES TO REQUESTS FOR ADMISSION:

1. Admit that Opposer's use of Opposer's Trademarks was earlier in time than Applicant's adoption and use of Applicant's Trademark.

RESPONSE: Objection. This request is vague and overly broad. Without waiving such objection, Applicant admits that Opposer has used the mark "Lupin" prior to Applicant's use of the mark "LuPPiN." Applicant lacks sufficient information or knowledge to admit

or deny matters relating to the goods or services on which Opposer has used the mark "Lupin" prior to Opposer's use of the mark "LuPPiN" other than those listed in Opposer's federal registrations for the "Lupin" mark.

2. Admit that, prior to November 17, 2014, you had knowledge of the use by Opposer of Opposer's Trademarks.

RESPONSE: Denied.

3. Admit that you are aware of no facts or evidence that contravene Opposer's claim that Opposer commenced use of Opposer's Trademark LUPIN as covered by Reg. No. 4,024,405 on or around July 1, 2005.

RESPONSE: Admitted. Such admission does not relate to any facts or evidence which may subsequently be disclosed during discovery.

4. Admit that you are aware of no facts or evidence that contravene Opposer's claim that Opposer commenced use of Opposer's Trademark LUPIN (and Design) as covered by Reg. No. 4,874,579 in or around 2005.

RESPONSE: Admitted. Such admission does not relate to any facts or evidence which may subsequently be disclosed during discovery.

5. Admit that you are aware of no facts or evidence that contravene Opposer's claim that Opposer commenced use of Opposer's Trademarks prior to November 17, 2014.

RESPONSE: Admitted. Such admission does not relate to any facts or evidence which may subsequently be disclosed during discovery.

6. Admit that you are of aware of no facts or evidence that contravene Opposer's claim that Opposer used Opposer's Trademarks continuously in commerce since at least prior to November 17, 2014 through to the date the Notice of Opposition in this matter was filed.

RESPONSE: Admitted. Such admission does not relate to any facts or evidence which may subsequently be disclosed during discovery.

7. Admit that you did not provide seminars in the fields of Lupus, Lupus treatment options and the importance of clinical trials under Applicant's Trademark as of November 17, 2014, in commerce that may be regulated by the U.S. Congress.

RESPONSE: Objection. This request is irrelevant to the issues in dispute in this

Opposition and is not reasonably calculated to lead to the discovery of admissible evidence. Without waiving such objection, Applicant admits that no such seminars had been actually conducted as of November 17, 2014 under Applicant's Trademark, but denies that Applicant had not used Applicant's Trademark in commerce in connection with such services as of November 17, 2014.

8. Admit that you did not provide one-on-one mentoring in the fields of Lupus, Lupus treatment options and the importance of clinical trials under Applicant's Trademark as of November 17, 2014, in commerce that may be regulated by the U.S. Congress.

RESPONSE: Objection. This request is irrelevant to the issues in dispute in this Opposition and is not reasonably calculated to lead to the discovery of admissible evidence. Without waiving such objection, Applicant admits that no such one-on-one mentoring had been actually provided as of November 17, 2014 under Applicant's Trademark, but denies that Applicant had not used Applicant's Trademark in commerce in connection with such services as of November 17, 2014.

9. Admit that you did not provide training to Lupus patients to teach other Lupus patients about the nature of Lupus, available treatments and the importance of clinical trials under Applicant's Trademark as of November 17, 2014, in commerce that may be regulated by the U.S. Congress.

RESPONSE: Objection. This request is irrelevant to the issues in dispute in this Opposition and is not reasonably calculated to lead to the discovery of admissible evidence. Without waiving such objection, Applicant admits that no such training had been actually provided as of November 17, 2014 under Applicant's Trademark, but denies that Applicant had not used Applicant's Trademark in commerce in connection with such services as of November 17, 2014.

10. Admit that you did not organize support groups for Lupus patients who are undergoing treatment and clinical trials under Applicant's Trademark as of November 17, 2014, in commerce that may be regulated by the U.S. Congress.

RESPONSE: Objection. This request is irrelevant to the issues in dispute in this Opposition and is not reasonably calculated to lead to the discovery of admissible evidence. Without waiving such objection, Applicant admits that no such support groups had been actually organized as of November 17, 2014 under Applicant's Trademark, but denies that Applicant had not used Applicant's Trademark in commerce in connection with such services as of November 17, 2014.

11. Admit that you did not conduct support groups for Lupus patients who are undergoing treatment and clinical trials under Applicant's Trademark as of November 17, 2014,

in commerce that may be regulated by the U.S. Congress.

RESPONSE: Objection. This request is irrelevant to the issues in dispute in this Opposition and is not reasonably calculated to lead to the discovery of admissible evidence. Without waiving such objection, Applicant admits that no such support groups had been actually conducted as of November 17, 2014 under Applicant's Trademark, but denies that Applicant had not used Applicant's Trademark in commerce in connection with such services as of November 17, 2014.

12. Admit that you did not organize support groups for the caregivers of Lupus patients who are undergoing treatment and clinical trials under Applicant's Trademark as of November 17, 2014, in commerce that may be regulated by the U.S. Congress.

RESPONSE: Objection. This request is irrelevant to the issues in dispute in this Opposition and is not reasonably calculated to lead to the discovery of admissible evidence. Without waiving such objection, Applicant admits that no such support groups had been actually organized as of November 17, 2014 under Applicant's Trademark, but denies that Applicant had not used Applicant's Trademark in commerce in connection with such services as of November 17, 2014.

13. Admit that you did not conduct support groups for the caregivers of Lupus patients who are undergoing treatment and clinical trials under Applicant's Trademark as of November 17, 2014, in commerce that may be regulated by the U.S. Congress.

RESPONSE: Objection. This request is irrelevant to the issues in dispute in this Opposition and is not reasonably calculated to lead to the discovery of admissible evidence. Without waiving such objection, Applicant admits that no such support groups had been actually conducted as of November 17, 2014 under Applicant's Trademark, but denies that Applicant had not used Applicant's Trademark in commerce in connection with such services as of November 17, 2014.

14. Admit that you did not provide one-on-one mentoring in the fields of Lupus, Lupus treatment options and the importance of clinical trials under Applicant's Trademark prior to November 17, 2014, in commerce that may be regulated by the U.S. Congress.

RESPONSE: See response to Request No. 8 above.

15. Admit that you did not provide training to Lupus patients to teach other Lupus patients about the nature of Lupus, available treatments and the importance of clinical trials under Applicant's Trademark prior to November 17, 2014, in commerce that may be regulated by the U.S. Congress.

RESPONSE: See response to Request No. 9 above.

16. Admit that you did not organize support groups for Lupus patients who are undergoing treatment and clinical trials under Applicant's Trademark prior to November 17, 2014, in commerce that may be regulated by the U.S. Congress.

RESPONSE: See response to Request No. 10 above.

17. Admit that you did not conduct support groups for Lupus patients who are undergoing treatment and clinical trials under Applicant's Trademark prior to November 17, 2014, in commerce that may be regulated by the U.S. Congress.

RESPONSE: See response to Request No. 11 above.

18. Admit that you did not organize support groups for the caregivers of Lupus patients who are undergoing treatment and clinical trials under Applicant's Trademark prior to November 17, 2014, in commerce that may be regulated by the U.S. Congress.

RESPONSE: See response to Request No. 12 above.

19. Admit that you did not conduct support groups for the caregivers of Lupus patients who are undergoing treatment and clinical trials under Applicant's Trademark prior to November 17, 2014, in commerce that may be regulated by the U.S. Congress.

RESPONSE: See response to Request No. 13 above.

20. Admit that you did not provide seminars in the fields of Lupus, Lupus treatment options and the importance of clinical trials under Applicant's Trademark as of January 21, 2015, in commerce that may be regulated by the U.S. Congress.

RESPONSE: Objection. This request is irrelevant to the issues in dispute in this Opposition and is not reasonably calculated to lead to the discovery of admissible evidence. Without waiving such objection, Applicant admits that no such seminars had been actually provided as of January 21, 2015 under Applicant's Trademark, but denies that Applicant had not used Applicant's Trademark in commerce in connection with such services as of January 21, 2015.

21. Admit that you did not provide one-on-one mentoring in the fields of Lupus, Lupus treatment options and the importance of clinical trials under Applicant's Trademark as of January 21, 2015, in commerce that may be regulated by the U.S. Congress.

RESPONSE: Objection. This request is irrelevant to the issues in dispute in this

Opposition and is not reasonably calculated to lead to the discovery of admissible evidence. Without waiving such objection, Applicant admits that no such one-on-one mentoring had been actually provided as of January 21, 2015 under Applicant's Trademark, but denies that Applicant had not used Applicant's Trademark in commerce in connection with such services as of January 21, 2015.

22. Admit that you did not provide training to Lupus patients to teach other Lupus patients about the nature of Lupus, available treatments and the importance of clinical trials under Applicant's Trademark as of January 21, 2015, in commerce that may be regulated by the U.S. Congress.

RESPONSE: Objection. This request is irrelevant to the issues in dispute in this Opposition and is not reasonably calculated to lead to the discovery of admissible evidence. Without waiving such objection, Applicant admits that no such training had been actually provided as of January 21, 2015 under Applicant's Trademark, but denies that Applicant had not used Applicant's Trademark in commerce in connection with such services as of January 21, 2015.

23. Admit that you did not organize support groups for Lupus patients who are undergoing treatment and clinical trials under Applicant's Trademark as of January 21, 2015, in commerce that may be regulated by the U.S. Congress.

RESPONSE: Objection. This request is irrelevant to the issues in dispute in this Opposition and is not reasonably calculated to lead to the discovery of admissible evidence. Without waiving such objection, Applicant admits that no such support groups had been actually organized as of January 21, 2015 under Applicant's Trademark, but denies that Applicant had not used Applicant's Trademark in commerce in connection with such services as of January 21, 2015.

24. Admit that you did not conduct support groups for Lupus patients who are undergoing treatment and clinical trials under Applicant's Trademark as of January 21, 2015, in commerce that may be regulated by the U.S. Congress.

RESPONSE: Objection. This request is irrelevant to the issues in dispute in this Opposition and is not reasonably calculated to lead to the discovery of admissible evidence. Without waiving such objection, Applicant admits that no such support groups had been actually conducted as of January 21, 2015 under Applicant's Trademark, but denies that Applicant had not used Applicant's Trademark in commerce in connection with such services as of January 21, 2015.

25. Admit that you did not organize support groups for the caregivers of Lupus patients who are undergoing treatment and clinical trials under Applicant's Trademark as of

January 21, 2015, in commerce that may be regulated by the U.S. Congress.

RESPONSE: Objection. This request is irrelevant to the issues in dispute in this Opposition and is not reasonably calculated to lead to the discovery of admissible evidence. Without waiving such objection, Applicant admits that no such support groups had been actually organized as of January 21, 2015 under Applicant's Trademark, but denies that Applicant had not used Applicant's Trademark in commerce in connection with such services as of January 21, 2015.

26. Admit that you did not conduct support groups for the caregivers of Lupus patients who are undergoing treatment and clinical trials under Applicant's Trademark as of January 21, 2015, in commerce that may be regulated by the U.S. Congress.

RESPONSE: Objection. This request is irrelevant to the issues in dispute in this Opposition and is not reasonably calculated to lead to the discovery of admissible evidence. Without waiving such objection, Applicant admits that no such support groups had been actually conducted as of January 21, 2015 under Applicant's Trademark, but denies that Applicant had not used Applicant's Trademark in commerce in connection with such services as of January 21, 2015.

27. Admit that no Lupus patients were enrolled in the LUPPIN program as of November 17, 2014.

RESPONSE: Objection. This request is irrelevant to the issues in dispute in this Opposition and is not reasonably calculated to lead to the discovery of admissible evidence. Without waiving such objection, Applicant admits that no Lupus patients were enrolled in the LUPPIN program as of November 17, 2014.

28. Admit that no Lupus caregivers were enrolled in the LUPPIN program as of November 17, 2014.

RESPONSE: Objection. This request is irrelevant to the issues in dispute in this Opposition and is not reasonably calculated to lead to the discovery of admissible evidence. Without waiving such objection, Applicant admits that no Lupus caregivers were enrolled in the LUPPIN program as of November 17, 2014.

29. Admit that the document produced at APB-00422-APB000467 was created by Applicant and is for use to train participants in the LUPPIN program.

RESPONSE: Objection. This request is irrelevant to the issues in dispute in this Opposition and is not reasonably calculated to lead to the discovery of admissible evidence. Without waiving such objection, this is admitted with the caveat that this

document is a draft and not a final version of the training manual.

30. Admit that the document produced at APB-00422-APB000467 does not display Applicant's Trademark.

RESPONSE: Objection. This request is irrelevant to the issues in dispute in this Opposition and is not reasonably calculated to lead to the discovery of admissible evidence. Without waiving such objection, this is admitted.

31. Admit that Applicant does not provide training materials bearing Applicant's Trademark to participants in the LUPPIN program.

RESPONSE: Objection. This request is irrelevant to the issues in dispute in this Opposition and is not reasonably calculated to lead to the discovery of admissible evidence. Without waiving such objection, this is admitted because Applicant has limited its use of Applicant's Trademark in light of the uncertainty posed by this Opposition.

32. Admit that LUPIN and LUPPIN are similar in appearance.

RESPONSE: Objection. This request is vague and overly broad. Without waiving such objection, this is admitted.

33. Admit that LUPPIN is similar to LUPIN with the exception of an additional letter "P".

RESPONSE: Objection. This request is vague and overly broad. Without waiving such objection, this is denied on the ground that Applicant's Trademark is LuPPiN and not LUPPIN, which further distinguishes it from LUPIN.

34. Admit that the additional letter "P" in Applicant's word mark LUPPIN is not separately pronounced.

RESPONSE: Objection. This request is vague and overly broad. Without waiving such objection, this is admitted.

35. Admit that the additional letter "P" in Applicant's word mark LUPPIN is silent.

RESPONSE: Objection. This request is vague and overly broad. Without waiving such objection, this is admitted.

36. Admit that Applicant's Trademark may be pronounced as LOO-pin.

RESPONSE: Objection. This request is vague and overly broad. Without waiving such objection, this is admitted.

37. Admit that Opposer's Trademark and the Applicant's Trademark are phonetically similar.

RESPONSE: Objection. This request is vague and overly broad. Without waiving such objection, this is admitted.

38. Admit that Opposer's Trademark and Applicant's Trademark are identical when spoken or heard.

RESPONSE: Objection. This request is vague and overly broad. Without waiving such objection, this is admitted.

39. Admit that Applicant displays an image of a wolf on its website at http://ampelbiosolutions.com/lrxl-stat/.

RESPONSE: Objection. This request is irrelevant to the issues in dispute in this Opposition and is not reasonably calculated to lead to the discovery of admissible evidence. Without waiving such objection, Applicant admits that the following logo is displayed at such webpage:

40. Admit that Ampel does not charge Lupus patients for participation in Applicant's LUPPIN program.

RESPONSE: Objection. This request is irrelevant to the issues in dispute in this Opposition and is not reasonably calculated to lead to the discovery of admissible evidence. Without waiving such objection, this is admitted.

41. Admit that Ampel participates in initiatives to repurpose existing pharmaceutical products for use in the treatment of Lupus.

RESPONSE: Objection. This request is irrelevant to the issues in dispute in this Opposition and is not reasonably calculated to lead to the discovery of admissible evidence. Without waiving such objection, this is admitted.

42. Admit that anti-malarial medications may be used in the treatment of Lupus.

RESPONSE: Denied with respect to the United States, although Applicant believes that such medications may be used to treat Lupus in other countries.

43. Admit that nonsteroidal anti-inflammatory drugs (NSAIDs) may be used in the treatment of Lupus.

RESPONSE: Admitted, although such use is generally not recommended in light of the side effects of NSAIDs.

44. Admit that celecoxib is a type of NSAID that may be used to treat Lupus.

RESPONSE: Admitted, although such use is generally not recommended in light of the side effects of NSAIDs.

45. Admit that corticosteroids may be used in the treatment of Lupus.

RESPONSE: Admitted.

46. Admit that statins may be used in the treatment of Lupus.

RESPONSE: Admitted.

47. Admit that ACE inhibitors may be used in the treatment of Lupus.

RESPONSE: Admitted.

48. Admit that the majority of Lupus patients are women between the ages of 15 and 45.

RESPONSE: Admitted.

49. Admit that Lupus is an autoimmune disease.

RESPONSE: Admitted.

50. Admit that headache is a common symptom of Lupus.

RESPONSE: Objection. This request is vague and overly broad. Without waiving such objection, this is admitted.

51. Admit that shortness of breath is a common symptom of Lupus.

RESPONSE: Objection. This request is vague and overly broad. Without waiving such objection, this is denied.

52. Admit that confusion is a common symptom of Lupus.

RESPONSE: Objection. This request is vague and overly broad. Without waiving such objection, this is denied.

53. Admit that chest pain is a common symptom of Lupus.

RESPONSE: . Objection. This request is vague and overly broad. Without waiving such objection, this is denied.

54. Admit that skin rashes are a common symptom of Lupus.

RESPONSE: Objection. This request is vague and overly broad. Without waiving such objection, this is denied.

55. Admit that joint pain is a common symptom of Lupus.

RESPONSE: Objection. This request is vague and overly broad. Without waiving such objection, this is admitted.

56. Admit that joint stiffness is a common symptom of Lupus.

RESPONSE: Objection. This request is vague and overly broad. Without waiving such objection, this is admitted.

57. Admit that joint swelling is a common symptom of Lupus.

RESPONSE: Objection. This request is vague and overly broad. Without waiving such objection, this is denied.

58. Admit that anemia is a common symptom of Lupus.

RESPONSE: Objection. This request is vague and overly broad. Without waiving such objection, this is denied.

59. Admit that light sensitivity is a common symptom of Lupus.

RESPONSE: Objection. This request is vague and overly broad. Without waiving such objection, this is denied.

60. Admit that fever is a common symptom of Lupus.

RESPONSE: Objection. This request is vague and overly broad. Without waiving such objection, this is denied.

61. Admit that kidney problems are a common symptom of Lupus.

RESPONSE: Objection. This request is vague and overly broad. Without waiving such objection, this is denied.

62. Admit that edema is a common symptom of Lupus.

RESPONSE: Objection. This request is vague and overly broad. Without waiving such objection, this is denied.

63. Admit that fatigue is a common symptom of Lupus.

RESPONSE: Objection. This request is vague and overly broad. Without waiving such objection, this is admitted.

64. Admit that muscle aches are a common symptom of Lupus.

RESPONSE: Objection. This request is vague and overly broad. Without waiving such objection, this is admitted.

65. Admit that muscle pain is a common symptom of Lupus.

RESPONSE: Objection. This request is vague and overly broad. Without waiving such objection, this is admitted.

66. Admit that muscle weakness is a common symptom of Lupus.

RESPONSE: Objection. This request is vague and overly broad. Without waiving such objection, this is admitted.

67. Admit that Lupus may affect the nervous system.

RESPONSE: Objection. This request is vague and overly broad. Without waiving such objection, this is admitted.

68. Admit that most Lupus patients will experience some type of "skin involvement" during the course of the disease (see Doc No. APB-00443).

RESPONSE: Objection. This request is vague and overly broad. Without waiving such objection, this is admitted.

69. Admit that Lupus patients may experience symptoms involving their eyes.

RESPONSE: Objection. This request is vague and overly broad. Without waiving such objection, this is denied.

70. Admit that Opposer's Trademark LUPIN is a strong mark as applied to the goods covered by Reg. Nos. 4,024,405 and 4,874,579.

RESPONSE: Objection. This request is vague and overly broad and calls for a legal conclusion. Without waiving such objection, Applicant lacks sufficient knowledge to admit or deny this request.

71. Admit that Opposer's Trademark LUPIN is a distinctive mark as applied to the goods covered by Reg. Nos. 4,024,405 and 4,874,579.

RESPONSE: Objection. This request is vague and overly broad and calls for a legal conclusion. Without waiving such objection, Applicant lacks sufficient knowledge to admit or deny this request.

72. Admit that documents Bates Numbered documents APB-00001 – APB-00124 and APB-00400 – APB-00467 produced by Applicant in this proceeding are authentic for purposes of admission during the testimony period in this matter. If denied, specify which documents cannot be authenticated pursuant to 37 C.F.R. § 2.120.

RESPONSE: Admitted.

73. Admit that documents Bates Numbered documents APB-00001 – APB-00124 and APB-00400 – APB-00467 produced by Applicant in this proceeding were created and maintained by Applicant in the ordinary course of business. If denied, specify which documents were not created and maintained by Applicant in the ordinary course of business.

RESPONSE: Admitted.

AMPEL, LLC
Respondent

/s/ Patrick C. Asplin

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Counsel for Applicant/Respondent

CERTIFICATE OF SERVICE

I hereby certify that on October 16, 2017, I forwarded the foregoing *Responses to Opposer's First Set of Requests for Admission* to the Opposer's attorneys by email to the email address listed below:

Thomas H. Curtin, Esq.
Powley & Gibson, P.C.
304 Hudson Street, 2nd Floor
New York, NY 10013
thcurtin@powleygibson.com
Counsel for Opposer

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

IN THE U.S. PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

----------x
LUPIN PHARMACEUTICALS, INC.,

Opposer, Opposition No. 91226322

v.

AMPEL, LLC,

Applicant.
----------x

EXHIBIT E

TO

DECLARATION OF THOMAS H. CURTIN IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT BY OPPOSER LUPIN PHARMACEUTICALS, INC.

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

CHARLOTTESVILLE, VIRGINIA

ATKINSON-BAKER, INC.
COURT REPORTERS
Telephone: 1-800-288-3376
Website: www.depo.com

REPORTED BY: Cheryl McGrory
FILE NO.: AB09E51

Communications and Administration. We're in the process of trying to update the website.

Q Okay. And what was the company that made the website in the first place?

A I don't remember exactly. The first part of it was Blue, and it was right across the border in Greene County. I don't remember. It was several years ago.

Q Okay. And you don't work with them any longer?

A I don't. I'm sure you can find it in Google. They were advertising that they made our website, so --

Q Okay. So they -- the company is a web design company?

A Yes.

Q Okay. So is it -- is it any -- any other -- do they do any other types of marketing?

A They're a web design company.

Q Only. Okay. All right.

Okay. I'll go ahead and show you what was marked yesterday as Exhibit 3. You can go ahead and give the reporter --

A Okay. Sure.

Q All right. Do you recognize what that is?

A It looks like part of our website.

Q Take your time and look through there.

A That looks like our website. Is that correct?

A So there's registering of the name and actually creating the website. Which are you asking me about?

Q Let's start with when the domain was registered, if you know.

A I'm pretty sure that was shortly after we founded, which was in the summer of 2013.

Q Okay. And do you know when the website first went active?

A I think it was about a year later.

Q Okay. So that was like summer 2014 --

A Summer or fall --

Q -- approximately?

A -- 2014.

Q Okay.

A I don't remember exactly when it was launched, but certainly it was in preparation for some time, so --

Q Okay. And did it look generally like Exhibit 3 when it launched?

A I think the content here was on the website, but obviously a printout is going to look very different than a website format, so --

Q Okay. So the same -- the content hasn't changed dramatically?

A Our content is always changing on the website. We have a news blog. We're updating it all the time. So I

COMMONWEALTH OF VIRGINIA AT LARGE, to wit:

I, Cheryl McGrory, Notary Public for the Commonwealth of Virginia at large, whose commission expires July 31, 2019, do certify that at 10:07 a.m. on September 27, 2017, at 530 East Main Street, Charlottesville, Virginia, with all parties being present, the aforementioned appeared before me, was sworn by me, and was thereupon examined by counsel, that the deposition was taken down stenographically and thereafter transcribed via computer-aided transcription under my direction and that the foregoing is a true, correct, and full transcript of the testimony adduced.

Before completion of the deposition, review of the transcript was requested. If requested, any changes made by the deponent (and provided to the reporter) during the period allowed are appended hereto.

I further certify that I am neither related to nor otherwise associated with any counsel or party to this proceeding, nor otherwise interested in the event thereof.

IN WITNESS WHEREOF, I have hereunto set my hand this 7th day of October, 2017.

Cheryl McGrory

Cheryl McGrory, Notary Public
Commonwealth of Virginia at Large
Notary Registration No. 7131870

IN THE U.S. PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

----------x
LUPIN PHARMACEUTICALS, INC.,

Opposer, Opposition No. 91226322

v.

AMPEL, LLC,

Applicant.
----------x

EXHIBIT F

TO

DECLARATION OF THOMAS H. CURTIN IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT BY OPPOSER LUPIN PHARMACEUTICALS, INC.

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

CHARLOTTESVILLE, VIRGINIA

ATKINSON-BAKER, INC.
COURT REPORTERS
Telephone: 1-800-288-3376
Website: www.depo.com

REPORTED BY: Cheryl McGrory
FILE NO.: AB09E52

Q And that's -- and you're the co-founder, also, of the applicant, AMPEL, LLC?

A Correct. They're the same entities.

Q And in addition to your title as Chief Executive Officer, you're also Chief Medical Officer of --

A Correct.

Q And can you tell me what the difference is between the Chief Medical Officer and the Chief Scientific Officer officer at AMPEL?

A Well, the Chief Executive Officer is really involved with all -- overseeing all aspects of the company, especially with regard to fundraising. The Chief Medical Officer specifically has responsibilities related to the clinical trials, as one of our activities relates to functioning as a kind of boutique CRO that runs clinical trials in lupus, and that requires specific medical knowledge and medical input. So the Chief Medical Officer primarily is involved in providing that expertise in the clinical trial arena.

Q Now, you use the acronym CRO. Can you --

A Clinical Research Organization. It's an organization that is primarily involved in planning and carrying out clinical trials. We do that in the lupus space and also in a few other areas, but predominantly in lupus.

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?

MR. ASPLIN: Again, any discussions between --
THE WITNESS: Right.
MR. ASPLIN: -- with respect to a formal written legal opinion.
THE WITNESS: All right.
I had full confidence in my counsel.
BY MR. CURTIN:
Q Okay. Well, I'm trying to get into whether or not your counsel -- well, let's back it up. Did you ever request an opinion from counsel as to the availability of the right to register the mark?
A Yes.
Q Okay. You did. And did you also request an opinion from your attorney regarding the right to use the mark LuPPiN?
A Yes. We discussed that.
MR. CURTIN: Just off the record for a second.
(Discussion off the record.)
BY MR. CURTIN.
Q Is it true that part of AMPEL's stated goals as a company is to try to repurpose existing FDA-approved pharmaceuticals to treat lupus?
A Correct.
Q Okay. Is it true that lupus is a chronic disease?

A Yes.
Q And that one has it basically for their entire life?
A Yes.
Q Okay. And is it true at this point in time that there's no cure -- no known cure for lupus?
A Correct.
Q Okay. So the purpose of repurposing of existing pharmaceuticals is to alleviate the symptoms suffered by lupus patients; correct?
A Well, that could be one goal. The goal we're more interested in is finding the molecular pathways that drive this disease and finding drugs that deal with the underlying abnormalities and, as a result of that, cause the entire disease to become quiescent, although we don't -- you know, a cure was sort of a grandiose term. We think that something which would actually lead to remission in disease activity is much more possible and something that we would be looking for.
Q Well, you know, in terms of making lupus quiescent or remission of the disease, isn't that exhibited through lack of existence of symptoms in a patient?
A Yes. But, for example, patients may have -- may experience headache related to lupus cerebritis. One could treat the headache with analgesics, with opioids. Some do.

trying to deduce which pathways are abnormal in lupus. Some of those have genetic abnormalities, and we can deduce from the genes that seem to be associated with lupus what the pathogenesis relates to, but we don't have the luxury of being able to target a causative agent because we don't know what the causative agent is. But there are large numbers of molecular pathways that seem to be abnormal in lupus. And by interfering with those or blocking those or amplifying them, depending upon what we're talking about, we expect that the inflammation that causes tissue damage will be ameliorated and, as a result of that, the signs and symptoms will get better.

Q And the only way to do this is through clinical trials using different drugs?

A Is to identify the drugs and then to do clinical trials to show they're effective.

Q Is it possible that a combination of drugs would work?

A It's -- I mean, nowadays lupus is treated with a combination of drugs. Most patients are on three or four drugs, and most clinical trials, for ethical reasons, require adding a new compound onto what's called standard of care. So most of the trials involve taking patients who have active disease on standard of care, which could be two or three drugs, and adding either placebo or the test drug

on top of standard of care. So you're always in the situation where there are multiple drugs on board and you're trying to discern whether or not there's benefit from the additional drug compared to additional placebo on top of standard of care.

Q Now, AMPEL works with pharmaceutical companies to identify existing pharmaceuticals that can hopefully be repurposed for lupus; is that correct?

A AMPEL does the bioinformatic analysis to identify potential drugs that could be useful lupus and then approaches the pharmaceutical companies about -- with evidence about the potential utility of a compound they own or have a patent on and then tries to persuade them of the value of carrying out a clinical trial in lupus. In some circumstances, more recently, companies have come to us to analyze some of their data to see whether or not we can discern that a drug they own may be useful. But that's less common. More often, we do the work and then approach them.

Q Okay. Can you, as you sit here today, name the various pharmaceutical companies that you have approached with the results of your analysis?

A [redacted], many others. So just -- that's just [redacted] right off the top of my head.

Q [redacted]

[redacted]

A [redacted]

Q [redacted]

A [redacted], but every --

Q Okay.

A -- one you can think of, we have approached.

Q Okay. And these are both domestic and foreign-based pharmaceutical companies, I take it.

A Well, that's a distinction without a meaning. They all have U.S. affiliates, so --

Q But like, for instance, you mentioned [redacted] the other day, the [redacted] --

A [redacted], we work with. We work with [redacted], which is in [redacted] We've worked with [redacted], which largely is in [redacted]. But all of them have U.S.-based --

Q Okay.

A -- companies. But we've been to both U.S. and foreign companies to talk about it.

Q And you -- I believe you testified the other day that you yourself go to Europe for some conventions -- correct? -- for rheumatology.

A Both conventions and to visit drug companies. Yes.

Q And in the end, I mean, AMPEL has identified about 157 potential --

A That we have scored, yes.

Q Scored.

A And at that period of time. We're talking 2014. Now it's up to probably 280 or so. And of that, probably 20 or 25 have looked very promising. And we pursued them with the pharma companies that hold intellectual property on those drugs.

Q And when you say intellectual property, are you talking about patents on --

A Patents.

Q -- on the compounds?

A Correct. Those horrible things that these companies survive on.

Q I could have sworn you were an owner of some patents. Are you?

A As I told you, my patents are a sad story that I even pay no attention to.

Q Just wandering children?

A Right.

Q So you have -- well, now -- originally had 157 back in 2014 --

A Right.

Q -- and now you have up to about 280.

A Right.
Q And then from there you -- you scored them and then --
A It narrows it down to perhaps 20, 25.
Q And you've identified the makers of those --
A Yes.
Q -- pharmaceutical preparations?
A Yes, when there was a maker.
Q Okay. When there was a maker. Okay.
Some are generic?
A Some are generic. Some are no longer in the Orange Book. So there are a variety of different compounds, yes. Some are food supplements, all kinds of different things we've identified.
Q Interesting.
Does the Orange Book list the maker of an FDA-approved drug?
It does?
MR. ASPLIN: You have to say yes or no.
BY MR. CURTIN:
Q If the --
A Yes.
Q Okay. Has to be an audible answer.
A And you have to be careful. You asked me does it list those who are marketing the drug. Who makes the

Q But I'm looking at the first page, at the very top there.
A Correct.
Q That researchers with the wolf at the top there?
A Right.
Q So that's -- this is when you're using wolf imagery?
A Right, just there.
Q Okay.
A It's not anything we use repetitively. It was put on the website.
Q Okay.
A This one is our image for the -- this LRxL --
Q Referring to the image on page 3 of the --
A Correct.
Q -- exhibit? Okay.
Now, let's turn back to the word mark LuPPiN. Now, has AMPEL always used the mark with the lower case u and the lower case i, or were there different variations and times?
A It's always been with the lower case u. The i there, it -- I would imagine sometimes during the early development, but the final version had a lower case i.
Q So, for instance, let's look at Exhibit 7.
(Document handed to the witness.)

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

investigators attend that meeting. So this was in Boston at 6:30 in the morning. And this was the -- a meeting for -- the first meeting for the LuCIN investigators to get together.

Q Now, relating to LuCIN, when did you launch LuCIN?

A LuCIN was -- this was basically the launch meeting.

Q For all your --

A Right. But --

Q For --

A -- it really took another two years for it to get operational.

Q Okay.

A But this was the first meeting to discuss the concept.

Q Why 6:30 in the morning?

A Has to do with rules of the American College of Rheumatology, that they only give you meeting room -- they control all the hotels and they don't want anything to compete with their scheduled events. So you can meet at 7:00 at night, which means you're competing with large amounts of alcohol being given out at other meetings, or you can meet at 6:30 in the morning with the assumption that everybody's looking for some coffee. So that's the

reason.

Q And I don't -- sorry to re-plow the ground from your testimony the other day, but how many people were present when you gave this presentation in Boston, November --

A Somewhere between 80 and 120, I would guess. I mean I tried to look it up. Unfortunately, I really don't have much records back from these days. But it's somewhere -- my recollection, it was probably 80 to 120 people, somewhere in that range.

Q And most of these were the investigators?

A Investigators. They're clinical coordinators. Some of their trainees who work as sub-investigators. There were --

Q So this is kind of like --

A -- a lot of people.

Q Sorry. I didn't mean to talk over you, but LuCIN is kind of like -- it was a crowd-sourcing? These investigators --

A No, no, no. These -- this is a -- a network of investigators that are committed doing clinical trials in lupus.

Q Okay.

A Crowd-sourcing we did with the LinkedIn site, which involved some lupus -- some LuCIN investigators and

some people who had no connection even with clinical trials but were interested in LuCIN -- in lupus. These were people who are interested in participating and doing clinical trials as a network in order to develop new treatments for lupus.

Q Okay. Now -- all right. So turning back to 114, this was the first time that the LuPPiN mark was used before the general public, I guess. And in this instance only the -- only the -- the u was lower case; correct?

A It was, but I'd also point out that this was very early days in all of this. For example, the logo for LuCIN itself is not what wound up as the official logo. The -- the face of the phone -- for the LuPRO phone app is not anything at all that looks like what the -- what the final product looked like. I -- you know, I think that there are a lot of aspirational things in here, and it's difficult for me to pick out the case of the I and to say that it's more important than the fact that the entire LuCIN logo is totally different, for example. I like this one, but it was voted down. I thought this was kind of nice. Don't you like that?

MR. CURTIN: Witness is referring to the --

THE WITNESS: With the butterfly?

MR. CURTIN: -- logo on the first page.

THE WITNESS: Kind of pretty. Don't you like

that? Anyway, it was voted down. So -- so there -- this was a very -- meeting at a very early time.

BY MR. CURTIN:

Q Okay.

A And the purpose was more to present the overall vision than the specific details.

Q You didn't have any -- well, I'm saying product, but here we're talking about services. You didn't have any services that you were going to be offering that day, though?

A Correct. We did not have services we were offering that day, but we did have the commitment to start work on developing these various things. And that, again, includes the phone app, which is here, identified on page 118, which looks again very nice, but it doesn't have anything to do with what ours finally evolved. LuPIN was one of those offerings. And, again, we had an aspirational governing structure, which really turned out to be different than the governing structure that's on page 116. We had a number of drugs listed here, which were, we thought, of interest, but many of them never evolved. For example, we have quinacrine here. That turned out to be impossible. We had some discussions with [redacted]. We had -- many of these things were really aspirational at that time and to determine the level of enthusiasm of the

investigators for the entire concept.

Q Okay.

A [redacted]. This was November 2014 when we had discussions about that and had enough information to present that. So, as I said, this entire document indicates the scope of what we were beginning to work on, plan, et cetera, et cetera, but I think there are many aspects of it that when finally developed turned out to be somewhat different than the details that are put in here.

Q Okay. Now, you made this presentation, I take it.

A Correct.

Q And you went through every single slide?

A At 6:30 in the morning I went through every single slide.

Q How many people were awake during this presentation?

A They were excited, actually, and we fed them a lot of really high carbohydrate muffins and things. So they were all having a sugar high that crashed at 7:30 in the morning, but I was done by then.

Q I counted slides, and there are about 42 slides

stylistic P's other than the fact it made it hard to print it in the application.

Q Turning back to the application, then, it's accurate to say that the LuPPiN mark as depicted in your application, which alleges a date of first use of November 17th, 2014, doesn't align with the actual use of the mark in the -- in the PowerPoint that was done in Boston on -- on that same date.

MR. ASPLIN: Let me object to the form.

Go ahead.

THE WITNESS: You'd have to ask that question in a little bit more simplified way. I'm not quite sure I understand what --

BY MR. CURTIN:

Q Okay.

A -- you're asking me.

Q Okay. Use some visual -- I have in front of me Exhibit 7. And I'm turning to page 114, which I refer you to.

A Um-hmm.

Q So my question is, you are aware that you -- you've testified that you filed -- your -- AMPEL filed an application on January 1st, 2015, for the mark LuPPiN in a stylish form, which included the lower case u and a lower case i. My question is, then, it's accurate to say that

your application alleges a date of first use of November 17th, 2014, but, looking at page 114, you were not using the mark in the same style as -- that -- as it appears in your application?

MR. ASPLIN: Let me just state my objection to the form.

Go ahead.

THE WITNESS: It was -- the word was the important aspect. In our minds, it was LUPPIN. It is correct that there is a capital I in the -- in the presentation in 2014, but we were still working on developing the concept of LUPPIN under the name of LUPPIN with two P's.

BY MR. CURTIN:

Q Okay. Well, regardless of the presentation of the mark, this is -- this piece, the November 17th, 2014 --

A Right.

Q -- was largely an aspirational document meant to get the word out about --

A Correct.

Q -- your program; correct?

A Correct.

Q And -- but at that point, to confirm, you -- you were not at that point -- AMPEL, at that point, was not prepared to offer service -- actual services --

A But AMPEL --
Q -- under that mark?
A AMPEL --
MR. ASPLIN: Let me state my objection.
Object to the form.
Go ahead.
THE WITNESS: AMPEL was developing the concept.
BY MR. CURTIN:
Q Okay. Just to be clear, though, when you were in Boston on November 17th, 2014, you or anyone else at AMPEL did not provide any educational services or training of lupus patients?
A We did not offer the training because we're still developing the concept and working on eventually developing the training manual.
Q And similarly --
A That's correct.
Q -- in Boston, as of November 17th, 2014, AMPEL did not provide any -- did not organize or conduct any support groups for lupus patients?
A That is correct.
MR. CURTIN: Okay.
Why don't we take a break? We've been going about an hour.
MR. ASPLIN: Okay.

Q So -- and -- and that was all in connection -- and you had to complete that manual before you actually did the actual service of organizing and conducting the actual support groups?

MR. ASPLIN: Object to the form.

Go ahead.

THE WITNESS: Yes. I mean, the program was a process in which patients were identified and then brought into a central place in order to receive the training in order to carry out the activity. And so the first step was to create the training manual. And I would guess that was -- probably took two months prior to -- started probably January or so, the planning of that meeting. And then subsequently was the work to complete the manual. So that occupied a good part of 2016.

BY MR. CURTIN:

Q Okay. Now, let's -- let's look at Exhibit 10, which is the manual.

A Um-hmm.

(Document handed to the witness.)

THE WITNESS: Um-hmm.

BY MR. CURTIN:

Q And you helped create that manual; correct?

A Correct.

Q And can you tell me whether the mark LuPPiN

appears anywhere within that document?
A Does not.
Q You understand that your application covers services only at this point in time? Has AMPEL ever offered or sold any goods under the LuPPiN mark?
A Goods.
Q Physical objects.
A We don't -- we don't sell goods.
Q You just -- the services that are --
A Services.
Q -- listed in the --
A Correct.
Q -- in the application? Okay.
Now, do you -- aside from the develop- -- the activities that you were -- you testified about in terms of developing the Class 41 and Class 45 services under the LuPPiN mark, did you ever -- you being AMPEL -- ever actually conclude a transactional sale of those services?
A No, we did not.
Q Okay. Did you ever provide those services free of charge under the LuPPiN mark?
A No, we did not.
Q And as a result of -- it's -- it's true that you never generated any revenues from the sale or distribution of those services --

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.

you, and the interaction wouldn't necessarily be focused on my joints are in bad shape. So that was really the discussion. And the patients are -- we really wanted a -- the patient input, and we didn't want them to think that this whole thing was already prepared. And so we really just wanted to explain to them what had happened in rheumatoid arthritis as a basis so then they could provide us with really unbiased input into how it could work in lupus.

Q Okay. We talked about the website and the brochure and we were talking about the conferences. The Boston conference where you launched, that was mostly professionals in attendance --

A Correct.

Q -- mainly rheumatologists; correct?

A Rheumatologists, some trainees and some nurses who act as clinical coordinators for clinical trials.

Q Okay. To your knowledge, were there any lupus patients present?

A Not to my knowledge.

Q Okay. And then the -- the New York presentation before the Board of Directors, there was about a dozen potential sponsors there?

A A dozen members of the Board of Directors of this organization. The organization was a potential

sponsor.

Q Right. And I believe you testified that certain individuals there had relatives who suffered from lupus. But, to your knowledge, were any lupus patients present at your --

A They're all --

Q -- presentation?

A -- members of the Board who have lupus. I cannot tell you whether or not they were present or not.

Q Okay. But other members who were present, they have relatives who are affected with it?

A Correct.

Q Okay. And then the Gaithersburg conference, there were about a hundred to two hundred professionals, again, in the pharma field and in biotech?

A Most of them were in the biotech field, and most of them were either scientists or administrative people in biotech companies.

Q Do you have any idea whether any LuPPiN patients were present? I mean --

A We didn't specific- --

Q -- lupus present -- lupus patients.

A We didn't specifically ask, so I don't know.

Q Okay. So looking at the ways you've communicated your LuPPiN mark before you switched over to

patient partner due to the opposition, whether the website or the brochure or the conferences, your -- your efforts at promoting and advertising LuPPiN were predominantly directed at professionals in the rheumatology field or in biotech and/or, you know, potential trainees, you know, such as UVA --

A Correct.

Q -- students?

A Or pharma, in personal conversations, but not -- we don't market to pharma. We interact with them in the ways that I discussed with you.

Q Now, how does AMPEL make money?

A Well, we print it in the basement. We make money by being supported by either grants or by contracts with pharma or support by voluntary organizations.

Q Okay. Now, the first one is grants. Is that like grants from the NIH?

A Mostly from private foundations.

Q Okay. Any grants from pharmaceutical companies?

A We have contracts with pharmaceutical companies and we do have one or two grants from pharmaceutical companies.

Q Okay. And usually when you have these contracts or grants from pharmaceutical companies, it relates to a drug of theirs that you're trying to develop to --

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 [redacted] 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.

A You may know that.
Q I've heard rumors.
Rather than test your memory, I'm just going to ask you whether you agree that the following are symptoms of lupus so we can have at least a baseline as to what symptoms exhibit themselves to those afflicted by lupus. So I have extreme fatigue. Is that --
A Yes.
Q Headache?
A Yes.
Q Painful or swollen joints?
A Yes.
Q Fever?
A Yes.
Q Anemia?
A Yes.
Q Swelling in the feet, legs, hand and/or eyes?
A Swelling in the feet, hands, legs or eyes. Um...
Q How about swelling?
A Possibly.
Q Possibly? Okay.
A Possibly.
Q Pleurisy?
A Pleuritis, yes.

Q Pleuritis. Can you explain for the record what pleuritis is?
A Inflammation of the membrane that surrounds the lung. Pleurisy is kind of a lay term that describe the symptoms related to pleuritis, but we don't really use it very much.
Q Okay.
A In -- in lupus you wouldn't use it. It's mostly thought to be related to infectious disease. So it's pleuritis, but yes.
Q Rash on the face?
A Yes.
Q Photosensitivity?
A Yes.
Q Hair loss?
A Yes.
Q Abnormal blood clotting?
A Possibly.
Q Raynaud's disease?
A Phenomenon, yes.
Q Could you explain for the record what Raynaud's disease is?
A When you're exposed to the cold, the tips of your fingers and sometimes your toes, even your ears, the vessels constrict and you get decreased blood flow through

here and really the fingers blanch. And it's very painful. So these individuals who have it -- and most of them don't have lupus, but there can be some that have lupus that also have it -- wind up having to wear gloves all the time and can actually develop necrosis of the tissue on the tip of the fingers. It's not pleasant.

Q Mouth and nose ulcers?

A Yes.

Q Can you think of any others off the top of your head?

A You forgot kidney involvement.

Q Kidneys. Also mental confusion?

A Yes. Central center system and peripheral nervous system involvement: confusion, stroke, seizures, psychosis, peripheral neuropathy, lots of things.

Q Could you define what peripheral neurothapy [sic] means?

A Neuropathy.

Q Neuropathy.

A P-A-T-H-Y. N-E-U-R-O-P-A-T-H-Y. Basically, you get inflammation around the nerves, and depending upon what the nerve is, you could either get loss of motor function or loss in sensation or can get extreme sensation of pain if the nerve is irritated.

Q Does lupus have an adverse effect on the

musculoskeletal system?

A Well, it causes arthritis. So it certainly is a cause of arthritis. And I imagine -- we don't usually call that an adverse event but it is a cause of arthritis.

Q You mentioned that we had -- you narrowed it down to 157 drugs from the Orange Book that --

A Right.

Q -- might be possibly effective to treat lupus, and then I think you said --

A Right.

Q -- actually the number is up to 280.

A Right.

Q But you -- I think you've narrowed it down to 20-some-odd.

A We scored all of those compounds, and then the ones that had reasonably high scores were the ones that we were interested in advancing into clinical trials.

Q Okay. Can you name what the 20 or 25 are?

A Right off the top of my head?

Q Well, I mean, you can try. I can leave a blank in the transcript, if that's easier.

A So the leading -- actually, you have it. You have a list of it in the paper we discussed two --

Q Is this --

A -- days ago.

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 --

Q -- with lupus?
A -- between 180 thousand and 1.5 million in the United States.
Q Okay. And they're predominantly African-American women?
A No. They're predominantly Caucasian women because there are more Caucasian women in the United States than there are African-American women. But the prevalence is much higher in African-Americans.
Q So, per capita, they're -- they're the highest --
A Right. So the prevalence is fourfold higher in African-American women, but only 12 percent of the population is African-American. So, overall, there are still more white women that have the disease, but predominantly the disease affects African-Americans more and the disease is much more aggressive.
Q Do men get lupus?
A One out of ten patients is a male.
Q So your plan with LuPPiN, if you proceed with it, is basically -- is it to replicate the success you had down with rheumatology in --
A Correct.
Q -- Texas?
A But specifically focused on recruitment for

clinical trials. And that's really the focus of this program, is to develop a cadre of patients who are comfortable talking about lupus and talking to other patients about the value of participating in clinical trials.

Q How are you going to meet these patients?

A They're referred by the principal investigators at the various sites that I mentioned, the LuCIN sites.

Q Are you speaking about the academic sites?

A Correct. They'll all be from academic sites and they'll all have certain characteristics: ability to learn complicated material, ability to interact with other patients, interest in providing educational material to other patients, a variety of characteristics. So it'll be a very limiting group of individuals.

Q Okay. Now, you said that you have conducted some clinical trials --

A Correct.

Q -- albeit not under the LuPPiN name; is that correct?

A Correct.

Q I had number [redacted], where you said it was less than that.

A Well, we have [redacted] going on right at the moment, [redacted] starting in beginning of

next year.

Q Okay. And of those [redacted], they're all involving -- are they all [redacted]

A [redacted]

Q [redacted]

A [redacted]

Q Okay. It's kind of like any of these autism groups or whatnot?

A Autism, cancer. In our group it's the -- we have the same kind of organizations.

Q Okay. Now, would the clinical trial -- is it conducted at the academic sites?

A Correct.

Q Okay.

A So they're all multi-center trials which involve anywhere from 8 to 25 different sites. They all follow a very strict protocol. All the data gets collected in a very regimented way. Many of them are regulated by the FDA, some not, but they're all carried out in the same style as though they were regulated by the FDA.

Q So you follow FDA protocols when you're doing these?

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

[redacted]

Q. Now, you mentioned the pharmaceutical company's contract with you, private foundation's contract with you, and you also need grants.

A. Right.

Q. What percentage of the revenue that AMPEL derives from all its activities are directly related to pharmaceutical companies?

A. Directly related. You mean --

Q. Well, that -- you know, that you -- you -- whether it's a grant or a contract from a pharmaceutical company vis-à-vis, you know, as -- as opposed a grant from

the government as opposed to a grant or a contract with a, you know, a lupus foundation or volunteer organization?

A I mean, I'd have to look at the books to be specific, but I would guess probably, I don't know, [redacted] of it comes from pharma, something like that. But I would have to look at my records to be precise about that.

Q Is it split fairly evenly between pharma, the government grants and the private foundations?

A Pretty much.

Q Okay. Have you ever conducted -- you being AMPEL -- ever conducted educational seminars under the LuPPiN mark?

A No.

Q Have you ever provided mentoring under the LuPPiN mark?

A No.

Q Have you ever provided training under the LuPPiN mark?

A No.

Q Have you ever organized and conducted support groups under the LuPPiN mark?

A No. That was easy. Got rid of a whole page there.

Q I know. I had all these follow-up questions and

you -- let's look at Exhibit 3, please, which is your website.

A Um-hmm.

Q And I just direct your attention to pages APB-0007 to 8.

A Um-hmm. Here you go.

Q And just for the record, Janssen, Kadmon, Pfizer and GSK are all pharmaceutical companies; is that accurate?

A Kadmon is a biotech startup. Janssen is a pharmaceutical company. Who are the others?

Q Pfizer and --

A Pfizer and GSK --

Q GlaxoSmithKline?

A -- yes. Yes.

Q Okay. And is it accurate to say, then, that Janssen and Pfizer and GlaxoSmithKline are all, quote, clients and collaborators of AMPEL?

A [redacted]

Q [redacted]

A [redacted]

Q [redacted]

A [redacted]

Q Okay. So in other words, if you're doing trials with them, they would --

A If we have an active contract with them, then we would list them here. We -- the website, we're being very, uh, very grand here. So we would -- [redacted]

Q Okay. Just looking at the marks themselves, would you agree with me that both parties' respective marks consist of two syllables?

A Which two marks are you talking about?

Q I'm talking about --

A Lupin and LuPPiN?

Q -- well -- yeah. Well, yeah, our -- our mark --

A Lupin and LuPPiN --

Q -- being the --

A -- are both --

Q -- opposer's mark --

A Okay.

Q -- and your mark.

A Okay. Just to be specific --

Q Okay.

A -- yes, they both have two syllables.

Q Okay. And in connection with AMPEL's mark, you pronounce the second P. It's not Lup-pin, it's Loo-pin; is

that correct?

A It's Loo-pin.

Q As in Lou Costello, and pin as in --

A Correct.

Q -- pins and needles. Okay.

A Correct. Lou Costello and pins and needles?

Q Now, just looking at the marks in terms of the letters in the marks, the literal element of the mark. Aside from the lowercasing of the u and the i, would you agree with me that the only difference between the parties' respective marks is that your mark has an additional P?

A Correct.

Q Okay. We talked about the [redacted] trials going on right now.

A Right.

Q [redacted]

A [redacted]

Q [redacted]

A [redacted]

Q Who else helped you, helped -- I mean, the seven rheumatologists and the -- and the --

A And the patients.

Q And the patients? Okay.

A Correct.

Q And to your -- to your knowledge, are the -- are the -- are the therapies here, listed in 446 through 448, are they fairly inclusive of a list of the drugs that will -- that can relieve the symptoms of lupus?

A These are the drugs that are used to treat lupus. Yes. Not all of them are approved for lupus but they're used to treat lupus.

Q Right. So this -- these are examples of drug repurposing?

A No. No. These are drugs that are currently part of the regimen that's used to lupus patients.

Q Oh, okay. Now, you when -- when you say regimen, do you mean like more than one drug or just one drug --

A Most patients with lupus are treated by multiple -- with multiple drugs. And in general, it's quite common for people to be on corticosteroids, an antimalarial drug and often one of these immunosuppressant drugs. So that's a common regimen. Some of them are treated with this BENLYSTA®, the last drug, the last drug

listed.

Q How has BENLYSTA® done in terms of its efficacy in treating lupus?

A It was efficacious enough to get approved but not thought to be very efficacious by the community.

Q And I notice the first one is antiinflammatory drugs.

A Correct.

Q Ibuprofen, that's like Advil, right?

A Correct.

Q And naproxen, that's like Aleve?

A Correct.

Q And then there's cel- -- what is CELEBREX®, anyway? What is that usually intended for?

A It's, again, used as a nonspecific analgesic or a way to reduce inflammation.

Q Okay.

A We don't encourage those drugs to be used for lupus because they can have an adverse effect on the kidney; however, these drugs, as you mentioned, are widely available over the counter and are used broadly by many, many doctors for anything that ails a patient. And so although the specialists don't encourage them and frequently try to remove them from patients, they are still widely used.

COMMONWEALTH OF VIRGINIA AT LARGE, to wit:

I, Cheryl McGrory, Notary Public for the Commonwealth of Virginia at large, whose commission expires July 31, 2019, do certify that at 9:57 a.m. on September 28, 2017, at 530 East Main Street, Charlottesville, Virginia, with all parties being present, the aforementioned appeared before me, was sworn by me, and was thereupon examined by counsel, that the deposition was taken down stenographically and thereafter transcribed via computer-aided transcription under my direction and that the foregoing is a true, correct, and full transcript of the testimony adduced.

Before completion of the deposition, review of the transcript was requested. If requested, any changes made by the deponent (and provided to the reporter) during the period allowed are appended hereto.

I further certify that I am neither related to nor otherwise associated with any counsel or party to this proceeding, nor otherwise interested in the event thereof.

IN WITNESS WHEREOF, I have hereunto set my hand this 10th day of October, 2017.

Cheryl McGrory

Cheryl McGrory, Notary Public
Commonwealth of Virginia at Large
Notary Registration No. 7131870

IN THE U.S. PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

----------x
LUPIN PHARMACEUTICALS, INC.,

Opposer, Opposition No. 91226322

v.

AMPEL, LLC,

Applicant.
----------x

EXHIBIT G

TO

DECLARATION OF THOMAS H. CURTIN IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT BY OPPOSER LUPIN PHARMACEUTICALS, INC.

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

CHARLOTTESVILLE, VIRGINIA

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REPORTED BY: Cheryl McGrory
FILE NO.: AB09E50

encompass? Is that just the entire state of Virginia or what -- what geographic areas?

A The governor is very interested in the entire state of Virginia. There are universities in Blacksburg, in Charlottesville, in Northern Virginia and also in Richmond.

Q Um-hmm.

A And there are -- is interest among all of those to grow something. There's one large pharmaceutical company in the region. It's in Maryland --

Q Um-hmm.

A -- which is AstraZeneca. So they have interest in growing the biotech arena both in Maryland and Virginia. So there's a fair amount of interest throughout the state in trying to develop a more developed biotech activity.

Q Okay. And that also includes like the Baltimore/D.C. kind of corridor?

A Well, the NIH is there. There's a so-called 270 corridor, which is -- goes up from -- from Bethesda, actually, north into Maryland. And there are a number of biotech companies that are there, mostly developed out of either Johns Hopkins or the NIH.

Q Okay. All right. So have you been involved in organizations specifically related to lupus?

A I've been involved with one of the

A Correct.

Q All right. And so you are a co-founder of AMPEL?

A Correct.

Q And when was AMPEL founded?

A Four years and six weeks ago.

Q And why was AMPEL founded?

A Well, as I mentioned, I had been doing consulting for the pharmaceutical industry, and to a certain degree it was sort of frustrating because in the area that we were particularly interested in lupus there was not very much going on. And we recognized that there were certain problems with developing drugs in lupus. And after a considerable amount of discussion with my co-founder, we thought that we might be able to develop some solutions to those problems. So we created a company. And one of the initial things that we thought would be a reasonable approach would be to develop activities in what's called drug repositioning. And what that essentially means is to identify a drug that's already been approved for human use. And by understanding its mechanism of action and the derangements in particular diseases, one could match an approved drug with a new indication. And so we began that, and it was relatively successful. And, again, it sort of stimulated certain activity in the

pharmaceutical industry which had become really quite stagnant because of business considerations. Because of early failed trials, it looked like it was an insurmountable disease problem and there were other ways that companies could make substantial sums of money. And so lupus sort of got left off the table of consideration. So our goal was to stimulate interest. And by doing that, by, again, pushing this repositioning effort, understanding that when a drug has been approved for human use, it's passed a number of hurdles, including toxicology, which is a major reason that drugs fail, because they turn out to be toxic. So a drug that's been approved has already demonstrated to be safe. And that means that the pathway to approval is much quicker because you don't have to do all the exposure data, you don't have to do a lot of the toxicology study, just a question now of whether or not the drug is active. And so we were able to convince a number of companies that it would be worth looking at some of their products in lupus.

Q Okay. All right. Now, just to go back and define for the -- those of us who aren't in the medical field a couple of the terms that you've used now, now you mentioned mechanism of action for a particular drug. What --

A Right.

introduce it into humans, you have to do animal studies, two species usually -- rats and dogs, sometimes monkeys -- in order to show that there's no immediate lethal toxicity of the drug. That's before the drug goes into people. But realistically you don't really know what the side effect profile is until it gets into people. And so in drug development, the first stage, so-called Phase I is putting the drug usually into normal individuals to see whether or not there are immediate side effects. And many drugs don't make it through that because there are unacceptable side effects. But then as the drug is developed -- is being developed, the -- the -- the -- many more patients are exposed to the drug and then you get a full analysis of what the side effect profile really is. And many drugs don't make it through those clinical phases because the side effect profile is just unacceptable, especially if the efficacy, or the effectiveness, is not great. So every drug company does whatever they can to de-risk their product, but, quite honestly, there's no predicting adverse events. However, when you start with a drug that's already approved for human use, all of that analysis of its potential side effects has already been carried out. So you know the drug can be given to people with a certain safety profile. So it makes it much less risky to start at that point and to say, well, this drug is already approved

for disease X, here's the side effect profile, we think that side effect profile is okay, it's not perfect but it's not so bad that we wouldn't even think about using it for a chronic disease. And then you've passed that step. Now you just have to show that the drug is actually effective in the disease.

Q And what -- what is a chronic disease?

A Chronic diseases -- many of the diseases we deal with in rheumatology, rheumatoid arthritis, lupus, these are diseases that basically appear to be lifelong. Once you get them, you have them for the rest of your life. And you can manage them. Sometimes you can get into very good stages where the disease is not very active. But in most circumstances it's thought that without medicine the diseases will come back. So these are chronic diseases. Other examples are Alzheimer's disease, a variety of other diseases that don't seem to be capable of being cured by current medicine and without treatment basically will last you, to some degree, for the rest of your life.

Q And stepping back just a little bit, what -- in general, can you describe what you mean by the field of rheumatology?

A Rheumatology is a field that's -- deals with a number of chronic autoimmune diseases: rheumatoid arthritis, psoriatic arthritis, lupus, scleroderma, a

A So one of the real problems, basically, the standard of care is not approved by the FDA. There are three drugs that have been approved, the latest of which is -- was approved just a few years ago but is thought not to be very effective. So the bulk of drugs that are approved are not the ones that are used for treatment. So that's a real problem in drug development.

Q And what are the ones that have been approved?

A So aspirin has been approved, steroids have been approved, a drug called hydroxychloroquine have been approved. And the last drug was approved just a few years ago, which is a monoclonalantibody called belimumab. But all the standard of care is basically immunosuppressant drugs of various sorts, and none of them have been approved for lupus but they've been approved for other things.

Q Okay. So can you combine a number of drugs that have been approved for something else and use them for treatment of --

A That's what the --

Q -- certain symptoms?

A -- community does, in general. They use a number of immunosuppressive drugs that have been approved for other indications to treat these individuals.

Q What do you mean by the community?

A The practicing community of rheumatologists who

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?

A Nine. Nine in the clinical operations group and another nine or ten or so -- the numbers change depending upon the seasons -- in the -- in the bioinformatics group.

Q Okay. And those are all -- are those full-time employees?

A Most of them are either full-time employees -- we do -- we have a lot of interns from UVA as well.

Q Sure. So can you describe what it is you talked about going out and, you know, sort of pitching your trials? Can you describe sort of the marketing efforts for AMPEL generally?

A You're looking at the marketing effort. I've worked for many years, as I mentioned earlier, as a consultant for the pharmaceutical company. And I've fortunately been right more than I've been wrong. And I've established relationships with key people in most of the large companies. So the companies are willing to listen to me now. Remarkable. So I have the opportunity, when we have the data, to meet with them at a relatively high level in order to introduce a proposal. And because of their experience with me and us now, they tend to listen more than they would to just anybody walking in off the street. So because many of these discussions really are an ongoing dialogue that's gone on for years with some of these companies, they tend to listen. And, you know, there's

also intracompany politics where sometimes they have a similar idea and need support for that idea and, in addition, because the cost of doing clinical trials is prohibitively expensive. So to do a relatively small trial of a new product might cost a company, I don't know, anywhere between 25 and a hundred million dollars. So that decision is not made lightly. We provide an alternative where we can get the information, comparable information, probably of higher quality, in the range of five to ten million. So it gets their attention, and we've been relatively successful in identifying these kinds of activities and convincing some of the companies that they -- this would be a way to pursue a drug of interest without necessarily having a cost which became unrealistic.

Q So how are you, in the first place, getting in front of them? Are you meeting them in --

A Well, we --

Q -- conferences?

A -- know that. I mean, you know, as I said, I've been doing this for such a long period of time. I mean, I have trainees who are in the pharmaceutical industry. I have people I've worked with before I went to the NIH that are in the pharmaceutical industry. I have people who I knew in -- three companies ago and are now at a company. So -- and we meet them in meetings. We meet them on a

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?

A Well, the big players are Teva, Mylan and -- what's the one -- Sandoz. Those are the three big ones that we -- that I know of. But I only know them because Teva had a -- has one pharmaceutical, one proper pharmaceutical, other than a generic. And I know Mylan. And I have never had any contact with Sandoz since they became Sandoz.

Q And would you -- would it surprise you to learn that Lupin is the fourth largest generic pharmaceutical in the U.S., by prescriptions?

A I -- I have no --

MR. ASPLIN: Let me just state an objection to the form.

Go ahead. You can answer.

THE WITNESS: Yeah. I mean, I have no information about -- I do not follow generic companies at all. I don't know very much about them.

BY MS. MORALES:

Q And how many clinical trials have been conducted by AMPEL or coordinated by AMPEL?

A Currently we have -- I think we're conducting [redacted] at the moment, and [redacted] are coming up in the next few months.

Q All right. Do you have a title at AMPEL?

A I have a -- CEO --

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.

Q Okay. And does that -- I mean, does the capitalization make any difference to the pronunciation?

A I'm not sure that you pronounce a letter differently if it's capitalized or not, but we certainty didn't think about that. It just looks prettier, that's all. In -- in LuCIN, the I is investigator. All right? So we certainly didn't want to in any way diminish the investigators, which was the big thing. Here, it didn't really matter because patient partner was important. So it just looked prettier, that's all, not -- not a particularly tremendously thought out strategic decision.

Q And you said LUP was maybe considered. Were there any other -- any other names that were considered at that time?

A Yeah. I can't remember exactly what they were, but we'd play with all kinds of different combinations of letters, all of which started with L-U. And we tried a variety of other things. But this one wound up being the one that kind of captured the essence of the program the best we thought.

Q Okay. What was wrong with some of the others?

A Either sounded funny or we would -- we were really making up words that -- including letters in the acronym that really didn't describe what the program was about.

A Reimagine, R-I, Lupus Investigation Treatment and Education. We're being into acronyms.

Q All right. Now, at the time that -- around 2014, when the LuPPiN name was selected, had you heard of Lupin Pharmaceuticals?

A No.

Q And so the -- I guess, do you recognize the only difference between the two marks is an extra P in your company's mark?

MR. ASPLIN: I'm going to object to the form.

Go ahead and answer.

THE WITNESS: You know, I haven't studied Lupin Pharmaceuticals that carefully. I don't know. Do they capitalize their P and their N as well? I don't know. I don't know.

BY MS. MORALES:

Q But there's only one letter difference; is that correct?

