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IMPRIMIS PHARMACEUTICALS, INC.

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

SOUTHERN DIVISION

ALLERGAN USA, INC.,

Plaintiff,

v.

IMPRIMIS PHARMACEUTICALS, INC.,

Defendants.

Case No. _____

COMPLAINT

JURY TRIAL DEMANDED

Allergan USA, Inc. brings this action against Defendant Imprimis Pharmaceuticals, Inc. ("Imprimis") and alleges the following:

I. NATURE OF ACTION

1. Allergan brings this action to stop Imprimis from illegally manufacturing and selling unapproved new drugs under the false guise that it is engaged in lawful "compounding" and from engaging in false and misleading advertising and promotion of its unapproved new drugs. Federal and state law require drug manufacturers to demonstrate that their drugs are safe and effective in order to obtain regulatory approval to market them. Imprimis purports to avoid the drug-approval requirement by falsely presenting its products as lawfully "compounded" when in fact Imprimis's products are mass-manufactured standardized formulations of unapproved new drugs that cannot lawfully be sold and that threaten patient safety. The United States Food and Drug Administration ("FDA") has warned Imprimis against mass manufacturing unapproved new drugs under the guise of compounding, has found serious deficiencies in Imprimis's production practices, and has observed that Imprimis's use of ingredients that are unfit for human consumption poses risks to patient safety.

2. Section 43(a) of the Lanham Act protects those engaged in commerce from precisely this type of unfair competition and false advertising by creating a cause of action for those like Allergan who are harmed by it. 15 U.S.C. § 1125(a)(1).

3. California's Unfair Competition Law ("UCL") also exists to prevent these unscrupulous practices by "prohibiting unfair, dishonest, deceptive, destructive, fraudulent and discriminatory practices by which fair and honest competition is destroyed or prevented." Cal. Bus. & Prof. Code §§ 17001, 17200.

4. California regulates the manufacture and sale of prescription drugs under the state's Sherman Food, Drug, and Cosmetic Law (the "Sherman Law"). As relevant here, the Sherman Law specifies that "[n]o person shall sell, deliver, or

give away any new drug" that has not been approved by the California Department of Health Services or FDA. Cal. Health & Safety Code § 111550(a)–(b). The Sherman Law's drug-approval provision is designed to ensure that when Californians are treated with prescription drugs, they can rest assured that the products are safe and effective for their intended uses.

5. Imprimis is disregarding this basic provision of the Sherman Law. Rather than invest the time and resources necessary to research, develop, and test its products in order to ensure that they are safe and effective and to obtain regulatory approval to market them, Imprimis is simply creating, patenting, trademarking, marketing, and selling standardized, mass-manufactured unapproved new drugs throughout California and the United States, under the false guise of "compounding."

6. Although Imprimis claims to be producing "high-quality compounded formulations," *see* www.imprimisrx.com/ (last visited Sept. 6, 2017), the company in reality is mass-manufacturing and marketing unapproved standardized drugs. "Compounding" is "a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient." FDA, *Compounding and the FDA: Questions and Answers* (Oct. 6, 2015), *available at* https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339764.htm#what (last visited Sept. 6, 2017); *see also* United States Pharmacopeia—National Formulary (USP-NF), General Chapter 1075, *Good Compounding Practices*. Imprimis's mass-manufacturing and marketing of standardized drugs is the antithesis of compounding.

7. Imprimis's business model is based on creating a portfolio of standardized new unapproved new drugs that are branded under one name (e.g., Simple Drops™) and intended to be used for the same purpose (e.g., to treat

glaucoma). Many of Imprimis's standardized new drugs are essentially a copy of one or more commercially available, FDA-approved drugs. Imprimis essentially copies commercially available drugs by, for example, combining an active ingredient from one FDA-approved drug with another active ingredient from a different FDA-approved drug.

8. Imprimis then patents, trademarks, mass-produces, and distributes these unproven, unapproved, and potentially ineffective or dangerous standardized drugs from facilities inside and outside California to the citizens of this State and other states. Using an extensive sales force and marketing program, Imprimis typically promotes its drugs as being more convenient than commercially available FDA-approved drugs because, for example, patients can use one product that combines the active ingredients from two separate FDA-approved drugs, rather than having to use the two separate drugs.

9. Testing new drugs and obtaining the legally required regulatory approval to sell them is time-consuming and very costly. Ignoring the California Department of Health Services' and FDA's drug approval requirements provides Imprimis an unfair competitive advantage over law-abiding pharmaceutical manufacturers like Allergan. Worse, it puts patients at risk by exposing them to drugs and combinations of drugs that have not been shown to be safe or effective.

10. Three examples of products that Imprimis has manufactured and marketed in large volumes in California and elsewhere are: Dropless Therapy®, LessDrops®, and Simple Drops™. Dropless Therapy® (which comes in two standardized fixed-dose versions) and LessDrops® (which comes in three standardized fixed-dose versions) are used to treat patients during and after cataract surgery and other ocular surgery. Each version of Dropless Therapy® and LessDrops® combines active ingredients in fixed-dose combinations from two or more FDA-approved products; both products are purportedly sterile. Simple Drops™ is used to treat glaucoma. Five of the six versions of Simple Drops™

combine active ingredients from two or more FDA-approved products in fixed-dose combinations; the sixth contains a single active ingredient in the same dosage strength as FDA-approved branded and generic drugs.

11. Upon information and belief, Dropless Therapy®, Less Drops®, and Simple Drops™ are but a few of numerous other products that Imprimis manufactures—by replicating FDA-approved products, by combining active ingredients from FDA-approved products to create a new, unapproved product, or by otherwise creating experimental formulations—and then mass-markets without approval.

12. Additionally, Imprimis has in its "development pipeline" a new dry eye therapy, called Klarity. *See* Imprimis Investor Presentation (Mar. 2017), Ex. A. Allergan is informed and believes that Imprimis intends to market Klarity without seeking approval. Imprimis has boasted that Klarity will be "a cornerstone" of its "new dry eye program," and that Imprimis "look[s] forward to competing in the over $2 billion U.S. dry eye market." *PRNewswire, Imprimis Pharmaceuticals Acquires Exclusive License to Patented Ophthalmic Formulation for Dry Eye Disease* (Apr. 6, 2017), *available at* http://www.prnewswire.com/news-releases/imprimis-pharmaceuticals-acquires-exclusive-license-to-patented-ophthalmic-formulation-for-dry-eye-disease-300435684.html (last visited Sept. 6, 2017). Imprimis intends to mass-produce and market this unapproved new drug in direct competition with Allergan's FDA-approved Restasis®.

13. Compounding is typically appropriate when the medical needs of an individual patient cannot be met by a commercially available, approved drug. For example, if a patient has an allergy and needs a medication to be made without a dye contained in the commercially available, approved drug, compounding may be appropriate. Or if an elderly patient or a child cannot swallow a pill and needs a medicine in liquid form where the commercially available, approved drug is

available only in tablet form, compounding may provide a solution for that patient. Compounding is thus traditionally a one-to-one service: when a patient has medical needs that cannot be met by commercially available, approved drugs, a pharmacy compounds a medication and dispenses it to the patient according to a unique prescription tailored to the patient's medical needs.

