IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HARTIG DRUG COMPANY, INC., on behalf of itself and all others similarly situated,	)	
Plaintiff,	)	
v.	)	C.A. No. _____
SENJU PHARMACEUTICAL CO., LTD. KYORIN PHARMACEUTICAL CO., LTD. and ALLERGAN, INC.,	)	JURY TRIAL DEMANDED
Defendants.	)	CLASS ACTION

COMPLAINT

Plaintiff Hartig Drug Company, Inc., on behalf of itself and all others similarly situated, alleges against Defendants Senju Pharmaceutical Co., Ltd., Kyorin Pharmaceutical Co. Ltd., and Allergan, Inc. (collectively "Defendants") as follows:

I. NATURE OF THE ACTION

1. This is an antitrust class action arising out of Defendants' scheme to unlawfully exclude or delay generic competition in the market for gatifloxacin opthalmic formulations (generic versions of Zymar or Zymaxid). Plaintiffs bring this putative class action on behalf of all direct purchasers in the United States who purchased or paid for branded Zymar or Zymaxid products from June 15, 2010 until the anticompetitive effects of Defendants' unlawful conduct cease (the "Class Period").

2. Defendants engage in the manufacture, marketing, and sale of brand name pharmaceuticals Zymar and Zymaxid. Zymar and Zymaxid are gatifloxacin opthalmic formulations, which are used to treat bacterial infections, particularly bacterial conjunctivitis

(pinkeye). Gatifloxacin ophthalmic formulations are big business—by 2009, Zymar's annual U.S. sales reached approximately $100 million.

3. As detailed by competitor Apotex in its own antitrust lawsuit against Defendants, Defendants engaged in numerous unlawful anticompetitive acts and practices, including: a) filing sham patent lawsuits, including baseless appeals after those suits were thrown out; b) fraud upon the United States Patent & Trademark Office ("USPTO"); and c) product hopping to preclude pharmacies from being able to substitute generic gatifloxacin ophthalmic formulations for Defendants' more expensive branded drugs. Complaint, *Apotex Inc. et al v. Senju Pharma. Co. Ltd. et al*, D.I. 1, C.A. No. 12-cv-0196-SLR (D. Del. Feb. 16, 2012) (D.I. 1).

4. Defendants brought at least *six* unsuccessful patent proceedings against generic competitors for Zymar and Zymaxid. Defendants brought these objectively baseless lawsuits in order to delay generic entry into the gatifloxacin opthalmic formulary market, thus unlawfully maintaining Defendants' monopolistic profits for Zymar and Zymaxid.

5. Defendants attempted to defraud the USPTO by filing a materially misleading *ex parte* request for reexamination of Defendants' patent claims. Defendants' submissions to the USPTO were materially misleading because, among other things, they withheld invalidating and contradictory material information from the USPTO in an attempt to deceive and mislead the USPTO regarding the patentability of the amended claims.

6. Finally, Defendants engaged in their product hopping strategy by introducing Zymaxid, a 0.5% gatifloxacin ophthalmic solution, to replace Zymar, which is a 0.3% gatifloxacin ophthalmic solution. By replacing Zymar with Zymaxid, Defendants were able to further impede generic substitution of their products. *See* Federal Trade Commission's Brief As *Amicus Curiae*, *Mylan Pharma. Inc. et al. v. Warner Chilcott PLC et al.*, No. 2:12-cv-03824

(E.D. Pa.), Dkt. No. 116-2, (hereinafter, "FTC Amicus Brief"), at 8-9 ("minor non-therapeutic changes to the brand product, such as a dosage or form change" at the time of generic entry constitutes product hopping).

7. Wrongful suppression of generic competition, as occurred here, results in enormous overcharge damages to direct purchasers of the drug at issue. This is because generic versions of brand-name drugs are typically much less expensive than their brand-name counterparts, and because purchasers typically switch rapidly from a brand to a generic once the generic becomes available. Indeed, instead of facing decreased prices for Zymaxid due to generic competition, Defendants actually *raised* their prices several times. *See* Allergan 10-K 2011: "Effective July 9, 2011, we increased the published U.S. list price for... *Zymaxid* ® ... by an additional fourteen percent"; Allergan 10-K 2012: "Effective January 7, 2012, we increased the published U.S. list price for ... *Zymaxid* ® by eight percent"; Allergan 10-K 2013: "Effective January 5, 2013, we increased the published U.S. list price for ... *Zymaxid* ® by five percent."

8. Defendants' unlawful scheme effectively denied direct purchasers of Zymar and Zymaxid the benefits of competition and of less expensive, generic versions. As a result, Plaintiff and members of the Class, defined below, have paid supracompetitive prices for Zymar and Zymaxid and its generic equivalents.

II. PARTIES

9. Plaintiff Hartig Drug Company, Inc. ("Hartig") is a corporation organized under the laws of the State of Iowa. During the Class Period, Hartig purchased branded Zymar and Zymaxid directly from AmerisourceBergen Drug Corporation ("Amerisource"). Amerisource has conveyed, assigned, and transferred to Hartig all of its rights, title and interest in and to all causes of action it may have against Defendants under the antitrust laws of the United States or

of any state arising out of or relating to Amerisource's purchase of Zymar and Zymaxid to the extent such product was subsequently resold to Hartig during the time at issue in this case. Amerisource directly purchased branded Zymar and Zymaxid from Defendants during the class period.

10. Defendant Senju Pharmaceutical Co., Ltd. ("Senju") is a corporation organized under the laws of Japan having a place of business at 2-5-8, Hirano-machi, Chuo-ku, Osaka 541-0046, Japan.

11. Defendant Kyorin Pharmaceutical Co. Ltd. ("Kyorin") is a corporation organized under the laws of Japan having a place of business at 5, Kanda Surugadai 2-chonie, Chiyoda-ku, Tokyo 101-8311 Japan.

12. Defendant Allergan, Inc. ("Allergan") is a Delaware corporation having a place of business at 2525 Dupont Drive, Irvine, California, 92612.

13. On information and belief, Allegan manufactures, offers for sale, and sells pharmaceutical products throughout the United States, including in this judicial district.

14. On information and belief, Senju and Kyorin manufacture pharmaceutical products sold throughout the United States, including in this judicial district.

III. JURISDICTION AND VENUE

15. This Court has subject matter jurisdiction based on 28 U.S.C. §§ 1331 and 1337(a) and 15 U.S.C. § 15.

16. Upon information and belief, venue is proper in this judicial district under 15 U.S.C. § 22 and 28 U.S.C. §§ 1391(b) and (c), because Defendants transact business within this district and the interstate trade and commerce described in this complaint is carried out, in substantial part, in this district.

IV. THE REGULATORY SYSTEM GOVERNING PHARMACEUTICALS IN THE UNITED STATES

A. New Drug Applications

17. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, ("FD&C Act") as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), and the Medicare Prescription Drug, Improvement and Modernization Act of 2003, codified at 21 U.S.C. § 355(j) and 35 U.S.C. § 271(e) (2005), establish procedures designed to facilitate competition from lower-priced generic drugs.

18. Approval by the Food and Drug Administration ("FDA") – the governmental body charged with regulating the pharmaceutical industry – is required before a company may sell a new drug in interstate commerce in the United States. 21 U.S.C. § 355(a). Pre-market approval for a new drug must be sought by filing a new drug application ("NDA") with the FDA under § 355(b) of the FD&C Act demonstrating that the drug is safe and effective for its intended use.

19. New drugs that are approved for sale in the United States by the FDA are often covered by patents, which provide the patent owner with the ability to exclude others from making, using, and/or selling (depending on the scope of the patent) that new drug in the United States for the duration of the patents. Patent holders may also gain extensions of an original patent pursuant to the Hatch-Waxman Act, 21 U.S.C. § 355.