A Well, but the form looks -- I would guess the capital P is in the middle, and the capital N makes it look different to me, but --

Q All right. So stepping back again, you said -- you know, as you mentioned, there's, you know, a ton of patient partner programs, apparently, that are existing. Can you -- well, first of all, what -- what -- what do you

background, more than you want to know. So there's a fundamental problem with all of our diseases, and that is that there's very little training in medical school about any of the rheumatic diseases. We had -- we did surveys in those days, and we discovered that for all of musculoskeletal problems, everything, in the entire four years of medicine there's an average of about 15 hours of exposure. So the net result was that docs really were uncomfortable, especially primary care doctors, dealing with any of these diseases and were involved then in working on the curriculum of the medical school and what could we do to change this. And one of the things that we discovered was that if we could offer a program where medical students would learn how to do a musculoskeletal exam, would provide us another few hours of exposure to talk about rheumatoid arthritis and other diseases. And at that time there had been some patients trained in how to teach a joint exam at the University of Arizona, and we were fortunate enough that one of them moved to Dallas. And so around that woman we developed this entire program, where we highly selected patients because they had to basically be in a role where they would educate medical students. And, you know, one of the major courses of medical school that they teach you is arrogance. So you need to try to train people -- is really a very tough role

to stick patients into a training program of professionals and have them listen to the patient and grade the student. So we had very high standards of who we recruited. We recruited a number of patients, and they really became a fantastic group of people. In fact, it still is operational in Dallas now. And that was the beginning of it. And we expanded that. We actually trained the residents. We trained, actually, rheumatologists. We actually used this group to train international rheumatologists on how to do a joint exam for major clinical trials of drugs that were -- been approved. And then we had the group, and then we began to think of other things that this group could be used for because they're highly intelligent, very good at interacting with people and supportive and they were able to accomplish the initial task with great success. So we then began to actually have them work in the clinic, interact with other patients, actually take questionnaire information from patients. And we wrote papers on this. You could read them if you have nothing better to do. And then we also begin, in the late '80s, to involve them in recruitment for clinical trials because we began doing a lot of clinical trials toward the end of the '80s. So that's how the program developed, and we had a huge amount of experience with it. And a program was eventually supported by a pharmaceutical company at

that time called Searle that doesn't exist anymore. And Searle supported actually training of patient partner programs in a variety of places in the U.S. and then all over the world. So these folks wound up traveling to some pretty exotic places teaching other patients how to do the joint exams and how to do many of the other things. So we had a model of about 20 years of experience on what worked, what didn't work, et cetera, et cetera, with that. And that was the original patient partner program. And the concept of patient partner was what they really wanted because they didn't want to be thought of as an advocate. They weren't advocating for anything other than a good joint exam or a good experience in a clinic or to explain what a clinical trial was about. And they wanted to be felt -- wanted to be thought of by other patients as more of a partner in the process. So that's where the name came from.

Q And do you remember that first patient that you had worked with --

A Yes.

Q -- in Texas?

What was her name?

A Valerie Branch. Unfortunately, she passed away about four years ago, but she's known all over the world based on her activities in this arena. And she had

devastating rheumatoid arthritis. I actually don't have any idea how she got out of bed every day. But she shlepped around the entire world meeting people in England, in France and got to South Africa, I mean, teaching this program and -- and educating people about what it was like to have this disease and how by working with other patients she could make it better for them. If you Google Valerie Branch, you will see all of this is actually pretty moving.

Q And then --

A I'm giving you a lot of Google homework.

Q They call it Dr. Google, I think.

All right. Did the Texas program ever include a lupus component?

A No.

(Lupin Exhibit No. 3 was marked for identification.)

BY MS. MORALES:

Q Another document for you.

A Oh, my goodness.

Q Can you tell us what that is?

A I imagine it's a xerox of something from our website, I guess. I don't know. Is that about what it is?

Q You produced it.

A Well, actually, not me personally, but it was produced for us. It looks like probably something from --

maybe from our website.

Q Okay. And do you know about what time that might have been, what time frame that might have been up?

A I guess would be sometime around 2/14, something like that. I don't know when it was made. Wasn't very much -- wasn't updated very much after that, but I think it was around that time.

Q Okay.

A 2015. I don't know.

Q Did you have a role in creating AMPEL's website?

A I mean, in terms of discussing the general content, certainly yes, but I'm certainly not able to do this kind of work. I'm not a -- I'm not a web designer.

Q Do you know who wrote the content?

A I would imagine this was probably a group effort. We have a person who does this for us. I'm sure Amrie contributed. I'm sure I contributed. But I'm -- I -- I really don't have any specific knowledge of when this particular content was prepared.

Q You said you have a person who does that. Is that someone internal at --

A Yes.

Q -- AMPEL?

Okay. Do you have a formal marketing department?

A Except for the RA program, which is still going on, I'm not aware of anything that is comparable.

Q Okay. So if I go and Google patient partners, what -- what sorts of programs am I going to find?

MR. ASPLIN: I'm going to object to the form.

Go ahead.

THE WITNESS: Well, I mean, I can tell you what happened when I Goggled it, but it was a couple of years ago. I found a variety of programs, some of which would fall into what you call advocacy programs. Some fall into the realm of concierge programs, some fall into the realm of making some effort to make sure these people actually have health insurance, a variety of different kinds of programs that were quite different than this but mostly involved in providing some kind of help to a patient.

Q Do you know whether any of these so-called patient partner programs are sponsored by pharmaceutical companies?

A I would imagine some are, but I haven't really explored it that -- in that detail. Everything in our business is eventually supported by the pharmaceutical industry.

Q All right. So in your experience, then, with the patient partner programs, you mentioned, you know, certain ideal criteria for what -- what an individual who

A We've spoken to them in -- in general terms about patient partner programs, yes, but we haven't -- again, opposition, we haven't used the word "LuPPiN" because we wanted that clarified. They have lawyers, too.

MS. MORALES: It's been about another hour and I don't know how hungry anyone else is, but now is a good time the go off record and take lunch.

(Off the record, and a lunch recess was taken.)

(Lupin Exhibit No. 4 was marked for identification.)

BY MS. MORALES:

Q I'll hand you what's marked as Exhibit 4. Once you've had a chance to look through there, let me know.

A A long article.

Q All right. So are you familiar with this document?

A I sure am.

Q Hope so. Can you tell us what it is?

A It's just a review article about drug repositioning and various other things that we do at AMPEL.

Q And was this published?

A Yes, in this special issue of Lupus last year.

Q And it looks like you're listed as a coauthor; correct?

A I am.

A It's just a chemical entity, basically a chemical which is a drug or could be the beginning of a drug, just a chemical that might be useful for lupus.

Q All right. So going back to the sentence, it says that LRxL-STAT initiative was to examine all compounds approved by the FDA for any indication, approximately 11 hundred compounds per 68 hundred indications.

A Um-hmm.

Q And it talks about the process for narrowing down that list. Can you explain to us what -- what that process was for reviewing and narrowing the --

A So this --

Q -- 11 hundred?

A When this started, basically the FDA had -- they had what's called the Orange Book, a secret book. And this is a list of all the drugs that have ever been approved for human use in the United States minus the drugs that are no longer being marketed. So a lot of drugs, basically, when they become generic, nobody is interested in selling them anymore. So the -- the Orange Book addressed the drugs that are approved and basically actively being marketed by somebody. So that, in those days, was about 11 hundred different chemical entities. And each one of those is approved for multiple indications. So there are 11 hundred chemical entities approved for about 68 hundred indications

when this all began. And then, fundamentally, you know, a lot of them have nothing to do with lupus whatsoever. They're drugs for hypertension. They're drugs -- they're antibiotics. They're drugs for all kinds of stuff. So it's easy to screen those. And then you get back to about a few hundred. And then each of those was examined in terms of what it actually did and whether or not there was any indication that that action might be useful in lupus. So at the end of the day when all was said and done, we wound up with about 157 FDA-approved drugs that conceivably could be useful to treat lupus.

Q Are -- are the drugs that are in the Orange Book, are those all under patent?

A No. It just means that they're -- somebody's marketing them.

Q Okay.

A So, you know, patents are variable lengths of time these days, but many of them are not -- not being marketed by their original -- by the innovator company but by a generic company and usually multiple generic companies. But that's everything that was being sold at that time for human use as a drug. There are other things -- food supplements, a variety of other things -- that we -- we did score some of them, but mostly this relates to chemical entities that are approved by the FDA

for human use.

Q Okay. And in that same paragraph down in the -- top of the next page -- so that's 1152, Bates APB-00402 -- it mentioned in consideration of 71 new drugs approved by the FDA in 2014 and 2015.

A Correct.

Q Now, since -- since that time in 2015, have additional compounds been reviewed for the list?

A Yes.

Q Okay.

A It's an ongoing process. We keep doing it. As drugs are approved or as we become aware of new compounds, they -- it's an ongoing list.

Q Okay. How do you -- how do they come -- the new drugs come to your attention?

A Well, a variety of ways. We're continuously looking at these pathways that are back here that are suggested from gene expression and other kinds of analyses. And then from that we find either chemicals or drugs that they suggest, which we then go explore. In addition, the FDA is actively approving drugs, and we still get suggestions from the outside. So they're still pretty much the same pathways of getting to new chemical entities.

Q Okay. And is -- is there a list of the drugs that have been approved since the time that this article

was written?

A Yeah.

Q Okay.

A It comes out actually from the FDA. But we -- we -- we monitor that fairly carefully as they approve them.

Q Okay. So if I go to the FDA website, I can find --

A Um-hmm.

Q -- what's been approved?

A Um-hmm.

Q Okay. All right. And continuing on that same paragraph on the top of 1152, it says -- do you see where it says excluded from the literature search for all drugs, widely used for SLE, whether approved or not, as well as drugs known to be --

A Um-hmm.

Q -- in development?

A Right. So we were basically looking for new opportunities, new treatments. And we were not looking to reduplicate what pharma was doing. As I mentioned earlier, many of the treatments for lupus have not been approved. Some of them failed in clinical trials. Some of them were just -- have been used for such a long time, they've never been -- they have no patent life, et cetera, et cetera. So

there are a fair number of drugs that are actually used for lupus routinely that we didn't bother scoring. No sense scoring a drug that's already used. And if we knew that a pharmaceutical company was developing a Phase III program, basically a big commitment of money to develop a drug, there was no sense for us to spend our time determining whether or not the drug could be useful. It was already going to be tested. So we excluded all that.

Q And can you name any of those specific drugs that were excluded?

A Well, there were many, many, many of them, you know. We didn't look at any of the drugs that, for example, were being developed targeting interferon. So there's a -- an antibody called anifrolumab that targets the interferon receptor being developed initially by MedImmune and AstraZeneca. It's in a Phase III program. We weren't interested in doing that. They're already doing it. There are a number of others that have moved forward into Phase II or Phase III that pharma was obviously interested in, and we weren't going to pursue them at all.

Q What -- what is -- what are interferons or what is interferon?

A All right. So when you get a cold, on the way from -- home tonight from -- well, in two days from LaGuardia, you're going to get the sniffles because you

Phillies score. We rejected that.

Q So your lowercase letter, so you aren't as interested in, then, looks like.

A Yeah. Combined is, you know, C-o, so we didn't like that. Like Lupus, capital L, small u.

Q All right. So then it says score was focused on 76 FDA-approved or generally recognized as safe therapies that scored higher than commonly used SOC lupus --

A Right.

Q -- medication. So SOC is --

A Standard of care.

Q -- standard of care? Um-hmm.

So there were standard of care lupus medications that didn't end up --

A We scored --

Q -- on your list?

A Well, see, we -- the way we validated the scoring system was to score drugs that are part of the standard of care. So we wound up with a score, using CoLTs, of the drugs that are commonly used. And then we were looking for drugs that scored higher than those drugs. Scored lower, it's no advance. Right? Scored better, that's terrific.

Q Okay. So the standard of care drugs were your baseline, clinic?

of genes that are abnormally expressed and basically group them together by using basically the world's literature that's known about interactions between these genes and come up with pathways that may -- that are abnormally expressed in lupus and may be contributing to disease pathology.

Q And so when these pathways are abnormally expressed, does that -- does that then lead to specific symptoms?

A That's what we think, yes.

Q Okay.

A And then, basically -- but for this exercise, more importantly, you can find the checkpoints in these pathways and use drugs to inhibit the whole pathway.

Q And what are some of the common symptoms of lupus?

A Predominantly they have skin rash, arthritis, kidney involvement, progressive central nervous system involvement, a lot of fatigue. And then less frequently are involvement of other organs as well, but those are the main ones we worry about.

Q Okay. Involvement, is that a defined term in the --

A Well, various kinds of skin rashes, sometimes actually scarring, rashes of the skin, hair loss, things of

that nature. Kidney, you wind up with kidney failure. Arthritis of course can be -- can interfere with your ability to do your activities of life. And they have involvement of the central nervous system with everywhere -- everything from seizures to psychosis to decreased cognitive function. Bad disease. Nasty disease.

Q All right. So getting back to the lupus treatment list, I'll flip back to where we were, around page 1152. Let's go the top of 1153. That's Bates 00403.

A 1153. You know, you're probably the only person that's ever read this. Somehow I don't think you're interested in the science, though, but --

Q All right. So can you tell us what this Table 1 is?

A So Table 1, this is basically the candidate genes. Right? These are the candidate drugs that we started with. So they're all kinds of different things that we started with. And these are the ones that we scored. So there's probably -- I don't know what the final number is, a hundred and something, and all of these things are drugs. And the little superscript is the number that they got as a result of the CoLT score. So the ones with the higher numbers did better; the ones with the lower scores did worse.

Q Okay. And so --

sent in stuff. We never tracked who they were.

Q Okay. They -- did they put their names on the LinkedIn site when they --

A Some do. But, you know, LinkedIn is a complicated business. We just weren't monitoring who they were. We were just looking for suggestions.

Q Sure. All right. And then the last -- last bullet in that same section, it says that 15 pharma and biotech companies have inquired about sponsoring trials. Do you --

A Correct.

Q -- know who any of -- can you recall who any of those were?

A Mostly small biotech companies. I can't precisely remember. Most of them were biotech companies. Let me think about who they were. [redacted] was one, no longer in existence. I think [redacted] was one. But most of them were small -- smaller companies. A couple of representatives of big pharma called, but mostly those were groups that were looking for some kind of social support within a company that lupus was important. So I can remember a few, but not that many.

Q Okay.

A This was June 2014.

Q All right. Have any trials taken place as a

Q Okay.

A Add them to the list.

(Lupin Exhibit No. 7 was marked for identification.)

BY MS. MORALES:

Q All right. I'm going to hand you what we've marked as Exhibit 7.

A Yep.

Q All right. And just let me know when you've had a chance to look through that.

A It looks familiar.

Q What is it?

A Basically, slides from the meeting in 2014.

Q Is that a presentation that you gave?

A Yes.

Q Okay. What was the purpose of the presentation?

A Basically, we were organizing this network of investigators and this was sort of a kick-off meeting to tell them what we had been doing and what we expected to do in the future with regard to identifying drugs for treatment of lupus.

Q Is that the -- is the -- that the entire presentation?

A It was my presentation. There were other discussions about other matters that really weren't

relevant here, but there are -- this was the discussion that I presented.

Q Okay. And are all those -- are all those slides an accurate representation of the presentation as you gave it?

A Well, it was 6:30 in the morning, so I think it was. I think it's accurate.

Q You don't know what you said. Okay. Do you remember how many -- approximately how many people attended presentation?

A I would guess a hundred or so. 6:30 in the morning, is pretty good.

Q That's not bad.

And you said it was part of a larger -- larger program?

A Yeah. There were other discussions about what would happen with regard to organizing this network and how it might operate and things of that nature, mostly administrative stuff.

Q And was it part of a conference?

A This was held at -- it was a breakfast meeting at the annual meeting of the American College of Rheumatology --

Q Okay.

A -- in Boston.

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

it would be produced to us.

And the audience was medical professionals and --

A Correct. Rheumatologists. Correct.

Q All right. We're going to move on to the next presentation. This is Exhibit 8.

(Lupin Exhibit No. 8 was marked for identification.)

THE WITNESS: Okay. The graphics just keep getting better and better.

BY MS. MORALES:

Q All right. So once you've had a chance to look through that, can you --

A Right.

Q Can you tell us what this is?

A Yeah. This is a presentation to the Board of Directors of the then Alliance for Lupus Research.

Q Which is now -- can you --

A Lupus Research Alliance.

Q Okay.

A So these guys were interested in funding this activity and subsequently did fund it. So that was the reason to go talk with them.

Q And did you give this presentation?

A Yes, ma'am.

Q Okay. And you mentioned that some of them had relatives who were lupus patients?

A Right.

Q Now, were -- did any of those end up working with the LuPPiN program?

A No.

MS. MORALES: Okay. All right. So it looks -- we're going to take a break and hopefully not be too much longer after this.

(Brief recess.)

BY MS. MORALES:

Q I'm handing you what we're marking as Exhibit 9.

(Lupin Exhibit No. 9 was marked for identification.)

BY MS. MORALES:

Q Take a minute to read that, and when you've had a chance to review it, let me know.

A Yep.

Q And what is the document?

A A set of slides that I showed at a biotech forum at MedImmune in 2015. Sort of summarized what we were doing.

Q And what was the purpose of giving the presentation?

A Basically to advertise who we were.

Q Advertise to who?

A The rest of the biotech community in the Maryland-Virginia area.

Q What do you mean by the biotech community?

A There's a meeting that's put on every year hosted by MedImmune AstraZeneca where they invite many of the smaller either biotech or pharmaceutical companies in the region to come together for this meeting to kind of think about common problems, most of which are funding. But that's really the purpose of it. And this was one that was held in Gaithersburg in 2015. So we were fortunate enough to be identified and to have the opportunity to give them a five-minute presentation about what we're doing.

Q And how -- were you invited to give the presentation?

A Right.

Q Okay. And that was the -- Maryland Biotech Forum is the name of the --

A Correct.

Q -- conference?

And it's sponsored by MedImmune and AstraZeneca?

A Right, along with Virginia Bio and Maryland Bio and a number of the other organizations that are involved in trying to facilitate growth of a biotech sector in this region.

Q Okay. And we'd spoken about Virginia Bio earlier, I know. Is -- Maryland Bio, is that a similar type of organization?

A Yeah. They have these organizations in each state because especially around universities they have the idea that they can stimulate the growth of biotech jobs and that -- I think a governor -- one of the governors was -- was at this one. You know, Virginia or -- or Maryland. I can't remember which.

Q Okay. And do you know about how many people attended your presentation here?

A I would guess somewhere between one and two hundred. Big auditorium.

Q And these were professionals within the industry?

A Yeah, all within the biotech industry and, you know, some small pharma companies that are also in the region, as well as representatives of MedImmune and AstraZeneca.

Q Okay. Can you name any of the other companies that were at the meeting?

A If you give me some warning, I probably could have, but right at the moment -- whoever's in the region was there. There were a fair number of companies there.

Q Okay. And did you discuss the LuPPiN program at

this -- this --

A Yeah. It's on the last slide. It's been on the slides of the presentations, but it's various things that we were doing. I think on slide number whatever it is, at the end here, it's mentioned as some of the things that we'll do, we were engaged in.

Q Sure. And can you just read the number that starts with APB down at the bottom of that page?

A APB confidential 00078. Not sure why it's confidential. It was presented publicly. But anyway...

Q And what was discussed about the LuPPiN program at that point?

A I think we went through all of the things that we were engaged in at that time. [redacted]

Q [redacted]

A [redacted]

[redacted]

Q [redacted]

[redacted]

A [redacted]

[redacted]

Q And anyone else at the -- anyone else at the meeting show interest in --

A Yes. We talked to a number of local companies.

Q Um-hmm.

A Unfortunately, most of them were small and not in a position to fund anything. But, you know, we continued to discuss with a number of local companies advancing some of their products into clinical trials, but it's a slow process.

Q Okay. And did anyone begin participating in the LuPPiN program as a result of this --

A No.

Q -- meeting?

A No patients attended this.

Q Um-hmm.

A This is basically our outreach, part of our outreach. I mean, we don't market ourselves. We don't -- we have a website. I'm not -- they convinced me we need a website. Occasionally somebody responds to our website. People like you probably figure out who we are from our website. But, in general, the way we market ourselves is that we do it by word of mouth with our contacts, people that we've consulted with, meet with, meet at meetings like this. And that's generally our major effective way of marketing ourselves, including all the activities and, as you see, including, at that time, the LuPPiN program.

Q All right. I'm going to give you what we're marking as Exhibit 10.

(Lupin Exhibit No. 10 was marked for identification.)

BY MS. MORALES:

Q So once you've had a chance to look at this, let me know.

A Yep. Yep.

Q All right. So what -- can you just describe generally what this is?

A It was the manual of what the patient educator or patient partners would do and how -- what they would learn, what they'd have to master in order to become, basically, members of the LuPPiN network. This was from a

meeting in March of 2016, followed by a lot of work to create all this document. It has aspects that are related to what lupus is all about. And then a novel aspect of this was starting around the section page 29 here that had to do with education about what clinical trials were all about.

Q And you said that was novel. Is that -- why was that novel?

A Well, because they're very -- you know, there's a lot out there about what lupus is. You can go to the Web and you'll find dozens of places to find about what lupus, but there's really nothing out there that educate patients about what clinical research is, what clinical trials are all about, what the protections are all about, what the words are all about. And this is just all new information for patients. So this is -- this is really the heart of what we would have tried to teach them as we moved forward with this program, including all of their rights and protections and who everybody is and what Phase I and Phase II is. I mean, they're pretty proud of this product. This is actually very helpful. And patients -- patients had input into this. Investigators had input into this. This is, I think, a really -- really good contribution, and it would be the basis of the training manual for the LuPPiN group.

A The -- which meeting, now? We're --

Q The March 2016, where you formulated the manual.

A I'm thinking in the range of six to ten, probably in the range of eight. But I can't actually be precise about that, but I could provide that information if it was important.

(The following line was left blank at the request of counsel.)

Q And how many people, total, were at that meeting?

A Probably twice that, 12 to 14.

Q Okay. All right. If we can get the -- request that if we can get a copy of the subsequent version of that draft produced, we'd appreciate that.

And -- let's see. I think we discussed the differences in the spelling of the two marks.

A Um-hmm.

Q So, as -- as spoken, are the marks Lupin Pharmaceuticals -- the Lupin mark of my client and your LuPPiN program, are those identical as spoken?

A Well, we don't have the surname Pharmaceuticals.

Q But the words that -- the words Lupin?

A As far as I know, Lupin and LuPPiN sound the same.

COMMONWEALTH OF VIRGINIA AT LARGE, to wit:

I, Cheryl McGrory, Notary Public for the Commonwealth of Virginia at large, whose commission expires July 31, 2019, do certify that at 10:00 a.m. on September 26, 2017, at 530 East Main Street, Charlottesville, Virginia, with all parties being present, the aforementioned appeared before me, was sworn by me, and was thereupon examined by counsel, that the deposition was taken down stenographically and thereafter transcribed via computer-aided transcription under my direction and that the foregoing is a true, correct, and full transcript of the testimony adduced.

Before completion of the deposition, review of the transcript was requested. If requested, any changes made by the deponent (and provided to the reporter) during the period allowed are appended hereto.

I further certify that I am neither related to nor otherwise associated with any counsel or party to this proceeding, nor otherwise interested in the event thereof.

IN WITNESS WHEREOF, I have hereunto set my hand this 3rd day of October, 2017.

Cheryl McGrory, Notary Public
Commonwealth of Virginia at Large
Notary Registration No. 7131870

IN THE U.S. PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

----------x
LUPIN PHARMACEUTICALS, INC.,

Opposer, Opposition No. 91226322

v.

AMPEL, LLC,

Applicant.
----------x

EXHIBIT H

TO

DECLARATION OF THOMAS H. CURTIN IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT BY OPPOSER LUPIN PHARMACEUTICALS, INC.

Exhibit H is a true and correct copy of relevant excerpts of Applicant's November 17, 2014 presentation at the American College of Rheumatology annual meeting. Exhibit H is designated as CONFIDENTIAL under the Board's Standard Protective Order, and filed under seal.

IN THE U.S. PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

----------x
LUPIN PHARMACEUTICALS, INC.,

Opposer, Opposition No. 91226322

v.

AMPEL, LLC,

Applicant.
----------x

EXHIBIT I

TO

DECLARATION OF THOMAS H. CURTIN IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT BY OPPOSER LUPIN PHARMACEUTICALS, INC.

Exhibit I is a true and correct copy of relevant excerpts of Applicant's December 9, 2014 presentation at the Alliance for Lupus Research Board of Directors meeting. Exhibit I is designated as CONFIDENTIAL under the Board's Standard Protective Order, and filed under seal.

IN THE U.S. PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

----------x
LUPIN PHARMACEUTICALS, INC.,

Opposer, Opposition No. 91226322

v.

AMPEL, LLC,

Applicant.
----------x

EXHIBIT J

TO

DECLARATION OF THOMAS H. CURTIN IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT BY OPPOSER LUPIN PHARMACEUTICALS, INC.

Exhibit J is a true and correct copy of relevant excerpts of Applicant's March 31, 2015 presentation at the Maryland Biotech Forum. Exhibit J is designated as CONFIDENTIAL under the Board's Standard Protective Order, and filed under seal.

IN THE U.S. PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

----------x
LUPIN PHARMACEUTICALS, INC.,

Opposer, Opposition No. 91226322

v.

AMPEL, LLC,

Applicant.
----------x

EXHIBIT K

TO

DECLARATION OF THOMAS H. CURTIN IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT BY OPPOSER LUPIN PHARMACEUTICALS, INC.

Exhibit K is a true and correct copy of Applicant's draft patient educator training manual. Exhibit K is designated as CONFIDENTIAL under the Board's Standard Protective Order, and filed under seal.

IN THE U.S. PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

----------x
LUPIN PHARMACEUTICALS, INC.,

Opposer, Opposition No. 91226322

v.

AMPEL, LLC,

Applicant.
----------x

EXHIBIT L

TO

DECLARATION OF THOMAS H. CURTIN IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT BY OPPOSER LUPIN PHARMACEUTICALS, INC.

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

LUPIN PHARMACEUTICALS, INC.,

Opposer,

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

v.

AMPEL, LLC,

Respondent.

RESPONDENT'S ANSWERS TO OPPOSER'S SECOND SET OF INTERROGATORIES

Respondent/Applicant, Ampel, LLC ("Ampel"), by counsel and pursuant to the applicable provisions of 37 C.F.R. 2.120 and Rules 33, 34 and 36 of the Federal Rules of Civil Procedure ("FRCP"), hereby responds as follows to Opposer Lupin Pharmaceutical, Inc.'s ("Lupin") Second Set of Interrogatories:

GENERAL OBJECTIONS

Ampel repeats and adopts herein all of the General Objections set forth in its Answers to Lupin's First Set of Interrogatories, which answers were served on October 17, 2016, and all such General Objections shall apply to Lupin's Second Set of Interrogatories. Subject to such objections, which are incorporated into each specific answer, and without waiver thereof, Ampel specifically objects and responds to Lupin's Second Set of Interrogatories in correspondingly-numbered paragraphs as set forth below.

SPECIFIC OBJECTIONS AND ANSWERS TO INTERROGATORIES

INTERROGATORY NO. 1: Identify all of the symptoms of Lupus.

ANSWER: In addition to the General Objections set forth above, Ampel objects to this Interrogatory on the ground that it is not relevant to the subject matter of this action, nor is it reasonably calculated to lead to the discovery of admissible evidence. Further, the Opposer can obtain this information from numerous other sources.

Without waiving such objection, Ampel answers as follows:

The most common symptoms of Lupus are: extreme fatigue, headaches, painful or swollen joints, fever, anemia, swelling in feet, legs, hands, and/or around eyes, pleurisy, rash on face, photosensitivity, hair loss, abnormal blood clotting, Raynaud's disease, and mouth and nose ulcers.

INTERROGATORY NO. 2: Identify all pharmaceuticals on the "list" of pharmaceuticals referenced in APB0004 "that may assist in the treatment of Lupus."

ANSWER: In addition to the General Objections set forth above, Ampel objects to this Interrogatory on the ground that it is not relevant to the subject matter of this action, nor is it reasonably calculated to lead to the discovery of admissible evidence.

Without waiving this objection, Ampel answers as follows:

Such pharmaceuticals are not approved for the treatment of Lupus, but are pharmaceuticals for which there are preliminary indications that they may have efficacy in treating Lupus. These pharmaceuticals are described in the research paper entitled "Drug Repositioning in SLE: Crowd-sourcing, Literature-mining and Big Data Analysis" (the "Research Paper"). Ampel has disclosed a copy of the Research Paper herewith as Bates Nos. APB-00400 – APB-00420. See also Bates No. APB-00421.

INTERROGATORY NO. 3: Identify all of the "157 Drugs and Treatments" referenced in APB000016 including, without limitation, all "Interesting Drugs in Development for Other Indications."

ANSWER: In addition to the General Objections set forth above, Ampel objects to this Interrogatory on the ground that it is not relevant to the subject matter of this action, nor is it reasonably calculated to lead to the discovery of admissible evidence.

Without waiving this objection, Ampel answers as follows:

Such drugs and treatments are not approved for the treatment of Lupus, but are drugs and treatments for which there are preliminary indications that they may have efficacy in treating Lupus. These drugs and treatments are described in the Research Paper. See also Bates No. APB-00421.

INTERROGATORY NO. 4: Identify by title, date and place, all of the "medical conferences and seminars" identified by Applicant in response to Interrogatory No. 9, where Applicant promoted Applicant's Trademark and/or Applicant's Services offered thereunder.

ANSWER:

- The 2014 annual meeting of the American College of Rheumatology (ACR) which was held in Boston, Massachusetts from November 14-19, 2014.
- A presentation to the Board of Alliance of Lupus Research in New York City on December 9, 2014
- Maryland Biotech Forum in Gaithersburg, Maryland on March 31, 2015.

AMPEL, LLC
Respondent

/s/ Patrick Asplin
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CERTIFICATE OF SERVICE

I hereby certify that on December 2, 2016, I forwarded the foregoing *Respondent's Answers to Opposer's Second Set of Interrogatories* to the Opposer's attorneys by email to the email address listed below:

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Counsel for Opposer/Petitioner

/s/ Patrick Asplin
Counsel for Respondent

VERIFICATION OF ANSWERS TO INTERROGATORIES

BEFORE ME, the undersigned, personally appeared Amrie Grammer, Chief Operating Officer of Ampel, LLC, who being first duly sworn by me, said that she has read Respondent's Answers to Opposer's Second Set of Interrogatories and that the answers thereto are true and correct to the best of her knowledge and belief.

AMPEL, LLC

By: _____
Amrie Grammer, COO

COMMONWEALTH OF VIRGINIA,

CITY/COUNTY OF Albemarle, to-wit:

Subscribed, sworn to and acknowledged before me on this 1 day of December, 2016 by Amrie Grammer in her capacity as Chief Operating Officer of Ampel, LLC.

My commission expires: 11/30/2020.

_____
NOTARY PUBLIC

Registration No.: 7695082

JOHN STEWART RALSTON
COMMONWEALTH OF VIRGINIA
REGISTRATION NO. 7695082
MY COMM. EXPIRES 11/30/2020
NOTARY PUBLIC

IN THE U.S. PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

----------x
LUPIN PHARMACEUTICALS, INC.,

Opposer, Opposition No. 91226322

v.

AMPEL, LLC,

Applicant.
----------x

EXHIBIT M

TO

DECLARATION OF THOMAS H. CURTIN IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT BY OPPOSER LUPIN PHARMACEUTICALS, INC.

Lupus (2016) 25, 1150–1170
http://lup.sagepub.com

SPECIAL ARTICLE

Drug repositioning in SLE: crowd-sourcing, literature-mining and Big Data analysis

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Lupus patients are in need of modern drugs to treat specific manifestations of their disease effectively and safely. In the past half century, only one new treatment has been approved by the US Food and Drug Administration (FDA) for systemic lupus erythematosus (SLE). In 2014–2015, the FDA approved 71 new drugs, only one of which targeted a rheumatic disease and none of which was approved for use in SLE. Repositioning/repurposing drugs approved for other diseases using multiple approaches is one possible means to find new treatment options for lupus patients. "Big Data" analysis approaches this challenge from an unbiased standpoint whereas literature mining and crowd sourcing for candidates assessed by the CoLTs (Combined Lupus Treatment Scoring) system provide a hypothesis-based approach to rank potential therapeutic candidates for possible clinical application. Both approaches mitigate risk since the candidates assessed have largely been extensively tested in clinical trials for other indications. The usefulness of a multi-pronged approach to drug repositioning in lupus is highlighted by orthogonal confirmation of hypothesis-based drug repositioning predictions by "Big Data" analysis of differentially expressed genes from lupus patient samples. The goal is to identify novel therapies that have the potential to affect disease processes specifically. Involvement of SLE patients and the scientists that study this disease in thinking about new drugs that may be effective in lupus though crowd-sourcing sites such as LRxL-STAT (www.linkedin.com/in/lrxlstat) is important in stimulating the momentum needed to test these novel drug targets for efficacy in lupus rapidly in small, proof-of-concept trials conducted by LuCIN, the Lupus Clinical Investigators Network (www.linkedin.com/in/lucinstat). *Lupus* (2016) **25**, 1150–1170.

Key words: LRxL-STAT; LuCIN; drug repurposing; drug repositioning; Stelara; ustekinumab; IL12; IL23; quinacrine; krill oil; HSCT; stem cells; meditation; mindfulness; ruxolitinib; tofacitinib; JAK; MEDI-7169; IL21; secukinumab; IL17

Introduction

Drug repurposing is not a new concept. However, using an evidence-based approach to examine drugs approved for one indication for their potential in systemic lupus erythematosus (SLE) is uncharted territory. Repositioning, rescue, reprofiling, retooling, and retasking are other commonly used terms for the process of utilizing a drug approved or tested for one condition for a completely different disease.[1–3] Lupus patients and the rheumatologists that care for them are unconsciously familiar with the concept of "repurposed drugs" since SLE patients are routinely treated with drugs that were initially employed for other diseases such as hydroxychloroquine used for malaria, cyclophosphamide (CTX) used for cancer, mycophenolate approved for transplant rejection, and rituximab approved for lymphoma. Surprisingly, only four medications have been approved by the US Food and Drug Administration (FDA) for treatment of lupus patients (hydroxycholoroquine, aspirin, prednisone, and belimumab).

Even as recently as 2013, deciphering which approved drugs might be appropriate for lupus patients was a daunting task. A variety of approaches are described in Figure 1. Traditionally, as occurred in the lupus field, drugs were repurposed because of opportune clinical observations and/or off-target properties. Biotech/Pharma companies often look

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10.1177/0961203316657437

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Figure 1 Multi-pronged approaches to drug repositioning.

for drugs with similar structures or adverse events by rescreening against targets with related three-dimensional structural elements when attempting to repurpose existing compounds.[4,5] In the last few years, genome wide association studies (GWAS) began to identify potential disease-associated genetic perturbations that could serve as the basis of new target identification in many diseases,[6] including SLE.[7–9] Advances in bioinformatics approaches including analysis of differential expression of mRNA and miRNA,[10–19] as well as methylation status of promoter regions in patients compared to normals,[20,21] provide additional powerful tools to identify new targets of therapeutic intervention.

There is an intense interest from Biotech/Pharma to try to rescue pipeline drugs that failed in an additional indication or did not achieve FDA approval. Rheumatologists are also interested in repositioning drugs since Biotech/Pharma, with one exception, has not been successful in bringing new drugs for SLE patients to market. Moreover, standard-of-care (SOC) lupus treatments have serious side effects, and lack the necessary precision to target lupus pathways specifically and thereby address signs and symptoms of the disease in individual patients. Emphasizing the potential value of drug repositioning in lupus is that fact that belimumab (Benlysta, anti-BLyS/BAFF) is the only drug approved for SLE in the last 50 years.

These considerations stimulated a push in the spring of 2013 by the Alliance for Lupus Research (ALR) and the Lupus Research Institute (LRI) to launch a drug repositioning effort (www.linkedin.com/in/lrxlstat), LRxL (Lupus Treatment List)-STAT (SLE Treatment Acceleration Trials). Despite best efforts by academics and the pharmaceutical/biotech industry, the pace of development of new therapies for lupus patients is painfully slow. Even in well-described diseases with a large market forces, bringing a new drug through the FDA-approval process takes 10–15 years and $1.5–2.6 billion with less than a 10% success rate.[22] Lupus remains a serious unmet medical need and the need for rethinking the approach to find new therapies for SLE patients is urgent.[23,24]

The initial repositioning approach initiated by the ALR and LRI, now merged into one organization called the LRA (Lupus Research Alliance), was a combination of crowd-sourcing and literature mining. This generated a large number of drug candidates that were prioritized using a composite scoring system of drug attributes, the Combined Lupus Treatment Scoring (CoLTs) system. This system ranks compounds numerically based on scientific rationale, experience in lupus mice/human cells, previous clinical experience in autoimmunity, drug properties, and adverse event profile.[25,26] Parallel efforts with support from the John and Marcia Goldman Foundation resulted in the development of a novel comprehensive meta-analysis algorithm that interrogates data from more than 2000 lupus gene expression profiles from the periphery as well as synovium, skin and kidney.[27,28] Combining hypothesis-driven and non-biased approaches permits a better understanding of the systemic autoimmune and inflammatory networks operate in lupus and is useful to identify novel drugs as well as pathways that might be targets of therapeutic interventions.

LRxL-STAT: ranking potential treatments for SLE patients using CoLTs

Repositioning drugs into lupus has the potential to deliver new treatments to patients more quickly than standard drug development programs because early pre-clinical work as well as dosing, formulation, side effects, drug metabolism/interaction and pharmacokinetic/dynamic issues have already been characterized leaving only demonstration of efficacy in lupus to be determined. The 2013 goal of the LRxL-STAT initiative was to examine all compounds approved by the FDA for any indication (approximately 1100 compounds for 6800 indications), narrow down the list (LRxL) to those that may be efficacious in lupus patients (157 compounds), and to rank potential lupus treatments

using the evidence-based scoring system CoLTs. Consideration of 71 new drugs approved by the FDA in 2014–2015 generated an additional 10 candidates with an appropriate set of characteristics to consider for CoLT scoring. The LRxL was constructed with extensive input from the interested lupus community, including patients. Excluded from the literature search were all drugs widely used for SLE (whether approved or not) as well as drugs known to be in development for SLE by Biotech/Pharma. All data used were in the public domain and no drug combinations were addressed.

To compare and contrast candidates for repositioning into SLE, a novel scoring method was developed called CoLTs to rank the identified drugs/therapies comparatively by a number of essential characteristics, including scientific rationale, experience in lupus mice/human cells (pre-clinical), previous clinical experience in autoimmunity, drug properties and safety profile including adverse events.[29] Potential candidates were scored in each of five categories: small molecules, cellular therapies, complementary and alternative therapies as well as drugs in development (DiD). Of the 157 therapies initially screened, more than 20 had an appropriate set of characteristics to consider for testing in clinical trials for lupus, including drugs targeting cellular metabolism, kinases, the immune system, HDACs, complement as well as cellular therapies and non-drug interventions. Consideration of the drugs approved by the FDA in 2014–2015 generated additional candidates with an appropriate set of characteristics to consider for CoLT scoring and potential testing in lupus clinical trials,[30,31] including inhibitors of PI3K, PDE4, PARP, and HDACs as well as biologics with specificity for IL5, IL6, IL13, IL17alpha, VEGFR2, integrin receptors, and CD38. Newly approved PD1 checkpoint inhibitors that might have deletion as well as agonistic properties were also considered.

The objective of the CoLTs system was to develop a metric that could capture applicable information from the literature and yield a composite score that would plausibly suggest that a drug candidate might be successful in lupus clinical trials. Of significance, the CoLT score reflects the state of knowledge at the time the candidate was scored but was designed to be dynamic and incorporate new knowledge as it becomes available. The motivation to develop the CoLTs system was the need for an objective way to score candidates, taking into consideration both likely efficacy as well as expected adverse event profile in lupus patients. Although estimations of possible efficacy, including mechanism of action, experience in animal models, pathway abnormalities identified in lupus patients, and previous clinical experience in other autoimmune/inflammatory experience were all thought to be valuable and carefully scored, greater weight was given to the adverse event profile. The adverse event profile is of particular importance in SLE where treatments with drugs such as glucocorticoids and immunosuppressive agents increase risk of infections, which could limit the use of other immunomodulatory therapies. Finally, properties of the compounds, including route of administration, dosing, drug metabolism, and drug–drug interactions, were also scored, since they can be essential determinants of success in a chronic disease often treated with multiple drugs. Multiple iterations of the scoring system were considered in order to find the best combination of characteristics that separated drug candidates with a greater likelihood of success from those with a less attractive set of characteristics. The CoLTs system was validated by scoring a number of SOC agents and seeking face validity from experienced clinicians. The outcome was the CoLT score that provides a useful means to prioritize treatment candidates for SLE but is a dynamic, flexible measurement that takes into account new information about a therapy as it becomes available.

Initially, one hundred and fifty seven therapies were examined in detail by the LRxL-STAT initiative (99 small molecules, 41 biologics, 5 cellular therapies, and 12 CAM (complementary and alternative medicines; see www.linkedin.com/in/lrxlstat for the complete listing). The initial goal was to evaluate the likelihood of success of repositioning FDA-approved drug in SLE so the evaluation list scored with CoLTs was focused on the 76 FDA-approved or GRAS (Generally Recognized as Safe) therapies that scored higher than commonly used SOC lupus medications (Table 1). Drugs that scored higher than SOC medications were considered to be "high priority" and worth considering for small, proof-of-concept trials (STAT, SLE Treatment Acceleration Trials) that will potentially be carried out by the Lupus Clinical Investigators Network (LuCIN, www.linkedin.com/in/lucinstat).

As described previously and reviewed here, CoLT scores were calculated based on a numerical ranking system of -16 to $+11$ (Figures 2 and 3). All data used for scoring is in the public domain. Ten categories were scored for each candidate. Rationale was scored from 0 to $+3$, a sliding scale from "no role in lupus" receiving a zero and "demonstrated role in lupus pathogenesis" receiving a $+3$. Pre-clinical experience (lupus mice), lupus cells *in vitro*, lupus abnormality, autoimmunity clinical experience, and lupus clinical experience

Table 1 LRxL-STAT identifies candidate drugs for repositioning into SLE

FDA-approved biologics	FDA-approved biologics (cont.)	FDA-approved small molecules	FDA-approved small molecules (cont.)
Abatacept[8]	Infliximab[4]	Azathioprine (SOC)[5]	*N*-Acetyl cysteine[4]
Adalimumab[4]	Natalizumab[4]	Abacavir[−1]	Nelfinavir[2]
Belimumab (SOC)[5]	Ofatumumab[5]	Apremilast[5]	Nilotinib[0]
Certolizumab Pegol[4]	Pembrolizumab[2]	Bortezomib[6]	Orlistat[−1]
Eculizumab[7]	Rituximab[4]	Carfilzomib[4]	Panzopanib[−4]
Etanercept[5]	Tocilizumab[8]	Crizotinib[−4]	***Quinacrine***[7]
Golimumab[5]	***Ustekinumab***[10]	Dasatinib[−1]	Roflumilast[5]
		Dimethyl Fumarate[4]	Romidepsin[4]
Complementary small molecules (CAMs)	**Cellular therapies**	Dipyridamole[4]	Rosiglitazone[1]
		Erlotinib[−4]	Ruxolinib[5]
Creatinine[1]	Allogeneic HSCT[1]	Everolimus[3]	Sirolimus[2]
Curcumin[7]	***Autologous HSCT***[9]	Fingolimod[5]	Sorafenib[−3]
Nicotinamide adenine dinucleotide[4]	Mesenchymal SCT[2]	Glatiramer acetate[−2]	Statins (SOC)[3]
Omega-3 Fish Oil (Krill)[8]	Tregs[4]	Gefitinib[1]	Sunitinib[1]
Promethylation diet (choline, methionine, folic acid)[6]		Hydroxychloroquine (SOC)[5]	Tacrolimus[5]
Resveratrol[6]		Ibrutinib[4]	Tamoxifen[2]
Tetrahydrobiopterin[0]		Idelalisib[1]	Tenofovir[1]
TwHF (Thunder God Vine)[7]		Imatinib[4]	Teriflunomide[7]
Ergocalciferol (Vitamin D)[6]		Irinotecan[−1]	Thalidomide[−2]
		Lamivudine[3]	Tofacitinib[3]
Alternative medicine/therapies		Lapatinib[0]	Valproic Acid[0]
		Leflunomide[3]	Vandetanib[−7]
Acupuncture[1]		Lenalidomide[−5]	Vemurafenib[−6]
Meditation/mindfulness[5]		Metformin[1]	Vorinostat[6]
Yoga[3]			Zidovudine[−2]

categories were scored from −1 to +1; a candidate was given a score of −1 for "no benefit or not verified/present," zero for "not determined/equivocal," or +1 for positive evidence. Properties of each candidate were scored from −3 to +3, as detailed in Figure 2 based on route/frequency administration, characteristics, specificity, interactions with SOC medications. Since some drugs have been shown to induce lupus, this category was scored as −1 for "induces lupus" and zero for a drug that does not induce lupus. Metabolism of each compound was scored from −2 to zero. If a candidate utilizes p450 enzymes for metabolism *and* has greater than 20% excretion by the kidneys, the drug received a −2. If one condition was met, the drug received a −1. Zero was assigned if the drug was not heavily metabolized by liver cytochrome oxidases and excretion by the kidneys was less than 20%.

Adverse events were heavily weighted as a component of the CoLT score, numerically ranging from −5 to zero. The following formula was used to calculate the Adverse Events CoLTs sub-score: [sum of AE severity][#AEs] = ToxProduct → converted to whole number scale.

Adverse event (AE) severity scores (renal, liver, cardiovascular, infection, cytological, cancer, pulmonary, skin) from Medscape were used to calculate CoLTs "adverse event sub-score." Most FDA-assigned "Black Box Warning" (BBW) automatically were scored as a −5. Of note, hypersensitivity adverse events were not scored. Using the renal category as an example, since lupus patients are especially susceptible to kidney side effects, compounds were given a −4 for increasing/ inducing renal impairment /failure as well as for an increasing risk of renal toxicity or glomerulonephritis. Each event of increasing the risk of hypokalemia or hypophosphatemia was given a −1.

The CoLT scores of all LRxL-STAT repositioning candidates are shown in Table 1; in this table and below, CoLT scores are in superscript. Preclinical or clinical experience in autoimmune diseases was typically available in the literature for high priority candidates. SOC lupus medications Belimumab and Hydroxychloroquine (HCQ) received a CoLT score of 5 whereas Rituximab received a CoLT score of 4 (Figure 3). The top scoring candidates for repositioning in each category are bolded in Table 1 and are as follows: *biologic*, Stelara/ustekinumab[10] targeting the p40 subunit of IL12/23 (called IL12β); *small molecule*, the lysosomal neutralizer quinacrine;[7] *cellular therapy*, autologous hematopoietic stem cell

Rationale (0 to +3)	*None*	*Possible*	*Likely*	*Demonstrated*
Role in lupus pathogenesis	*0*	*1*	*2*	*3*
Lupus mice		*Done, no benefit*	*ND/conflicting results*	*Benefit*
(-1 to +1)		*-1*	*0*	*1*
Lupus cells in vitro		*Done, not verified*	*ND/conflicting results*	*Target identified*
(-1 to +1)		*-1*	*0*	*1*
Lupus Abnormality		*Studied, not present*	*ND/conflicting results*	*Target active/abnormal*
(-1 to +1)		*-1*	*0*	*1*
Autoimmunity		*Trial no effect/*	*ND/diff results*	*Beneficial trial/*
Clinical Experience (-1 to +1)		*conflicting results*	*diff diseases*	*Case report*
		-1	*0*	*1*
Lupus Clinical Experience		*Trial no effect/*	*ND/diff results*	*Beneficial trial/*
(-1 to +1)		*conflicting results*	*diff diseases*	*Case report*
		-1	*0*	*1*
Drug Properties (-3 to +3)		**DDI w SOC lupus drugs;*	**IV, chimeric,*	**SC, Hu or humanized,*
**for each*		*nonspecific w many targets*	*≤ BID*	*qDay, highly specific*
		-1	*0*	*1*
Induces Lupus (-1 to 0)		*Yes*	*No*	
		-1	*0*	
Drug Metabolism (-2 to 0)		*P450 issues &*	*p450 issues OR*	*NO p450 issues &*
		>20% kidney excretion	*>20% kidney excretion*	*<20% kidney excretion*
		-2	*-1*	*1*
Adverse Events (-5 to 0)				

Figure 2 Components of Combined Lupus Treatment Scoring (CoLTs) to rank potential candidates for repositioning in lupus. The CoLT score for each drug candidate was calculated based on a numerical scoring system of −16 to + 11. Rationale was scored based on scientific evidence for a role in lupus pathogenesis (0, no role; 1, possible role; 2, likely role; 3, demonstrated role). Preclinical evidence was assessed in lupus mice (−1, no benefit; 0, not determined (ND) or equivocal; 1, benefit) or *in vitro* with human cells (−1, not verified; 0, ND or equivocal; 1, target identified). Lupus abnormality was assessed (−1, studied but not present; 0, ND or studied with conflicting results; 1, target active or abnormal). Clinical experience was assessed in autoimmune disease or in lupus itself (−1, trial no effect or conflicting results; 0, ND or different results in different diseases; 1, beneficial trial or case report). Properties: −1 was given for non-specificity with many targets or for each drug–drug interaction (DDI) with SOC lupus drugs (corticosteroids, MMF, AZA, CTX, statins, ACE inhibitors): 0 if the drug is chimeric or administered IV or ≥ BID; for each of the following, 1 point was given: if the drug is Hu or humanized, administered SC, given once a day, specific for its target. Induces lupus? (0, no; 1, yes). Drug metabolism was assessed (−2, p450 metabolism and >20% kidney excretion; −1, p450 metabolism OR > 20% kidney excretion; 0, no p450 issues or < 20% kidney excretion). The rationale is summarized in Table 2.

transplantation;[5] *CAM*: omega-3 PUFA (krill oil)[8] and meditation/mindfulness[4]. (CoLT scores are indicated by superscript). All results were vetted by a committee of experts organized by the ALR and LRI in the spring of 2013 that reviewed the details of the CoLT scores (W Paul, Committee Chair with members J. Browning, M. Crow, J. Craft, M. Collins, P. Isakson, M. Sykes, and V. Werth).

The initial goal of scoring drugs approved by the FDA for a non-lupus indication with the hope of encouraging Biotech/Pharma to test efficacy in lupus patients was realized in the fall of 2015. Based on LRxL-STAT's high priority CoLT score, Janssen Pharmaceuticals decided to test efficacy of Stelara/ustekinumab in lupus, with a Phase IIa trial that began in the fall of 2015 (NCT-02349061). A number of the academic lupus centers that comprise the Lupus Clinical Investigators Network (LuCIN, www.linkedin.com/in/lucinstat) are participants in this trial of Stelara/ustekinumab in lupus patients.

The LRxL-STAT initiative is a living entity that is a vibrant and keeps up-to-date with all drugs approved by the FDA. In addition, the CoLT scoring is a dynamic process that was designed to constantly incorporate new information as it becomes available. Of all of the drugs approved by the FDA in 2014–2015, a number have potential to be high-priority candidates for repositioning into SLE as their targets are identical to drugs with high CoLT scores. Newly approved Ninlaro/ixazomib

	Belimumab	HCQ	Rituximab
Rationale (0 to +3)	2	3	2
Lupus mice (-1 to +1)	1	0	0
Lupus cells in vitro (-1 to +1)	1	1	0
Lupus Abnormality (-1 to +1)	1	1	1
Autoimmunity Clinical Experience (-1 to +1)	-1	1	1
Lupus Clinical Experience (-1 to +1)	1	1	0
Drug Properties (-3 to +3)	2	0	1
Induces Lupus (-1 to 0)	0	0	0
Metabolism of Drug (-2 to 0)	0	-1	0
Adverse Events (-5 to 0)	-2	-1	-1
CoLTs	5	5	3

Figure 3 Combined Lupus Treatment Scoring (CoLTs, −16 to 11) of lupus SOC and top-ranked drugs for repositioning in lupus (see Table 3).

Table 2 Categories of CoLT scoring

Rationale (0 to + 3)	*None*	*Possible*	*Likely*	*Demonstrated*
Role in lupus pathogenesis	*0*	*1*	*2*	*3*
Lupus mice		*Done, no benefit*	*ND/conflicting results*	*Benefit*
(−1 to + 1)		*−1*	*0*	*1*
Lupus cells in vitro		*Done, not verified*	*ND/conflicting results*	*Target identified*
(−1 to + 1)		*−1*	*0*	*1*
Lupus abnormality		*Studied, not present*	*ND/conflicting results*	*Target active/abnormal*
(−1 to + 1)		*−1*	*0*	*1*
Autoimmunity clinical experience (−1 to + 1)		*Trial no effect/conflicting results*	*ND/diff results diff diseases*	*Beneficial trial/case report*
		−1	*0*	*1*
Lupus clinical experience (−1 to + 1)		*Trial no effect/conflicting results*	*ND/diff results diff diseases*	*Beneficial trial/case report*
		−1	*0*	*1*
Drug properties (−3 to + 3)		**DDI w SOC lupus drugs; nonspecific w many targets*	**IV, chimeric, ≤ BID*	**SC, Hu or humanized, qDay, highly specific*
**for each*		*−1*	*0*	*1*
Induces lupus (−1 to 0)		*Yes*	*No*	
		−1	*0*	
Drug metabolism (−2 to 0)		*P450 issues & >20% kidney excretion*	*p450 issues OR >20% kidney excretion*	*NO p450 issues & <20% kidney excretion*
		−2	*−1*	*1*
Adverse events (−5 to 0)				

inhibits the proteasome in a similar manner as Velcade/bortezomib[6], resulting in intracellular build-up of ubiquitylated proteins followed by apoptosis. The IL6 antagonist Sylvant/siltuximab (anti-IL6) affects the same pathway as Actemra/tocilizumab[8] (anti-IL6R) and exerts anti-inflammatory effects as well as interferes with the differentiation/maintenance of plasma cells. Similar to the LRxL-STAT candidate vorinostat[6], Beldodaq/belinostat, Farydak/panobinostat, and givinostat are

Table 3 Rationale for CoLTs of top-ranked drugs for repositioning in lupus

	Belimumab	HCQ	Rituximab
Rationale (0 to +3)	2	3	2
Lupus mice (−1 to +1)	1	0	0
Lupus cells in vitro (−1 to +1)	1	1	0
Lupus abnormality (−1 to +1)	1	1	1
Autoimmunity clinical experience (−1 to +1)	−1	1	1
Lupus clinical experience (−1 to +1)	1	1	0
Drug properties (−3 to +3)	2	0	1
Induces lupus (−1 to 0)	0	0	0
Metabolism of drug (−2 to 0)	0	−1	0
Adverse events (−5 to 0)	−2	−1	−1
CoLTs	5	5	3

inhibitors of class I HDACs but also inhibit class II HDACs; both classes of HDACi induce intracellular accumulation of acetylated histones followed by apoptosis.

There are a number of newly approved biologics specific for lineage markers that delete lymphocytes in a variety of ways. Blinatumomab/Blincyto, a Dual-Affinity Re-Targeting (DART) antibody specific for CD3 and CD19 that was suggested to LRxL-STAT when it was in development, goes a step beyond rituximab[4] since it targets $CD3^+$ T cells as well as $CD19^+$ B cells, inducing $CD3^+$ T cells to kill targeted B cells. A newly approved biologic, daratumumab/Darzalex, targets CD38 which is highly expressed on autoantibody secreting plasma cells but is also expressed on a variety of other cell types and deletes them by ADCC.

A number of "first-in-class" drugs approved by the FDA in 2014-2015 may also be efficacious for lupus patients. The PDE4 small molecule inhibitors Daliresp/roflumilast and Otezla/apremilast receive high priority CoLT scores, 6 and 5 respectively. Phosphodiesterase-4 inhibitors prevent breakdown of cAMP and are anti-inflammatory because cAMP inhibition lowers the activation state of transcription factors required for the transcription of inflammatory cytokines such as IL12/IL23p40 and IL17. A new biologic targeting one of the products of Th17 cells through its specificity for IL17α, called secukinumab/Cosentyx receives a high CoLT score of 8.

A number of the drugs approved in 2014–2015 target proteins are relevant to the pathophysiology of lupus but do not score well on the CoLT scale because of other issues. Eliglustat/Cerdelga that inhibits glucosylceramide synthase may have some potential in lupus cerebritis but its lack of clinical experience in autoimmunity, mixed evidence from lupus mice, utilization of P450 for metabolism and high usage of kidneys for excretion makes it a low priority candidate for lupus drug repositioning. Another interesting candidate targets Th2 cytokines, mepolizumab/Nucala (IL5). The target of mepoliziumab/Nucala, IL5, is a potential biomarker of lupus nephritis and is one of the predictive markers in cerebrospinal fluid (CSF) for lupus cerebritis.[33] More work will need to be done to investigate the potential for mepoliziumab/Nucala to be repositioned into lupus. Although the integrin receptor antagonist vedolizumab/Entyvio was initially attractive for repositioning into lupus, further investigation revealed that it primarily targets inflammation in the gut by preventing the $\alpha_4\beta_7$ integrin subunit from binding to MAdCAM1. The VEGFR2 target of ramucirumab/Cyramza does not score well since the target has conflicting evidence in both the lupus mice and human lupus abnormality categories.[35] Nexavar/sorafenib, the previously approved small molecule antagonist of VEGFR2 as well as PDGFR and RAF, received a CoLT score of −3 due to AEs and toxicity. A variety of intracellular-signaling inhibitors were investigated as potential candidates for repositioning into lupus. Kinase inhibitors ceritinib/Zykadia (targeting ALK), selumetinib (targeting MEK1,2), idelalisib/Zydelig (targeting PI3K-delta), and osemertinib/Tagrisso (receptor TyrK inhibitor) were less attractive as potential candidates for repositioning into lupus because of severe adverse events that result in negative CoLT scores similar to the kinase inhibitor Xalkori/crizotinib[−4] (targeting ALK). The PARP (poly ADP-ribose polymerase) inhibitor olaparib/Lynparza that interferes with the DNA repair process and thus potential mutations leading to autoantibody production has good rationale, but its severe adverse event profile in combination with its utilization of P450 for metabolism and high usage of kidneys for excretion makes it a low priority candidate for lupus drug repositioning. Finally, adverse event profiles as well as negative results in lupus mouse models do not suggest that the checkpoint inhibitors, pembrolizumab/Keytruda (anti-PD1) and nivolumab/Opdivo (anti-PD1L1) are good candidates for repositioning into lupus. However, agonistic antibodies directed against PD1 remain an attractive target as a means to inhibit the function of activated T cells and especially T_{FH} cells.[37–39] Deleting anti-PD1 antibodies might also be worth considering in the future. Top priority drug

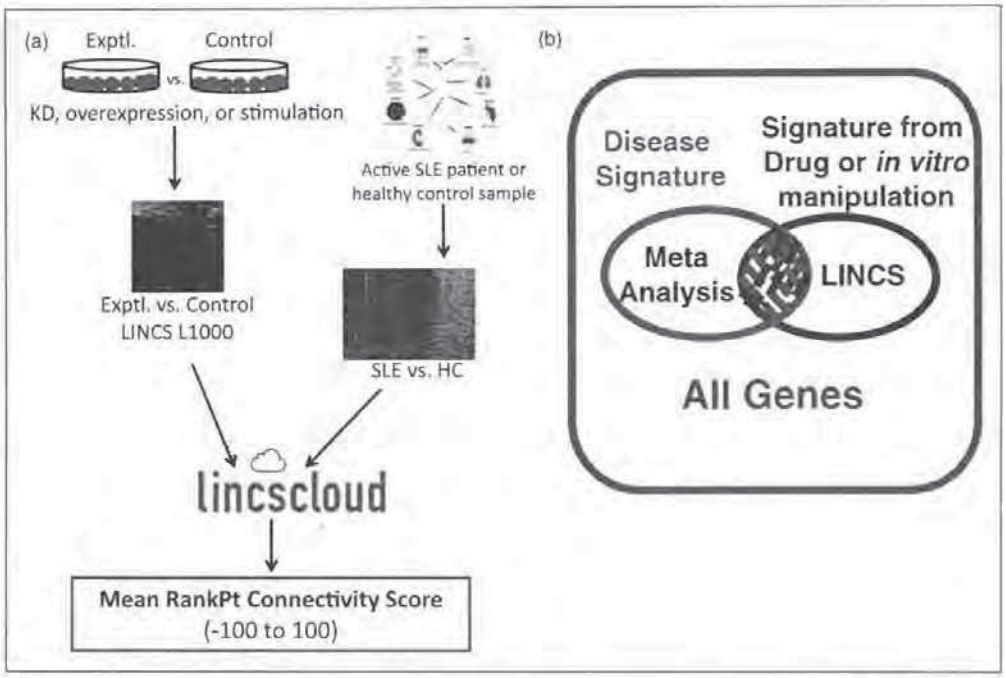

Figure 4 Gene expression approach to drug repositioning: predicting drug candidates using LINCS. Drug induced transcriptional modules in the LINCS database give insights into drug action as well as function(s) of groups of genes targeted by drugs. Signatures in the LINCS database generated by *in vitro* manipulation (deletion or overexpression) as well as drug incubation are compared to a disease signature (i.e., DE genes from peripheral B cells: SLE vs normal individuals).

candidates considered by LRxL-STAT for repositioning into SLE are shown in Table 1.

Bioinformatic confirmation of top ranked drugs for repositioning into lupus

To confirm high priority drugs identified by CoLT scoring through the LRxL-STAT initiative by orthogonal methodology and to identify more drug repositioning candidates for lupus patients, a second approach commonly used is the perturbagen database developed by the Broad Institute and publically available at http://www.lincscloud.org/l1000/ called LINCS (Library of Integrated Network-Based Cellular Signatures) (Figure 4). The LINCScloud is a searchable database that emerged from cMAP (connectivity MAP). The first version of cMAP was developed by the Broad Institute in 2006 using the Affymetrix human genome U133 (hgU133) microarray platform and consisted of a repository of four human cell lines treated with ~1300 drugs. Subsequently, the Broad Institute expanded the set to 7000 expression profiles and 13,000 compounds. A new technology called the L1000 platform was developed for the next major version of cMAP that is located at "lincscloud", using Luminex Flexmap 3D bead technology that contained far greater probe sets than the hgU133 arrays. The Broad's L1000 results are the publically available transcription response portion of LINCS, and currently contains representative information linking gene expression to perturbagen profiles, generated from more than 1.4 million gene expression profiles obtained from 25 major cell types that were antagonized by 20,413 chemical perturbagens and 22,119 knockout or overexpression genetic perturbagens.

Whereas LRxL-STAT is an hypothesis-driven literature-search approach involving crowd sourcing through the LinkedIn site, intensive literature mining and evaluation with the objective CoLT scoring tool (Figure 5), LINCS connectivity scoring affords the opportunity for a non-biased and experimentally-based comparison of the experimentally observed gene expression changes induced by various drugs and gene perturbations (i.e., what genes are up and downregulated by a given perturbagen) with gene expression abnormalities in lupus identified by meta-analysis of gene expression profiles.

As is standard practice to determine gene expression abnormalities, microarray data generated from

IN THE U.S. PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

----------x
LUPIN PHARMACEUTICALS, INC.,

Opposer, Opposition No. 91226322

v.

AMPEL, LLC,

Applicant.
----------x

EXHIBIT N

TO

DECLARATION OF THOMAS H. CURTIN IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT BY OPPOSER LUPIN PHARMACEUTICALS, INC.

United States of America
United States Patent and Trademark Office

ACORDA

Reg. No. 4,859,924

Registered Nov. 24, 2015

Int. Cls.: 5, 35, 38, 41, 42, and 44

TRADEMARK

SERVICE MARK

PRINCIPAL REGISTER

ACORDA THERAPEUTICS, INC. (DELAWARE CORPORATION)
420 SAW MILL RIVER ROAD
ARDSLEY, NY 10502

FOR: PHARMACEUTICAL AND BIOLOGICAL PREPARATIONS USED IN THE TREATMENT OF NEUROLOGICAL DISEASES, DISORDERS OR CONDITIONS, IN CLASS 5 (U.S. CLS. 6, 18, 44, 46, 51 AND 52).

FIRST USE 6-1-2001; IN COMMERCE 6-1-2001.

FOR: PROMOTING PUBLIC AWARENESS OF THE NEED FOR EDUCATION, RESEARCH, TREATMENT AND A CURE FOR NEUROLOGICAL AND MOBILITY DISEASES AND DISORDERS, IN CLASS 35 (U.S. CLS. 100, 101 AND 102).

FIRST USE 4-3-2008; IN COMMERCE 4-3-2008.

FOR: PROVIDING AN ONLINE FORUM FOR TRANSMISSION OF MESSAGES CONCERNING ISSUES RELATED TO NEUROLOGICAL DISEASES, DISORDERS OR CONDITIONS , IN CLASS 38 (U.S. CLS. 100, 101 AND 104).

FIRST USE 6-0-2008; IN COMMERCE 6-0-2008.

FOR: ENTERTAINMENT AND EDUCATIONAL SERVICES, NAMELY, PROVIDING LIVE AND ONLINE SEMINARS, CONFERENCES AND WORKSHOPS CONCERNING ISSUES RELATED TO NEUROLOGICAL DISEASES, DISORDERS AND CONDITIONS AND DISTRIBUTING INFORMATIONAL COURSE MATERIALS IN CONNECTION THEREWITH, IN CLASS 41 (U.S. CLS. 100, 101 AND 107).

FIRST USE 6-0-2009; IN COMMERCE 6-0-2009.

FOR: HOSTING AN ON-LINE COMMUNITY WEBSITE FEATURING INFORMATION RELATED TO NEUROLOGIC DISORDERS; COMPUTER SERVICES, NAMELY, CREATING AN ON-LINE COMMUNITY FOR REGISTERED USERS TO PARTICIPATE IN DISCUSSIONS, GET FEEDBACK FROM THEIR PEERS, FORM VIRTUAL COMMUNITIES, AND ENGAGE IN SOCIAL NETWORKING CONCERNING ISSUES RELATED TO NEUROLOGIC DISORDERS; PROVIDING A WEBSITE FEATURING TECHNOLOGY THAT ENABLES USERS TO SEARCH, WATCH, SHARE, AND COMMENT ON DOCUMENTS, VIDEOS, AUDIO AND

Michelle K. Lee

Director of the United States Patent and Trademark Office

Reg. No. 4,859,924 OTHER MULTIMEDIA CONTENT CONCERNING ISSUES RELATED TO NEUROLOGIC DISORDERS, IN CLASS 42 (U.S. CLS. 100 AND 101).

