

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

CÉSAR CASTILLO, INC., individually and
on behalf of all those similarly situated,

Plaintiff,

v.

TELIGENT, INC., PERRIGO COMPANY
PLC, TARO PHARMACEUTICAL
INDUSTRIES LTD., and TARO
PHARMACEUTICALS USA, INC.,

Defendants.

Civil Action No.

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

Plaintiff César Castillo, Inc. (“Plaintiff”), a corporation organized under the laws of the Commonwealth of Puerto Rico, with its principal place of business and headquarters located at Bo. Quebradas Arena, Rd. #1 Km. 26.0, Rio Piedras, Puerto Rico, 00926, files this civil action pursuant to Section 1 of the Sherman Act, Section 4 of the Clayton Act, and Rule 23 of the Federal Rules of Civil Procedure, for damages, costs of suit, and other relief as may be just and proper, on behalf of itself and a class of those similarly situated (“Class” as defined below) against the following Defendants, for their conspiracy to artificially fix, raise, maintain and/or stabilize the prices of generic econazole nitrate products (“econazole”):

Teligent, Inc.
105 Lincoln Avenue
Buena, NJ 08310

Perrigo Company PLC
Treasury Building
Lower Grand Canal St.
Dublin 2, Ireland

Taro Pharmaceutical Industries Ltd.
14 Hakitor St.
Haifa Bay, 2624761, Israel

Taro Pharmaceuticals USA, Inc.
Three Skyline Drive
Hawthorne, NY 10532

Based upon personal knowledge, information, belief, and investigation of counsel, Plaintiff specifically alleges as follows.

INTRODUCTION

1. Beginning no later than June of 2014, the major U.S. manufacturers of econazole conspired to artificially fix, raise, maintain and/or stabilize the prices of econazole sold throughout the United States, in violation of Section 1 of the Sherman Act.

2. Plaintiff seeks to represent a class consisting of all persons in the United States who purchased econazole directly from Defendants during the period beginning June 1, 2014, and through the present.

3. Generic econazole is a prescription topical cream antifungal used to treat a variety of inflammatory skin infections (including, e.g., tinea, pityriasis versicolor, tinea pedis, dermatophytosis, and eczema marginatum).

6. Plaintiff's allegations are based in part on information made public during government investigations of the Defendants and others for unlawful conduct in the generic drug industry. In 2014, the United States Department of Justice ("DOJ") commenced an criminal investigation of the generic drug industry, leading to its issuance of a grand jury subpoena to Defendant Taro Pharmaceuticals USA, Inc. ("Taro, Inc.") on September 8, 2016. Public filings have disclosed that the DOJ is investigating Taro Inc.'s generic drug pricing, and that econazole is not the only drug at issue.

7. The DOJ's 2014 investigation followed a Congressional hearing and investigation prompted by correspondence from the National Community Pharmacists Association ("NCPA") to the U.S. Senate Health Education Labor and Pensions ("HELP") Committee and the U.S. House Energy and Commerce Committee in January of 2014, requesting hearings as to the significant increases in generic drug pricing. The NCPA's news release reports price hikes on essential generic drugs exceeding 1,000% in some instances, according to its survey of over a thousand community pharmacists.¹

4. Defendants' price increases were contrary to their respective unilateral self-interests. Like any generic drug, econazole is a commodity product. Therefore, absent a conspiracy or factors justifying a price increase, if any manufacturer substantially increased the price of econazole, its competitors would not be expected to increase their prices by similar

¹ The letter is available at <https://www.ncpanet.org/pdf/leg/jan14/letter-generic-spikes.pdf>. The news release is available at <http://bit.ly/2i3WIg3>.

amounts, but would be expected seek to sell more econazole to that manufacturer's customers. In other words, it would be contrary to any manufacturer's unilateral self-interest to substantially increase its price for econazole unless it had agreed with the other manufacturers that they would do the same.

5. The only factors that would have justified such price increases would have been a significant increase in the costs of making econazole, a significant decrease in the supply of econazole, or a significant increase in demand for econazole. None of those transpired in 2014. Absent these factors, substantial price increases would have been contrary to each Defendant's unilateral self-interest absent the existence of a cartel.

JURISDICTION AND VENUE

6. This action arises under section 1 of the Sherman Act, 15 U.S.C. § 1 and section 4 of the Clayton Act, 15 U.S.C. § 15(a), and seeks to recover treble damages, costs of suit and reasonable attorneys' fees for the injuries sustained by Plaintiff and members of the Class resulting from Defendants' conspiracy to restrain trade in the United States. The Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1337(a), 1407, and 15 U.S.C. § 15.

7. Venue is proper in this District pursuant to 15 U.S.C. §§ 15(a), 22 and 28 U.S.C. §§ 1391(b), (c), and (d) because, during the Class Period, Defendants resided, transacted business, were found, or had agents in this District, and a substantial portion of their activity that affected the interstate trade and commerce discussed below has been carried out in this District.

8. During the Class Period, Defendants sold and shipped econazole in a continuous and uninterrupted flow of interstate commerce, including in this District. Defendants' conduct had direct, substantial, and reasonably foreseeable effects on interstate commerce in the United States, including in this District.

9. This Court has *in personam* jurisdiction over Defendants because each, either directly or through the ownership and/or control of its subsidiaries, *inter alia*: (a) transacted business throughout the United States, including in this District; (b) participated in the sale and distribution of econazole throughout the United States, including in this District; (c) had and maintained substantial aggregate contacts with the United States as a whole, including in this District; or (d) was engaged in an illegal price-fixing conspiracy that was directed at, and had a direct, substantial, reasonably foreseeable and intended effect of causing injury to, the business or property of persons and entities residing in, located in, or doing business throughout the United States, including in this District. Defendants also conduct business throughout the United States, including in this District, and they have purposefully availed themselves of the laws of the United States.