14. Because compounding occurs on the small scale of individual, patient-specific prescriptions tailored to meet medical needs that cannot be met by commercially available, approved drugs, it is generally not practical for compounded drugs to undergo clinical trials as is generally required to obtain regulatory approval to market a new drug. And the small scale of compounding means that the risks posed by unapproved compounded drugs are correspondingly limited. To preserve traditional compounding as a way to treat patients whose needs cannot be met by commercially available, approved drugs, California and federal law permits compounded drugs, in limited circumstances, to forgo approval by the California Department of Health Services or FDA.

15. Allergan fully recognizes the value and legal legitimacy of traditional compounding and does not, through this suit, seek to restrict such legal traditional compounding efforts. But when a company like Imprimis misuses this narrow exemption to mass manufacture and mass market standardized drugs that are not tailored to an individual patient's medical needs under the guise of compounding, thousands of patients may be at risk. Mass manufacturing and marketing drugs under the guise of compounding also undermines the drug-approval requirements that are central to the protection of the public from drugs that are unsafe, ineffective, or both.

16. Unlike Allergan and other law-abiding pharmaceutical manufacturers, Imprimis falsely claims to be engaged in compounding and thus to be exempt from the California and FDA approval requirements. And, in doing so, the company holds itself out as "pioneering a new commercial pathway in the pharmaceutical

industry." Imprimis, Our Story (Ex. B).

17. The only thing "new" about Imprimis's "commercial pathway" is the massive scale upon which it brazenly flouts the law. If a company could mass-manufacture and distribute drugs without the need to demonstrate that its drugs are safe and effective, that company would have an enormous competitive advantage over pharmaceutical manufacturers that comply with the law. Conducting clinical trials to prove safety and effectiveness is time-consuming and expensive—and economically risky, as some trials are not successful and those drugs are not approved. Flouting the entire system of pre-market approval for drugs allows Imprimis to avoid those costs and risks and instead take its desired products to market without established safety or efficacy.

18. The Sherman Law requires approval for new drugs for good reason. Drug approval is evidence-based, and it is essential to ensuring the quality, safety, and effectiveness of new drugs. When companies circumvent the drug-approval process, safety and efficacy are unknown. The danger is not merely theoretical, as mass manufacturing and distribution of unapproved new drugs in the guise of compounding has led to tragedy.

19. In 2012, for example, a massive fungal meningitis outbreak was caused by a contaminated drug that, like Imprimis's products, was mass manufactured and distributed in the guise of compounding. The contaminated drug, a purportedly sterile injectable similar to some of Imprimis's products, killed 64 people and sickened at least 751 others, in 20 different states. *See* FDA, *The Special Risks of Pharmacy Compounding* (Dec. 3, 2012), *available at* https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm107836.htm (last visited Sept. 6, 2017).

20. This risk is well known to Imprimis. Just last month, on August 4, 2017, FDA linked one of Imprimis's unapproved new drugs (an injectable curcumin emulsion) to two severe adverse events, one resulting in death and the

other sending the patient to the emergency room. *An FDA Investigation into Two Serious Adverse Events Associated with ImprimisRx's Compounded Curcumin Emulsion Product for Injection* (Aug. 4, 2017) (Exhibit C). FDA's investigation concluded that the risks of compounding underscored by the adverse events related to the curcumin emulsion included: (1) "the absence of a label warning about hypersensitivity reactions associated" with a non-pharmaceutical grade inactive ingredient that was in the product, (2) the use of a non-pharmaceutical grade active ingredient "that is not suitable for human consumption or therapeutic use and may contain impurities," and (3) "the IV administration of curcumin, despite the fact that the safety profile by this route of administration has not been established, nor has its effectiveness in treating eczema or thrombocytopenia." *Id.*at 3. Imprimis continues to deny responsibility, and instead has blamed the physician and the victim involved for misusing its product. PRNewsire, *Imprimis Statement Regarding Curcumin Emulsion FDA MedWatch Notice* (Aug. 7, 2017), *available at* http://www.prnewswire.com/news-releases/imprimis-statement-regarding-curcumin-emulsion-fda-medwatch-notice-300500193.html# (last visited Sept. 6, 2017).

21. Given Imprimis's willingness to flout the drug-approval requirements in pursuit of unlawful profits, it is perhaps not surprising that Imprimis also has repeatedly failed to implement appropriate quality and sterility controls.

22. As recently as July and August, 2017, FDA issued Imprimis an inspection summary (known as a "Form 483") and a Warning Letter describing serious health and safety concerns at Imprimis's facilities in Pennsylvania and New Jersey. In the Form 483, directed to the New Jersey facility, FDA observed consumer complaints of particulate matter in Imprimis's Tri-Moxi product (one of the formulations sold under the Dropless Therapy® brand), sanitation concerns with Imprimis's production personnel, concerns that the bottles into which Imprimis's products would be packaged were not sterile, and a lack of written

procedures for ensuring the "identity, strength, quality, and purity" of the products. FDA 483 for Imprimis NJOF, LLC, Ledgewood, NJ, at 4 (July 10, 2017) (Ex. D).

23. FDA's Warning Letter, directed to Imprimis's Pennsylvania facility, noted "serious deficiencies" in Imprimis's production practices, "which put patients at risk." It also warned Imprimis that any drugs distributed outside the narrow exemptions for compounding would require new drug approval and admonished Imprimis to "comprehensive[ly] assess[]" all aspects of its operations. *See* FDA Warning Letter 17-PHI-10 (Aug. 3, 2017) (Ex. E).

24. Compounding poses particular risks when done for ophthalmic products like those sold by Imprimis, and those risks are heightened when the compounded products are purportedly sterile injectable products, like Dropless Therapy®.

25. Among other examples, a compounded product containing triamcinolone acetonide and moxifloxacin hydrochloride (Tri-Moxi), a steroid antibiotic injectable used during ocular surgery, is suspected to have caused injuries earlier this year to patients in the Dallas-Fort Worth area, including unanticipated loss of vision and significant retinal damage. Clair Ballor, *Patients lose vision after routine cataract surgeries at Dallas Key-Whitman center*, The Dallas Morning News (Apr. 28, 2017), *available at* https://www.dallasnews.com/business/health-care/2017/04/27/patients-lose-vision-routine-cataract-surgeries-dallas-key-whitman-center (last visited Sept. 6, 2017). Although the products at issue are not presently understood to have come from Imprimis, Allergan is informed and believes that they contained the same active ingredients as Imprimis's Tri-Moxi Dropless Therapy® formulation and were used for the same purpose with the same route of administration.

26. The illegal manufacturing and distribution of unapproved new drugs threatens the public health, and Dropless Therapy®, LessDrops®, and Simple Drops™, as well as the other unproven and unapproved new drugs mass

manufactured and marketed by Imprimis, pose substantial risks to the public.

27. Imprimis is also engaged in false or misleading advertising and promotion. For example, and as alleged in greater detail below, Imprimis falsely tells customers that its products are lawfully compounded in accordance with the narrow exemptions from drug-approval requirements in federal and state law. In truth, Imprimis's entire business model is unlawful, and there are additional reasons why particular Imprimis products have not been, and cannot have been, legitimately compounded in accordance with those exemptions. This false or misleading promotion is essential to Imprimis's success, as doctors would be much less likely to purchase and use Imprimis's products if they knew that Imprimis's products are unapproved new drugs whose sale is unlawful.

28. As alleged in greater detail below, Imprimis's false or misleading advertising and promotion even includes touting its products as superior to the FDA-approved products with which they compete, a claim that is outrageous given the untested and unproven nature of Imprimis's products.