FIRST USE 6-0-2008; IN COMMERCE 6-0-2008.

FOR: PROVIDING INFORMATION AND ONLINE INFORMATION RELATING TO DIAGNOSTIC, PROPHYLACTIC AND THERAPEUTIC PROPERTIES OF PHARMACEUTICAL PREPARATIONS FOR THE PREVENTION AND TREATMENT OF DISEASES, DISORDERS AND CONDITIONS, IN CLASS 44 (U.S. CLS. 100 AND 101).

FIRST USE 8-18-2010; IN COMMERCE 8-18-2010.

THE MARK CONSISTS OF STANDARD CHARACTERS WITHOUT CLAIM TO ANY PARTICULAR FONT, STYLE, SIZE, OR COLOR.

OWNER OF U.S. REG. NOS. 2,913,451 AND 3,565,849.

SN 85-251,001, FILED 2-24-2011.

ALICIA COLLINS, EXAMINING ATTORNEY

REQUIREMENTS TO MAINTAIN YOUR FEDERAL TRADEMARK REGISTRATION

WARNING: YOUR REGISTRATION WILL BE CANCELLED IF YOU DO NOT FILE THE DOCUMENTS BELOW DURING THE SPECIFIED TIME PERIODS.

Requirements in the First Ten Years*
What and When to File:

First Filing Deadline: You must file a Declaration of Use (or Excusable Nonuse) between the 5th and 6th years after the registration date. *See* 15 U.S.C. §§1058, 1141k. If the declaration is accepted, the registration will continue in force for the remainder of the ten-year period, calculated from the registration date, unless cancelled by an order of the Commissioner for Trademarks or a federal court.

Second Filing Deadline: You must file a Declaration of Use (or Excusable Nonuse) **and** an Application for Renewal between the 9th and 10th years after the registration date.* *See* 15 U.S.C. §1059.

Requirements in Successive Ten-Year Periods*
What and When to File:

You must file a Declaration of Use (or Excusable Nonuse) **and** an Application for Renewal between every 9th and 10th-year period, calculated from the registration date.*

Grace Period Filings*

The above documents will be accepted as timely if filed within six months after the deadlines listed above with the payment of an additional fee.

***ATTENTION MADRID PROTOCOL REGISTRANTS:** The holder of an international registration with an extension of protection to the United States under the Madrid Protocol must timely file the Declarations of Use (or Excusable Nonuse) referenced above directly with the United States Patent and Trademark Office (USPTO). The time periods for filing are based on the U.S. registration date (not the international registration date). The deadlines and grace periods for the Declarations of Use (or Excusable Nonuse) are identical to those for nationally issued registrations. *See* 15 U.S.C. §§1058, 1141k. However, owners of international registrations do not file renewal applications at the USPTO. Instead, the holder must file a renewal of the underlying international registration at the International Bureau of the World Intellectual Property Organization, under Article 7 of the Madrid Protocol, before the expiration of each ten-year term of protection, calculated from the date of the international registration. *See* 15 U.S.C. §1141j. For more information and renewal forms for the international registration, see http://www.wipo.int/madrid/en/.

NOTE: Fees and requirements for maintaining registrations are subject to change. Please check the USPTO website for further information. With the exception of renewal applications for registered extensions of protection, you can file the registration maintenance documents referenced above online at http://www.uspto.gov.

NOTE: A courtesy e-mail reminder of USPTO maintenance filing deadlines will be sent to trademark owners/holders who authorize e-mail communication and maintain a current e-mail address with the USPTO. To ensure that e-mail is authorized and your address is current, please use the Trademark Electronic Application System (TEAS) Correspondence Address and Change of Owner Address Forms available at http://www.uspto.gov.

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Mark: ACORDA

ACORDA

US Serial Number: 85251001

Application Filing Date: Feb. 24, 2011

US Registration Number: 4859924

Registration Date: Nov. 24, 2015

Register: Principal

Mark Type: Trademark, Service Mark

Status: Registered. The registration date is used to determine when post-registration maintenance documents are due.

Status Date: Nov. 24, 2015

Publication Date: Jul. 24, 2012

Notice of Allowance Date: Sep. 18, 2012

Mark Information

Mark Literal Elements: ACORDA

Standard Character Claim: Yes. The mark consists of standard characters without claim to any particular font style, size, or color.

Mark Drawing Type: 4 - STANDARD CHARACTER MARK

Related Properties Information

Claimed Ownership of US Registrations: 2913451, 3565849

Goods and Services

Note: The following symbols indicate that the registrant/owner has amended the goods/services:

- Brackets [..] indicate deleted goods/services;
- Double parenthesis ((..)) identify any goods/services not claimed in a Section 15 affidavit of incontestability; and
- Asterisks *..* identify additional (new) wording in the goods/services.

For: Pharmaceutical and biological preparations used in the treatment of neurological diseases, disorders or conditions

International Class(es): 005 - Primary Class

U.S Class(es): 006, 018, 044, 046, 051, 052

Class Status: ACTIVE

Basis: 1(a)

First Use: Jun. 01, 2001

Use in Commerce: Jun. 01, 2001

For: Promoting public awareness of the need for education, research, treatment and a cure for neurological and mobility diseases and disorders

International Class(es): 035 - Primary Class

U.S Class(es): 100, 101, 102

Class Status: ACTIVE

Basis: 1(a)

First Use: Apr. 03, 2008

Use in Commerce: Apr. 03, 2008

For: Providing an online forum for transmission of messages concerning issues related to neurological diseases, disorders or conditions

International Class(es): 038 - Primary Class

U.S Class(es): 100, 101, 104

Class Status: ACTIVE

Basis: 1(a)

First Use: Jun. 2008 **Use in Commerce:** Jun. 2008

For: Entertainment and educational services, namely, providing live and online seminars, conferences and workshops concerning issues related to neurological diseases, disorders and conditions and distributing informational course materials in connection therewith

International Class(es): 041 - Primary Class **U.S Class(es):** 100, 101, 107

Class Status: ACTIVE

Basis: 1(a)

First Use: Jun. 2009 **Use in Commerce:** Jun. 2009

For: Hosting an on-line community website featuring information related to neurologic disorders; computer services, namely, creating an on-line community for registered users to participate in discussions, get feedback from their peers, form virtual communities, and engage in social networking concerning issues related to neurologic disorders; Providing a website featuring technology that enables users to search, watch, share, and comment on documents, videos, audio and other multimedia content concerning issues related to neurologic disorders

International Class(es): 042 - Primary Class **U.S Class(es):** 100, 101

Class Status: ACTIVE

Basis: 1(a)

First Use: Jun. 2008 **Use in Commerce:** Jun. 2008

For: Providing information and online information relating to diagnostic, prophylactic and therapeutic properties of pharmaceutical preparations for the prevention and treatment of diseases, disorders and conditions

International Class(es): 044 - Primary Class **U.S Class(es):** 100, 101

Class Status: ACTIVE

Basis: 1(a)

First Use: Aug. 18, 2010 **Use in Commerce:** Aug. 18, 2010

Basis Information (Case Level)

Filed Use:	No	**Currently Use:**	Yes	**Amended Use:**	No
Filed ITU:	Yes	**Currently ITU:**	No	**Amended ITU:**	No
Filed 44D:	No	**Currently 44D:**	No	**Amended 44D:**	No
Filed 44E:	No	**Currently 44E:**	No	**Amended 44E:**	No
Filed 66A:	No	**Currently 66A:**	No		
Filed No Basis:	No	**Currently No Basis:**	No		

Current Owner(s) Information

Owner Name: Acorda Therapeutics, Inc.

Owner Address: 420 Saw Mill River Road
Ardsley, NEW YORK 10502
UNITED STATES

Legal Entity Type: CORPORATION **State or Country Where Organized:** DELAWARE

Attorney/Correspondence Information

Attorney of Record

Attorney Name: Joseph C. Guagliardo, Esq. **Docket Number:** 127304.25/8

Attorney Primary Email Address: docketingpgh@pepperlaw.com **Attorney Email Authorized:** Yes

Correspondent

Correspondent Name/Address: JOSEPH C. GUAGLIARDO, ESQ.
PEPPER HAMILTON LLP
EIGHTEENTH & ARCH STS
3000 Two Logan Square
PHILADELPHIA, PENNSYLVANIA 19103
UNITED STATES

Phone:	215-981-4865	**Fax:**	412-281-0717
Correspondent e-mail:	guagliaj@pepperlaw.com maddoxd@pepperlaw.com catalant@pepperlaw.com	**Correspondent e-mail Authorized:**	Yes

Domestic Representative - Not Found

Prosecution History

Date	Description	Proceeding Number
Nov. 24, 2015	REGISTERED-PRINCIPAL REGISTER	
Oct. 17, 2015	NOTICE OF ACCEPTANCE OF STATEMENT OF USE E-MAILED	
Oct. 16, 2015	ALLOWED PRINCIPAL REGISTER - SOU ACCEPTED	
Sep. 24, 2015	STATEMENT OF USE PROCESSING COMPLETE	66230
Sep. 18, 2015	USE AMENDMENT FILED	66230
Sep. 18, 2015	TEAS CHANGE OF CORRESPONDENCE RECEIVED	
Sep. 18, 2015	TEAS STATEMENT OF USE RECEIVED	
Mar. 26, 2015	NOTICE OF APPROVAL OF EXTENSION REQUEST E-MAILED	
Mar. 25, 2015	EXTENSION 5 GRANTED	66230
Mar. 18, 2015	EXTENSION 5 FILED	66230
Mar. 18, 2015	TEAS EXTENSION RECEIVED	
Oct. 30, 2014	NOTICE OF APPROVAL OF EXTENSION REQUEST E-MAILED	
Oct. 29, 2014	EXTENSION 4 GRANTED	66230
Sep. 18, 2014	EXTENSION 4 FILED	66230
Oct. 24, 2014	NOTICE OF REVIVAL - E-MAILED	
Oct. 23, 2014	EXTENSION RECEIVED WITH TEAS PETITION	
Oct. 23, 2014	PETITION TO REVIVE-GRANTED	88889
Oct. 23, 2014	TEAS PETITION TO REVIVE RECEIVED	
Oct. 20, 2014	ABANDONMENT NOTICE MAILED - NO USE STATEMENT FILED	
Oct. 20, 2014	ABANDONMENT - NO USE STATEMENT FILED	99999
Mar. 27, 2014	NOTICE OF APPROVAL OF EXTENSION REQUEST E-MAILED	
Mar. 26, 2014	EXTENSION 3 GRANTED	66230
Mar. 17, 2014	EXTENSION 3 FILED	66230
Mar. 17, 2014	TEAS EXTENSION RECEIVED	
Sep. 24, 2013	NOTICE OF APPROVAL OF EXTENSION REQUEST E-MAILED	
Sep. 23, 2013	EXTENSION 2 GRANTED	66230
Sep. 18, 2013	EXTENSION 2 FILED	66230
Sep. 18, 2013	TEAS EXTENSION RECEIVED	
Apr. 05, 2013	NOTICE OF APPROVAL OF EXTENSION REQUEST E-MAILED	
Apr. 04, 2013	EXTENSION 1 GRANTED	66230
Mar. 16, 2013	EXTENSION 1 FILED	66230
Apr. 02, 2013	CASE ASSIGNED TO INTENT TO USE PARALEGAL	66230
Mar. 16, 2013	TEAS EXTENSION RECEIVED	
Sep. 18, 2012	NOA E-MAILED - SOU REQUIRED FROM APPLICANT	
Jul. 24, 2012	OFFICIAL GAZETTE PUBLICATION CONFIRMATION E-MAILED	
Jul. 24, 2012	PUBLISHED FOR OPPOSITION	
Jul. 04, 2012	NOTIFICATION OF NOTICE OF PUBLICATION E-MAILED	
Jun. 21, 2012	LAW OFFICE PUBLICATION REVIEW COMPLETED	73296
Jun. 20, 2012	ASSIGNED TO LIE	73296
Jun. 02, 2012	APPROVED FOR PUB - PRINCIPAL REGISTER	
Jun. 01, 2012	TEAS/EMAIL CORRESPONDENCE ENTERED	88889
Jun. 01, 2012	CORRESPONDENCE RECEIVED IN LAW OFFICE	88889
Jun. 01, 2012	TEAS REQUEST FOR RECONSIDERATION RECEIVED	
May 31, 2012	TEAS CHANGE OF CORRESPONDENCE RECEIVED	
Dec. 01, 2011	NOTIFICATION OF FINAL REFUSAL EMAILED	
Dec. 01, 2011	FINAL REFUSAL E-MAILED	
Dec. 01, 2011	FINAL REFUSAL WRITTEN	74819

Nov. 21, 2011	TEAS/EMAIL CORRESPONDENCE ENTERED	88889
Nov. 21, 2011	CORRESPONDENCE RECEIVED IN LAW OFFICE	88889
Nov. 21, 2011	TEAS RESPONSE TO OFFICE ACTION RECEIVED	
May 19, 2011	NOTIFICATION OF NON-FINAL ACTION E-MAILED	6325
May 19, 2011	NON-FINAL ACTION E-MAILED	6325
May 19, 2011	NON-FINAL ACTION WRITTEN	74819
May 19, 2011	ASSIGNED TO EXAMINER	74819
Mar. 01, 2011	NEW APPLICATION OFFICE SUPPLIED DATA ENTERED IN TRAM	
Feb. 28, 2011	NEW APPLICATION ENTERED IN TRAM	

TM Staff and Location Information

TM Staff Information - None

File Location

Current Location: PUBLICATION AND ISSUE SECTION **Date in Location:** Oct. 16, 2015

Int. Cls.: 5, 10, 41, and 44

Prior U.S. Cls.: 6, 18, 26, 39, 44, 46, 51, 52, 100, 101, and 107

United States Patent and Trademark Office

Reg. No. 3,596,709

Registered Mar. 24, 2009

TRADEMARK
SERVICE MARK
PRINCIPAL REGISTER

ALLERGAN

ALLERGAN, INC. (DELAWARE CORPORATION)
2525 DUPONT DRIVE
IRVINE, CA 92612

FOR: HOUSE MARK USED FOR A LINE OF PHARMACEUTICALS USED IN CONNECTION WITH ANTI-AGING, THE TREATMENT OF GLABELLAR LINES, FACIAL WRINKLES, ASYMMETRIES AND DEFECTS AND CONDITIONS OF THE HUMAN SKIN, FACIAL AESTHETIC SURGERY, FACIAL AESTHETIC RECONSTRUCTION, BREAST AESTHETICS AND ANTI-OBESITY, IN CLASS 5 (U.S. CLS. 6, 18, 44, 46, 51 AND 52).

FIRST USE 9-30-1990; IN COMMERCE 1-22-1992.

FOR: HOUSE MARK USED FOR A LINE OF MEDICAL DEVICES USED IN CONNECTION WITH ANTI-AGING, THE TREATMENT OF GLABELLAR LINES, FACIAL WRINKLES, ASYMMETRIES AND DEFECTS AND CONDITIONS OF THE HUMAN SKIN, FACIAL AESTHETIC SURGERY, FACIAL AESTHETIC RECONSTRUCTION, BREAST AESTHETICS AND ANTI-OBESITY, IN CLASS 10 (U.S. CLS. 26, 39 AND 44).

FIRST USE 11-30-2006; IN COMMERCE 11-30-2006.

FOR: PATIENT EDUCATION SERVICES, NAMELY, CLASSES, SEMINARS AND WORKSHOPS IN THE FIELDS OF BREAST AESTHETIC AND RECONSTRUCTION, FACIAL AESTHETIC AND ANTI-OBESITY SURGERY, IN CLASS 41 (U.S. CLS. 100, 101 AND 107).

FIRST USE 11-30-2006; IN COMMERCE 11-30-2006.

FOR: MEDICAL INFORMATIONAL SERVICES IN THE FIELD OF BREAST AESTHETIC AND RECONSTRUCTION, FACIAL AESTHETIC AND ANTI-OBESITY SURGERY, IN CLASS 44 (U.S. CLS. 100 AND 101).

FIRST USE 11-30-2006; IN COMMERCE 11-30-2006.

THE MARK CONSISTS OF STANDARD CHARACTERS WITHOUT CLAIM TO ANY PARTICULAR FONT, STYLE, SIZE, OR COLOR.

OWNER OF U.S. REG. NOS. 1,711,041, 2,147,765, AND OTHERS.

SN 78-952,383, FILED 8-15-2006.

LINDA ESTRADA, EXAMINING ATTORNEY

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Mark: ALLERGAN

ALLERGAN

US Serial Number:	78952383	**Application Filing Date:**	Aug. 15, 2006
US Registration Number:	3596709	**Registration Date:**	Mar. 24, 2009
Register:	Principal		
Mark Type:	Trademark, Service Mark		
Status:	A Sections 8 and 15 combined declaration has been accepted and acknowledged.		
Status Date:	Oct. 29, 2014		
Publication Date:	May 22, 2007	**Notice of Allowance Date:**	Aug. 14, 2007

Mark Information

Mark Literal Elements:	ALLERGAN
Standard Character Claim:	Yes. The mark consists of standard characters without claim to any particular font style, size, or color.
Mark Drawing Type:	4 - STANDARD CHARACTER MARK

Related Properties Information

Claimed Ownership of US Registrations:	1711041, 1748079, 2147765 and others

Goods and Services

Note: The following symbols indicate that the registrant/owner has amended the goods/services:

- Brackets [..] indicate deleted goods/services;
- Double parenthesis ((..)) identify any goods/services not claimed in a Section 15 affidavit of incontestability; and
- Asterisks *..* identify additional (new) wording in the goods/services.

For: House mark used for a line of pharmaceuticals used in connection with anti-aging, the treatment of glabellar lines, facial wrinkles, asymmetries and defects and conditions of the human skin, facial aesthetic surgery, facial aesthetic reconstruction, breast aesthetics and anti-obesity

International Class(es):	005 - Primary Class	**U.S Class(es):**	006, 018, 044, 046, 051, 052
Class Status:	ACTIVE		
Basis:	1(a)		
First Use:	Sep. 30, 1990	**Use in Commerce:**	Jan. 22, 1992

For: House mark used for a line of medical devices used in connection with anti-aging, the treatment of glabellar lines, facial wrinkles, asymmetries and defects and conditions of the human skin, facial aesthetic surgery, facial aesthetic reconstruction, breast aesthetics and anti-obesity

International Class(es):	010 - Primary Class	**U.S Class(es):**	026, 039, 044
Class Status:	ACTIVE		
Basis:	1(a)		
First Use:	Nov. 30, 2006	**Use in Commerce:**	Nov. 30, 2006

For: Patient education services, namely, classes, seminars and workshops in the fields of breast aesthetic and reconstruction, facial aesthetic and anti-obesity surgery

International Class(es):	041 - Primary Class	**U.S Class(es):**	100, 101, 107
Class Status:	ACTIVE		
Basis:	1(a)		
First Use:	Nov. 30, 2006	**Use in Commerce:**	Nov. 30, 2006

For: Medical informational services in the field of breast aesthetic and reconstruction, facial aesthetic and anti-obesity surgery

International Class(es):	044 - Primary Class	**U.S Class(es):**	100, 101
Class Status:	ACTIVE		
Basis:	1(a)		
First Use:	Nov. 30, 2006	**Use in Commerce:**	Nov. 30, 2006

Basis Information (Case Level)

Filed Use:	No	**Currently Use:**	Yes	**Amended Use:**	No
Filed ITU:	Yes	**Currently ITU:**	No	**Amended ITU:**	No
Filed 44D:	No	**Currently 44D:**	No	**Amended 44D:**	No
Filed 44E:	No	**Currently 44E:**	No	**Amended 44E:**	No
Filed 66A:	No	**Currently 66A:**	No		
Filed No Basis:	No	**Currently No Basis:**	No		

Current Owner(s) Information

Owner Name: Allergan, Inc.

Owner Address: 2525 Dupont Drive
Irvine, CALIFORNIA 92612
UNITED STATES

Legal Entity Type:	CORPORATION	**State or Country Where Organized:**	DELAWARE

Attorney/Correspondence Information

Attorney of Record - None

Correspondent

Correspondent Name/Address: Susan J. Hinchey
Allergan, Inc.
2525 Dupont Drive
IRVINE, CALIFORNIA 92612
UNITED STATES

Phone:	714-246-5507	**Fax:**	714-796-9381
Correspondent e-mail:	hinchey_susan@allergan.com	**Correspondent e-mail Authorized:**	Yes

Domestic Representative - Not Found

Prosecution History

Date	Description	Proceeding Number
Oct. 29, 2014	NOTICE OF ACCEPTANCE OF SEC. 8 & 15 - E-MAILED	
Oct. 29, 2014	REGISTERED - SEC. 8 (6-YR) ACCEPTED & SEC. 15 ACK.	70131
Oct. 29, 2014	CASE ASSIGNED TO POST REGISTRATION PARALEGAL	70131
Oct. 20, 2014	TEAS SECTION 8 & 15 RECEIVED	
Oct. 20, 2014	TEAS CHANGE OF CORRESPONDENCE RECEIVED	
Mar. 24, 2009	REGISTERED-PRINCIPAL REGISTER	
Feb. 17, 2009	LAW OFFICE REGISTRATION REVIEW COMPLETED	68123
Feb. 14, 2009	ALLOWED PRINCIPAL REGISTER - SOU ACCEPTED	
Jan. 29, 2009	EXAMINER'S AMENDMENT ENTERED	68123
Jan. 27, 2009	NOTIFICATION OF EXAMINERS AMENDMENT E-MAILED	

Jan. 27, 2009	EXAMINERS AMENDMENT E-MAILED	
Jan. 27, 2009	SU-EXAMINER'S AMENDMENT WRITTEN	76795
Oct. 08, 2008	NOTIFICATION OF FINAL REFUSAL EMAILED	
Oct. 08, 2008	FINAL REFUSAL E-MAILED	
Oct. 08, 2008	SU - FINAL REFUSAL - WRITTEN	76795
Sep. 16, 2008	TEAS/EMAIL CORRESPONDENCE ENTERED	88889
Sep. 16, 2008	CORRESPONDENCE RECEIVED IN LAW OFFICE	88889
Sep. 16, 2008	TEAS RESPONSE TO OFFICE ACTION RECEIVED	
Apr. 03, 2008	NOTIFICATION OF NON-FINAL ACTION E-MAILED	
Apr. 03, 2008	NON-FINAL ACTION E-MAILED	
Apr. 03, 2008	SU - NON-FINAL ACTION - WRITTEN	76795
Apr. 03, 2008	PREVIOUS ALLOWANCE COUNT WITHDRAWN	
Mar. 31, 2008	WITHDRAWN FROM ISSUE - EXAMINING ATTORNEY REQUEST	76795
Mar. 20, 2008	LAW OFFICE REGISTRATION REVIEW COMPLETED	68123
Mar. 19, 2008	ALLOWED PRINCIPAL REGISTER - SOU ACCEPTED	
Feb. 26, 2008	STATEMENT OF USE PROCESSING COMPLETE	64657
Feb. 26, 2008	EXTENSION 1 GRANTED	64657
Jan. 30, 2008	USE AMENDMENT FILED	64657
Jan. 30, 2008	EXTENSION 1 FILED	64657
Jan. 31, 2008	TEAS EXTENSION RECEIVED	
Jan. 31, 2008	TEAS STATEMENT OF USE RECEIVED	
Aug. 14, 2007	NOA MAILED - SOU REQUIRED FROM APPLICANT	
May 22, 2007	PUBLISHED FOR OPPOSITION	
May 02, 2007	NOTICE OF PUBLICATION	
Mar. 23, 2007	LAW OFFICE PUBLICATION REVIEW COMPLETED	68123
Mar. 23, 2007	ASSIGNED TO LIE	68123
Feb. 27, 2007	APPROVED FOR PUB - PRINCIPAL REGISTER	
Feb. 06, 2007	TEAS/EMAIL CORRESPONDENCE ENTERED	88889
Feb. 05, 2007	CORRESPONDENCE RECEIVED IN LAW OFFICE	88889
Feb. 05, 2007	TEAS RESPONSE TO OFFICE ACTION RECEIVED	
Dec. 14, 2006	NON-FINAL ACTION E-MAILED	6325
Dec. 14, 2006	NON-FINAL ACTION WRITTEN	76795
Dec. 07, 2006	ASSIGNED TO EXAMINER	76795
Aug. 18, 2006	NEW APPLICATION ENTERED IN TRAM	

Maintenance Filings or Post Registration Information

Affidavit of Continued Use: Section 8 - Accepted

Affidavit of Incontestability: Section 15 - Accepted

TM Staff and Location Information

TM Staff Information - None

File Location

Current Location: TMEG LAW OFFICE 104 **Date in Location:** Oct. 29, 2014

United States of America

United States Patent and Trademark Office

Reg. No. 4,250,217

Registered Nov. 27, 2012

Int. Cls.: 5, 35, 41, 42 and 44

TRADEMARK

SERVICE MARK

PRINCIPAL REGISTER

CELGENE CORPORATION (DELAWARE CORPORATION)
86 MORRIS AVENUE
SUMMIT, NJ 07901

FOR: PHARMACEUTICAL PREPARATIONS FOR USE IN THE TREATMENT OF IMMUNOLOGICAL, INFLAMMATORY AND NEUROLOGICAL DISORDERS , IN CLASS 5 (U.S. CLS. 6, 18, 44, 46, 51 AND 52).

FIRST USE 9-29-1998; IN COMMERCE 9-29-1998.

FOR: ADMINISTRATION OF PATIENT REIMBURSEMENT PROGRAMS; ADMINISTERING PHARMACY REIMBURSEMENT PROGRAMS AND SERVICES, IN CLASS 35 (U.S. CLS. 100, 101 AND 102).

FIRST USE 0-0-1986; IN COMMERCE 0-0-1986.

FOR: EDUCATIONAL CLASSES AND PROGRAMS IN THE FIELD OF THALIDOMIDE AND SAFETY ISSUES PERTAINING TO THALIDOMIDE, AND DISTRIBUTION OF WRITTEN MATERIALS THEREWITH; EDUCATION SERVICES, NAMELY, PROVIDING MENTORING, TUTORING, CLASSES, SEMINARS, AND WORKSHOPS IN THE FIELDS OF HIGHLIGHTING THE ADVANCEMENTS MADE IN CANCER TREATMENTS AND DISCUSSING THE IMPORTANCE OF CONTINUING RESEARCH TO DEVELOP INNOVATIVE NEW TREATMENTS, IN CLASS 41 (U.S. CLS. 100, 101 AND 107).

FIRST USE 0-0-1986; IN COMMERCE 0-0-1986.

FOR: DEVELOPMENT AND TESTING SERVICES IN THE FIELDS OF BIOTECHNOLOGY, CHEMISTRY AND PHARMACEUTICALS; PROVIDING AN INTERACTIVE WEB SITE THAT ENABLES USERS TO ENTER, ACCESS, TRACK, MONITOR AND GENERATE HEALTH AND MEDICAL INFORMATION AND REPORTS; SCIENTIFIC STUDY AND RESEARCH IN THE FIELDS OF THE PREVENTION, TREATMENT AND MANAGEMENT OF ILLNESS, HEALTH CARE DELIVERY AND THE SCIENTIFIC ASPECTS OF HEALTH CARE POLICY, HEALTH CARE COST MANAGEMENT AND FINANCING AS THESE FIELDS IMPACT ON QUALITY OF HEALTH CARE; RESEARCH IN THE FIELDS OF CHEMICALS AND PHARMACEUTICALS; RESEARCH AND TESTING SERVICES IN THE FIELDS OF CHEMICALS AND PHARMACEUTICALS; RESEARCH AND DEVELOPMENT OF NEW PRODUCTS FOR OTHERS IN THE FIELDS OF CHEMICALS AND PHARMACEUTICALS; PROVIDING

David J. Kappos

Director of the United States Patent and Trademark Office

Reg. No. 4,250,217 CLINICAL LABORATORY TESTING SERVICES, NAMELY, PHARMACOGENETIC TESTS, PREDICTIVE MEDICAL TESTS, PERSONALIZED MEDICAL TESTS, GENE SEQUENCING-BASED TESTS AND GENOTYPING BASED ON THE ASSESSMENT, DEVELOPMENT AND APPLICATION OF GENOMIC DISCOVERIES IN THE PHARMACEUTICAL, INFORMATICS AND CLINICAL DIAGNOSTIC INDUSTRIES; SCIENTIFIC RESEARCH SERVICES; SCIENTIFIC RESEARCH, NAMELY, DEVELOPMENT OF PHARMACEUTICALS OR DIAGNOSTIC METHODS FOR OTHERS, IN CLASS 42 (U.S. CLS. 100 AND 101).

FIRST USE 0-0-1986; IN COMMERCE 0-0-1986.

FOR: PROVIDING ON-LINE INFORMATION IN THE FIELD OF DIAGNOSIS AND TREATMENT OF CANCER; PROVIDING AN ON-LINE COMPUTER DATABASE FEATURING INFORMATION RELATING TO DIAGNOSIS AND TREATMENT OF CANCER; PROVIDING MEDICAL AND PHARMACEUTICAL INFORMATION SERVICES; PROVIDING LINKS TO WEB SITES OF OTHERS FEATURING INFORMATION ABOUT THE DIAGNOSIS AND TREATMENT OF CANCER, IN CLASS 44 (U.S. CLS. 100 AND 101).

FIRST USE 6-28-2001; IN COMMERCE 6-28-2001.

OWNER OF U.S. REG. NOS. 2,894,547, 3,439,630 AND OTHERS.

THE COLOR(S) BLUE IS/ARE CLAIMED AS A FEATURE OF THE MARK.

THE MARK CONSISTS OF A BLUE DESIGN IN THE SHAPE OF A "C" WITH THE WORDS "CELGENE" IN BLUE.

SER. NO. 85-637,385, FILED 5-29-2012.

TEJBIR SINGH, EXAMINING ATTORNEY

REQUIREMENTS TO MAINTAIN YOUR FEDERAL TRADEMARK REGISTRATION

WARNING: YOUR REGISTRATION WILL BE CANCELLED IF YOU DO NOT FILE THE DOCUMENTS BELOW DURING THE SPECIFIED TIME PERIODS.

Requirements in the First Ten Years*
What and When to File:

First Filing Deadline: You must file a Declaration of Use (or Excusable Nonuse) between the 5th and 6th years after the registration date. *See* 15 U.S.C. §§1058, 1141k. If the declaration is accepted, the registration will continue in force for the remainder of the ten-year period, calculated from the registration date, unless cancelled by an order of the Commissioner for Trademarks or a federal court.

Second Filing Deadline: You must file a Declaration of Use (or Excusable Nonuse) **and** an Application for Renewal between the 9th and 10th years after the registration date.* *See* 15 U.S.C. §1059.

Requirements in Successive Ten-Year Periods*
What and When to File:

You must file a Declaration of Use (or Excusable Nonuse) **and** an Application for Renewal between every 9th and 10th-year period, calculated from the registration date.*

Grace Period Filings*

The above documents will be accepted as timely if filed within six months after the deadlines listed above with the payment of an additional fee.

The United States Patent and Trademark Office (USPTO) will NOT send you any future notice or reminder of these filing requirements.

***ATTENTION MADRID PROTOCOL REGISTRANTS:** The holder of an international registration with an extension of protection to the United States under the Madrid Protocol must timely file the Declarations of Use (or Excusable Nonuse) referenced above directly with the USPTO. The time periods for filing are based on the U.S. registration date (not the international registration date). The deadlines and grace periods for the Declarations of Use (or Excusable Nonuse) are identical to those for nationally issued registrations. *See* 15 U.S.C. §§1058, 1141k. However, owners of international registrations do not file renewal applications at the USPTO. Instead, the holder must file a renewal of the underlying international registration at the International Bureau of the World Intellectual Property Organization, under Article 7 of the Madrid Protocol, before the expiration of each ten-year term of protection, calculated from the date of the international registration. *See* 15 U.S.C. §1141j. For more information and renewal forms for the international registration, see http://www.wipo.int/madrid/en/.

NOTE: Fees and requirements for maintaining registrations are subject to change. Please check the USPTO website for further information. With the exception of renewal applications for registered extensions of protection, you can file the registration maintenance documents referenced above online at http://www.uspto.gov.

Generated on: This page was generated by TSDR on 2017-11-06 13:11:01 EST

Mark: C CELGENE

US Serial Number: 85637385

Application Filing Date: May 29, 2012

US Registration Number: 4250217

Registration Date: Nov. 27, 2012

Register: Principal

Mark Type: Trademark, Service Mark

Status: Registered. The registration date is used to determine when post-registration maintenance documents are due.

Status Date: Nov. 27, 2012

Publication Date: Sep. 11, 2012

Mark Information

Mark Literal Elements: C CELGENE

Standard Character Claim: No

Mark Drawing Type: 3 - AN ILLUSTRATION DRAWING WHICH INCLUDES WORD(S)/ LETTER(S)/NUMBER(S)

Description of Mark: The mark consists of a blue design in the shape of a "c" with the words "CELGENE" in blue.

Color Drawing: Yes

Color(s) Claimed: The color(s) blue is/are claimed as a feature of the mark.

Design Search Code(s): 26.17.09 - Bands, curved; Bars, curved; Curved line(s), band(s) or bar(s); Lines, curved
27.03.01 - Geometric figures forming letters, numerals or punctuation

Related Properties Information

Claimed Ownership of US Registrations: 2894547, 3014168, 3439630 and others

Goods and Services

Note: The following symbols indicate that the registrant/owner has amended the goods/services:

- Brackets [..] indicate deleted goods/services;
- Double parenthesis ((..)) identify any goods/services not claimed in a Section 15 affidavit of incontestability; and
- Asterisks *..* identify additional (new) wording in the goods/services.

For: pharmaceutical preparations for use in the treatment of immunological, inflammatory and neurological disorders

International Class(es): 005 - Primary Class

U.S Class(es): 006, 018, 044, 046, 051, 052

Class Status: ACTIVE

Basis: 1(a)

First Use: Sep. 29, 1998

Use in Commerce: Sep. 29, 1998

For: Administration of patient reimbursement programs; administering pharmacy reimbursement programs and services

International Class(es): 035 - Primary Class

U.S Class(es): 100, 101, 102

Class Status: ACTIVE

Basis: 1(a)

First Use: 1986 **Use in Commerce:** 1986

For: educational classes and programs in the field of thalidomide and safety issues pertaining to thalidomide, and distribution of written materials therewith; education services, namely, providing mentoring, tutoring, classes, seminars, and workshops in the fields of highlighting the advancements made in cancer treatments and discussing the importance of continuing research to develop innovative new treatments

International Class(es): 041 - Primary Class **U.S Class(es):** 100, 101, 107

Class Status: ACTIVE

Basis: 1(a)

First Use: 1986 **Use in Commerce:** 1986

For: Development and testing services in the fields of biotechnology, chemistry and pharmaceuticals; providing an interactive web site that enables users to enter, access, track, monitor and generate health and medical information and reports; scientific study and research in the fields of the prevention, treatment and management of illness, health care delivery and the scientific aspects of health care policy, health care cost management and financing as these fields impact on quality of health care; research in the fields of chemicals and pharmaceuticals; research and testing services in the fields of chemicals and pharmaceuticals; research and development of new products for others in the fields of chemicals and pharmaceuticals; providing clinical laboratory testing services, namely, pharmacogenetic tests, predictive medical tests, personalized medical tests, gene sequencing-based tests and genotyping based on the assessment, development and application of genomic discoveries in the pharmaceutical, informatics and clinical diagnostic industries; scientific research services; scientific research, namely, development of pharmaceuticals or diagnostic methods for others

International Class(es): 042 - Primary Class **U.S Class(es):** 100, 101

Class Status: ACTIVE

Basis: 1(a)

First Use: 1986 **Use in Commerce:** 1986

For: providing on-line information in the field of diagnosis and treatment of cancer; providing an on-line computer database featuring information relating to diagnosis and treatment of cancer; providing medical and pharmaceutical information services; providing links to web sites of others featuring information about the diagnosis and treatment of cancer

International Class(es): 044 - Primary Class **U.S Class(es):** 100, 101

Class Status: ACTIVE

Basis: 1(a)

First Use: Jun. 28, 2001 **Use in Commerce:** Jun. 28, 2001

Basis Information (Case Level)

Filed Use:	Yes	**Currently Use:**	Yes	**Amended Use:**	No
Filed ITU:	No	**Currently ITU:**	No	**Amended ITU:**	No
Filed 44D:	No	**Currently 44D:**	No	**Amended 44D:**	No
Filed 44E:	No	**Currently 44E:**	No	**Amended 44E:**	No
Filed 66A:	No	**Currently 66A:**	No		
Filed No Basis:	No	**Currently No Basis:**	No		

Current Owner(s) Information

Owner Name: Celgene Corporation

Owner Address: 86 Morris Avenue
Summit, NEW JERSEY 07901
UNITED STATES

Legal Entity Type: CORPORATION **State or Country Where Organized:** DELAWARE

Attorney/Correspondence Information

Attorney of Record

Attorney Name: Camille M. Miller **Docket Number:** CELG-0393US2

Attorney Primary cmiller@cozen.com **Attorney Email** No

Email Address:		**Authorized:**	

Correspondent

Correspondent Name/Address:	CAMILLE M. MILLER COZEN O'CONNOR 1650 MARKET ST One Liberty Place PHILADELPHIA, PENNSYLVANIA 19103-3527 UNITED STATES
Phone:	2156657273
Fax:	2157012273
Correspondent e-mail:	cmiller@cozen.com
Correspondent e-mail Authorized:	Yes

Domestic Representative - Not Found

Prosecution History

Date	Description	Proceeding Number
Jul. 28, 2015	TEAS CHANGE OF CORRESPONDENCE RECEIVED	
Nov. 27, 2012	REGISTERED-PRINCIPAL REGISTER	
Sep. 11, 2012	OFFICIAL GAZETTE PUBLICATION CONFIRMATION E-MAILED	
Sep. 11, 2012	PUBLISHED FOR OPPOSITION	
Aug. 22, 2012	NOTIFICATION OF NOTICE OF PUBLICATION E-MAILED	
Aug. 07, 2012	LAW OFFICE PUBLICATION REVIEW COMPLETED	73296
Aug. 07, 2012	ASSIGNED TO LIE	73296
Jul. 23, 2012	APPROVED FOR PUB - PRINCIPAL REGISTER	
Jul. 23, 2012	EXAMINER'S AMENDMENT ENTERED	88888
Jul. 23, 2012	NOTIFICATION OF EXAMINERS AMENDMENT E-MAILED	6328
Jul. 23, 2012	EXAMINERS AMENDMENT E-MAILED	6328
Jul. 23, 2012	EXAMINERS AMENDMENT -WRITTEN	80804
Jul. 23, 2012	ASSIGNED TO EXAMINER	80804
Jun. 06, 2012	NOTICE OF DESIGN SEARCH CODE AND PSEUDO MARK MAILED	
Jun. 05, 2012	NEW APPLICATION OFFICE SUPPLIED DATA ENTERED IN TRAM	
Jun. 01, 2012	NEW APPLICATION ENTERED IN TRAM	

TM Staff and Location Information

TM Staff Information - None

File Location

Current Location:	PUBLICATION AND ISSUE SECTION	**Date in Location:**	Nov. 27, 2012

United States of America
United States Patent and Trademark Office

CTI BIOPHARMA

Reg. No. 5,166,752

Registered Mar. 21, 2017

Int. Cl.: 5, 41, 42

Service Mark

Trademark

Principal Register

CTI BIOPHARMA CORP. (WASHINGTON CORPORATION)
3101 WESTERN AVENUE
SEATTLE, WA 98121

CLASS 5: Pharmaceutical preparations and substances for the treatment of cancer and for use in chemotherapy treatment; Pharmaceutical preparations and substances for the treatment of immunological, oncological, inflammatory and infectious diseases and disorders; Pharmaceutical preparations used for the treatment of conditions secondary to the oncologic, immunological and inflammatory diseases; Pharmaceutical preparations and substances for the management and treatment of pain accompanying either the disease process or the associated treatment regimens

FIRST USE 12-18-2015; IN COMMERCE 12-18-2015

CLASS 41: Conducting seminars, classes, workshops, and training in the fields of pharmaceutical products and the treatment of medical disorders, the life sciences, clinical trials, health, medicine, oncology, hematology, cancer, and genetic disorders, and providing course materials in connection therewith; Online publications in the nature of articles, journals, and newsletters in the fields of pharmaceuticals and the treatment of medical disorders, the life sciences, clinical trials, health, medicine, oncology, hematology, cancer, and genetic disorders

FIRST USE 5-31-2014; IN COMMERCE 5-31-2014

CLASS 42: Research, development, engineering, testing, product evaluation, and inspection in the field of pharmaceutical preparations and products; Pharmaceutical research and development; Providing technical consultation in the field of pharmaceutical product research and development; Medical and scientific research, namely, conducting clinical trials for others for pharmaceutical preparations used for the treatment of cancer, immunological, inflammatory and infectious diseases, and pain; Scientific research, consulting, and advice in the fields of biotechnology, pharmaceutical research and development, and the life sciences; Pharmaceutical, medical and laboratory research services in the fields of pharmaceuticals, cancer, genetic disorders, and the life sciences; Providing medical testing services for research purposes and medical and scientific research information in the fields of pharmaceuticals, the life sciences, clinical trials, medicine, oncology, hematology, cancer, disease classification, and genetic disorders; and consultation related to the foregoing

FIRST USE 5-31-2014; IN COMMERCE 5-31-2014

THE MARK CONSISTS OF STANDARD CHARACTERS WITHOUT CLAIM TO ANY PARTICULAR FONT STYLE, SIZE OR COLOR

OWNER OF U.S. REG. NO. 1919206, 2674894, 3715268

Michelle K. Lee

Director of the United States Patent and Trademark Office

No claim is made to the exclusive right to use the following apart from the mark as shown: "BIOPHARMA"

SER. NO. 86-282,220, FILED 05-15-2014
YAT SYE I LEE, EXAMINING ATTORNEY

REQUIREMENTS TO MAINTAIN YOUR FEDERAL TRADEMARK REGISTRATION

WARNING: YOUR REGISTRATION WILL BE CANCELLED IF YOU DO NOT FILE THE DOCUMENTS BELOW DURING THE SPECIFIED TIME PERIODS.

Requirements in the First Ten Years*
What and When to File:

- ***First Filing Deadline:*** You must file a Declaration of Use (or Excusable Nonuse) between the 5th and 6th years after the registration date. See 15 U.S.C. §§1058 1141k. If the declaration is accepted, the registration will continue in force for the remainder of the ten-year period, calculated from the registration date, unless cancelled by an order of the Commissioner for Trademarks or a federal court.

- ***Second Filing Deadline:*** You must file a Declaration of Use (or Excusable Nonuse) and an Application for Renewal between the 9th and 10th years after the registration date.* See 15 U.S.C. §1059.

Requirements in Successive Ten-Year Periods*
What and When to File:

- You must file a Declaration of Use (or Excusable Nonuse) and an Application for Renewal between every 9th and 10th-year period, calculated from the registration date.*

Grace Period Filings*

The above documents will be accepted as timely if filed within six months after the deadlines listed above with the payment of an additional fee.

***ATTENTION MADRID PROTOCOL REGISTRANTS:** The holder of an international registration with an extension of protection to the United States under the Madrid Protocol must timely file the Declarations of Use (or Excusable Nonuse) referenced above directly with the United States Patent and Trademark Office (USPTO). The time periods for filing are based on the U.S. registration date (not the international registration date). The deadlines and grace periods for the Declarations of Use (or Excusable Nonuse) are identical to those for nationally issued registrations. See 15 U.S.C. §§1058, 1141k. However, owners of international registrations do not file renewal applications at the USPTO. Instead, the holder must file a renewal of the underlying international registration at the International Bureau of the World Intellectual Property Organization, under Article 7 of the Madrid Protocol, before the expiration of each ten-year term of protection, calculated from the date of the international registration. See 15 U.S.C. §1141j. For more information and renewal forms for the international registration, see http://www.wipo.int/madrid/en/.

NOTE: Fees and requirements for maintaining registrations are subject to change. Please check the USPTO website for further information. With the exception of renewal applications for registered extensions of protection, you can file the registration maintenance documents referenced above online at http://www.uspto.gov.

NOTE: A courtesy e-mail reminder of USPTO maintenance filing deadlines will be sent to trademark owners/holders who authorize e-mail communication and maintain a current e-mail address with the USPTO. To ensure that e-mail is authorized and your address is current, please use the Trademark Electronic Application System (TEAS) Correspondence Address and Change of Owner Address Forms available at http://www.uspto.gov.

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Mark: CTI BIOPHARMA

CTI BIOPHARMA

US Serial Number: 86282220

Application Filing Date: May 15, 2014

US Registration Number: 5166752

Registration Date: Mar. 21, 2017

Register: Principal

Mark Type: Trademark, Service Mark

TM5 Common Status Descriptor:

LIVE/REGISTRATION/Issued and Active

The trademark application has been registered with the Office.

Status: Registered. The registration date is used to determine when post-registration maintenance documents are due.

Status Date: Mar. 21, 2017

Publication Date: Dec. 15, 2015

Notice of Allowance Date: Feb. 09, 2016

Mark Information

Mark Literal Elements: CTI BIOPHARMA

Standard Character Claim: Yes. The mark consists of standard characters without claim to any particular font style, size, or color.

Mark Drawing Type: 4 - STANDARD CHARACTER MARK

Disclaimer: "BIOPHARMA"

Related Properties Information

Claimed Ownership of US Registrations: 1919206, 2674894, 3715268 and others

Goods and Services

Note: The following symbols indicate that the registrant/owner has amended the goods/services:

- Brackets [..] indicate deleted goods/services;
- Double parenthesis ((..)) identify any goods/services not claimed in a Section 15 affidavit of incontestability; and
- Asterisks *..* identify additional (new) wording in the goods/services.

For: Pharmaceutical preparations and substances for the treatment of cancer and for use in chemotherapy treatment; Pharmaceutical preparations and substances for the treatment of immunological, oncological, inflammatory and infectious diseases and disorders; Pharmaceutical preparations used for the treatment of conditions secondary to the oncologic, immunological and inflammatory diseases; Pharmaceutical preparations and substances for the management and treatment of pain accompanying either the disease process or the associated treatment regimens

International Class(es): 005 - Primary Class

U.S Class(es): 006, 018, 044, 046, 051, 052

Class Status: ACTIVE

Basis: 1(a)

First Use: Dec. 18, 2015

Use in Commerce: Dec. 18, 2015

For: Conducting seminars, classes, workshops, and training in the fields of pharmaceutical products and the treatment of medical disorders, the life sciences, clinical trials, health, medicine, oncology, hematology, cancer, and genetic disorders, and providing course materials in connection therewith; Online publications in the nature of articles, journals, and newsletters in the fields of pharmaceuticals and the treatment of medical disorders, the life sciences, clinical trials, health, medicine, oncology, hematology, cancer, and genetic disorders

International 041 - Primary Class

U.S Class(es): 100, 101, 107

Class(es):

Class Status: ACTIVE

Basis: 1(a)

First Use: May 31, 2014 **Use in Commerce:** May 31, 2014

For: Research, development, engineering, testing, product evaluation, and inspection in the field of pharmaceutical preparations and products; Pharmaceutical research and development; Providing technical consultation in the field of pharmaceutical product research and development; Medical and scientific research, namely, conducting clinical trials for others for pharmaceutical preparations used for the treatment of cancer, immunological, inflammatory and infectious diseases, and pain; Scientific research, consulting, and advice in the fields of biotechnology, pharmaceutical research and development, and the life sciences; Pharmaceutical, medical and laboratory research services in the fields of pharmaceuticals, cancer, genetic disorders, and the life sciences; Providing medical testing services for research purposes and medical and scientific research information in the fields of pharmaceuticals, the life sciences, clinical trials, medicine, oncology, hematology, cancer, disease classification, and genetic disorders; and consultation related to the foregoing

International Class(es): 042 - Primary Class **U.S Class(es):** 100, 101

Class Status: ACTIVE

Basis: 1(a)

First Use: May 31, 2014 **Use in Commerce:** May 31, 2014

Basis Information (Case Level)

Filed Use:	No	**Currently Use:**	Yes	**Amended Use:**	No
Filed ITU:	Yes	**Currently ITU:**	No	**Amended ITU:**	No
Filed 44D:	No	**Currently 44D:**	No	**Amended 44D:**	No
Filed 44E:	No	**Currently 44E:**	No	**Amended 44E:**	No
Filed 66A:	No	**Currently 66A:**	No		
Filed No Basis:	No	**Currently No Basis:**	No		

Current Owner(s) Information

Owner Name: CTI BIOPHARMA CORP.

Owner Address: 3101 WESTERN AVENUE
SEATTLE, WASHINGTON UNITED STATES 98121

Legal Entity Type: CORPORATION **State or Country Where Organized:** WASHINGTON

Attorney/Correspondence Information

Attorney of Record

Attorney Name: Frances M. Jagla **Docket Number:** 119854.0013

Attorney Primary Email Address: trademarks@lanepowell.com **Attorney Email Authorized:** Yes

Correspondent

Correspondent Name/Address: FRANCES M. JAGLA
LANE POWELL PC
601 SW 2ND AVE STE 2100
PORTLAND, OREGON UNITED STATES 97204

Phone: 2062237749 **Fax:** 5037782100

Correspondent e-mail: trademarks@lanepowell.com JaglaF@LanePowell.com **Correspondent e-mail Authorized:** Yes

Domestic Representative - Not Found

Prosecution History

Date	Description	Proceeding Number
Mar. 21, 2017	REGISTERED-PRINCIPAL REGISTER	
Feb. 16, 2017	NOTICE OF ACCEPTANCE OF STATEMENT OF USE E-MAILED	
Feb. 15, 2017	ALLOWED PRINCIPAL REGISTER - SOU ACCEPTED	
Jan. 25, 2017	TEAS/EMAIL CORRESPONDENCE ENTERED	76568

Jan. 25, 2017	CORRESPONDENCE RECEIVED IN LAW OFFICE	76568
Jan. 19, 2017	TEAS RESPONSE TO OFFICE ACTION RECEIVED	
Jan. 19, 2017	TEAS EXTENSION RECEIVED	
Sep. 26, 2016	NOTIFICATION OF NON-FINAL ACTION E-MAILED	
Sep. 26, 2016	NON-FINAL ACTION E-MAILED	
Sep. 26, 2016	SU - NON-FINAL ACTION - WRITTEN	83172
Sep. 02, 2016	NOTICE OF APPROVAL OF EXTENSION REQUEST E-MAILED	
Sep. 01, 2016	STATEMENT OF USE PROCESSING COMPLETE	70565
Aug. 08, 2016	USE AMENDMENT FILED	70565
Sep. 01, 2016	EXTENSION 1 GRANTED	70565
Aug. 08, 2016	EXTENSION 1 FILED	70565
Aug. 31, 2016	CASE ASSIGNED TO INTENT TO USE PARALEGAL	70565
Aug. 08, 2016	TEAS EXTENSION RECEIVED	
Aug. 08, 2016	TEAS STATEMENT OF USE RECEIVED	
May 06, 2016	ATTORNEY/DOM.REP.REVOKED AND/OR APPOINTED	
May 06, 2016	TEAS REVOKE/APP/CHANGE ADDR OF ATTY/DOM REP RECEIVED	
Feb. 09, 2016	NOA E-MAILED - SOU REQUIRED FROM APPLICANT	
Dec. 15, 2015	OFFICIAL GAZETTE PUBLICATION CONFIRMATION E-MAILED	
Dec. 15, 2015	PUBLISHED FOR OPPOSITION	
Nov. 25, 2015	NOTIFICATION OF NOTICE OF PUBLICATION E-MAILED	
Nov. 06, 2015	LAW OFFICE PUBLICATION REVIEW COMPLETED	76568
Oct. 26, 2015	APPROVED FOR PUB - PRINCIPAL REGISTER	
Oct. 20, 2015	TEAS/EMAIL CORRESPONDENCE ENTERED	88889
Oct. 19, 2015	CORRESPONDENCE RECEIVED IN LAW OFFICE	88889
Oct. 19, 2015	TEAS REQUEST FOR RECONSIDERATION RECEIVED	
Apr. 29, 2015	NOTIFICATION OF FINAL REFUSAL EMAILED	
Apr. 29, 2015	FINAL REFUSAL E-MAILED	
Apr. 29, 2015	FINAL REFUSAL WRITTEN	83172
Mar. 11, 2015	TEAS/EMAIL CORRESPONDENCE ENTERED	76568
Mar. 11, 2015	CORRESPONDENCE RECEIVED IN LAW OFFICE	76568
Mar. 06, 2015	ASSIGNED TO LIE	76568
Feb. 26, 2015	TEAS RESPONSE TO OFFICE ACTION RECEIVED	
Aug. 31, 2014	NOTIFICATION OF NON-FINAL ACTION E-MAILED	6325
Aug. 31, 2014	NON-FINAL ACTION E-MAILED	6325
Aug. 31, 2014	NON-FINAL ACTION WRITTEN	83172
Aug. 31, 2014	ASSIGNED TO EXAMINER	83172
Jul. 02, 2014	AUTOMATIC UPDATE OF ASSIGNMENT OF OWNERSHIP	
May 29, 2014	NOTICE OF PSEUDO MARK E-MAILED	
May 28, 2014	NEW APPLICATION OFFICE SUPPLIED DATA ENTERED IN TRAM	
May 19, 2014	NEW APPLICATION ENTERED IN TRAM	

TM Staff and Location Information

TM Staff Information - None

File Location

Current Location: PUBLICATION AND ISSUE SECTION **Date in Location:** Feb. 15, 2017

Assignment Abstract Of Title Information

Summary

Total Assignments: 1 **Registrant:** CTI BIOPHARMA CORP.

Assignment 1 of 1

Conveyance: CHANGE OF NAME

Reel/Frame: 5309/0737 **Pages:** 3

Date Recorded: Jun. 26, 2014

Supporting assignment-tm-5309-0737.pdf

Documents:	

Assignor

Name:	CELL THERAPEUTICS, INC.	**Execution Date:**	May 30, 2014
Legal Entity Type:	CORPORATION	**State or Country Where Organized:**	WASHINGTON

Assignee

Name:	CTI BIOPHARMA CORP.		
Legal Entity Type:	CORPORATION	**State or Country Where Organized:**	WASHINGTON
Address:	3101 WESTERN AVENUE SEATTLE, WASHINGTON 98121		

Correspondent

Correspondent Name:	JOANNE LUDOVICI
Correspondent Address:	500 NORTH CAPITOL STREET, NW MCDERMOTT WILL & EMERY LLP WASHINGTON, DC 20001

Domestic Representative - Not Found

Int. Cls.: 5, 41, and 44

Prior U.S. Cls.: 6, 18, 44, 46, 51, 52, 100, 101, and 107

United States Patent and Trademark Office

Reg. No. 3,473,825

Registered July 22, 2008

TRADEMARK
SERVICE MARK
PRINCIPAL REGISTER

DAYTRANA

SHIRE PHARMACEUTICALS IRELAND LIMITED (IRELAND CORPORATION)
6 FITZWILLIAM SQUARE
DUBLIN, IRELAND 2

FOR: PHARMACEUTICAL PREPARATIONS FOR THE TREATMENT OF DISORDERS OF THE CENTRAL NERVOUS SYSTEM , IN CLASS 5 (U.S. CLS. 6, 18, 44, 46, 51 AND 52).

FIRST USE 6-0-2005; IN COMMERCE 6-0-2005.

FOR: PROVIDING SEMINARS, CONFERENCES AND INSTRUCTIONAL CLASSES FEATURING INFORMATION REGARDING PHARMACEUTICAL PRODUCTS AND SERVICES, IN CLASS 41 (U.S. CLS. 100, 101 AND 107).

FIRST USE 6-0-2005; IN COMMERCE 6-0-2005.

FOR: PROVIDING MEDICAL INFORMATION IN THE FIELD OF PHARMACEUTICAL PRODUCTS AND SERVICES, IN CLASS 44 (U.S. CLS. 100 AND 101).

FIRST USE 6-0-2005; IN COMMERCE 6-0-2005.

THE MARK CONSISTS OF STANDARD CHARACTERS WITHOUT CLAIM TO ANY PARTICULAR FONT, STYLE, SIZE, OR COLOR.

SN 78-776,854, FILED 12-20-2005.

GINA FINK, EXAMINING ATTORNEY

Generated on: This page was generated by TSDR on 2017-11-06 14:11:40 EST

Mark: DAYTRANA

DAYTRANA

US Serial Number: 78776854

Application Filing Date: Dec. 20, 2005

US Registration Number: 3473825

Registration Date: Jul. 22, 2008

Register: Principal

Mark Type: Trademark, Service Mark

Status: A Sections 8 and 15 combined declaration has been accepted and acknowledged.

Status Date: Jul. 31, 2014

Publication Date: Nov. 21, 2006

Notice of Allowance Date: Feb. 13, 2007

Mark Information

Mark Literal Elements: DAYTRANA

Standard Character Claim: Yes. The mark consists of standard characters without claim to any particular font style, size, or color.

Mark Drawing Type: 4 - STANDARD CHARACTER MARK

Goods and Services

Note: The following symbols indicate that the registrant/owner has amended the goods/services:

- Brackets [..] indicate deleted goods/services;
- Double parenthesis ((...)) identify any goods/services not claimed in a Section 15 affidavit of incontestability; and
- Asterisks *...* identify additional (new) wording in the goods/services.

For: Pharmaceutical preparations for the treatment of disorders of the central nervous system

International Class(es): 005 - Primary Class

U.S Class(es): 006, 018, 044, 046, 051, 052

Class Status: ACTIVE

Basis: 1(a)

First Use: Jun. 2005

Use in Commerce: Jun. 2005

For: Providing seminars, conferences and instructional classes featuring information regarding pharmaceutical products and services

International Class(es): 041 - Primary Class

U.S Class(es): 100, 101, 107

Class Status: ACTIVE

Basis: 1(a)

First Use: Jun. 2005

Use in Commerce: Jun. 2005

For: Providing medical information in the field of pharmaceutical products and services

International Class(es): 044 - Primary Class

U.S Class(es): 100, 101

Class Status: ACTIVE

Basis: 1(a)

First Use: Jun. 2005

Use in Commerce: Jun. 2005

Basis Information (Case Level)

Filed Use: No

Currently Use: Yes

Amended Use: No

Filed ITU:	Yes	**Currently ITU:**	No	**Amended ITU:**	No
Filed 44D:	No	**Currently 44D:**	No	**Amended 44D:**	No
Filed 44E:	No	**Currently 44E:**	No	**Amended 44E:**	No
Filed 66A:	No	**Currently 66A:**	No		
Filed No Basis:	No	**Currently No Basis:**	No		

Current Owner(s) Information

Owner Name: NOVEN THERAPEUTICS, LLC

Owner Address: 11960 SW 144 STREET
MIAMI, FLORIDA 33186
UNITED STATES

Legal Entity Type: LIMITED LIABILITY COMPANY

State or Country Where Organized: DELAWARE

Attorney/Correspondence Information

Attorney of Record

Attorney Name: Jay G. Kolman, Esq.

Docket Number: 005157.00019

Attorney Primary Email Address: jkolman@noven.com

Attorney Email Authorized: Yes

Correspondent

Correspondent Name/Address: Jay G. Kolman, Esq.
Noven Therapeutics, LLC
11960 S.W. 144 Street
Miami, FLORIDA 33186
UNITED STATES

Phone: 305.253.5099

Fax: 305.251.1887

Correspondent e-mail: jkolman@noven.com khoyt@noven.com

Correspondent e-mail Authorized: Yes

Domestic Representative

Domestic Representative Name: Helen Hill Minsker

Phone: 202-824-3000

Fax: 202-824-3001

Domestic Representative e-mail: BWPTOTM@bannerwitcoff.com

Domestic Representative e-mail Authorized: Yes

Prosecution History

Date	Description	Proceeding Number
Jul. 22, 2017	COURTESY REMINDER - SEC. 8 (10-YR)/SEC. 9 E-MAILED	
Jul. 31, 2014	NOTICE OF ACCEPTANCE OF SEC. 8 & 15 - E-MAILED	
Jul. 31, 2014	REGISTERED - SEC. 8 (6-YR) ACCEPTED & SEC. 15 ACK.	70132
Jul. 30, 2014	CASE ASSIGNED TO POST REGISTRATION PARALEGAL	70132
Jul. 15, 2014	TEAS SECTION 8 & 15 RECEIVED	
Oct. 20, 2010	AUTOMATIC UPDATE OF ASSIGNMENT OF OWNERSHIP	
Jul. 22, 2008	REGISTERED-PRINCIPAL REGISTER	
Jun. 17, 2008	LAW OFFICE REGISTRATION REVIEW COMPLETED	66213
Jun. 16, 2008	ALLOWED PRINCIPAL REGISTER - SOU ACCEPTED	
Jun. 06, 2008	TEAS/EMAIL CORRESPONDENCE ENTERED	66213
Jun. 06, 2008	CORRESPONDENCE RECEIVED IN LAW OFFICE	66213
Jun. 05, 2008	TEAS REQUEST FOR RECONSIDERATION RECEIVED	
Apr. 18, 2008	NOTIFICATION OF FINAL REFUSAL EMAILED	
Apr. 18, 2008	FINAL REFUSAL E-MAILED	
Apr. 18, 2008	SU - FINAL REFUSAL - WRITTEN	76464
Mar. 19, 2008	AMENDMENT FROM APPLICANT ENTERED	66213

Mar. 19, 2008	CORRESPONDENCE RECEIVED IN LAW OFFICE	66213
Mar. 19, 2008	ASSIGNED TO LIE	66213
Feb. 26, 2008	PAPER RECEIVED	
Sep. 03, 2007	NOTIFICATION OF NON-FINAL ACTION E-MAILED	
Sep. 03, 2007	NON-FINAL ACTION E-MAILED	
Sep. 03, 2007	SU - NON-FINAL ACTION - WRITTEN	76464
Sep. 01, 2007	STATEMENT OF USE PROCESSING COMPLETE	66154
Aug. 10, 2007	USE AMENDMENT FILED	66154
Aug. 10, 2007	PAPER RECEIVED	
Feb. 13, 2007	NOA MAILED - SOU REQUIRED FROM APPLICANT	
Nov. 21, 2006	PUBLISHED FOR OPPOSITION	
Nov. 01, 2006	NOTICE OF PUBLICATION	
Sep. 28, 2006	LAW OFFICE PUBLICATION REVIEW COMPLETED	76539
Sep. 27, 2006	ASSIGNED TO LIE	76539
Sep. 19, 2006	APPROVED FOR PUB - PRINCIPAL REGISTER	
Sep. 18, 2006	TEAS/EMAIL CORRESPONDENCE ENTERED	76985
Aug. 18, 2006	CORRESPONDENCE RECEIVED IN LAW OFFICE	76985
Aug. 18, 2006	TEAS RESPONSE TO OFFICE ACTION RECEIVED	
Jun. 19, 2006	NON-FINAL ACTION E-MAILED	6325
Jun. 19, 2006	NON-FINAL ACTION WRITTEN	76464
Jun. 19, 2006	ASSIGNED TO EXAMINER	76464
Dec. 28, 2005	NEW APPLICATION ENTERED IN TRAM	

Maintenance Filings or Post Registration Information

Affidavit of Continued Use: Section 8 - Accepted

Affidavit of Incontestability: Section 15 - Accepted

TM Staff and Location Information

TM Staff Information - None

File Location

Current Location: TMEG LAW OFFICE 109 **Date in Location:** Jul. 31, 2014

Assignment Abstract Of Title Information

Summary

Total Assignments: 1 **Registrant:** Shire Pharmaceuticals Ireland Limited

Assignment 1 of 1

Conveyance: ASSIGNS THE ENTIRE INTEREST

Reel/Frame: 4296/0182 **Pages:** 6

Date Recorded: Oct. 14, 2010

Supporting Documents: assignment-tm-4296-0182.pdf

Assignor

Name: SHIRE PHARMACEUTICALS IRELAND LIMITED **Execution Date:** Oct. 01, 2010

Legal Entity Type: CORPORATION **State or Country Where Organized:** IRELAND

Assignee

Name: NOVEN THERAPEUTICS, LLC

Legal Entity Type: LIMITED LIABILITY COMPANY **State or Country Where Organized:** DELAWARE

Address: 11960 SW 144 STREET
MIAMI, FLORIDA 33186

Correspondent

Correspondent Name:	JAY G. KOLMAN, ESQ.
Correspondent Address:	11960 SW 144 STREET MIAMI, FL 33186

Domestic Representative - Not Found

United States of America
United States Patent and Trademark Office

Reg. No. 4,653,200

Registered Dec. 9, 2014

Int. Cls.: 5, 41, and 44

TRADEMARK

SERVICE MARK

PRINCIPAL REGISTER

ENDO PHARMACEUTICALS INC. (DELAWARE CORPORATION)
1400 ATWATER DRIVE
MALVERN, PA 19355

FOR: A LINE OF PHARMACEUTICAL PREPARATIONS, NAMELY, ANALGESICS AND PAIN MANAGEMENT PREPARATIONS, PREPARATIONS FOR THE TREATMENT OF CANCERS, PREPARATIONS FOR THE TREATMENT OF UROLOGICAL DISEASES AND DISORDERS, PREPARATIONS FOR THE TREATMENT OF SCHIZOPHRENIA; PREPARATIONS FOR THE TREATMENT OF DISEASES AND DISORDERS OF THE ENDOCRINE SYSTEM, HORMONE REPLACEMENT PREPARATIONS, IN CLASS 5 (U.S. CLS. 6, 18, 44, 46, 51 AND 52).