10. By reason of the unlawful activities alleged herein, Defendants substantially affected commerce throughout the United States, causing injury to Plaintiff and members of the Class. Defendants, directly and through their agents, engaged in activities affecting all states, to restrict output and fix, raise, maintain and/or stabilize prices in the United States for econazole, which unreasonably restrained trade and adversely affected the market for econazole.

11. Defendants' conspiracy and unlawful conduct described herein adversely affected persons and entities in the United States who directly purchased econazole manufactured by Defendants, including Plaintiff and the members of the Class.

PARTIES

A. Plaintiff

12. Plaintiff César Castillo, Inc. is a corporation organized under the laws of the Commonwealth of Puerto Rico, with its principal place of business and headquarters located at

Bo. Quebradas Arena, Rd. #1 Km. 26.0, Rio Piedras, Puerto Rico, 00926. During the Class Period, Plaintiff purchased econazole directly from one or more Defendants. As a direct and proximate result of Defendants' collusion, manipulative conduct, and unlawful acts, Plaintiff was injured in its business or property.

B. Defendants

13. Defendant Teligent, Inc. ("Teligent") is a Delaware corporation with its principal place of business and manufacturing facilities in Buena, New Jersey. Teligent markets and sells generic econazole throughout the United States. Teligent is a specialty generic pharmaceutical company engaged in the development, manufacture, and marketing of generic topical and branded generic injectable pharmaceuticals, and markets its products primarily to drug wholesalers, retail drug chains, distributors, and government agencies. Before October 2015, Teligent operated under the name IGI Laboratories, Inc. ("IGI Labs"). During the Class Period, Teligent sold generic econazole to purchasers in this District and throughout the United States..

14. Defendant Perrigo Company PLC ("Perrigo") is an international consumer healthcare and pharmaceutical company with its principal place of business in Dublin, Ireland. Perrigo develops, manufactures, and markets generic and specialty pharmaceutical drugs, including econazole, throughout the United States. Perrigo's U.S. headquarters is in Allegan, Michigan. During the Class Period, Perrigo sold generic econazole to purchasers in this District and throughout the United States.

15. Defendant Taro Pharmaceutical Industries Ltd. ("Taro Ltd.") is an Israeli company with its principal place of business in Haifa Bay, Israel. Taro Ltd. develops, manufactures, and markets prescription drugs, including econazole, throughout the United States. Taro Ltd. has operated in the United States principally through its subsidiary, defendant Taro

Pharmaceuticals USA, Inc. (“Taro, Inc.”). During the Class Period, Taro Ltd. sold generic econazole to purchasers in this District and throughout the United States.

16. Defendant Taro Inc. is a New York corporation with its principal place of business in Hawthorne, New York. Taro, Inc. is a wholly-owned subsidiary of Taro Ltd. and is responsible for the marketing and sale of generic econazole throughout the United States. During the Class Period, Taro, Inc. sold generic econazole to purchasers in this District and throughout the United States.

17. Various other entities and individuals currently unknown to Plaintiffs may have also participated as co-conspirators in the acts complained of and/or performed acts that aided and abetted and/or otherwise furthered the conspiracy’s objectives and unlawful conduct alleged herein.

CLASS ALLEGATIONS

18. Plaintiff brings this action on behalf of itself and, pursuant to Federal Rules of Civil Procedure 23(a) and 23(b)(3), as representative of a class (the “Class”) defined as follows:

All persons who or entities which purchased econazole directly from any of the Defendants, or any current or former subsidiary or affiliate thereof, or any co-conspirator, in the United States, during the period from and including June 1, 2014 through the present. Excluded from the Class are Defendants and their officers, directors, management, employees, subsidiaries, or affiliates, and all governmental entities.

19. The Class Members are so numerous and geographically dispersed that joinder of all members is impracticable.

20. Plaintiff’s claims are typical of the claims of the other Class Members. Plaintiff and other Class members have all sustained damage in that, during the Class Period, they purchased econazole at artificially maintained, non-competitive prices, established by the Defendants’ actions in connection with the violations alleged herein.

21. Plaintiff will fairly and adequately protect the interests of all Class Members. Plaintiff has purchased econazole directly from at least one of the Defendants. Plaintiff has retained counsel competent and experienced in class action and antitrust litigation. Plaintiff's interests are coincident with, and not antagonistic to, the interests of the other Class Members.

22. Common questions of law and fact exist with respect to all Class Members and predominate over any questions solely affecting individual members. The common legal and factual questions, which do not vary among Class Members include, but are not limited to, the following:

(a) Whether and to what extent Defendants and their co-conspirators engaged in a contract, combination, or conspiracy to fix, raise, maintain, or stabilize the prices of econazole in the United States;

(b) The scope and duration of the contract, combination, or conspiracy, the identity of its participants, and the acts undertaken in its furtherance;

(c) The effect of the contract, combination, or conspiracy on the prices of econazole in the United States during the Class Period;

(d) Whether and to what extent Defendants' conduct resulted in supracompetitive prices for econazole;

(e) Whether and to what extent Defendants' conduct injured Plaintiff and other Class Members; and

(f) The appropriate measure of damages sustained by Plaintiff and other Class Members.

23. A class action is superior to any other method for the fair and efficient adjudication of these issues, as joinder of all members is impracticable. The damages suffered

by many Class Members are small in relation to the expense and burden of individual litigation, and therefore, it is highly impractical for such Class Members to individually attempt to redress the wrongful anticompetitive conduct alleged herein.

