JS 44 (Rev 07/16)

# **CIVIL COVER SHEET**

The JS 44 evil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

PHILADELPHIA FEDER WELFARE FUND	RATION OF TEACHER	RS HEALTH AND		MYLAN INC., MYL TARO PHARMAC	LAN PHARMACEUTICA EUTICALS USA INC.,	ALS INC., SANDOZ, INC.,
(b) County of Residence of First Listed Plaintiff Philadelphia, PA  (EXCEPT IN U.S. PLAINTIFT CASES)				NOTE IN LAND CO	of First Listed Defendant (IN U.S. PLAINTIFF CASES)  ONDEMNATION CASES, USE 1 OF LAND INVOLVED	
(c) Attorneys (Firm Name, EDELSON & Associates 3 Terry Drive, Suite 205 215-867-2399		er)		Attorneys (If Known)		
II. BASIS OF JURISD	ICTION (Place an "X" in C	One Box (Only)	III. CI	<u>I</u> TIZENSHIP OF P	RINCIPAL PARTIES	(Place an "X" in One Box for Plaintif
☐ 1 US Government Plaintiff	→ 3 Federal Question (U.S. Government Not a Party)		1	(For Diversity Cases Only) <b>P</b>	FF DEF  1	and (Ine Box for Defendant)  PTF DEF  rincipal Place
☐ 2 US Government Defendant	☐ 4 Diversity (Indicate Citizens)	inp of Parties in Item III)			2	Another State
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IV. NATURE OF SUI			1 65			
CONTRACT  110 Insurance 120 Marine 130 Miller Act 140 Negotiable Instrument 150 Recovery of Overpayment & Enforcement of Judgmen 151 Medicare Act 152 Recovery of Defaulted Student Loans (Excludes Veterans) 153 Recovery of Overpayment of Veteran's Benefits 160 Stockholders' Suits 190 Other Contract 195 Contract Product Liability 196 Franchise  REAL PROPERTY 210 Land Condemnation 220 Foreclosure 230 Rent Lease & Ejectment 240 Torts to Land 245 Tort Product Liability	PERSONAL INJURY  310 Airplane 315 Airplane Product Liability 320 Assault, Libel & Slander 330 Federal Employers' Liability 340 Marine 345 Marine Product Liability 350 Motor Vehicle Product Liability 360 Other Personal Injury 360 Personal Injury Medical Malpractice CIYIL RIGHTS 441 Voting 442 Employment 443 Housing/ Accommodations 445 Amer w/Disabilities - Employment 446 Amer w/Disabilities - Other 448 Education	PERSONAL INJURY    365 Personal Injury -   Product Liability   367 Health Care/   Pharmaceutical   Personal Injury   Product Liability   368 Asbestos Personal   Injury Product Liability   PERSONAL PROPERT   370 Other Fraud   371 Truth in Lending   380 Other Personal   Property Damage   385 Property Damage   Product Liability   PRISONER PETITIONS   Habeas Corpus:   463 Alien Detainee   510 Motions to Vacate   Sentence   530 General   535 Death Penalty   Other:	62	Drug Related Seizure of Property 21 USC 881 Of Other  LABOR Drait Labor Standards Act Labor/Management Relations Draitway Labor Act Family and Medical Leave Act Other Labor Litigation Employee Retirement Income Security Act  IMMIGRATION Naturalization Application Other Immigration Other Immigration Other Immigration	### BANKRUPTCY  ### 422 Appeal 28 USC 158  ### 423 Withdrawal	OTHER STATUTES  375 False Claims Act 376 Qui Tam (31 USC 3729(a)) 400 State Reapportionment 410 Antitrust 430 Banks and Banking 450 Commerce 460 Deportation 470 Racketeer Influenced and Corrupt Organizations 480 Consumer Credit 490 Cable/Sat TV 850 Securities/Commodities/ Exchange 890 Other Statutory Actions 891 Agricultural Acts 893 Environmental Matters 895 Freedom of Information Act 896 Arbitration 899 Administrative Procedure Act/Review or Appeal of Agency Decision 950 Constitutionality of State Statutes
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VI. CAUSE OF ACTIO	ON Brief description of ca	iuse:				omipramine Hydrochloride.
VII. REQUESTED IN COMPLAINT:		IS A CLASS ACTION		EMANDS		if demanded in complaint:
VIII. RELATED CASE IF ANY	(See instructions):	ДОН HONORAS	Æ Cyn	thia M. Rufe	DOCKET NUMBER 2:	
DATE 4-6-1	<u> </u>	SIGNATURE OF AFTO	RVC	FREYWAR		
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# IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