20. Pursuant to 21 U.S.C. § 355(b), the pioneer drug manufacturer must list in its NDA those patents that cover the drug for which FDA approval is being sought. The manufacturer must also list any patents that claim a method of using the drug that could reasonably be asserted against an unlicensed manufacturer or seller of the drug. Once the NDA is approved by the FDA, any such patents are listed with the NDA in a publication known as the

Approved Drug Products With Therapeutic Equivalence Evaluations, commonly referred to as the "Orange Book."

21. Federal regulations impose strict limitations on the types of patents that an NDA holder can submit to the FDA for listing in the Orange Book. *See generally* 21 C.F.R. § 314.53. One such limitation is imposed by 21 C.F.R. § 314.53(b), which explicitly prohibits NDA holders from listing any patent in the Orange Book unless a claim of infringement could reasonably be asserted on the basis of such a patent.

22. Despite the FDA regulations that limit the types of patents that NDA holders can list in the Orange Book, it has regrettably become common for brand-name pharmaceutical companies to list in the Orange Book any and every patent they can obtain, so as to force generic manufacturers to file what is commonly known as a "Paragraph IV certification." *See infra* ¶¶ 28-31.

23. The FDA does not police the listing of patents. The FDA employs no adjudicatory or other process to determine whether a patent submitted by an NDA holder qualifies for listing in the Orange Book. The FDA has stated that it lacks the resources and expertise to review the patents submitted in connection with NDAs.

24. As a result, the FDA's role in the patent listing process is purely ministerial, and it relies entirely upon the good faith of the NDA holder submitting the patent for listing.

B. Generic Drugs

25. Generic drugs are drugs that the FDA has found to be bioequivalent to their corresponding brand name drugs. A generic drug provides identical therapeutic benefits and has the same side effects and safety profile as its corresponding brand-name drug.

26. Generic drugs invariably cost substantially less than the branded drugs to which

they are bioequivalent. Typically, the first generic version of a brand-name drug is sold at a substantial discount to the brand, followed by increasingly steeper discounts as more generics of that drug enter the market.

27. Under the Hatch-Waxman Act, a generic drug manufacturer may seek expedited FDA approval to market a generic version of a brand name drug with an approved NDA by filing an Abbreviated New Drug Application ("ANDA"). 21 U.S.C. § 355(j). An ANDA relies on the safety and efficacy data already filed with the FDA by the manufacturer of the equivalent brand name drug.

28. After an applicant has submitted its ANDA to the FDA it must file a patent certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii). Four types of certifications are available:

a. The brand-name manufacturer has not filed patent information with the FDA (a "Paragraph I certification");

b. The patent or patents listed in the Orange Book have expired (a "Paragraph II certification");

c. The patent will expire on a date in the future, and the generic manufacturer does not seek to market its generic version of the drug prior to the date of expiration (a "Paragraph III certification"); or

d. The patent is invalid or not infringed by the generic manufacturer's product (a "Paragraph IV certification").

29. A generic drug applicant must serve the brand-name drug company with a copy of any certification under Paragraph IV. The filing of a Paragraph IV certification constitutes a "technical act of infringement" under Hatch-Waxman, which grants jurisdiction to the federal courts over a patent infringement action concerning that drug. The NDA holder has forty-five

days from the date of the notice to institute such an action against the generic manufacturer under 35 U.S.C. § 271(e)(2). *See* 21 U.S.C. § 355(j)(5)(B)(iii). If such a suit is initiated, the FDA's approval of the ANDA is automatically stayed for up to thirty months. 21 U.S.C. § 355(j)(5)(B)(iii).

30. Because of this thirty-month stay, the mere filing of an infringement action in response to a Paragraph IV certification, regardless of the action's underlying merit, gives the brand-name company the functional equivalent of a self-effectuating preliminary injunction blocking the entry of a generic competitor, without the brand-name drug company's ever having to establish likelihood of success on the merits, irreparable harm, that the balance of hardships tips in its favor, or that the public good is served by the blocking of entry.

31. An improper Orange Book listing has additional anticompetitive effects, because the first generic manufacturer to file an ANDA with a Paragraph IV certification is, upon FDA approval, granted a 180-day period of marketing exclusivity in relation to other generic manufacturers. 21 U.S.C. § 355(j)(5)(B)(iv). This 180-day exclusivity period is awarded to the first Paragraph IV filer regardless of whether or not the brand company institutes pre-approval patent infringement litigation in response to the Paragraph IV certification. Absent an improper Orange Book listing, no Paragraph IV certification would be required and, thus, no generic company would receive 180-day exclusivity; rather, multiple generic competitors would enter the market simultaneously.

32. Defendants were at all times fully familiar with their ability to delay the entry of generic competition by the improper manipulation of the patent listing and pre-approval litigation provisions of the Hatch-Waxman Amendments.

C. The Consumer Benefits of Generic Drugs

33. The first generic drugs to enter a market usually cost 30% to 50% below the price of their brand-name equivalents. Because generic and branded drugs are fully interchangeable in terms of safety and efficacy, the vast majority of patients are switched to the less expensive generic in place of the brand-name drug by their pharmacy benefit managers.

34. Almost all states (and the District of Columbia) encourage generic competition through laws that allow pharmacists to substitute brand-name drugs with their "AB-rated" generic equivalents, unless a physician directs or the patient requests otherwise.

35. However, while generic drugs save consumers billions of dollars, these savings come at the expense of additional profits to brand-name drug companies. As a result of lower prices and ease of substitution, consumers routinely switch from the brand drug to an AB-rated drug upon its introduction. Consequently, bioequivalent generic drugs typically capture over 80% of a brand drug's sales within six months of market entry. *See* Federal Trade Commission, "Authorized Generic Drugs: Short-Term Effects and Long-Term Impact" (2011), Ch. 4, n.6, *available at* http://www.ftc.gov/os/2011/08/2011genericdrugreport.pdf .

V. DEFENDANTS' ANTICOMPETITIVE SCHEME

A. Kyorin and Senju scheme to create an unlawful monopoly in the market for gatifloxacin ophthalmic formulations by making materially false and misleading representations to the USPTO to obtain the '045 patent.

36. Gatifloxacin is a quinolone antibiotic first patented by researchers at Kyorin in 1990 in U.S. Patent No. 4,980,470 ("the '470 patent"). The '470 patent, which expired on June 15, 2010, claims the molecule gatifloxacin and discloses that gatifloxacin may be formulated in various dosage forms, including in eye drops.

37. As early as 1995, Hiromichi Kodaira and other researchers at Kyorin began

formulating aqueous liquid ophthalmic formulations, *i.e.*, eye drops, containing gatifloxacin, disodium edetate, sodium chloride, and other excipients.

38. At that time, however, Kyorin did not seek patent protection for these aqueous liquid ophthalmic formulations of gatifloxacin containing disodium edetate, sodium chloride, and other excipients. On information and belief, Kyorin did not seek additional patent protection for the formulations made by its researchers because Kyorin knew that those formulations would not have been patentable in view of the '470 patent and its knowledge of other ophthalmic formulations.

39. Instead, Kyorin entered into a license agreement with Senju in 1997 that allowed Senju to develop and market aqueous liquid ophthalmic formulations of gatifloxacin. The license agreement also required that any patent that might be filed by Senju in the area of gatifloxacin ophthalmic formulations would be jointly assigned to Kyorin and Senju.

40. After Kyorin and Senju entered into the license agreement, Senju prepared various aqueous liquid ophthalmic formulations containing gatifloxacin and tested them for efficacy.