FACTUAL ALLEGATIONS

A. Overview of Generic Drug Market

1. Generic drugs lead to lower prices

24. Generic drugs typically provide consumers with a lower cost alternative to brand-name drugs while providing the same treatment. Specifically:

A generic drug is the same as a brand name drug in dosage, safety, strength, how it is taken, quality, performance, and intended use. Before approving a generic drug product, FDA requires many rigorous tests and procedures to assure that the generic drug can be substituted for the brand name drug. The FDA bases evaluations of substitutability, or “therapeutic equivalence,” of generic drugs on scientific evaluations. By law, a generic drug product must contain the identical amounts of the same active ingredient(s) as the brand name product. Drug products evaluated as “therapeutically equivalent” can be expected to have equal effect and no difference when substituted for the brand name product.²

25. Further, “[d]rug products classified as therapeutically equivalent can be substituted with the full expectation that the substituted product will produce the same clinical effect and safety profile as the prescribed product.”³

26. Generic versions of brand drugs are priced significantly below the brand versions. Because of the price differentials, and other institutional features of the pharmaceutical market, generic versions are liberally and substantially substituted for their brand counterparts. In every state, pharmacists are permitted (and, in some states, required) to substitute a generic product for a brand product unless the doctor has indicated that the prescription for the brand product must

² FDA, Generic Drugs: Questions and Answers, *available at* <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm>.

³ *Id.*

be dispensed as written. States adopted substitution laws following the federal government's 1984 enactment of the Hatch-Waxman Act (discussed in more detail below).

27. The FDA has recognized that “[g]eneric competition is associated with lower drug prices[.]”⁴ A Federal Trade Commission study reached the same conclusion finding that in a “mature generic market, generic prices are, on average, 85% lower than the pre-entry branded drug prices.”⁵ Economic literature in the healthcare market further confirms that competition by generic products results in lower prices for consumers. In the period before generic entry, a brand drug commands 100% of the market share for that drug and the brand manufacturer can set the price without the impact of competitive market forces. Once the first generic enters the market, however, a brand drug rapidly loses sales, on average 90% within a year.⁶ As more generic manufacturers enter the market, prices for generic versions of a drug predictably will continue to decrease because of competition among the generic manufacturers, and the loss of sales volume by the brand drug to the corresponding generic accelerates as more generic options are available to purchasers:⁷

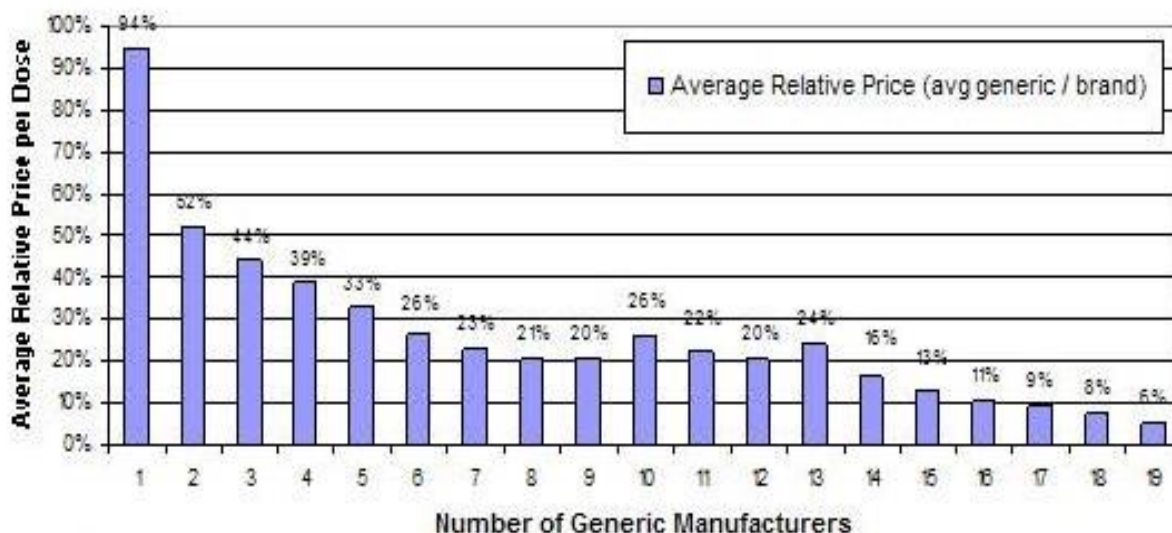
⁴ FDA, Generic Competition and Drug Prices, *available at* <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm>.

⁵ FTC, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS, at 8 (Jan. 2010), *available at* <https://www.ftc.gov/reports/pay-delay-how-drug-company-pay-offs-costconsumers-billions-federal-trade-commission-staff>.

⁶ *Id.*

⁷ See, e.g., Ernst R. Berndt et al., *Authorized Generic Drugs, Price Competition, and Consumers' Welfare*, HEALTH AFFAIRS, 26, no. 3 (2007):790-799.

Generic Competition and Drug Prices



Source: FDA analysis of retail sales data from IMS Health, IMS National Sales Perspective (TM), 1999-2004, extracted February 2005

28. A mature generic market, such as the markets for doxycycline and digoxin, has several generic competitors. Due to the fact that each generic is readily substitutable for another generic of the same brand drug, the products behave like commodities, with pricing being the main differentiating feature and the basis for competition among manufacturers.⁸ Over time, generics' pricing nears the generic manufacturers' marginal costs.

29. Generic competition usually enables purchasers to (a) purchase generic versions of the brand drug at a substantially lower price than the brand drug, and/or (b) purchase the brand drug at a reduced price. Generic competition to a single blockbuster brand drug product can result in billions of dollars in savings to direct purchasers, consumers, insurers, local, state, and

⁸ See, e.g., FTC, AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACT, at 17 (Aug. 2011) (“[G]eneric drugs are commodity products marketed to wholesalers and drugstores primarily on the basis of price.”); Congressional Budget Office, “How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry” (July 1998).

federal governments, and others. Indeed, one study found that the use of generic medicines saved the United States healthcare system \$254 billion in 2014 alone, and \$1.68 trillion between 2005 and 2014.⁹

2. How generic drugs come to market

30. Under the Federal Food, Drug, and Cosmetic Act (“FDCA”), manufacturers that create a new drug must obtain FDA approval to sell the product by filing a New Drug Application (“NDA”). 21 U.S.C. §§ 301-392. An NDA must include specific data concerning the safety and effectiveness of the drug, as well as information on applicable patents. 21 U.S.C. § 355(a), (b).