# CASE MANAGEMENT TRACK DESIGNATION FORM

Telephone	FAX Numbe	er	E-Mail Address	
(215) 867-2399	(267) 685-0676		medelson@edelson-law.com	
<u>4-6-17</u> Date	Marc H. Edelson Attorney-at-	law	Attorney for Plaintiff	<u> </u>
(f) Standard Management –	Cases that do not t	fall into any o	one of the other tracks.	( )
(e) Special Management – C commonly referred to as the court. (See reverse s management cases.)	complex and that	need special	or intense management by	(x)
(d) Asbestos – Cases involvi exposure to asbestos.	ing claims for pers	onal injury o	r property damage from	( )
(c) Arbitration – Cases requ	ired to be designate	ed for arbitra	tion under Local Civil Rule 53.2.	( )
(b) Social Security – Cases 1 and Human Services den				( )
(a) Habeas Corpus – Cases 1	brought under 28 U	J.S.C. § 2241	through § 2255.	( )
SELECT ONE OF THE FO	OLLOWING CAS	SE MANAGI	EMENT TRACKS:	
plaintiff shall complete a Ca filing the complaint and serv side of this form.) In the edesignation, that defendant s	se Management Tree a copy on all defe event that a defend shall, with its first a rties, a Case Manage	rack Designat ndants. (See lant does not appearance, s gement Track	eduction Plan of this court, counstion Form in all civil cases at the tin § 1:03 of the plan set forth on the reagree with the plaintiff regarding tubmit to the clerk of court and ser a Designation Form specifying the d.	ne of verse ; said ve on
MYLAN INC.		:	NO.	
PHILADELPHIA FEDERATION TEACHERS HEALTH AND WI on behalf of itself and all others V.	ELFARE FUND,	: :	CIVIL ACTION	

(Civ. 660) 10/02

# Case 2:17-cv-01557-CMR Document 1 Filed 04/06/17 Page 3 of 41 UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA - DESIGNATION FORM to be used by counsel to indicate the category of the case for the purpose of assignment to appropriate calendar. 1816 Chestnut St, Philadelphia, PA 19103 Address of Plaintiff; MYLAN INC. 1000 Mylan Boulevard, Canonsburg, Pennsylvania, 15317 Place of Accident, Incident or Transaction: Philadelphia, PA (Use Reverse Side For Additional Space) Does this civil action involve a nongovernmental corporate party with any parent corporation and any publicly held corporation owning 10% or more of its stock? (Attach two copies of the Disclosure Statement Form in accordance with Fed.R.Civ.P. 7.1(a)) Does this case involve multidistrict litigation possibilities? No□ Yes□ RELATED CASE, IF ANY: Case Number: 2:17-cv-00724 Judge Honorable Cynthia M. Rufe Date Terminated: Civil cases are deemed related when yes is answered to any of the following questions: 1. Is this case related to property included in an earlier numbered suit pending or within one year previously terminated action in this court? 2. Does this case involve the same issue of fact or grow out of the same transaction as a prior suit pending or within one year previously terminated action in this court? 3. Does this case involve the validity or infringement of a patent already in suit or any earlier numbered case pending or within one year previously terminated action in this court? Yes□ No 🔀 4. Is this case a second or successive habcas corpus, social security appeal, or pro se civil rights case filed by the same individual? No CIVIL: (Place / in ONE CATEGORY ONLY) A. Federal Question Cases: B. Diversity Jurisdiction Cases: 1. 