FIRST USE 3-0-2012; IN COMMERCE 3-0-2012.

FOR: EDUCATIONAL SERVICES, NAMELY, CONDUCTING CLASSES, SEMINARS, AND WORKSHOPS IN THE FIELD OF MEDICAL DEVICES AND TECHNIQUES, NONE OF THE FOREGOING PRIMARILY IN THE FIELD OF ENDOCRINOLOGY OR USED TO IDENTIFY THE NAME OF OR USED IN CONNECTION WITH ANY CONFERENCES, CONVENTIONS, EXHIBITIONS OR EXPOSITIONS, IN CLASS 41 (U.S. CLS. 100, 101 AND 107).

FIRST USE 3-0-2012; IN COMMERCE 3-0-2012.

FOR: PROVIDING ONLINE INFORMATION ON THE SUBJECTS OF PHARMACEUTICAL PREPARATIONS, MEDICAL DEVICES AND TECHNIQUES, NONE OF THE FOREGOING PRIMARILY IN THE FIELD OF ENDOCRINOLOGY OR USED TO IDENTIFY THE NAME OF OR USED IN CONNECTION WITH ANY CONFERENCES, CONVENTIONS, EXHIBITIONS OR EXPOSITIONS, IN CLASS 44 (U.S. CLS. 100 AND 101).

FIRST USE 3-0-2012; IN COMMERCE 3-0-2012.

OWNER OF U.S. REG. NOS. 2,004,648, 2,921,176, AND OTHERS.

THE COLOR(S) GREY AND YELLOW IS/ARE CLAIMED AS A FEATURE OF THE MARK.

THE MARK CONSISTS OF THE LITERAL ELEMENT OF THE MARK "ENDO" SHOWN IN GREY IN LOWER CASE FONT. TO THE LEFT OF THE LITERAL ELEMENT IS THE LOGO

Michelle K. Lee

Deputy Director of the United States Patent and Trademark Office

Reg. No. 4,653,200 FORM OF THE LETTER "E" SHOWN IN TWO SHADES OF YELLOW IN LOWER CASE FONT.

SN 85-498,455, FILED 12-19-2011.

SOPHIA S. KIM, EXAMINING ATTORNEY

REQUIREMENTS TO MAINTAIN YOUR FEDERAL TRADEMARK REGISTRATION

WARNING: YOUR REGISTRATION WILL BE CANCELLED IF YOU DO NOT FILE THE DOCUMENTS BELOW DURING THE SPECIFIED TIME PERIODS.

Requirements in the First Ten Years*
What and When to File:

First Filing Deadline: You must file a Declaration of Use (or Excusable Nonuse) between the 5th and 6th years after the registration date. *See* 15 U.S.C. §§1058, 1141k. If the declaration is accepted, the registration will continue in force for the remainder of the ten-year period, calculated from the registration date, unless cancelled by an order of the Commissioner for Trademarks or a federal court.

Second Filing Deadline: You must file a Declaration of Use (or Excusable Nonuse) **and** an Application for Renewal between the 9th and 10th years after the registration date.* *See* 15 U.S.C. §1059.

Requirements in Successive Ten-Year Periods*
What and When to File:

You must file a Declaration of Use (or Excusable Nonuse) **and** an Application for Renewal between every 9th and 10th-year period, calculated from the registration date.*

Grace Period Filings*

The above documents will be accepted as timely if filed within six months after the deadlines listed above with the payment of an additional fee.

The United States Patent and Trademark Office (USPTO) will NOT send you any future notice or reminder of these filing requirements.

***ATTENTION MADRID PROTOCOL REGISTRANTS:** The holder of an international registration with an extension of protection to the United States under the Madrid Protocol must timely file the Declarations of Use (or Excusable Nonuse) referenced above directly with the USPTO. The time periods for filing are based on the U.S. registration date (not the international registration date). The deadlines and grace periods for the Declarations of Use (or Excusable Nonuse) are identical to those for nationally issued registrations. *See* 15 U.S.C. §§1058, 1141k. However, owners of international registrations do not file renewal applications at the USPTO. Instead, the holder must file a renewal of the underlying international registration at the International Bureau of the World Intellectual Property Organization, under Article 7 of the Madrid Protocol, before the expiration of each ten-year term of protection, calculated from the date of the international registration. *See* 15 U.S.C. §1141j. For more information and renewal forms for the international registration, see http://www.wipo.int/madrid/en/.

NOTE: Fees and requirements for maintaining registrations are subject to change. Please check the USPTO website for further information. With the exception of renewal applications for registered extensions of protection, you can file the registration maintenance documents referenced above online at http://www.uspto.gov.

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Mark: E ENDO

US Serial Number:	85498455	**Application Filing Date:**	Dec. 19, 2011
US Registration Number:	4653200	**Registration Date:**	Dec. 09, 2014
Register:	Principal		
Mark Type:	Trademark, Service Mark		
TM5 Common Status Descriptor:	LIVE/REGISTRATION/Issued and Active The trademark application has been registered with the Office.		
Status:	Registered. The registration date is used to determine when post-registration maintenance documents are due.		
Status Date:	Dec. 09, 2014		
Publication Date:	Sep. 24, 2013	**Notice of Allowance Date:**	Nov. 19, 2013

Mark Information

Mark Literal Elements:	E ENDO
Standard Character Claim:	No
Mark Drawing Type:	3 - AN ILLUSTRATION DRAWING WHICH INCLUDES WORD(S)/ LETTER(S)/NUMBER(S)
Description of Mark:	The mark consists of the literal element of the mark "ENDO" shown in grey in lower case font. To the left of the literal element is the logo form of the letter "E" shown in two shades of yellow in lower case font.
Color Drawing:	Yes
Color(s) Claimed:	The color(s) grey and yellow is/are claimed as a feature of the mark.
Design Search Code(s):	26.01.08 - Circles having letters or numerals as a border; Circles having punctuation as a border; Letters, numerals or punctuation forming or bordering the perimeter of a circle 26.01.21 - Circles that are totally or partially shaded. 26.07.28 - Diamond shapes (miscellaneous overall shape); Miscellaneous designs with overall diamond shape, including letters forming or comprising a diamond

Related Properties Information

International Registration Number:	1142442
International Application(s) /Registration(s) Based on this Property:	A0030366/1142442
Claimed Ownership of US Registrations:	2004648, 2317044, 2921176 and others

Goods and Services

Note: The following symbols indicate that the registrant/owner has amended the goods/services:

- Brackets [..] indicate deleted goods/services;
- Double parenthesis ((..)) identify any goods/services not claimed in a Section 15 affidavit of incontestability; and
- Asterisks *..* identify additional (new) wording in the goods/services.

For: A line of pharmaceutical preparations, namely, analgesics and pain management preparations, preparations for the treatment of cancers, preparations for the treatment of urological diseases and disorders, preparations for the treatment of schizophrenia; preparations for the treatment of diseases and disorders of the endocrine system, hormone replacement preparations

International Class(es): 005 - Primary Class **U.S Class(es):** 006, 018, 044, 046, 051, 052

Class Status: ACTIVE

Basis: 1(a)

First Use: Mar. 2012 **Use in Commerce:** Mar. 2012

For: Educational services, namely, conducting classes, seminars, and workshops in the field of medical devices and techniques, none of the foregoing primarily in the field of endocrinology or used to identify the name of or used in connection with any conferences, conventions, exhibitions or expositions

International Class(es): 041 - Primary Class **U.S Class(es):** 100, 101, 107

Class Status: ACTIVE

Basis: 1(a)

First Use: Mar. 2012 **Use in Commerce:** Mar. 2012

For: Providing online information on the subjects of pharmaceutical preparations, medical devices and techniques, none of the foregoing primarily in the field of endocrinology or used to identify the name of or used in connection with any conferences, conventions, exhibitions or expositions

International Class(es): 044 - Primary Class **U.S Class(es):** 100, 101

Class Status: ACTIVE

Basis: 1(a)

First Use: Mar. 2012 **Use in Commerce:** Mar. 2012

Basis Information (Case Level)

Filed Use:	No	**Currently Use:**	Yes	**Amended Use:**	No
Filed ITU:	Yes	**Currently ITU:**	No	**Amended ITU:**	No
Filed 44D:	No	**Currently 44D:**	No	**Amended 44D:**	No
Filed 44E:	No	**Currently 44E:**	No	**Amended 44E:**	No
Filed 66A:	No	**Currently 66A:**	No		
Filed No Basis:	No	**Currently No Basis:**	No		

Current Owner(s) Information

Owner Name: Endo Pharmaceuticals Inc.

Owner Address: 1400 Atwater Drive
Malvern, PENNSYLVANIA UNITED STATES 19355

Legal Entity Type: CORPORATION **State or Country Where Organized:** DELAWARE

Attorney/Correspondence Information

Attorney of Record

Attorney Name: Camille M. Miller

Attorney Primary Email Address: cmiller@cozen.com **Attorney Email Authorized:** Yes

Correspondent

Correspondent Name/Address: Camille M. Miller
Cozen O'Connor
1900 Market Street
Philadelphia, PENNSYLVANIA UNITED STATES 19103

Phone: 215-665-7273 **Fax:** 215-701-2273

Correspondent e-mail: cmiller@cozen.com **Correspondent e-mail Authorized:** Yes

Domestic Representative - Not Found

Prosecution History

Date	Description	Proceeding Number
Jun. 25, 2015	ATTORNEY/DOM.REP.REVOKED AND/OR APPOINTED	
Jun. 25, 2015	TEAS REVOKE/APP/CHANGE ADDR OF ATTY/DOM REP RECEIVED	
Dec. 09, 2014	REGISTERED-PRINCIPAL REGISTER	
Nov. 07, 2014	NOTICE OF ACCEPTANCE OF STATEMENT OF USE E-MAILED	
Nov. 06, 2014	ALLOWED PRINCIPAL REGISTER - SOU ACCEPTED	
Aug. 20, 2014	TEAS/EMAIL CORRESPONDENCE ENTERED	88889
Aug. 20, 2014	CORRESPONDENCE RECEIVED IN LAW OFFICE	88889
Aug. 20, 2014	TEAS RESPONSE TO OFFICE ACTION RECEIVED	
Aug. 14, 2014	NOTIFICATION OF NON-FINAL ACTION E-MAILED	
Aug. 14, 2014	NON-FINAL ACTION E-MAILED	
Aug. 14, 2014	SU - NON-FINAL ACTION - WRITTEN	73350
Jun. 12, 2014	STATEMENT OF USE PROCESSING COMPLETE	70565
May 19, 2014	USE AMENDMENT FILED	70565
Jun. 09, 2014	CASE ASSIGNED TO INTENT TO USE PARALEGAL	70565
May 19, 2014	TEAS STATEMENT OF USE RECEIVED	
May 19, 2014	APPLICANT/CORRESPONDENCE CHANGES (NON-RESPONSIVE) ENTERED	88888
May 19, 2014	TEAS CHANGE OF OWNER ADDRESS RECEIVED	
Mar. 26, 2014	ASSIGNMENT OF OWNERSHIP NOT UPDATED AUTOMATICALLY	
Nov. 19, 2013	NOA E-MAILED - SOU REQUIRED FROM APPLICANT	
Sep. 24, 2013	OFFICIAL GAZETTE PUBLICATION CONFIRMATION E-MAILED	
Sep. 24, 2013	PUBLISHED FOR OPPOSITION	
Sep. 04, 2013	NOTIFICATION OF NOTICE OF PUBLICATION E-MAILED	
Aug. 20, 2013	LAW OFFICE PUBLICATION REVIEW COMPLETED	70884
Aug. 19, 2013	ASSIGNED TO LIE	70884
Aug. 06, 2013	EXPARTE APPEAL TERMINATED	498455
Aug. 06, 2013	APPROVED FOR PUB - PRINCIPAL REGISTER	
Aug. 01, 2013	JURISDICTION RESTORED TO EXAMINING ATTORNEY	498455
Feb. 08, 2013	EX PARTE APPEAL-INSTITUTED	498455
Feb. 08, 2013	EXPARTE APPEAL RECEIVED AT TTAB	
Aug. 09, 2012	NOTIFICATION OF FINAL REFUSAL EMAILED	
Aug. 09, 2012	FINAL REFUSAL E-MAILED	
Aug. 09, 2012	FINAL REFUSAL WRITTEN	73350
Jul. 18, 2012	TEAS/EMAIL CORRESPONDENCE ENTERED	88889
Jul. 17, 2012	CORRESPONDENCE RECEIVED IN LAW OFFICE	88889
Jul. 17, 2012	TEAS RESPONSE TO OFFICE ACTION RECEIVED	
Jan. 18, 2012	NOTIFICATION OF NON-FINAL ACTION E-MAILED	6325
Jan. 18, 2012	NON-FINAL ACTION E-MAILED	6325
Jan. 18, 2012	NON-FINAL ACTION WRITTEN	73350
Jan. 17, 2012	ASSIGNED TO EXAMINER	73350
Dec. 31, 2011	NOTICE OF DESIGN SEARCH CODE MAILED	
Dec. 30, 2011	NEW APPLICATION OFFICE SUPPLIED DATA ENTERED IN TRAM	
Dec. 22, 2011	NEW APPLICATION ENTERED IN TRAM	

TM Staff and Location Information

TM Staff Information - None

File Location

Current Location: PUBLICATION AND ISSUE SECTION **Date in Location:** Nov. 06, 2014

Assignment Abstract Of Title Information

Summary

Total Assignments: 3 **Registrant:** Endo Pharmaceuticals Inc.

Assignment 1 of 3

Conveyance: CONFIRMATORY GRANT OF SECURITY INTEREST IN UNITED STATES TRADEMARKS

Reel/Frame: 5242/0195 **Pages:** 51

Date Recorded: Mar. 20, 2014

Supporting Documents: assignment-tm-5242-0195.pdf

Assignor

Name: AMS RESEARCH CORPORATION **Execution Date:** Feb. 28, 2014

Legal Entity Type: CORPORATION **State or Country Where Organized:** DELAWARE

Name: ENDO PHARMACEUTICALS, INC. **Execution Date:** Feb. 28, 2014

Legal Entity Type: CORPORATION **State or Country Where Organized:** DELAWARE

Name: ENDO PHARMACEUTICALS SOLUTIONS, INC. **Execution Date:** Feb. 28, 2014

Legal Entity Type: CORPORATION **State or Country Where Organized:** DELAWARE

Name: GENERICS BIDCO I, LLC **Execution Date:** Feb. 28, 2014

Legal Entity Type: LIMITED LIABILITY COMPANY **State or Country Where Organized:** DELAWARE

Name: GENERICS BIDCO II, LLC **Execution Date:** Feb. 28, 2014

Legal Entity Type: LIMITED LIABILITY COMPANY **State or Country Where Organized:** DELAWARE

Name: GENERICS INTERNATIONAL (US), INC. **Execution Date:** Feb. 28, 2014

Legal Entity Type: CORPORATION **State or Country Where Organized:** DELAWARE

Name: QUARTZ SPECIALTY PHARMACEUTICALS, LLC **Execution Date:** Feb. 28, 2014

Legal Entity Type: LIMITED LIABILITY COMPANY **State or Country Where Organized:** DELAWARE

Name: VINTAGE PHARMACEUTICALS, LLC **Execution Date:** Feb. 28, 2014

Legal Entity Type: LIMITED LIABILITY COMPANY **State or Country Where Organized:** DELAWARE

Name: LASERSCOPE **Execution Date:** Feb. 28, 2014

Legal Entity Type: CORPORATION **State or Country Where Organized:** CALIFORNIA

Assignee

Name: DEUTSCHE BANK AG NEW YORK BRANCH, AS COLLATERAL AGENT

Legal Entity Type: CORPORATION **State or Country Where Organized:** GERMANY

Address: 60 WALL STREET
NEW YORK, NEW YORK 10005

Correspondent

Correspondent Name: FATIMA CARRILLO/WHITE & CASE LLP

Correspondent Address: 1155 AVENUE OF THE AMERICAS
PATENT & TRADEMARK DEPARTMENT
NEW YORK, NY 10036

Domestic Representative - Not Found

Assignment 2 of 3

Conveyance: RELEASE BY SECURED PARTY

Reel/Frame: 6045/0001 **Pages:** 92

Date Recorded: Apr. 28, 2017

Supporting assignment-tm-6045-0001.pdf

Documents:

Assignor

Name: DEUTSCHE BANK AG NEW YORK BRANCH
Execution Date: Apr. 27, 2017
Legal Entity Type: BANK
State or Country Where Organized: GERMANY

Assignee

Name: ENDO PHARMACEUTICALS, INC. (FOR ITSELF AND AS SUCCESSOR TO AMS RESEARCH CORPORATION, AND LASERSCOPE)
Legal Entity Type: CORPORATION
State or Country Where Organized: DELAWARE
Address: 1400 ATWATER DRIVE
MALVERN, PENNSYLVANIA 19355

Name: ENDO PHARMACEUTICALS SOLUTIONS, INC.
Legal Entity Type: CORPORATION
State or Country Where Organized: DELAWARE
Address: 1400 ATWATER DRIVE
MALVERN, PENNSYLVANIA 19355

Name: GENERICS BIDCO I, LLC
Legal Entity Type: LIMITED LIABILITY COMPANY
State or Country Where Organized: DELAWARE
Address: 130 VINTAGE DRIVE
HUNTSVILLE, ALABAMA 35811

Name: GENERICS INTERNATIONAL (US), INC. (AS SUCCESSOR TO GENERICS INTERNATIONAL (US), INC.)
Legal Entity Type: CORPORATION
State or Country Where Organized: NEW YORK
Address: 130 VINTAGE DRIVE
HUNTSVILLE, ALABAMA 35811

Name: QUARTZ SPECIALTY PHARMACEUTICALS, LLC
Legal Entity Type: LIMITED LIABILITY COMPANY
State or Country Where Organized: DELAWARE
Address: 130 VINTAGE DRIVE
HUNTSVILLE, ALABAMA 35811

Name: VINTAGE PHARMACEUTICALS, LLC (AS SUCCESSOR TO BOCA PHARMACAL, LLC)
Legal Entity Type: LIMITED LIABILITY COMPANY
State or Country Where Organized: DELAWARE
Address: 130 VINTAGE DRIVE
HUNTSVILLE, ALABAMA 35811

Correspondent

Correspondent Name: SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
Correspondent Address: FOUR TIMES SQUARE
MONIQUE L. RIBANDO
NEW YORK, NY 10036

Domestic Representative - Not Found

Assignment 3 of 3

Conveyance: SECURITY INTEREST
Reel/Frame: 6080/0570
Pages: 19
Date Recorded: Jun. 08, 2017
Supporting Documents: assignment-tm-6080-0570.pdf

Assignor

Name: ENDO PHARMACEUTICALS INC.
Execution Date: Apr. 27, 2017
Legal Entity Type: CORPORATION
State or Country Where Organized: DELAWARE

Assignee

Name: WILMINGTON TRUST, NATIONAL ASSOCIATION, AS COLLATERAL TRUSTEE

Legal Entity Type: NATIONAL ASSOCIATION

State or Country Where Organized: UNITED STATES

Address: 1100 NORTH MARKET STREET
WILMINGTON, DELAWARE 19890

Correspondent

Correspondent Name: LATHAM & WATKINS LLP

Correspondent Address: 650 TOWN CENTER DRIVE, SUITE 2000
COSTA MESA, CA 92626

Domestic Representative - Not Found

Proceedings

Summary

Number of Proceedings: 3

Type of Proceeding: Opposition

Proceeding Number: 91225197

Filing Date: Dec 04, 2015

Status: Terminated

Status Date: Mar 09, 2016

Interlocutory Attorney: MARY CATHERINE FAINT

Defendant

Name: Endo Medical (USA) International Trade Co., Ltd.

Correspondent Address: ENDO MEDICAL (USA) INTERNATIONAL TRADE CO LTD
245 E MAIN ST STE 115
ALHAMBRA CA UNITED STATES , 91801-7507

Correspondent e-mail: aciusa@foxmail.com

Associated marks

Mark	Application Status	Serial Number	Registration Number
ENDO+ME	Abandoned - After Inter-Partes Decision	86600248	

Plaintiff(s)

Name: Endo Pharmaceuticals, Inc.

Correspondent Address: CAMILLE M MILLER
COZEN O'CONNOR
1900 MARKET STREET
PHILADELPHIA PA UNITED STATES , 19103

Correspondent e-mail: cmiller@cozen.com

Associated marks

Mark	Application Status	Serial Number	Registration Number
ENDO	Renewed	71360540	324936
ENDO	Renewed	74464554	2004648
ENDO	Renewed	75431737	2189503
ENDO	Renewed	76453299	2921176
E ENDO	Registered	85498455	4653200

Prosecution History

Entry Number	History Text	Date	Due Date
1	FILED AND FEE	Dec 04, 2015	
2	NOTICE AND TRIAL DATES SENT; ANSWER DUE:	Dec 04, 2015	Jan 13, 2016
3	PENDING, INSTITUTED	Dec 04, 2015	
4	P MOT FOR DEFAULT JUDGMENT	Jan 29, 2016	
5	BD DECISION: SUSTAINED	Mar 09, 2016	
6	TERMINATED	Mar 09, 2016	

Type of Proceeding: Exparte Appeal

Proceeding Number: 85498455 **Filing Date:** Feb 08, 2013

Status: Terminated **Status Date:** Aug 06, 2013

Interlocutory Attorney:

Plaintiff(s)

Name: Endo Pharmaceuticals Inc.

Correspondent Address: JAMES R MEYER
SCHNADER HARRISON SEGAL & LEWIS LLP
1600 MARKET ST , STE 3600
PHILADELPHIA PA UNITED STATES , 19103-7286

Correspondent e-mail: trademarks@schnader.com

Associated marks

Mark	Application Status	Serial Number	Registration Number
E ENDO	Registered	85498455	4653200

Prosecution History

Entry Number	History Text	Date	Due Date
1	APPEAL TO BOARD	Feb 08, 2013	
2	APPEAL ACKNOWLEDGED	Feb 08, 2013	
3	INSTITUTED	Feb 08, 2013	
4	APPLICANT REQ TO EXT	Mar 30, 2013	
5	SUSPENDED	Apr 05, 2013	
6	APPLICANT REQ FOR REMAND	Jul 28, 2013	
7	JURISDICTION RESTORED / REMANDED TO EXAMINER	Aug 01, 2013	
8	TERMINATED	Aug 06, 2013	

Type of Proceeding: Opposition

Proceeding Number: 91206732 **Filing Date:** Aug 28, 2012

Status: Terminated **Status Date:** Sep 02, 2013

Interlocutory Attorney: YONG OH (RICHARD) KIM

Defendant

Name: EndoClot Plus, Inc.

Correspondent Address: JAMES CAI
SCHEIN & CAI LLP
111 N MARKET ST STE 1020
SAN JOSE CA UNITED STATES , 95113

Correspondent e-mail: jcai@sacattorneys.com

Associated marks

Mark	Application Status	Serial Number	Registration Number
ENDOCLOT	Registered	85322084	4412920

Plaintiff(s)

Name: Endo Pharmaceuticals Inc.

Correspondent Address: RONALD J. VENTOLA II ESQ
SCHNADER HARRISON SEGAL & LEWIS LLP
1600 MARKET STREET SUITE 3600
PHILADELPHIA PA UNITED STATES , 19103

Correspondent e-mail: rventola@schnader.com , trademarks@schnader.com

Associated marks

Mark	Application Status	Serial Number	Registration Number
ENDO	Renewed	71360540	324936
ENDO	Renewed	74464554	2004648

ENDO	Renewed	75431737	2189503
ENDO	Renewed	76453299	2921176
ENDOCET	Renewed	74519259	1993892
ENDODAN	Renewed	74519256	1995948
ENDOCARE	Renewed	74533825	1897762
ENDO GENERIC PRODUCTS	Renewed	75347955	2267677
ENDO ENDO GENERIC PRODUCTS	Cancelled - Section 8	76607520	3075226
ENDO LABORATORIES	Renewed	75347956	2317044
TEAM ENDO	Cancelled - Section 8	76639353	3155766
E ENDO	Registered	85498455	4653200
ENDO HEALTH SOLUTIONS	Abandoned - No Statement Of Use Filed	85549539	
ENDO	Registered	85549674	4605917
E	Registered	85549621	4347658

Prosecution History

Entry Number	History Text	Date	Due Date
1	FILED AND FEE	Aug 28, 2012	
2	NOTICE AND TRIAL DATES SENT; ANSWER DUE:	Aug 28, 2012	Oct 07, 2012
3	PENDING, INSTITUTED	Aug 28, 2012	
4	ANSWER	Oct 05, 2012	
5	STIP TO SUSP PEND SETTL NEGOTIATIONS	Mar 12, 2013	
6	SUSPENDED	Mar 13, 2013	
7	STIP TO SUSP PEND SETTL NEGOTIATIONS	Apr 19, 2013	
8	SUSPENDED	Apr 19, 2013	
9	STIP TO SUSP PEND SETTL NEGOTIATIONS	May 16, 2013	
10	SUSPENDED	May 16, 2013	
11	STIP TO SUSP PEND SETTL NEGOTIATIONS	Jun 19, 2013	
12	SUSPENDED	Jun 19, 2013	
13	W/DRAW OF OPPOSITION	Aug 19, 2013	
14	BD DECISION: DISMISSED W/ PREJ	Sep 02, 2013	
15	TERMINATED	Sep 02, 2013	

United States of America

United States Patent and Trademark Office

Reg. No. 4,144,097

Registered May 15, 2012

Int. Cls.: 5 and 41

TRADEMARK

SERVICE MARK

PRINCIPAL REGISTER

LUNDBECK LLC (DELAWARE LIMITED LIABILITY COMPANY)
FOUR PARKWAY NORTH
DEERFIELD, IL 60015

FOR: PHARMACEUTICAL PREPARATIONS MADE IN SIGNIFICANT PART FROM CLOBAZAM FOR THE PREVENTION AND TREATMENT OF DISORDERS OF THE NERVOUS SYSTEM, IN CLASS 5 (U.S. CLS. 6, 18, 44, 46, 51 AND 52).

FIRST USE 1-3-2012; IN COMMERCE 1-3-2012.

FOR: HEALTH EDUCATIONAL SERVICES FOR DOCTORS AND PATIENTS, NAMELY, CONDUCTING PROGRAMS TO INCREASE PATIENT AWARENESS AND COMPLIANCE RELATING TO DISORDERS OF THE NERVOUS SYSTEM, AND DISTRIBUTING RELATED HEALTH EDUCATION MATERIALS IN CONNECTION THEREWITH, IN CLASS 41 (U.S. CLS. 100, 101 AND 107).

FIRST USE 1-3-2012; IN COMMERCE 1-3-2012.

NO CLAIM IS MADE TO THE EXCLUSIVE RIGHT TO USE "CLOBAZAM", APART FROM THE MARK AS SHOWN.

THE COLOR(S) GREEN, WHITE AND BLUE IS/ARE CLAIMED AS A FEATURE OF THE MARK.

THE MARK CONSISTS OF A SHIELD-SHAPED OBJECT CONTAINING CURVED LINES IN BLUE AND WHITE IN THE LOWER PORTION AND THE UPPER PORTION IS SHADED GREEN. THE SHIELD-SHAPED OBJECT APPEARS ABOVE THE WORDS "ONFI" AND "(CLOBAZAM) IV". THE WORD "ONFI" APPEARS IN BLUE AND THE WORDS "(CLOBAZAM) IV" APPEAR IN GREEN.

SN 85-290,502, FILED 4-8-2011.

ERNEST SHOSHO, EXAMINING ATTORNEY

David J. Kappos

Director of the United States Patent and Trademark Office

REQUIREMENTS TO MAINTAIN YOUR FEDERAL TRADEMARK REGISTRATION

WARNING: YOUR REGISTRATION WILL BE CANCELLED IF YOU DO NOT FILE THE DOCUMENTS BELOW DURING THE SPECIFIED TIME PERIODS.

Requirements in the First Ten Years*
What and When to File:

First Filing Deadline: You must file a Declaration of Use (or Excusable Nonuse) between the 5th and 6th years after the registration date. *See* 15 U.S.C. §§1058, 1141k. If the declaration is accepted, the registration will continue in force for the remainder of the ten-year period, calculated from the registration date, unless cancelled by an order of the Commissioner for Trademarks or a federal court.

Second Filing Deadline: You must file a Declaration of Use (or Excusable Nonuse) **and** an Application for Renewal between the 9th and 10th years after the registration date.* *See* 15 U.S.C. §1059.

Requirements in Successive Ten-Year Periods*
What and When to File:

You must file a Declaration of Use (or Excusable Nonuse) **and** an Application for Renewal between every 9th and 10th-year period, calculated from the registration date.*

Grace Period Filings*

The above documents will be accepted as timely if filed within six months after the deadlines listed above with the payment of an additional fee.

The United States Patent and Trademark Office (USPTO) will NOT send you any future notice or reminder of these filing requirements.

***ATTENTION MADRID PROTOCOL REGISTRANTS:** The holder of an international registration with an extension of protection to the United States under the Madrid Protocol must timely file the Declarations of Use (or Excusable Nonuse) referenced above directly with the USPTO. The time periods for filing are based on the U.S. registration date (not the international registration date). The deadlines and grace periods for the Declarations of Use (or Excusable Nonuse) are identical to those for nationally issued registrations. *See* 15 U.S.C. §§1058, 1141k. However, owners of international registrations do not file renewal applications at the USPTO. Instead, the holder must file a renewal of the underlying international registration at the International Bureau of the World Intellectual Property Organization, under Article 7 of the Madrid Protocol, before the expiration of each ten-year term of protection, calculated from the date of the international registration. *See* 15 U.S.C. §1141j. For more information and renewal forms for the international registration, see http://www.wipo.int/madrid/en/.

NOTE: Fees and requirements for maintaining registrations are subject to change. Please check the USPTO website for further information. With the exception of renewal applications for registered extensions of protection, you can file the registration maintenance documents referenced above online at http://www.uspto.gov.

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Mark: ONFI (CLOBAZAM) IV

US Serial Number:	85290502	**Application Filing Date:**	Apr. 08, 2011
US Registration Number:	4144097	**Registration Date:**	May 15, 2012
Register:	Principal		
Mark Type:	Trademark, Service Mark		
Status:	Registered. The registration date is used to determine when post-registration maintenance documents are due.		
Status Date:	May 15, 2012		
Publication Date:	Dec. 06, 2011	**Notice of Allowance Date:**	Jan. 31, 2012

Mark Information

Mark Literal Elements:	ONFI (CLOBAZAM) IV
Standard Character Claim:	No
Mark Drawing Type:	3 - AN ILLUSTRATION DRAWING WHICH INCLUDES WORD(S)/ LETTER(S)/NUMBER(S)
Description of Mark:	The mark consists of a shield-shaped object containing curved lines in blue and white in the lower portion and the upper portion is shaded green. The shield-shaped object appears above the words "Onfi" and "(clobazam) IV". The word "Onfi" appears in blue and the words "(clobazam) IV" appear in green.
Color Drawing:	Yes
Color(s) Claimed:	The color(s) green, white and blue is/are claimed as a feature of the mark.
Disclaimer:	"CLOBAZAM"
Design Search Code(s):	24.01.02 - Shields or crests with figurative elements contained therein or superimposed thereon 26.01.03 - Incomplete circles (more than semi-circles); Circles, incomplete (more than semi-circles) 26.17.09 - Curved line(s), band(s) or bar(s); Bars, curved; Lines, curved; Bands, curved

Goods and Services

Note: The following symbols indicate that the registrant/owner has amended the goods/services:

- Brackets [..] indicate deleted goods/services;
- Double parenthesis ((..)) identify any goods/services not claimed in a Section 15 affidavit of incontestability; and
- Asterisks *..* identify additional (new) wording in the goods/services.

For:	pharmaceutical preparations made in significant part from clobazam for the prevention and treatment of disorders of the nervous system		
International Class(es):	005 - Primary Class	**U.S Class(es):**	006, 018, 044, 046, 051, 052
Class Status:	ACTIVE		
Basis:	1(a)		
First Use:	Jan. 03, 2012	**Use in Commerce:**	Jan. 03, 2012

For:	health educational services for doctors and patients, namely, conducting programs to increase patient awareness and compliance relating to disorders of the nervous system, and distributing related health education materials in connection therewith		
International Class(es):	041 - Primary Class	**U.S Class(es):**	100, 101, 107

Class Status: ACTIVE

Basis: 1(a)

First Use: Jan. 03, 2012 **Use in Commerce:** Jan. 03, 2012

Basis Information (Case Level)

Filed Use:	No	**Currently Use:**	Yes	**Amended Use:**	No
Filed ITU:	Yes	**Currently ITU:**	No	**Amended ITU:**	No
Filed 44D:	No	**Currently 44D:**	No	**Amended 44D:**	No
Filed 44E:	No	**Currently 44E:**	No	**Amended 44E:**	No
Filed 66A:	No	**Currently 66A:**	No		
Filed No Basis:	No	**Currently No Basis:**	No		

Current Owner(s) Information

Owner Name: LUNDBECK LLC

Owner Address: 6 Parkway North
Deerfield, ILLINOIS 60015
UNITED STATES

Legal Entity Type: LIMITED LIABILITY COMPANY **State or Country Where Organized:** DELAWARE

Attorney/Correspondence Information

Attorney of Record

Attorney Name: Claudia A. Smith **Docket Number:** 1101391-0002

Attorney Primary Email Address: trademarkdocket@whitecase.com **Attorney Email Authorized:** Yes

Correspondent

Correspondent Name/Address: Claudia A. Smith
White & Case LLP
1155 Avenue of the Americas
Patent and Trademark Department
New York, NEW YORK 10036
UNITED STATES

Phone: 212-819-8200 **Fax:** 212-354-8113

Correspondent e-mail: trademarkdocket@whitecase.com **Correspondent e-mail Authorized:** Yes

Domestic Representative

Domestic Representative Name: Claudia A. Smith **Phone:** 212-819-8200

Fax: 212-354-8113

Domestic Representative e-mail: trademarkdocket@whitecase.com **Domestic Representative e-mail Authorized:** Yes

Prosecution History

Date	Description	Proceeding Number
May 15, 2017	COURTESY REMINDER - SEC. 8 (6-YR) E-MAILED	
Aug. 11, 2016	APPLICANT/CORRESPONDENCE CHANGES (NON-RESPONSIVE) ENTERED	88888
Aug. 11, 2016	TEAS CHANGE OF OWNER ADDRESS RECEIVED	
Jun. 12, 2014	ATTORNEY/DOM.REP.REVOKED AND/OR APPOINTED	
Jun. 12, 2014	TEAS REVOKE/APP/CHANGE ADDR OF ATTY/DOM REP RECEIVED	
Aug. 07, 2013	AUTOMATIC UPDATE OF ASSIGNMENT OF OWNERSHIP	
May 15, 2012	REGISTERED-PRINCIPAL REGISTER	
Apr. 10, 2012	NOTICE OF ACCEPTANCE OF STATEMENT OF USE E-MAILED	

Apr. 07, 2012	LAW OFFICE REGISTRATION REVIEW COMPLETED	66213
Apr. 06, 2012	ALLOWED PRINCIPAL REGISTER - SOU ACCEPTED	
Apr. 05, 2012	STATEMENT OF USE PROCESSING COMPLETE	76874
Mar. 15, 2012	USE AMENDMENT FILED	76874
Apr. 05, 2012	CASE ASSIGNED TO INTENT TO USE PARALEGAL	76874
Mar. 15, 2012	TEAS STATEMENT OF USE RECEIVED	
Mar. 07, 2012	AUTOMATIC UPDATE OF ASSIGNMENT OF OWNERSHIP	
Jan. 31, 2012	NOA E-MAILED - SOU REQUIRED FROM APPLICANT	
Dec. 06, 2011	OFFICIAL GAZETTE PUBLICATION CONFIRMATION E-MAILED	
Dec. 06, 2011	PUBLISHED FOR OPPOSITION	
Nov. 16, 2011	NOTIFICATION OF NOTICE OF PUBLICATION E-MAILED	
Oct. 28, 2011	LAW OFFICE PUBLICATION REVIEW COMPLETED	66213
Oct. 28, 2011	APPROVED FOR PUB - PRINCIPAL REGISTER	
Oct. 27, 2011	TEAS/EMAIL CORRESPONDENCE ENTERED	88889
Oct. 26, 2011	CORRESPONDENCE RECEIVED IN LAW OFFICE	88889
Oct. 26, 2011	TEAS RESPONSE TO OFFICE ACTION RECEIVED	
Oct. 26, 2011	TEAS CHANGE OF CORRESPONDENCE RECEIVED	
Jul. 15, 2011	NOTIFICATION OF NON-FINAL ACTION E-MAILED	6325
Jul. 15, 2011	NON-FINAL ACTION E-MAILED	6325
Jul. 15, 2011	NON-FINAL ACTION WRITTEN	78067
Jul. 15, 2011	PREVIOUS ALLOWANCE COUNT WITHDRAWN	
Jul. 08, 2011	WITHDRAWN FROM PUB - OG REVIEW QUERY	76621
Jun. 30, 2011	LAW OFFICE PUBLICATION REVIEW COMPLETED	66213
Jun. 29, 2011	ASSIGNED TO LIE	66213
Jun. 11, 2011	APPROVED FOR PUB - PRINCIPAL REGISTER	
Jun. 11, 2011	ASSIGNED TO EXAMINER	78067
Apr. 14, 2011	NOTICE OF DESIGN SEARCH CODE MAILED	
Apr. 13, 2011	NEW APPLICATION OFFICE SUPPLIED DATA ENTERED IN TRAM	
Apr. 12, 2011	NEW APPLICATION ENTERED IN TRAM	

TM Staff and Location Information

TM Staff Information - None

File Location

Current Location: PUBLICATION AND ISSUE SECTION **Date in Location:** Apr. 07, 2012

Assignment Abstract Of Title Information

Summary

Total Assignments: 1 **Registrant:** LUNDBECK LLC

Assignment 1 of 1

Conveyance: MERGER EFFECTIVE 12/31/2011

Reel/Frame: 4725/0389 **Pages:** 5

Date Recorded: Feb. 28, 2012

Supporting Documents: assignment-tm-4725-0389.pdf

Assignor

Name: LUNDBECK INC. **Execution Date:** Dec. 28, 2011

Legal Entity Type: CORPORATION **State or Country Where Organized:** ILLINOIS

Assignee

Name: LUNDBECK LLC

Legal Entity Type: LIMITED LIABILITY COMPANY **State or Country Where Organized:** DELAWARE

Address: FOUR PARKWAY NORTH
DEERFIELD, ILLINOIS 60015

Correspondent

Correspondent Name: JAMES A. THOMAS

Correspondent Address: P.O. BOX 1886
DURHAM, NC 27702-1886

Domestic Representative - Not Found

United States of America
United States Patent and Trademark Office

PROTEUS

Reg. No. 4,902,550

Registered Feb. 16, 2016

Int. Cls.: 5, 9, 10, 41, and 44

TRADEMARK

SERVICE MARK

PRINCIPAL REGISTER

PROTEUS DIGITAL HEALTH, INC. (DELAWARE CORPORATION)
2600 BRIDGE PARKWAY, SUITE 101
REDWOOD CITY, CA 94065

FOR: A HOUSE MARK FOR, BOTH PRESCRIPTION AND OVER-THE-COUNTER, INGESTIBLE MEDICATIONS, PLACEBO PILLS, PHARMACEUTICALS, DIAGNOSTIC PREPARATIONS, AND THERAPEUTIC PREPARATIONS CONTAINING INGESTIBLE SENSORS FOR USE IN CONNECTION WITH HUMANS AND ANIMALS, IN CLASS 5 (U.S. CLS. 6, 18, 44, 46, 51 AND 52).

FIRST USE 8-1-2015; IN COMMERCE 8-1-2015.

FOR: A HOUSE MARK FOR SEMICONDUCTORS, SEMICONDUCTOR CHIPS, SEMICONDUCTOR DEVICES, AND SEMICONDUCTOR POWER ELEMENTS; A HOUSE MARK FOR COMPUTER SOFTWARE FOR PROCESSING AND SHARING DATA RELATED TO MEDICATIONS, PHARMACEUTICALS, NUTRACEUTICALS, SUPPLEMENTS, PHYSIOLOGY, HEALTH, NUTRITION, FITNESS, AND WELLNESS AND DATA COLLECTED BY, OR UTILIZED IN CONJUNCTION WITH A MEDICAL DEVICE, IN CLASS 9 (U.S. CLS. 21, 23, 26, 36 AND 38).

FIRST USE 8-1-2015; IN COMMERCE 8-1-2015.

FOR: A HOUSE MARK FOR IMPLANTABLE, NON-IMPLANTABLE AND PORTABLE MEDICAL AND DIAGNOSTIC DEVICES, NAMELY, PATIENT MONITORS, WEARABLE PATIENT SENSORS, INGESTIBLE SENSORS, AND WIRELESS TRANSCEIVERS USED FOR RECEIVING AND TRANSMITTING DATA RELATED TO MEDICATIONS, HEALTH, NUTRITION, FITNESS, AND WELLNESS OF HUMANS AND ANIMALS, IN CLASS 10 (U.S. CLS. 26, 39 AND 44).

FIRST USE 8-1-2015; IN COMMERCE 8-1-2015.

FOR: A HOUSE MARK FOR TRAINING AND TEACHING IN THE FIELD OF PREVENTION, DIAGNOSIS AND TREATMENT OF MEDICAL CONDITIONS; A HOUSE MARK FOR PROVIDING A WEBSITE FEATURING INFORMATION ABOUT PHYSICAL FITNESS OF HUMANS AND ANIMALS; A HOUSE MARK FOR PROVIDING PATIENTS AND PATIENT GUARDIANS PERSONAL SUPPORTS SERVICES RELATING TO PATIENT CARE, NAMELY,

Michelle K. Lee

Director of the United States Patent and Trademark Office

Reg. No. 4,902,550 PROVIDING INFORMATION ABOUT PATIENT PHYSICAL FITNESS FOR HUMANS AND ANIMALS, IN CLASS 41 (U.S. CLS. 100, 101 AND 107).

FIRST USE 8-1-2015; IN COMMERCE 8-1-2015.

FOR: A HOUSE MARK FOR MEDICAL CONSULTATION AND CLINICIAN SERVICES; A HOUSE MARK FOR PROVIDING TEMPORARY USE OF NON-DOWNLOADABLE SOFTWARE GIVING MEDICAL PROFESSIONALS, PATIENTS, AND USERS ACCESS TO DATA RELATING TO SERVICES AND ANALYSIS IN THE FIELDS OF MEDICINE, HEALTH, NUTRITION, FITNESS AND WELLNESS OF HUMANS AND ANIMALS; A HOUSE MARK FOR PROVIDING A WEBSITE FEATURING INFORMATION ABOUT MEDICATIONS, HEALTH, NUTRITION, MENTAL FITNESS, AND WELLNESS OF HUMANS AND ANIMALS; A HOUSE MARK FOR PROVIDING PATIENTS AND PATIENT GUARDIANS PERSONAL SUPPORTS SERVICES RELATING TO PATIENT CARE, NAMELY, PROVIDING INFORMATION ABOUT PATIENT MEDICATION REGIMENT, HEALTH, NUTRITION, MENTAL FITNESS, WELLNESS, AND TREATMENT OF MEDICAL DISORDERS FOR HUMANS AND ANIMALS, IN CLASS 44 (U.S. CLS. 100 AND 101).

FIRST USE 8-1-2015; IN COMMERCE 8-1-2015.

THE MARK CONSISTS OF STANDARD CHARACTERS WITHOUT CLAIM TO ANY PARTICULAR FONT, STYLE, SIZE, OR COLOR.

OWNER OF U.S. REG. NOS. 3,963,272, 3,987,195, AND 4,605,675.

SN 86-351,820, FILED 7-29-2014.

BRITTANY ESTELL, EXAMINING ATTORNEY

REQUIREMENTS TO MAINTAIN YOUR FEDERAL TRADEMARK REGISTRATION

WARNING: YOUR REGISTRATION WILL BE CANCELLED IF YOU DO NOT FILE THE DOCUMENTS BELOW DURING THE SPECIFIED TIME PERIODS.

Requirements in the First Ten Years*
What and When to File:

First Filing Deadline: You must file a Declaration of Use (or Excusable Nonuse) between the 5th and 6th years after the registration date. *See* 15 U.S.C. §§1058, 1141k. If the declaration is accepted, the registration will continue in force for the remainder of the ten-year period, calculated from the registration date, unless cancelled by an order of the Commissioner for Trademarks or a federal court.

Second Filing Deadline: You must file a Declaration of Use (or Excusable Nonuse) **and** an Application for Renewal between the 9th and 10th years after the registration date.* *See* 15 U.S.C. §1059.

Requirements in Successive Ten-Year Periods*
What and When to File:

You must file a Declaration of Use (or Excusable Nonuse) **and** an Application for Renewal between every 9th and 10th-year period, calculated from the registration date.*

Grace Period Filings*

The above documents will be accepted as timely if filed within six months after the deadlines listed above with the payment of an additional fee.

***ATTENTION MADRID PROTOCOL REGISTRANTS:** The holder of an international registration with an extension of protection to the United States under the Madrid Protocol must timely file the Declarations of Use (or Excusable Nonuse) referenced above directly with the United States Patent and Trademark Office (USPTO). The time periods for filing are based on the U.S. registration date (not the international registration date). The deadlines and grace periods for the Declarations of Use (or Excusable Nonuse) are identical to those for nationally issued registrations. *See* 15 U.S.C. §§1058, 1141k. However, owners of international registrations do not file renewal applications at the USPTO. Instead, the holder must file a renewal of the underlying international registration at the International Bureau of the World Intellectual Property Organization, under Article 7 of the Madrid Protocol, before the expiration of each ten-year term of protection, calculated from the date of the international registration. *See* 15 U.S.C. §1141j. For more information and renewal forms for the international registration, see http://www.wipo.int/madrid/en/.

NOTE: Fees and requirements for maintaining registrations are subject to change. Please check the USPTO website for further information. With the exception of renewal applications for registered extensions of protection, you can file the registration maintenance documents referenced above online at http://www.uspto.gov.

NOTE: A courtesy e-mail reminder of USPTO maintenance filing deadlines will be sent to trademark owners/holders who authorize e-mail communication and maintain a current e-mail address with the USPTO. To ensure that e-mail is authorized and your address is current, please use the Trademark Electronic Application System (TEAS) Correspondence Address and Change of Owner Address Forms available at http://www.uspto.gov.

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Mark: PROTEUS

PROTEUS

US Serial Number: 86351820

Application Filing Date: Jul. 29, 2014

US Registration Number: 4902550

Registration Date: Feb. 16, 2016

Register: Principal

Mark Type: Trademark, Service Mark

TM5 Common Status Descriptor:

LIVE/REGISTRATION/Issued and Active

The trademark application has been registered with the Office.

Status: Registered. The registration date is used to determine when post-registration maintenance documents are due.

Status Date: Feb. 16, 2016

Publication Date: Mar. 17, 2015

Notice of Allowance Date: May 12, 2015

Mark Information

Mark Literal Elements: PROTEUS

Standard Character Claim: Yes. The mark consists of standard characters without claim to any particular font style, size, or color.

Mark Drawing Type: 4 - STANDARD CHARACTER MARK

Related Properties Information

Claimed Ownership of US Registrations: 3963272, 3987195, 4605675

Goods and Services

Note: The following symbols indicate that the registrant/owner has amended the goods/services:

- Brackets [..] indicate deleted goods/services;
- Double parenthesis ((..)) identify any goods/services not claimed in a Section 15 affidavit of incontestability; and
- Asterisks *..* identify additional (new) wording in the goods/services.

For: A house mark for, both prescription and over-the-counter, ingestible medications, placebo pills, pharmaceuticals, diagnostic preparations, and therapeutic preparations containing ingestible sensors for use in connection with humans and animals

International Class(es): 005 - Primary Class

U.S Class(es): 006, 018, 044, 046, 051, 052

Class Status: ACTIVE

Basis: 1(a)

First Use: Aug. 01, 2015

Use in Commerce: Aug. 01, 2015

For: A house mark for semiconductors, semiconductor chips, semiconductor devices, and semiconductor power elements; a house mark for computer software for processing and sharing data related to medications, pharmaceuticals, nutraceuticals, supplements, physiology, health, nutrition, fitness, and wellness and data collected by, or utilized in conjunction with a medical device

International Class(es): 009 - Primary Class

U.S Class(es): 021, 023, 026, 036, 038

Class Status: ACTIVE

Basis: 1(a)

First Use: Aug. 01, 2015 **Use in Commerce:** Aug. 01, 2015

For: A house mark for implantable, non-implantable and portable medical and diagnostic devices, namely, patient monitors, wearable patient sensors, ingestible sensors, and wireless transceivers used for receiving and transmitting data related to medications, health, nutrition, fitness, and wellness of humans and animals

International Class(es): 010 - Primary Class **U.S Class(es):** 026, 039, 044

Class Status: ACTIVE

Basis: 1(a)

First Use: Aug. 01, 2015 **Use in Commerce:** Aug. 01, 2015

For: A house mark for training and teaching in the field of prevention, diagnosis and treatment of medical conditions; a house mark for providing a website featuring information about physical fitness of humans and animals; a house mark for providing patients and patient guardians personal supports services relating to patient care, namely, providing information about patient physical fitness for humans and animals

International Class(es): 041 - Primary Class **U.S Class(es):** 100, 101, 107

Class Status: ACTIVE

Basis: 1(a)

First Use: Aug. 01, 2015 **Use in Commerce:** Aug. 01, 2015

For: A house mark for medical consultation and clinician services; a house mark for providing temporary use of non-downloadable software giving medical professionals, patients, and users access to data relating to services and analysis in the fields of medicine, health, nutrition, fitness and wellness of humans and animals; A house mark for providing a website featuring information about medications, health, nutrition, mental fitness, and wellness of humans and animals; A house mark for providing patients and patient guardians personal supports services relating to patient care, namely, providing information about patient medication regiment, health, nutrition, mental fitness, wellness, and treatment of medical disorders for humans and animals

International Class(es): 044 - Primary Class **U.S Class(es):** 100, 101

Class Status: ACTIVE

Basis: 1(a)

First Use: Aug. 01, 2015 **Use in Commerce:** Aug. 01, 2015

Basis Information (Case Level)

Filed Use:	No	**Currently Use:**	Yes	**Amended Use:**	No
Filed ITU:	Yes	**Currently ITU:**	No	**Amended ITU:**	No
Filed 44D:	No	**Currently 44D:**	No	**Amended 44D:**	No
Filed 44E:	No	**Currently 44E:**	No	**Amended 44E:**	No
Filed 66A:	No	**Currently 66A:**	No		
Filed No Basis:	No	**Currently No Basis:**	No		

Current Owner(s) Information

Owner Name: PROTEUS DIGITAL HEALTH, INC.

Owner Address: 2600 Bridge Parkway, Suite 101
Redwood City, CALIFORNIA UNITED STATES 94065

Legal Entity Type: CORPORATION **State or Country Where Organized:** DELAWARE

Attorney/Correspondence Information

Attorney of Record

Attorney Name: May Mowzoon **Docket Number:** PRO-T23-US

Attorney Primary Email Address: paralegal@danalegalservices.com **Attorney Email Authorized:** Yes

Correspondent

Correspondent Name/Address: MAY MOWZOON
DANA LEGAL SERVICES
325 SHARON PARK DR
MENLO PARK, CALIFORNIA UNITED STATES 94025-6805

Phone:	(623) 335-2947		
Correspondent e-mail:	paralegal@danalegalservices.com may@danalegalservices.com docket@danalegalservices.com jubin@danalegalservices.com pam@danalegalservices.com	**Correspondent e-mail Authorized:**	Yes

Domestic Representative - Not Found

Prosecution History

Date	Description	Proceeding Number
Feb. 16, 2016	REGISTERED-PRINCIPAL REGISTER	
Jan. 13, 2016	NOTICE OF ACCEPTANCE OF STATEMENT OF USE E-MAILED	
Jan. 12, 2016	ALLOWED PRINCIPAL REGISTER - SOU ACCEPTED	
Jan. 01, 2016	TEAS/EMAIL CORRESPONDENCE ENTERED	88889
Dec. 31, 2015	CORRESPONDENCE RECEIVED IN LAW OFFICE	88889
Dec. 31, 2015	TEAS RESPONSE TO OFFICE ACTION RECEIVED	
Dec. 15, 2015	NOTIFICATION OF NON-FINAL ACTION E-MAILED	
Dec. 15, 2015	NON-FINAL ACTION E-MAILED	
Dec. 15, 2015	SU - NON-FINAL ACTION - WRITTEN	90338
Nov. 23, 2015	STATEMENT OF USE PROCESSING COMPLETE	75298
Nov. 06, 2015	USE AMENDMENT FILED	75298
Nov. 19, 2015	CASE ASSIGNED TO INTENT TO USE PARALEGAL	75298
Nov. 06, 2015	TEAS STATEMENT OF USE RECEIVED	
May 12, 2015	NOA E-MAILED - SOU REQUIRED FROM APPLICANT	
Mar. 17, 2015	OFFICIAL GAZETTE PUBLICATION CONFIRMATION E-MAILED	
Mar. 17, 2015	PUBLISHED FOR OPPOSITION	
Feb. 25, 2015	NOTIFICATION OF NOTICE OF PUBLICATION E-MAILED	
Feb. 06, 2015	LAW OFFICE PUBLICATION REVIEW COMPLETED	70997
Feb. 03, 2015	APPROVED FOR PUB - PRINCIPAL REGISTER	
Feb. 02, 2015	EXAMINER'S AMENDMENT ENTERED	88888
Feb. 02, 2015	NOTIFICATION OF EXAMINERS AMENDMENT E-MAILED	6328
Feb. 02, 2015	EXAMINERS AMENDMENT E-MAILED	6328
Feb. 02, 2015	EXAMINERS AMENDMENT -WRITTEN	90338
Jan. 21, 2015	PREVIOUS ALLOWANCE COUNT WITHDRAWN	
Dec. 16, 2014	WITHDRAWN FROM PUB - OG REVIEW QUERY	99910
Dec. 04, 2014	LAW OFFICE PUBLICATION REVIEW COMPLETED	70997
Dec. 04, 2014	ASSIGNED TO LIE	70997
Nov. 15, 2014	APPROVED FOR PUB - PRINCIPAL REGISTER	
Nov. 14, 2014	EXAMINER'S AMENDMENT ENTERED	88888
Nov. 14, 2014	NOTIFICATION OF EXAMINERS AMENDMENT E-MAILED	6328
Nov. 14, 2014	EXAMINERS AMENDMENT E-MAILED	6328
Nov. 14, 2014	EXAMINERS AMENDMENT -WRITTEN	90338
Nov. 11, 2014	ASSIGNED TO EXAMINER	90338
Aug. 06, 2014	NEW APPLICATION OFFICE SUPPLIED DATA ENTERED IN TRAM	
Aug. 01, 2014	NEW APPLICATION ENTERED IN TRAM	

TM Staff and Location Information

TM Staff Information - None

File Location

Current Location:	PUBLICATION AND ISSUE SECTION	**Date in Location:**	Jan. 12, 2016

United States of America

United States Patent and Trademark Office

Reg. No. 4,641,478

Registered Nov. 18, 2014

Int. Cls.: 1, 5, 9, 10, 16, 35, 38, 40, 41, and 44

TRADEMARK

SERVICE MARK

PRINCIPAL REGISTER

SANOFI (FRANCE SOCIETE ANONYME)
54 RUE LA BOÉTIE
PARIS, FRANCE 75008

FOR: CHEMICALS FOR USE IN THE MANUFACTURE OF PHARMACEUTICAL PREPARATIONS AND SUBSTANCES, IN CLASS 1 (U.S. CLS. 1, 5, 6, 10, 26 AND 46).

FIRST USE 6-15-2011; IN COMMERCE 6-5-2011.

FOR: HOUSE MARK FOR A FULL LINE OF VACCINES, PHARMACEUTICAL PREPARATIONS BOTH PRESCRIPTION AND OVER-THE-COUNTER, FOR BOTH HUMAN AND ANIMAL USE, IN CLASS 5 (U.S. CLS. 6, 18, 44, 46, 51 AND 52).

FIRST USE 6-15-2011; IN COMMERCE 6-15-2011.

FOR: COMPUTER SOFTWARE FOR PHARMACEUTICAL AND MEDICAL DEVELOPMENT, COMPUTER SOFTWARE FOR DATABASE MANAGEMENT IN THE FIELD OF HEALTHCARE; COMPUTERS AND COMPUTER SOFTWARE FOR USE IN SEARCHING FOR, MANAGING, AND PROVIDING HEALTHCARE INFORMATION IN PATIENT RECORDS MANAGEMENT, IN WORD PROCESSING, IN DATABASE MANAGEMENT, AND AS A SPREADSHEET IN THE FIELD OF HEALTHCARE BY PHYSICIANS AND HEALTHCARE TECHNICIANS, PHARMACISTS, SCIENTISTS, RESEARCHERS AND OTHER PERSONNEL; AUDIO AND VIDEO RECORDINGS FEATURING HEALTHCARE INFORMATION AND PHARMACEUTICAL AND MEDICAL DEVELOPMENTS, IN CLASS 9 (U.S. CLS. 21, 23, 26, 36 AND 38).

FIRST USE 6-15-2011; IN COMMERCE 6-15-2011.

FOR: SURGICAL, MEDICAL AND VETERINARY APPARATUS AND INSTRUMENTS, NAMELY, INHALERS FOR THERAPEUTIC USE SOLD EMPTY AND PARTS AND FITTINGS THEREFOR; DEVICES FOR THE INJECTION OF MEDICINES, NAMELY, PENS FOR INJECTION, IN CLASS 10 (U.S. CLS. 26, 39 AND 44).

FIRST USE 6-15-2011; IN COMMERCE 6-15-2011.

Michelle K. Lee

Deputy Director of the United States Patent and Trademark Office

Reg. No. 4,641,478 FOR: NEWSPAPERS, PERIODICALS, JOURNALS, AND BOOKS IN THE FIELDS OF PHARMACEUTICALS AND MEDICAL DEVELOPMENTS, IN CLASS 16 (U.S. CLS. 2, 5, 22, 23, 29, 37, 38 AND 50).

FIRST USE 6-15-2011; IN COMMERCE 6-15-2011.

FOR: BUSINESS CONSULTATION SERVICES; CONSULTATION SERVICES, NAMELY, PROVIDING CONSUMER INFORMATION REGARDING PRODUCTS; ADVERTISING AND MARKETING; BUSINESS ADMINISTRATION AND MANAGEMENT IN THE FIELDS OF HEALTHCARE; DISTRIBUTION OF PRINTED PROMOTIONAL MATERIALS IN THE FIELD OF HEALTHCARE; PROMOTING PUBLIC AWARENESS REGARDING HEALTHCARE, IN CLASS 35 (U.S. CLS. 100, 101 AND 102).

FIRST USE 6-15-2011; IN COMMERCE 6-15-2011.

FOR: TELECOMMUNICATIONS SERVICES, NAMELY, TRANSMISSION OF INFORMATION VIA TELEPHONE AND COMPUTER TERMINALS THROUGH INTERNET WEB SITES REGARDING HEALTHCARE; TRANSMISSION OF INFORMATION FOR OTHERS IN THE FIELD OF HEALTHCARE, COMMUNICATION OF INFORMATION ADDRESSED TO PATIENTS OR HEALTHCARE PROFESSIONALS VIA COMPUTER AND INTERNET; PROVIDING ONLINE CHAT ROOMS AND ELECTRONIC BULLETIN BOARDS FOR THE TRANSMISSION OF MESSAGES AMONG COMPUTER USERS CONCERNING HEALTHCARE, PHARMACEUTICALS, PHARMACEUTICAL AND MEDICAL DEVELOPMENTS, IN CLASS 38 (U.S. CLS. 100, 101 AND 104).

FIRST USE 6-15-2011; IN COMMERCE 6-15-2011.

FOR: CUSTOM MANUFACTURE OF CHEMICAL, BIOCHEMICAL, AND CELL BASED ASSAYS ON BEHALF OF OTHERS; CUSTOM MANUFACTURE OF PHARMACEUTICALS; STORAGE AND DELIVERY OF PHARMACEUTICAL PRODUCTS, CHEMICAL PRODUCTS FOR PHARMACEUTICAL USE, IN CLASS 40 (U.S. CLS. 100, 103 AND 106).

FIRST USE 6-15-2011; IN COMMERCE 6-15-2011.

FOR: EDUCATIONAL SERVICES, NAMELY, CONDUCTING SEMINARS, WORKING GROUPS, TRAINING AND CONFERENCES IN THE FIELD OF HEALTHCARE; PUBLISHING OF PERIODICALS, BOOKS, GUIDES AND DATABASES IN THE MEDICAL FIELD, AND PROVIDING DIGITAL EDUCATIONAL MATERIALS THEREWITH; CONDUCTING ONLINE EDUCATIONAL EXHIBITIONS FEATURING DISPLAYS AND INTERACTIVE EXHIBITS IN THE FIELD OF HEALTHCARE, IN CLASS 41 (U.S. CLS. 100, 101 AND 107).

FIRST USE 6-15-2011; IN COMMERCE 6-15-2011.

FOR: PROVIDING MEDICAL INFORMATION AND EDUCATIONAL INFORMATION IN THE FIELD OF HEALTHCARE; HEALTH CARE SERVICES; MEDICAL CONSULTATION; DISEASE MANAGEMENT PROGRAMS CONCERNING HEALTHCARE, IN CLASS 44 (U.S. CLS. 100 AND 101).

FIRST USE 6-15-2011; IN COMMERCE 6-15-2011.

THE MARK CONSISTS OF AN INCOMPLETE BLACK CIRCLE WITH A SILHOUETTE OF A STYLIZED BIRD AS THE CUT-OUT PORTION.

SN 85-277,159, FILED 3-25-2011.

RON FAIRBANKS, EXAMINING ATTORNEY

REQUIREMENTS TO MAINTAIN YOUR FEDERAL TRADEMARK REGISTRATION

WARNING: YOUR REGISTRATION WILL BE CANCELLED IF YOU DO NOT FILE THE DOCUMENTS BELOW DURING THE SPECIFIED TIME PERIODS.

Requirements in the First Ten Years*
What and When to File:

First Filing Deadline: You must file a Declaration of Use (or Excusable Nonuse) between the 5th and 6th years after the registration date. *See* 15 U.S.C. §§1058, 1141k. If the declaration is accepted, the registration will continue in force for the remainder of the ten-year period, calculated from the registration date, unless cancelled by an order of the Commissioner for Trademarks or a federal court.

Second Filing Deadline: You must file a Declaration of Use (or Excusable Nonuse) **and** an Application for Renewal between the 9th and 10th years after the registration date.* *See* 15 U.S.C. §1059.

Requirements in Successive Ten-Year Periods*
What and When to File:

You must file a Declaration of Use (or Excusable Nonuse) **and** an Application for Renewal between every 9th and 10th-year period, calculated from the registration date.*

Grace Period Filings*

The above documents will be accepted as timely if filed within six months after the deadlines listed above with the payment of an additional fee.

The United States Patent and Trademark Office (USPTO) will NOT send you any future notice or reminder of these filing requirements.

***ATTENTION MADRID PROTOCOL REGISTRANTS:** The holder of an international registration with an extension of protection to the United States under the Madrid Protocol must timely file the Declarations of Use (or Excusable Nonuse) referenced above directly with the USPTO. The time periods for filing are based on the U.S. registration date (not the international registration date). The deadlines and grace periods for the Declarations of Use (or Excusable Nonuse) are identical to those for nationally issued registrations. *See* 15 U.S.C. §§1058, 1141k. However, owners of international registrations do not file renewal applications at the USPTO. Instead, the holder must file a renewal of the underlying international registration at the International Bureau of the World Intellectual Property Organization, under Article 7 of the Madrid Protocol, before the expiration of each ten-year term of protection, calculated from the date of the international registration. *See* 15 U.S.C. §1141j. For more information and renewal forms for the international registration, see http://www.wipo.int/madrid/en/.

NOTE: Fees and requirements for maintaining registrations are subject to change. Please check the USPTO website for further information. With the exception of renewal applications for registered extensions of protection, you can file the registration maintenance documents referenced above online at http://www.uspto.gov.

Generated on: This page was generated by TSDR on 2017-11-06 14:02:59 EST

Mark:

US Serial Number: 85277159

Application Filing Date: Mar. 25, 2011

US Registration Number: 4641478

Registration Date: Nov. 18, 2014

Register: Principal

Mark Type: Trademark, Service Mark

TM5 Common Status Descriptor:

LIVE/REGISTRATION/Issued and Active

The trademark application has been registered with the Office.

Status: Registered. The registration date is used to determine when post-registration maintenance documents are due.

Status Date: Nov. 18, 2014

Publication Date: Sep. 13, 2011

Notice of Allowance Date: Nov. 08, 2011

Mark Information

Mark Literal Elements: None

Standard Character Claim: No

Mark Drawing Type: 2 - AN ILLUSTRATION DRAWING WITHOUT ANY WORDS(S)/ LETTER(S)/NUMBER(S)

Description of Mark: The mark consists of an incomplete black circle with a silhouette of a stylized bird as the cut-out portion.

Color(s) Claimed: Color is not claimed as a feature of the mark.