29. Allergan has suffered and is suffering competitive injuries as a result of Imprimis's unlawful activities. For example, many of Imprimis's unapproved new drugs compete with Allergan's approved ophthalmic drugs (e.g., Zymaxid®, Pred Forte®, Pred Mild®, Pred-G®, Acular®, Acuvail®, Lumigan®, Alphagan P®, and Combigan®). And, Imprimis itself expressly states that its pipeline product, Klarity, will compete with Allergan's product, Restasis®, a leading FDA-approved drug in the dry eye space.. *See* Imprimis Investor Presentation (Ex. A).

30. Allergan brings this action to stop Imprimis from illegally manufacturing, marketing, selling, and distributing unapproved new drugs and from engaging in false and misleading advertising and promotion.

II. PARTIES

31. Allergan USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business in Parsippany,

New Jersey. Allergan, USA, Inc. also has a significant business presence in California (including in this District).

32. Defendant Imprimis Pharmaceuticals, Inc., is a corporation incorporated in Delaware. Its principal place of business is located at 12264 El Camino Real, Suite 350, San Diego, California 92130.

33. Imprimis owns and operates facilities in California and New Jersey. The California facility is located in this District, at 9257 Research Drive, Irvine, California 92618. This facility has done business as Imprimis Rx and as Park Compounding.

34. Part of the Imprimis facility in Ledgewood, New Jersey is registered as a 503B outsourcing facility under Section 503B of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 353b. The other part of the facility, located at the same address (1705 Route 46 West, Ledgewood, New Jersey), purportedly operates under Section 503A of the FDCA, *id.* § 353a. Imprimis has also done business in New Jersey through Pharmacy Creations, located at 540 Route 10 West, Randolph, New Jersey.

35. In June 2017, Imprimis announced the sale of a facility in Folcroft, Pennsylvania, which had done business as ImprimisRx and as TAG Pharmacy. And, in June 2016, Imprimis ceased operations at a facility in Texas, which had done business as ImprimisRx and as Central Allen Pharmacy.

36. Imprimis sells its products throughout California, including in this District, and nationwide.

III. JURISDICTION AND VENUE

37. This Court has subject matter jurisdiction under 15 U.S.C. § 21(a) and 28 U.S.C. §§ 1331 and 1367.

38. This Court has personal jurisdiction over Imprimis because Imprimis's principal place of business is in California and Allergan's claims arise out of or relate to Imprimis's contacts with California.

39. Venue in this District is proper under 28 U.S.C. § 1391.

IV. FACTUAL ALLEGATIONS

A. Imprimis's Unlawful Business Model

40. Imprimis is a pharmaceutical company that formulates, manufactures, markets, sells, and distributes unapproved new drugs that it claims are "compounded" drugs. Imprimis, Our Story (Ex. B). Imprimis markets dozens of drugs as alternatives to FDA-approved drugs in all 50 States, including California, in many therapeutic areas, including ophthalmology, urology, and dermatology. *See id*; *see also* Imprimis Pharmaceuticals, Inc., 10-Q SEC Filing, dated Aug. 10, 2017, *available at* http://filings.irdirect.net/data/1360214/000149315217008881/form10-q.pdf (last visited Sept. 6, 2017).

41. At the time Imprimis was founded in 2011, the company was focused on bringing drug candidates to market legitimately under the FDCA's Section 505(b)(2) pathway. *See* M.E. Garza, *Imprimis' Platform Set to Bring Library Drug Formulations Quickly to Market*, Seeking Alpha (May 30, 2013), *available at* http://seekingalpha.com/article/1469981-imprimis-platform-set-to-bring-library-drug-formulations-quickly-to-market (last visited Sept. 6, 2017). Section 505(b)(2), codified at 21 U.S.C. § 355(b)(2), permits a drug manufacturer in certain circumstances to obtain FDA approval to market a new drug that is essentially a copy of an existing FDA-approved drug with regard to its active ingredient but that reflects certain physical or chemical differences. Changes that may be appropriate for Section 505(b)(2) applications include different dosage strengths, different dosage forms (e.g., a solid oral dosage form instead of a transdermal patch), different routes of administration (e.g., intravenous instead of intrathecal), different formulations (e.g., a gel instead of an ointment), and the combination of active ingredients that have previously been approved individually. *See* FDA, *Guidance for Industry: Applications Covered by Section 505(b)(2)* (Oct.

1999) pp. 4–5, *available at* http://www.fda.gov/downloads/Drugs/.../Guidances/ucm079345.pdf (last visited Sept. 6, 2017).

42. A Section 505(b)(2) applicant must provide data sufficient to support the safety and effectiveness of the new drug's differences from the reference product. Because a Section 505(b)(2) drug contains the same active ingredient as an already-approved drug, a Section 505(b)(2) application generally requires less data than an ordinary new drug application under Section 505(b)(1). As a result, the Section 505(b)(2) pathway generally permits an applicant to bring its drug to market faster, and with less expense, than the ordinary new drug approval pathway under Section 505(b)(1).

43. But the Section 505(b)(2) pathway was not fast enough or cheap enough for Imprimis. In 2013, the company shifted strategies to further shorten the time to market for certain "proprietary formulations," despite the fact that this new strategy was illegal. *Imprimis Pharmaceuticals (Immy) to Shift Focus, Discontinues Impracor Phase 3 Program to Focus on Other Areas*, BioSpace (Nov. 6, 2013), *available at* http://www.biospace.com/News/imprimis-pharmaceuticals-to-shift-focus/314584 (last visited Sept. 6, 2017). The new strategy involved out-licensing unapproved new drugs to compounding pharmacies for mass manufacture, while at the same time pursuing an investigational new drug application ("INDA") for the new drugs with FDA. An INDA is necessary to engage in the clinical trials that are often needed to support a Section 505(b)(2) new drug application. Under this new strategy, Imprimis marketed, sold, and distributed large quantities of new drugs before it even began developing data about the safety and effectiveness of the new drugs, and well before it engaged with the State or FDA to begin the drug-approval process.

44. Eventually, however, even this strategy—i.e., mass manufacturing and marketing unapproved new drugs under the guise of compounding for a limited time, until the new drugs were approved through the Section 505(b)(2) pathway—

proved to be too slow and not sufficiently profitable for Imprimis. So Imprimis decided to dispense with any pretense of having many of its products approved at all and opted instead simply to mass manufacture and market them in perpetuity, under the guise of compounding.

45. As Imprimis's Chief Executive Officer, Mark Baum, explained on September 9, 2015:

> The way that we play is—we are bringing novel formulations . . . proprietary formulations that are either patented or patent pending that you would otherwise really take through a 505(b)(2) process. So, these are well-characterized FDA-approved generic drugs that we use in a new way . . . [t]he difference is that we don't take the risk of going through a clinical development program. Instead we make them available through compounding pharmacies and soon outsourcing facilities that we own so that we can get to market rapidly, and hopefully, and this is part of our vision, . . . [to produce] beautiful returns for our shareholders.

Ophthalmology Innovation Summit, *OIS Podcast: Imprimis' Baum on Disrupting Compound Pharmacies* (Sept. 15, 2015), at 2 (Ex. F).