41. In August 1998, Senju filed a patent application which named Senju researchers Katsuhiro Inada and Shinichi Yasueda as the only inventors. The patent application claimed aqueous liquid ophthalmic formulations comprising gatifloxacin and disodium edetate, as well as methods for preparing such formulations.

42. Inada and Yasueda assigned their rights in the patent application jointly to Senju and Kyorin.

43. Kyorin participated in the patent prosecution efforts even though it was aware that the compositions claimed in the patent application were first invented by Kyorin researcher

Kodaira and his colleagues at Kyorin several years earlier and that the compositions were not invented by Senju's Inada and Yasueda.

44. On December 25, 2001, the patent application naming Inada and Yasueda issued as U.S. Patent No. 6,333,045 ("the '045 patent"). The original claims of the '045 patent read as follows:

1. An aqueous liquid pharmaceutical composition which comprises Gatifloxacin or its salt and disodium edetate.

2. The aqueous liquid pharmaceutical composition according to claim 1, wherein pH of the composition is within the range of 5 to 8.

3. The aqueous liquid pharmaceutical composition according to claim 1, where the composition is in the form of eye drops.

4. The aqueous liquid pharmaceutical composition according to claim 1, where the composition is in the form of ear drops.

5. The aqueous liquid pharmaceutical composition according to claim 1, where the composition is in the form of nasal drops.

6. A method for raising corneal permeability of Gatifloxacin which comprises incorporating disodium edetate into eye drops containing Gatifloxacin or its salt.

7. A method for preventing precipitation of Gatifloxacin crystals which comprises incorporating disodium edetate into an aqueous liquid preparation containing Gatifloxacin or its salt.

8. A method for preventing coloration of Gatifloxacin which comprises incorporating disodium edetate into an aqueous liquid preparation containing Gatifloxacin or its salt.

9. The aqueous liquid pharmaceutical composition according to claim 2, where the composition is in the form of eye drops.

10. The aqueous liquid pharmaceutical composition according to claim 2, where the composition is in the form of ear drops.

11. The aqueous liquid pharmaceutical composition according to claim 2, where the composition is in the form of nasal drops.

The '045 patent is set to expire on February 20, 2020.

B. Kyorin and Senju give Allergan a license to market gatifloxacin ophthalmic formulations in the United States, including a license under the '045 patent, and Allergan begins marketing gatifloxacin ophthalmic solution, 0.3%, under the brand name Zymar.

45. In 2000, Kyorin and Senju licensed to Allergan the right—including a license under the '045 patent—to market aqueous liquid gatifloxacin ophthalmic products in the United States.

46. On May 29, 2002, Allergan filed New Drug Application ("NDA") No. 21-493 on behalf of the Defendants seeking approval to market in the United States gatifloxacin ophthalmic solution, 0.3%, under the brand name Zymar.

47. On March 28, 2003, the FDA approved NDA No. 21-493 for Zymar.

48. Allergan began marketing Zymar in the United States shortly after receiving FDA approval.

49. In March 2004, Allergan entered into an agreement with one of its generic competitors, Lupin, in which Lupin agreed to promote Zymar to high volume pediatric prescribers on Allergan's behalf.[1] Lupin's press release noted that Zymar was already the "#1 prescribed ophthalmic fluoroquinolone among eye care professionals in the United States." *Id.*

50. By 2009, Zymar's annual U.S. sales reached approximately $100 million.

C. Apotex files an ANDA for gatifloxacin ophthalmic solution, 0.3%, to compete with Defendants.

51. Allergan listed three patents in the Orange Book for NDA No. 21-493: the '470 patent, the '045 patent, and U.S. Patent No. 5,880,283 ("the '283 patent") (claiming a particular

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[1] http://agn.client.shareholder.com/releasedetail.cfm?ReleaseID=131943; http://www.lupinpharmaceuticals.com/newsroom_b.html

crystalline form of gatifloxacin).

52. On July 18, 2007, Apotex filed ANDA No. 79-084 seeking approval to sell a generic gatifloxacin ophthalmic solution, 0.3%.

53. Apotex's ANDA contained paragraph IV certifications to the '283 and '045 patents. Apotex was the first to file an ANDA for gatifloxacin ophthalmic solution, 0.3%, that contained a paragraph IV certification. Accordingly, the filing provides Apotex the right to 180 days of marketing exclusivity. Apotex also filed a paragraph III certification with respect to the'470 patent, certifying that Apotex would not market its generic gatifloxacin ophthalmic solution, 0.3%, until that patent (and any applicable extensions to that patent) expired on June 15, 2010.

54. As required by the Hatch-Waxman Act, Apotex notified Defendants that Apotex had filed ANDA No. 79-084 seeking approval to sell a generic gatifloxacin ophthalmic solution, 0.3%, and provided to Defendants a letter setting forth that Apotex's proposed ANDA product would not infringe any valid claim of the '283 and '045 patents.

D. Defendants file litigation against Apotex to prevent or delay Apotex from marketing its proposed ANDA product in competition with Defendants.

55. On November 29, 2007, Defendants sued Apotex alleging infringement of the '283 and '045 patents. Because Defendants filed their complaint within 45 days of receipt of Apotex's notice letter, Defendants enjoyed an automatic 30-month stay of FDA approval of Apotex's ANDA.

56. But for Defendants' lawsuit, on information and belief, Apotex would have brought to market a generic version of Zymar shortly after the expiration of the '470 patent on June 15, 2010. As a result of Defendants' sham patent lawsuits against potential generic entrants, Plaintiff and class members still do not have access to a generic version of Zymar.

57. On information and belief, Defendants filed suit against Apotex on the '283 and '045 patents despite knowing that: (i) Apotex did not use the crystalline gatifloxacin hydrate form claimed in the '283 patent; and (ii) the claims of the '045 patent were invalid as obvious.

58. On June 23, 2008, Defendants dismissed all claims against Apotex related to the '283 patent.

59. On information and belief, in approximately May 2009, Defendants were informed by their expert that at least claim 8 of the '045 patent would have been invalid as obvious.

60. On information and belief, Defendants also knew that because claim 8 was invalid as obvious, as a matter of law, at least claims 1-3 and 9 of the '045 patent also would be obvious. Defendants, however, continued to assert claims 1-3 and 9 against Apotex.

E. Defendants engage in product hopping while extending their monopoly through their paragraph IV lawsuit against Apotex

61. Product hopping is an illegal practice whereby a manufacturer attempts to "interfere with the mechanism by which generic drugs compete by making modest non-therapeutic changes to its product, and effectively prevent generic competition, not because the reformulated product is preferred by consumers, but simply because it is different." FTC Amicus Brief, at 6. The manufacturer thus "game[s] the regulatory structure that governs the approval and sale of generic drugs, thereby frustrating the efforts of federal and state policymakers to facilitate price competition in pharmaceutical markets." *Id.* at 6; Herbert Hovenkamp et al., IP and Antitrust 15-75 (2d. ed. 2010) ("Product-hopping seems clearly to be an effort to game the rather intricate FDA rules. . . . The patentee is making a product change with no technological benefit solely in order to delay competition.").