Indemnity Contract, Marine Contract, and All Other Contracts 1. 

Insurance Contract and Other Contracts 2. D FELA 2. 

Airplane Personal Injury 3. 

Jones Act-Personal Injury 3. 

Assault, Defamation 4. XAntitrust 4. 

Marine Personal Injury 5. 
Patent 5. 

Motor Vehicle Personal Injury 6. □ Labor-Management Relations 6. 

Other Personal Injury (Please specify) 7. D Civil Rights 7. 

Products Liability 8. 

Habeas Corpus 8. 

Products Liability — Asbestos 9. □ Securities Act(s) Cases 9. 

All other Diversity Cases 10. □ Social Security Review Cases (Please specify) 11. □ All other Federal Question Cases (Please specify) ARBITRATION CERTIFICATION (Check Appropriate Category) Liberato P. Verderame, , counsel of record do hereby certify: XX Pursuant to Local Civil Rule 53.2, Section 3(c)(2), that to the best of my knowledge and belief, the damages recoverable in this civil action case exceed the sum of \$150,000.00 exclusive of interest and costs; Relief other than monetary damages is sough 80279 Astorney-at-Law Attorney I.D.# NOTE: A trial de novo will be a trial by jury only if there has been compliance with F.R.C.P. 38. I certify that, to my knowledge, the within case is not related to any pl se now pending or within one year previously terminated action in this court except as noted above. 4-6-11 80279 Attorney-at-Law Attorney I.D.#

CIV. 609 (5/2012)

# UNITED STATES DISTRICT COURT EASTERN DISTRICT OF PENNSYLVANIA

PHILADELPHIA FEDERATION OF TEACHERS HEALTH AND WELFARE FUND, on behalf of itself and all others similarly situated,

Plaintiffs,

V.

MYLAN INC., MYLAN PHARMACEUTICALS INC., SANDOZ, INC., TARO PHARMACEUTICALS USA INC.,

Defendants.

CLASS ACTION COMPLAINT
DEMAND FOR JURY TRIAL

No:

Plaintiff, Philadelphia Federation of Teachers Health and Welfare Fund, ("PFTHWF" or "Plaintiff") brings this action both individually and on behalf of a class of persons or entities which purchased, paid and/or provided reimbursement for some or all of the purchase price of generic Clomipramine Hydrochloride capsules manufactured by Defendants, Mylan Inc., Mylan Pharmaceuticals Inc. (collectively "Mylan"), Sandoz, Inc. ("Sandoz"), and Taro Pharmaceuticals USA, Inc. ("Taro"), (each a "Defendant" or collectively "Defendants").

#### I. <u>INTRODUCTORY STATEMENT</u>

- 1. Defendants are accused of engaging in a conspiracy to fix, maintain, and/or stabilize the prices of generic Clomipramine Hydrochloride capsule products. All allegations herein are based on information and belief, except for those relating to the Plaintiff.
- 2. Clomipramine Hydrochloride is a generic tricyclic antidepressant, used to treat obsessive compulsive disorder (OCD). It restores the balance of certain natural substances (serotonin, among others) in the brain. It decreases obsessive behaviors, and reduces the urge to perform repeated tasks that interfere with daily living. Generic Clomipramine Hydrochloride has

been available since 1996.

- 3. According to the U.S. Food and Drug Administration, nearly eight out of ten prescriptions filled in the United States are generics. Generic drugs are required to have the same active ingredient, strength, dosage form, and route of administration as the brand name product. Historically, generic drugs have sold at seventy-five percent less than the branded version. As of June 2015, it was estimated that consumers save \$8 to 12 billion per year at the pharmacy.
- 4. Skyrocketing price increases for generic drugs, frequently in lockstep by multiple manufacturers, recently has caused multiple federal and state agencies to launch investigations into the generic drug industry's pricing practices, including the House Committee on Oversight and Government Reform, the Subcommittee on Primary Health and Aging, Senate Committee on Health, Education, Labor and Pensions, the Justice Department, and multiple states' attorneys general.
- 5. These price increases do not stem from competitive behavior caused by, for instance, supply shortages or changed product demand. Rather, Defendants have engaged in a broad and wide-ranging conspiracy to fix, raise, maintain and stabilize generic drugs' prices, and to allocate customers and markets for them. Defendants effectuated their conspiracy by direct business-to-business contacts among generic drug manufacturers, secret communications and meetings, and/or joint participation taken under the guise of trade associations like the Generic Pharmaceutical Association ("GPhA"). For example, representatives from Defendants attended GPhA's Annual Meeting in Orlando, Florida during February 2013 and GPhA meetings in