46. Imprimis refers to this business model as a "new commercial pathway." Imprimis, Our Story (Ex. B). Selling new drugs without required approvals—and avoiding the expense, delay, and risk inherent in obtaining approval—would indeed be an attractive "commercial pathway" if it were legal. But it is not. And for good reason: circumventing the drug-approval process puts patients at risk by exposing them to drugs that might or might not be safe or effective. The point of requiring pre-market approval based on safety and effectiveness is to place the risk that a drug development candidate will turn out not to be safe or effective on the pharmaceutical company seeking to develop the drug; the pharmaceutical company will lose money if it invests in development of a drug that turns out not to be safe or effective. Imprimis's unlawful business model shifts that risk onto patients, who may suffer far worse fates than losing money if they use drugs that are unsafe or ineffective.

47. The existence of the pre-market approval requirement for Section 505(b)(2) drug candidates testifies to the fact that the safety and effectiveness of a new drug combining two active ingredients previously approved in separate drugs cannot be taken for granted. Combining active ingredients, changing the route of administration, changing the dosage form, or making the other types of changes contemplated by Section 505(b)(2) can have significant implications for safety and effectiveness. Indeed, FDA historically has been skeptical of fixed-dose combination ophthalmic products and has specifically declined to approve certain combinations.

48. Although Imprimis ignores the drug-approval process put in place by law to ensure product safety and efficacy, it is assiduous in its attention to sales and marketing tactics. Imprimis spends a significant amount of resources to patent its products, trademark the product names, and employ a national sales force to mass-market its products across the country.

49. Imprimis's investor presentations are unabashed about the mass manufacture of its flagship products, often predicting millions of dollars in sales. *See* Imprimis Investor Presentation (Ex. A); Imprimis Investor Presentation (Nov. 2014) (Ex. G). In at least one presentation, Imprimis graphically shows how its sales of unapproved "compounded" products will reduce sales and use of FDA-approved products for glaucoma and dry eye, and in conjunction with ocular surgery. *See* Imprimis Investor Presentation (Ex. A).

50. Imprimis has a national manufacturing operation, dedicated to supplying "all 50 states." Imprimis Pharmaceuticals, Inc. SEC Form 10-Q, *supra*. The company boasts that its customer network includes 1,700 ophthalmologists, surgery centers, and managed care organizations, and in recent months, it has sought to expand market share in Ohio, Illinois, Michigan, Wisconsin and Nevada. Imprimis Pharmaceuticals, Inc., Form 8-K, filed with the Securities and Exchange Commission (Aug. 10, 2017), *available at* https://seekingalpha.com/filing/3637563

(last visited Sept. 6, 2017). Imprimis also announced in April 2017 that it had entered into a three-year exclusive sales representation agreement with the largest distributor of ophthalmic products in the Midwest to market its unapproved products in 13 Midwestern states. Imprimis, Press Release, *Imprimis Pharmaceuticals and Precision Lens Sign Agreement to Expand Imprimis' Ophthalmic Portfolio Market Opportunity in the U.S. Midwest* (April 18, 2017), *available at* http://irdirect.net/prviewer/release/id/2441768 (last visited Sept. 6, 2017).

51. Upon information and belief, more than 5% of the products manufactured at Imprimis's Irvine facility are shipped interstate.

B. Examples – Dropless Therapy®, LessDrops®, and Simple Drops™

52. Although Imprimis markets many products, three of the "novel" and "proprietary" drugs that it mass manufactures and markets are ophthalmic products used during or after cataract and other ocular surgery or to treat glaucoma:

a. Dropless Therapy® refers to two new injectable drugs, which are purportedly sterile, that are used during cataract and other ocular or intraocular surgeries. Each new drug comes in a fixed-dose combination of active ingredients that are used separately in FDA-approved drugs: (1) Tri-Moxi (15/1 mg/mL) combines triamcinolone acetonide (a steroid) and moxifloxacin hydrochloride (an antibiotic), and (2) Tri-Moxi-Vanc (15 mg/1 mg/10 mg/mL) combines triamcinolone acetonide and moxifloxacin hydrochloride with another antibiotic, vancomycin. Of these ingredients, Allergan is informed and believes that only triamcinolone acetonide has been approved by FDA for injection into the eye; moxifloxacin hydrochloride is FDA-approved for ophthalmic use only as a topical drop; and vancomycin has not been FDA-approved for use in ophthalmology at all. Imprimis's website promotes Dropless Therapy® as a way to reduce

issues with patient compliance (i.e., patient failure to comply with post-surgical topical eye drop regimens). Imprimis, Dropless Cataract Surgery (Ex. H).

b. LessDrops® refers to three new topical drugs that are eye drops for use following LASIK, PRK, cataract, and other ocular surgeries. Each is purportedly sterile and comes in a fixed-dose combination of active ingredients that are used separately in FDA-approved topical ophthalmic drugs: (1) Pred-Gati (1/0.5%) combines prednisolone acetate (a steroid) and gatifloxacin (an antibiotic); (2) Pred-Nepaf (1/0.1%) combines prednisolone acetate and nepafenac (a nonsteroidal anti-inflammatory (NSAID)); and (3) Pred-Gati-Nepaf (01/0.5/0.1%) combines prednisolone acetate, gatifloxacin and nepafenac. Imprimis's website promotes LessDrops® as a way to "significantly reduce the number of eye drops needed after ocular surgery" and thus to reduce patient compliance issues. Imprimis, LessDrops (Ex. I).

c. Simple Drops™ refers to six new topical drugs that are eye drops marketed to treat glaucoma. Each new drug is purportedly sterile. One drug, LAT™, contains a single active ingredient, latanoprost in a 0.005% solution; that single active ingredient is commercially available in both branded and generic FDA-approved drugs in the same strength. The other five drugs come in fixed-dose combinations of active ingredients that are typically used separately in FDA-approved drugs: (1) TIM-LAT™ (0.5%/0.005%), a combination of timolol and latanoprost; (2) BRIM-DOR™ (0.15/2%), a combination of brimonidine and dorzolamide; (3) TIM-BRIM-DOR™ (0.5/0.15/2%), a combination of timolol, brimonidine, and dorzolamide; (4) TIM-DOR-LAT™ (0.5%/2%/0.005%), a

> combination of timolol, dorzolamide, and latanoprost; and (5) TIM-BRIM-DOR-LAT™ (0.5%/0.15%/2%/0.005%), a combination of timolol, brimonidine, dorzolamide, and lataoprost. Imprimis's website promotes Simple Drops™ as a way to make glaucoma treatment regimens more convenient: "Simple Drops conveniently provides multiple glaucoma medications into a single bottle. Provide your patients with a simple treatment option for their glaucoma." Imprimis, Simple Drops (Ex. J).

53. Notably, Imprimis does not claim that Dropless Therapy®, LessDrops®, and Simple Drops™ are being tailored to meet an individual patient's medical needs where commercially available products, including Allergan's products, are unsuitable. To the contrary, they are designed to treat *any* patient who has had ocular surgery, in the case of Dropless Therapy® and LessDrops®, and *any* patient who has glaucoma, in the case of Simple Drops™. Rather than claim that these unapproved products are tailored to meet individual patients' medical needs not met by FDA-approved, commercially available drugs, Imprimis touts these products as simply being more convenient than FDA-approved, commercially available drugs. In any event, given the massive scale on which Imprimis is manufacturing and marketing these products—in standardized formulations—any assertion that they are tailored to meet individual patients' needs would be transparently false.