31. The Hatch-Waxman Act, enacted in 1984, simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs.¹⁰ Hatch-Waxman allows a manufacturer seeking approval to sell a generic version of a brand drug to file an Abbreviated New Drug Application (“ANDA”). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer’s NDA, and must show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug, and is absorbed at the same rate and to the same extent as the brand drug. This establishes that the generic drug is pharmaceutically equivalent and bioequivalent (together, “therapeutically equivalent”) to the brand drug. The FDA assigns generic drugs that are therapeutically equivalent to and are of the same dosage strength and form

⁹ Generic Pharmaceutical Association, *Generic Drug Savings in the U.S.*, at 1 (2015), available at http://www.gphaonline.org/media/wysiwyg/PDF/GPhA_Savings_Report_2015.pdf.

¹⁴ See Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

as their brand counterpart an “AB” rating.

32. Most drug companies that want to introduce a generic drug to the market file an ANDA with the FDA’s Center for Drug Evaluation and Research, Office of Generic Drugs. The only exception is for so-called “authorized generics,” which are generics launched under the brand company’s NDA but typically priced like other generics.

33. Generic drugs that are bioequivalent to a brand drug (sometimes called the “Reference Listed Drug” or “RLD”) are assigned a Therapeutic Equivalence Code (“TE Code”). An oral generic drug product will be coded “AB” if bioequivalence is demonstrated. The purpose of this coding is to allow users to determine whether the FDA has evaluated a particular approved product as therapeutically equivalent to other pharmaceutically equivalent products and to provide information on the basis of the FDA’s evaluations. Thus, generic drugs that are AB-rated to the brand share the same safety and efficacy characteristics and are the same dosage size and form.

B. The Generic Econazole Market

34. The market for generic econazole is mature, as the product has been on the market since 1999. Physicians prescribed econazole for more than one million patients in the United States during the Class Period. In 2015 alone, total sales revenue for econazole spiked to well over \$400 million, which exceeds the sales revenue for the same products from 2011-2014 combined. This type of revenue growth in a mature market reflects Defendants’ collusion.

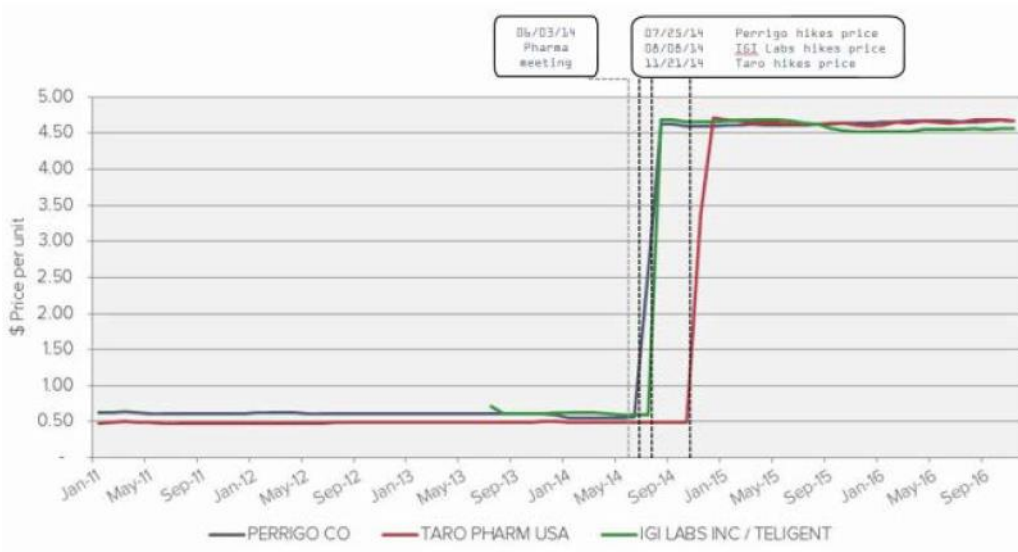
35. Over the course of the class period, Defendants dominated the market for econazole, with their sales comprising approximately 94% of all U.S. econazole sales and 97.3% of the generic econazole market. Those shares, as well as the Defendants’ respective shares, have

remained substantially constant over the last several years. In 2014 Perrigo’s econazole sales exceeded \$146 million, Taro’s exceeded \$41 million, and Teligent’s exceeded \$14 million.

36. Prior to June 2014, the pricing of generic econazole had remained stable for years. However, prices increased sharply in the four months following June 2014, when generic pharmaceutical manufacturers met for a conference of the Generic Pharmaceutical Association (“GPhA”) in Bethesda, Maryland.



Defendants’ Econazole List Prices



37. In the months following the June 2014 GPhA meeting, Defendants effected a coordinated series of price increases, jointly raising econazole prices by 539% in the second half of 2014 alone, and maintaining prices at that level thereafter. These price increases occurred in lockstep, with all Defendants raising prices to virtually identical levels in a four-month period:



38. There have been no drug shortages, supply disruptions, increases in demand for econazole or Defendants' costs, or any other lawful market phenomena, to explain the price

increases. Federal law requires drug manufacturers to report drug shortages to the FDA. None of the Defendants reported any such shortages or supply disruptions during the relevant period. In fact, Defendants cannot proffer any meaningful explanation for their simultaneous price increases. Tellingly, there were no similar price increases in other developed countries, where prices have generally remained flat.