62. The FTC has explained how brand drug manufacturers engage in such product

hopping:

> [F]irst, the brand manufacturer makes minor non-therapeutic changes to the brand product, such as a dosage or form change. Next, prior to generic entry, it removes the original product from the marketplace. . . . Such conduct can push patients and physicians to abandon the original product. In this way, a brand manufacturer can convert existing market demand for the original product to its reformulated product – not because physicians and patients prefer it, but simply because the original product is no longer as available . . . . Once the original version of the brand product is less available or more expensive, physicians will stop writing prescriptions for it. Because the prescription must contain, among other things, the same dosage and form as the generic for a pharmacist to substitute it for the brand, a product switch will effectively eliminate substitution at the pharmacy counter and thus meaningful generic competition. . . .
>
> As a practical matter, if a generic cannot be substituted at the pharmacy counter, the economically meaningful market for the generic product disappears. Generic substitution is based, in part, on the premise that generic products will not be promoted like brand drugs. While the generic can attempt to market a non-substitutable generic product directly to prescribing physicians, such a costly undertaking undermines the ability of generic companies to offer the lower price benefits that the federal and state regulatory framework was intended to foster. Moreover, such marketing, even if effective in causing physicians to prescribe the particular company's generic product, does not guarantee the sale of that product when the patient goes to the pharmacy. The pharmacy may stock a different company's generic and unless the physician has ordered "dispense as written" the pharmacy can fill the prescription with the alternative generic. Indeed, a company that does not bear the cost of such marketing to physicians is likely to offer a lower-priced generic product. Thus, by definition and design generic drugs are lower-cost substitutes that do not compete with the promotional efforts of brand drug firms. If the brand manufacturer reformulates its product before a generic receives FDA approval, the generic's only practical option is to go back to the drawing board and reformulate its own product to be bioequivalent to the brand reformulation and thus substitutable at the pharmacy.

FTC Amicus Brief, at 13-15 (citations omitted).

63. As the FTC further explained:

> The potential for anticompetitive product redesign is particularly acute in the pharmaceutical industry. In most other industries, the success of a new product in the marketplace reflects consumer choice. In the pharmaceutical industry, however, the success of a product switching scheme does not depend on whether consumers prefer the reformulated version of the product over the original, or whether the reformulated version provides any medical benefit. Instead, as the

> district court in *Abbott Labs v. Teva (Tricor)* explained, "[t]he nature of the pharmaceutical drug market" does not always permit "the merits of any new product [to] be tested by unfettered consumer choice."
>
> For example, prior to facing generic competition, a brand company can introduce a reformulated product, and simply withdraw the original product, as the plaintiffs alleged in Tricor. In such a situation, consumers do not choose the reformulated product based on its merits; instead, the brand forces the switch by removing the product from the market and preventing consumers from weighing the relative merits of competing products. A brand company can achieve the same result through indirect means (such as by raising the price of the original product by a meaningful amount or by creating supply shortages of the original product prior to facing generic competition) so that there is effectively no longer a market for the original product when a generic would be ready to enter.

FTC Amicus Brief, at 17-18 (citations omitted).

64. Defendants took advantage of the delay arising from their patent litigation to bring to market Zymaxid, a new gatifloxacin ophthalmic solution, 0.5%. Defendants did so solely to extend Defendants' monopoly over gatifloxacin ophthalmic formulations.

65. On June 12, 2009, Apotex received tentative approval of its ANDA for gatifloxacin ophthalmic solution, 0.3%. Because Apotex was still subject to the automatic thirty-month stay triggered by Defendants' lawsuit, in June 2009, Apotex could not then receive final approval or market its gatifloxacin ophthalmic solution, 0.3%.

66. On July 30, 2009, less than two months after Apotex had received tentative approval of its ANDA, Allergan filed NDA No. 22-548 for gatifloxacin ophthalmic solution, 0.5%, brand name Zymaxid.

67. On information and belief, the formulation for Zymaxid contains the same components in substantially similar concentrations as that for Zymar, except that the concentration of gatifloxacin contained in Zymaxid is 0.5% instead of 0.3%, as in Zymar.

68. On information and belief, Allergan filed the NDA for Zymaxid as a new

product, rather than as a supplement to the NDA for Zymar, despite Zymaxid being the same product with only a higher concentration of gatifloxacin, in an attempt to exclude further competition by obtaining three (3) additional years of regulatory exclusivity for the product and allowing Allergan to list the '283 and '045 patents in the Orange Book and require new certifications against the same patents.

69. Allergan filed its NDA for Zymaxid as part of a product switching strategy to deny Plaintiff and class members access to Apotex's low cost generic gatifloxacin ophthalmic solution, 0.3%. When an ANDA is approved, the approved product is given a therapeutic equivalence rating in the Orange Book. If the ANDA product is given an "A" rating, then FDA has determined that the generic product described in the ANDA is a therapeutic equivalent of the NDA product referenced by the ANDA.

70. Where an ANDA product receives an "A" rating, absent a prescriber's contrary instruction, the ANDA product may be substituted by pharmacies instead of the referenced NDA product (*i.e.*, the brand name product) when filling a prescription identifying the brand name or the generic name for the drug.

71. An ANDA product receiving an "A" rating with reference to an NDA may not, however, be substituted by pharmacies for a product approved in another NDA, no matter how similar the NDA products are to one another. For example, an ANDA product referencing the NDA for Zymar gatifloxacin ophthalmic solution may not be substituted by a pharmacy when receiving a prescription for Zymaxid ophthalmic solution.

72. On May 18, 2010, FDA approved Allergan's NDA No. 22-548 for Zymaxid.

73. Upon Zymaxid's approval, Allergan listed the '283 and '045 patents in the Orange Book in connection with Zymaxid. Allergan listed the '045 patent in the Orange Book

despite knowing that the '045 patent was invalid. Upon launching Zymaxid in July 2010, Allergan stopped marketing and promoting Zymar to physicians and marketed and promoted Zymaxid instead. Allergan stopped its promotion of Zymar to physicians in order to dissuade physicians from prescribing Zymar and to encourage physicians to switch all of their prescriptions for gatifloxacin ophthalmic solution from Zymar to Zymaxid. *See* Allergan 10-K (2011) at 10 ("The FDA approved *Zymaxid* in 2010 and, in February 2011, we announced the discontinuation of *Zymar* (gatifloxacin ophthalmic solution) 0.3% in the United States due to strong physician acceptance of *Zymaxid*.").

74. On information and belief, Zymaxid does not possess any clinical or therapeutic benefit or superiority in comparison to Zymar. On further information and belief, Zymaxid does not have any greater clinical or therapeutic efficacy than Zymar.

75. FDA's approval of Zymaxid does not give Allergan any right to promote Zymaxid as having a superior clinical or therapeutic benefit in comparison to Zymar.

76. Indeed, on information and belief, at the time the Zymaxid NDA was filed, Allergan was aware of studies conducted by Senju that demonstrated that aqueous liquid formulations containing 0.5% gatifloxacin did *not* demonstrate an increase in efficacy as compared to formulations containing 0.3% gatifloxacin.

F. Defendants file a baseless motion for new trial against Apotex in an effort to buy time to switch sales to their second gatifloxacin ophthalmic solution product and to hinder Apotex's entry.

77. On June 14, 2010, the District Court entered an opinion and judgment finding claims 1-3 and 6-9 of the '045 patent invalid as obvious. Claims 4 and 5, relating to nose and ear drops, were not asserted at trial.

78. Because Allergan had received FDA approval and had started marketing the

second gatifloxacin ophthalmic solution product just a month earlier, Allergan needed more time to complete its switching strategy before Apotex entered the market. Accordingly, Allergan embarked on a two-pronged strategy to further delay and frustrate Apotex's ability to market a low-cost generic gatifloxacin ophthalmic solution product.

79. First, Defendants filed a baseless motion seeking a new trial and/or reconsideration on the invalidity of claim 7. On information and belief, Defendants filed this motion for the sole purpose of instigating further delay independent of the outcome of the motion.

80. On November 3, 2010, in response to Defendants' motion, the District Court opened its judgment of obviousness with respect to claim 7 of the '045 patent for the limited purpose of allowing the parties to submit additional evidence on the issue of the relationship between the scientific principles of solubility and precipitation.

81. In April and May 2011, the District Court conducted a two-day evidentiary hearing to allow the parties to submit additional evidence on the issue of the relationship between the scientific principles of solubility and precipitation.