54. Mr. Baum predicts that Dropless Therapy® and LessDrops® eventually could be used for *all* of the 3.8 million cataract surgeries performed annually in the United States, and Imprimis claims that the products have already captured over 10% of that market. *See* Imprimis Pharmaceuticals' (IMMY) CEO Mark Baum on Q2 2016 Results – Earnings Call Transcript (Aug. 15, 2016), *available at* http://seekingalpha.com/article/3999761-imprimis-pharmaceuticals-immy-ceo-mark-baum-q2-2016-results-earnings-call-transcript?page=2 (last

visited Sept. 6, 2017).

55. In August 2016, Mr. Baum stated that Imprimis was making drugs for about 10,000 cataract and other ophthalmic surgeries per week and that it continues to "capture market share from much larger pharmaceutical companies." *See id*. And, on July 27, 2017, Imprimis announced that Dropless Therapy® and LessDrops® have been used in "more than one million patient eyes" over a span of three years. *Imprimis, Press Release, Imprimis Pharmaceuticals Patent-Pending Dropless and LessDrops Formulations Exceed One Million Patient Eyes Milestone* (July 27, 2017), *available at* http://irdirect.net/prviewer/release/id/2614074 (last visited Sept. 6, 2017).

56. Also, since the launch of Simple Drops™ in May 2017, Mr. Baum has announced that he believes that with Imprimis's "proprietary offerings," it can "make a significant impact and take market share away from many of the larger or incumbent players," in the glaucoma space, as it has in other ophthalmic markets. *Seeking Alpha, Imprimis Pharmaceuticals' IMMY CEO Mark Baum on Q2 2017 Results – Earnings Call Transcript* (Aug. 5, 2017), *available at* https://seekingalpha.com/article/4097866-imprimis-pharmaceuticals-immy-ceo-mark-baum-q2-2017-results-earnings-call-transcript?page=3 (last visited Sept. 6, 2017). Allergan is one of those larger and incumbent players.

57. Finally, Imprimis has announced it that it has a "development pipeline" that includes, among others, combination eyedrops to treat dry eye, to compete with FDA-approved Restasis®, manufactured and sold by Allergan. *See* Imprimis Investor Presentation (Mar. 2017), *supra*. Imprimis is hoping to launch Klarity, an "innovative and patented ophthalmic topical solution and gel technology for patients with moderate to severe dry eye disease," in the coming months. *Seeking Alpha, Imprimis Pharmaceuticals' IMMY CEO Mark Baum on Q2 2017 Results – Earnings Call Transcript*, *supra*. When the "much larger pharmaceutical companies" from which Imprimis has been unlawfully taking

market share refer to a "development pipeline," they are referring to drugs that they hope to obtain FDA approval to market. Imprimis, by contrast, appears to have no plans to seek approval to market Klarity.

58. Dropless Therapy®, LessDrops®, and Simple Drops™ are mass manufactured and mass marketed, and they have not been approved by California's Department of Health Services or FDA.

C. Imprimis's Deficient and Unlawful Manufacturing Practices Put Patients At Risk

59. Imprimis's cavalier attitude toward the fundamental requirement of drug approval is matched by its neglect of basic drug manufacturing practices. As a result, there is even more reason to worry that Imprimis's untested and unproven drugs are unsafe or ineffective.

60. Recent FDA enforcement activities highlight these risks. FDA has cited Imprimis's Irvine facility (also known as Park Compounding and ImprimisRx Compounding Pharmacy) for potential or actual violations of cGMPs, controls required by law to ensure that drugs are not subpotent, superpotent, contaminated, or otherwise adulterated. For example:

a. March 2016—FDA released an initial inspection notice citing eight potential violations of cGMPs, at least one of which raised sterility concerns regarding ophthalmic solutions. *See* FDA Form 483 (Mar. 14, 2016) (Ex. K).

b. March 2016—FDA released an amended inspection notice citing eight potential violations of cGMPs, at least one of which raised sterility concerns regarding ophthalmic solutions. *See* Amended FDA Form 483 (Mar. 14, 2016) (Ex. L).

c. June 2015—FDA released its referral letter to the California State Board of Pharmacy, notifying California that the Irvine facility "deviat[ed] from appropriate sterile practice standards that, if not

corrected, could lead to contamination of drugs, potentially putting patients at risk." FDA Referral Letter to California State Board of Pharmacy re: Sterility Concerns at Park Compounding (June 23, 2015) (Ex. M).

d. FDA also released an inspection report citing seven potential cGMP violations, including violations that could lead to problems with sterility (e.g., "Each batch of drug product purporting to be sterile is not laboratory tested to determine conformance to such requirements"). *See* FDA Form 483 Inspection Report for South Coast Specialty Compounding, Inc. (dba Park Compounding) (July 2, 2014) (Ex. N).

61. More recently, on March 31, 2017, FDA issued a Form 483 Inspection Report citing Imprimis's Irvine facility for failure to maintain and follow up on product complaints. According to the Form 483, Imprimis received a notification of an adverse event associated with the intravenous administration of a curcumin solution and at least "69 Quality Related Events (QRE), including ADEs [adverse drug events] and product quality complaints" in 2016 and the first quarter of 2017. *See* FDA Form 483 (Mar. 31, 2017) (Ex. O).

62. Just days earlier, on March 20, 2017, FDA also issued a Warning Letter to the Irvine facility highlighting "serious deficiencies in [the Irvine facility's] practices for producing sterile drug products, which put patients at risk." FDA, Warning Letter WL# 21-17 (Mar. 20, 2017) (Ex. P). In that letter, FDA observed "that drug products intended or expected to be sterile were prepared, packed, or held under insanitary conditions, whereby they may have become contaminated with filth or rendered injurious to health, causing [the Irvine facility's] drug products to be adulterated under section 501(a)(2)(A) of the FDCA." *Id*.

63. The Irvine facility is not the only Imprimis facility to receive

manufacturing violation notices. FDA has frequently cited Imprimis's Pharmacy Creations New Jersey facility due to sterility issues. *See* FDA Form 483 for Pharmacy Creations (Sept. 30, 2015) (Ex. Q); *see also* FDA Warning Letter to Pharmacy Creations (June 23, 2014) (Ex. R); FDA Form 483 for Pharmacy Creations (Aug. 19, 2013) (Ex. S); Imprimis's New Jersey facility was forced to recall products because of sterility concerns. *See* Pharmacy Creations Voluntary Recall Notice (Sept. 14, 2014) (Ex. T).

64. In addition, Imprimis's Pennsylvania facility has been cited as well. FDA Form 483 for ImprimisRx Pharmacy LLC (Aug. 1, 2016) (Ex. U).

65. Just two months ago, on July 10, 2017, FDA cited Imprimis's New Jersey facility for a number of violations. FDA observed that Imprimis had received consumer complaints that there were "black/grey particles" and "unknown particles" in Imprimis's Tri-Moxi product (one of the Dropless Therapy® formulations). FDA further observed that there were "no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess," that Imprimis's "[p]roduction personnel were not practicing good sanitation and health habits," and that there was "no assurance" that the bottles in which Imprimis packages its Pred-Gati and Pred-Gati-Nepaf products were "sterilized" or "free of residue." FDA Form 483 for Imprimis NJOF, LLC, Ledgewood, NJ (Ex. D).