39. Accepted economic principles dictate that, when there are multiple generics on the market, prices should remain stable at highly competitive levels, and should not increase suddenly and substantially absent anticompetitive conduct. The increase as to econazole is highly suggestive of Defendants' collective market dominance, absent which their pricing excesses would be disciplined by losing market share to non-colluding competitors.

40. Defendants' collective dominance is further reflect in the Herfindahl-Hirschman Index ("HHI") figures for econazole. The HHI reduces the market shares of all firms in an industry to a single number so as to measure their collective market power, and is generally considered indicative of the degree of competition among such firms. An HHI of 0 indicates a perfectly competitive market. The United States Department of Justice and the Federal Trade Commission designate any industry with an HHI over 2,500 as "highly concentrated." Since the beginning of 2012, econazole's HHI on average has exceeded 4,500.

C. Defendants' Annual Reports and Investor Communications

41. According to Teligent's 2015 Annual Report, econazole accounted for 45% of the company's total revenue in 2015, and 38% of its total revenue in 2014.

42. On an October 24, 2014 earnings call, Teligent President and CEO Jason Grenfell-Gardner observed that Teligent's price increases had significantly raised the company's revenues: "Year-to-date in 2014, we recognized \$9.3 million in sales of [Teligent]

label products, that's an increase of 123% over the same period last year. This growth has been driven partially through . . . some significant price increases for core products in the portfolio.”

43. Grenfell-Gardner and Jenniffer Collins, Teligent's CFO, continued to recognize the “favorable pricing environment” for econazole in a March 2, 2015, earnings call for the fourth quarter of 2014. On a subsequent call, Collins attributed the company's 56% increase in revenue over the same period in 2014 to econazole, noting that the product represented 53% of the company's total revenue for the first quarter of 2015.

44. Perrigo's 2015 Annual Report reflected its intention to “broaden[] leadership in our core base business of extended topical products with limited competition and attractive margins.”

45. During the August 14, 2014 fourth quarter earnings call, held within months of the increase in econazole prices, Joseph C. Papa, chairman, CEO and President of Perrigo noted that prescription drugs, such as econazole, provided the “greatest upside” for pricing. He cited prescription drugs for Perrigo's “record results, growing sales 12% with an adjusted operating margin of 46%” during the 2015 first quarter earnings call on February 7, 2015.

46. During a November 10, 2014, earnings call, Taro CEO Kal Sundaram attributed the company's significant growth to price increases:

In 2010, as per IMS data, Taro was ranked third among the genetic dermatology companies in USA. In terms of sales, now it is ranked number one for the past three years. U.S. remains the dominant market for Taro. Taro's earnings per share also has grown 50% CAGR, compounded annual growth, since 2010. Taro's sales and earnings growth is attributable to upward price adjustments and the prudent life cycle management of our product portfolio while our overall volumes remain relatively constant and we remain cautious about the long-term sustainability of these prices. Our sales and earnings growth is attributable to upward price adjustments and prudent life cycle management of our portfolio, while our overall volumes remain relatively constant. Again market to volume fluctuations can happen for very different reasons as and when a new generation product comes, it will have impact on the older generation product. And once again I am saying

generics remain to be sort of, what do you say cost value for money and competitive. I don't think there will be any significant—we have seen any significant impact of volume shifting because of price adjustments.

46. Sundaram again emphasized Taro's strategy of relying upon high-priced generics in a November 4, 2015, earnings call, stating that "We are a specialty generic company, so by definition, our portfolio will be obviously narrow but sort of focused. We operate in niche markets; smaller volumes, but better priced."

D. Defendants' Collusion Opportunities at Trade Association Meetings

47. Generic drug manufacturers attend industry trade shows throughout the year, including those hosted by the GPhA, the National Association of Chain Drug Stores, the Healthcare Distribution Management Association (now the Healthcare Distribution Alliance), and Efficient Collaborative Retail Marketing.

48. The DOJ is reportedly looking closely at trade associations. According to an intelligence report from Policy and Regulatory Report, a source that was given inside information by someone with knowledge of the DOJ's investigation, the DOJ is looking closely "at trade associations as part of their investigation as having been one potential avenue for facilitating the collusion between salespeople at different generic producers."¹¹

49. The GPhA describes itself as "the nation's leading trade association for manufacturers and distributors of generic prescription drugs, manufacturers of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic industry."

See <http://www.gphaonline.org/about/the-gpha-association/>. GPhA was formed in 2000 from the

¹¹ Eric Palmer, *Actavis gets subpoena as DOJ probe of generic pricing moves up food chain*, FiercePharma, Aug. 7, 2015 (available at <http://bit.ly/2hHE6iK>).

merger of three industry trade associations: GPhA, the National Association of Pharmaceutical Manufacturers, and the National Pharmaceutical Alliance.

50. According to GPhA's website, "GPhA member companies supply approximately 90 percent of the generic prescription drugs dispensed in the U.S. each year." *See* <http://bit.ly/2i8kCon>. GPhA further claims that, "[b]y becoming part of GPhA, you can participate in shaping the policies that govern the generic industry and help secure the future of this vital pharmaceutical market segment. In addition, GPhA provides valuable membership services, such as business networking opportunities, educational forums, access to lawmakers and regulators, and peer-to-peer connections." *Id.*

51. Representatives of each of the defendants attended the GPhA meetings in Bethesda, Maryland on June 3-4, 2014, and November 2-4, 2014.

E. Industry Commentary

52. Comments from industry analysts suggest manufacturers' alternative explanations for price increases are pretextual and intended to obscure Defendants' conspiracy. In a report dated April 21, 2015, Sector & Sovereign Research concluded that: "A plausible explanation is that generic manufacturers . . . are cooperating to raise the prices of products whose characteristics (low sales due to either very low prices or very low volumes) accommodate price inflation." *See US Generic Inflation Continues in 1Q15*, Apr. 21, 2015 (available at <http://bit.ly/2i0NkJT>).