 $<sup>\</sup>frac{http:\ www.fda.gov\ Drugs Resources For You/Consumers\ Buying Using Medicine Safely\ Understanding Generic Drugs\ ucm 167991.htm.$ 

http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm144456.htm.

Bethesda, Maryland in June 2013. Shortly after these meetings, the price for generic Clomipramine Hydrochloride increased by extraordinary amounts.

- 6. During October 2014, Rep. Elijah Cummings, Ranking Member of the House Committee on Oversight and Government Reform, and Sen. Bernie Sanders, Chairman of the Subcommittee on Primary Health and Aging of the Senate Committee on Health, Education, Labor and Pensions, launched investigations into soaring pricing for generic drugs. Senator Sanders noted "[m]ore than one out of four Americans do not fill their prescriptions because they cannot afford the cost." As a result of joint document requests sent to generic drug manufacturers, the investigative committee received over 300,000 pages of documents. According to Representative Cummings, these documents "provide an insider's view into how drug company executives are lining their own pockets at the expense of some of the most vulnerable families in our nation."
- 7. The Department of Justice ("DOJ") and the Connecticut Attorney General's Office ("CTAG") have both issued subpoenas to as many as a dozen generic drug companies concerning prices of at least two dozen drugs. The DOJ's subpoenas arose from a grand jury proceeding in the Eastern District of Pennsylvania that is investigating whether Defendants and other drug manufacturers conspired to fix generic drug prices.
- 8. On September 8, 2016, Defendant Mylan received subpoenas or requests for information concerning its marketing and pricing of generic drugs, as well as communications with competitors.
- 9. Likewise, on September 9, 2016, Defendant, Taro Pharmaceutical Industries Ltd., parent company of Taro U.S.A., and two of its senior officers were served grand jury subpoenas in connection with DOJ's antitrust investigation demanding documents related to Taro's generic pharmaceutical products, pricing and communications with competitors.

- 10. Additionally, on December 14, 2016, the attorneys general ("AG") of twenty states filed a complaint against multiple generic manufacturers of doxycycline hyclate for conspiring to fix the prices and allocate the market for this medication.<sup>3</sup> On March 1, 2017, an amended complaint was filed, in which the attorneys general of an additional twenty states joined, and added additional claims of violations of states' antitrust laws, in addition to the alleged violations of federal antitrust laws.
- 11. Significantly, the AG Complaint indicates that these actions by the generic manufacturers of doxycycline hyclate were not isolated and limited to that drug. Rather, the AG Complaint mentions a "wide-ranging" series of conspiracies implicating numerous different drugs and competitors.<sup>4</sup>
- 12. The conduct includes schemes to fix and maintain prices, allocate markets and otherwise thwart competition which has caused "significant, lasting and ultimately harmful rippling effect in the United States healthcare system, which is still ongoing today."<sup>5</sup>
- 13. The AG Complaint acknowledged that "[m]ost of the conspiratorial communications were intentionally done in person or by cell phone, in an attempt to avoid creating a record of their illegal conduct. The generic drug industry, through the aforementioned opportunities to collude at trade shows, customer events and smaller more intimate dinners and meetings, allowed these communications to perpetuate. When communications were made in writing, or by text message, some of the Defendants even took overt and calculated steps to destroy evidence of those communications."
  - 14. Clomipramine Hydrochloride is one of the generic drugs which has experienced

<sup>&</sup>lt;sup>3</sup> State of Connecticut v. Aurobindo Pharma USA, Inc., No. 3:16-cv-2056 VLB (D. Conn.).