66. On August 3, 2017, FDA issued Imprimis a Warning Letter following an inspection of Imprimis's facility in Pennsylvania, noting "serious deficiencies in [Imprimis's] practices for producing drug products, which put patients at risk." FDA warned Imprimis that, "[s]hould you compound and distribute drug products that do not meet the conditions of section 503A, the compounding and distribution of such drugs would be subject to the new drug approval requirement, the requirement to label drug products with adequate directions for use, and the drug

CGMP regulations." FDA "strongly recommend[ed]" that Imprimis "undertake a comprehensive assessment of operations, including facility design, procedures, personnel, processes, maintenance, materials, and systems." *See* FDA Warning Letter 17-PHI-10 (Ex. E).

67. Most recently, on August 4, 2017, FDA issued a report following an investigation into two adverse reactions, one resulting in death, following infusions of Imprimis's curcumin emulsion product, which contains PEG 40 castor oil. FDA noted several risks, including "the absence of a label warning about hypersensitivity reactions associated with the PEG 40 castor oil; the use of an ungraded inactive ingredient, i.e., PEG 40 castor oil, that is not suitable for human consumption or therapeutic use and may contain impurities such as [diethylene glycol]; and the IV administration for curcumin, despite the fact that its safety profile by this route of administration has not been established, nor has its effectiveness in treating eczema or thrombocytopenia." *An FDA Investigation into Two Serious Adverse Events Associated with ImprimisRx's Compounded Curcumin Emulsion Product for Injection* (Ex. C). Incredibly, Imprimis blamed the physicians for this tragedy. PRNewswire, *Imprimis Statement Regarding Curcumin Emulsion FDA MedWatch Notice* (Aug. 7, 2017), *available at* http://irdirect.net/prviewer/release/id/2631758 (last visited Sept. 6, 2017).

68. Upon information and belief, each of Imprimis's facilities, and the Irvine facility in particular, manufactures drugs for sale within California and throughout the United States before receipt of a patient prescription.

D. <u>Imprimis's False and Misleading Advertising and Promotion</u>

69. Imprimis has made, and is continuing to make, false and misleading statements regarding its products in advertising and promotion.

70. Imprimis makes the false and misleading claim that it operates "under the regulatory framework of the Drug Quality & Security Act (2013) and state pharmacy laws." Imprimis Website, Quality Assurance (Ex. V). This assertion

falsely implies that Imprimis complies with all provisions of the FD&C Act, including Sections 503A or 503B.

71. Section 503A exempts compounding pharmacies from the new drug-approval requirement under strict limits that ensure that this exemption applies only to legitimate, traditional compounding—and not to mass-manufacturing standardized but unapproved new drugs in the guise of compounding. Imprimis's reliance on Section 503A to claim that its business model is lawful is false and misleading for multiple reasons.

72. For example, one condition of Section 503A's exemption from the drug-approval requirement is that the drug at issue must have been "compounded for an identified individual patient based on the receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the individual patient." 21 U.S.C. 353a(a). This provision tracks traditional compounding's patient-specific nature and is entirely inconsistent with Imprimis's business model of mass-manufacturing standardized drugs.

73. In keeping with traditional compounding's raison d'etre of meeting patient needs that cannot be met by commercially available, approved products, Section 503A provides that its exemption does not apply to a company that "compound[s] regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product," and further specifies that "a drug product in which there is a change, made for an identified individual patient, which produces for that patient a significant difference," does not constitute such a copy. 21 U.S.C. 353a(b)(1)(D) & (2). Imprimis's mass-manufacturing model is equally inconsistent with this provision.

74. Similarly, to ensure that Section 503A does not become a loophole that unscrupulous companies can drive a truck through to mass-manufacture

unapproved new drugs under the guise of compounding, Congress specified that (with an exception not applicable here) a purported Section 503A pharmacy may not ship more than "5 percent of [its] total prescription orders" out of the state where it is located. 21 U.S.C. 353a(b)(3). Imprimis's ambitious statements about nationwide sales, described above, make clear that it is exceeding this 5% limit, including at its Irvine facility.

75. Imprimis also makes the false and misleading claim that it can lawfully manufacture and sell LessDrops® because that product comes from an Imprimis "503B Outsourcing Facility." Imprimis's webpage states: "ORDER NOW Order . . . LessDrops from 503B Outsourcing Facility today. No patient information required." Imprimis, LessDrops (Ex I). That statement is false and misleading for multiple reasons.

76. Section 503B, like Section 503A, is an exemption from the drug-approval requirements, but the exemption in Section 503B is limited to "outsourcing facilities" registered with FDA that comply with that provision's conditions. Whereas Section 503A tracks the traditional understanding of legitimate pharmacy compounding as distinct from drug manufacturing, Section 503B creates a new exemption that permits larger-scale preparation of unapproved new drugs, but only under strictly limited circumstances driven by specific public health needs that cannot be met by commercially available, approved drugs—e.g., when there is a shortage of the approved drug. Section 503B does not permit companies to mass manufacture and market unapproved new drugs that are essentially copies of commercially available, FDA-approved drugs, when there is no drug shortage or individual patient clinical need. Imprimis's business model violates multiple conditions in Section 503B.

77. Section 503B provides that its exemption does not apply if, among other things, the drug is "essentially a copy of one or more approved drugs." 21 U.S.C. 353b(a)(5). And that provision goes on to define "essentially a copy of an

approved drug" to include, among other things, "a drug, a component of which is a bulk drug substance that is a component of an approved drug . . . unless there is a change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug." 21 U.S.C. 353b(d)(2)(B). Imprimis's LessDrops® are "essentially a cop[ies] of one or more approved drugs" because each standardized formulation combines "bulk drug substance[s] that [are] component[s] of . . . approved drug[s]" and because, again, the sheer scale of Imprimis's mass-manufacturing and distribution of the product makes it impossible to say that LessDrops® reflects "a change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner." As noted, Imprimis's promotion does not even purport to claim such a patient-specific clinical difference; instead, Imprimis's promotion is based on the asserted convenience of combining approved drugs into a new, unapproved product.

78. Imprimis's advertising claim that LessDrops® can lawfully be sold because it comes from a 503B outsourcing facility is false or misleading for the additional reason that certain bulk drug substances used to manufacture LessDrops® are not eligible for use in a 503B facility. Among other requirements for using bulk drug substances to compound a drug in a 503B facility, in order to obtain the exemption from the drug-approval requirement, the bulk drug substances must appear on an FDA list "identifying bulk drug substances for which there is a clinical need"; otherwise, the drug compounded from such bulk drug substances must appear on FDA's drug shortage list. 21 U.S.C. § 353b(a)(2)(A). Neither is true for LessDrops®. No version of LessDrops® appears on FDA's drug shortage list, and neither gatifloxacin nor nepafenac (at least one of which is contained in all versions of LessDrops®) appears on FDA's bulk substances list. *See* Bulk Substances Nominated for Use in Compounding Under Section 503B of the Food Drug & Cosmetic Act (July 1, 2017), *available at* http://www.fda.gov/

downloads/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/UCM467374.pdf (last visited Sept. 6, 2017).

79. In addition, Imprimis is engaging in false and misleading promotion by claiming that Dropless Therapy® is more effective in treating infection and inflammation following intraocular surgery than topical medications (some of which are FDA-approved). A video on Imprimis's "Go Dropless" website states: "The patient is protected from infection and inflammation even more effectively than can be achieved with expensive, inconvenient, and irritating topical medications." GoDropless.com, *Technique Portal, Tranzonular Injection Animation, Dropless ™ Cataract Surgery*, at 0:47, *available at* http://portal.godropless.com/page/2/ (last visited Sept. 6, 2017). Upon information and belief, having opted not to comply with the drug-approval requirements mandated by law, Imprimis has no basis to claim that its product is safe or effective at all, let alone to claim that it is superior to approved products whose safety and effectiveness have been rigorously established. Exacerbating the misleading nature of this superiority claim, Imprimis's websites fail to disclose any risk information associated with Dropless Therapy®.