53. Bloomberg News reported the following:

Bill Drilling, an owner of a pharmacy in Sioux City, Iowa, apologizes as he rings up a customer's three-month supply of the heart medicine digoxin. The total is \$113.12—almost 10 times the cost for the same prescription in August.

* * *

"This is starting to create hardship," he says. Many of his customers fall into what is known as the Medicare "doughnut hole," a coverage gap in which patients pay

47.5 percent of branded-drug costs and 79 percent of a generic's price. Russ Clifford, a retired music teacher, learned digoxin's cost had jumped more than fourfold when he picked up his 30-day supply in mid-November. Clifford and his wife have had to dip into savings to pay their rising pharmaceutical bills.

Alan Katz, *Surprise! Generic-Drug Prices Spike*, Dec. 12, 2013 (available at <http://bloom.bg/2hqDgZW>).

F. Government Investigations

54. Defendants' price increases have resulted in scrutiny from both federal and state government authorities.

55. Taro Ltd.'s SEC Form 6-K, filed on September 9, 2016, announced that Taro Inc., "as well as two senior officers in its commercial team, received grand jury subpoenas from the United States Department of Justice, antitrust Division, seeking documents relating to corporate and employee records, generic pharmaceutical products and pricing, communications with competitors and others regarding the sale of generic pharmaceutical products, and certain other related matters."

56. The DOJ's mere issuance of grand jury subpoenas is highly indicative of anticompetitive conduct. The DOJ's *Antitrust Division Manual* provides that "staff should consider carefully the likelihood that, if a grand jury investigation developed evidence confirming the alleged anticompetitive conduct, the Division would proceed with a criminal prosecution."¹¹ And if a grand jury request memorandum is approved by the DOJ field office chief, "a grand jury request should be emailed to the ATR-CRIM-ENF [Antitrust Criminal Enforcement Division]."¹² Then, "[t]he DAAG [Deputy Assistant Attorney General] for Operations, the Criminal DAAG, and the Director of Criminal Enforcement will make a recommendation to the Assistant Attorney General. If approved by the Assistant Attorney General, letters of authority are issued for all attorneys who will participate in the grand jury

investigation.”¹³ Finally, “[t]he investigation should be conducted by a grand jury in a judicial district where venue lies for the offense, such as a district from or to which price-fixed sales were made or where conspiratorial communications occurred.”¹⁴

57. No later than November 3, 2014, the DOJ opened a wide-ranging grand jury investigation into the marketing and pricing practices of generic drugs, which has resulted in the issuance of grand jury subpoenas several generic drug manufacturers.

58. Congress has also taken an interest in the matter. On October 2, 2014, U.S. Senator Bernie Sanders and U.S. Congressman Elijah Cummings sent letters to several generic drug manufacturers, including Defendants Lannett and Mylan, asking for detailed information regarding their generic drug price increases, which included the following:

This dramatic increase in generic drug prices results in decreased access for patients. According to the National Community Pharmacists Association (NCPA), a 2013 member survey found that pharmacists across the country “have seen huge upswings in generic drug prices that are hurting patients and pharmacies ability to operate” and “77% of pharmacists reported 26 or more instances over the past six months of a large upswing in a generic drug’s acquisition price.” These price increases have a direct impact on patients’ ability to purchase their needed medications. The NCPA survey found that “pharmacists reported patients declining their medication due to increased co-pays,” and “84% of pharmacists said that the acquisition price/lagging reimbursement trend is having a ‘very significant’ impact on their ability to remain in business to continue serving patients.”

Ltr. from Sen. Sanders and Rep. Cummings to A. Bedrosian, Oct. 2, 2014 (available at <http://bit.ly/2iaYFaM>).

59. On November 20, 2014, Senator Sanders’ Senate Subcommittee on Primary Health and Aging held a hearing entitled “Why Are Some Generic Drugs Skyrocketing In Price?” The committee heard testimony from pharmacist, who explained “it was extremely concerning when about a year ago, pharmacies began noticing a rash of dramatic price increases for many common, previously low-cost generic drugs.”¹⁷ Using generic digoxin and

doxycycline as examples of two of the generic drugs with price spikes, the pharmacist explained:

A recent example from my own experience is the price of Digoxin—a drug used to treat heart failure. The price of this medication jumped from about \$15 for 90 days’ supply, to about \$120 for 90 days’ supply. That’s an increase of 800%. One of my patients had to pay for this drug when he was in the Medicare Part D coverage gap in 2014. Last year, when in the coverage gap he paid the old price. This year he paid the new price. Needless to say, the patient was astounded, and thought I was overcharging him. The patient called all around to try to get the medicine at the old, lower price, but to no avail. This caused him lots of stress and time, and caused us lots of stress and time in explaining the situation, reversing, and rebilling the claim. This example is typical of how these price spikes put consumers and pharmacists in a bad position, often grasping at straws for explanations. And all the while, everyone pays more, including the patient, the pharmacy, and the insurer (often the federal government).

Testimony of Rob Frankil, Independent Pharmacist and Member of the National Community Pharmacists Association (NCPA), November 20, 2014, at 3-4 (available at <http://bit.ly/2iewtDK>).

60. Additional congressional hearings concerning the dramatic rise of generic drug prices were held in December 2015 and February 2016. At the U.S. Senate, Special Committee on Aging’s December 9, 2015 hearing, the Director of the Drug Information Service of the University of Utah noted the deleterious effect these drug prices have had on patient access and healthcare: “[w]hen medication prices increase in an unpredictable and dramatic way, this can create an access issue for hospitals and patients. If hospitals cannot afford to stock a product in the same amount due to price increases, this effectively creates a shortage.”