<sup>&</sup>lt;sup>4</sup> Id. at ¶9.

<sup>&</sup>lt;sup>5</sup> Id. at ¶8.

<sup>&</sup>lt;sup>6</sup> Id. at ¶13.

recent, unusually high, price increases. During August 2016, the United States Government Accountability Office (GAO) issued a report to Congress which evaluated generic drugs' price history from 2010 through the second quarter of 2015.<sup>7</sup> The GOA found that 315 of the 1,441 established drugs in its market study experienced an extraordinary price increase<sup>8</sup> while many other generic drugs continued to decline in price.

- 15. During June 2013, Defendants began simultaneously increasing prices for generic Clomipramine Hydrochloride capsules. By March 2015, the prices for generic Clomipramine Hydrochloride capsules increased by 1,800% to as much as 3,300%. The current prices for generic Clomipramine Hydrochloride capsules remains over 1,360 to 2,550% higher than December 2012 prices.
- 16. Plaintiff believes that generic Clomipramine Hydrochloride's extraordinary price increases result from a conspiracy among these Defendants to fix, raise, maintain and stabilize generic drugs' prices, and to allocate customers and markets for generic Clomipramine Hydrochloride capsules. These increases were neither the product of a competitive market, nor made necessary by any increased manufacturing costs. Defendants' price increases resulted from their conspiracy to restrain trade.
- 17. Defendants' conspiracy has further benefited from oligopolistic market conditions, caused by the low number of competitors and barriers to entry in the generic Clomipramine Hydrochloride market. Such conditions have allowed Defendants to sustain anticompetitive behaviors such as their increased pricing as of the filing of this Complaint.
  - 18. Defendants' conspiracy to fix, raise, maintain and stabilize the prices of generic

<sup>&</sup>lt;sup>7</sup> Part D Generic Drug Prices Declined Overall, but Some Had Extraordinary Price Increases GAO-16-706: Published: Aug 12, 2016. Publicly Released: Sep 12, 2016.

<sup>&</sup>lt;sup>8</sup> Defined as a price increase of at least 100 percent. *Id. at* 12.

Clomipramine Hydrochloride capsules has caused and continues to cause consumers and thirdparty payors to pay supracompetitive prices for generic Clomipramine Hydrochloride.

- 19. Plaintiff brings this civil antitrust action on behalf of a proposed class of endpayors who indirectly purchased, reimbursed, or otherwise paid for generic Clomipramine Hydrochloride capsules.
- 20. Plaintiff seeks to certify a class, the "Injunctive Class", composed of all individuals and entities in the United States or its territories who indirectly purchased, paid, and provided reimbursement for some or all of the purchase price for Clomipramine Hydrochloride capsules, other than for resale, for consumption by itself, its families, or its members, employees, insureds, participants, or beneficiaries, from at least June 1, 2013 to the present through and including the date that the anticompetitive effects of Defendants' unlawful conduct ceased (the "Class Period").
- 21. Plaintiff also seeks to certify a class, the "Damages Class", composed of all individuals and entities who, in Alabama, Arizona, California, District of Columbia, Florida, Hawaii, Iowa, Kansas, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Mexico, New York, North Carolina, North Dakota, Oregon, Rhode Island, South Dakota, Tennessee, Utah, Vermont, West Virginia, and Wisconsin, indirectly purchased, paid, and provided reimbursement for some or all of the purchase price for Clomipramine Hydrochloride capsules, other than for resale, for consumption by itself, its families, or its members, employees, insureds, participants, or beneficiaries, from at least June 1, 2013 to the present (the "Class Period"), through and including the date that the anticompetitive effects of Defendants' unlawful conduct ceased.
- 22. Plaintiff seeks overcharge damages and other relief arising out of Defendants' agreement not to compete in the market for generic Clomipramine Hydrochloride capsules.