80. Imprimis is also engaging in false and misleading promotion by claiming on its "Go Dropless" website that "95% of cataract surgeons surveyed would prefer Dropless Therapy®." Go Dropless (Ex. W). This claim relies on a purported 2014 survey of 21 cataract surgeons, which is too small a sample size to support a claim like this. Moreover, upon information and belief, Imprimis did not inform the surgeons it purportedly surveyed that Go Dropless Therapy® was an unapproved new drug or inform them of the risks associated with Go Dropless Therapy®.

E. Imprimis's Activities Violate the Sherman Law's Drug-Approval Provisions

81. Imprimis's manufacture, marketing, sale, and distribution of

unapproved new drugs, such as Dropless Therapy®, Less Drops®, and Simple Drops™, under the guise of compounding, violates California's Sherman Law.

82. California's Sherman Law provides that "[n]o person shall sell, deliver, or give away any new drug" that has not been approved by FDA or by the State of California. Cal. Health & Safety Code § 111550(a)–(b).

83. The Sherman Law incorporates "[a]ll regulations relating to . . . new drug applications . . . adopted pursuant to Section 505" of the FD&C Act. *Id*. § 110110(a).

84. California's Sherman Law and the FD&C Act's definitions of "drug" and "new drug" are the same. *See id*. § 109925(c) (drug), § 109980 (new drug); 21 U.S.C. § 321(g)(1), (p).

85. California's Sherman Law incorporates the FD&C Act's requirement that pharmaceutical manufacturers must comply with the drug manufacturing provisions in the FD&C Act, including provisions regarding new drug approval processes, adequate directions for use in drug labeling, and cGMPs. *See* 21 U.S.C §§ 355, 352(f)(1), 351(a)(2)(B); Cal. Health & Safety Code § 110105.

86. Imprimis is violating California's Sherman Law because it has not obtained the approval of either the California Department of Health Services or FDA to introduce any of the new drugs that it is manufacturing, marketing, selling, and distributing, such as Dropless Therapy®, Less Drops®, and Simple Drops™, into commerce. *See id*. § 111550(a)–(b).

F. Imprimis's Activities Violate The Lanham Act's Prohibition on False or Misleading Descriptions or Representations of Fact

87. The Lanham Act protects those engaged in commerce from unfair competition by the use of false or misleading descriptions of fact, or false or misleading representations of fact, in commercial advertising or promotion. 15 U.S.C. § 1125(a)(1).

88. The Lanham Act creates a cause of action against "[a]ny person who,

on or in connection with any goods or services . . . uses in commerce any . . . false or misleading description of fact, or false or misleading representation of fact, which . . . is likely to cause confusion, or to cause mistake, or to deceive as to the . . . approval of his or her goods, services, or commercial activities by another person, or . . . in commercial advertising or promotion, misrepresents the nature, characteristics, [or] qualities . . . of his or her . . . goods, services, or commercial activities." 15 U.S.C. § 1125(a).

89. Imprimis is violating the Lanham Act because its advertising and promotion for its unapproved new drugs, including but not limited to Dropless Therapy®, LessDrops®, and Simple Drops™, is materially misleading to healthcare professionals and consumers. Imprimis "misrepresents the nature, characteristics, [or] qualities" of its products by misleading consumers and healthcare professionals into believing that its business model complies with the FD&C Act and California law and that its products thus may lawfully be sold. Further, Imprimis has made false or misleading claims about the safety and efficacy of its products and has misleadingly failed to disclose material information regarding the health risks they pose.

90. Imprimis's false and misleading advertising and promotion is material and reasonably relied on by consumers and healthcare professionals. These representations have caused, and will cause, doctors and consumers to change their purchasing decisions and purchase Imprimis's drugs instead of Allergan's drugs. Neither healthcare professionals nor consumers would purchase Imprimis's products if they knew the truth.

91. Imprimis's false or misleading statements were made in interstate commerce.

92. Allergan has suffered and will continue to suffer actual damages as a result of Imprimis's unfair competition.

G. Imprimis's Activities Violate The False Advertising Provisions of the Sherman Law

93. The Sherman Law additionally makes it unlawful for anyone to "disseminate any false advertisement [about] any . . . drug," and "[a]n advertisement is false if it is false or misleading in any particular." Cal. Health & Safety Code § 110390. "In determining whether the labeling or advertisement of a . . . drug . . . is misleading, all representations made or suggested by statement, word, design, device, sound, or any combination of these, shall be taken into account." *Id*. § 110290. "The extent that the labeling or advertising fails to reveal facts concerning" the drug "shall also be considered." *Id*.

94. Under the Sherman Law, it is also unlawful "to advertise a drug . . . represented to have an effect" on "[d]iseases, disorders, or conditions of the eye," when the drug has not been approved or cleared for marketing for that purpose. *Id*. § 110403, § 110405.

95. Imprimis is violating the Sherman Law because the advertising and promotional materials for its unapproved new drugs, which are manufactured and marketed under the guise of compounding (e.g., Dropless Therapy®, LessDrops®, and Simple Drops™), are misleading to California consumers and healthcare professionals. Despite the fact that reasonable consumers and healthcare professionals would expect these products to be approved drugs and to be safe and effective, Imprimis's advertising and promotional materials for those products fail to disclose that neither the California Department of Health Services nor FDA has approved those products. In addition, Imprimis's advertising and promotion for its products is false or misleading by virtue of baseless superiority claims and the failure to disclose material risk information (e.g., warnings about potential adverse events, contraindications, and adverse drug interactions). *See id*. §§ 111330, 111375, 110398, 111440, 111445.

96. Upon information and belief, Imprimis is violating the Sherman Law

because it has advertised Dropless Therapy®, and LessDrops®, Simple Drops™, and its other unapproved ophthalmic new drugs that are manufactured and marketed under the guise of compounding, to have an effect on eye conditions. *See id*. § 110403.

97. In the future, Imprimis is intending to manufacture and distribute numerous other products, including ophthalmic products, in violation of the Sherman Law's false advertising provisions.

H. Imprimis's Activities Violate California's Compounding Regulations

98. California law prohibits drug compounding "prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug preparation either orally or in writing." Cal. Code Regs. tit. 16, § 1735.2(a).

99. Imprimis is violating Cal. Code Regs. tit. 16, § 1735.2(a) (and section 503(A) of the FDCA) because it provides Dropless Therapy®, LessDrops®, and/or Simple Drops™ to physicians for "office use" in advance of receiving a valid prescription.

100. California's compounding regulations prohibit the compounding of any drug that is "a copy or essentially a copy of one or more commercially available drug products, unless that drug product appears on an ASHP (American Society of Health-System Pharmacists) or FDA list of drugs that are in short supply at the time of compounding and at the time of dispense, and the compounding of that drug preparation is justified by a specific, documented medical need made known to the pharmacist prior to compounding." *Id*. § 1735.2(d).