82. On December 20, 2011, the Court filed an opinion finding claim 7 of the '045 patent invalid as obvious and re-entered judgment in the case. In the opinion, the Court concluded that Defendants' additional evidence was "irrelevant at best, and unreliable at worst."

G. Defendants commit fraud on the United States Patent and Trademark Office.

83. On February 25, 2011, in the midst of the proceedings over Defendants' baseless motion for a new trial against Apotex before the District Court, Defendants filed with the USPTO an *ex parte* request for the reexamination of claims 1-3, 6, 8, and 9 of the '045 patent seeking to amend the claims. At the time of the reexamination request, these six claims were

subject to a judgment ruling them invalid as obvious.

84. As part of the reexamination request, Defendants filed the trial opinion, excerpts of the trial record, and certain expert reports that were favorable to their position on reexamination.

85. Defendants, however, did not file excerpts of the trial record and expert reports disclosing that Kyorin's researchers had been the first to make and test gatifloxacin ophthalmic formulations covered by the '045 patent claims, nor did they produce evidence which showed that the formulations as claimed by the '045 patent did not exhibit unexpected results, the existence of which could have supported patentability.

86. Defendants also did not file the deposition testimony by their own expert, which conceded that preparing the aqueous liquid compositions containing 0.3 w/v% gatifloxacin and 0.01 w/v% disodium edetate would have been obvious based upon the well-known use of disodium edetate to prevent coloration of aqueous liquid drug formulations.

87. This withheld information was material and shows that the added reexamination claims of the '045 patent were obvious and invalid as a matter of law. Defendants also withheld information demonstrating that they made a material misrepresentation as to the actual inventors of the subject matter claimed in the reexamination claims.

88. Defendants also amended reexamination claim 6 knowing that the added limitations to the claimed methods were not supported by the written description of the '045 patent specification, and thus reexamined claim 6 was invalid.

89. On information and belief, Defendants withheld this invalidating and contradictory material information in an attempt to deceive and mislead the USPTO regarding the patentability of the amended claims.

90. On information and belief, Defendants sought reexamination of claims 1-3, 6, 8, and 9 despite knowing that these reexamination claims in amended form were still invalid as obvious and/or for violating the written description requirement of 35 U.S.C. § 112, ¶ 1.

91. Defendants did not inform either the District Court or Apotex when they filed their request for reexamination.

92. As part of the post-hearing briefing on claim 7, and contemporaneously with the reexamination proceeding, Defendants requested the District Court also reconsider its judgment of the invalidity of claims 1-3 and 9 of the '045 patent in light of the additional evidence they submitted on claim 7. Nevertheless, shortly after making this request, Senju and Kyorin cancelled claims 1-3, 8, and 9 of the '045 patent in the reexamination proceedings, mooting any issue as to their obviousness. Senju and Kyorin, however, did not advise the District Court of the reexamination proceeding or that they had cancelled these claims.

93. Senju and Kyorin then submitted new claims 12-16 in the reexamination to narrow the scope of the compositions that had been claimed in claims 1-3 and 9, which were dropped.

94. On information and belief, Senju and Kyorin committed fraud on the USPTO by seeking new claims 12-16 (aqueous liquid compositions comprising gatifloxacin and disodium edetate) which as a matter of law are invalid in light of Defendants' and/or their expert's concession that claim 8 (incorporating disodium edetate into a liquid aqueous gatifloxacin composition for the purpose of preventing coloration) is invalid.

95. On information and belief, Senju and Kyorin committed fraud on the USPTO by failing to disclose the Kyorin researchers' prior invention of gatifloxacin ophthalmic formulations containing disodium edetate and sodium chloride.

96. On October 25, 2011, the USPTO issued a reexamination certificate determining that amended claim 6 and new claims 12-16 are patentable over the materials submitted by Senju and Kyorin in the reexamination. These claims read as follows:

> 6. A method for raising corneal permeability of an aqueous pharmaceutical Gatifloxacin eye drop solution comprising Gatifloxacin or its salt, having a pH from above 5 to about 6 containing from about 0.3 to about 0.8 w/v% Gatifloxacin or its salt which comprises incorporating about 0.01 w/v% disodium edetate into [eye drops containing Gatifloxacin or its salt] said Gatifloxacin eye drop solution.
>
> 12. An aqueous liquid pharmaceutical eye drop composition which comprises from about 0.3 to about 0.8 w/v% Gatifloxacin or its salt, about 0.01 w/v% disodium edetate, and wherein the aqueous liquid pharmaceutical composition has a pH from about 5 to about 6.
>
> 13. The aqueous liquid pharmaceutical eye drop composition according to claim 12, comprising about 0.3 w/v% Gatifloxacin or its salt.
>
> 14. The aqueous liquid pharmaceutical eye drop composition according to claim 12, comprising about 0.5 w/v% Gatifloxacin or its salt.
>
> 15. The aqueous liquid pharmaceutical eye drop composition according to claim 12, comprising at least one isotonic agent selected from the group consisting of sodium chloride, potassium chloride, glycerin, mannitol and glucose.
>
> 16. The aqueous liquid pharmaceutical eye drop composition according to claim 14, wherein the at least one isotonic agent is sodium chloride.

97. In the Examiner's Statement of Reasons for Patentability and/or Confirmation, the Examiner states that the prior art fails:

> to teach or reasonably suggest, alone or in combination...an aqueous liquid pharmaceutical eye drop composition that comprises the claimed amounts of gatifloxacin (from about 0.3 w/v% to about 0.8 w/v% gatifloxacin or its salt) and the incorporation of disodium edetate in the particular amounts that are recited in the claims (about 0.01[sic] w/v% disodium edetate) at a pH from about 5 to about 6 (**claim 12**).

98. The Examiner further suggested that claim 12 was patentable because Senju and Kyorin submitted evidence of a secondary consideration that favored patentability—unexpected results of increased corneal permeability for the claimed compositions, without evidence of

other secondary considerations.

99. But for Senju's and Kyorin's fraud on the USPTO, the Examiner would not have reached these conclusions and the reexamined claims of the '045 patent would not have issued.

H. Defendants use the delay caused by Defendants' anti-competitive conduct to eliminate Apotex as a competitor in the market and prevent entry of a low cost gatifloxacin ophthalmic solution product.

100. After the District Court found claims 1-3 and 6-9 of the '045 patent invalid in July 2010, Allergan stopped marketing and promoting Zymar to physicians and marketed and promoted Zymaxid instead.

101. On information and belief, Allergan stopped its promotion of Zymar to physicians in order to dissuade physicians from prescribing Zymar and to encourage physicians to switch all of their prescriptions for gatifloxacin ophthalmic solution from Zymar to Zymaxid.

102. During the delay resulting from Allergan's anticompetitive conduct, Allergan's efforts were successful in effectively removing Zymar from the market. The intended and actual effect of this conduct was to continue to deny Plaintiff and class members access to a low-cost generic gatifloxacin ophthalmic solution product.

I. Defendants file a second baseless lawsuit against Apotex's gatifloxacin ophthalmic solution, 0.3%, alleging infringement of the reexamined claims in an attempt to further their monopoly over gatifloxacin ophthalmic formulations.

103. On August 19, 2011, Apotex's ANDA for gatifloxacin ophthalmic solution, 0.3%, received final approval from the FDA. Apotex's ANDA for gatifloxacin ophthalmic solution, 0.3%, is listed in the Orange Book with an AT designation, meaning that it is considered a therapeutic equivalent of Zymar.