Design Search Code(s): 03.15.19 - Birds or bats in flight or with outspread wings
03.15.24 - Stylized birds and bats
03.15.25 - Crows; Robins; Ravens; Cardinals; Woodpeckers; Doves; Other birds; Pigeons
26.01.03 - Circles, incomplete (more than semi-circles); Incomplete circles (more than semi-circles)
26.01.21 - Circles that are totally or partially shaded.

Goods and Services

Note: The following symbols indicate that the registrant/owner has amended the goods/services:

- Brackets [..] indicate deleted goods/services;
- Double parenthesis ((..)) identify any goods/services not claimed in a Section 15 affidavit of incontestability; and
- Asterisks *..* identify additional (new) wording in the goods/services.

For: chemicals for use in the manufacture of pharmaceutical preparations and substances

International Class(es): 001 - Primary Class

U.S Class(es): 001, 005, 006, 010, 026, 046

Class Status: ACTIVE

Basis: 1(a)

First Use: Jun. 15, 2011

Use in Commerce: Jun. 15, 2011

For: house mark for a full line of vaccines, pharmaceutical preparations both prescription and over-the-counter, for both human and animal

use

International Class(es): 005 - Primary Class **U.S Class(es):** 006, 018, 044, 046, 051, 052

Class Status: ACTIVE

Basis: 1(a)

First Use: Jun. 15, 2011 **Use in Commerce:** Jun. 15, 2011

For: computer software for pharmaceutical and medical development, computer software for database management in the field of healthcare; computers and computer software for use in searching for, managing, and providing healthcare information in patient records management, in word processing, in database management, and as a spreadsheet in the field of healthcare by physicians and healthcare technicians, pharmacists, scientists, researchers and other personnel; audio and video recordings featuring healthcare information and pharmaceutical and medical developments

International Class(es): 009 - Primary Class **U.S Class(es):** 021, 023, 026, 036, 038

Class Status: ACTIVE

Basis: 1(a)

First Use: Jun. 15, 2011 **Use in Commerce:** Jun. 15, 2011

For: surgical, medical and veterinary apparatus and instruments, namely, inhalers for therapeutic use sold empty and parts and fittings therefor; devices for the injection of medicines, namely, pens for injection

International Class(es): 010 - Primary Class **U.S Class(es):** 026, 039, 044

Class Status: ACTIVE

Basis: 1(a)

First Use: Jun. 15, 2011 **Use in Commerce:** Jun. 15, 2011

For: newspapers, periodicals, journals, and books in the fields of pharmaceuticals and medical developments

International Class(es): 016 - Primary Class **U.S Class(es):** 002, 005, 022, 023, 029, 037, 038, 050

Class Status: ACTIVE

Basis: 1(a)

First Use: Jun. 15, 2011 **Use in Commerce:** Jun. 15, 2011

For: Business consultation services; consultation services, namely, providing consumer information regarding products; advertising and marketing; business administration and management in the fields of healthcare; distribution of printed promotional materials in the field of healthcare; promoting public awareness regarding healthcare

International Class(es): 035 - Primary Class **U.S Class(es):** 100, 101, 102

Class Status: ACTIVE

Basis: 1(a)

First Use: Jun. 15, 2011 **Use in Commerce:** Jun. 15, 2011

For: telecommunications services, namely, transmission of information via telephone and computer terminals through internet web sites regarding healthcare; transmission of information for others in the field of healthcare, communication of information addressed to patients or healthcare professionals via computer and internet; providing online chat rooms and electronic bulletin boards for the transmission of messages among computer users concerning healthcare, pharmaceuticals, pharmaceutical and medical developments

International Class(es): 038 - Primary Class **U.S Class(es):** 100, 101, 104

Class Status: ACTIVE

Basis: 1(a)

First Use: Jun. 15, 2011 **Use in Commerce:** Jun. 15, 2011

For: custom manufacture of chemical, biochemical, and cell based assays on behalf of others; custom manufacture of pharmaceuticals; storage and delivery of pharmaceutical products, chemical products for pharmaceutical use

International Class(es): 040 - Primary Class **U.S Class(es):** 100, 103, 106

Class Status: ACTIVE

Basis: 1(a)

First Use: Jun. 15, 2011 **Use in Commerce:** Jun. 15, 2011

For: educational services, namely, conducting seminars, working groups, training and conferences in the field of healthcare; publishing of periodicals, books, guides and databases in the medical field, and providing digital educational materials therewith; conducting online educational exhibitions featuring displays and interactive exhibits in the field of healthcare

International Class(es): 041 - Primary Class **U.S Class(es):** 100, 101, 107

Class Status: ACTIVE

Basis: 1(a)

First Use: Jun. 15, 2011 **Use in Commerce:** Jun. 15, 2011

For: Providing medical information and educational information in the field of healthcare; health care services; medical consultation; disease management programs concerning healthcare

International Class(es): 044 - Primary Class **U.S Class(es):** 100, 101

Class Status: ACTIVE

Basis: 1(a)

First Use: Jun. 15, 2011 **Use in Commerce:** Jun. 15, 2011

Basis Information (Case Level)

Filed Use:	No	**Currently Use:**	Yes	**Amended Use:**	No
Filed ITU:	Yes	**Currently ITU:**	No	**Amended ITU:**	No
Filed 44D:	No	**Currently 44D:**	No	**Amended 44D:**	No
Filed 44E:	No	**Currently 44E:**	No	**Amended 44E:**	No
Filed 66A:	No	**Currently 66A:**	No		
Filed No Basis:	No	**Currently No Basis:**	No		

Current Owner(s) Information

Owner Name: SANOFI

Owner Address: 54 rue La Boétie
Paris FRANCE 75008

Legal Entity Type: SOCIETE ANONYME **State or Country Where Organized:** FRANCE

Attorney/Correspondence Information

Attorney of Record

Attorney Name: Susan Upton Douglass **Docket Number:** SYN 1102913

Attorney Primary Email Address: sdouglass@frosszelnick.com **Attorney Email Authorized:** Yes

Correspondent

Correspondent Name/Address: SUSAN UPTON DOUGLASS
FROSS ZELNICK LEHRMAN & ZISSU, P.C.
4 TIMES SQUARE, 17TH FLOOR
NEW YORK, NEW YORK UNITED STATES 10036

Phone: 212-813-5900 **Fax:** 212-813-5901

Correspondent e-mail: sdouglass@frosszelnick.com **Correspondent e-mail Authorized:** Yes

Domestic Representative

Domestic Representative Name: Susan Upton Douglass **Phone:** 212-813-5900

Fax: 212-813-5901

Domestic Representative e-mail: sdouglass@frosszelnick.com **Domestic Representative e-mail Authorized:** Yes

Prosecution History

		Proceeding

Date	Description	Number
Apr. 05, 2017	REVIEW OF CORRESPONDENCE COMPLETE - ADDRESS UPDATED	88889
Jan. 31, 2017	CORRESPONDENCE RECEIVED IN LAW OFFICE	
Nov. 29, 2014	CERTIFICATE OF CORRECTION ISSUED	75184
Nov. 29, 2014	CASE ASSIGNED TO POST REGISTRATION PARALEGAL	75184
Nov. 20, 2014	TEAS SECTION 7 REQUEST RECEIVED	
Nov. 18, 2014	REGISTERED-PRINCIPAL REGISTER	
Oct. 15, 2014	NOTICE OF ACCEPTANCE OF STATEMENT OF USE E-MAILED	
Oct. 14, 2014	ALLOWED PRINCIPAL REGISTER - SOU ACCEPTED	
Sep. 20, 2014	TEAS/EMAIL CORRESPONDENCE ENTERED	88889
Sep. 19, 2014	CORRESPONDENCE RECEIVED IN LAW OFFICE	88889
Sep. 19, 2014	TEAS RESPONSE TO OFFICE ACTION RECEIVED	
Jun. 16, 2014	NOTIFICATION OF NON-FINAL ACTION E-MAILED	
Jun. 16, 2014	NON-FINAL ACTION E-MAILED	
Jun. 16, 2014	SU - NON-FINAL ACTION - WRITTEN	76463
May 12, 2014	STATEMENT OF USE PROCESSING COMPLETE	69302
May 07, 2014	USE AMENDMENT FILED	69302
May 07, 2014	TEAS STATEMENT OF USE RECEIVED	
Nov. 08, 2013	NOTICE OF APPROVAL OF EXTENSION REQUEST E-MAILED	
Nov. 07, 2013	EXTENSION 4 GRANTED	69302
Nov. 05, 2013	EXTENSION 4 FILED	69302
Nov. 05, 2013	TEAS EXTENSION RECEIVED	
May 10, 2013	NOTICE OF APPROVAL OF EXTENSION REQUEST E-MAILED	
May 09, 2013	EXTENSION 3 GRANTED	69302
May 08, 2013	EXTENSION 3 FILED	69302
May 08, 2013	TEAS EXTENSION RECEIVED	
Nov. 08, 2012	NOTICE OF APPROVAL OF EXTENSION REQUEST E-MAILED	
Nov. 07, 2012	EXTENSION 2 GRANTED	69302
Nov. 06, 2012	EXTENSION 2 FILED	69302
Nov. 07, 2012	CASE ASSIGNED TO INTENT TO USE PARALEGAL	69302
Nov. 06, 2012	TEAS EXTENSION RECEIVED	
May 04, 2012	NOTICE OF APPROVAL OF EXTENSION REQUEST E-MAILED	
May 02, 2012	EXTENSION 1 GRANTED	98765
May 02, 2012	EXTENSION 1 FILED	98765
May 02, 2012	TEAS EXTENSION RECEIVED	
Mar. 07, 2012	APPLICANT/CORRESPONDENCE CHANGES (NON-RESPONSIVE) ENTERED	88888
Mar. 07, 2012	TEAS CHANGE OF OWNER ADDRESS RECEIVED	
Nov. 08, 2011	NOA E-MAILED - SOU REQUIRED FROM APPLICANT	
Sep. 13, 2011	OFFICIAL GAZETTE PUBLICATION CONFIRMATION E-MAILED	
Sep. 13, 2011	PUBLISHED FOR OPPOSITION	
Aug. 05, 2011	LAW OFFICE PUBLICATION REVIEW COMPLETED	59554
Aug. 02, 2011	APPROVED FOR PUB - PRINCIPAL REGISTER	
Aug. 02, 2011	EXAMINER'S AMENDMENT ENTERED	88888
Aug. 02, 2011	NOTIFICATION OF EXAMINERS AMENDMENT E-MAILED	6328
Aug. 02, 2011	EXAMINERS AMENDMENT E-MAILED	6328
Aug. 02, 2011	EXAMINERS AMENDMENT -WRITTEN	76463
Jul. 28, 2011	PREVIOUS ALLOWANCE COUNT WITHDRAWN	
Jul. 25, 2011	WITHDRAWN FROM PUB - OG REVIEW QUERY	76621
Jul. 13, 2011	LAW OFFICE PUBLICATION REVIEW COMPLETED	59554
Jul. 13, 2011	ASSIGNED TO LIE	59554
Jun. 19, 2011	APPROVED FOR PUB - PRINCIPAL REGISTER	
Jun. 19, 2011	EXAMINER'S AMENDMENT ENTERED	88888
Jun. 19, 2011	NOTIFICATION OF EXAMINERS AMENDMENT E-MAILED	6328
Jun. 19, 2011	EXAMINERS AMENDMENT E-MAILED	6328
Jun. 19, 2011	EXAMINERS AMENDMENT -WRITTEN	76463

Jun. 11, 2011	ASSIGNED TO EXAMINER	76463
Jun. 01, 2011	AUTOMATIC UPDATE OF ASSIGNMENT OF OWNERSHIP	
May 13, 2011	TEAS AMENDMENT ENTERED BEFORE ATTORNEY ASSIGNED	88889
May 13, 2011	TEAS VOLUNTARY AMENDMENT RECEIVED	
Mar. 30, 2011	NOTICE OF DESIGN SEARCH CODE MAILED	
Mar. 29, 2011	NEW APPLICATION OFFICE SUPPLIED DATA ENTERED IN TRAM	
Mar. 29, 2011	NEW APPLICATION ENTERED IN TRAM	

Maintenance Filings or Post Registration Information

Change in Registration: Yes

Correction made to Registration: In the statement, line 6, "In Commerce 6-5-2011" should be deleted, and In Commerce 6-15-2011 should be inserted.

TM Staff and Location Information

TM Staff Information - None

File Location

Current Location: POST REGISTRATION **Date in Location:** Nov. 29, 2014

Assignment Abstract Of Title Information

Summary

Total Assignments: 1 **Registrant:** SANOFI

Assignment 1 of 1

Conveyance: CHANGE OF NAME

Reel/Frame: 4550/0001 **Pages:** 16

Date Recorded: May 27, 2011

Supporting Documents: assignment-tm-4550-0001.pdf

Assignor

Name: SANOFI-AVENTIS **Execution Date:** May 06, 2011

Legal Entity Type: SOCIETE ANONYME **State or Country Where Organized:** FRANCE

Assignee

Name: SANOFI

Legal Entity Type: SOCIETE ANONYME **State or Country Where Organized:** FRANCE

Address: 174, AVENUE DE FRANCE
PARIS, FRANCE 75013

Correspondent

Correspondent Name: G MATHEW LOMBARD

Correspondent Address: 1115 BROADWAY
12 FL
NEW YORK, NY 10010

Domestic Representative - Not Found

United States of America

United States Patent and Trademark Office

SEE MORE. TREAT SMARTER.

Reg. No. 5,205,582

Registered May 16, 2017

Int. Cl.: 5, 10, 41

Service Mark

Trademark

Principal Register

BTG International Limited (UNITED KINGDOM private limited company)
5 Fleet Place
London UNITED KINGDOM EC4M7RD

CLASS 5: Pharmaceutical, medicinal substances, namely, pharmaceutical preparations for the treatment of cancer, pharmaceutical preparations and substances for the treatment of thrombosis, embolisms, drug delivery agents, namely, preparations and substances for facilitating the delivery of pharmaceutical and medicinal preparations and substances; preparations and substances for facilitating the delivery of pharmaceutical and medicinal preparations and substances, namely, drug delivery agents consisting of compounds that facilitate delivery of a wide range of pharmaceuticals; pharmaceutical preparations and substances for use in the circulatory system; pharmaceutical preparations and substances for embolisation; pharmaceutical preparations and substances for embolisation of tumours and arteriovenous malformations (AVMs); pharmaceutical preparations and substances for use in the circulatory system for the treatment of tumours and AVMs; transarterial chemoembolisation pharmaceutical preparations; pharmaceutical preparations and substances for facilitating the delivery of pharmaceutical and medicinal preparations and substances, namely, therapeutic agents for delivery of radioactive materials to target sites within the body for the treatment of cancer

FIRST USE 12-23-2015; IN COMMERCE 12-23-2015

CLASS 10: Surgical, medical apparatus and instruments, namely, medical device, apparatus and instruments for treating cancer; drug delivery embolisation apparatus, instruments and systems; apparatus and instruments for use in the circulatory system, namely, catheters, injection syringes and sealed vials; medical apparatus and instruments for embolisation; surgical and medical apparatus and instruments, namely, catheters, injection syringes and sealed vial devices for dispensing microspheres during embolisation procedures in blood vessels and in the circulatory system; embolisation apparatus, instruments and systems comprising surgical and medical instruments for embolization, namely, embolic devices for use in treating cancer and tumors, embolic devices for treating arteriovenous malformations (AVMs) of the body, and embolic devices for use in treating tumors; drug delivery embolisation systems; drug delivery apparatus and instruments namely, a drug delivery system comprised of injection syringes and sealed vials; injection syringes for use with catheters; apparatus and instruments for use in the circulatory system, namely, catheters, injection syringes and sealed vials for dispensing microspheres during embolisation procedures in blood vessels and in the circulatory system; medical apparatus and instruments for embolization, namely, medical devices in the nature of particles, namely, embolic microspheres for embolization; surgical and medical apparatus and instruments for embolisation, namely, embolisation apparatus, instruments and systems comprising microspheres and injection syringes for use in blood vessels and the circulatory system to carry out embolisation; surgical and medical apparatus and instruments for use in the circulatory system; surgical and medical apparatus for use in treatment of, arterio-venous

Michelle K. Lee

Director of the United States Patent and Trademark Office

malformations; syringes for use in treatment of, arterio-venous malformations

FIRST USE 12-23-2015; IN COMMERCE 12-23-2015

CLASS 41: Education, namely, developing, arranging and conducting educational seminars, workshops and programs and providing courses of instruction in the fields of healthcare, the use of pharmaceuticals and medical devices, medical research, surgery, medical science, medicine, medical diseases, disorders and related treatments; provision of educational content namely, providing on-line instruction in the fields of healthcare, the use of pharmaceuticals and medical devices, medical research, surgery, medical science, medicine, medical diseases, disorders and related treatments; providing computer, electronic and online databases featuring information about medical education in the field of healthcare, medicine, medical treatment and patient care; training in the use and operation of pharmaceutical products, pharmaceutical preparations, radiopharmaceutical preparations, medical devices, medical imaging apparatus and medical research apparatus and consultation relating thereto; educational services, namely, conducting live and online seminars, classes, workshops, lectures, panel discussions, and training programs in the fields of healthcare, the use of pharmaceutical and medical devices, medical research, surgery, medical science, medicine and medical diseases, disorders and related treatments; Educational services, namely, providing non-downloadable webinars in the fields of healthcare, the use of pharmaceuticals and medical devices, medical research, surgery, medical science, medicine, medical diseases, disorders and related treatments; educational services, namely, conducting live and online seminars, classes, workshops, lectures, panel discussions and training in the field of health; educational services, namely, providing non-downloadable webinars in the field of health; education services, namely, conducting online and telephonic instruction and courses in the fields of health and medical issues

FIRST USE 1-26-2017; IN COMMERCE 1-26-2017

THE MARK CONSISTS OF STANDARD CHARACTERS WITHOUT CLAIM TO ANY PARTICULAR FONT STYLE, SIZE OR COLOR

SER. NO. 86-764,515, FILED 09-22-2015
DAVID AARO BROOKSHIRE, EXAMINING ATTORNEY

REQUIREMENTS TO MAINTAIN YOUR FEDERAL TRADEMARK REGISTRATION

WARNING: YOUR REGISTRATION WILL BE CANCELLED IF YOU DO NOT FILE THE DOCUMENTS BELOW DURING THE SPECIFIED TIME PERIODS.

Requirements in the First Ten Years*
What and When to File:

- ***First Filing Deadline:*** You must file a Declaration of Use (or Excusable Nonuse) between the 5th and 6th years after the registration date. See 15 U.S.C. §§1058 1141k. If the declaration is accepted, the registration will continue in force for the remainder of the ten-year period, calculated from the registration date, unless cancelled by an order of the Commissioner for Trademarks or a federal court.

- ***Second Filing Deadline:*** You must file a Declaration of Use (or Excusable Nonuse) and an Application for Renewal between the 9th and 10th years after the registration date.* See 15 U.S.C. §1059.

Requirements in Successive Ten-Year Periods*
What and When to File:

- You must file a Declaration of Use (or Excusable Nonuse) and an Application for Renewal between every 9th and 10th-year period, calculated from the registration date.*

Grace Period Filings*

The above documents will be accepted as timely if filed within six months after the deadlines listed above with the payment of an additional fee.

***ATTENTION MADRID PROTOCOL REGISTRANTS:** The holder of an international registration with an extension of protection to the United States under the Madrid Protocol must timely file the Declarations of Use (or Excusable Nonuse) referenced above directly with the United States Patent and Trademark Office (USPTO). The time periods for filing are based on the U.S. registration date (not the international registration date). The deadlines and grace periods for the Declarations of Use (or Excusable Nonuse) are identical to those for nationally issued registrations. See 15 U.S.C. §§1058, 1141k. However, owners of international registrations do not file renewal applications at the USPTO. Instead, the holder must file a renewal of the underlying international registration at the International Bureau of the World Intellectual Property Organization, under Article 7 of the Madrid Protocol, before the expiration of each ten-year term of protection, calculated from the date of the international registration. See 15 U.S.C. §1141j. For more information and renewal forms for the international registration, see http://www.wipo.int/madrid/en/.

NOTE: Fees and requirements for maintaining registrations are subject to change. Please check the USPTO website for further information. With the exception of renewal applications for registered extensions of protection, you can file the registration maintenance documents referenced above online at http://www.uspto.gov.

NOTE: A courtesy e-mail reminder of USPTO maintenance filing deadlines will be sent to trademark owners/holders who authorize e-mail communication and maintain a current e-mail address with the USPTO. To ensure that e-mail is authorized and your address is current, please use the Trademark Electronic Application System (TEAS) Correspondence Address and Change of Owner Address Forms available at http://www.uspto.gov.

Generated on: This page was generated by TSDR on 2017-11-06 13:57:47 EST

Mark: SEE MORE. TREAT SMARTER.

SEE MORE. TREAT SMARTER.

US Serial Number:	86764515	**Application Filing Date:**	Sep. 22, 2015
US Registration Number:	5205582	**Registration Date:**	May 16, 2017
Filed as TEAS RF:	Yes	**Currently TEAS RF:**	Yes
Register:	Principal		
Mark Type:	Trademark, Service Mark		
Status:	Registered. The registration date is used to determine when post-registration maintenance documents are due.		
Status Date:	May 16, 2017		
Publication Date:	Jul. 12, 2016	**Notice of Allowance Date:**	Sep. 06, 2016

Mark Information

Mark Literal Elements:	SEE MORE. TREAT SMARTER.
Standard Character Claim:	Yes. The mark consists of standard characters without claim to any particular font style, size, or color.
Mark Drawing Type:	4 - STANDARD CHARACTER MARK

Goods and Services

Note: The following symbols indicate that the registrant/owner has amended the goods/services:

- Brackets [..] indicate deleted goods/services;
- Double parenthesis ((..)) identify any goods/services not claimed in a Section 15 affidavit of incontestability; and
- Asterisks *..* identify additional (new) wording in the goods/services.

For: Pharmaceutical, medicinal substances, namely, pharmaceutical preparations for the treatment of cancer, pharmaceutical preparations and substances for the treatment of thrombosis, embolisms, drug delivery agents, namely, preparations and substances for facilitating the delivery of pharmaceutical and medicinal preparations and substances; preparations and substances for facilitating the delivery of pharmaceutical and medicinal preparations and substances, namely, drug delivery agents consisting of compounds that facilitate delivery of a wide range of pharmaceuticals; pharmaceutical preparations and substances for use in the circulatory system; pharmaceutical preparations and substances for embolisation; pharmaceutical preparations and substances for embolisation of tumours and arteriovenous malformations (AVMs); pharmaceutical preparations and substances for use in the circulatory system for the treatment of tumours and AVMs; transarterial chemoembolisation pharmaceutical preparations; pharmaceutical preparations and substances for facilitating the delivery of pharmaceutical and medicinal preparations and substances, namely, therapeutic agents for delivery of radioactive materials to target sites within the body for the treatment of cancer

International Class(es):	005 - Primary Class	**U.S Class(es):**	006, 018, 044, 046, 051, 052
Class Status:	ACTIVE		
Basis:	1(a)		
First Use:	Dec. 23, 2015	**Use in Commerce:**	Dec. 23, 2015

For: Surgical, medical apparatus and instruments, namely, medical device, apparatus and instruments for treating cancer; drug delivery embolisation apparatus, instruments and systems; apparatus and instruments for use in the circulatory system, namely, catheters, injection syringes and sealed vials; medical apparatus and instruments for embolisation; surgical and medical apparatus and instruments, namely, catheters, injection syringes and sealed vial devices for dispensing microspheres during embolisation procedures in blood vessels and in the circulatory system; embolisation apparatus, instruments and systems comprising surgical and medical instruments for embolization, namely, embolic devices for use in treating cancer and tumors, embolic devices for treating arteriovenous malformations (AVMs) of the body, and embolic devices for use in treating tumors; drug delivery embolisation systems; drug delivery apparatus and instruments namely, a drug delivery system comprised of injection syringes and sealed vials; injection syringes for use with catheters; apparatus and instruments for use in the circulatory system, namely, catheters, injection syringes and sealed vials for dispensing microspheres during embolisation procedures in blood vessels and in the circulatory system; medical apparatus and instruments for embolization, namely, medical devices in the nature of particles, namely, embolic microspheres for embolization; surgical and medical apparatus and instruments for embolisation, namely, embolisation apparatus, instruments and systems comprising microspheres and injection syringes for use in blood vessels and the circulatory system to carry out embolisation; surgical

and medical apparatus and instruments for use in the circulatory system; surgical and medical apparatus for use in treatment of, arterio-venous malformations; syringes for use in treatment of, arterio-venous malformations

International Class(es): 010 - Primary Class
U.S Class(es): 026, 039, 044
Class Status: ACTIVE
Basis: 1(a)
First Use: Dec. 23, 2015
Use in Commerce: Dec. 23, 2015

For: Education, namely, developing, arranging and conducting educational seminars, workshops and programs and providing courses of instruction in the fields of healthcare, the use of pharmaceuticals and medical devices, medical research, surgery, medical science, medicine, medical diseases, disorders and related treatments; provision of educational content namely, providing on-line instruction in the fields of healthcare, the use of pharmaceuticals and medical devices, medical research, surgery, medical science, medicine, medical diseases, disorders and related treatments; providing computer, electronic and online databases featuring information about medical education in the field of healthcare, medicine, medical treatment and patient care; training in the use and operation of pharmaceutical products, pharmaceutical preparations, radiopharmaceutical preparations, medical devices, medical imaging apparatus and medical research apparatus and consultation relating thereto; educational services, namely, conducting live and online seminars, classes, workshops, lectures, panel discussions, and training programs in the fields of healthcare, the use of pharmaceutical and medical devices, medical research, surgery, medical science, medicine and medical diseases, disorders and related treatments; Educational services, namely, providing non-downloadable webinars in the fields of healthcare, the use of pharmaceuticals and medical devices, medical research, surgery, medical science, medicine, medical diseases, disorders and related treatments; educational services, namely, conducting live and online seminars, classes, workshops, lectures, panel discussions and training in the field of health; educational services, namely, providing non-downloadable webinars in the field of health; education services, namely, conducting online and telephonic instruction and courses in the fields of health and medical issues

International Class(es): 041 - Primary Class
U.S Class(es): 100, 101, 107
Class Status: ACTIVE
Basis: 1(a)
First Use: Jan. 26, 2017
Use in Commerce: Jan. 26, 2017

Basis Information (Case Level)

Filed Use:	No	**Currently Use:**	Yes	**Amended Use:**	No
Filed ITU:	Yes	**Currently ITU:**	No	**Amended ITU:**	No
Filed 44D:	No	**Currently 44D:**	No	**Amended 44D:**	No
Filed 44E:	No	**Currently 44E:**	No	**Amended 44E:**	No
Filed 66A:	No	**Currently 66A:**	No		
Filed No Basis:	No	**Currently No Basis:**	No		

Current Owner(s) Information

Owner Name: BTG International Limited
Owner Address: 5 Fleet Place
London EC4M7RD
UNITED KINGDOM
Legal Entity Type: private limited company
State or Country Where Organized: UNITED KINGDOM

Attorney/Correspondence Information

Attorney of Record

Attorney Name: Jonathan A. Hyman
Docket Number: RJENK70.032T
Attorney Primary Email Address: efiling@knobbe.com
Attorney Email Authorized: Yes

Correspondent

Correspondent Name/Address: JONATHAN A. HYMAN
Knobbe Martens Olson & Bear Llp
2040 Main St Fl 14
Irvine, CALIFORNIA 92614-8214
UNITED STATES
Phone: 310-551-3450
Fax: 949-760-9502
Correspondent e-mail: efiling@knobbe.com
jonathan.hyman@knobbe.com
Correspondent e-mail Authorized: Yes

Domestic Representative

Domestic Representative Name:	Jonathan A. Hyman	**Phone:**	310-551-3450
Fax:	949-760-9502		
Domestic Representative e-mail:	efiling@knobbe.com	**Domestic Representative e-mail Authorized:**	Yes

Prosecution History

Date	Description	Proceeding Number
May 16, 2017	REGISTERED-PRINCIPAL REGISTER	
Apr. 11, 2017	NOTICE OF ACCEPTANCE OF STATEMENT OF USE E-MAILED	
Apr. 08, 2017	ALLOWED PRINCIPAL REGISTER - SOU ACCEPTED	
Mar. 17, 2017	STATEMENT OF USE PROCESSING COMPLETE	71906
Mar. 06, 2017	USE AMENDMENT FILED	71906
Mar. 16, 2017	CASE ASSIGNED TO INTENT TO USE PARALEGAL	71906
Mar. 06, 2017	TEAS STATEMENT OF USE RECEIVED	
Sep. 06, 2016	NOA E-MAILED - SOU REQUIRED FROM APPLICANT	
Jul. 12, 2016	OFFICIAL GAZETTE PUBLICATION CONFIRMATION E-MAILED	
Jul. 12, 2016	PUBLISHED FOR OPPOSITION	
Jun. 22, 2016	NOTIFICATION OF NOTICE OF PUBLICATION E-MAILED	
Jun. 02, 2016	APPROVED FOR PUB - PRINCIPAL REGISTER	
Jun. 02, 2016	EXAMINER'S AMENDMENT ENTERED	88888
Jun. 02, 2016	NOTIFICATION OF EXAMINERS AMENDMENT E-MAILED	6328
Jun. 02, 2016	EXAMINERS AMENDMENT E-MAILED	6328
Jun. 02, 2016	EXAMINERS AMENDMENT -WRITTEN	90330
May 17, 2016	TEAS/EMAIL CORRESPONDENCE ENTERED	88889
May 16, 2016	CORRESPONDENCE RECEIVED IN LAW OFFICE	88889
May 16, 2016	TEAS RESPONSE TO OFFICE ACTION RECEIVED	
Jan. 09, 2016	NOTIFICATION OF NON-FINAL ACTION E-MAILED	6325
Jan. 09, 2016	NON-FINAL ACTION E-MAILED	6325
Jan. 09, 2016	NON-FINAL ACTION WRITTEN	90330
Jan. 09, 2016	ASSIGNED TO EXAMINER	90330
Sep. 28, 2015	NEW APPLICATION OFFICE SUPPLIED DATA ENTERED IN TRAM	
Sep. 25, 2015	NEW APPLICATION ENTERED IN TRAM	

TM Staff and Location Information

TM Staff Information - None

File Location

Current Location:	PUBLICATION AND ISSUE SECTION	**Date in Location:**	Apr. 08, 2017

United States of America
United States Patent and Trademark Office

Reg. No. 4,560,891

Registered July 1, 2014

Int. Cls.: 5, 10, 41, and 44

TRADEMARK

SERVICE MARK

PRINCIPAL REGISTER

FRESENIUS MEDICAL CARE DEUTSCHLAND GMBH (FED REP GERMANY LIMITED LIABILITY COMPANY)
ELSE-KROENER-STRASSE 1
BAD HOMBURG, FED REP GERMANY 61352

FOR: PHARMACEUTICAL PRODUCTS FOR DIALYSIS RELATED THERAPY, NAMELY, PHARMACEUTICAL SOLUTIONS AND CONCENTRATES USED IN DIALYSIS RELATED THERAPY; PHARMACEUTICAL PREPARATIONS USED IN DIALYSIS RELATED THERAPY; DISINFECTANTS USED IN DIALYSIS THERAPY, NAMELY, DISINFECTANT HAND WASH, DISINFECTANTS FOR MEDICAL INSTRUMENTS, DISINFECTANTS FOR SANITARY PURPOSES, AND DISINFECTANTS FOR THE SKIN; NUTRITIONAL PRODUCTS, NAMELY, NUTRITIONAL SUPPLEMENTS, NUTRITIONAL SUPPLEMENT PILLS AND INFUSION SOLUTIONS USED IN ASSOCIATION WITH DIALYSIS THERAPY , IN CLASS 5 (U.S. CLS. 6, 18, 44, 46, 51 AND 52).

FIRST USE 8-0-2013; IN COMMERCE 8-0-2013.

FOR: PHARMACEUTICAL PRODUCTS, NAMELY, INJECTION DEVICE FOR PHARMACEUTICALS SOLD EMPTY; MEDICAL INSTRUMENTS AND APPARATUS, AND MEDICAL TECHNICAL DEVICES ALL USED IN DIALYSIS RELATED THERAPY, NAMELY, DIALYSIS MACHINES, DIALYSERS, DIALYSIS FILTERS, DIALYSIS MONITORS, CONTINUOUS RENAL THERAPY MACHINES, HEMOFILTRATION AND HEMODIALYSIS MACHINES, ALL FOR DIALYSIS RELATED THERAPY AND PARTS THEREOF; MEDICAL BAGS FOR MEDICAL FLUIDS FOR USE IN DIALYSIS; DIALYSIS PUMPS; MEDICAL SYRINGES; NEEDLES FOR MEDICAL USE; CATHETERS FOR DIALYSIS; CANULAE; CLOSURE CAPS FOR CATHETERS AND OTHER PARTS AND FITTINGS IN DIALYSIS THERAPY; TUBING FOR USE IN DIALYSIS THERAPY; LOCKS FOR CATHETERS AND OTHER PARTS AND FITTINGS FOR USE IN DIALYSIS THERAPY; ADAPTERS AND CONNECTERS FOR USE IN CONNECTION WITH EQUIPMENT IN DIALYSIS THERAPY, IN CLASS 10 (U.S. CLS. 26, 39 AND 44).

FIRST USE 6-0-2013; IN COMMERCE 6-0-2013.

FOR: EDUCATIONAL SERVICES, NAMELY, TRAINING, CLASSES, AND SEMINARS IN THE FIELD OF DIALYSIS THERAPY; EDUCATION SERVICES, NAMELY, PROVIDING EDUCATIONAL DEMONSTRATIONS, WORKSHOPS, AND MOTIVATIONAL SPEAKERS IN THE FIELD OF DIALYSIS THERAPY, IN CLASS 41 (U.S. CLS. 100, 101 AND 107).

UNITED STATES PATENT AND TRADEMARK OFFICE · DEPARTMENT OF COMMERCE

Michelle K. Lee

Deputy Director of the United States Patent and Trademark Office

Reg. No. 4,560,891 FIRST USE 11-0-2012; IN COMMERCE 11-0-2012.

FOR: MEDICAL SERVICES PROVIDED IN DIALYSIS RELATED THERAPY, MEDICAL SERVICES PROVIDED IN DIALYSIS CENTRES; MEDICAL SERVICES, IN CLASS 44 (U.S. CLS. 100 AND 101).

FIRST USE 2-0-2013; IN COMMERCE 2-0-2013.

OWNER OF U.S. REG. NOS. 2,300,248 AND 3,679,063.

THE MARK CONSISTS OF A GEOMETRIC ANGLE DESIGN COMPRISED OF THREE LINES AND HAVING AN OVERALL TRIANGULAR SHAPE.

SN 85-742,560, FILED 10-1-2012.

MARY ROSSMAN, EXAMINING ATTORNEY

REQUIREMENTS TO MAINTAIN YOUR FEDERAL TRADEMARK REGISTRATION

WARNING: YOUR REGISTRATION WILL BE CANCELLED IF YOU DO NOT FILE THE DOCUMENTS BELOW DURING THE SPECIFIED TIME PERIODS.

Requirements in the First Ten Years*
What and When to File:

First Filing Deadline: You must file a Declaration of Use (or Excusable Nonuse) between the 5th and 6th years after the registration date. *See* 15 U.S.C. §§1058, 1141k. If the declaration is accepted, the registration will continue in force for the remainder of the ten-year period, calculated from the registration date, unless cancelled by an order of the Commissioner for Trademarks or a federal court.

Second Filing Deadline: You must file a Declaration of Use (or Excusable Nonuse) **and** an Application for Renewal between the 9th and 10th years after the registration date.* *See* 15 U.S.C. §1059.

Requirements in Successive Ten-Year Periods*
What and When to File:

You must file a Declaration of Use (or Excusable Nonuse) **and** an Application for Renewal between every 9th and 10th-year period, calculated from the registration date.*

Grace Period Filings*

The above documents will be accepted as timely if filed within six months after the deadlines listed above with the payment of an additional fee.

The United States Patent and Trademark Office (USPTO) will NOT send you any future notice or reminder of these filing requirements.

***ATTENTION MADRID PROTOCOL REGISTRANTS:** The holder of an international registration with an extension of protection to the United States under the Madrid Protocol must timely file the Declarations of Use (or Excusable Nonuse) referenced above directly with the USPTO. The time periods for filing are based on the U.S. registration date (not the international registration date). The deadlines and grace periods for the Declarations of Use (or Excusable Nonuse) are identical to those for nationally issued registrations. *See* 15 U.S.C. §§1058, 1141k. However, owners of international registrations do not file renewal applications at the USPTO. Instead, the holder must file a renewal of the underlying international registration at the International Bureau of the World Intellectual Property Organization, under Article 7 of the Madrid Protocol, before the expiration of each ten-year term of protection, calculated from the date of the international registration. *See* 15 U.S.C. §1141j. For more information and renewal forms for the international registration, see http://www.wipo.int/madrid/en/.

NOTE: Fees and requirements for maintaining registrations are subject to change. Please check the USPTO website for further information. With the exception of renewal applications for registered extensions of protection, you can file the registration maintenance documents referenced above online at http://www.uspto.gov.

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Mark:

US Serial Number: 85742560

Application Filing Date: Oct. 01, 2012

US Registration Number: 4560891

Registration Date: Jul. 01, 2014

Register: Principal

Mark Type: Trademark, Service Mark

TM5 Common Status Descriptor:

LIVE/REGISTRATION/Issued and Active

The trademark application has been registered with the Office.

Status: Registered. The registration date is used to determine when post-registration maintenance documents are due.

Status Date: Jul. 01, 2014

Publication Date: Sep. 17, 2013

Notice of Allowance Date: Nov. 12, 2013

Mark Information

Mark Literal Elements: None

Standard Character Claim: No

Mark Drawing Type: 2 - AN ILLUSTRATION DRAWING WITHOUT ANY WORDS(S)/ LETTER(S)/NUMBER(S)

Description of Mark: The mark consists of a geometric angle design comprised of three lines and having an overall triangular shape.

Color(s) Claimed: Color is not claimed as a feature of the mark.

Design Search Code(s): 24.15.02 - Arrows forming any other geometric figure
24.15.25 - Other arrows
26.05.12 - Triangles with bars, bands and lines
26.17.12 - Angles (geometric); Chevrons

Related Properties Information

Claimed Ownership of US Registrations: 2300248, 3679063

Goods and Services

Note: The following symbols indicate that the registrant/owner has amended the goods/services:

- Brackets [..] indicate deleted goods/services;
- Double parenthesis ((...)) identify any goods/services not claimed in a Section 15 affidavit of incontestability; and
- Asterisks *..* identify additional (new) wording in the goods/services.

For: Pharmaceutical products for dialysis related therapy, namely, pharmaceutical solutions and concentrates used in dialysis related therapy; pharmaceutical preparations used in dialysis related therapy; disinfectants used in dialysis therapy, namely, disinfectant hand wash, disinfectants for medical instruments, disinfectants for sanitary purposes, and disinfectants for the skin; nutritional products, namely, nutritional supplements, nutritional supplement pills and infusion solutions used in association with dialysis therapy

International Class(es):	005 - Primary Class	**U.S Class(es):**	006, 018, 044, 046, 051, 052
Class Status:	ACTIVE		
Basis:	1(a)		
First Use:	Aug. 2013	**Use in Commerce:**	Aug. 2013

For: Pharmaceutical products, namely, injection device for pharmaceuticals sold empty; Medical instruments and apparatus, and medical technical devices all used in dialysis related therapy, namely, dialysis machines, dialysers, dialysis filters, dialysis monitors, continuous renal therapy machines, hemofiltration and hemodialysis machines, all for dialysis related therapy and parts thereof; medical bags for medical fluids for use in dialysis; dialysis pumps; medical syringes; needles for medical use; catheters for dialysis; canulae; closure caps for catheters and other parts and fittings in dialysis therapy; tubing for use in dialysis therapy; locks for catheters and other parts and fittings for use in dialysis therapy; adapters and connecters for use in connection with equipment in dialysis therapy

International Class(es):	010 - Primary Class	**U.S Class(es):**	026, 039, 044
Class Status:	ACTIVE		
Basis:	1(a)		
First Use:	Jun. 2013	**Use in Commerce:**	Jun. 2013

For: Educational services, namely, training, classes, and seminars in the field of dialysis therapy; education services, namely, providing educational demonstrations, workshops, and motivational speakers in the field of dialysis therapy

International Class(es):	041 - Primary Class	**U.S Class(es):**	100, 101, 107
Class Status:	ACTIVE		
Basis:	1(a)		
First Use:	Nov. 2012	**Use in Commerce:**	Nov. 2012

For: Medical services provided in dialysis related therapy, medical services provided in dialysis centres; medical services

International Class(es):	044 - Primary Class	**U.S Class(es):**	100, 101
Class Status:	ACTIVE		
Basis:	1(a)		
First Use:	Feb. 2013	**Use in Commerce:**	Feb. 2013

Basis Information (Case Level)

Filed Use:	No	**Currently Use:**	Yes	**Amended Use:**	No
Filed ITU:	Yes	**Currently ITU:**	No	**Amended ITU:**	No
Filed 44D:	No	**Currently 44D:**	No	**Amended 44D:**	No
Filed 44E:	No	**Currently 44E:**	No	**Amended 44E:**	No
Filed 66A:	No	**Currently 66A:**	No		
Filed No Basis:	No	**Currently No Basis:**	No		

Current Owner(s) Information

Owner Name: Fresenius Medical Care Deutschland GmbH

Owner Address: Else-Kroener-Strasse 1
Bad Homburg GERMANY 61352

Legal Entity Type: LIMITED LIABILITY COMPANY **State or Country Where Organized:** GERMANY

Attorney/Correspondence Information

Attorney of Record

Attorney Name: Scott D. Woldow **Docket Number:** 033956.015

Attorney Primary Email Address: sdwoldow@sgrlaw.com **Attorney Email Authorized:** Yes

Correspondent

Correspondent Name/Address: Scott D. Woldow
SMITH, GAMBRELL & RUSSELL, LLP
1055 Thomas Jefferson St., NW

Suite 400
WASHINGTON, DISTRICT OF COLUMBIA UNITED STATES 20007

Phone:	202-973-2612	**Fax:**	202-263-4312
Correspondent e-mail:	sdwoldow@sgrlaw.com docketing@sgrlaw.com	**Correspondent e-mail Authorized:**	Yes

Domestic Representative

Domestic Representative Name:	Scott D. Woldow	**Phone:**	202-263-4300
Fax:	202-263-4329		
Domestic Representative e-mail:	sdwoldow@sgrlaw.com	**Domestic Representative e-mail Authorized:**	Yes

Prosecution History

Date	Description	Proceeding Number
Jul. 01, 2014	REGISTERED-PRINCIPAL REGISTER	
May 30, 2014	NOTICE OF ACCEPTANCE OF STATEMENT OF USE E-MAILED	
May 29, 2014	LAW OFFICE REGISTRATION REVIEW COMPLETED	68171
May 28, 2014	ALLOWED PRINCIPAL REGISTER - SOU ACCEPTED	
May 23, 2014	STATEMENT OF USE PROCESSING COMPLETE	65362
Apr. 29, 2014	USE AMENDMENT FILED	65362
May 22, 2014	CASE ASSIGNED TO INTENT TO USE PARALEGAL	65362
Apr. 29, 2014	TEAS STATEMENT OF USE RECEIVED	
Nov. 12, 2013	NOA E-MAILED - SOU REQUIRED FROM APPLICANT	
Sep. 17, 2013	OFFICIAL GAZETTE PUBLICATION CONFIRMATION E-MAILED	
Sep. 17, 2013	PUBLISHED FOR OPPOSITION	
Aug. 28, 2013	NOTIFICATION OF NOTICE OF PUBLICATION E-MAILED	
Aug. 09, 2013	LAW OFFICE PUBLICATION REVIEW COMPLETED	68171
Aug. 09, 2013	ASSIGNED TO LIE	68171
Jul. 27, 2013	APPROVED FOR PUB - PRINCIPAL REGISTER	
Jul. 26, 2013	TEAS/EMAIL CORRESPONDENCE ENTERED	88889
Jul. 25, 2013	CORRESPONDENCE RECEIVED IN LAW OFFICE	88889
Jul. 25, 2013	TEAS RESPONSE TO OFFICE ACTION RECEIVED	
Jul. 25, 2013	TEAS CHANGE OF CORRESPONDENCE RECEIVED	
May 30, 2013	TEAS CHANGE OF CORRESPONDENCE RECEIVED	
Feb. 04, 2013	NOTIFICATION OF NON-FINAL ACTION E-MAILED	6325
Feb. 04, 2013	NON-FINAL ACTION E-MAILED	6325
Feb. 04, 2013	NON-FINAL ACTION WRITTEN	72153
Jan. 29, 2013	ASSIGNED TO EXAMINER	72153
Oct. 06, 2012	NOTICE OF DESIGN SEARCH CODE MAILED	
Oct. 05, 2012	NEW APPLICATION OFFICE SUPPLIED DATA ENTERED IN TRAM	
Oct. 04, 2012	NEW APPLICATION ENTERED IN TRAM	

TM Staff and Location Information

TM Staff Information - None

File Location

Current Location:	PUBLICATION AND ISSUE SECTION	**Date in Location:**	May 29, 2014

IN THE U.S. PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

----------x
LUPIN PHARMACEUTICALS, INC.,

Opposer, Opposition No. 91226322

v.

AMPEL, LLC,

Applicant.
----------x

EXHIBIT O

TO

DECLARATION OF THOMAS H. CURTIN IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT BY OPPOSER LUPIN PHARMACEUTICALS, INC.

(/home.html)

Frequently Asked Questions

What is the Patient Partnership Program (PPP)?

The Patient Partnership Program is a global forum made up of a small group of members from AstraZeneca teams and patients/carers with personal or professional experience in a given disease area whose goal is to learn from each other and co-create patient centric medicines and solutions throughout drug development.

Who can participate in the Patient Partnership Program?

Although it will eventually cover many disease areas, the PPP currently includes eligible individuals living with moderate to severe asthma, moderate to severe lupus, ovarian cancer, or lung cancer, as well as current or past carers for ovarian cancer or lung cancer patients. PPP partners must also have personal or professional experience in such areas as medicine, scientific research, health marketing, patient advocacy/government affairs, health education, market access, drug safety and/or digital health. The program also requires advisors to be:

- 18 years or older
- Fluent in English (written and spoken)
- Resident of either Canada, Germany, United Kingdom, USA, Spain, Belgium, Italy, China, South Korea, Japan, or Australia.

What do Patient Partnership Program Partners do?

Based upon their area(s) of functional expertise and their personal health experiences, PPP partners will share their opinions, ideas, perspectives and insights with AZ teams about projects in a number of different areas such as clinical development, marketing or disease

education. Meetings may take place via telephone, email, video conference and/or in-person.

What level of time commitment is required if I decide to join the Patient Partnership Program? Time commitment will vary depending on project needs and meeting types e.g. telephone, email, and in-person meetings. Once enrolled and patient partners are matched to specific projects, project details such as patient partner's role and responsibilities and time commitments will be discussed and agreed upon between AZ project sponsors and patient partners prior to initiation of activities. It is anticipated that discussions over telephone or video conference may require less number of hours than in-person meetings which may require travel time. You are not obligated to participate in an activity if invited to do so.

Is travel required? It is anticipated that most work will be co-created via teleconference/video conference or email. Extensive travel is not anticipated (likely no more than once or twice per year for a day or two, if at all).

Why must I sign the Privacy Notice & Consent Authorization to participate? AstraZeneca takes the privacy and security of your Personal Data very seriously. The Privacy Notice and Consent Authorization is used to outline and agree on what personal data we will collect from you and how we will use it. We are happy to explain the Authorization in greater detail and discuss any of your specific questions or concerns individually as needed. We are unable to consider you for the program without a signed Authorization confirming your willingness to share your personal and health information. Additional information about the way AstraZeneca handles privacy can be found at **www.astrazenecaprivacynotice.com (https://www.astrazenecaprivacynotice.com/home.html)**

Will you share my personal information with anyone outside of the program? No. Your personal information is securely collected, stored as confidential and will be used for internal purposes only. We will not share your data with 3rd parties and this data will not be used to market any products or services to you.

Why is the program limited to particular countries? The PPP is currently focused on Canada, Germany, United Kingdom, USA, Spain, Belgium, Italy, China, South Korea, Japan and Australia, depending on the disease area. We may include additional countries and disease areas in the future.

Why does the Patient Partnership Program only include asthma, ovarian cancer, lupus and lung cancer? The 2016 pilot phase focused on moderate to severe asthma and ovarian cancer. Shortly afterward, lupus and lung cancer were also added. We are learning best practices to create the most effective Patient Partnership Program from these initial efforts and will add additional disease areas in the near future.

Am I required to be using a product or treatment made by AstraZeneca to be a part of the program? No. Depending on the disease area of the PPP you are applying for, you may be required to be on a maintenance medication, but not on any AstraZeneca products specifically.

Will I be paid for my time and participation? Compensation for your time and services will be considered and confirmed based upon specific activity needs. If an activity requires travel, the Patient Partnership Program will reimburse you for any reasonable expenses.

Are the Patient Partnership Program staff employees of AstraZeneca? The Patient Partnership Program is managed entirely by AstraZeneca employees in order to foster lasting relationships and open lines of communication with our patient partners. AstraZeneca has employed the aid of HealthiVibe, a trusted service provider, to assist in the recruitment of patient partners for this program. For more information about HealthiVibe, please visit **www.healthivibe.com (/exit-ramp/_jcr_content/content.html?returnpage=/content/WebsiteServices/Global/395-patient-partnership-program/en/en/cookies.html&targetpage=https://www.healthivibe.com)**

What level of technology expertise is required to participate in the program? The majority of our communication and activities will take place via email, teleconference, or videoconference. If you are not already comfortable with this level of technology use, please let us know.

May I share my experiences of participating in the Patient Partnership Program on social media? No. We may at times share confidential and/or proprietary information and materials with you, which may belong exclusively to AstraZeneca. We ask that you discuss with us prior to mentioning the name of AstraZeneca and/or using any AstraZeneca information that you obtain during this program. We will explain the terms and conditions of participating in this program via an agreement that will be provided to you in advance of participating in any activities.

How can I give feedback about the Patient Partnership Program? We have much to learn from you and always welcome your feedback in order to make this program a positive experience for you, your families and also future partners. Please share your ideas and feedback by email at **PPP@healthivibe.com. (mailto:PPP@healthivibe.com)**

How many individuals will be enrolled in the Patient Partnership Program? Approximately a total of 10-12 per disease area.

How long will I be required to participate in the Patient Partnership Program? Our patient partners are contracted for a minimum period of 1 year, and may be renewed.

May I leave the program if I choose? Yes. You have the right to terminate participation with the Patient Partnership Program at any time. Please contact us by email at **PPP@healthivibe.com (mailto:PPP@healthivibe.com)** should you wish to terminate your participation in the program.

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New Resource Offers 24/7 Support for those with Mental Illness

PUBLISHED26 September 2016

Danei Edelen uses the NAMI AIR app to stay connected to supportive resources wherever she is.

Nine years ago, Danei Edelen was established in her career as a marketing executive and happily raising a family with her husband in Ohio. Then something unexpected happened. “After five nights of no sleep, hallucinations, I sought hospitalization,” Danei said. She subsequently learned she had experienced a psychotic break caused by an underlying and undiagnosed mental illness called bipolar disorder.

Bipolar disorder is a chronic mental illness that causes shifts in mood and energy level. One in five adults in the U.S. experiences a mental health issue in a given year and one in twenty-five lives with a serious mental illness such as schizophrenia or bipolar disorder.

Danei is now working again, however, maintaining her well-being is a daily challenge. She regularly attends a mental health support group called Connections, part of a national network created in 2007 by the National Alliance on Mental Illness (NAMI) with founding support from

AstraZeneca. Danei credits much of her success to support she has received from others experiencing similar mental health challenges. Since the inception of Connections, more than 45,000 patients and caregivers have benefitted from the program.

Not everyone can attend an in-person support group and sudden shifts in mood and mental stability can occur at any time. To help those living with mental illness, AstraZeneca is now supporting NAMI to offer a 24/7 virtual community through a mobile application called NAMI AIR. AIR stands for Anonymous, Inspiring, Relatable. "The AIR app fills a void in our ability to deliver support and allows us to reach a wider audience through a new platform," said Mary Giliberti, Executive Director for NAMI.

The NAMI AIR application extends the peer-to-peer support that has made Connections so successful to anyone who has a mobile phone. AIR provides a community where users can anonymously share experiences and stories, offer support to others who may need it, and connect to professional resources.

In just one year, NAMI AIR has attracted more than 11,000 users and the community is growing steadily. The app is also providing a steady referral service to NAMI's in-person support groups and to their hotline. As Giliberti said, "We [NAMI] are grateful to the AstraZeneca team for thinking 'outside of the box' and developing this important project with us, which aligns so well with our mutual interests."

AstraZeneca's partnership with NAMI is part of our commitment to make a meaningful difference for patients and communities beyond our medicines. "Addressing patient needs such as social and emotional support are central to our commitment to putting patients first," said Catherine Datto, Medical Lead, Neuroscience at AstraZeneca. "NAMI has been an excellent partner for more than ten years, helping us to deliver on this commitment for those struggling with mental health challenges. We are honored to continue to grow and evolve our work together to continue responding to patient needs."

You can learn more and download the NAMI AIR App from the App store for iPhone or Google Play for Android.

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I have read this warning and will not be using any of the contained product information for clinical purposes.

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Patients

COMMITTED TO IMPROVING THE LIVES OF PATIENTS WORLDWIDE

Underlying our commitment is a proven dedication to changing the course of human health through bold pursuits in science and transformational medicines. Our commitment to medical progress goes hand in hand with our promise to patients: all who can benefit from our discoveries should have the opportunity to do so. At Celgene, patients always come first.

Celgene **Patient Support** ›

Discover a dedicated, central point of contact to help patients and healthcare professionals access Celgene products. ›

Online **Patient Resources** ›

Find a list of organizations that provide helpful information for patients, caregivers, and healthcare providers. ›

REMS – **Pharmacy Network** ›

Identify specialty pharmacies that are contracted to fill prescriptions for the Risk Evaluation and Mitigation Strategy (REMS) restricted distribution programs for Celgene. ›

Glossary ›

Learn about some of the complicated terms a healthcare provider may use. ›

Related **Links**

Learn about Celgene therapies and services. ›

Find out more about our commitment to patient safety. ›

Locate clinical trials involving Celgene therapies. ›

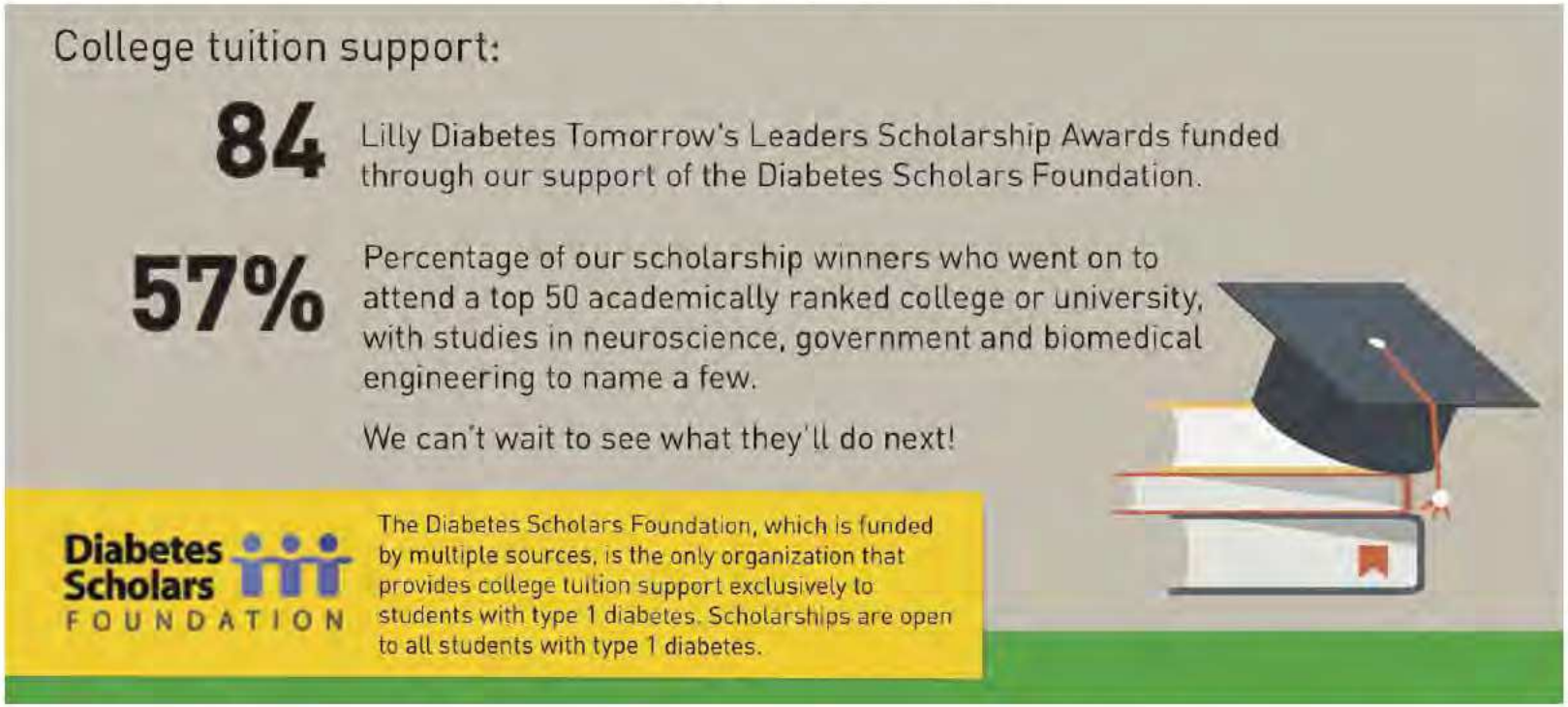
Lilly | DIABETES

MENU

College is an important point in the lives of young adults – when they take on full responsibility for their diabetes care. Lilly Diabetes supports programs to help with this transition.

THE DIABETES SCHOLARS FOUNDATION

Lilly Diabetes shares the Diabetes Scholars Foundation's (DSF) belief that young people with type 1 diabetes should live their lives to the fullest. That's why we've donated over $600,000 to DSF since 2012 in support of educational scholarships.



"The Diabetes Scholars Foundation is so grateful that Lilly Diabetes continues to support our mission to empower people with type 1 diabetes," said Mary Podjasek, president, Diabetes Scholars Foundation. "Because of successful partnerships like these, so many young adults living with type 1 diabetes are able to follow their dreams."

Learn more about the Diabetes Scholars Foundation college scholarship program here. To see all the ways Lilly Diabetes supports people with type 1 diabetes through scholarships click here.

COLLEGE DIABETES NETWORK: FOR THE HIGHS AND LOWS OF COLLEGE LIFE

The College Diabetes Network (CDN) creates a community of young adults with diabetes through its national network of campus-based chapters and empowers all students through the hub of resources available on their website. Campus life and independence are complicated enough without diabetes. CDN helps to make this transition a little easier. Lilly Diabetes is proud to be the organization's first Founding Level Corporate Member.

Originally founded in 2009 by a college student, CDN started out as a small student group on one campus but quickly grew into a national organization with chapters throughout the country. CDN's mission is to empower and improve the lives of students living with diabetes through peer support and access to information and resources.

"CDN's partnership with Lilly Diabetes began when Lilly Diabetes became our first Founding Level Corporate Partner. Lilly's commitment to our mission from the very beginning has been an integral part of our community's growth. But even more important and impactful is their continued commitment to collaboration- helping us to transform the experience of all young adults with diabetes" said Christina Roth, CDN's CEO and Founder.

Find out about the College Diabetes Network and check to see if there is a chapter on your campus.

Support you need to live with chronic granulomatous disease (CGD)

Your CGD support service team understands what you're going through. They're there to answer questions, give support, and help make life with CGD easier. Your team includes a dedicated case manager and CGD nurse educator who will work closely with you at every step along your journey—from CGD education to treatment information. These services are free of charge and built around our 3 key principles: guide, support, and connect.

Guide - Helping you get your medicine

- Work with your doctor's office to simplify the process of starting your medicine
- Help address financial barriers for you by researching your insurance benefits, finding out what your insurance will cover, and connecting you to financial assistance options
- Work with your specialty pharmacy to schedule the shipments of your medicine
- Provide you with refill reminders for your prescription

Support - Providing you with assistance and answers

- Serve as your dedicated personal resource and main point of contact for your ongoing needs
- Provide CGD education and answer any treatment-related questions
- Help you stay on therapy through any life changes, such as moving or loss of insurance or employment
- Respond to your questions and concerns, and connect you with the right resources to get answers

Connect - Bringing you together with the community

- Connect you and your family to others living with CGD through social media communities, peer-mentor programs, and live events
- Provide you and your family with helpful resources to help manage the day-to-day challenges of living with CGD
- Introduce you and your family to CGD advocacy groups for more support

To learn more about the support services that are available for patients and caregivers, call 1 (877) 305-7704.

For additional support and resources that are dedicated to helping patients and families living with CGD, please visit these organizations to learn more.

Chronic Granulomatous Disease Association

http://www.cgdassociation.org (http://www.cgdassociation.org)

The Chronic Granulomatous Disease Association is a nonprofit organization dedicated to helping those with CGD and advancing research toward a cure. The group provides helpful disease information, support for parents and patients, and other valuable tools and resources for the CGD community.

Global Genes

https://globalgenes.org (https://globalgenes.org)

Global Genes is a leading nonprofit organization for patients and families fighting rare and genetic diseases like CGD. Their mission is to provide connections and resources so people can become activists for their disease and feel empowered to keep moving forward.

Immune Deficiency Foundation

http://primaryimmune.org (http://primaryimmune.org)
The Immune Deficiency Foundation (IDF) is a national nonprofit patient organization dedicated to improving the lives of people with different kinds of primary immunodeficiency diseases, such as CGD. IDF provides a wide variety of resources for people with CGD, including information about diagnosis and treatment options, at www.livingwithcgd.org (http://www.livingwithcgd.org).

Jeffrey Modell Foundation

http://www.info4pi.org (http://www.info4pi.org)
The Jeffrey Modell Foundation is a nonprofit organization devoted to diagnosis, meaningful treatments, and cures for primary immunodeficiency diseases. Thirty years after its creation, the organization continues its mission of hope, advocacy, and action by supporting the medical and global patient community.

National Organization for Rare Disorders

https://rarediseases.org (https://rarediseases.org)
The National Organization for Rare Disorders (NORD) is a patient advocacy organization dedicated to people with rare diseases and the groups that help them. NORD provides patients and families with helpful advocacy information, assistance programs, and connections to patient organizations.

Important Safety Information

What is ACTIMMUNE® (Interferon gamma-1b) used for?

ACTIMMUNE® is part of a drug regimen used to treat Chronic Granulomatous Disease, or CGD. CGD is a genetic disorder, usually diagnosed in childhood, that affects some cells of the immune system and the body's ability to fight infections effectively. CGD is often treated (though not cured) with antibiotics, antifungals, and ACTIMMUNE.

ACTIMMUNE is also used to slow the worsening of severe, malignant osteopetrosis (SMO). SMO is a genetic disorder that affects normal bone formation and is usually diagnosed in the first few months after birth.

When should I not take ACTIMMUNE?

Don't use ACTIMMUNE if you are allergic to interferon-gamma, *E coli*-derived products, or any ingredients contained in the product.

What warnings should I know about ACTIMMUNE?

At high doses, ACTIMMUNE can cause (flu-like) symptoms, which may worsen some pre-existing heart conditions.

ACTIMMUNE may cause decreased mental status, walking disturbances, and dizziness, particularly at very high doses. These symptoms are usually reversible within a few days upon dose reduction or discontinuation of therapy.

Bone marrow function may be suppressed with ACTIMMUNE, and decreased production of cells important to the body may occur. This effect, which can be severe, is usually reversible when the drug is discontinued or the dose is reduced.

Taking ACTIMMUNE may cause reversible changes to your liver function, particularly in patients less than 1 year old. Your doctor should monitor your liver function every 3 months, and monthly in children under 1 year.

In rare cases, ACTIMMUNE can cause severe allergic reactions and/or rash. If you experience a serious reaction to ACTIMMUNE, discontinue it immediately and contact your doctor or seek medical help.

What should I tell my healthcare provider?

Be sure to tell your doctor about all the medications you are taking.

Tell your doctor if you:

- are pregnant or plan to become pregnant or plan to nurse
- have a cardiac condition such as irregular heartbeat, heart failure, or decreased blood flow to your heart
- have a history of seizures or other neurologic disorders
- have, or have had, reduced bone marrow function. Your doctor will monitor these cells with blood tests at the beginning of therapy and at 3-month intervals on ACTIMMUNE therapy

What are the side effects of ACTIMMUNE?

The most common side effects with ACTIMMUNE are "flu-like" symptoms such as fever, headache, chills, muscle pain, or fatigue, which may decrease in severity as treatment continues. Bedtime administration of ACTIMMUNE may help reduce some of these symptoms. Acetaminophen may be helpful in preventing fever and headache.

What other medications might interact with ACTIMMUNE?

Some drugs may interact with ACTIMMUNE to potentially increase the risk of damage to your heart or nervous system, such as certain chemotherapy drugs. Tell your doctor about all other medications you are taking.