101. Imprimis is violating Cal. Code Regs. tit. 16, § 1735.2(d) with regard to Dropless Therapy®, LessDrops®, and Simple Drops™. Those products are essentially copies of commercially available drugs. To manufacture those products, Imprimis either uses the same active ingredient in an FDA-approved

product, in the same strength, or it combines active ingredients from two or more commercially available approved drugs. In addition, no version of Dropless Therapy®, LessDrops®, or Simple Drops™ is on an ASHP or FDA list of drugs that are in short supply. Further, the compounding of Dropless Therapy®, LessDrops®, and Simple Drops™ is not justified by a specific medical need, made known to the pharmacist prior to compounding. To the contrary, those products are mass marketed to any patient undergoing cataract or other ocular surgery, in the case of Dropless Therapy® and LessDrops®, and to any patient with glaucoma, in the case of Simple Drops™—all in the name of convenience, rather than any purported patient-specific medical need.

102. California law requires compounding facilities to establish: (1) a methodology "appropriate to compounded drug preparations" that may be "used to validate [the] integrity [and] quality . . . of compounded drug preparations," and (2) "a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug preparations." *Id*. §§ 1735.5(c)(5), 1735.8.

103. Upon information and belief—and as evidenced by FDA's letters—Imprimis is violating Cal. Code Regs. tit. 16, § 1735.5(c)(5) and Cal. Code Regs. tit. 16, § 1735.8 because its Irvine facility (1) has not established an appropriate methodology to validate the integrity and quality of its drugs and (2) lacks a quality assurance plan.

104. California compounding regulations also require that compounding facilities "maintain documentation demonstrating that personnel involved in compounding have the skills and training required to properly and accurately perform their assigned responsibilities and documentation demonstrating that all personnel involved in compounding are trained in all aspects of policies and procedures." *Id*. § 1735.7.

105. Upon information and belief—and as evidenced by FDA's letters—

Imprimis is violating Cal. Code Regs. tit. 16, § 1735.7. FDA found that Imprimis's Irvine facility's method of evaluating "the competency of all personnel who engage in [compounding] operations . . . is inadequate" because "personnel do not perform media fills under conditions that closely simulate the most challenging or stressful conditions encountered during routine aseptic operations." FDA Referral Letter to California State Board of Pharmacy re: Sterility Concerns at Park Compounding (Ex. M).

106. Upon information and belief, Imprimis is manufacturing (and intending to manufacture) numerous products in violation of California's compounding regulations, at least some of which are essentially copies of commercially available drugs, not on an ASHIP or FDA list of drugs that are in short supply, and/or not justified by a specific medical need, made known to the pharmacist prior to compounding.

107. Upon information and belief, Imprimis is planning to mass manufacture and market new drugs that have not been approved by FDA or the California Department of Health Services, that contain combinations of active ingredients that FDA or the California Department of Health Services has explicitly declined to approve.

V. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

Violation of the Lanham Act

(15 U.S.C. § 1051, *et seq.*)

108. Allergan realleges and incorporates by reference each and every allegation set forth above as if fully stated herein.

109. Imprimis's practices, as described in this Complaint, constitute unfair competition and false advertising in violation of the Lanham Act, 15 U.S.C. § 1125(a).

110. Imprimis has violated the Lanham Act by using "false or misleading

descriptions of fact" and "false or misleading representations of fact" in its commercial advertising or promotion that "misrepresent[] the nature, characteristics, [or] qualities" of its business model and products, as set forth above. These include (by way of example only) its promotion of its business model as lawful and its products as superior.

111. Imprimis has violated the Lanham Act by making false and misleading statements about its products' compliance with federal and state laws, making unsupported and false or misleading claims about product safety and efficacy, and failing to disclose material information regarding risks associated with its products.

112. Allergan has suffered injury in fact and actual damages resulting from Imprimis's false and misleading advertising and promotion and unfair competitive practices, including the cost of corrective advertising needed to counter Imprimis's false and misleading advertising.

113. Allergan seeks disgorgement of Imprimis's profits and injunctive relief requiring Imprimis to cease its false and misleading advertising and promotion and unfair competitive practices.

SECOND CLAIM FOR RELIEF

Violation of California's Unfair Competition Law (UCL)

(Cal. Bus. & Prof. Code § 17200, et. seq.)

114. Allergan realleges and incorporates by reference each and every allegation set forth above as if fully stated herein.

115. Imprimis's practices, as described in this complaint, constitute unlawful and/or unfair business practices in violation of California's UCL, Cal. Bus. & Prof. Code, § 17200, *et seq*.

116. Imprimis's products, including Dropless Therapy®, LessDrops®, and Simple Drops™, are "drugs" under California and federal law, namely Health & Safety Code sections 109925(b)–(c), 110110, and 21 U.S.C. § 321(g)(1) and 21

C.F.R. § 310.527(a), because they are intended to cure, mitigate, treat, or prevent disease and/or affect the structure and/or function of the human body and are promoted by Imprimis for those purposes and used by healthcare professionals and consumers in California for those purposes.

117. Imprimis's products are "new drugs" under California law, namely Health & Safety Code section 109980, and 21 U.S.C. § 321(p)(1) and 21 C.F.R. § 310.527(a), as incorporated by Health & Safety Code section 110110, because they are not generally recognized by qualified experts as safe and effective for their intended uses.

118. Imprimis's products have not been approved by FDA or by the California Department of Health Services as required by Health & Safety Code sections 111550(a)–(b) and 21 U.S.C. § 355 *et seq*.

119. Imprimis has violated the UCL by unlawfully marketing, selling, and distributing its products in violation of the California Sherman Law.

120. Imprimis has also violated the UCL by unlawfully marketing, selling, and distributing its products in violation of the Sherman Law's false advertising provisions.

121. Imprimis has also violated the UCL by unlawfully marketing, selling, and distributing its products in violation of California's compounding regulations.

122. Imprimis's practices as alleged in this Complaint constitute unfair business practices in violation of the UCL because they are substantially injurious to consumers and any utility of such practices is outweighed by the harm to consumers. Imprimis's practices violate California's legislative policy of protecting patients and consumers by prohibiting the marketing, sale, and distribution of new drugs that have not been approved by FDA or the California Department of Health Services. Imprimis's practices have caused and are causing substantial injuries to Allergan and the public. Those injuries are not outweighed by any benefits.

123. Allergan has suffered injury in fact and actual damages because of Imprimis's unlawful and unfair business practices.

124. Allergan seeks declaratory and injunctive relief requiring Imprimis to cease the unlawful actions and misconduct alleged.

VI. PRAYER FOR RELIEF

WHEREFORE, Allergan respectfully requests that this Court enter judgment in its favor:

1. A preliminary and permanent injunction, enjoining Defendant from continuing the unlawful and unfair business practices alleged in this Complaint;

2. A judgment that Defendant violated the Lanham Act, 15 U.S.C. § 1051, *et seq.*;

3. A judgment that Defendant violated California Business and Professions Code section 17200, *et. seq.*;

4. Damages and other monetary relief according to proof;

5. Declaratory relief;

6. Attorneys' fees and costs incurred in this action;

7. Prejudgment interest; and

8. Any further relief the Court may deem just and proper.

VII. REQUEST FOR JURY TRIAL

Allergan demands a trial by jury on all claims and issues so triable.

Dated: September 7, 2017

KING & SPALDING LLP

By: /s/ ***Joseph N. Akrotirianakis***
JOSEPH N. AKROTIRIANAKIS

Attorneys for Plaintiff
ALLERGAN USA, INC.