104. On November 28, 2011, Defendants filed a second lawsuit against Apotex seeking a declaratory judgment that Apotex's gatifloxacin ophthalmic solution, 0.3%—the same

product accused of infringing the '045 patent in the first lawsuit—infringes reexamined claims 6 and 12-16 of that patent. Complaint, *Senju Pharmaceutical Co. Ltd. et al v. Apotex Inc. et al*, C.A. No. 11-cv-1171-SLR (D. Del. Nov. 28, 2011).

105. On information and belief, Defendants filed the second lawsuit asserting the '045 patent despite knowing that Apotex's gatifloxacin ophthalmic solution, 0.3%, did not infringe any valid and enforceable claim of the '045 patent. Defendants filed this second lawsuit in an effort to prevent Apotex from marketing its ANDA product.

106. Further, on information and belief, Defendants filed the second lawsuit despite knowing that the claims and relief sought were precluded by the doctrines of claim preclusion and/or claim splitting. On September 17, 2012, the District Court held that Defendants claimed were barred by claim preclusion, and on March 31, 2014, the Federal Circuit affirmed the District Court's judgment in favor of Apotex. *Senju Pharm.* Co. *v. Apotex Inc.*, 891 F. Supp. 2d 656 (D. Del. 2012), *aff'd*, 746 F.3d 1344 (Fed. Cir. 2014); Case No. 13-1027, D.I. 47 (Fed. Cir. May 7, 2014) (mandate issued).

107. Despite receiving FDA approval, Apotex has not launched a generic to Zymar. On information and belief, Apotex's discontinuance was due to Defendants' anticompetitive actions.

J. Defendants file baseless patent lawsuits against other generic competitors, Lupin Pharmaceuticals and Hi-Tech Pharmacal

108. In addition to their baseless lawsuits against Apotex, Defendants also filed several sham lawsuits against other generic entrants, in order to extend their monopoly over gatifloxacin opthalmic formulations.

109. On March 31, 2011, Defendants filed a lawsuit against Lupin for infringement of the '045 patent, in response to Lupin's paragraph IV certification and ANDA filing for a generic Zymaxid (0.5%). Complaint, C.A. No. 11-cv-271-SLR (D. Del. Mar. 31, 2011).

110. On May 18, 2011, Defendants filed a second lawsuit against Lupin for infringement of the same patent, for Lupin's ANDA related to Zymar (0.3%). Complaint, C.A. No. 11-cv-439-SLR (D. Del. May 18, 2011). And on October 11, 2011, Defendants filed a lawsuit against Hi-Tech Pharmacal for infringement of the '045 patent, in response to Hi-Tech "either directly or indirectly" submitting an ANDA for a generic Zymaxid (0.5%). Complaint, C.A. No. 11-cv-926-SLR (D. Del. Oct. 11, 2011).

111. On July 1, 2013, Lupin received tentative approval of its ANDA for gatifloxacin ophthalmic solution, 0.5%.

112. Defendants' lawsuits against Lupin and Hi-Tech Pharmacal were consolidated, and as it had when Defendants brought the same patent infringement claims against Apotex, the District Court of Delaware found Defendants' patent invalid for obviousness. C.A. No. 11-cv-271-SLR, D.I. 190 (Aug. 9, 2013) (taking note of but not relying on the analysis of the '045 patent in the Apotex litigation). The court also refused Defendants' request for an injunction barring Lupin and Hi-Tech Pharmacal from marketing their generic equivalents of Zymar and Zymaxid while Defendants appealed the ruling to the Federal Circuit. D.I. 209 (Aug. 26, 2013).

113. On August 28, 2013, Lupin received final approval of its ANDA for gatifloxacin ophthalmic solution, 0.5%.

114. The Federal Circuit affirmed the District Court's denial of an injunction barring the generic entrants from marketing generic Zymar and Zymaxid. *Senju Pharma v. Lupin Ltd.*, Case No. 13-1630, D.I. 34 (Fed. Cir. Sept. 30, 2013). The patent litigation remains pending.

115. Lupin launched its generic Zymaxid on October 3, 2013, which remains the only generic version of either Zymar or Zymaxid on the market today.

116. On April 9, 2014, Hi-Tech Pharmacal received tentative approval of its ANDA

for gatifloxacin ophthalmic solution, 0.3%. It has not yet received final approval.

K. Defendants file a third baseless lawsuit against Apotex to block entry of a generic equivalent to Zymaxid.

117. On February 10, 2012, Defendants filed a third lawsuit against Apotex for patent infringement, this time in response to Apotex's ANDA to bring a generic Zymaxid (0.5%) to market, again with paragraph IV certification. Complaint, ¶ 33, C.A. No. 12-cv-159-SLR (D. Del. Feb. 10, 2012).

118. Despite having filed this lawsuit, Defendants stipulated that this third lawsuit against Apotex would be precluded by the court's decision in Defendants' case against Lupin. On September 30, 2013, the parties entered a stipulated order and final judgment, agreeing to dismiss Apotex's counterclaims, to enter adverse judgment against the brand name companies under principles of collateral estoppel based on the *Lupin* judgment, and agreeing to vacate this judgment if Defendants succeeded on their appeal of *Lupin* to the Federal Circuit. Stipulation and Order, C.A. No. 12-cv-159-SLR, D.I. 83 (Sept. 30, 2013).

L. Defendants file more baseless lawsuits against other generic competitors.

119. On May 15, 2013, Defendants filed a lawsuit against Strides, Inc. and Agila Specialties Private Limited, in response to Strides and Agila's ANDAs to bring a generic Zymar (0.3%) and Zymaxid (0.5%) to market, again with paragraph IV certifications. Complaint, ¶¶ 25, 35, C.A. No. 13-cv-851-SLR (D. Del. May 15, 2013).

120. Despite having filed this lawsuit, Defendants offered to stipulate that the lawsuit would be precluded by the court's decision in Defendants' case against Lupin. Pls.' Answering Br. in Opp. to Defs.' Mot. to Dismiss, C.A. No. 13-cv-851-SLR, D.I. 15 (D. Del. Sept. 27, 2013).

121. On May 2, 2014, Defendants filed a lawsuit against Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc., in response to Aurobindo's recent ANDA to bring a generic

Zymaxid (0.5%) to market, again with a Paragraph IV certification. Complaint, ¶ 31, C.A. No. 14-cv-579-SLR (D. Del. May 2, 2014).

M. Defendants' scheme to block the entry of generic equivalents of Zymar and Zymaxid from the market resulted in vast profits for Defendants at the expense Plaintiff and the Class.

122. Defendants' anticompetitive actions delayed the entry of any generic competition from the market for over three years (at least from June 15, 2010 until October 3, 2013), and has limited generic competition even today to a single generic competitor offering a generic to Zymaxid only.

123. Defendants engaged in the anticompetitive actions described in this Complaint with the purpose of excluding or delaying generic entrants to the market, and in order to maintain their monopolistic pricing for Zymar and Zymaxid. Indeed, Defendants reported increasing the list price of Zymaxid over a period of several years while they drew out their litigation against potential generic competitors. *See* Allergan 10-K 2011: "Effective July 9, 2011, we increased the published U.S. list price for... *Zymaxid* ® ... by an additional fourteen percent"; Allergan 10-K 2012: "Effective January 7, 2012, we increased the published U.S. list price for ... *Zymaxid* ® by eight percent"; Allergan 10-K 2013: "Effective January 5, 2013, we increased the published U.S. list price for ... *Zymaxid* ® by five percent."

124. Defendants' anticompetitive actions resulted in Plaintiff and members of the Class paying higher prices for gatifloxacin opthalmic formulations than they would have paid if a generic equivalent to Zymar or Zymaxid had been available throughout the class period.

V. MARKET POWER AND RELEVANT MARKET

125. At all relevant times, Allergan had monopoly power over Zymar and Zymaxid because it had the power to maintain the price of the drug it sold as Zymar and Zymaxid at

supra-competitive levels without losing substantial sales to other products prescribed and/or used for the same purposes as Zymar and Zymaxid, with the exception of AB-rated generic versions of Zymar and Zymaxid.