61. On February 24, 2015, Senator Sanders and Congressman Cummings sent a letter requesting that the Office of the Inspector General (“OIG”) of the Department of Health and Human Services “examine recent increases in the prices being charged for generic drugs and the effect these price increases have had on generic drug spending within the Medicare and

Medicaid programs.”¹⁹ The OIG responded to the request on April 13, 2015 advising would examine pricing for the top 200 generic drugs to “determine the extent to which the quarterly [Average Manufacturer Pricing] exceeded the specified inflation factor.”¹²

62. According to a November 3, 2016, *Bloomberg* report: “U.S. prosecutors are bearing down on generic pharmaceutical companies in a sweeping criminal investigation into suspected price collusion” and that, according to the DOJ, “the first charges could emerge by the end of the year.” As predicted, on December 12, 2016, the DOJ charged two generic industry executives with criminal counts related to price collusion for generic doxycycline hyclate and glyburide.

63. The DOJ investigation of price-fixing in the generic drug industry is ongoing.

G. The Econazole Market is Conducive to an Effective Conspiracy.

64. Characteristics specific to the market for econazole in the United States make it conducive to a price-fixing agreement.

65. **The Market is Highly Concentrated:** The domestic econazole market is highly concentrated. Three manufacturers substantially control the entire market. *See supra* ¶ 40.

66. **The Market has High Barriers to Entry:** Conspiracies that raise product prices above competitive levels will, all things being equal, attract to the relevant market new firms seeking to benefit from supracompetitive prices. But when barriers to entering the market are significant, new firms are less likely to do so. Barriers to entry thereby facilitate the maintenance of a price-fixing conspiracy. Significant barriers limit entry into the econazole market. Econazole production is capital-intensive, subject to high manufacturing costs, high intellectual property costs, and expenses related to regulatory approval and oversight.

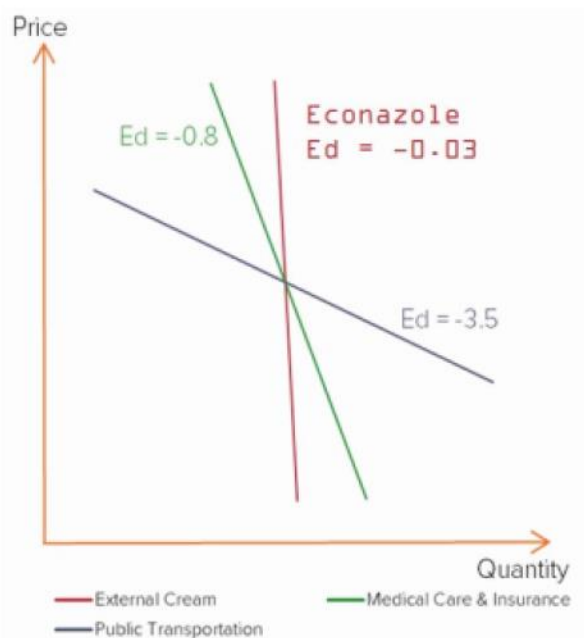
¹² Ltr., D. Levinson to Sen. Sanders, Apr. 13, 2015 (available at <http://bit.ly/2iboYLF>).

67. **Demand for Econazole is Inelastic:** “Elasticity” is a term that describes the sensitivity of demand for a product to changes in its price. Demand is “inelastic” if an increase in its price results in a relatively small decline in demand for the product. Demand is inelastic in markets—such as the econazole market—in which customers cannot readily substitute alternative products, or do without a product altogether.

68. For competitors to profit from colluding to raise prices above competitive levels, demand for their product must be relatively inelastic at competitive prices. Otherwise, increased prices would reduce their sales as customers abandoned their products. Inelastic demand thus facilitates collusion.

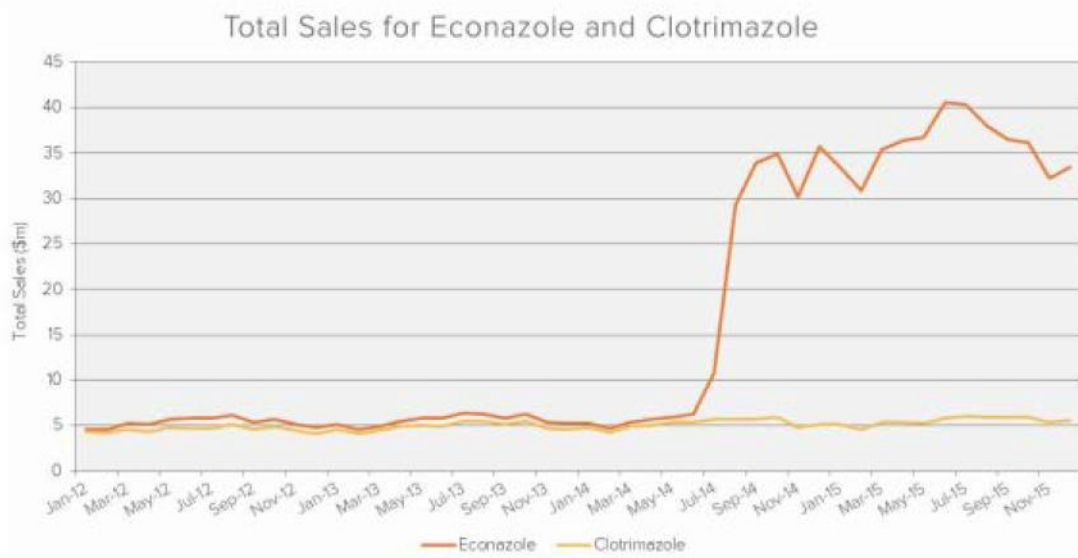
69. Demand for econazole is highly inelastic. A meaningful increase in the price for econazole would not induce purchasers to switch to another product in significant numbers, as there is no reasonable substitute for econazole available at a lower price.