Avoid taking ACTIMMUNE at the same time as a vaccination.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch (http://www.fda.gov/medwatch), or call 1-800-FDA-1088 (tel:1-800-332-1088). You may also contact the Horizon Pharma Medical Information Department toll-free at 1-866-479-6742 (tel:1-866-479-6742) or medicalinformation@horizonpharma.com (mailto:medicalinformation@horizonpharma.com).

The risk information provided here is not comprehensive. To learn more, talk about ACTIMMUNE with your healthcare provider or pharmacist. The FDA-approved product labeling can be found at http://www.ACTIMMUNE.com (http://www.ACTIMMUNE.com/chronic-granulomatous-disease) or 1-866-479-6742 (tel:1-866-479-6742).

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

Patient Advocacy Overview

When patients benefit, everyone benefits.

It's a belief that we hold at our core and runs through everything we do. And it's why we partner with more than 50 patient advocacy groups, from large global organizations to small, local groups, addressing the needs of people living with common disorders to those struggling with very rare diseases.

Each year, our more than 1,000 employees take part in hundreds of advocacy events around the world supporting people living with diseases that our medicines help treat, including rare disorders and rheumatic conditions. Through these interactions, we're able to listen, learn and support the creation of new resources that address the most pressing unmet needs.

The following are just a few examples of our advocacy efforts:

- #RAREIS CAMPAIGN – ELEVATING THE FACES OF THE RARE DISEASE COMMUNITY

In February of 2017, we launched *RAREis™*, an initiative that aims to elevate the voices, faces and experiences of people living with rare diseases, as well as highlight programs and resources for the rare disease community. The campaign is anchored by an Instagram page (https://www.instagram.com/rareis____/) that showcases photos of people touched by rare disease and captures elements of their patient, caregiver or advocate experience.

To learn more, read the RAREis campaign's inaugural press release (http://ir.horizon-pharma.com/releasedetail.cfm?ReleaseID=1014862) and watch the video below.

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- UCD IN COMMON™ – CREATED FOR AND FROM THE UCD COMMUNITY

Created in collaboration with people living with a urea cycle disorder (UCD), their families, caregivers and healthcare professionals, *UCD in Common* offers supportive, educational and interactive resources.

A website and Facebook page provide shareable videos and lifestyle tips as well as low-protein recipes for people living with a UCD who must restrict their protein intake because of its effect of elevating ammonia levels.

"*UCD in Common* is a labor of love for those of us who collaborated with Horizon on its creation," said Guadalupe M., mother of a young daughter with a UCD and one of 13 members of Horizon Pharma's UCD patient and caregiver working group.

"In working together with other families, we noticed many challenges we had in common at different stages of our journey. As the initiative evolves, we're excited to hear from more families so that we can find strength through our individual experiences and inspire others to confidently face the challenges of managing a UCD."

To learn more, visit the community's website, UCDinCommon.com (https://www.ucdincommon.com/), or Facebook page (https://www.facebook.com/UCDinCommon), and watch the video below.

- SCHOLARSHIPS FOR THE IMMUNE DEFICIENCY FOUNDATION'S NATIONAL CONFERENCE

The Immune Deficiency Foundation's (IDF) National Conference will include a special symposium and activities for people affected by Chronic Granulomatous Disease (CGD). In addition to learning from experts, it's an incredible opportunity for those living with the disease to meet peers who are also dealing with the rare disease.

Horizon Pharma sponsored scholarships that IDF provided for individuals and families with CGD to attend the conference in June 2017. Scholarships included retreat registration, hotel room, and limited travel.

People affected by CGD may apply for future scholarships by visiting IDFNAtionalConference.org/Scholarships (http://idfnationalconference.org/Scholarships).

- CGD™ CONNECTIONS

CGD Connections is a community resource for people with chronic granulomatous disease (CGD), a rare disease affecting about 1 in every 200,000 people in the United States. Through a dedicated Facebook page, *CGD Connections* offers practical advice and helpful information about living with and managing CGD, as well as a place to share with others living with CGD.

To learn more, visit the CGD Connections Facebook page (https://www.facebook.com/CGDConnections/).

- KNOW CYSTINOSIS™

Know Cystinosis is a website dedicated to helping people with cystinosis, a rare, genetic metabolic condition. The site provides education about the disease as well as tips for living with cystinosis, including guides for talking with children, planning for school and college and more.

To learn more, visit KnowCystinosis.com (http://www.knowcystinosis.com/).

- HORIZON NEPHROPATHIC CYSTINOSIS SCHOLARSHIP (HNCS)

Global Genes, a leading global rare disease patient advocacy organization, and Horizon Pharma have partnered to provide people living with nephropathic cystinosis an opportunity to further their education and pursue long-term career goals through a special scholarship.

“In our experience working alongside people living with rare diseases, we’ve witnessed an increasing resilience to overcome adversity and pursue long-term goals,” said Rob Metz, senior vice president, patient advocacy, Horizon Pharma plc. “We hope that these scholarships will give inspiration to many people living with the daily challenges of nephropathic cystinosis. Global Genes is an ideal partner to lead this effort, given the organization’s track record providing connections and resources for the rare disease community.”

- SUPPORTING THE NURSING COMMUNITY, HEROES OF CARING

The “Heroes of Caring” project was created to recognize and celebrate the extraordinary work of nurses who commit themselves to rheumatology care. This collaborative initiative—between the non-profit professional nursing organization, Rheumatology Nurses Society (RNS) and Horizon Pharma—captures the real-life stories and work of those caring for patients worldwide.

To learn more, visit HeroesofCaring.org (http://www.HeroesofCaring.org/) and watch the video below.

Rheumatoid Nurses Society

Our Company (Http://Www.Horizonpharma.Com/Company/About-Us/)

Our Medicines (Http://Www.Horizonpharma.Com/Medicines/Portfolio/)

Our Patients (Http://Www.Horizonpharma.Com/Patients/Our-Commitment/)

Our Culture (Http://Www.Horizonpharma.Com/Culture-Values/)

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Global

Patient Group Funding

Novartis works with many organizations that advocate for patients around the world. These organizations play a crucial role by informing and supporting patients, as well as safeguarding the rights of patients and caregivers. Further, patient organizations provide healthcare companies with important advice from their own perspective. Interacting with patient organizations enables Novartis to learn about and understand unmet patient needs, as well as barriers to treatment success. This information can guide us in developing therapies and solutions that effectively address these needs.

In all our interactions with patient groups, we are committed to working ethically and transparently while respecting their integrity. Novartis fully complies with all legal and statutory requirements regarding the disclosure of patient group support as a minimum standard in any country.

Novartis discloses our relationships with patient organizations by March 31 every year, in compliance with the Code of Practice (http://www.efpia.eu/documents/44/100/National-Member-Associations-Code-of-Practice-on-relationships-between-the-pharmaceutical-industry-and-patient-organisations) on Relationships between the Pharmaceutical Industry and Patient Organizations set by the European Federation of Pharmaceutical Industries and Associations (EFPIA (http://www.efpia.eu)). Novartis fully recognizes that it has many common interests with patient organizations that represent and support the needs of patients and their caregivers. Novartis endorses the EFPIA Code ensuring that its relationships with patient organizations take place in an ethical and transparent manner.

- Download the 2016 report (PDF 0.9 MB) (https://www.novartis.com/sites/www.novartis.com/files/patient-support-web-report-

Related Links

Payments to Healthcare Professionals (/about-us/corporate-responsibility/doing-business-responsibly/transparency/payments-healthcare-professionals)

Responsible Procurement (/about-us/corporate-responsibility/doing-business-responsibly/responsible-procurement)

Positions (/about-us/corporate-responsibility/resources/positions)

Standards of Integrity (/about-us/corporate-responsibility/doing-business-responsibly/ethics-compliance/standards-integrity)

Annual Report 2016

Review the strategy and annual performance of Novartis and read letters from our Chairman and CEO.

Learn More (https://www.novartis.com/news/annual-report-2016)

2016.pdf)

- Download the 2015 report (PDF 0.5 MB) (https://www.novartis.com/sites/www.novartis.com/files/patient-support-web-report-2015.pdf)
- Download the 2014 report (PDF 3 MB) (https://www.novartis.com/sites/www.novartis.com/files/patient-support-web-report-2014.pdf)
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- Download the 2012 report (PDF 3 MB) (https://www.novartis.com/sites/www.novartis.com/files/patient-support-web-report-2012.pdf)

Read our position on patient group interaction and support (PDF 62 KB) (https://www.novartis.com/sites/www.novartis.com/files/patient-organization-interaction-disclosure-support.pdf)

Read the EFPIA Code (http://transparency.efpia.eu/the-efpia-code-2)

LUP-003029

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IBRANCE™
palbociclib | 125 mg capsules

Please see full Prescribing Information, Important Safety Information, and Indications for IBRANCE.

PERSONALIZED SUPPORT

We go one step further to connect you to the resources you need, when you need them

At Pfizer Oncology Together, we're here to help. Your dedicated Care Champion will provide you with personalized support—all in one place. Whether it's answers to your questions or help with treatment and financial resources, we're here to offer assistance when you need it most.

SUPPORT BEYOND TREATMENT

IBRANCE SUPPORT

Important Safety Information and Indications

IBRANCE may cause serious side effects, including:

Low white blood cell counts (neutropenia). Low white blood cell counts are very common when taking IBRANCE and may cause serious infections that can lead to death. Your doctor should check your white blood cell counts before and during treatment.

If you develop low white blood cell counts during treatment with IBRANCE, your doctor may stop your treatment, decrease your dose, or may tell you to wait to begin your

LUP-003030

Our Care Champions can guide you with resources that can make a difference in managing your day-to-day life, including nutrition information, help getting to and from your appointments, and connecting you with support groups so that you never feel alone. For problems big and small, you'll always have a place to turn.*

Financial Support

Find options to help cover the cost of your medicine—regardless of your insurance coverage.

Support Connections

Connect to local, community, and patient outreach programs that offer comfort and support.

Ongoing Education

Get guidance on living with cancer, including tips on lifestyle, nutrition, and talking with loved ones.

Lodging and Transportation

Learn about local programs that offer help with transportation or lodging while on treatment.

Custom Check-ins

Schedule check-ins that work around you —offering support when you need it and want it.

Workplace Guidance

Receive tools and support to help you prepare for leaving or returning to work after being diagnosed.

*Some services are provided through third-party patient advocacy organizations.

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IBRANCE SUPPORT

IBRANCE ANSWERS

Whether or not you're new to IBRANCE, IBRANCE Answers is here to offer insights, facts, and resources throughout your treatment. You can sign up for ongoing support to help you learn more about IBRANCE and to receive free resources, like our Patient Brochure, Caregiver Guide, Pill Organizer, and Treatment Journal.

LEARN MORE

MBC TOGETHER

A diagnosis of metastatic breast cancer isn't something you have to face alone. A strong support system can help you in your fight against MBC. That's why MBC Together is here for you and your loved ones. Find support and resources from this inspiring community of women who don't allow their diagnosis to define them.

The MBC Together Mentor Program offers women taking IBRANCE, or their caregivers, the opportunity to speak directly with a patient or caregiver ambassador by phone, one-on-one.

LEARN MORE

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Important Safety Information and Indications

IBRANCE may cause serious side effects, including:

Low white blood cell counts (neutropenia). Low white blood cell counts are very common when taking IBRANCE and may cause serious infections that can lead to death. Your doctor should check your white blood cell counts before and during treatment.

If you develop low white blood cell counts during treatment with IBRANCE, your doctor may stop your treatment, decrease your dose, or may tell you to wait to begin your treatment cycle. Tell your doctor right away if you have signs and symptoms of low white blood cell counts or infections such as fever and chills.

Before you take IBRANCE, tell your doctor if you:

- have fever, chills, or any other signs or symptoms of infection.
- have liver or kidney problems.
- have any other medical conditions.
- are pregnant or plan to become pregnant; IBRANCE can harm your unborn baby.
  - Females who are able to become pregnant and who take IBRANCE should use effective birth control during treatment and for at least 3 weeks after stopping IBRANCE.
  - Males who are taking IBRANCE and have female partners who can become pregnant should use effective birth control during treatment with IBRANCE and for 3 months after the final dose of IBRANCE.
- are breastfeeding or plan to breastfeed; it is not known if IBRANCE passes into your breast milk. You and your doctor should decide if you will take IBRANCE or breastfeed. You should not do both.

Common side effects of IBRANCE include:

- Low red blood cell counts and low platelet counts. Call your doctor right away if you develop any of these symptoms during treatment:
  - dizziness
  - shortness of breath
  - weakness
  - bleeding or bruising more easily
  - nosebleeds

Other common side effects include: infections, tiredness, nausea, sore mouth, abnormalities in liver blood tests, diarrhea, hair thinning or hair loss, vomiting, rash, and loss of appetite.

IBRANCE may cause fertility problems in males. This may affect your ability to father a child. Talk to your doctor if this is a concern for you.

Th[illegible]

Indications

IBRANCE is a prescription medicine used to treat hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) breast cancer that has spread to other parts of the body (metastatic) in combination with:

- an aromatase inhibitor as the first hormonal based therapy in women who have gone through menopause, or
- fulvestrant in women with disease progression following hormonal therapy.

Please see Full Prescribing Information and Patient Information.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

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Pfizer Oncology together™

Patient Support. Financial Assistance. Together.

FOR LIVE SUPPORT, CALL 1-844-9-IBRANCE
(Monday–Friday 8 AM–8 PM ET)

LUP-003034

Welcome to Sanofi

in the United States

LUP-003035

Resources for Patients

You are here :

- Home Page >
- Patients and Providers >
- Resources for Patients

- Patients and Providers
  - Resources for Healthcare Providers
  - Resources for Patients

Resources for Patients

- Email to a friend

The following Sanofi US health websites and resources, categorized according to therapeutic area, provide information on a wide variety of diseases and conditions.

- Atopic Dermatitis
- Diabetes
- Cardiovascular
- Infectious Diseases
- Rare Diseases
- Vaccination

Atopic Dermatitis

EczemaExposed.com is a consumer disease awareness website designed to engage and educate adults who are dealing with atopic dermatitis in their lives. EczemaExposed.com educates through interactive tools, a quiz, and engaging content defining atopic dermatitis, the itch-scratch cycle, and an underlying root cause of AD - inflammation under the skin. People suffering with AD can register for a self-empowerment program, *Atopic Dermatitis Insider*, hosted on EczemaExposed.com. *Atopic Dermatitis Insider* teaches proactive behavior skills to help the person suffering with AD to manage their symptoms of persistent itch and pain, empower adults to better advocate for their atopic dermatitis treatment needs with their HCP, and better self-care by through learned skills to manage their symptoms.

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Diabetes

Diabetes Sanofi Twitter Page

Follow the Sanofi US Diabetes Twitter feed at twitter.com/Diabetes_Sanofi to receive tweets on diabetes information and tips to live a healthier lifestyle.

Resources:

Contact us

Sanofi US

55 Corporate Drive
Bridgewater, NJ 08807

- Via email
- Tel: 800-981-2491

American Diabetes Association: www.diabetes.org
American Association of Diabetes Educators: www.aadenet.org
National Diabetes Education Program: www.ndep.nih.gov
American Dietetic Association: www.eatright.org
Follow Sanofi US diabetes (www.twitter.com/diabetes_sanofi) on Twitter to learn more about our engagement in the U.S. diabetes community. Through our tweets, we share statistics and insights, as well as links to valuable diabetes resources.

Sanofi US Diabetes Facebook Page

'Like' the Sanofi US Diabetes Facebook page at www.facebook.com/sanofiUSDiabetes/ to participate in and stay up-to-date on relevant discussions regarding life with diabetes.

The DX: The Diabetes Experience

TheDX.com is a digital diabetes destination with a mix of interesting stories, both original and curated from trusted sources. discover information, inspiration and practical advice. it's about life and life with diabetes.

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Cardiovascular

Take Down Cholesterol

Visit www.takedowncholesterol.com/ to learn about the causes, effects and management of high LDL cholesterol. Get expert tips and advice, access educational resources, set cholesterol health goals and sign up for a personalized plan that can help you make positive changes for better heart health.

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Rare Diseases

Fabry Community

Fabry disease is one of several rare genetic disorders known as lysosomal storage disorders. Fabry Community provides resources and education for Fabry patients, caregivers, and healthcare professionals. Visit www.FabryCommunity.com to learn the causes, diagnosis and management of Fabry disease.

Gaucher Care

Gaucher disease is an inherited genetic disorder affecting 1 in 40,000-60,000 people worldwide. Gaucher Care provides people living with Gaucher, and their friends and families, information about the disease, treatment options and supportive care. www.GaucherCare.com/ is also an educational resource for healthcare professionals to learn about the causes, diagnosis, and management of Gaucher disease.

MPS I Disease

MPS I disease is an inherited genetic disorder caused by a deficiency in an enzyme called alpha-L-iduronidase. Learn more about MPS I disease, its symptoms, and how it's passed on through families at www.mps1disease.com/. Hear from other MPS I patients, get tips on how to cope, find out more about disease management, and access additional resources and support.

Pompe Community

Pompe disease is a progressive neuromuscular disorder. Visit www.pompe.com to learn more about the signs and symptoms, diagnosis and testing, and strategies and resources for living with Pompe disease. The Pompe community also provides information for healthcare professionals about the disease's pathology, clinical manifestations, and diagnostic and management options.

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Infectious Diseases

Clostridium Difficile

Clostridium difficile (C. difficile) is a very common bacterium that can live in the human gut. Some people have it without symptoms, while in others it can range from mild diarrhea to severe colitis and in some cases, death. 350,000 Americans are hospitalized every year due to *C. difficile*. Sanofi Pasteur is conducting the Cdiffense trial to evaluate the safety, immunogenicity and efficacy of an investigational vaccine for the prevention of primary symptomatic *C. Difficile*. To learn more about study enrollment and primary symptomatic *C. Difficile* infection, visit: www.cdiffense.org/.

Influenza

Influenza, or 'the flu', is a contagious illness that can be severe or life threatening, especially for older adults. Immune systems weaken with age, which makes the flu harder for older people to fight. Flu + You is an educational program from the National Council on Aging and Sanofi Pasteur that provides information about the seriousness of the flu, the importance of prevention and available vaccine options. To learn more, visit Flu + You.

Meningitis

Meningitis is an inflammation of the lining of the brain and spinal cord and although rare, it is potentially life threatening. Because teens and young adults are at increased risk, the Centers for Disease Control and Prevention recommend vaccination for adolescents 11 through 18 years of age. The National Association of School Nurses have joined together as Voices of Meningitis to inform parents about meningococcal disease that can potentially cause death or disability to otherwise healthy teens within just 1 day. Voices of Meningitis is an educational initiative made possible through Sanofi Pasteur. To learn more, visit Voices of Meningitis.

Vaccination

Immunization

The choice to immunize a child against infectious diseases is an important decision, often confounded by a lot of confusing information about immunizations. Helpful, factual information about childhood vaccines is available at ImmYounity, a website by Sanofi Pasteur, that also includes information about vaccination throughout adulthood. ImmYounity is grounded in science in order to make the informed decisions about immunization.

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US.COR.16.11.006

Last update: December 19, 2016

PERSONALIZED SUPPORT FROM TEVA'S SHARED SOLUTIONS®

Teva's Shared Solutions® understands and cares about how relapsing MS (RMS) can affect you. We will stand side by side with you to provide the resources and support you need to help you achieve your RMS management goals.

Through financial support, training and nurse support, and educational resources, Teva's Shared Solutions® will partner with you throughout your COPAXONE® therapy experience.

Watch the video below to learn more, and download the Shared Solutions® brochure (PDF) to read anytime.

"Since Day One of this journey, Shared Solutions® has been side by side with me."

-Sonia, Teva Survey Respondent

Financial Support

Teva's Shared Solutions® is dedicated to helping you find affordable access to COPAXONE® therapy—we can assist you in searching for financial solutions that may help prevent financial concerns from getting in the way of starting and staying on COPAXONE®.

Teva's Shared Solutions® financial support includes:

COPAXONE Co-pay Solutions®

If you're eligible for COPAXONE Co-pay Solutions®, your co-pay for 3-times-a-week COPAXONE® 40 mg could be lowered to $0 per month out of pocket.†† Terms and conditions apply. Call Teva's Shared Solutions® for information about COPAXONE Co-pay Solutions® for

Use SHOW MORE

COPAXONE® (glatiramer acetate injection) is prescription medicine used for the treatment of people with relapsing forms of multiple sclerosis (MS).

Important Safety Information

working hard for you to help make your COPAXONE® affordable.

Terms and Conditions

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Training and Nurse Support

Teva's Shared Solutions® is dedicated to providing you with support, education, and training to enhance your COPAXONE® therapy experience. Teva-trained nurses are caring professionals who can come to your home and work with you to create a personalized injection plan, help you maintain your commitment to therapy, and help you achieve your treatment goals.

Teva's Shared Solutions® training and nurse support includes:

MS-certified nurse phone support, 24/7

Teva's Shared Solutions® is there for you whenever you need support. Compassionate MS-certified nurses are available by phone around the clock—so you will always have the one-on-one support you need.

1-on-1 injection training

Be confident with your injection technique throughout your therapy experience. Before you inject for the first time, you should be trained by a doctor or nurse, even if you have used an injectable therapy before. Be sure to call Teva's Shared Solutions® at 1-800-887-8100 to set up an appointment for free, in-home, 1-on-1 injection training when you start COPAXONE® therapy and at any time throughout your treatment experience.

Tools for therapy tracking

Teva's Shared Solutions® has carefully and thoughtfully created resources to help you stay on track with COPAXONE®; we've developed innovative, interactive injection-tracking tools to help you manage your COPAXONE® injections and stay the course with COPAXONE®.

Nurse support

Teva's Shared Solutions® offers in-person support from dedicated Teva-trained nurses, who focus on educating you about RMS and COPAXONE® therapy, and offer caring support through 1-on-1 injection training throughout your therapy experience. These committed professionals partner with you to help you stay on track with your COPAXONE®.

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Educational Resources

Teva's Shared Solutions® cares about empowering you to stay committed to your COPAXONE® therapy. We can connect you with resources, people, and programs to help you obtain knowledge about COPAXONE® and RMS. We can provide ways for you to stay current on the latest RMS management tools and Teva's COPAXONE® developments, while creating opportunities for you to meet and interact with others who are also living with RMS.

Teva's Shared Solutions® educational resources include:

Educational programs
Teva's Shared Solutions® feels strongly about keeping you connected to the MS community. That is why we provide you with live educational events, webcasts, and teleconferences to help you stay informed and empowered.

Peer resources
Teva's Shared Solutions® recognizes the importance of making a personal connection with someone who has had similar experiences. Shared Solutions® connects you with an MS Peer so you can get support from someone who can relate to your experience of living with RMS. To learn more from the perspective of an MS Peer, check out the MS Peer Spotlight. MS Peers are peers with relapsing forms of MS who are compensated by Teva.

Personalized communication
Teva's Shared Solutions® is committed to staying close in touch. You will receive personalized ongoing contact from the team at Teva's Shared Solutions® via email, mail, or phone, so you can be confident knowing that you have someone with you every step of the way.

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Shared Solutions® Services Tool

GET SUPPORT

Personalized service from Shared Solutions®

EXPLORE VIRTUAL PROFILES

To find out what offerings are most relevant to your needs, try Teva's Shared Solutions® Services Tool today.

Use

COPAXONE® (glatiramer acetate injection) is prescription medicine used for the treatment of people with relapsing forms of multiple sclerosis (MS).

Important Safety Information

Do not take COPAXONE® if you are allergic to glatiramer acetate or mannitol.

Some patients report a short-term reaction right after injecting COPAXONE®. This reaction can involve flushing (feeling of warmth and/or redness), chest tightness or pain with heart palpitations, anxiety, and trouble breathing. These symptoms generally appear within minutes of an injection, last about 15 minutes, and do not require specific treatment. During the postmarketing period, there have been reports of patients with similar symptoms who received emergency medical care. If symptoms become severe, call the emergency phone number in your area. Call your doctor right away if you develop hives, skin rash with irritation, dizziness, sweating, chest pain, trouble breathing, or severe pain at the injection site. If any of the above occurs, do not give yourself any more injections until your doctor tells you to begin again.

Chest pain may occur either as part of the immediate postinjection reaction or on its own. This pain should only last a few minutes. You may experience more than one such episode, usually beginning at least one month after starting treatment. Tell your doctor if you experience chest pain that lasts for a long time or feels very intense.

A permanent indentation under the skin (lipoatrophy or, rarely, necrosis) at the injection site may occur, due to local destruction of fat tissue. Be sure to follow proper injection technique and inform your doctor of any skin changes.

The most common side effects in studies of COPAXONE® are redness, pain, swelling, itching, or a lump at the site of injection, flushing, rash, shortness of breath, and chest pain. These are not all of the possible side effects of COPAXONE®. For a complete list, ask your doctor or pharmacist. Tell your doctor about any side effects you have while taking COPAXONE®.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see full Prescribing Information for Teva's COPAXONE®.

Connect with us on Lift MS Blog & Facebook:

CALL A MS-CERTIFIED NURSE
1.800.887.8100

Injections for 3-times-a-week COPAXONE® 40 mg must be at least 48 hours apart.

†Applies only to daily COPAXONE® 20 mg. Certain limits and restrictions apply.
Terms and Conditions for daily COPAXONE® include: COPAXONE Co-pay Solutions® is open to both new and existing patients who are residents of the US or Puerto Rico and who have commercial prescription insurance coverage for COPAXONE® 20 mg. The offer is not valid for uninsured patients or patients covered in whole or in part by Medicaid, Medicare, TRICARE, or any other federal or state government pharmaceutical assistance plan or program (regardless of whether a specific prescription is covered), or by private health benefit programs that reimburse for the entire cost of prescription drugs. Use of this offer must be consistent with the terms of any drug benefit provided by a health insurer, health plan, or private third-party payor. This offer is void in Massachusetts and where otherwise prohibited by law, taxed, or restricted. No additional purchase is required. This offer is valid only at participating pharmacies and may be changed or discontinued at any time without notice. This program is not health insurance.

††Applies only to 3-times-a-week COPAXONE® 40 mg. Certain limits and restrictions apply.
Terms and Conditions for 3-times-a-week COPAXONE® include: COPAXONE Co-pay Solutions® is open to both new and existing patients who are residents of the US or Puerto Rico and who have commercial prescription insurance coverage for COPAXONE® 40 mg. The offer is not valid for uninsured patients or patients covered in whole or in part by Medicaid, Medicare, TRICARE, or any other federal or state government pharmaceutical assistance plan or program (regardless of whether a specific prescription is covered), or by private health benefit programs that reimburse for the entire cost of prescription drugs. Use of this offer must be consistent with the terms of any drug benefit provided by a health insurer, health plan, or private third-party payor. This offer is void where prohibited by law, taxed, or restricted. No additional purchase is required. This offer is valid only at participating pharmacies and may be changed or discontinued at any time without notice. This program is not health insurance.

LUP-003044

TEVA SUPPORT SOLUTIONS®

1-844-838-2211
Monday–Friday, 9AM–7PM ET
www.TevaSupportSolutions.com

PERSONALIZED EDUCATION & SUPPORT FROM CLINICAL NURSE EDUCATORS

Our Clinical Nurse Educators care about your treatment experience. These trusted nurses are highly trained, well educated, and properly licensed in your state. These Clinical Nurse Educators can provide you with personalized support and education at a location that is convenient for you.

Contact Teva Support Solutions® to learn if there is a Clinical Nurse Educator available in your area. Call **1-844-838-2211**, Monday through Friday, 9 AM to 7 PM ET.

FOR PRODUCT INFORMATION FOR CINQAIR® (RESLIZUMAB) INJECTION, VISIT CINQAIR.COM >

TEVA SUPPORT SOLUTIONS®

Using Toujeo® Here's How.

Important Safety Information | Full Prescribing Information (http://products.sanofi.us/toujeo/toujeo.pdf)

Read Full Transcript

Start your once-daily, long-acting insulin Toujeo treatment off right by learning how to use the Toujeo SoloStar® pen. This video walks you through what you need to know about using the Toujeo SoloStar pen.

"I like the small needle, the push button injection—and a dosing window I can actually see."

—Gail, a real Toujeo patient

What's on this page:

Is the Toujeo Solostar pen easy to use? People said "yes"

At the end of a 4-week study, 95% of type 2 first-time insulin users rated the Toujeo SoloStar pen as easy to use.

All patients in the study were trained how to use the pen by their healthcare providers.

It is important to ask your healthcare provider how to use the pen before using it.

The redesigned Toujeo SoloStar prefilled pen is based on the award-winning design of the Lantus® (insulin glargine injection) 100 Units/mL SoloStar pen.

*The study compared Toujeo SoloStar, FlexPen®, and KwikPen® in a laboratory environment; doses were not delivered into tissue.

The Toujeo SoloStar pen can stay 6 weeks out of the fridge after first use.

Once a day, every day

Toujeo is a long-acting insulin that should be taken once daily at the same time each day. It releases gradually with no pronounced peak or wear-off between doses.

Dial in your recommended dose

Insulin first-timers:

Everybody's diabetes is different. Expect your starting dose to be adjusted over time. Often, it will be increased until your doctor working with you finds the Toujeo dose you need.

Already long-acting insulin users:

Expect to start at the same dose as your other long-acting insulin, and your doctor may adjust as necessary.

Having a routine can help

Work with your doctor to pick a time that fits your schedule, and take Toujeo at that same time each day to help with blood sugar control around the clock. A good way to help remember is to find something that you already do at the same time each day. For example:

Right after your morning walk

When your favorite TV show starts

Before you go to bed

Get your own Coach to help you get started

You get lots of advice about diabetes. But how do you make sense of it all? Once you discuss your treatment plan with your doctor, Toujeo COACH can help. Whether you're just beginning long-acting insulin, or are already on it, it's nice to have someone to turn to. And of course, it's at no cost to you. You need a Toujeo prescription to get started on COACH.

Get only the support you want, the way you want it

One size does not fit all. With Toujeo COACH, you decide how you want your Nurse Coach to communicate with you. You can receive calls, e-mails, or texts.

Your own Nurse Coach

Once you sign up, your Nurse Coach will reach out and be your regular contact. It's all about helping you work toward better managing your diabetes based on your doctor's treatment plan.

Tips tailored for you

Want tips? Your Nurse Coach can help. Topics include: meal planning, blood sugar testing, how to inject insulin, medication reminders, and more.

Once you have a prescription, you can sign up

Everyone starting Toujeo can get a Coach.

LUP-003048

Most common and Serious side effects

When taking any medication, it's important to understand how it might affect your body, and Toujeo is no different. Before starting Toujeo, talk to your doctor about all the possible side effects.

For all insulins, including Toujeo, the most common side effect is hypoglycemia. Ask your doctor about the signs and symptoms of hypoglycemia, how to monitor your blood sugar, and what to do if you have a hypoglycemic event.

Toujeo may cause serious side effects including severe allergic reactions. Get medical help right away if you have:

- A rash over your whole body
- Extreme drowsiness, dizziness, or confusion
- Shortness of breath
- Trouble breathing
- Swelling of your face, tongue, or throat
- Fast heartbeat

These are not all the possible side effects of Toujeo. Talk with your doctor about possible side effects.
For more detailed information, see the full Important Safety Information and full Prescribing Information. (http://products.sanofi.us/toujeo/toujeo.pdf)

Also keep in mind

Do not use a syringe to remove Toujeo from your Solostar disposable prefilled pen. Never reuse needles or share insulin pens even if the needle has been changed.

FAQs: Questions people ask about Toujeo

If you're like most people, you have questions. Let us break down the answers to some of the questions most often asked about diabetes—and Toujeo.

- **Why should I consider insulin?**
- **What should I know about long-acting insulin?**
- **How can adding an insulin like Toujeo help me?**
- **Why should I take Toujeo at the same time each day?**
- **Can Toujeo be taken with diabetes pills?**
- **Will I need to change the dose or how often I take mealtime insulin while on Toujeo?**
- **If Toujeo is more concentrated, why is it recommended to start with a 1-to-1 conversion from Lantus?**
- **Will I need a higher dose of Toujeo than Lantus later on?**
- **What is the most common side effect of Toujeo?**

IN THE U.S. PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

----------x
LUPIN PHARMACEUTICALS, INC.,

Opposer, Opposition No. 91226322

v.

AMPEL, LLC,

Applicant.
----------x

EXHIBIT P

TO

DECLARATION OF THOMAS H. CURTIN IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT BY OPPOSER LUPIN PHARMACEUTICALS, INC.

AMPEL BIO SOLUTIONS LLC

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 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.

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 in 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-depth 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 were 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 path to advancing Lupus treatments. Under LRxL™, AMPEL conducted extensive research to compile valuable information relating to the potential treatments and therapies for Lupus. A core component of this information is the development of what is simply referred to as LRxL™, an actual list of all pharmaceuticals that may assist in the treatment of Lupus. Under its LRxL™ program, AMPEL will continue its research efforts and will update and revise the LRxL™ as appropriate. 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-rich trials on the novel and interesting agents of the Lupus Treatment List that have a high likelihood 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 summit in November of 2014.

LuCIN STAT™ -

An initial core initiative of LuCIN™ is LuCIN STAT,™ ground-breaking research and clinical trials dedicated to testing the identified Lupus therapies. Under the LUCIN STAT™ program, LuCIN™ will focus on SLE treatment and acceleration trials for the Lupus therapies that are added to the LRxL™.

LuPPiN™

LuPPiN™, or the Lupus Patient Partner Integrator Network, is AMPEL's patient centric program to develop a network of caregivers, patients and patient advocates dedicated to assisting and supporting Lupus patients. LuPPiN™ has its roots in Dr. Peter Lipsky's internationally recognized 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 detect 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 important contribution patients can make in the development of new treatments. Working together with Lupus advocacy organizations and individuals, AMPEL through its LuPPiN™ program is pushing the boundaries of clinical research and developing ways of improving the clinical trial experience by actively engaging patient involvement.

CoLTs™

AMPEL BioSolutions has developed a unique and proprietary system for assessing the efficacy of Lupus treatment known as CoLTs™. CoLTs™ enables potential Lupus therapies to be scored and ranked based on defined criteria. As part of its CoLTs™ program, AMPEL BioSolutions provides analysis of Lupus therapies to its partners who

are testing existing Lupus therapies and/or hereafter-discovered Lupus therapies. Parties that are interested in utilizing CoLTs™ should contact AMPEL.

Lupus Drug Candidates

Kadmon, KD025 ROCK2 inhibitor

Janssen, Stelara IL-12/23 inhibitor

Clients & Collaborators

Alliance *for* Lupus Research

PREVENT. TREAT. CURE.

Lupus Research Institute

janssen

PHARMACEUTICAL COMPANIES OF Johnson & Johnson

Kadmon

Pfizer

gsk
GlaxoSmithKline

About AMPEL

AMPEL BioSolutions is a biomedical research consultation firm specializing in translational and personalized medicine including drug and target identification, protocol design and management, biomarker identification, and bioinformatic analysis.

Read more...

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- Drug Repurposing
- Rapid Results
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- Clinical Trial Design & Management
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- Disease Biomarkers

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Press Releases

27 2016
SEP
27 2016

NEW RESULTS PUBLISHED DEMONSTRATE EFFECTIVENESS OF AMPEL'S INNOVATIVE SYSTEM

New results published in the professional journal Lupus demonstrate the effectiveness of an innovative system developed to identify promising treatments for lupus among existing drugs approved for use in other...

JUN
22 2016

PILOT STUDY WITH UVA TO EXPLORE MORE WAYS TO TACKLE LUPUS

"A pilot study at UVa Research Park will explore the science behind the old saying "mind over matter." A local company called AMPEL Biosolutions is teaming up with the University of Virginia...

24 2015
22 2015
15 2015
09 2015

26 2014
20 2014
02 2014

Contact AMPEL

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Charlottesville, Virginia 22911

434-296-2675 (AMPL)

Fax: 434-964-9586

info@ampel.org

Get Map

IN THE U.S. PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

----------x
LUPIN PHARMACEUTICALS, INC.,

Opposer, Opposition No. 91226322

v.

AMPEL, LLC,

Applicant.
----------x

EXHIBIT Q

TO

DECLARATION OF THOMAS H. CURTIN IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT BY OPPOSER LUPIN PHARMACEUTICALS, INC.

NewsRoom

8/10/15 Chain Drug Rev. 73
2015 WLNR 25225428

Chain Drug Review

August 10, 2015

Volume 37; Issue 12

Allergan to sell generic drug business to Teva for $40.5 billion.

JERUSALEM -- Teva Pharmaceutical Industries Ltd. says it will pay $40.5 billion in cash and stock for Allergan's generic drugs unit in an acquisition that will reinforce Teva's position as the world's No. 1 maker of generics. In another deal, **Lupin** Ltd. announced that it would buy Gavis Pharmaceuticals LLC in an $880 million transaction.

The Teva-Allergan deal, believed to be the largest in Israel's corporate history, gives Teva stronger economies of scale. Industry analysts assert that Teva, which dropped its hostile pursuit of Mylan, will likely have to sell off some chugs to allay antitrust concerns of the Federal Trade Commission.

Allergan, which is recognized for its Botox anti-wrinkle treatment, became the third-largest generic drug maker in the United States after combining with Actavis in March.

"This transaction delivers on Teva's strategic objectives in both generics and specialty," said president and chief executive officer Erez Vigodman. "Through our acquisition of Allergan Generics, we will establish a strong foundation for long-term, sustainable growth, anchored by leading generics capabilities and a world-class late-stage pipeline that will accelerate our ability to build an exceptional portfolio of products--both in generics and specialty as well as the intersection of the two. Our respective portfolios of generic medicines and applications are highly complementary, providing Teva with high-quality growth and earnings visibility, and the scale and resources to expand upon our specialty capabilities.

"Given our in-depth knowledge and understanding of Allergan's world-class generics business, we are confident we can realize the projected synergies and accretion inherent in this acquisition for our stockholders and integrate Allergan Generics quickly into Teva. With pro forma revenues of approximately $26 billion and combined EBITDA [earnings before interest, taxes, depreciation and amortization] of approximately $9.5 billion anticipated in 2016, this acquisition reinforces our strategy, accelerates growth and diversifies revenues both by product and geographically, supporting our new business model. I strongly believe that as a result of our strengthened financial profile following this transaction, we will be even better positioned to reap the benefits of Teva's integrated, innovative specialty and generic research to support top line growth and expand our portfolio across the business."

In another example of consolidation, **Lupin** has entered into a definitive agreement to acquire privately held Gavis Pharmaceuticals. The transaction has been unanimously approved by the boards of both companies.

The acquisition enhances **Lupin**'s scale in the U.S. generics market and also broadens **Lupin**'s pipeline in dermatology, controlled substance products and other high-value and niche generics. Gavis brings to **Lupin** a highly skilled U.S.-based research and development organization that complements **Lupin's** Coral Springs, Fla., inhalation R&D center.

Gavis' New Jersey-based manufacturing facility will become **Lupin**'s first manufacturing site in the U.S.

Gavis is a privately held company specializing in formulation development, manufacturing, packaging, sales, marketing and distribution of pharmaceutical products. It recorded sales of $96 million in fiscal year 2014, and it has over 250 New Jersey-based employees. Gavis currently has 66 Abbreviated New Drug Application (ANDA) filings pending approval of the Food and Drug Administration and a pipeline of more than 65 representing niche dosage forms.

Gavis' pending filings address a market value of about $9 billion. The combined company will have a portfolio of 101 in-market products, 164 cumulative filings pending approval and a deep pipeline of products under development for the U.S. The acquisition creates the fifth-largest portfolio of ANDA filings with the FDA, addressing a $63.8 billion market.

---- Index References ----

Company: "TEVA" LIMITED LIABILITY CO; CNA HOLDINGS INC; CNA HOLDINGS LLC; TEVA PHARMACEUTICAL INDUSTRIES LTD; ALLERGAN PLC; GAVIS PHARMACEUTICALS LLC; **LUPIN** LTD; MYLAN NV; TEVA PHARMACEUTICAL INDUSTRIES LTD

News Subject: (Business Management (1BU42); Corporate Events (1CR05); Corporate Groups & Ownership (1XO09); Mergers & Acquisitions (1ME39))

Industry: (Drug Approval Process (1DR91); Drug Discovery & Development Process (1DR41); Generic Drugs (1GE93); Pharmaceuticals (1PH33); Pharmaceuticals & Biotechnology (1PH13); Pharmaceuticals Research & Development (1PH57))

Region: (Americas (1AM92); New Jersey (1NE70); North America (1NO39); U.S. Mid-Atlantic Region (1MI18); USA (1US73))

Language: EN

Other Indexing: (Erez Vigodman; Erez Vigodman; Coral Springs) (Israel)

Keywords: (Business); (Pharmaceuticals and cosmetics industries); (Retail industry); (Pharmaceutical industry); (Generic drugs); (Pharmaceutical industry); (Generic drugs)

Company Terms: Teva Pharmaceutical Industries Ltd.

Sic: 2833; 2834

Naics Code: 325411; 325412

Ticker Symbol: TEVA

Word Count: 578

End of Document

NewsRoom

5/23/14 Baltimore Bus. J. (Pg. Unavail. Online)
2014 WLNR 14200034

Baltimore Business Journal

May 23, 2014

Baltimore's pharmaceutical companies at work

Carolyn Proctor

A spotlight on some of the pharmaceuticals being developed by local firms.

Actavis Inc. is currently developing a new treatment for infertility, and also two new long-acting contraceptives. Long-acting contraceptives currently on the market include injections, implants and IUDs.Cerecor Inc. has a new antidepressant in Phase II development designed to treat severely depressed and suicidal patients by taking effect much faster than current drugs on the market.Eisai Inc. has a large number of drugs in development right now, including many to treat various forms of cancer, and several neurology medications treating Alzheimer's disease, seizures and insomnia.Gliknik Inc. has two drugs in Phase II development that are made to generate immune responses against cancer, so that one's immune system can actually attack a cancerous tumor.**Lupin** Ltd., parent of Baltimore's **Lupin** Pharmaceuticals Inc., is currently developing new anti-diabetic drugs, new medications for pain and inflammation, new treatments for auto-immune diseases such as rheumatoid arthritis, cancer treatments, anti-virals and treatments for central nervous system disorders.

---- Index References ----

Company: **LUPIN** LTD; EISAI INC; ACTAVIS PLC; CERECOR INC; GLIKNIK INC

Industry: (Drug Discovery & Development Process (1DR41); Healthcare Practice Specialties (1HE49); Cancer Drugs (1CA21); Pharmaceuticals (1PH33); Oncology & Hematology (1ON95); Pharmaceuticals Research & Development (1PH57); Allergy & Immunology (1AL96); Internal Medicine (1IN54); Drug Approval Process (1DR91); Healthcare (1HE06); Immunology (1IM66); Drugs (1DR89); Pharmaceuticals & Biotechnology (1PH13))

Region: (Maryland (1MA47); Americas (1AM92); U.S. Mid-Atlantic Region (1MI18); USA (1US73); North America (1NO39))

Language: EN

Word Count: 197

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NewsRoom

NewsRoom

4/10/14 Balt. Sun 10A
2014 WLNR 9690858

Baltimore Sun (MD)

April 10, 2014

Section: BUSINESS MARYLAND

DAILY BRIEFING

THE BALTIMORE SUN

Two bidders will vie for 1st Mariner Bank today

1st Mariner Bank, Baltimore's largest independent bank, will go to auction this morning with two bidders vying for the bank. Parent company First Mariner Bancorp is selling the bank as part of the parent's Chapter 11 bankruptcy, filed Feb. 10. The bank's deposits, loans, contracts and other business will not be affected as the bank is not included in the bankruptcy. A court filing by the company Wednesday said the bank has received one bid, which was not identified, in addition to the previously disclosed bid by a group of investors led by the New York investment firm Priam Capital. "More than one qualified bid has been received by the bid deadline," according to the filing, which paves the way for today's private auction under the court-approved procedures. Priam has made the only publicly known bid, for just under $4.8 million. It also would recapitalize the bank with $80 million to $100 million. Attorneys for the bank and for creditors could not be reached Wednesday. First Mariner's bankruptcy capped a year- long struggle to recover after residential loans soured during the housing bust. After today's auction, which is closed to the public, the bank is required to identify the successful bidder in a court filing within one business day. The winning bidder will require court approval at a hearing April 14. Priam would have been considered the successful bidder if no others had made offers.

-- Lorraine Mirabella

Epic Pharmacies will seek successor to retiring CEO

Cockeysville-based Epic Pharmacies Inc. said Wednesday it is searching for a CEO and president to replace Angelo Voxakis, who plans to retire at the end of the year. Voxakis, a longtime advocate for community pharmacies and a pharmacy owner, has led the national network of independently owned pharmacies for 16 years. The company has formed an executive search committee. Epic has grown from 300 member pharmacies to 1,500 since Voxakis joined the co-op of community pharmacies. Membership in Epic Pharmacy Network Inc., which offers centralized contracting services, also has grown, from 280 to 2,200 stores. Epic, formed in 1982, offers programs and services while returning its net revenues to its members.

-- Lorraine Mirabella

Lupin's name on harbor building marks expansion

Lupin Pharmaceuticals Inc. has placed its name in lights over the Inner Harbor, a mark of the Indian drug manufacturer's growing presence since the company located its U.S. headquarters in Baltimore more than a decade ago. **Lupin**, which today sells about 70 different generic products in the United States, started with three people in small offices at the World Trade Center in the early 2000s. It now employs more than 60 people on two floors at 111 S. Calvert Street, part of a U.S.

workforce about 200-strong, said Mary Furlong, executive vice president of corporate development. “We thought it was important to put our name out there, to signal to people that this is a good, growing company here in the U.S.,” Furlong said. The Baltimore office focuses on sales and marketing, as well as human resources and financing. Research and development historically has occurred in India, but the company opened a Florida R&D center last year, and plans to announce a second facility this year. **Lupin** is looking “very seriously” at Maryland for the site, Furlong said. **Lupin** first selected Baltimore for its proximity to the Food and Drug Administration, as well as connections to the Northeast corridor, she said. The company acquired signage rights after it added a second floor last summer.

-- Natalie Sherman

---- Index References ----

Company: **LUPIN** PHARMACEUTICALS INC; FIRST MARINER BANCORP; Priam Capital

News Subject: (Business Management (1BU42); Corporate Events (1CR05); Bankruptcies (1BA08))

Industry: (Healthcare Services (1HE13); Financial Services (1FI37); Drugstores (1DR73); Healthcare (1HE06); Pharmacy (1PH23); Banking (1BA20))

Region: (North America (1NO39); USA (1US73); Maryland (1MA47); U.S. Mid-Atlantic Region (1MI18); Americas (1AM92))

Language: EN

Other Indexing: (Epic Pharmacies Inc.; Epic Pharmacy Network Inc.) (Lorraine Mirabella; Angelo Voxakis; Mary Furlong; Natalie Sherman; Lorraine Mirabella Lupin)

Edition: FINAL

Word Count: 586

End of Document

NewsRoom

1/6/14 Chain Drug Rev. 82
2014 WLNR 2255289

Chain Drug Review

January 6, 2014

Volume 36; Issue 1

Generics are set to make more inroads.

BURLINGTON, Mass. -- Between now and 2020, 40 blockbuster brands will lose patent exclusivity in the United States, according to Decision Resources, a pharmaceutical and health care research and advisory firm.

In a report released last month, it says the loss of brand sales to generics is forecast to exceed $155 billion over this period.The largest single-year loss of brand exclusivity will occur in 2015, and through 2020 the share of generics opportunities will increasingly shift from small-molecule drugs to branded biologics and recombinant proteins.

Drug manufacturers are encountering difficulty in generating replacement blockbusters because of cost pressures imposed by insurers, patients and physicians.The Wall Street Journal recently reported that of 271 drugs that have been launched since 2006, only 13 have garnered sales of over $1 billion, down from 33 of 257 medications that were introduced over the previous five years.

”Blockbusters are not going to be that common anymore,” Ganesh Vedarajan, who leads the oncology and specialty therapeutics sector of ZS Associates told the newspaper.

ZS, a sales and marketing management consultant to pharmaceutical manufacturers, recently reviewed about 500 drug launches.It found that those that were introduced between 2006 and 2010 averaged $143 million in annual sales in the United States three years after arriving on the market.That compared with $208 million in annual sales in the United States for the previous five years.

The trend is continuing.In December, the Food and Drug Administration approved more than a half-dozen generic versions of Cymbalta, the antidepressant that’s now Eli Lilly & Co.’s top-selling drug.The six genetics manufacturers--Teva Pharmaceutical Industries and India’s **Lupin**, Sun Phanna, Torrent Pharmaceuticals, Aurobindo Pharma and Dr. Reddy’s--quickly began rolling out their versions.Analysts predict that branded Cymbalta is likely to see most of its sales evaporate quickly.

Like other innovator companies, Lilly is attempting to push its in-development drugs to market.But industry observers assert that even should the new therapies receive regulatory FDA approval, those products may not deliver as much as Lilly once hoped.

---- Index References ----

Company: DR REDDYS LABORATORIES LIMITED ADR; DOW JONES AND CO INC; TEVA PHARMACEUTICAL INDUSTRIES LTD; **LUPIN** LTD; AUROBINDO PHARMA LTD; ZS ASSOCIATES INC; TORRENT PHARMACEUTICALS LTD; ELI LILLY AND CO

News Subject: (Major Corporations (1MA93))

Industry: (Drug Discovery & Development Process (1DR41); Generic Drugs (1GE93); Pharmaceuticals & Biotechnology (1PH13); Pharmaceuticals Research & Development (1PH57); Pharmaceuticals (1PH33); Drug Approval Process (1DR91))

Region: (Americas (1AM92); North America (1NO39))

Language: EN

Other Indexing: (Sun Phanna) (Reddy; Ganesh Vedarajan)

Keywords: (Business); (Pharmaceuticals and cosmetics industries); (Retail industry); (Pharmaceutical Preparations); (Generic Drugs); (Forecasts, trends, outlooks); (Pharmaceutical industry); (Pharmaceutical industry - Forecasts and trends); (Generic drugs); (Proteins)

Product: Medicinal Chemicals & Botanical Products; Pharmaceuticals; Medicinal and Botanical Manufacturing; Pharmaceutical Preparation Manufacturing

Sic: 2833; 2834

Naics Code: 325411; 325412

Word Count: 334

End of Document

News

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Blog

HDMA Honors Pharmaceutical and Consumer Product Manufacturers With Annual DIANA Awards

June 3, 2014

ARLINGTON, Va. — HDMA honored pharmaceutical and consumer product manufacturers at its 2014 Business and Leadership Conference in Phoenix, Ariz., through the presentation of the Association's annual Distribution Industry Awards for Notable Achievements in Healthcare (the DIANA awards).

The DIANA awards have recognized supply chain excellence and successful trading partner relationships since 1959. The awards honor pharmaceutical and consumer product manufacturers for developing innovative new product introductions and promotions for the healthcare distribution industry. Manufacturers also are recognized for advancing trade relations by fostering strong trading partner relationships with HDMA distributor members and creating exceptional business practices that benefit the entire healthcare supply chain.

In addition, presented for the second year, the DIANA Manufacturer Partner of the Year recognizes companies for their active participation in the Association. The winning companies have at least

five consecutive years of membership, regularly participate in HDMA conferences, serve on Association committees, and show support through event attendance and sponsorships.

HDMA President and CEO John M. Gray said, "We are pleased to honor our manufacturer trading partners for their innovative and collaborative efforts with distributors, as well as the time and effort they devote to HDMA's important mission."

2014 DIANA Manufacturer Partner of the Year Winners:

HDMA Manufacturer Member With Sales to Healthcare Distributors of More Than $500 Million:
Mylan Inc.

HDMA Manufacturer Member With Sales to Healthcare Distributors of Less Than $500 Million:
Upsher-Smith Laboratories, Inc.

2014 DIANA Winners:

Best New Product Introduction or Promotion Awards

Branded Pharmaceutical Products: **Eisai, Inc.**, for **Belviq®**
Generic Pharmaceutical Products: **Citron Pharma LLC**, for **Duloxetine DR Capsules USP**
Over-the-Counter and Home Healthcare Products: **Merck Consumer Care**, for **Oxytrol® for Women**

Best Overall Manufacturer Awards

Branded Pharmaceutical Product Manufacturer with Sales to Healthcare Distributors of Less Than $300 Million:
Winner: **Depomed, Inc.**
First Merit Finalist: Avion Pharmaceuticals

Second Merit Finalist: Upsher-Smith Laboratories, Inc.

Branded Pharmaceutical Product Manufacturer with Sales to Healthcare Distributors of More Than $300 Million:
Winner: **Forest Pharmaceuticals, Inc.**
First Merit Finalist: Boehringer Ingelheim Pharmaceuticals, Inc.
Second Merit Finalist: Eisai, Inc.

Generic Pharmaceutical Product Manufacturer with Sales to Healthcare Distributors of Less Than $100 Million:
Winner: **Alvogen, Inc.**
First Merit Finalist: Lannett Company
Second Merit Finalist: Breckenridge Pharmaceutical, Inc.

Generic Pharmaceutical Product Manufacturer with Sales to Healthcare Distributors of More Than $100 Million:
Winner: **Actavis, Inc.**
First Merit Finalist: Lupin Pharmaceuticals, Inc.
Second Merit Finalist: Amneal Pharmaceutical

Consumer Product Manufacturer
Winner: **BD Medical – Diabetes Care**
First Merit Finalist: Merck & Co., Inc.
Second Merit Finalist: Novartis Consumer Health, Inc.

ABOUT HDA

HDA is the national association representing primary healthcare distributors, the vital link between the nation's pharmaceutical manufacturers and healthcare providers. Each business day, HDA member companies ensure that over 15 million prescription medicines and healthcare products are delivered safely and efficiently to more than 200,000 pharmacies,

hospitals, long-term care facilities, clinics and others nationwide. HDA and its members work daily to provide value and achieve cost savings, an estimated $42 billion each year to our nation's healthcare system.

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NewsRoom

8/7/15 Sun Sentinel (Fort Lauderdale, Fla.) 1D
2015 WLNR 23466224

Sun Sentinel, Fort Lauderdale, FL

August 7, 2015

Section: Business

Indian drugmaker opens Coral Springs lab
Talent in pharmaceutical industry is lure

A leading drugmaker from India took an unusual path to opening its $13 million research center in Coral Springs.

Lupin Pharmaceuticals decided nearly three years ago to expand into the business of inhalation products for asthma and respiratory diseases and began a global search for an expert in that field.

It found a top scientist from China, Dr. Xian-Ming Zeng, who was living in Broward County and working for an Israeli company, then hired him.

Zeng suggested the Indian heavyweight set up its new venture in Broward, tapping South Florida's skilled talent in the life-sciences industry, research centers and universities.

Lupin checked out the area and found lots of strong local employees available, a business-friendly environment and competitive costs, CEO Vinita Gupta said in an interview.

"Attracting people to the area has been fairly easy for us," added Gupta, who said the lack of a state income tax helps draw talent from elsewhere to Florida. The 47-year-old CEO keeps her main home across Alligator Alley in Naples as she expands **Lupin**'s business in the U.S. and globally.

Lupin has committed to employ an initial 45 people at its new research-and-development center at salaries averaging more than $100,000, said David Coddington, vice president of the Greater Fort Lauderdale Alliance, Broward's economic development group.

The state, county and local governments will provide $315,000 in tax incentives for the venture, once **Lupin** sustains those 45 jobs in the life-sciences industry targeted for growth, Coddington said.

Lupin's debut in South Florida comes as the company has agreed to buy Gavis Pharmaceuticals of New Jersey for $880 million. That deal, expected to close this fall, will let **Lupin** start U.S. production and boost its drug pipeline.

Gupta, a pharmacist by profession, has been spearheading **Lupin**'s U.S. and global push since graduating with an MBA from Northwestern University's Kellogg School.

Her father started **Lupin** in Mumbai, India, 48 years ago with a focus on making drugs to treat tuberculosis and built it into one of his country's key drugmakers. He then asked his daughter to expand operations abroad.

Gupta said her team's plan resulted in $850 million in U.S. sales last year, adding that it should top $1 billion this year. The

company also has been expanding in Japan and, in the past 18 months, has done six acquisitions to help grow in Latin America and Europe, she added.

Plans call for **Lupin** to grow in global sales to $5 billion in roughly three years from $2 billion last year, Gupta said.

Lupin's investment also highlights India's emergence as a global player and business partner for Florida.

While India is not among the 13 countries where Florida has a business development office, ties are growing. Last year, Florida's direct-goods trade with India topped $1 billion, making India the No. 32 trade partner for the state. More than 20 companies from India now have investments in the state in industries targeted for growth, according to Enterprise Florida, the state's public-private economic development agency.

Indian-owned companies in South Florida include Cambridge Integrated Services Group, CPG Solutions, Diamedix Corp., Digital Risk, Econocaribe Consolidators, Immunovision, JAS Diagnostics, Reliance Globalcom Services, and Whyte and Mackay (Americas), Enterprise Florida said.

Photo: Michael Tse and Linda DeLaPaz check equipment in a new lab at Lupin Pharmaceuticals in Coral Springs. MARK RANDALL/STAFF PHOTOGRAPHER

---- Index References ----

Company: CPG SOLUTIONS LLC; DIAMEDIX CORP; DIGITAL RISK LLC; ECONOCARIBE CONSOLIDATORS INC; GAVIS PHARMACEUTICALS LLC; INTEGRATED SERVICES GROUP INC; IMMUNOVISION INC; JAS DIAGNOSTICS INC; **LUPIN** PHARMACEUTICALS INC; RELIANCE GLOBALCOM SERVICES INC; WHYTE AND MACKAY LTD; CAMBRIDGE INTEGRATED SERVICES GROUP INC; CAMBRIDGE INTEGRATED SERVICES GROUP INC

News Subject: (Economic Development (1EC65); Economics & Trade (1EC26); Emerging Market Countries (1EM65))

Industry: (Pharmaceuticals (1PH33); Pharmaceuticals & Biotechnology (1PH13); Pharmaceuticals & Biotechnology Industry Highlights (1PH07); Pharmaceuticals Wholesale Distribution (1PH35))

Region: (Americas (1AM92); Asia (1AS61); Florida (1FL79); India (1IN24); Indian Subcontinent (1IN32); North America (1NO39); Southern Asia (1SO52); U.S. Southeast Region (1SO88); USA (1US73))

Language: EN

Other Indexing: (CAMBRIDGE INTEGRATED SERVICES) (Linda DeLaPaz; Vinita Gupta; Vinita Gupta; Xian-Ming Zeng; David Coddington; Michael Tse; Mark C.M. Randall; Mark Randall)

Keywords: (DRUG)

Edition: Palm Beach

Word Count: 558

End of Document

Health Care & Pharma

Indian officials discuss pharma firms' expanding presence in United States

By Anjalee Khemlani, June 12, 2017 at 3:00 AM

Manish Singhal, assistant secretary general of the Federation of Indian Chambers of Commerce and Industry. - (ANJALEE KHEMLANI)

What seems like contradictory politics for the life sciences industry, which is focused on global growth, is actually encouraging Indian interest.

On one side of the globe, Indian Prime Minister Narendra Modi has pushed the “Make in India” campaign

to encourage more local production of goods.

On the other, U.S. President Donald Trump is pushing “Buy American, Hire American” to encourage local production and decrease the dependency on foreign countries like China, as well as decrease the use of H-1B visa workers.

But rather than be discouraged, Indian companies are actually ramping up their presence and efforts to locate or produce for the U.S. market.

The latest proof of that is Lupin Pharmaceuticals opening a manufacturing facility in Somerset last month.

Lupin joins Sun Pharmaceuticals and Dr. Reddy’s Laboratories as Indian pharma firms in the state.

Right now, roughly 30 percent of generics in the U.S. come from India, according to Sumani Dash, director and country head of the U.S. and Canada for the Confederation of Indian Industry.

ABOVE: The India Pavilion at the Interphex conference in New York City. - (ALUN JONES)

Dash said the result is billions of dollars invested in state-of-the-art manufacturing in the state, as well as expansion of commercial space — a fact well-known by the local municipalities.

Which is why the companies that manufacture drugs in India are ramping up their presence at shows like the recent Interphex.

Interphex is one of the largest and oldest conferences for pharmaceutical, biotechnology and medical device development and manufacturing, having been around for 38 years and attracting more than 600 companies each year for the three-day event in New York City.

The conference saw a growth after just two years of introducing a special section for Indian companies — the India Pavilion — and the group's organizers are only planning to continue the upward trend.

Last year, the India Pavilion was about 6,000 square feet, with 34 vendors. This year, it went up by 600 square feet to include a total of 46 vendors, according to an Interphex spokesperson.

The enthusiasm today is a far cry from two years ago, when pharmaceuticals came under fire from the FDA after negative audit results and more stringent rules that some Indian companies felt were targeting them.

Since then, Dash said, the companies have worked with the FDA to improve, and asked for a level playing field.

Mahendra Mehta, managing director of Parle Global Technologies in Pennsylvania, said India is growing into a good competitor for the U.S. players.

"You need cheaper drugs here, you don't want your health care costs to go up … so you would look at India to be a good partner," Mehta said. "India does have a huge potential for outsourcing. Countries like the U.S. and European countries should be working with India because it's a nice country to deal with in terms of English-speaking staff."

Besides, the Indian companies believe the U.S. is not ready to serve its own market as far as demand is concerned.

"U.S. is a bigger market and I don't think they'll be able to manufacture everything in the U.S. even if they plan right now. There are many companies who are already based in the U.S. now; that gives us an advantage. India has many FDA-approved plants, so we are already ready to serve the U.S. market," Mehta said.

Manish Singhal, assistant secretary general of the Federation of Indian Chambers of Commerce and Industry, said the ambitions and frugality of Indian companies should not be underestimated.

"Generally, the way the Indian mindset works is, if I develop this (product) and have to earn something out of it, let me earn $1 per (item) and sell 100 rather than just earning $10 per (item) and selling just 10," Singhal said.

And the argument being made by the companies is that, with the downward pressure on drug pricing, it only makes sense to seek the cost effectiveness and frugality that India offers.

Or, as Singhal put it, "I mean, when we can send a satellite to the moon at one-tenth the cost, medicine is nothing."

More From This Industry

- **Horizon BCBSNJ CEO announces retirement; COO to take over**
- **Johnson & Johnson launches innovation contest for novel skincare products**
- **Holy Name Medical adds two practices in North Jersey**
- **Summit Medical Group adds Bergen County-based medical practice**

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7/24/15 The Deal (Pg. Unavail. Online)
2015 WLNR 22609943

Deal, The

July 24, 2015

India's **Lupin** buys U.S.-based generics company Gavis Pharmaceuticals

Laura Cooper

Mumbai, India-based **Lupin** Ltd. announced two deals this week, including the $880 million purchase of Gavis Pharmaceuticals LLC and Novel Laboratories Inc. in order to expand its US generics business.

The acquisition of Somerset, N.J.-based Gavis helps **Lupin** build its presence in the U.S. generic market and broadens its pipeline in dermatology, controlled substances and other niche generics. The N.J.-based company will also provide **Lupin** its first manufacturing site in the U.S.

According to a statement about the acquisition from **Lupin**, Gavis had sales of $96 million over the course of 2014. The statement also noted that Gavis has 66 abbreviated new drug applications -- an application for the approval of an already approved drug -- that are pending in front of the Food and Drug Administration. The drugs that are the subject of those filings have a potential market of about $9 billion, the company said.

The generic pharmaceutical company has a number of drugs, including Amlodipine, which treats high blood pressure, Hydrocodone Bitartrat, a cough suppressant and antifungal Nystatin, among many others.

"This is a pivotal acquisition for **Lupin** as it aligns with our goal to expand and deepen our US presence. GAVIS has a strong track record of delivering highly differentiated products in a short time and is poised for continued strong growth as it delivers on its existing pipeline," said **Lupin** CEO Vinita Gupta, in the statement.

Lupin also announced on Friday that the company made a strategic asset purchase from German pharmaceutical company Temmler Pharma Gmbh & Co., a part of Aenova Group. The terms of the agreement call for **Lupin** to purchase Temmler's specialty product portfolio that includes 13 products focusing on the central nervous system and rare diseases.

Lupin is a pharmaceutical company working in the branded and generic drug areas mostly for treatments in the cardiovascular, diabetology, asthma, anti-infective and pediatric fields. It is the fifth largest generic drug maker in the U.S. and third largest Indian pharmaceutical company.

Lupin worked with a legal team at Brown Rudnick LLP including Rob Funsten, Katy Gardner, Mary Bucci, Steve Cheng, Mary Ambacher, Sarah Wilk and Andrew Oliver, Vince Guglielmotti, Barbara Kelly, James Maynor, Doug Cohen, Kyle Johnson, Jeff Vigliotti and Mark Leonardo.

Gavis retained JP Morgan Chase as its financial adviser and Latham and Watkins LLP as its legal counsel.

http://pipeline.thedeal.com/tdd/ViewArticle.dl?id=13231244

---- Index References ----

Company: AENOVA GROUP GMBH; BROWN RUDNICK LLP; GAVIS PHARMACEUTICALS LLC; JPMORGAN CHASE AND CO; LATHAM AND WATKINS LLP; **LUPIN** LTD; NOVEL LABORATORIES INC; TEMMLER PHARMA GMBH AND CO KG

News Subject: (Emerging Market Countries (1EM65))

Industry: (Drug Approval Process (1DR91); Drug Discovery & Development Process (1DR41); Generic Drugs (1GE93); Pharmaceuticals (1PH33); Pharmaceuticals & Biotechnology (1PH13); Pharmaceuticals Research & Development (1PH57); Pharmaceuticals Wholesale Distribution (1PH35))

Region: (Asia (1AS61); India (1IN24); Indian Subcontinent (1IN32); Southern Asia (1SO52))

Language: EN

Other Indexing: (Jeff Vigliotti; Rob Funsten; Kyle D. Johnson; Kyle Johnson; Vince Guglielmotti; Andrew Oliver; Mary Ambacher; Mark Leonardo; Vinita Gupta; Vinita Gupta; Sarah Wilk; Mary Bucci; Barbara Kelly; James Maynor; Steve Cheng; Katy Gardner; Doug Cohen) (New Jersey; North America; Northeast; United States; United States - East)

Word Count: 390

End of Document

NewsRoom

8/24/15 Drug Store News 76
2015 WLNR 26426969

Drug Store News

August 24, 2015

Volume 37; Issue 8

Lupin acquires Gavis.