126. A small, but significant, non-transitory price increase for Zymar or Zymaxid by Allergan would not have caused a significant loss of sales.

127. Zymar and Zymaxid do not exhibit significant, positive cross-elasticity of demand with respect to price with any product other than AB-rated generic versions of Zymar and Zymaxid.

128. There are no reasonably interchangeable drug products that are available to prescribing physicians for the indications for which gatifloxacin opthalmic formulations are prescribed.

129. Allergan needed to control only Zymar, Zymaxid and their AB-rated generic equivalents, and no other products, in order to maintain the prices of Zymar and Zymaxid profitably at supra-competitive prices. Only the market entry of competing, AB-rated generic versions of Zymar and Zymaxid would render Allergan unable to profitably maintain its current prices of Zymar and Zymaxid without losing substantial sales.

130. Allergan also sold Zymar and Zymaxid at prices well in excess of marginal costs, and substantially in excess of competitive prices, and enjoyed high profit margins.

131. Defendants have had, and exercised, the power to exclude and restrict competition to Zymar, Zymaxid and AB-rated bioequivalents.

132. Allergan, at all relevant times, enjoyed high barriers to entry with respect to competition to the above-defined relevant product market due to patent and other regulatory protections and high costs of entry and expansion.

133. To the extent that Plaintiffs are legally required to prove monopoly power through circumstantial evidence by first defining a relevant product market, Plaintiffs allege that the relevant market is gatifloxacin opthalmic formulations (Zymar and Zymaxid and its AB-rated generic equivalents). During the period relevant to this case, Allergan has been able to profitably maintain the price of gatifloxacin opthalmic formulations well above competitive levels.

134. The relevant geographic market is the United States and its territories. At least until October 3, 2013, Allergan's market share in the relevant market was 100%, implying a substantial amount of monopoly power.

VI. ANTICOMPETITIVE EFFECT

135. Defendants' anticompetitive conduct has enabled them to: (a) prevent and delay the entry of less expensive generic versions of Zymar and Zymaxid in the United States; (b) fix, raise, maintain, or stabilize the price of Zymar and Zymaxid; and (c) allocate 100% of the U.S. market for gatifloxacin opthalmic formulations to Allergan, at least until October 3, 2013.

136. During the relevant period, class members purchased Zymar and Zymaxid directly from Allergan. As a result of the Defendants' illegal conduct, these purchasers were compelled to pay artificially inflated prices for gatifloxacin opthalmic formulations. Those prices were substantially higher than the prices that Plaintiff and class members would have paid absent the illegal conduct alleged in this complaint.

137. As a consequence, purchasers of Zymar and Zymaxid have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount, forms, and components of such damages will be calculated after discovery and upon proof at trial.

138. Defendants' efforts to restrain competition in the market for gatifloxacin opthalmic formulations have substantially affected interstate and foreign commerce.

139. Defendants' unlawful concerted action has delayed or prevented the sale of generic Zymar and Zymaxid in the United States, and unlawfully enabled Allergan to sell Zymar and Zymaxid at artificially inflated, supra-competitive prices. But for Defendants' illegal, ongoing conduct, generic competition to Zymar and Zymaxid would have occurred before October 3, 2013, and there would be multiple generic competitors on the market today.

VII. CLASS ACTION ALLEGATIONS

140. Plaintiff brings this action on behalf of itself and, under Rules 23(a) and (b)(3) of the Federal Rules of Civil Procedure, as representative of a Class defined as follows:

> All persons or entities in the United States who purchased branded Zymar or Zymaxid directly from any of the Defendants at any time from June 15, 2010 until the anticompetitive effects of Defendants' unlawful conduct cease.

Excluded from the Class are Defendants, and their officers, directors, management, employees, subsidiaries, and affiliates, and all federal governmental entities.

141. But for Defendants' anticompetitive actions, generic versions of Zymar and Zymaxid would have been available before October 3, 2013 and there would be multiple generic competitors on the market today. But for Defendants' anticompetitive actions, Apotex would have brought to market a generic version of Zymar shortly after the expiration of the '470 patent on June 15, 2010. Other generic competitors would have gone to market shortly after their ANDAs were approved by the FDA. As a result of Defendants' unlawful conduct, there remains no generic version of Zymar available on the market. As a result of Defendants' unlawful conduct, Plaintiff and class members have paid higher prices for gatifloxacin ophthalmic formulations.

142. Members of the Class are so numerous that joinder is impracticable. Plaintiff believes the Class numbers in at least the dozens. Further, the Class is readily identifiable from information and records in the possession of Defendants. Direct notice to members of the Class should be feasible upon obtaining the relevant information and records in the possession of Defendants.

143. Plaintiff's claims are typical of those of each of the Class members. Plaintiff and Class members were damaged by the same wrongful conduct of Defendants, *i.e.*, as a direct and proximate result of Defendants' wrongful conduct, they paid artificially inflated prices for Zymar and Zymaxid and were deprived of the benefits of earlier and robust competition from cheaper generic versions of those products.

144. Plaintiff will fairly and adequately protect and represent the interests of the Class. The interests of Plaintiff are coincident with, and not antagonistic to, the interests of the Class members.

145. Plaintiff is represented by counsel with experience in the prosecution of class action antitrust litigation, with particular experience in class action antitrust litigation involving pharmaceutical products.

146. Questions of law and fact common to the Class members predominate over questions that may affect only individual Class members, because Defendants have acted on grounds generally applicable to the entire Class, thereby making overcharge damages with respect to the Class as a whole appropriate. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

147. Questions of law and fact common to the Class include, but are not limited to:

(a) whether Defendants conspired to willfully maintain and/or enhance Allergan's

monopoly power over gatifloxacin opthalmic formulations;

(b) whether Defendants conspired to create an unlawful monopoly in the market for gatifloxacin opthalmic formulations by making misrepresentations to the USPTO to obtain the '045 patent;

(c) whether Defendants conspired to suppress generic competition to Zymar or Zymaxid;

(d) whether Defendants filed litigation against Apotex, Lupin, Hi-Tech Pharmacal, Strides and Agila, and/or Aurobindo to prevent or delay them from marketing their generic equivalents of Zymar and Zymaxid in competition with Defendants;

(e) whether Defendants took advantage of the delay arising from the patent litigation and automatic 30-month stay of FDA approval of generic Zymar to bring to market a new gatifloxacin ophthalmic solution, 0.5% Zymaxid, and to extend their monopoly over gatifloxacin ophthalmic formulations;

(f) whether Allergan possessed market power or monopoly power over gatifloxacin ophthalmic formulations;

(g) whether Defendants' above-described conduct has substantially affected interstate and intrastate commerce;

(h) whether, and to what extent, Defendants' conduct caused antitrust injury (*i.e.*, overcharges) to Plaintiff and the Class members and if so, the appropriate measure of damages.

148. Class action treatment is the superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual

actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress for claims that could not practicably be pursued individually, substantially outweigh potential difficulties in management of this class action.

149. Plaintiff knows of no special difficulty that could be encountered in this action that would preclude its maintenance as a class action.

150. Certification of the Class is appropriate under Fed. R. Civ. P. 23(b)(3) because the above common questions of law or fact predominate over any questions affecting individual Class members, and a class action is superior to other available methods for the fair and efficient adjudication of this controversy.

151. Defendants' wrongful actions are generally applicable to the Class members as a whole, for which Plaintiff seeks, *inter alia,* damages.

152. Absent a class action, Defendants would retain the benefits of their wrongdoing despite their serious violations of the law and infliction of harm on Plaintiff and Class members.