70. For the million-plus patients regularly prescribed generic econazole, it is a necessity that must be purchased regardless of price. In fact, econazole’s demand curve is almost perfectly inelastic. As shown in the graph below, a 539% increase in price for econazole leads to only a 17% decrease in quantity demanded. Compare this with medical care and insurance, though, where a 125% price increase would result in no more quantity being demanded. The defendants can exhibit cartel behavior due to this highly inelastic demand. The defendants can significantly raise econazole prices with minimal effect on quantity demanded, and still receive a massive upside of a significant increase in revenue:



Examples	Ed	% Change in Price	% Change in Qd	Elasticity
Econazole	-0.01	539%	-17%	Highly inelastic
Medical Care and Insurance	-0.80	125%	-100%	Relatively inelastic
Public Transportation	-3.50	29%	-100%	Highly elastic

71. **Econazole Lacks for Substitutes:** While there are other topical drugs on the market, there are significant barriers to change treatments. Even with a large increase in price for econazole, very few users switched to another drug. For example, compare total sales for econazole to clotrimazole, another drug in the same class as econazole. The graph below shows sales for the two drugs between January 2012 and late 2015 and indicates that, despite the price hike, clotrimazole's sales remained steady. This lack of increase to clotrimazole's sales indicates that very few patients switched to another drug even in the face of a significant price spike:



72. **Econazole is a Fungible Product:** Because all econazole is the same, price is the predominant factor driving customers' purchasing decisions. The interchangeability of econazole products facilitated Defendants' conspiracy by enabling coordination on price that would be more difficult if Defendants sold products that varied in composition and/or performance.

73. **Absence of Competitive Sellers:** Defendants have maintained supracompetitive pricing for generic econazole throughout the Class Period. Thus, Defendants have oligopolistic market power in the generic econazole market, which enables Defendants to increase prices without losing market share to non-conspirators. No competitors outside the conspiracy have emerged to undercut Defendants' supracompetitive pricing.

74. **Defendants Had Ample Opportunities To Meet and Conspire:** Defendants had numerous opportunities to conspire in person under the guise of legitimate business meetings. In particular, Defendants are members of the GPhA, and attend other industry events and meetings, which provide opportunities to communicate. Defendants' representatives regularly attended meetings of GPhA and meetings of other trade associations during the Class

Period. The DOJ is reportedly investigating trade associations like GPhA as a potential avenue for facilitating collusion among generic drug manufacturers as part of its ongoing investigation into anticompetitive pricing activities in generic drug markets.

ANTITRUST INJURY

75. During the Class Period, Plaintiff and Class Members purchased econazole directly from Defendants. As a result of the Defendants' anticompetitive conduct, Plaintiff and Class Members paid more for econazole than they would have and thus suffered substantial damages. This is a cognizable antitrust injury and constitutes harm to competition under the federal antitrust laws.

76. Because Defendants' unlawful conduct has successfully restrained competition in the market, Plaintiff and Class Members have sustained, and continue to sustain, significant losses in the form of artificially inflated prices paid to Defendants. The full amount of such damages will be calculated after discovery and upon proof at trial.

77. Defendants' anticompetitive conduct is ongoing, and as a result Plaintiff and the Class continue to pay supracompetitive prices for econazole.

CLAIM FOR RELIEF

VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1

78. Plaintiff incorporates and re-alleges, as though fully set forth herein, each of the paragraphs set forth above.

79. Defendants are *per se* liable under Section 1 of the Sherman Act, 15 U.S.C. § 1, for the injuries and damages caused by their contract, combination, and conspiracy in restraint of trade as alleged herein.

80. There is no legitimate, non-pretextual, procompetitive business justification for Defendants' conspiracy that outweighs its harmful effect. Even if there were some conceivable justification, the conspiracy is broader than necessary to achieve such a purpose.

81. As set forth above, in violation of Section 1 of the Sherman Antitrust Act, Defendants entered into agreements with one another as to the output and pricing of econazole in the United States. This conspiracy was *per se* unlawful price-fixing, or alternatively, was an unlawful restraint of trade under the rule of reason.

82. Each Defendant has committed at least one overt act to further the conspiracy alleged in this Complaint.

83. The conspiracy had its intended effect, as Defendants benefited from their collusion and the restraint of competition, both of which artificially inflated the prices of econazole, as described herein.

84. As a result of Defendants' unlawful conduct, Plaintiff and Class Members have been injured in their business and property in that they have paid more for econazole than they otherwise would have paid in the absence of Defendants' unlawful conduct. The full amount of such damages is presently unknown but will be determined after discovery and upon proof at trial.

85. Defendants' unlawful conduct as alleged herein poses a significant, continuing threat of antitrust injury for which injunctive relief is appropriate under Section 16 of the Clayton Act.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff and Class Members pray for relief as set forth below:

A. Certification of the action as a Class Action pursuant to Federal Rule of Civil

Procedure 23, and appointment of Plaintiff as Class Representative and its counsel of record as Class Counsel;

B. Permanent injunctive relief that enjoins Defendants from violating the antitrust laws and requires them to take affirmative steps to dissipate the effects of their violations;

C. That acts alleged herein be adjudged and decreed to be unlawful restraints of trade in violation of the Sherman Act, 15 U.S.C. § 1;

D. A judgment against Defendants, jointly and severally, for the damages sustained by Plaintiff and the Class defined herein, and for any additional damages, penalties, and other monetary relief provided by applicable law, including treble damages;

E. By awarding Plaintiff and Class Members pre-judgment and post-judgment interest as provided by law, and that such interest be awarded at the highest legal rate from and after the date of service of the Complaint in this action;

F. The costs of this suit, including reasonable attorney fees; and

G. Such other and further relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff, on behalf of itself and others similarly situated, hereby requests a jury trial, pursuant to Federal Rule of Civil Procedure 38, on any and all claims so triable.

Dated: December 27, 2016

Respectfully submitted,

/s/ Lisa J. Rodriguez

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