MUMBAI -- Lupin announced on July 23 that it will acquire Gavis Pharmaceuticals and Novel Laboratories in a $880 million, cash- and debt-free transaction. Both Lupin and Gavis' boards of directors unanimously approved the vote.

Through the acquisition, Lupin will expand its reach in the U.S. generics market, as well as in dermatology, controlled-substance products and other high-value and niche generics.

---- Index References ----

Company: GAVIS PHARMACEUTICALS LLC; LUPIN LTD; NOVEL LABORATORIES INC

Industry: (Generic Drugs (1GE93); Pharmaceuticals (1PH33); Pharmaceuticals & Biotechnology (1PH13))

Language: EN

Other Indexing: (United States; India; United States)

Keywords: (Business); (Pharmaceuticals and cosmetics industries); (Retail industry); (Pharmaceutical industry Mergers, acquisitions and divestments); (Acquisitions & mergers); (Pharmaceutical industry Mergers, acquisitions and divestments)

Company Terms: Lupin (India) Mergers, acquisitions and divestments

Sic: 2833; 2834

Naics Code: 325411

Word Count: 63

NewsRoom

NewsRoom

9/26/16 Chain Drug Rev. 104
2016 WLNR 31097024

Chain Drug Review

September 26, 2016

Volume 38; Issue 14

Lupin Pharmaceuticals.

BALTIMORE -- Lupin Pharmaceuticals Inc. is dedicated to delivering high-quality, branded and generic pharmaceutical products trusted by health care professionals and patients across the United States.

Lupin is currently the fifth-largest generic pharmaceutical company in the U.S. by prescriptions dispensed, with 5.5% generic market share, according to IMS Health.

Lupin's journey began in 2003 with three Baltimore-based employees and Lupin's first U.S. generic product approval. As a market share leader in 44 generic products and among the top three in 79 products in the U.S., Lupin now markets a total of 124 products, according to IMS Health.

Last fiscal year, Lupin generated over $887 million in net revenues, contributing 43% of the company's global revenues.

In March of this year, Lupin completed its acquisition of privately held U.S.-based Gavis Pharmaceuticals LLC and Novel Laboratories Inc. Novel has since been renamed Lupin Somerset. The Gavis-Novel acquisition positions Lupin as having the fifth-largest pipeline of ANDA (Abbreviated New Drug Application) filings with the Food and Drug Administration. Lupin notes that it has brought significant, high-quality, affordable medications to the marketplace, which has helped fuel the growth of the company's business.

Today, Lupin has 45 first-to-file products, which include 25 exclusive FTF opportunities.

The momentum of Lupin's sustained growth year over year is a result of a valuable pipeline, solid customer relationships and smooth execution. Lupin has 163 ANDAs pending FDA approval and a deep pipeline of products under development for the U.S.

Lupin has a strong corporate culture of excellence in place, ensuring strict adherence to FDA regulations year after year.

Last fiscal year, Lupin launched 21 new products, including the successful commercialization of the exclusive generic equivalent of Glumetza. The majority of Lupin's products are vertically integrated, which ensures quality control throughout each step of product development and manufacturing. This gives Lupin an unparalleled advantage over its competitors, the company points out, as it is able to control its supply chain while offering competitive pricing.

Recent generic launches include diclofenac topical solution, 1.5% (Pennsaid 1.5%); norgestimate and ethinyl estradiol tablets (Ortho Tri-Cyclen); Blisovi Fe 1.5/30 tablets (Loestrin Fe 1.5/30); Blisovi Fe 1/20 tablets (Loestrin Fe 1/20); and zolpidem tartrate sublingual, CIV tablets (Intermezzo).

Lupin aims to continue to strengthen its market presence by launching new products and expanding its pipeline to offer

medications in such new therapeutic areas as dermatology, pediatrics, women's health, inhalation and complex injectables.

Lupin says its steadfast commitment to quality and reliability has resulted in the company consistently delivering high-quality products, and its ongoing investment in technological capabilities will position the company to ensure customer satisfaction for years to come.

111 South Calvert St.

24th Floor

Baltimore, Md. 21202

Key contact: BOB HOFFMAN

Executive Vice President, U.S. Generics

Phone: (410) 576-2000

lupinpharmaceuticals.com

LUPIN'S RECENT GENERIC LAUNCHES BRAND EQUIVALENT Diclofenac Topical Solution 1.5% Pennsaid 1.5% Norgestimate/Ethinyl Estradiol Tablets Ortho Tri-Cyclen Blisovi Fe 1.5/30 Tablets Loestrin Fe 1.5/30 Blisovi Fe 1/20 Tablets Loestrin Fe 1/20 Zolpidem Tartrate Sublingual CIV Tablets Intermezzo

---- Index References ----

Company: GAVIS PHARMACEUTICALS LLC; **LUPIN** PHARMACEUTICALS INC; NOVEL LABORATORIES INC

Industry: (Drug & Device Approvals (1US85); Drug Approval Process (1DR91); Drug Discovery & Development Process (1DR41); Generic Drugs (1GE93); Healthcare (1HE06); Healthcare Regulatory (1HE04); Pharmaceuticals (1PH33); Pharmaceuticals & Biotechnology (1PH13); Pharmaceuticals Research & Development (1PH57))

Region: (Americas (1AM92); Maryland (1MA47); North America (1NO39); U.S. Mid-Atlantic Region (1MI18); USA (1US73))

Language: EN

Other Indexing: (Maryland; Maryland)

Keywords: (Business); (Pharmaceuticals and cosmetics industries); (Retail industry); (Generic drugs); (Generic drugs)

Sic: 2834

Naics Code: 325412

Word Count: 487

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NewsRoom

10/3/14 Miami Herald 248
2014 WLNR 27586555

Miami Herald (FL)

October 3, 2014

Lupin to expand in Coral Springs, add 45 jobs

Nancy Dahlberg; The Miami Herald

Lupin, a pharmaceutical company headquartered in India, announced this week it will be expanding in Coral Springs, including building a new laboratory by the end of the year. The expansion will create at least 45 high-skilled positions in Broward County, the company said.

What makes Lupin's announcement particularly significant is that its new facility will focus on the research and development of new drugs, said Todd Holt, director of business development for the Greater Fort Lauderdale Alliance , with an expertise in the life science industry. Nearly 1,000 biotech, pharmaceutical and medical devices companies call Florida home, according to Enterprise Florida. Broward County has more than 500 life science companies, and recruiting companies with high-paying R&D jobs is a goal of the Alliance.

Xian-Ming Zeng, Lupin's senior vice president of Inhalation Research and Development, believes the company can recruit high-quality scientists from the South Florida area. "There is a unique opportunity to collaborate with the area's universities and explore long-term recruitment solutions. Not only does this mean the cost of recruiting is lower but the resulting candidates are highly-trained and desirable as employees," he said in a statement.

Lupin, a U.S.-owned subsidiary of Lupin Limited of Mumbai, is the fifth largest generics player by prescription. Lupin's local facility will focus on inhalation products for the treatment of asthma, allergic rhinitis, chronic obstructive pulmonary diseases and other lung diseases, the company said.

Enterprise Florida, the Greater Fort Lauderdale Alliance , Broward County, CareerSource Florida and the Florida Department of Economic Opportunity worked together on the expansion plan.

---- Index References ----

Company: LUPIN LTD

News Subject: (Health & Family (1HE30))

Industry: (Allergy & Immunology (1AL96); Asthma (1AS17); Healthcare (1HE06); Healthcare Practice Specialties (1HE49); Infectious Diseases (1IN99); Internal Medicine (1IN54); Pharmaceuticals (1PH33); Pharmaceuticals & Biotechnology (1PH13); Pharmaceuticals Wholesale Distribution (1PH35); Respiratory & Pulmonary (1RE29); Upper Respiratory Disease (1UP05))

Region: (Americas (1AM92); Florida (1FL79); North America (1NO39); U.S. Southeast Region (1SO88); USA (1US73))

Language: EN

Other Indexing: (Inhalation Research) (Todd Holt)

Keywords: (XC/any.company); (XC/any.private); (NT/NEC)

Word Count: 258

End of Document

NewsRoom

NewsRoom

3/13/14 Boston Globe B
2014 WLNR 6815767

Boston Globe (MA)

March 13, 2014

Section: Business

Ruling negates key Pfizer patent
Rivals seek slice of lucrative sales for arthritis drug

Linda A. Johnson; Associated Press

TRENTON, N.J. — A federal court invalidated the key patent for one of Pfizer's most lucrative medicines, potentially opening the door for cheaper generic versions 18 months sooner than expected and cutting into the drugmaker's profit.

Pfizer Inc., still trying to make up for the loss of about $7 billion in annual sales since generic competition challenged its cholesterol fighter Lipitor in December 2011, could lose a couple of billion more if the court decision on the Celebrex patent stands. The world's second-biggest drugmaker said it disagrees with the ruling and will pursue all available remedies, including immediately -appealing Wednesday's ruling -b-y Judge Arenda Allen of -Virginia's Eastern District Court in Norfolk.

Celebrex, Pfizer's fourth-bestselling product, brought in $2.9 billion in worldwide sales last year. The anti-inflammatory pill is widely used for arthritis and acute pain. Celebrex has been on the market for more than a decade, so Pfizer's gross profit margin on the drug may exceed 90 percent.

Trading of Pfizer shares on the New York Stock Exchange was briefly halted before the announcement. Shares closed at $31.98, down 44 cents, or 1.4 percent, but near Pfizer's 52-week high. In after-hours trading, shares fell another 7 cents.

The case involves a reissue patent that prevented US sales of generic versions until Dec. 2, 2015. Last March, the US Patent & Trademark Office granted Pfizer the reissue patent, which corrected what Pfizer called technical deficiencies in the original patent covering the conditions treated by the drug's active ingredient, celecoxib. Those include acute pain and menstrual pain, rheumatoid and osteo arthritis, and a painful spinal joint disorder called ankylosing spondylitis.

Five makers of generic drugs have been seeking Food and Drug Administration permission to sell generic Celebrex starting on May 30, when the drug's original patent expires.

New York-based Pfizer sued, alleging patent infringement by the companies: Teva Pharmaceuticals USA Inc., Mylan Pharmaceuticals Inc., Lupin Pharmaceuticals USA Inc., Apotex Inc., and Watson Laboratories Inc., which became Actavis Inc. early last year after a merger.

The suit had been scheduled for a trial beginning on March 19, but Judge Allen told the parties last week she would rule on motions they had filed in the case, instead of holding a trial.

"Odds are in favor of generics launching early," Bernstein Research analyst Dr. Timothy Anderson wrote to investors. He estimates Pfizer's earnings per share would then be -reduced by 4 percent this year and 8 percent in 2015.

In another development for the drugmaker Wednesday, Pfizer said its blockbuster vaccine against pneumonia and other infections met its goal of preventing illness in vulnerable elderly patients in a large study.

The company's Prevnar 13 protects against 13 strains of pneumococcal disease, which can also cause children's ear infections and life-threatening bloodstream infections.

The study, which included about 85,000 patients aged 65 or older, found that compared with study participants getting a placebo, those getting the vaccine had about 46 percent fewer cases of pneumonia.

---- Index References ----

Company: ACTAVIS LLC; APOTEX INC; MYLAN PHARMACEUTICALS INC; PFIZER INC; TEVA PHARMACEUTICALS USA INC; WATSON LABORATORIES INC FLORIDA

News Subject: (Health & Family (1HE30); Major Corporations (1MA93))

Industry: (Arthritis (1AR77); Generic Drugs (1GE93); Healthcare (1HE06); Healthcare Practice Specialties (1HE49); Internal Medicine (1IN54); Orthopedics & Rheumatology (1OR79); Pharmaceuticals (1PH33); Pharmaceuticals & Biotechnology (1PH13); Rheumatic Diseases (1RH30))

Region: (Americas (1AM92); New York (1NE72); North America (1NO39); U.S. Mid-Atlantic Region (1MI18); USA (1US73))

Language: EN

Other Indexing: (**Lupin** Pharmaceuticals USA Inc.) (Lipitor; Timothy Anderson; Arenda Allen)

Word Count: 481

End of Document

NewsRoom

11/23/14 Chi. Trib. 1
2014 WLNR 32975569

Chicago Tribune

November 23, 2014

Section: News

Why are the prices of generic drugs soaring?

Once prescribed to keep escalating health care costs down, copies of brand-name pills carry a new side effect: Sticker shock

Ellen Jean Hirst, Tribune reporter

A photo caption accompanying this story contains corrected material, published Nov. 27, 2014.

After calling for a routine prescription refill, Craig Elliott got a rude shock: His bill was going up fivefold.

The 44-year-old piano tuner and guitar instructor from Elgin, who has health insurance, used to pay $20 for a three-month supply of his generic epilepsy drug as a member of Walgreen's Prescription Savings Club. But recently, the price shot up to more than $100, forcing him to order month by month.

"I'll get by ... (but) I don't like now having a larger bill every month," Elliott said.

Countless other Americans are feeling the same sticker shock at the drugstore. Historically costing pennies on the dollar compared with a brand-name drug, generic drugs have long been considered a vital weapon in the fight to contain soaring health care costs. But in the past year, the price of many generics is disconcertingly moving in the wrong direction, drawing the attention of Congress and pinching the wallets of consumers as well as pharmacies and insurers.

"We are talking about the need of the American people to be able to afford the medicine that their doctors prescribe," U.S. Sen. Bernie Sanders, I-Vt., chairman of a Senate health care subcommittee, said at a hearing on the issue Thursday. "There appears to be now a trend in the industry where a number of drugs are going up at extraordinary rates. ... We wanted to know if there was a rational economic reason as to why patients saw these price increases or whether it was simply a question of greed."

Experts say raw material shortages, consolidation in the industry and medical advancements that make replicating brand-name drugs more expensive have all contributed to skyrocketing costs.

According to Catamaran, a Schaumburg-based pharmacy benefit manager that administers prescription drug programs, consumers and insurers paid an average of $13.14 per prescription for the 50 most popular generics in 2010. In 2014, they paid $62.10, a 373 percent increase. Today, more than a third of available generics cost insurers and consumers more than $100 per prescription, company data show.

"People who don't have insurance, they're picking up the full fare of these drugs," said Catamaran Chief Medical Officer Dr. Sumit Dutta. "And they're often not in the best place to handle the cost of these medications."

A Pembroke Consulting analysis of federal data shows the price pharmacies pay for generics over the past year has soared too, by as much as 17,700 percent in one case. One in 11 generic drugs have more than doubled in acquisition cost for pharmacies over the past year.

To cope, insurance companies have introduced copay tiers to their plans to offset rising generic prices, Dutta said.

Deerfield-based Walgreen Co., which cited skyrocketing generic drug prices as an obstacle for 2015 profits, has a similar tiered system with its Prescription Savings program, a membership plan that offers discounts on services and drugs. The generic epilepsy drug Elliott takes, carbamazepine, had previously been on its list of value-priced generics but was removed when the price increased, a Walgreen spokesman said. According to Pembroke Consulting, pharmacies in July 2014 paid between 10 percent less or 60 percent more for the drug -- depending on the dose -- compared with a year earlier.

A spokeswoman for Teva Pharmaceuticals, one of six manufacturers of the epilepsy drug according to the U.S. Food and Drug Administration website, declined to say why the price of carbamazepine has been rising.

”Teva is committed to ensuring access and providing high-quality, affordable medicines to U.S. patients,” the spokeswoman said in an emailed response. “While it is possible to find examples of generic medicines that have increased in price, these select instances are not indicative of the overall market trend.”

The largest price increase from 2013 to 2014 was for a 500 milligram capsule of tetracycline, an antibiotic used to treat bacterial infections. That dose went up in price 17,714 percent, from 5 cents per pill to $8.59. An FDA spokeswoman said a more than two-year shortage due to unavailability of raw materials to make the drug, as well as manufacturing issues, was resolved in March.

While raw material shortages are one factor behind price increases, health analysts say market competition -- or lack thereof -- also plays a role. Sometimes, drug manufacturers opt to discontinue a line because the presence of other manufacturers results in pricing pressures, which cut into profits. They also feel pressure to specialize product lines and consolidate through mergers and acquisitions, creating even more pricing power for the remaining manufacturers.

And as medicine advances and drugs become more expensive and difficult to imitate, fewer companies are willing to invest in making generic versions of brand-name drugs that move off patent protection.

When chemotherapy drug Xeloda moved off patent in December 2013, a generic version, capecitabine, came to market. Today, it costs just $40 less per prescription than it did when it was a branded drug -- $2,660 instead of $2,700, a 1.5 percent decrease, according to Catamaran data.

The rising prices caught the attention of Congress, and last month Sanders and Maryland’s Rep. Elijah Cummings requested financial documents from 14 pharmaceutical companies across the country. Northbrook-based Marathon Pharmaceuticals is among those being investigated.

Marathon makes drugs for rare diseases and is the only company manufacturing two drugs that are used for heart diseases -- Isuprel and Nitropress, a spokesman said. The price of those drugs increased nearly five times from November 2012 to September 2014, according to the Health Care Supply Chain Association, which represents large group purchasing organizations for hospitals.

Marathon said it doesn’t think it should have been included in the investigation, even though the two drugs it makes are no longer covered by patents. The company did not dispute the roughly 400 percent increase in the price of the two drugs, but said it has spent more than $200 million on the drugs, including buying intellectual property from Hospira last year and investments in the drugs, a cost not usually incurred by generic drug “copycats.”

A Hospira spokeswoman declined to elaborate on why the company sold the drugs beyond saying they were divested “for business reasons.”

”Again, it’s a drug that someone owned that we had to buy, we had to pay for it,” Marathon General Counsel Pat Morris said.

“And we have to do this in the face of (the fact that) a generic drug could come in tomorrow and take all of our sales.”

Some experts have said prices will come down when other pharmaceutical companies recognize an opportunity to share in the profits of some of the drugs that have skyrocketed in price. Buyer consolidation should help too, they said.

Last year, CVS Caremark announced a partnership with Cardinal Health, giving it more generic drug buying power. Walgreen Co. works with AmerisourceBergen and Alliance Boots, and McKesson announced its acquisition of Celesio in January. Those three groups wield a huge amount of purchasing power, which should keep generic drug prices down.

”What the American people are entitled to know,” Sanders said, “is why there are a number of generic drugs that have seen a huge increase in prices in recent years.”

- - -

Quick facts

What is a generic drug?

Generic drugs are chemically identical to brand name drugs, equally effective and prescribed for the same purposes.

How do generic drugs come to market?

Drug companies submit an application to the U.S. Food and Drug Administration for approval to make and sell a generic drug, but those applications can’t be approved until the all patents and exclusivity for the brand-name drug have expired. Patents expire after 20 years and exclusivity can last up to seven years.

Why were generic drugs introduced?

Generic drugs help combat the rising cost of health care and allow market competition for brand-name drugs.

Who makes generic drugs?

The top five U.S. companies by unbranded generic prescriptions dispensed are Teva Pharmaceuticals USA, Mylan Labs, Actavis, Sandoz, and **Lupin** Pharma, respectively, according to the Generic Pharmaceutical Association.

SOURCES: U.S. Food and Drug Administration, Generic Pharmaceutical Association

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Photo: Craig Elliott, a music teacher from Elgin, saw the bill for his epilepsy drug jump around 400 percent (this sentence as published has been corrected in this text). STACEY WESCOTT/TRIBUNE
Photo: Craig Elliott, whose anti-seizure medication leaped from $20 to $100, has managed to afford the hike, but he says he’s smarting from the sticker shock. STACEY WESCOTT/TRIBUNE
Graphic: Generic drug prices on the rise
About half of generic drugs purchased by pharmacies went up in price from 2013 to 2014, with 1 in 11 doubling in price. Typically, the cost of generics should decrease over time. The biggest increase for a dose was just over 17,714 percent.
BREAKDOWN OF GENERIC DRUG PRICE CHANGES
Among a representative sample of 2,376 unique doses of generic drugs, from July 2013 to July 2014
Price change 0% - 100%
16% increased 0 to 4.99%

8% increased 5 to 9.99%
9% increased 10 to 24.99%
9% increased 25 to 99.9%
9% increased 100% or more
19% decreased 0 to 4.99%
14%decreased 5 to 9.99%
13% decreased 10 to 24.99%
3% decreased 25 to 94.6%
Explore a searchable table of the 2,376 drugs chicagotribune.com/genericdrugs
10 EXAMPLES: CHANGE IN DRUG COST
For average price per unit
July 2013: Low/high price
July 2014: Low/high price
Range in price change for various doses
Drug / What drug is used for:
Tetracycline / Bacterial infections
Captopril / High blood pressure, heart failure
Clomipramine / Obsessive-compulsive disorder
Desonide / Skin issues: itching, dryness, swelling
Levothyroxine / Low thyroid activity
Carbamazepine / Seizures, epilepsy
Simvastatin / High cholesterol
Omeprazole / Acid reflux
Glyburide / Type 2 diabetes
Rizatriptan / Migraine headaches
SOURCE: Pembroke Consulting analysis of Centers for Medicare & Medicaid Services data files
TRIBUNE
- See the microfilm for a complete version of this graphic.\

---- Index References ----

Company: ACTAVIS PLC; AMERISOURCEBERGEN CORP; CVS HEALTH CORP; CARDINAL HEALTH INC; CELESIO AG; HOSPIRA INC; **LUPIN** PHARMA CANADA LTD; MARATHON PHARMACEUTICALS LLC; MCKESSON CORP; MYLAN INC; PEMBROKE CONSULTING INC; SANDOZ GMBH; TEVA PHARMACEUTICAL INDUSTRIES LTD; TEVA PHARMACEUTICALS USA INC; WALGREEN CO

Industry: (Generic Drugs (1GE93); Pharmaceuticals (1PH33); Pharmaceuticals & Biotechnology (1PH13); Pharmaceuticals Cost-Benefits (1PH30); Pharmaceuticals Wholesale Distribution (1PH35))

Language: EN

Other Indexing: (Elijah Cummings; Sumit Dutta; Bernie Sanders; STACEY WESCOTT; Catamaran; Nitropress; Pat Morris; Craig Elliott)

Keywords: CONSUMER WATCH

Edition: Final

Word Count: 1594

End of Document

NewsRoom

IN THE U.S. PATENT AND TRADEMARK OFFICE BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

----------x

LUPIN PHARMACEUTICALS, INC.,

Opposer, Opposition No. 91226322

v.

AMPEL, LLC,

Applicant.

----------x

AFFIDAVIT OF JAY LISKA IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT BY OPPOSER LUPIN PHARMACEUTICALS, INC.

STATE OF MARYLAND)
) ss.:
COUNTY OF BALTIMORE)

JAY LISKA, being duly sworn, deposes and says:

1. I am the Director of Marketing for Lupin Pharmaceuticals, Inc. (hereinafter "Lupin" or "Opposer"). I make this affidavit in support of the Motion for Summary Judgment brought by Lupin against Applicant Ampel, LLC (hereinafter "Ampel" or "Applicant") in the subject action.

2. I have been employed by Lupin since August 2011 and have held the position of Director of Marketing since that time. The facts in this affidavit are based upon my personal knowledge as well as on the records, data, and documents I have reviewed and are discussed herein and annexed hereto, all of which are kept in the ordinary course of business of Lupin.

3. **[CONFIDENTIAL]** [redacted]

4. **[CONFIDENTIAL]** [redacted]

5. Lupin advertises its products under the LUPIN Mark through various channels and media platforms including: Opposer's website at lupinpharmaceuticals.com; internet banner ads; internet pop-up ads; television infomercials on networks including *Lifetime* and *Oxygen*; print advertisements in medical journals and pharmaceutical trade journals, pharmaceutical bulletins, and specialty consumer medical publications; and underwriting and sponsorship of pharmaceutical and medical seminars.

6. Examples of the various trade publications and medical journals in which Lupin's

pharmaceutical products have been advertised under the LUPIN Mark include: *Infectious Disease in Children*; *Clinical Psychiatry Today*; *Pharmacy Times*; *Chain Drug Review*; *Contemporary OB/GYN*; and the *American Academy of Pediatrics Newsletter*, as well as online outlets of certain of these and other publications. Since 2012, Lupin also has advertised in publications that are available to consumers either in doctors' offices and lobbies of medical care centers, as well as directly to consumer subscribers. Such publications include *ADDitude Magazine*; *Asthma & Allergy Today*; *Ready Set Grow*; and *Drug Topics*. True and correct copies of representative samples of advertising featuring the LUPIN Mark are attached hereto as Exhibit A.

7. Lupin also provides underwriting and sponsorship support to pharmaceutical and medical seminars, such as the following national meetings:

- Society of Maternal Fetal Medicine ("SMFM") 2016 Annual Meeting in Atlanta, Georgia, and 2017 Annual Meeting in Las Vegas, Nevada, both attended by approximately two thousand (2,000) people;
- American College of Obstetrics & Gynecology ("ACOG") 2016 Annual Meeting in Washington, DC and 2017 Annual Meeting in San Diego, California, both attended by approximately five thousand (5,000) people;
- Association of Women's Health, Obstetric and Neonatal Nurses ("AWHONN") 2016 Convention in Grapevine, Texas and 2017 Convention in New Orleans, Louisiana, both attended by approximately three thousand (3,000) people; and
- Society of Obstetrics & Gynecological Hospitalists ("SOGH") 2016 Annual Clinical Meeting in Denver, Colorado and 2017 Annual Clinical Meeting in New Orleans, Louisiana, both attended by approximately five hundred (500) people.

Lupin also sponsors regional and local pharmaceutical and medical seminars, including the following recent conferences:

- AWHONN South Carolina Division conference, held in October 2017 in Columbia, South Carolina;

- AWHONN Maryland conference, held in October 2017 in Linthicum Heights, Maryland;
- Maryland ACOG District conference, held in October 2017 in Baltimore, Maryland;
- Maryland Society of Health System Pharmacists Fall Seminar, held in September 2017 in Baltimore, Maryland;
- AWHONN Louisiana, held in October 2017 in Baton Rouge, Louisiana; and
- New Jersey Obstetrical & Gynecological Society Semi Annual Conference, held in November 2017 in Monroe Township, New Jersey.

8. [CONFIDENTIAL] [redacted]

9. To the extent it is able to do so under the laws and codes of conduct governing the marketing activities of pharmaceutical companies, Lupin provides a variety of collateral merchandise that features and promotes the LUPIN Mark, including such goods as mugs, reusable grocery bags, car air fresheners, memo pads, and pens. True and correct copies of representative samples of such products are attached hereto as Exhibit B.

10. Lupin has retained the services of several advertising agencies as well as hundreds of vendors in conjunction with Lupin's efforts to promote, advertise, and market pharmaceutical products under the LUPIN Mark including, by way of example, CCG Marketing Solutions, bfw Advertising, Brand Equity Rx, HealthLogiX LLC, DoctorDirectory.Com Inc., Arches

Technology, Paratus Health Systems, Asembia, LLC, Atom Strategic Consulting, CoverMyMeds LLC, 3D Exhibits, Inc., and Viscadia Inc.

11. As a result of Lupin's efforts to promote its mark, the LUPIN Mark is well and favorably known, identifying Lupin exclusively as the source or origin of a wide variety of pharmaceutical products and collateral products and services.

12. Lupin also provides information to consumers through its website regarding its products and educational information on the treatment of various conditions. True and correct copies of relevant examples are attached hereto as Exhibit C.

JAY LISKA

Sworn to before me this
14th day of December, 2017

NOTARY PUBLIC

CATHERINE M. CARLSON
NOTARY PUBLIC
BALTIMORE COUNTY
MARYLAND
MY COMMISSION EXPIRES SEPT. 28 2019

IN THE U.S. PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

----------x
LUPIN PHARMACEUTICALS, INC.,

Opposer, Opposition No. 91226322

v.

AMPEL, LLC,

Applicant.
----------x

EXHIBIT A

TO

AFFIDAVIT OF JAY LISKA IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT BY OPPOSER LUPIN PHARMACEUTICALS, INC.

The Bottom Line...

ALINIA® is the only FDA-approved product for the treatment of diarrhe by *Giardia lamblia* or *Cryptosporidium parvum* in children 1 year of age a

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

$25 CO-PAY SAVINGS PROGRAM*

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 the formulation.
- The pharmacokinetics of nitazoxanide in patients with compromised renal or hepatic function have not been studie nitazoxanide must be administered with caution to patients with hepatic and biliary disease, to patients with renal c 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
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Please see ALINIA® Brief Summary of Prescribing Information on the adjacent page.

Reference: 1. ALINIA® Prescribing Information.

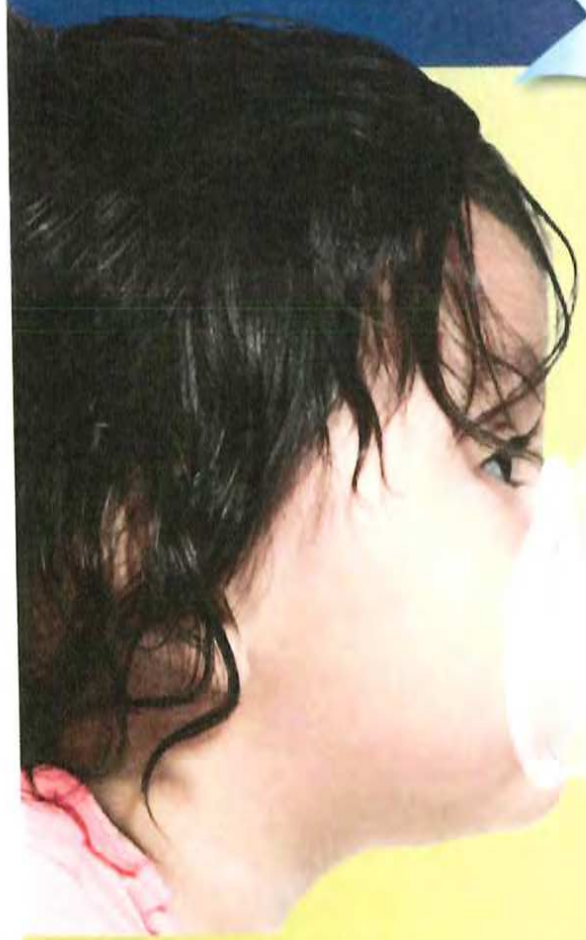
*Terms and conditions apply.

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

LUPIN PHARMACEUTICALS, INC

Now Available—InspiraChamber

COMING SOON
InspiraMask™ in a Large Size



A Unique VHC That's* ***Customized for Kids***

InspiraChamber® with SootherMask™

InspiraChamber® with InspiraMask

InspiraChamber® anti-static VHC

INDICATIONS FOR USE

InspiraChamber® Anti-Static Valved Holding Chamber (VHC) is intended to be used by patients who are under the care or treatment of a physician or licensed healthcare professional. The device is intended to be used by these patients to administer aerosolized medication from most pressurized Metered Dose Inhalers (pMDIs). The intended environments are the home, hospitals and clinics.

Please see Cautions and Notes on opposite page.

For more product information, visit our website at
www.inspirachamber.com

*Valved Holding Chamber.

InspiraChambe

Anti-Static Valved Holding Chamber
with SootherMask® and InspiraMask®

LUPIN

Now Available—InspiraChamber®

COMING SOON
InspiraMask™ in a Large Size

A Unique VHC That's* ***Customized for Kids***

InspiraChamber® with SootherMask™

InspiraChamber® with InspiraMask™

InspiraChamber® anti-static VHC

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Please see Cautions and Notes on opposite page.

For more product information, visit our website at ***www.inspirachamber.com***

*Valved Holding Chamber.

LUPIN PHARMACEUTICALS, INC.

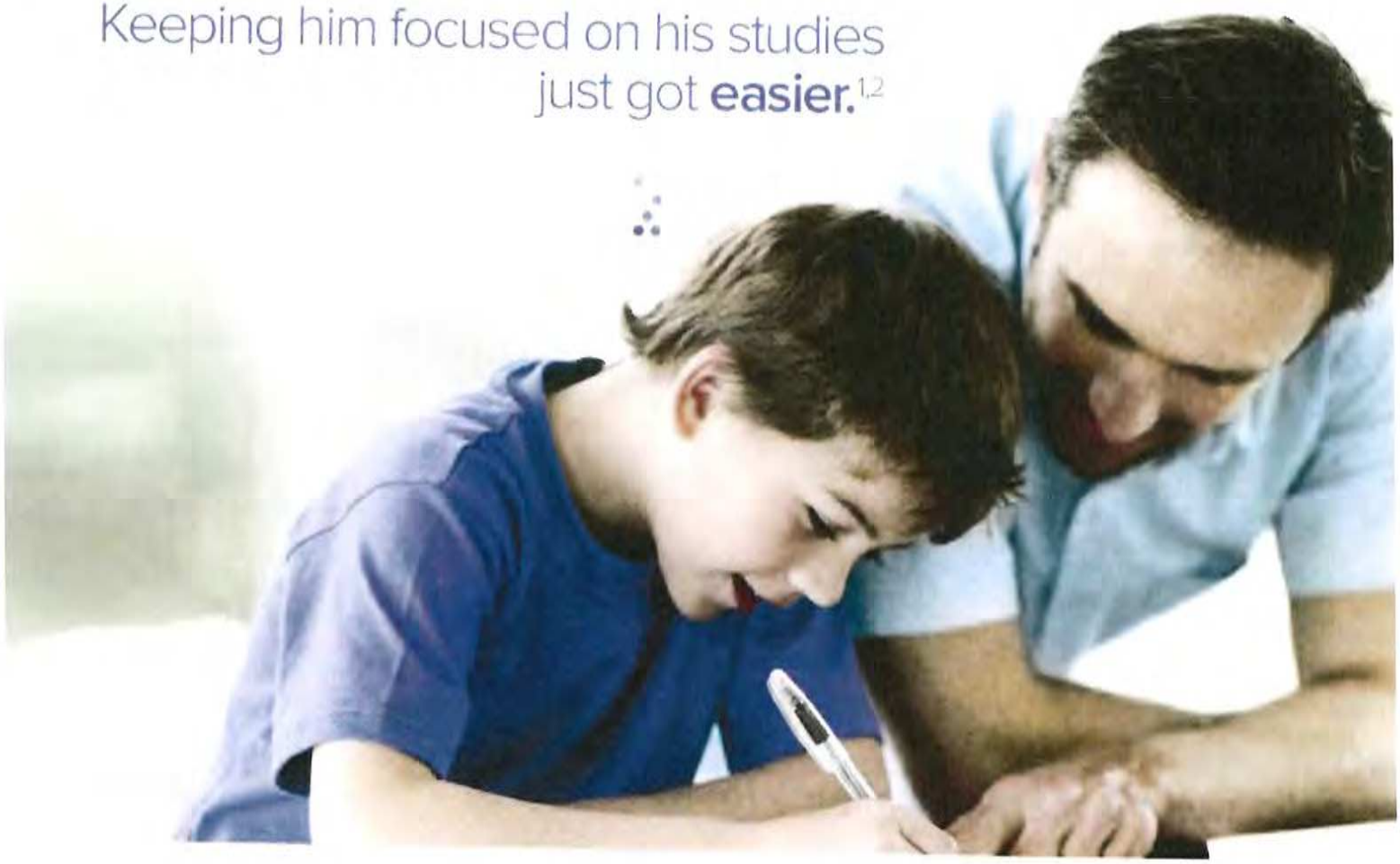
InspiraChamber®

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

The Difference Is By Design

Methylphenidate HCl®
Chewable Tablets

Keeping him focused on his studies just got **easier.**[1,2]



MPORTANT SAFETY INFORMATION

NDICATION

lethylphenidate Hydrochloride Chewable Tablets are a central ervous system stimulant prescription medicine that are used for ıe treatment of Attention Deficit and Hyperactivity Disorder (ADHD).

DRUG ABUSE AND DEPENDENCE

Methylphenidate Hydrochloride Chewable Tablets should be given :autiously to emotionally unstable patients, such as those with a ıistory of drug dependence or alcoholism, because such patients nay increase dosage on their own initiative.

Chronically abusive use can lead to marked tolerance and psychic dependence with varying degrees of abnormal behavior. Frank ›sychotic episodes can occur, especially with parenteral abuse. Careful supervision is required during drug withdrawal, since severe lepression as well as the effects of chronic overactivity can be ınmasked. Long-term follow-up may be required because of the ıatient's basic personality disturbances.

Methylphenidate HCl Chewable Tablets are contraindicated:

- In patients with marked anxiety, tension, and agitation, since the drug may [illegible]
- During treatment with monoamine oxidase inhibitors (MA and also within a minimum of 14 days following discontinua of an MAOI (hypertensive crises may result).

• Children, adolescents, or adults who are being considered treatment with stimulant medications should have a careful his (including assessment for a family history of sudden deat ventricular arrhythmia) and physical exam to assess for presence of cardiac disease, and should receive further car evaluation if findings suggest such a disease.

This product should be taken with at least 8 ounce (a full glass) of water or other fluid. Taking this produ without adequate fluid may cause it to swell and caus choking. If your patient experiences chest pain, vomiting, c difficulty in swallowing or breathing after taking this produc they should seek immediate attention.

• Sudden death has been reported in children and adolesce with structural cardiac abnormalities or other serious heart proble Sudden death, stroke, and myocardial infarction have b reported in adults taking stimulant drugs at usual doses for AD

nidate HCl© Chewable IR Tablets, go.

bing for a patient newly diagnosed with ADHD or one who might benefit from therapy for specific activities or weekends, Methylphenidate HCl Chewable osing you can tailor to fit your patient's needs.[3,4]

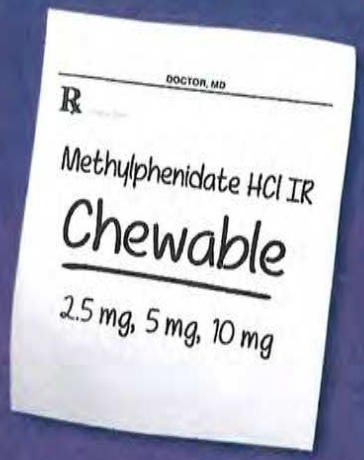
Chewable Tablets

ediate-Release Chewable Tablet available[5,6]

formulation kids may prefer**[7]

osing[8]

Chewable tablets)



provides a choice for patients and parents – ng Chewable for kids on the go.

*Methylin® is a registered trademark of Mallinckrodt LLC.
**Not recommended for children under 6 years of age.

INFORMATION CONT'D

Administration of stimulants may behavior disturbance and thought pre-existing psychotic disorder.

nitiating treatment with a stimulant, depressive symptoms should be letermine if they are at risk for bipolar ern for possible induction of a mixed/ tients.

notic or manic symptoms: Treatment- manic symptoms in children and or history of psychotic illness or mania nts at usual doses.

painful erections have been reported n both pediatric and adult patients. bnormally sustained or frequent and seek immediate medical attention.

nines may cause suppression of growth. ored during treatment with stimulants, growing or gaining height or weight as ave their treatment interrupted.

ADHD are associated with peripheral vasculopathy, including Raynaud's phenomenon. Signs and symptoms generally improve after reduction in dose or discontinuation of drug. Careful observation for digital changes is necessary during treatment with ADHD stimulants.

- Nervousness and insomnia are the most common adverse reactions but are usually controlled by reducing dosage and omitting the drug in the afternoon or evening. Other reactions include hypersensitivity; anorexia; nausea; dizziness; palpitations; headache; dyskinesia; drowsiness; blood pressure and pulse changes; tachycardia; angina; cardiac arrhythmia; abdominal pain; weight loss during prolonged therapy; libido changes; and rhabdomyolysis.
- Methylphenidate Hydrochloride Chewable Tablets should not be used in children under six years, since safety and efficacy in this age group have not been established.
- Adequate studies to establish safe use of Methylphenidate HCl Chewable Tablets during pregnancy have not been conducted. Patients should be advised to tell their physicians if they are pregnant, planning to become pregnant, or breastfeeding.

Please see Brief Summary of Full Prescribing Information on the following page.

n-Deficit/Hyperactivity Disorder: Clinical Approaches and Challenges." Jonathan R. Stevens, MD, MPH, E. Wilens, MD, and Theodore A. Stern, MD. Prim Care Companion CNS Disord. 2013; 15(2): PCC.12f01472.
Methylphenidate Hydrochloride Chewable Tablets [package insert]. Somerset, NJ: GAVIS Pharmaceuticals; , Food and Drug Administration website, http://www.accessdata.fda.gov/scripts/cder/ob/. December 2015.
Committee for Medicinal Products for Human Use (CHMP), European Medicines Agency. Reflection paper: paediatric population (EMEA/CHMP/PEG/194810/2005). "Safety of chewable tablets for children." Michele Journal of Asthma (2002), vol. 39, No. 5, p: 391-403.

LUPIN PHARMACEUTICALS, INC.

MPH1001-1215V2

usually improve within 48 hours. Short courses of steroids are generally safe and may help avoid hospitalization. Side effects may include temporary irritability and poor sleeping.

Preventative Measures

* An inhaled corticosteroid (also known as a preventative inhaler) works directly on the lung tissue to decrease swelling in the lower airways. Preventative medication needs to be taken daily as directed, using the correct technique. An aerosol inhaler should be used with a spacer device. A spacer device with a mask is recommended for children under five years of age. Children five years and older may be ready for a spacer device with a mouthpiece. Your healthcare provider should demonstrate how to use the medication. If medicines are not taken correctly, they may not get into the lower airways and decrease swelling, causing the asthma symptoms. Always rinse your child's mouth after inhaled corticosteroids to prevent thrush. Talk to your provider if you are considering stopping your child's medication. Remember that asthma is controlled and your child is without symptoms because of the medication. If you stop asthma medications, the asthma symptoms often return within two to four weeks.
* Always know where your child's quick-relief medicine is, and make sure it is not empty and not expired.
* For children who also have allergies:
  - Taking antihistamines and nasal steroids can help control allergies.
  - More expensive measures may include:
    - Remove carpets from the home.
    - Use HEPA vacuum cleaners that have a filter (hospital grade).

Keep hairy or furry pets out of your child's bedroom

  - Avoid having animals in the house. If you cannot keep pets outdoors, keep those with fur or hair out of your child's bedroom.
  - Consider having your child evaluated by an allergist to discuss possible allergy shots or allergy drops.

Monitoring and Responding to Asthma Symptoms

Asthma can be controlled, but recognizing when your child's asthma is not controlled is also important. The following signs may mean your child's asthma is a problem:

* Asthma symptoms need a quick-relief medicine two or more days a week.
* Asthma symptoms limit activity.
* Your child is waking up at night from asthma symptoms two or more times a month.
* Your child needs oral steroids for asthma flare-ups two or more times a year.

If you notice any of these problems, make an appointment with your provider to discuss what can be done to get the asthma well controlled.

Asthma Flare-ups

Keep your child's asthma well controlled by using daily controller medications prescribed by your provider and by avoiding

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

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

$25 CO-PAY SAVINGS PROGRAM*

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.

LUPIN PHARMACEUTICALS, INC

 LP-AL-017-01V1 R08.14

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]

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.

Ahh...
AllerNaze™

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

LUPIN PHARMACEUTICALS, INC.

E-Z on the nose

LUP-002334

Profile

LUPIN
PHARMACEUTICALS, INC.

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

Profile

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

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.

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.

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®

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

Wockhardt

PARSIPPANY, N.J. — Wockhardt Ltd. is a pharmaceutical and biotechnology company headquartered in Mumbai, India. Wockhardt is a global pharmaceutical and biotechnology organization, providing affordable, high-quality medicines for a healthier world. It is a research-based global health care enterprise with relevance in the fields of pharmaceuticals, biotechnology and a chain of advanced super specialty hospitals.

Wockhardt is a business in transition. New and innovative business models are in motion to make the most of emerging opportunities. A new drive for growth today permeates every mind-set, process and techno-innovation within Wockhardt. Wockhardt is looking for new ways of thinking, new ways of working and new ways to touch people's lives.

In the field of pharmaceuticals, Wockhardt is gaining a reputation in several parts of the world as a name to trust. Over the past 45 years, starting from its roots in India, Wockhardt has grown to a billion-dollar worldwide organization that today spans 14 countries on five continents. Over 8,000 employees working in offices, 12 manufacturing facilities, three research centers and hospitals are completely dedicated to building an important trust in its products.

Wockhardt draws strength from the formidable foundation of trust built over the years through delivering quality products by continuously investing in R&D and modern manufacturing technologies, as well as contemporary processes. This enables it to deliver world-class quality products. Wockhardt doesn't merely formulate medicines, it formulates trust.

"We believe that quality medicines begin with strong science and that the quality of our products is directly related to the integrity of our people," says a company spokeswoman. Over 525 quality-control and quality-assurance scientists guarantee that Wockhardt's products, 12 worldwide manufacturing facilities and three research centers meet the strict quality standards set by the FDA. World-class global R&D facilities are at the heart of Wockhardt's pledge and commitment to deliver high quality medicines at affordable prices, and all are fully compliant with cGMP quality standards.

Wockhardt created its U.S. subsidiary, Wockhardt USA LLC, in early 2004 with a modest portfolio of three FDA-approved generic products. In October 2007, Wockhardt Ltd. acquired Chicago-based Morton Grove Pharmaceuticals, expanding Wockhardt's product line in the United States with a 125,000-square-foot state-of-the-art facility.

Wockhardt USA is leading the way in developing the most complete, high-quality line of generic oral solids, liquids, topicals and injectables available in the United States. Wockhardt USA provides more than 258 NDCs spanning over 67 product families. Wockhardt USA is also expanding its emerging branded products portfolio. It has been producing and distributing quality products in the United States for over nine years and has received over 110 ANDA approvals to date. Wockhardt USA has now become the largest overseas business for Wockhardt, contributing more than 51% of global revenues.

Key products in the Wockhardt USA product line include: azithromycin tablets, ceftriaxone injection, enalapril tablets, hydrocodone and homatropine syrup, megestrol acetate oral suspension, metoprolol succinate ER tablets, nystatin oral suspension and phenytoin oral suspension.

WOCKHARDT USA LLC

20 Waterview Blvd.
Parsippany, N.J. 07054

Key contact:

MIKE CRANEY
Senior Vice President of Sales and Marketing

Phone: **(630) 761-3917**
Fax: **(630) 761-3918**

wockhardtusa.com

Breckenridge Pharmaceutical

BOCA RATON, Fla. — Breckenridge Pharmaceutical Inc. is an own-label generic pharmaceutical company that was founded in 1983 and is headquartered in Boca Raton, Fla.

Breckenridge is the U.S. subsidiary of PENSA, the generic arm of Esteve SA.

In 2013 Breckenridge launched several Abbreviated New Drug Applications (ANDAs), including: carbinoxamine maleate tablets and liquid, cilostazol tablets (Pletal), lansoprazole capsules (Prevacid), pioglitazone capsules (Actos), propranolol LA capsules (Inderal LA) and rizatriptan IR and ODT tablets (Maxalt & Maxalt MLT). The company has plans to launch several more products in the immediate future.

On September 11, Breckenridge expanded its current product portfolio and R&D pipeline by acquiring 18 Cypress Pharmaceutical ANDAs from Pernix Therapeutics. The acquisition included seven products formerly marketed by Cypress as well as several that are filed with the Food and Drug Administration and/or in development.

"These assets are a natural fit and complement the Breckenridge portfolio," says executive vice president Larry Lapila.

In June, the company announced that it filed a Paragraph IV for the ANDA of Megace ES by Strativa Pharmaceuticals, a division of Par Pharmaceutical Inc. and Alkermes Pharma Ireland Ltd. This patent challenge is a continuing part of the company's larger aggressive Paragraph IV strategy commenced a few years ago.

Since the beginning of 2011, Breckenridge has filed 12 Paragraph IV patent challenges and intends to continue that trend in the next several years, focusing on niche Paragraph IV opportunities with certain barriers to entry.

Breckenridge partners with contract developers and manufacturers throughout the world and continues to focus its efforts on product development to ensure that it provides its customers with a steady stream of new items. The company is working on over 60 ANDAs, many of which are currently filed and pending FDA approval, with many more projects in various stages of development.

Breckenridge is offered numerous product and marketing opportunities and is collaborating with over a dozen companies. This will position the company for significant growth in the coming years.

The company is the exclusive authorized-generic distributor for all Metafolin-containing brand products developed and distributed by Pamlab Inc., a Nestlé Health Science subsidiary. All Breckenridge authorized generics are subject to exclusive patent licenses and sublicenses. Breckenridge's authorized generics are pharmaceutically identical to their Pamlab brand counterparts and are the only generic products to contain Metafolin (a registered trademark of Merck KGaA, Darmstadt, Germany).

Breckenridge also markets the only authorized versions of patented Sumalate iron-containing products: Ferrex 28, Ferrex 150 Plus, Ferrex 150 Forte Plus, Multigen, Multigen Plus and Multigen Folic through an exclusive license and supply agreement with Albion Laboratories. Sumalate was previously used in the TherRx brand products: Niferex, Chromagen, Precare and Repliva.

Breckenridge markets about 70 products in a variety of dosage forms and therapeutic categories.

Breckenridge Pharmaceutical, Inc

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Executive Vice President

MARTY SCHATZ
Senior Vice President of Sales

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Fax: **(561) 989-0819**

bpirx.com

Lupin Pharmaceuticals

BALTIMORE — Lupin Pharmaceuticals, Inc. (LPI) is the U.S. wholly owned subsidiary of Lupin Ltd, which is among the top five pharmaceutical companies in India.

Headquartered in Baltimore, Lupin is dedicated to delivering high-quality, branded and generic medications trusted by health care professionals and patients.

Lupin is celebrating 10 years of success in the U.S. generics market. The company entered the U.S. generic pharmaceutical market in 2003 with the ANDA approval for cefuroxime axetil tablets.

Lupin's tremendous growth over the past 10 years can be attributed to a strong pipeline, solid customer relationships and flawless execution. Lupin is ranked fifth in terms of generic prescriptions dispensed, and reported year-over-year growth of 52% in fiscal 2013 with revenues of $548 million, up from $361 million in 2012.

Lupin has earned the trust of its customers after consistently delivering high-quality products at an affordable price. Its manufacturing capabilities have expanded over the past several years with the addition of numerous state-of-the-art facilities that ensures cutting-edge response time.

Executives stress that Lupin's ability to execute is what sets it apart from other generic manufactures.

The company's world-class facilities are built to manufacture and deliver a wide range of finished products to the U.S. market. All facilities are in constant compliance with quality, safety, environment standards as laid down by governments and regulators such as the U.S. Food and Drug Administration.

Lupin is one of the world's most vertically integrated global pharmaceutical companies and remains the leader in therapeutic categories such as cephalosporins, cardiovasculars and antituberculosis products.

Furthermore, Lupin develops its own API which enables the company to offer competitive pricing as well as manage its inventory.

The company is dedicated to continuing to expand its business; recently launching an oral contraceptive franchise, investing in research and development, and putting emphasis on a strong pipeline. Lupin is currently offering 60 generic products and more than 260 SKUs.

Lupin has 186 filed ANDA's and over 100 products in development. It is also the market share leader on the overwhelming majority of its products, including lisinopril and lisinopril hydrochlorothiazide tablets.

As of June, the company had 25 of its 52 products in the No. 1 position in terms of market share. Furthermore, 42 of those 52 products were in the top-three position.

As part of its community initiatives, Lupin is involved with multiple charitable organizations throughout the year, such as the Red Cross, the Salvation Army and United Way.

LUPIN PHARMACEUTICALS, INC.

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Key contact:

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Senior Vice President of Sales and Marketing, Generics Division

Phone: **(866) 587-4617**
Fax: **(410) 576-2221**

lupinpharmaceuticals.com

Lupin Pharmaceuticals Inc.

BALTIMORE — Lupin Pharmaceuticals Inc.'s emphasis on technology and differentiation allows it to thrive in uncharted business areas such as distinctive therapeutic categories and hard-to-manufacture drugs.

The company has a rich pipeline consisting of niche products, first-to-files, and pharmaceuticals needing dedicated facilities or having high barriers to entry.

Lupin's record of success has resulted from a valuable pipeline, strong customer relationships and the pursuit of flawless execution. With a commitment to grow through new market entries, bold launches and strategic acquisitions, Lupin is dedicated to exceeding the expectations of its trade partners.

With more than $1.4 billion in international sales, Lupin is the 14th-largest generic drug company worldwide.

Since the launch of its U.S. generics division six and a half years ago Lupin has debuted 42 products in more than 200 dosage strengths and packaging sizes in the United States, with its offerings spanning several major therapeutic categories.

The company has the leading market share for half of its portfolio, and some four-fifths of its products have a top-three market share.

Based on the total number of prescriptions dispensed, Lupin is the No. 5 generic pharmaceutical company, and Lupin has been one of the fastest-growing drug companies for three straight years in the United States, according to IMS Health's National Prescription Audit.

Lupin's consistent growth is not just reflected by numbers but also in the company's ability to enter new categories and launch first-to-market products.

Lupin premiered 13 new generic medications in 2011, including three oral contraceptives that marked the company's entry into the category. Lupin anticipates approvals for approximately 30 new oral contraceptives over the next few years.

In addition, Lupin debuted the first Food and Drug Administration-approved generic equivalent of Shionogi Inc.'s Fortamet (metformin HCl extended-release tablets).

The company gained final FDA approval on 15 new products from January 2011 to July 2012. And Lupin's pipeline covers new therapeutic areas such as dermatologics and oncology, and new dosage forms including ophthalmics and otics.

Lupin has invested 7.5% of its net sales into R&D, allowing it to create one of the broadest generic pipelines in the world. Between January 2011 and June 2012 the company filed 39 Abbreviated New Drug Applications (ANDAs) with the FDA. Lupin continues to sustain its standing as one of the top-10 ANDA filers for the domestic market, with 23 cumulative first-to-file opportunities for the U.S. generics sector.

To exceed the domestic demand for generics, Lupin has expanded production capacity over the past several years at all of its best-in-class manufacturing plants, and it continues to strengthen its efficient supply chain.

Technological advances were also instituted for energy conservation and environmental protection. All of the company's capital spending is focused on meeting the growing demands of Lupin's customers.

LUPIN PHARMACEUTICALS, INC.

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Alvogen

PINE BROOK, N.J. — Alvogen is building a forward-looking generic pharmaceuticals company through its choice of products, partners and markets and use of a consolidated global supply chain. Its mission is to rethink generics.

The company has over 40 pharmaceutical products in development and registration for the United States and another 150 that are being introduced in several markets.

To rethink generics the company is pursuing both global reach and local expertise. Alvogen has regulatory, development and manufacturing operations in Asia and Europe as well as North America.

Company executives say rethinking generics requires an innovative company with an established history. Alvogen's future is built on the solid foundation of its Norwich, N.Y., manufacturing plant.

With 125 years in operation, the Norwich facility has become a thriving, full-service pharmaceutical manufacturer of prescription and over-the-counter products with an unsurpassed regulatory compliance record.

The company maintains an annual manufacturing capacity of over 5 billion tablets and capsules and has 375,000 square feet of development and production space.

Through a lean Six Sigma process, Alvogen focuses on continuous improvement in quality and customer service. It develops first-to-file and complex products, including controlled-release pharmaceuticals, at its R&D facility in Pine Brook, N.J., about 25 miles from Manhattan.

Staffed by several teams with deep experience in formulation and analytical chemistry and with proven track records in filing and bringing to market first-to-file ANDAs, the R&D facility strengthens in-house development capabilities.

Alvogen's expanding product pipeline comprises a wide range of molecules, and they cover most therapeutic categories, including oncology, cardiology, respiratory, neurology and gastroenterology.

As it continues to rethink generics the company is challenging the status quo with products that reduce costs and improve care. Package size and quantity can affect pharmacy productivity and profitability, so Alvogen customizes package quantities for each product based on typical doses and frequency of refills.

The company's product labeling is customer-focused, with four-color labels including medication images and strength indicators, helping assure that pharmacists accurately fill scripts.

By rethinking costs to enhance patient care, Alvogen is creating a new standard for generics — one that lets pharmacies optimize inventory, boost productivity, enhance customer care and reduce costs throughout stores and chains.

"At the heart of Alvogen's innovative products and processes is a passionate team of experts and thought leaders with decades of industry experience," says a company spokesman. "They foster quality, service and support that adds value to pharmacies and consumers."

Alvogen

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Pine Brook, N.J. 07058

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WILLIAM HILL,
Vice President of U.S. Sales and Marketing

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www.alvogen.us.com

Teva Pharmaceutical Industries

NORTH WALES, Pa. —Teva Pharmaceuticals is the leading generic drug company in the United States. In 2011 Teva accounted for 17.1% of U.S. generic prescriptions, with one out of every six U.S. generic prescriptions being filled with a Teva product. Teva introduced 16 generic products in 2011, with 162 ANDAs pending Food and Drug Administration approval as of May 15, 2012. The company markets the broadest product line in the industry with nearly 400 generic products in over 1,200 dosage strengths and packaging sizes, covering all major therapeutic categories.

Teva Pharmaceutical Industries Ltd., is a global organization that combines the world's leading generics business with a world-class specialty pharmaceutical business. The company's mission is to provide a broad range of affordable and effective medicines to patients around the world. Teva operates in about 60 countries and has 56 finished dosage pharmaceutical manufacturing sites, 21 API production sites and 17 pharmaceutical R&D centers worldwide. Approximately 48% of the company's revenue is generated in the United States.

In addition to its leadership in the generics market, Teva has a significant and growing branded pharmaceutical portfolio. Teva has branded products in several therapeutic classes including CNS, respiratory, women's health, and oncology. Brands currently on the market include Copaxone, Azilect, Nuvigil, ProAir, Treanda and a sizable women's health portfolio. The company also has over 40 products in various stages of clinical development.

Teva has identified biopharmaceuticals — in particular, biosimilars — as an important long-term growth opportunity and has established a dedicated research, development and manufacturing infrastructure. The company's joint venture with Switzerland-based Lonza Group Ltd. provides access to the expertise and infrastructure of the world's largest producer of biological API. Teva's biopharmaceutical R&D facilities specialize in different technologies, including the proprietary albumin fusion technology, which can be used to create long-acting biological products.

Teva's vision is to make quality health care accessible. The company's Government Affairs team occupies an office on Capitol Hill and works on behalf of American consumers to advance both innovation and patient access to needed therapies. Additionally, Teva launched the Smart-Health.com website, where patients can learn about generic pharmaceuticals and why they are an important element of high-quality, affordable health care. Teva is the leading provider of affordable generic medicines. Its robust pipeline of future products is a source of continuing value to American consumers.

Teva's recent generic drug introductions (brand equivalent in parentheses) include clopidogrel tablets USP (Plavix), escitalopram tablets USP (Lexapro), fluvastatin capsules USP (Lescol), irbesartan and hydrochlorothiazide tablets USP (Avalide), irbesartan tablets USP (Avapro), methotrexate injection USP (N/A), methylphenidate hydrochloride extended-release capsules LA (Ritalin LA), montelukast sodium chewable tablets (Singulair), montelukast sodium tablets (Singulair), olanzapine and fluoxetine capsules USP (Symbyax), oxaliplatin injection (Eloxatin), quetiapine fumarate tablets (Seroquel), voriconazole tablets (Vfend).

TEVA Pharmaceuticals

1090 Horsham Road
North Wales, Pa. 19454

Phone: (800) 545-8800

www.tevapharm.com

IN THE U.S. PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

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LUPIN PHARMACEUTICALS, INC.,

Opposer, Opposition No. 91226322

v.

AMPEL, LLC,

Applicant.
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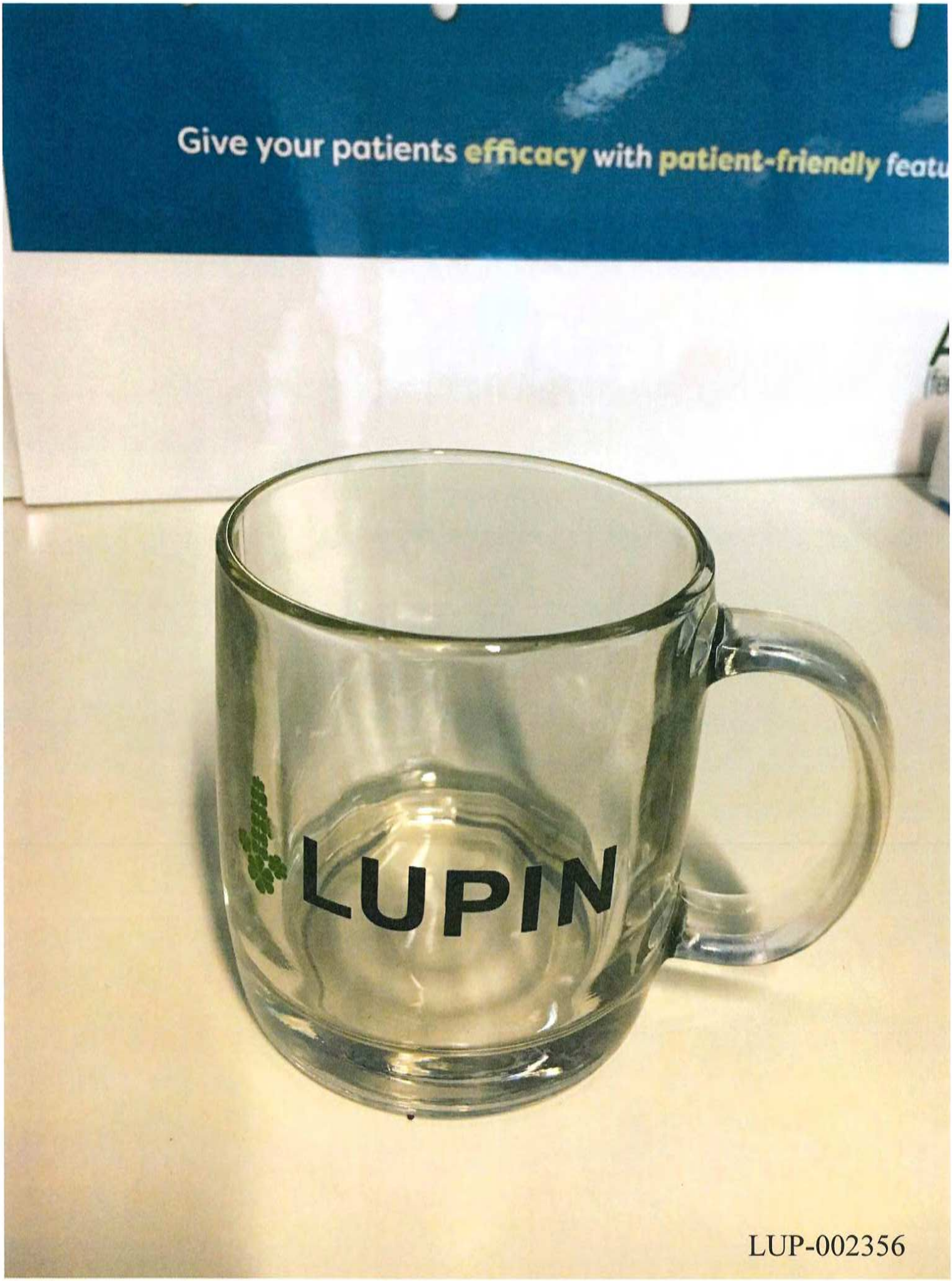
EXHIBIT B

TO

AFFIDAVIT OF JAY LISKA IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT BY OPPOSER LUPIN PHARMACEUTICALS, INC.