VIII. CLAIMS FOR RELIEF

COUNT I

Monopolization in Violation of Section 2 of the Sherman Act

153. Plaintiff repeats and incorporates by reference the allegations in the preceding paragraphs as if fully set forth herein.

154. At all times throughout the class period, Allergan possessed monopoly power in the market for gatifloxacin ophthalmic solution, which includes Zymar, Zymaxid, and generic equivalents thereof.

155. Allergan has willfully maintained, and unless restrained by the Court will

continue to willfully maintain, that power by anticompetitive and unreasonably exclusionary conduct. Allergan has acted with an intent to illegally maintain its monopoly power in the gatifloxacin ophthalmic solution market, and its illegal conduct has enabled it to do so, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

156. At all material times, Allergan manufactured, promoted, distributed, and sold substantial amounts of gatifloxacin ophthalmic solution in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States.

157. The relevant product market is gatifloxacin ophthalmic solution for the treatment of bacterial infections.

158. Gatifloxacin ophthalmic solution is not reasonably interchangeable with other products that treat bacterial infections.

159. Gatifloxacin ophthalmic solutions are the only approved quinolone antibiotic ophthalmic solutions that contain the preservatives and permeability enhancers disodium edetate and benzalkonium chloride, which Allergan advertises as allowing for increased microbial resistance in comparison to other quinolone antibiotic ophthalmic solution products.

160. At all relevant times at least until October 3, 2013, Allergan maintained monopoly pricing power in the gatifloxacin ophthalmic solution market.

161. Allergan could and did impose significant, non-transitory price increases without losing sufficient sales to render gatifloxacin ophthalmic solution unprofitable.

162. At all relevant times at least until October 3, 2013, Allergan had a 100% market share in the gatifloxacin ophthalmic solution market.

163. The relevant geographic market is the United States and its territories.

164. But for Defendants' unlawful actions, Plaintiff and class members would have

benefitted from the presence of a low-cost generic gatifloxacin ophthalmic solution (0.3%) alternative to Zymar that Apotex, Lupin, or Strides and Agila could and would have supplied during the class period.

165. But for Defendants' unlawful actions, Plaintiff and class members would have benefitted from the presence of a low-cost generic gatifloxacin ophthalmic solution (0.5%) alternative to Zymaxid that Apotex, Lupin, Hi-Tech Pharmacal, Strides and Agila, and/or Aurobindo could and would have supplied during the class period.

166. Plaintiff and the Class are entitled to recover treble damages for their injuries under Section 4 of the Clayton Act, 15 U.S.C. § 15.

COUNT II

Conspiracy to Monopolize
in Violation of Section 2 of the Sherman Act

167. Plaintiff repeats and incorporates by reference the allegations in the preceding paragraphs as if fully set forth herein.

168. Defendants have deliberately contracted, combined, or conspired with the specific intent to achieve a monopoly and have committed the overt acts described herein in furtherance of the conspiracy in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

169. At all material times, Defendants manufactured, promoted, distributed, and sold substantial amounts of gatifloxacin ophthalmic solution in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States.

170. The relevant product market is gatifloxacin ophthalmic solution for the treatment of bacterial infections.

171. Gatifloxacin ophthalmic solution is not reasonably interchangeable with other products that treat bacterial infections.

172. Gatifloxacin ophthalmic solutions are the only approved quinolone antibiotic ophthalmic solutions that contain the preservatives and permeability enhancers disodium edetate and benzalkonium chloride, which Allergan advertises as allowing for increased microbial resistance in comparison to other quinolone antibiotic ophthalmic solution products.

173. At all relevant times at least until October 3, 2013, Allergan maintained monopoly pricing power in the gatifloxacin ophthalmic solution market.

174. Allergan could and did impose significant, non-transitory price increases without losing sufficient sales to render gatifloxacin ophthalmic solution unprofitable.

175. At all relevant times at least until October 3, 2013, Allergan maintained a 100% market share in the gatifloxacin ophthalmic solution market.

176. The relevant geographic market is the United States and its territories.

177. But for Defendants' unlawful actions, Plaintiff and class members would have benefitted from the presence of a low-cost generic gatifloxacin ophthalmic solution (0.3%) alternative to Zymar that Apotex, Lupin, or Strides and Agila could and would have supplied during the class period.

178. But for Defendants' unlawful actions, Plaintiff and class members would have benefitted from the presence of a low-cost generic gatifloxacin ophthalmic solution (0.5%) alternative to Zymaxid that Apotex, Lupin, Hi-Tech Pharmacal, Strides and Agila, or Aurobindo could and would have supplied during the class period.

179. Plaintiff and the Class are entitled to recover treble damages for their injuries under Section 4 of the Clayton Act, 15 U.S.C. § 15.

COUNT III

Unreasonable Restraint of Trade in Violation of Section 1 of the Sherman Act

180. Plaintiff repeats and incorporates by reference the allegations in the preceding paragraphs as if fully set forth herein.

181. Defendants have illegally contracted, combined, or conspired to restrain trade in the gatifloxacin ophthalmic formulation market in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

182. At all material times, Defendants manufactured, promoted, distributed, and sold substantial amounts of gatifloxacin ophthalmic solution in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States.

183. The relevant product market is gatifloxacin ophthalmic solution for the treatment of bacterial infections.

184. Gatifloxacin ophthalmic solution is not reasonably interchangeable with other products that treat bacterial infections.

185. Gatifloxacin ophthalmic solutions are the only approved quinolone antibiotic ophthalmic solutions that contain the preservatives and permeability enhancers disodium edetate and benzalkonium chloride, which Allergan advertises as allowing for increased microbial resistance in comparison to other quinolone antibiotic ophthalmic solution products.

186. At all relevant times at least until October 3, 2013, Allergan maintained monopoly pricing power in the gatifloxacin ophthalmic solution market.

187. Allergan could and did impose significant, non-transitory price increases without losing sufficient sales to render gatifloxacin ophthalmic solution unprofitable.

188. At all relevant times at least until October 3, 2013, Allergan had a 100% market

share in the gatifloxacin ophthalmic solution market.

189. The relevant geographic market is the United States and its territories.

190. But for Defendants' unlawful actions, Plaintiff and class members would have benefitted from the presence of a low-cost generic gatifloxacin ophthalmic solution (0.3%) alternative to Zymar that Apotex, Lupin, or Strides and Agila could and would have supplied during the class period.

191. But for Defendants' unlawful actions, Plaintiff and class members would have benefitted from the presence of a low-cost generic gatifloxacin ophthalmic solution (0.5%) alternative to Zymaxid that Apotex, Lupin, Hi-Tech Pharmacal, Strides and Agila, or Aurobindo could and would have supplied during the class period.

192. Plaintiff and the Class are entitled to recover treble damages for their injuries under Section 4 of the Sherman Act, 15 U.S.C. § 15.

IX. JURY TRIAL DEMAND

193. Under Federal Rule of Civil Procedure 38, Plaintiff demands a trial by jury of all issues so triable in the complaint.

X. PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully prays that:

(a) The acts alleged herein be adjudged and decreed to be unlawful and willful acts of monopolization in violation of Section 2 of the Sherman Act;

(b) The acts alleged herein be adjudged and decreed to be unlawful and willful acts in restraint of trade in violation of Section 1 of the Sherman Act;

(c) Plaintiff and the Class be awarded three-fold the damages determined to have been sustained, and that judgment be entered against Defendants in favor of Plaintiff and the

Class;

(d) Plaintiff and the Class recover its costs of suit, including reasonable attorneys' fees as provided by law; and

(e) Plaintiff and the Class be granted such other, further, and different relief as the nature of the case may require or as may be determined to be just, equitable, and proper by this Court.

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