Give your patients efficacy with patient-friendly featu
LUPIN

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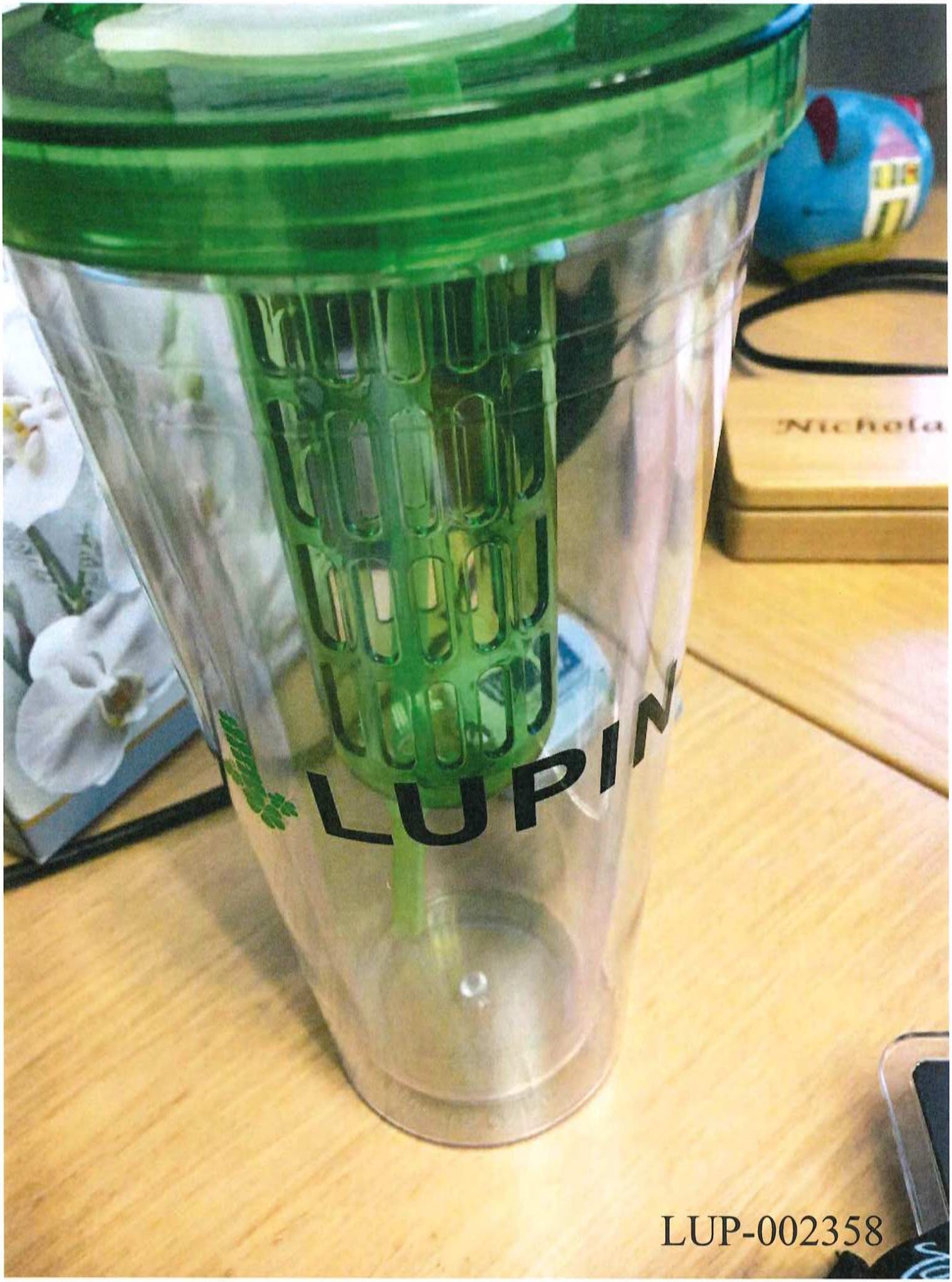


LUP-002358

LUP-002359


InspiraChamber
Anti-Static Valved Holding Chamber
with SootherMask™ and InspiraMask™
www.inspirachamber.com
LUPIN
PHARMACEUTICALS, INC.
IC1003-V1-1214

IN THE U.S. PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

----------x
LUPIN PHARMACEUTICALS, INC.,

Opposer, Opposition No. 91226322

v.

AMPEL, LLC,

Applicant.
----------x

EXHIBIT C

TO

AFFIDAVIT OF JAY LISKA IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT BY OPPOSER LUPIN PHARMACEUTICALS, INC.

Support

Stay on Track with Lifestyle Changes

Exercise

If your triglyceride levels are too high, it's time to get moving—literally! The easiest way to begin is to start walking more and sitting less. Talk to your doctor to find out what level of exercise is healthy for you, and start building up those muscles.

Muscles do more than move your body—they help your body make more of the "good" HDL cholesterol you need.

Diet

Here too, you may benefit from some professional advice—from your doctor, nurse, or dietician. They can help you set up a healthy eating plan to:

- Limit such dietary sources of cholesterol as red meats, full-fat dairy products, and foods that contain trans-fatty acids

Keep carbohydrates under control—"carbs" are an important part of a healthy diet, but if you are getting more than 60% of

ANTARA® (fenofibrate) Important Patient Information

Uses

ANTARA® (fenofibrate) capsules is used to treat high cholesterol and high triglyceride levels in your blood.

ANTARA® and Your Diet

LUP-002945

1. National Cholesterol Education Program (NCEP). Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluations, and Treatment of High Blood Cholesterol in Adults. Adult Treatment Panel III—Final Report. NIH Publication No. 02-5215. September 2002.

ANTARA® (fenofibrate) Important Patient Information

Uses

ANTARA® (fenofibrate) capsules is used to treat high cholesterol and high triglyceride levels in your blood.

ANTARA® and Your Diet

LUP-002946

ANTARA® (fenofibrate) Important Patient Information

Uses

ANTARA® (fenofibrate) capsules is used to treat high cholesterol and high triglyceride levels in your blood.

ANTARA® and Your Diet

Talk with your doctor about a cholesterol-lowering diet prior to being prescribed ANTARA®. You should continue this diet during treatment with ANTARA®. ANTARA® can be taken without regard to meals.

ANTARA® and Heart Disease

The effects of ANTARA® on heart and non-heart-related disease resulting in disability and death has not been established. Fenofibrate, the active ingredient in ANTARA®, was not shown to reduce sickness or death due to heart disease in patients with type 2 diabetes mellitus (T2DM).

ANTARA® and Dosing

Your kidneys are your body's main way of removing ANTARA® from your system. The starting dose of ANTARA® is 90 mg per day. If you have reduced kidney function, your ANTARA® treatment should start at a dosage of 30 mg/day. If you are elderly, you should also be started at a dosage of 30 mg/day. Speak to your doctor about your health and dosing amounts that are right for you.

Who Should Not Take ANTARA®?

ANTARA® should not be used by nursing mothers, people who are allergic or sensitive to fenofibrates, who have liver disease, gallbladder disease or severe kidney problems.

Fenofibrates and Checking Your Liver Function

Fenofibrates may be associated with increasing certain liver enzymes found in the blood. These enzymes are called serum transaminases. Your doctor should monitor your liver function regularly. If your levels continue to be 3 times higher than the normal limit, your cholesterol-lowering treatment with ANTARA® should be stopped. Ask your doctor about your liver function and at what intervals you should have it checked.

Fenofibrates in Combination With a Statin Medication

Taking ANTARA® while also taking a statin medication (HMG-CoA reductase inhibitor) should be avoided unless you and your doctor decide the benefits outweigh the risks. Speak to your doctor if you are taking a statin. Using a fibrate alone, even without a statin, can occasionally result in muscle inflammation and skeletal muscle disorders. If you experience any type of muscle pain, tenderness, or weakness, contact your doctor

ANTARA® (fenofibrate) Important Patient Information

Uses

ANTARA® (fenofibrate) capsules is used to treat high cholesterol and high triglyceride levels in your blood.

ANTARA® and Your Diet

LUP-002947

ANTARA® (fenofibrate) Important Patient Information

Uses

ANTARA® (fenofibrate) capsules is used to treat high cholesterol and high triglyceride levels in your blood.

ANTARA® and Your Diet

LUP-002948

InspiraChamber
The Difference Is By Design

INTRODUCING InspiraMask™ in a Large Size

HOME | PAT ENT RESOURCES | PRODUCT INFORMATION | CLINICAL STUDIES | LINKS | SOURCES | INSTRUCTIONS FOR USE

InspiraChamber® with SootherMask™ and InspiraMask™

LATEX | BPA FREE | DISHWASHER SAFE

Get the Most From Your Asthma Medicine[5]

In order for inhaled asthma medicines to work well, they need to reach the lungs. Attaching a spacer to your prescribed asthma inhaler (or a pediatric spacer to your child's inhaler) helps the medicine do just that. Using a spacer is recommended for anyone who uses an asthma inhaler.

A spacer is a plastic tube that creates "space" between your mouth and the aerosolized medicine from the inhaler. This allows the medicine to move more easily into the lungs. A valved holding chamber, like InspiraChamber®, is a type of spacer with additional features designed to enhance the delivery of inhaled asthma therapies.

Patient Value—Designed to Enhance Delivery of Aerosol Therapy[1-4]

InspiraChamber® with SootherMask™ and InspiraMask™—

The only VHC with 3 options in 1 Rx

InspiraChamber® Small and Medium sizes come with 3 options in 1 Rx: the InspiraChamber® mouthpiece, a SootherMask™, and an InspiraMask™

InspiraChamber® mouthpiece with InspirAlert™ audible signal:

— Sounds at a lower, more clinically appropriate inspiratory flow rate than AeroChamber Plus® Flo-Vu®, OptiChamber® Advantage, and OptiChamber® Diamond[4]

SootherMask™ with SealVision™ visual indicator

— The only mask with a pacifier slot to hold the child's own pacifier

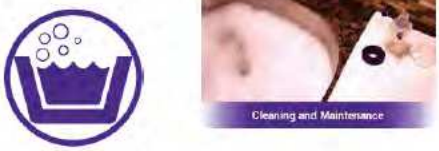
InspiraMask™ with SealVision™ visual indicator

— Confirms seal at a very low inspiratory flow vs AeroChamber Plus® Flo-Vu® and OptiChamber® Diamond[4]

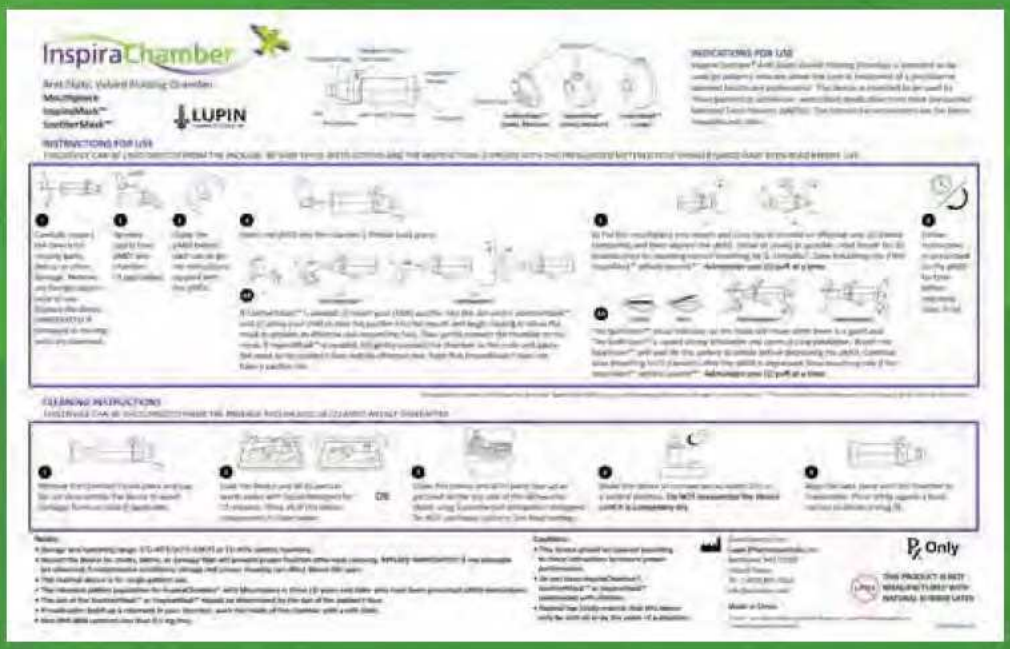
Click Below to Learn More

Instructional Use Videos

LUP-002980



InspiraChamber® Instructions for Use



Allergy & Asthma Network (AAN)

American Academy of Allergy, Asthma & Immunology (AAAAI)

National Asthma Education and Prevention Program

American Lung Association

(NAEPP)

INDICATIONS FOR USE

InspiraChamber® Anti-Static Valved Holding Chamber (VHC) is intended to be used by patients who are under the care or treatment of a physician or licensed healthcare professional. The device is intended to be used by these patients to administer aerosolized medication from most pressurized Metered Dose Inhalers (pMDIs). The intended environments are the home, hospitals and clinics.

Cautions:

- Do not leave InspiraChamber®, SootherMask™ or InspiraMask™ unattended with children.

Notes:

- Storage and operating range: 5°C–40°C (41°F–104°F) at 15–95% relative humidity.
- Inspect the device for cracks, debris, or damage that will prevent proper function after each cleaning. REPLACE IMMEDIATELY if any damages are observed. Environmental conditions, storage and proper cleaning can affect device life span.
- This medical device is for single-patient use.
- The intended patient population for InspiraChamber® with Mouthpiece is three (3) years and older who have been prescribed pMDI medications.
- The size of the SootherMask™ or InspiraMask™ should be determined by the size of the patient's face.
- If medication build-up is observed in your chamber, wash the inside of the chamber with a soft cloth according to the Instructions for Use to ensure proper performance.

Methylphenidate HCl®
Chewable Tablets
2.5 mg • 5 mg • 10 mg

Methylphenidate Hydrochloride Chewable Tablets are a federally controlled substance (CII) because it can be abused or lead to dependence. Keep Methylphenidate Hydrochloride Chewable Tablets in a safe place to prevent misuse and abuse. Selling or giving away Methylphenidate Hydrochloride Chewable Tablets may harm others, and is against the law. See Important Safety Information below.

Growing Up with Attention Deficit and Hyperactivity Disorder (ADHD)

How Methylphenidate HCl Chewable Tablets Can Help

Important Safety Information

Read More

Methylphenidate Hydrochloride Chewable Tablets are a federally controlled substance (CII) because it can be abused or lead to dependence. Keep Methylphenidate Hydrochloride Chewable tablets in a safe place to prevent misuse and abuse. Selling or giving away Methylphenidate Hydrochloride Chewable Tablets may harm others, and is against the law.

Tell your doctor if you or your child have (or have a family history of) ever abused or been dependent on alcohol, prescription medicines or street drugs.

Who should not take Methylphenidate Hydrochloride Chewable Tablets?

Methylphenidate Hydrochloride Chewable Tablets should not be taken if you or your child:

- are very anxious, tense, or agitated

LUP-002983

How Methylphenidate HCl Chewable Tablets Can Help

Discover how >

Understanding ADHD

Learn more >

Plan for Success

Get started >

Important Safety Information

Read More

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Methylphenidate Hydrochloride Chewable Tablets should not be taken if you or your child:

- are very anxious, tense, or agitated

CAUTION PHENYLKETONURICS: Methylphenidate Hydrochloride Chewable Tablets contain phenylalanine.

What is the most important information I should know about Methylphenidate Hydrochloride Chewable Tablets?

The following have been reported with use of methylphenidate HCl and other stimulant medicines:

1. Heart-related problems

- sudden death in patients who have heart problems or heart defects
- stroke and heart attack in adults
- increased blood pressure and heart rate

Tell your doctor if you or your child have any heart problems, heart defects, high blood pressure, or a family history of these problems. Your

Important Safety Information

Read More

Methylphenidate Hydrochloride Chewable Tablets are a federally controlled substance (CII) because it can be abused or lead to dependence. Keep Methylphenidate Hydrochloride Chewable tablets in a safe place to prevent misuse and abuse. Selling or giving away Methylphenidate Hydrochloride Chewable Tablets may harm others, and is against the law.

Tell your doctor if you or your child have (or have a family history of) ever abused or been dependent on alcohol, prescription medicines or street drugs.

Who should not take Methylphenidate Hydrochloride Chewable Tablets?

Methylphenidate Hydrochloride Chewable Tablets should not be taken if you or your child:

- are very anxious, tense, or agitated

- Tell your doctor if you have or your child has numbness, pain, skin color change, or sensitivity to temperature in your fingers or toes.
- **Call your doctor right away if you have or your child has any signs of unexplained wounds appearing on fingers or toes while taking Methylphenidate Hydrochloride Chewable Tablets**

What are the side effects of Methylphenidate Hydrochloride Chewable Tablets?

Serious side effects include:

- slowing of growth (height and weight) in children
- seizures, mainly in patients with a history of seizures
- eyesight changes or blurred vision
- painful and prolonged erections (priapism) have occurred with methylphenidate. If you or your child develop priapism, seek medical help right away. Because of the potential for lasting damage, priapism

Common side effects include:

- nervousness
- trouble sleeping
- headache
- stomach ache
- fast heartbeat
- nausea

Important Safety Information

Read More

Methylphenidate Hydrochloride Chewable Tablets are a federally controlled substance (CII) because it can be abused or lead to dependence. Keep Methylphenidate Hydrochloride Chewable tablets in a safe place to prevent misuse and abuse. Selling or giving away Methylphenidate Hydrochloride Chewable Tablets may harm others, and is against the law.

Tell your doctor if you or your child have (or have a family history of) ever abused or been dependent on alcohol, prescription medicines or street drugs.

Who should not take Methylphenidate Hydrochloride Chewable Tablets?

Methylphenidate Hydrochloride Chewable Tablets should not be taken if you or your child:

- are very anxious, tense, or agitated

HOME

ABOUT METHYLPHENIDATE

- What is Methylphenidate?
- Taking Methylphenidate
- Side Effects of Methylphenidate

ADHD IN CHILDREN

- ADHD Signs, Diagnosis and Treatment
- FAQs for ADHD

ADHD IN ADULTS

- ADHD Signs, Diagnosis and Treatment
- FAQs for ADHD

HEALTHCARE PROVIDERS

- Physicians
- Pharmacists

HELPFUL RESOURCES

- ADHD Support

SAFETY INFORMATION

FULL PRESCRIBING INFORMATION

CONTACT US

LUPIN PHARMACEUTICALS INC

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Baltimore, MD 21202
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Fax: 866-587-4627
www.lupinpharmaceuticals.com
Email: Info@Askarm.Com

PP-MPH-US-0034

Important Safety Information

Read More

Methylphenidate Hydrochloride Chewable Tablets are a federally controlled substance (CII) because it can be abused or lead to dependence. Keep Methylphenidate Hydrochloride Chewable tablets in a safe place to prevent misuse and abuse. Selling or giving away Methylphenidate Hydrochloride Chewable Tablets may harm others, and is against the law.

Tell your doctor if you or your child have (or have a family history of) ever abused or been dependent on alcohol, prescription medicines or street drugs.

Who should not take Methylphenidate Hydrochloride Chewable Tablets?

Methylphenidate Hydrochloride Chewable Tablets should not be taken if you or your child:

- are very anxious, tense, or agitated

LUP-002987

LUPIN
PHARMACEUTICALS, INC.

Growing Up With ADHD

How Methylphenidate HCl® **Chewable Tablets** Can Help

Methylphenidate HCl®
Chewable Tablets

ADHDchewable.com

LUP-002988


LUP-002989

You're reading this because your child has been diagnosed with Attention Deficit Hyperactivity Disorder (ADHD). First things first. Your child isn't to blame for his or her behavior – and through treatment and counseling it's both treatable and manageable. But going through the vast amount of information available on ADHD can be stressful.

We know you must have a lot of questions, and we're here to help. This booklet was created to guide you and your family from the onset to understand what ADHD is, how it's diagnosed and how it's treated. It's natural to be concerned about your child, but resources and professional help are readily available, and can help you, your child and your family lead happy, productive lives.

ADHD? What's That?

ADHD is a behavioral disorder that affects people at all stages of life, but is most often identified in young children. While relatively common, it can lead to behavioral troubles that are difficult to control without proper treatment.[1]

1. ADHD, Inattentive[1]

Your child may have difficulty paying close attention to details and make careless mistakes in schoolwork or other activities. He or she may often be easily distracted by extraneous stimuli, and forgetful in everyday activities.

2. ADHD, Hyperactive/Impulsive[1]

Your child may often fidget with hands or feet or squirm in his or her seat. They may often have difficulty playing or engaging in leisure activities quietly. He or she may be extremely talkative and interrupt other conversations.

3. ADHD, Combined[1]

Your child exhibits symptoms from both types of ADHD.

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How is ADHD Diagnosed?

Diagnosing ADHD is a complex and involved process. There's much more to it than administering a simple exam or running a blood test. Your child's physician must observe, evaluate and rely on several methods of assessment before making a diagnosis.[1] **These methods may include:**

+ Psychological tests
+ Interviews with your child and family members
+ Behavior evaluations completed by parents and teachers
+ Review of school and medical records
+ Physical and neurodevelopmental screening
+ Learning disability screening and intelligence testing
+ Vision and hearing tests or formal speech and language assessments

Methylphenidate HCl chewable does not treat all symptoms of ADHD, but it can provide your child some relief from easy distractions, short attention spans, hyperactivity and/or impulsivity. For more information, see the Medication Guide located in the back of this booklet.

Sometimes, a diagnosis can bring more questions than answers. What can you do to help your child? How do you explain the diagnosis to your child and his or her peers? There are no easy answers, and every child is different. Fortunately, there are many steps you can take as a parent to help your child lead a fulfilling life both at home and at school.

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How is ADHD Treated?

There isn't a simple solution for ADHD, and treatment can sometimes be complicated – but it helps and it's worth it. The best form of treatment for your child involves a combination of several important elements. These various methods work together to provide a unified approach for children diagnosed with ADHD:

1. **Behavior Management.** Helping your child learn appropriate behavior both at home and at school is a key aspect of treating ADHD. While this booklet contains some helpful information on parenting a child with ADHD, it's important that you consult your child's physician and school counselor for additional direction on how to best handle behavioral issues with your child.[1]

2. **Education about diagnosis and treatment.** The more you know about your child's condition, the more you can help. At the end of this booklet there are resources listed that can provide additional information and help ease any anxiety you may have. Forums, wikis and e-books are all freely accessible with an Internet connection, and many local communities can also offer support.[1]

3. **Educational programs and support.** There are many educational programs and support groups available to help you and your child adjust to living with ADHD. He or she may qualify for Section 504 or IDEA (Individuals with Disabilities Education Act) services. Support groups can introduce you and your child to other parents and children who are dealing with ADHD, and provide you with an outlet when times get stressful.

4. **Medication.** The most common type of medication used for treating ADHD is called a stimulant. Although it may seem unusual to treat ADHD with a medication considered a stimulant, it actually has a calming effect on children with ADHD. Many types of stimulant medications are available.[2] A few other ADHD medications are non-stimulants and work differently than stimulants.[2] For many children, ADHD medications reduce hyperactivity and impulsivity, and improve their ability to focus, work and learn.[2] Medication may also improve physical coordination.[2]

How Methylphenidate Can Help

Your child's physician may have prescribed Methylphenidate Hydrochloride chewable tablets to help your child deal with his or her ADHD. Methylphenidate comes in the form of a chewable, easy-to-take tablet. It's the only short-acting, Immediate-Release Chewable Tablet currently on the market, making it an appealing option for patients who only need medication during certain parts of their day.[3,4] It also provides a choice in a formulation that some children may prefer.[5] And convenient, precise dosing makes administration a breeze for kids and parents who are on the go.[6]

Children Who Should Not Take Methylphenidate

Before your child begins taking Methylphenidate, be sure to tell your doctor if any of the following apply to your child:

+ Your child is anxious, tense or agitated.
+ Your child has any allergies.
+ Your child has glaucoma.
+ Your child has tics or Tourette's syndrome, or a family history of Tourette's syndrome. Tics are hard-to-control repeated movements or sounds.
+ Your child is taking (or has taken within the past 14 days) an anti-depression medicine called a monoamine oxidase inhibitor (MAOI).
+ Your child has circulation problems in fingers and toes.
+ Your child has seizures or has had an abnormal brain wave test (EEG).
+ Your child has a history of heart-related issues, especially heart defects or serious heart problems/conditions, and is at a greater risk.
+ Your child suffers from mental problems including psychosis, mania, bipolar illness or depression.

If you notice any unusual symptoms develop while your child is taking Methylphenidate, be sure to contact your child's physician immediately.

What can you do?

There are steps that you can take as a parent in order to ensure your child's success with managing ADHD. And proper treatment of ADHD through medication and behavioral counseling can help family members, teachers and others see the true potential of your child.

+ Help yourself understand ADHD. There are thousands of ADHD-related websites and reputable sources that contain useful information. Parenting forums can help you get in touch with other parents whose families deal with ADHD on a daily basis. However, it's important to be on the lookout and learn to distinguish accurate medical facts from inaccurate information provided by non-professionals. Be cautious of websites or companies that claim to have a cure for ADHD. While there is currently no cure for ADHD, there are many things you can do in order to make the symptoms manageable for both your child and your family.

+ Help your child understand ADHD. It's important that you help your child understand the diagnosis in words that make sense to him or her. Ensure that he or she knows that it's nothing to be embarrassed about. The diagnosis is nothing he or she caused or could have prevented. Help your child understand that by cooperating and participating in different methods of treatment, life will become easier for the whole family, both at school and at home.

For Your Child ...

While life with a child with ADHD can be stressful for everyone, it's important to remember that it's most difficult for him or her.

+ Acknowledge and support the things your child is good at. Children diagnosed with ADHD often excel in activities such as computers, art or individual sports. When your child finds something he or she is good at, encourage participation and allow him or her to experience accomplishment and success.

+ Help build his or her social skills. Other children will often have trouble understanding why children diagnosed with ADHD exhibit behaviors such as aggressiveness or hyperactivity. Your child may be mistreated as an outsider simply because others don't comprehend what he or she is going through. Because of this, it's important to encourage activities that will help your child learn how to behave well, cooperate and make friends.

+ Accept that there will be bad days. You should be prepared for them, and find ways to deal with them in a way that minimizes the negative impact on your child. When times get rough, it's a smart idea to team up with another adult family member or caregiver so that you don't become overly stressed.

At Home ...

Taking care of another family member with ADHD can be stressful at times. It's important that you take care of yourself, because if you become ill due to stress or lack of sleep, you can no longer be of support to your child.

+ Join a community support group. There are support groups all over the world that exist to help parents who have children with ADHD. Check with your physician, school, local church or community center for recommendations. There are also anonymous support groups online. It's important to choose one that you're comfortable with, as you will benefit most from being around people you can trust and speak openly with.

+ Consider getting psychiatric help for your child, yourself – and possibly your other family members. ADHD is stressful for everyone involved. Professional counseling can help relieve stress and provide guidance on how to handle the challenges that may arise.

+ Don’t depend on trial and error. It’s crucial to have a plan for successful behavior management from the get go. It’s important to develop and present your child with a program that suits his or her individual needs. You can work with your physician, attend parent-training classes or consult specialized books to help.

+ Consistency ensures success. Once a plan is developed, make sure that everyone who is in your child’s life on a regular basis follows it. Whether you’re disciplining unwelcome behavior or rewarding good behavior, consistency is key in effectively managing ADHD.

+ Make sure your other children do not feel neglected. Your child requires a lot of attention and support in order to live a productive life. It’s not unusual for siblings to feel like they do not receive enough attention as a result. This can lead to siblings acting out and causing problems in the family environment. Make sure you set aside some one-on-one time, or enlist the help of other family members to ensure all of your children receive the attention they deserve.

At School ...

You are the most important support member in your child's life – no one understands him or her the way you do. So it's important to stick up for your child, especially in environments where you can't always be present, such as school. A good way to start is by scheduling a meeting with your child's teacher, special educator, principal or guidance counselor. Explain to them your child's diagnosis and treatment plan. It's important that you discuss and cooperate with the school in order to ensure your child's success, but always stand your ground and speak up on your child's behalf.

+ Educate yourself about educational rights for children with ADHD. Teach yourself about the education laws that protect your child's right to learn. The Individuals with Disabilities Education Act (IDEA) and Section 504 of the Rehabilitation Act will help you maximize your child's educational opportunities.

+ Become your child's record keeper and advocate. You will receive crucial information about your child from evaluations, test results, behavior records, medical history and more. Since you are the only one who will have access to all of this information, it's important that you manage and share it with the right people in order to maximize the effectiveness of treatment.

+ Collaborate with your child's teacher in order to put together and keep track of a behavioral record. Your child's teacher spends a large amount of time with him or her – almost as much as you do. This makes teachers a valuable ally when it comes to tracking your child's behavior and progress. Ask your child's teacher to keep a behavioral record that covers topics such as ability to focus, behavior control, impulse control, cooperation and homework performance.

It All Comes Together

With a behavioral management plan and the help of medication such as Methylphenidate, ADHD can be treated, and your child can lead a normal and productive life. A strict adherence to the right combination of treatments can give your child a new sense of self-worth and positive, controllable behavior.

Are there any adverse effects to keep in mind?

As with any prescription medicine, there are some important side effects to look out for. It is crucial to your child's health and well-being to remain vigilant of serious side effects. The following have been reported with use of Methylphenidate HCl and other stimulant medicines.

1. Heart-related problems:

+ stroke and heart attack in adults
+ increased blood pressure and heart rate
+ sudden death in patients who have heart problems or heart defects

Tell your doctor if you or your child have any heart problems, heart defects, high blood pressure or a family history of these problems. Your doctor should check your child carefully for heart problems before starting Methylphenidate Hydrochloride chewable tablets. Your doctor should check your child's blood pressure and heart rate regularly during treatment with Methylphenidate Hydrochloride chewable tablets.

Call your doctor right away if your child has any signs of heart problems such as chest pain, shortness of breath or fainting while taking Methylphenidate Hydrochloride chewable tablets.

2. Mental (Psychiatric) problems:

+ new or worse behavior and thought problems
+ new or worse bipolar illness
+ new or worse aggressive behavior or hostility
+ new psychotic symptoms (such as hearing voices, believing things that are not true, are suspicious) or new manic symptoms

Tell your doctor about any mental problems you or your child have, or about a family history of suicide, bipolar illness or depression. Call your doctor right away if your child has any new or worsening mental symptoms or has problems while taking Methylphenidate Hydrochloride chewable tablets, especially seeing or hearing things that are not real, believing things that are not real or are suspicious.

3. Circulation problems in fingers and toes

+ Tell your doctor if your child has numbness, pain, skin color change or sensitivity to temperature in his or her fingers or toes.
+ Call your doctor right away if your child has any signs of unexplained wounds appearing on fingers or toes while taking Methylphenidate Hydrochloride chewable tablets.

What Are the Possible Side Effects of Methylphenidate?

Tell your doctor if your child has side effects that are bothersome or do not go away such as:

+ Nervousness
+ Trouble sleeping
+ Headache
+ Stomach ache
+ Fast heart beat
+ Nausea
+ Decreased appetite
+ Dizziness
+ Weight loss

Less common side effects include:

+ Slowing of growth (height and weight) in children
+ Seizures, mainly in patients with a history of seizures
+ Eyesight changes or blurred vision
+ Painful and prolonged erections (priapism) have occurred with Methylphenidate. If your child develops priapism, seek medical help right away. Because of the potential for lasting damage, a doctor should evaluate priapism immediately.

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How a Balanced Diet Can Help

Making sure your child gets the right nutrition goes a long way toward helping them deal with the everyday challenges that come with ADHD. While no specific foods have been directly linked to causing ADHD, different foods may affect a child in different ways. By paying attention to what your child eats and ensuring that they get the minerals, fiber and vitamins they need, you can teach healthy habits that will benefit them for the rest of their lives.[7]

A nutritious diet includes:[7]

+ Fruits and Vegetables
+ Whole Grains
+ Protein
+ Healthy Fats such as omega-3 fatty acids, polyunsaturated fats and monounsaturated fats

Avoid or limit foods that contain high amounts of:[7]

+ Sugar (cereals, candy and other sweets)
+ Trans fats (processed and fast foods)
+ Saturated fats (dairy, meat and poultry)

References

[1] "Attention Deficit Hyperactivity Disorder (ADHD)." NIMH RSS. N.p., n.d. Web.

[2] "Stimulant Drugs to Treat ADHD: Types, Side Effects, and More." WebMD. WebMD, n.d. Web.

[3] "Clinical Practice guideline based on a review of evidence includes companion guide to implementation" Wolraich, Mark L., M.D., FAAP. What's New in ADHD Diagnosis, Treatment? The American Academy of Pediatrics, 2011.

[4] "Using Stimulants for Attention-Deficit/Hyperactivity Disorder: Clinical Approaches and Challenges." Jonathan R. Stevens, MD, MPH, corresponding author Timothy E. Wilens, MD, and Theodore A. Stern, MD. Prim Care Companion CNS Disord. 2013; 15(2): PCC.12f01472. Published online 2013 Mar 28.

[5] Committee for Medicinal Products for Human Use (CHMP), European Medicines Agency. Reflection paper: formulations of choice for the pediatric population (EMEA/CHMP/PEG/194810/2005).

[6] "Safety of chewable tablets for children." Michele Th., Knorr B., Vada E., Reiss Th. Journal of Asthma (2002), vol. 39, No. 5, p: 391-403.

[7] "Diet Tips and Snack Ideas for kids with ADHD." Healthline. N.p., n.d. Web.

Helpful Resources

Education and support for both you and your child will help pave the way for successful treatment. Below are some relevant resources that can help you manage your child's ADHD and put you in touch with other parents who are going through the same issues. Your entire family will benefit from understanding and learning how to cope with ADHD.

ADDitude Magazine

www.additudemag.com

The American Academy of Child and Adolescent Psychiatry

www.aacap.org

Attention Deficit Disorder Association (ADDA)

www.add.org

Children and Adults with Attention Deficit/Hyperactivity Disorder

www.chadd.org

National Center for Learning Disabilities (NCLD)

www.ncld.org

National Resource Center on ADHD

www.help4adhd.org

PRESCRIBING INFORMATION

Methylphenidate Hydrochloride Chewable Tablets CII
GAVIS Pharmaceuticals, LLC

DESCRIPTION

Methylphenidate hydrochloride is a mild central nervous system (CNS) stimulant, available as 2.5 mg, 5 mg and 10 mg chewable tablets for oral administration. Methylphenidate hydrochloride is methyl α-phenyl-2-piperidineacetate hydrochloride, and its structural formula is

Methylphenidate hydrochloride USP is a white to off-white powder. Its solutions are acid to litmus. It is soluble in water, alcohol, and chloroform.

Each Methylphenidate Hydrochloride Chewable Tablet, for oral administration, contains 2.5 mg, 5 mg or 10 mg of methylphenidate hydrochloride USP. In addition, Methylphenidate Hydrochloride Chewable Tablets also contain the following inactive ingredients: aspartame, maltose, microcrystalline cellulose, grape flavor, pregelatinized starch, phosphoric acid, and stearic acid.

CLINICAL PHARMACOLOGY

Methylphenidate is a racemic mixture comprised of the d- and l-threo enantiomers. The d-threo enantiomer is more pharmacologically active than the l-threo enantiomer.

Methylphenidate HCl is a central nervous system (CNS) stimulant.

The mode of therapeutic action in humans is not completely understood, but methylphenidate presumably activates the brain stem arousal system and cortex to produce its stimulant effect. Methylphenidate is thought to block the reuptake of norepinephrine and dopamine into the presynaptic neuron and increase the release of these monoamines into the extraneuronal space.

There is neither specific evidence which clearly establishes the mechanism whereby Methylphenidate Hydrochloride Chewable Tablets produces its mental and behavioral effects in children, nor conclusive evidence regarding how these effects relate to the condition of the central nervous system.

Pharmacokinetics

Absorption

Methylphenidate Hydrochloride Chewable Tablets are readily absorbed. Following oral administration of Methylphenidate Hydrochloride Chewable Tablets, peak plasma methylphenidate concentrations are achieved at about 1 to 2 hours. Methylphenidate Hydrochloride Chewable Tablets have been shown to be bioequivalent to Ritalin® tablet. The mean Cmax following a 20 mg dose is approximately 10 ng/mL.

Food Effect

In a study in adult volunteers investigating the effects of a high-fat meal on the bioavailability of Methylphenidate Hydrochloride Chewable Tablets at a dose of 20 mg, the presence of food delayed the peak concentrations by approximately 1 hour (1.5 hours, fasted and 2.4 hours, fed). Overall, a high-fat meal increased the AUC of Methylphenidate Hydrochloride Chewable Tablets by about 20%, on average. Through a cross-study comparison, the magnitude of food effect is found to be comparable between the Methylphenidate Hydrochloride Chewable Tablets and Ritalin, the immediate release tablet.

Metabolism and Excretion

In humans, methylphenidate is metabolized primarily via deesterification to alpha-phenylpiperidine acetic acid (PPA, ritalinic acid). The metabolite has little or no pharmacologic activity.

After oral dosing of radiolabeled methylphenidate in humans, about 90% of the radioactivity was recovered in urine. The main urinary metabolite was PPA, accounting for approximately 80% of the dose.

The pharmacokinetics of the Methylphenidate Hydrochloride Chewable Tablets have been studied in healthy adult volunteers. The mean terminal half-life (t½) of methylphenidate following administration of 20 mg Methylphenidate Hydrochloride Chewable Tablets (t½ = 3 hours) is comparable to the mean terminal t½ following administration of Ritalin (methylphenidate hydrochloride immediate-release tablets) (t½ = 2.8 hours) in healthy adult volunteers.

Special Populations

Gender – The effect of gender on the pharmacokinetics of methylphenidate after Methylphenidate Hydrochloride Chewable Tablets administration has not been studied.

Race – The influence of race on the pharmacokinetics of methylphenidate after Methylphenidate Hydrochloride Chewable Tablets administration has not been studied.

Age – The pharmacokinetics of methylphenidate after Methylphenidate Hydrochloride Chewable Tablets administration have not been studied in pediatrics.

Renal Insufficiency

There is no experience with the use of Methylphenidate Hydrochloride Chewable Tablets in patients with renal insufficiency. After oral administration of radiolabeled methylphenidate in humans, methylphenidate was extensively metabolized and approximately 80% of the radioactivity was excreted in the urine in the form of ritalinic acid. Since renal clearance is not an important route of methylphenidate clearance, renal insufficiency is expected to have little effect on the pharmacokinetics of Methylphenidate Hydrochloride Chewable Tablets.

Hepatic Insufficiency

There is no experience with the use of Methylphenidate Hydrochloride Chewable Tablets in patients with hepatic insufficiency.

INDICATIONS AND USAGE

Attention Deficit Disorders, Narcolepsy

Attention Deficit Disorders (previously known as Minimal Brain Dysfunction in Children). Other terms being used to describe the behavioral syndrome below include: Hyperkinetic Child Syndrome, Minimal Brain Damage, Minimal Cerebral Dysfunction, Minor Cerebral Dysfunction.

Methylphenidate Hydrochloride Chewable Tablets are indicated as an integral part of a total treatment program which typically includes other remedial measures (psychological, educational, social) for a stabilizing effect in children with a behavioral syndrome characterized by the following group of developmentally inappropriate symptoms: moderate-to-severe distractibility, short attention span, hyperactivity, emotional lability, and impulsivity. The diagnosis of this syndrome should not be made with finality when these symptoms are only of comparatively recent origin. Nonlocalizing (soft) neurological signs, learning disability, and abnormal EEG may or may not be present, and a diagnosis of central nervous system dysfunction may or may not be warranted.

Special Diagnostic Considerations

Specific etiology of this syndrome is unknown, and there is no single diagnostic test. Adequate diagnosis requires the use not only of medical but of special psychological, educational, and social resources.

Characteristics commonly reported include: chronic history of short attention span, distractibility, emotional lability, impulsivity, and moderate-to-severe hyperactivity; minor neurological signs and abnormal EEG. Learning may or may not be impaired. The diagnosis must be based upon a complete history and evaluation of the child and not solely on the presence of one or more of these characteristics.

Drug treatment is not indicated for all children with this syndrome. Stimulants are not intended for use in the child who exhibits symptoms secondary to environmental factors and/or primary psychiatric disorders, including psychosis. Appropriate educational placement is essential and psychosocial intervention is generally necessary. When remedial measures alone are insufficient, the decision to prescribe stimulant medication will depend upon the physician's assessment of the chronicity and severity of the child's symptoms.

CONTRAINDICATIONS

Marked anxiety, tension, and agitation are contraindications to Methylphenidate Hydrochloride Chewable Tablets, since the drug may aggravate these symptoms. Methylphenidate Hydrochloride Chewable Tablets are contraindicated also in patients known to be hypersensitive to the drug, in patients with glaucoma, and in patients with motor tics or with a family history or diagnosis of Tourette's syndrome.

Methylphenidate Hydrochloride Chewable Tablets are contraindicated during treatment with monoamine oxidase inhibitors, and also within a minimum of 14 days following discontinuation of a monoamine oxidase inhibitor (hypertensive crises may result).

WARNINGS

Serious Cardiovascular Events

Sudden Death and Pre-Existing Structural Cardiac Abnormalities or Other Serious Heart Problems

Children and Adolescents – Sudden death has been reported in association with CNS stimulant treatment at usual doses in children and adolescents with structural cardiac abnormalities or other serious heart problems. Although some serious heart problems alone carry an increased risk of sudden death, stimulant products generally should not be used in children or adolescents with known serious structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, or other serious cardiac problems that may place them at increased vulnerability to the sympathomimetic effects of a stimulant drug.

Adults – Sudden deaths, stroke, and myocardial infarction have been reported in adults taking stimulant drugs at usual doses for ADHD. Although the role of stimulants in these adult cases is also unknown, adults have a greater likelihood than children of having serious structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, coronary artery disease, or other serious cardiac problems. Adults with such abnormalities should also generally not be treated with stimulant drugs.

Hypertension and other Cardiovascular Conditions

Stimulant medications cause a modest increase in average blood pressure (about 2 to 4 mmHg) and average heart rate (about 3 to 6 bpm), and individuals may have larger increases. While the mean changes alone would not be expected to have short-term consequences, all patients should be monitored for larger changes in heart rate and blood pressure. Caution is indicated in treating patients whose underlying medical conditions might be compromised by increases in blood pressure or heart rate, e.g., those with pre-existing hypertension, heart failure, recent myocardial infarction, or ventricular arrhythmia.

Assessing Cardiovascular Status in Patients being Treated with Stimulant Medications

Children, adolescents, or adults who are being considered for treatment with stimulant medications should have a careful history (including assessment for a family history of sudden death or ventricular arrhythmia) and physical exam to assess for the presence of cardiac disease, and should receive further cardiac evaluation if findings suggest such disease (e.g., electrocardiogram and echocardiogram). Patients who develop symptoms such as exertional chest pain, unexplained syncope, or other symptoms suggestive of cardiac disease during stimulant treatment should undergo a prompt cardiac evaluation.

Psychiatric Adverse Events

Pre-Existing Psychosis – Administration of stimulants may exacerbate symptoms of behavior disturbance and thought disorder in patients with a pre-existing psychotic disorder.

Bipolar Illness – Particular care should be taken in using stimulants to treat ADHD in patients with comorbid bipolar disorder because of concern for possible induction of a mixed/manic episode in such patients. Prior to initiating treatment with a stimulant, patients with comorbid depressive symptoms should be adequately screened to determine if they are at risk for bipolar disorder; such screening should include a detailed psychiatric history, including a family history of suicide, bipolar disorder, and depression.

Emergence of New Psychotic or Manic Symptoms – Treatment emergent psychotic or manic symptoms, e.g., hallucinations, delusional thinking, or mania in children and adolescents without a prior history of psychotic illness or mania can be caused by stimulants at usual doses. If such symptoms occur, consideration should be given to a possible causal role of the stimulant, and discontinuation of treatment may be appropriate. In a pooled analysis of multiple short-term, placebo-controlled studies, such symptoms occurred in about 0.1% (4 patients with events out of 3482 exposed to methylphenidate or amphetamine for several weeks at usual doses) of stimulant-treated patients compared to 0 in placebo-treated patients.

Aggression – Aggressive behavior or hostility is often observed in children and adolescents with ADHD, and has been reported in clinical trials and the post-marketing experience of some medications indicated for the treatment of ADHD. Although there is no systematic evidence that stimulants cause aggressive behavior or hostility, patients beginning treatment for ADHD should be monitored for the appearance of or worsening of aggressive behavior or hostility.

Seizures

There is some clinical evidence that stimulants may lower the convulsive threshold in patients with prior history of seizures, in patients with prior EEG abnormalities in absence of seizures, and, very rarely, in patients without a history of seizures and no prior EEG evidence of seizures. In the presence of seizures, the drug should be discontinued.

Priapism

Prolonged and painful erections, sometimes requiring surgical intervention, have been reported with methylphenidate products in both pediatric and adult patients. Priapism was not reported with drug initiation but developed after some time on the drug, often subsequent to an increase in dose. Priapism has also appeared during a period of drug withdrawal (drug holidays or discontinuation): Patients who develop abnormally sustained or frequent and painful erections should seek immediate medical attention.

Peripheral Vasculopathy, Including Raynaud's Phenomenon

Stimulants, including Methylphenidate Hydrochloride Chewable Tablets, used to treat ADHD are associated with peripheral vasculopathy, including Raynaud's phenomenon. Signs and symptoms are usually intermittent and mild; however, very rare sequelae include digital ulceration and/or soft tissue breakdown. Effects of peripheral vasculopathy, including Raynaud's phenomenon, were observed in post-marketing reports at different times and at therapeutic doses in all age groups throughout the course of treatment. Signs and symptoms generally improve after reduction in dose or discontinuation of drug. Careful observation for digital changes is necessary during treatment with ADHD stimulants. Further clinical evaluation (e.g., rheumatology referral) may be appropriate for certain patients.

Long-Term Suppression of Growth

Careful follow-up of weight and height in children ages 7 to 10 years who were randomized to either methylphenidate or non-medication treatment groups over 14 months, as well as in naturalistic subgroups of newly methylphenidate-treated and non-medication treated children over 36 months (to the ages of 10 to 13 years), suggests that consistently medicated children (i.e., treatment for 7 days per week throughout the year) have a temporary slowing in growth rate (on average, a total of about 2 cm less growth in height and 2.7 kg less growth in weight over 3 years), without evidence of growth rebound during this period of development.

Published data are inadequate to determine whether chronic use of amphetamines may cause a similar suppression of growth, however, it is anticipated that they likely have this effect as well. Therefore, growth should be monitored during treatment with stimulants, and patients who are not growing or gaining height or weight as expected may need to have their treatment interrupted.

Visual Disturbance

Difficulties with accommodation and blurring of vision have been reported with stimulant treatment.

USE IN CHILDREN LESS THAN SIX YEARS OF AGE

Methylphenidate Hydrochloride Chewable Tablets should not be used in children under six years, since safety and efficacy in this age group have not been established.

DRUG ABUSE AND DEPENDENCE

Methylphenidate Hydrochloride Chewable Tablets should be given cautiously to emotionally unstable patients, such as those with a history of drug dependence or alcoholism, because such patients may increase dosage on their own initiative.

Chronically abusive use can lead to marked tolerance and psychic dependence with varying degrees of abnormal behavior. Frank psychotic episodes can occur, especially with parenteral abuse. Careful supervision is required during drug withdrawal, since severe depression as well as the effects of chronic overactivity can be unmasked. Long-term follow-up may be required because of the patient's basic personality disturbances.

PRECAUTIONS

General

Patients with an element of agitation may react adversely; discontinue therapy if necessary.

Periodic CBC, differential, and platelet counts are advised during prolonged therapy.

Drug treatment is not indicated in all cases of this behavioral syndrome and should be considered only in light of the complete history and evaluation of the child. The decision to prescribe Methylphenidate Hydrochloride Chewable Tablets should depend on the physician's assessment of the chronicity and severity of the child's symptoms and their appropriateness for his/her age.

Prescription should not depend solely on the presence of one or more of the behavioral characteristics.

When these symptoms are associated with acute stress reactions, treatment with Methylphenidate Hydrochloride Chewable Tablets is usually not indicated.

Long-term effects of Methylphenidate Hydrochloride Chewable Tablets in children have not been well established.

Information for Patients

Prescribers or other health professionals should inform patients, their families, and their caregivers about the benefits and risks associated with treatment with methylphenidate and should counsel them in its appropriate use. A patient Medication Guide is available for Methylphenidate Hydrochloride Chewable Tablets. The prescriber or health professional should instruct patients, their families, and their caregivers to read the Medication Guide and should assist them in understanding its contents. Patients should be given the opportunity to discuss the contents of the Medication Guide and to obtain answers to any questions they may have.

Physicians are advised to discuss the following issues with patients for whom they prescribe Methylphenidate Hydrochloride Chewable Tablets:

Choking – Taking this product without adequate fluid may cause it to swell and block your throat or esophagus and may cause choking. Do not take this product if you have difficulty in swallowing. If you experience chest pain, vomiting, or difficulty in swallowing or breathing after taking this product, seek immediate medical attention.

Directions – Take this product (child or adult dose) with at least 8 ounces (a full glass) of water or other fluid. Taking this product without enough liquid may cause choking. See choking warning.

Priapism

Advise patients, caregivers, and family members of the possibility of painful or prolonged penile erections (priapism). **Instruct the patient to seek immediate medical attention in the event of priapism.**

Circulation Problems in Fingers and Toes [Peripheral Vasculopathy, Including Raynaud's Phenomenon]

• Instruct patients beginning treatment with Methylphenidate Hydrochloride Chewable Tablets about the risk of peripheral vasculopathy, including Raynaud's Phenomenon, and associated signs and symptoms: fingers or toes may feel numb, cool, painful, and/or may change color from pale, to blue, to red.

• Instruct patients to report to their physician any new numbness, pain, skin color change, or sensitivity to temperature in fingers or toes.

• Instruct patients to call their physician immediately with any signs of unexplained wounds appearing on fingers or toes while taking Methylphenidate Hydrochloride Chewable Tablets.

• Further clinical evaluation (e.g., rheumatology referral) may be appropriate for certain patients.

Phenylketonurics – Phenylalanine is a component of aspartame. Each 2.5 mg Methylphenidate Hydrochloride Chewable Tablet contains 0.42 mg of phenylalanine; each 5.0 mg Methylphenidate Hydrochloride Chewable Tablet contains 0.84 mg of phenylalanine and each 10.0 mg Methylphenidate Hydrochloride Chewable Tablet contains 1.68 mg of phenylalanine.

Drug Interactions

Methylphenidate Hydrochloride Chewable Tablets may decrease the hypotensive effect of guanethidine. Use cautiously with pressor agents.

Human pharmacologic studies have shown that Methylphenidate hydrochloride may inhibit the metabolism of coumarin anticoagulants, anticonvulsants (phenobarbital, diphenylhydantoin, primidone), phenylbutazone, and tricyclic drugs (imipramine, clomipramine, desipramine). Downward dosage adjustments of these drugs may be required when given concomitantly with Methylphenidate hydrochloride.

Carcinogenesis, Mutagenesis, Impairment of Fertility

In a lifetime carcinogenicity study carried out in B6C3F1 mice, methylphenidate caused an increase in hepatocellular adenomas and, in males only, an increase in hepatoblastomas, at a daily dose of approximately 60 mg/kg/day. This dose is approximately 30 times and 2.5 times the maximum recommended human dose on a mg/kg and mg/m^2 basis, respectively. Hepatoblastoma is a relatively rare rodent malignant tumor type. There was no increase in total malignant hepatic tumors. The mouse strain used is sensitive to the development of hepatic tumors, and the significance of these results to humans is unknown.

Methylphenidate did not cause any increase in tumors in a lifetime carcinogenicity study carried out in F344 rats; the highest dose used was approximately 45 mg/kg/day, which is approximately 22 times and 4 times the maximum recommended human dose on a mg/kg and mg/m^2 basis, respectively.

Methylphenidate was not mutagenic in the in vitro Ames reverse mutation assay or in the in vitro mouse lymphoma cell forward mutation assay. Sister chromatid exchanges and chromosome aberrations were increased, indicative of a weak clastogenic response, in an in vitro assay in cultured Chinese Hamster Ovary (CHO) cells. The genotoxic potential of methylphenidate has not been evaluated in an in vivo assay.

Usage in Pregnancy

Adequate animal reproduction studies to establish safe use of Methylphenidate Hydrochloride Chewable Tablets during pregnancy have not been conducted. However, in a recently conducted study, methylphenidate has been shown to have teratogenic effects in rabbits when given in doses of 200 mg/kg/day, which is approximately 167 times and 78 times the maximum recommended human dose on a mg/kg and a mg/m^2 basis, respectively. In rats, teratogenic effects were not seen when the drug was given in doses of 75 mg/kg/day, which is approximately 62.5 and 13.5 times the maximum recommended human dose on a mg/kg and a mg/m^2 basis, respectively. Therefore, until more information is available, methylphenidate should not be prescribed for women of childbearing age unless, in the opinion of the physician, the potential benefits outweigh the possible risks.

ADVERSE REACTIONS

Nervousness and insomnia are the most common adverse reactions but are usually controlled by reducing dosage and omitting the drug in the afternoon or evening. Other reactions include hypersensitivity (including skin rash, urticaria,

fever, arthralgia, exfoliative dermatitis, erythema multiforme with histopathological findings of necrotizing vasculitis, and thrombocytopenic purpura); anorexia; nausea; dizziness; palpitations; headache; dyskinesia; drowsiness; blood pressure and pulse changes, both up and down; tachycardia; angina; cardiac arrhythmia; abdominal pain; weight loss during prolonged therapy; libido changes; and rhabdomyolysis. There have been rare reports of Tourette's syndrome.

Toxic psychosis has been reported. Although a definite causal relationship has not been established, the following have been reported in patients taking this drug: instances of abdominal liver function, ranging from transaminase elevation to hepatic coma; isolated cases of cerebral arteritis and/or occlusion; leukopenia and/or anemia; transient depressed mood; a few instances of scalp hair loss. Very rare reports of neuroleptic malignant syndrome (NMS) have been received, and, in most of these, patients were concurrently receiving therapies associated with NMS. In a single report, a ten year old boy who had been taking methylphenidate for approximately 18 months experienced an NMS-like event within 45 minutes of ingesting his first dose of venlafaxine. It is uncertain whether this case represented a drug-drug interaction, a response to either drug alone, or some other cause.

In children, loss of appetite, abdominal pain, weight loss during prolonged therapy, insomnia, and tachycardia may occur more frequently; however, any of the other adverse reactions listed above may also occur.

OVERDOSAGE

Signs and symptoms of acute overdosage, resulting principally from overstimulation of the central nervous system and from excessive sympathomimetic effects, may include the following: vomiting, agitation, tremors, hyperreflexia, muscle twitching, convulsions (may be followed by coma), euphoria, confusion, hallucinations, delirium, sweating, flushing, headache, hyperpyrexia, tachycardia, palpitations, cardiac arrhythmias, hypertension, mydriasis, dryness of mucous membranes, and rhabdomyolysis.

Consult with a Certified Poison Control Center regarding treatment for up-to-date guidance and advice.

Treatment consists of appropriate supportive measures. The patient must be protected against self-injury and against external stimuli that would aggravate overstimulation already present. Gastric contents may be evacuated by gastric lavage. In the presence of severe intoxication, use a carefully titrated dosage of a *short-acting* barbiturate before performing gastric lavage. Other measures to detoxify the gut include administration of activated charcoal and a cathartic.

Intensive care must be provided to maintain adequate circulation and respiratory exchange; external cooling procedures may be required for hyperpyrexia.

Efficacy of peritoneal dialysis or extracorporeal hemodialysis for methylphenidate overdosage has not been established.

DOSAGE AND ADMINISTRATION

Dosage should be individualized according to the needs and responses of the patient.

Directions – Take this product (child or adult dose) with at least 8 ounces (a full glass) of water or other fluid. Taking this product without enough liquid may cause choking. See choking warning.

Adults

Administer in divided doses 2 or 3 times daily, preferably 30 to 45 minutes before meals. Average dosage is 20 to 30 mg daily. Some patients may require 40 to 60 mg daily. In others, 10 to 15 mg daily will be adequate. Patients who are unable to sleep if medication is taken late in the day should take the last dose before 6 p.m.

Children (6 years and over)

Methylphenidate Hydrochloride Chewable Tablets should be initiated in small doses, with gradual weekly increments. Daily dosage above 60 mg is not recommended.

If improvement is not observed after appropriate dosage adjustment over a one-month period, the drug should be discontinued.

Chewable Tablets: Start with 5 mg twice daily (before breakfast and lunch) with gradual increments of 5 to 10 mg weekly.

If paradoxical aggravation of symptoms or other adverse effects occur, reduce dosage, or, if necessary, discontinue the drug.

Methylphenidate Hydrochloride Chewable Tablets should be periodically discontinued to assess the child's condition. Improvement may be sustained when the drug is either temporarily or permanently discontinued.

Drug treatment should not and need not be indefinite and usually may be discontinued after puberty.

HOW SUPPLIED

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.

Bottles of 100 .....NDC 43386-570-01

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.

Bottles of 100 .....NDC 43386-571-01

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.

Bottles of 100 .....NDC 43386-572-01

Protect from moisture. Dispense in tight container with child-resistant closure.

Storage: Store at 20º to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Ritalin is a registered trademark of Novartis Corporation.

Manufactured by:
Novel Laboratories Inc.
400 Campus Drive,
Somerset, NJ 08873
USA

Manufactured for:
GAVIS Pharmaceuticals, LLC
Somerset, NJ 08873

PI5700000202
Rev. 12/2015

MEDICATION GUIDE

Methylphenidate Hydrochloride Chewable Tablets CII 2.5 mg, 5 mg, and 10 mg

Read the Medication Guide that comes with Methylphenidate Hydrochloride Chewable Tablets before you or your child starts taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your doctor about your or your child's treatment with Methylphenidate Hydrochloride Chewable Tablets.

What is the most important information I should know about Methylphenidate Hydrochloride Chewable Tablets?

The following have been reported with use of methylphenidate HCl and other stimulant medicines.

1. Heart-related problems:

- **sudden death in patients who have heart problems or heart defects**
- **stroke and heart attack in adults**
- **increased blood pressure and heart rate**

Tell your doctor if you or your child have any heart problems, heart defects, high blood pressure, or a family history of these problems.

Your doctor should check you or your child carefully for heart problems before starting Methylphenidate Hydrochloride Chewable Tablets.

Your doctor should check you or your child's blood pressure and heart rate regularly during treatment with Methylphenidate Hydrochloride Chewable Tablets.

Call your doctor right away if you or your child has any signs of heart problems such as chest pain, shortness of breath, or fainting while taking Methylphenidate Hydrochloride Chewable Tablets.

2. Mental (Psychiatric) problems:

All Patients

- **new or worse behavior and thought problems**
- **new or worse bipolar illness**
- **new or worse aggressive behavior or hostility**

Children and Teenagers

- **new psychotic symptoms (such as hearing voices, believing things that are not true, are suspicious) or new manic symptoms**

Tell your doctor about any mental problems you or your child have, or about a family history of suicide, bipolar illness, or depression.

Call your doctor right away if you or your child have any new or worsening mental symptoms or problems while taking Methylphenidate Hydrochloride Chewable Tablets, especially seeing or hearing things that are not real, believing things that are not real, or are suspicious.

3. Circulation problems in fingers and toes

[Peripheral vasculopathy, including Raynaud's phenomenon]: fingers or toes may feel numb, cool, painful, and/or may change color from pale, to blue, to red.

- Tell your doctor if you have or your child has numbness, pain, skin color change, or sensitivity to temperature in your fingers or toes.
- **Call your doctor right away if you have or your child has any signs of unexplained wounds appearing on fingers or toes while taking Methylphenidate Hydrochloride Chewable Tablets.**

What Are Methylphenidate Hydrochloride Chewable Tablets?

Methylphenidate Hydrochloride Chewable Tablets are a central nervous system stimulant prescription medicine. Methylphenidate Hydrochloride Chewable Tablets are tablets that are made to be chewed and swallowed. **They are used for the treatment of Attention Deficit and Hyperactivity Disorder (ADHD).** Methylphenidate Hydrochloride Chewable Tablets may help increase attention and decrease impulsiveness and hyperactivity in patients with ADHD.

Methylphenidate Hydrochloride Chewable Tablets should be used as a part of a total treatment program for ADHD that may include counseling or other therapies.

Methylphenidate Hydrochloride Chewable Tablets are also used in the treatment of a sleep disorder called narcolepsy.

Methylphenidate Hydrochloride Chewable Tablets are a federally controlled substance (CII) because it can be abused or lead to dependence. Keep Methylphenidate Hydrochloride Chewable Tablets in a safe place to prevent misuse and abuse. Selling or giving away Methylphenidate Hydrochloride Chewable Tablets may harm others, and is against the law.

Tell your doctor if you or your child have (or have a family history of) ever abused or been dependent on alcohol, prescription medicines or street drugs.

Who should not take Methylphenidate Hydrochloride Chewable Tablets?

Methylphenidate Hydrochloride Chewable Tablets should not be taken if you or your child:

- are very anxious, tense, or agitated
- have an eye problem called glaucoma
- have tics or Tourette's syndrome, or a family history of Tourette's syndrome. Tics are hard to control repeated movements or sounds.
- are taking or have taken within the past 14 days an antidepression medicine called a monoamine oxidase inhibitor or MAOI.
- are allergic to anything in Methylphenidate Hydrochloride Chewable Tablets. See the end of this Medication Guide for a complete list of ingredients.

Methylphenidate Hydrochloride Chewable Tablets should not be used in children less than 6 years old because it has not been studied in this age group.

Methylphenidate Hydrochloride Chewable Tablets may not be right for you or your child. Before starting Methylphenidate Hydrochloride Chewable Tablets tell your or your child's doctor about all health conditions (or a family history of) including:

- heart problems, heart defects, high blood pressure
- mental problems including psychosis, mania, bipolar illness, or depression
- tics or Tourette's syndrome
- seizures or have had an abnormal brain wave test (EEG)
- circulation problems in fingers and toes

Tell your doctor if you or your child is pregnant, planning to become pregnant, or breastfeeding.

Can Methylphenidate Hydrochloride Chewable Tablets be taken with other medicines?

Tell your doctor about all of the medicines that you or your child take including prescription and nonprescription medicines, vitamins, and herbal supplements.

Methylphenidate Hydrochloride Chewable Tablets and some medicines may interact with each other and cause serious side effects. Sometimes the doses of other medicines will need to be adjusted while taking Methylphenidate Hydrochloride Chewable Tablets.

Your doctor will decide whether Methylphenidate Hydrochloride Chewable Tablets can be taken with other medicines.

Especially tell your doctor if you or your child takes:

- anti-depression medicines including MAOIs
- seizure medicines
- blood thinner medicines
- blood pressure medicines
- cold or allergy medicines that contain decongestants

Know the medicines that you or your child takes. Keep a list of your medicines with you to show your doctor and pharmacist.

Do not start any new medicine while taking Methylphenidate Hydrochloride Chewable Tablets without talking to your doctor first.

How should Methylphenidate Hydrochloride Chewable Tablets be taken?

- **Take Methylphenidate Hydrochloride Chewable Tablets exactly as prescribed.** Your doctor may adjust the dose until it is right for you or your child.
- Methylphenidate Hydrochloride Chewable Tablets are usually taken 2 to 3 times a day.
- Take Methylphenidate Hydrochloride Chewable Tablets 30 to 45 minutes before a meal.

- **Chew Methylphenidate Hydrochloride Chewable Tablets well and swallow with at least 8 ounces (a full glass) of water or other liquid. Methylphenidate Hydrochloride Chewable Tablets can swell and cause choking if enough liquid is not taken with them. Get emergency medical care if you have chest pain, vomiting, or trouble swallowing, or breathing after taking a Methylphenidate Hydrochloride Chewable Tablet.**

- From time to time, your doctor may stop Methylphenidate Hydrochloride Chewable Tablets treatment for awhile to check ADHD symptoms.
- Your doctor may do regular checks of the blood, heart, and blood pressure while taking Methylphenidate Hydrochloride Chewable Tablets. Children should have their height and weight checked often while taking Methylphenidate Hydrochloride Chewable Tablets. Methylphenidate Hydrochloride Chewable Tablets treatment may be stopped if a problem is found during these check-ups.
- **If you or your child takes too much Methylphenidate Hydrochloride Chewable Tablets or overdoses, call your doctor or poison control center right away, or get emergency treatment.**

What are possible side effects of Methylphenidate Hydrochloride Chewable Tablets?

See **"What is the most important information I should know about Methylphenidate Hydrochloride Chewable Tablets?"** for information on reported heart and mental problems.

Other serious side effects include:

- slowing of growth (height and weight) in children
- seizures, mainly in patients with a history of seizures
- eyesight changes or blurred vision
- Painful and prolonged erections (priapism) have occurred with methylphenidate. If you or your child develop priapism, seek medical help right away. Because of the potential for lasting damage, priapism should be evaluated by a doctor immediately.

Common side effects include:

- nervousness
- trouble sleeping
- headache
- stomach ache
- fast heart beat
- nausea
- decreased appetite
- dizziness
- weight loss

Talk to your doctor if you or your child has side effects that are bothersome or do not go away.

This is not a complete list of possible side effects. Ask your doctor or pharmacist for more information.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store Methylphenidate Hydrochloride Chewable Tablets?

- Store Methylphenidate Hydrochloride Chewable Tablets in a safe place at room temperature, 68° to 77°F (20° to 25°C). Protect from moisture.
- **Keep Methylphenidate Hydrochloride Chewable Tablets and all medicines out of the reach of children.**

General information about Methylphenidate Hydrochloride Chewable Tablets

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Methylphenidate Hydrochloride Chewable Tablets for a condition for which it was not prescribed. Do not give Methylphenidate Hydrochloride Chewable Tablets to other people, even if they have the same condition. It may harm them and it is against the law.

This Medication Guide summarizes the most important information about Methylphenidate Hydrochloride Chewable Tablets. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about Methylphenidate Hydrochloride Chewable Tablets that was written for healthcare professionals.

What are the ingredients in Methylphenidate Hydrochloride Chewable Tablets?

CAUTION PHENYLKETONURICS: Methylphenidate Hydrochloride Chewable Tablets contain phenylalanine.

Active Ingredient: methylphenidate hydrochloride USP

Inactive Ingredients: aspartame, maltose, microcrystalline cellulose, grape flavor, pregelatinized starch, phosphoric acid, and stearic acid.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Manufactured by:
Novel Laboratories Inc.
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Somerset, NJ 08873
USA

Manufactured for:
GAVIS Pharmaceuticals, LLC
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PI5700000202
Rev. 12/2015

LUPIN
PHARMACEUTICALS, INC.

MPH1003-1215V3

CERTIFICATE OF SERVICE

I hereby certify that on this 29th day of December, 2017, the foregoing Motion for Summary Judgment is being served upon the attorney for Applicant via email to:

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