23. Defendants' coordinated conduct as alleged herein was designed to and did raise, fix, maintain, or stabilize the price of generic Clomipramine Hydrochloride capsules. As a result, Defendants violated sections 1 and 3 of the Sherman Act, 15 U.S.C. §§ 1, 3, and the various state antitrust and consumer protection laws enumerated below. Plaintiff seeks damages and injunctive relief to prevent Defendants from continuing and maintaining the anticompetitive combination, conspiracy, or agreement alleged in this complaint.

# II. JURISDICTION AND VENUE

- 24. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1337 and 15 U.S.C. §§ 1, 3 and 26. This Court has subject matter jurisdiction over the state law claims pursuant to the Class Action Fairness Act of 2005, 28 U.S.C. §§ 1332(d) and 1367, in that this is a class action in which there are over 100 members of the Class (as defined herein); the matter in controversy exceeds the sum of \$5,000,000.00, exclusive of interest and costs; and at least one member of the Class is a citizen of a state different from that of one of the Defendants.
- 25. Jurisdiction and venue are proper in this Court under 28 U.S.C. § 1391 because Defendants transact business in this District. A substantial part of the interstate trade and commerce involved and affected by the violations of the antitrust laws was and is carried on in part within this District. The acts complained of have and will continue to have substantial effects in this District.

#### III. PARTIES

#### A. Plaintiff

26. Plaintiff Philadelphia Federation of Teachers Health and Welfare Fund ("PFTHWF") is a voluntary employee benefits plan organized pursuant to § 501(c) of the Internal

Revenue Code for the purpose of providing health benefits to eligible participants and beneficiaries. PFTHWF maintains its principal place of business in Philadelphia, Pennsylvania. PFTHWF provides health benefits, including prescription drug benefits, to approximately 34,000 participants, and their spouses and dependents. During the Class Period, PFTHWF purchased and paid for some or all the purchase price for generic Clomipramine Hydrochloride capsules, thereby suffering injury to its business and property by reimbursing more for this product than it would have absent Defendants' anticompetitive conduct to fix, raise, maintain, and stabilize the prices and allocate markets and customers.

#### B. Defendants

- 27. Defendant, Mylan Inc. ("Mylan"), is a Pennsylvania corporation with its principal place of business at 1000 Mylan Boulevard, Canonsburg, Pennsylvania, 15317. Mylan Inc. is a global generic and specialty pharmaceuticals company which also operates several divisions and subsidiaries including Mylan Pharmaceuticals Inc. During the Class Periods, Mylan Inc. marketed and sold generic Clomipramine Hcl capsules in this District and throughout the United States through its subsidiary, Mylan Pharmaceuticals Inc.
- 28. Defendant, Mylan Pharmaceuticals Inc., is a West Virginia corporation with its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. During the Class Periods, Mylan Pharmaceuticals sold Clomipramine Hcl capsules in this District and throughout the United States.
- 29. Defendant, Sandoz, Inc. ("Sandoz") is a Colorado corporation with a principal place of business at 100 College Rd. West, Princeton, New Jersey, 08540. Sandoz, Inc., is the United States affiliate of Sandoz International GmbH, a company organized and existing under the laws of Germany, having its principal place of business in Holzkirchen, Germany. Sandoz, Inc. is responsible for the distribution of drugs developed and manufactured by Sandoz

International. Together, Sandoz International and Sandoz, Inc. operate as the generic pharmaceuticals division of Novartis International AG, a global healthcare company based in Switzerland. Sandoz markets and sells generic Clomipramine Hcl in this District and throughout the United States.

- 30. Defendant, Taro Pharmaceuticals U.S.A., Inc. ("Taro"), is a New York corporation with its principal place of business at 3 Skyline Drive, Suite 120, Hawthorne, New York, 10532. Taro U.S.A. markets and sells generic Clomipramine throughout the United States. Taro is a wholly-owned subsidiary of Taro Pharmaceutical Industries Ltd., an Israeli company with its principal place of business in Haifa, Israel. Taro markets and sells generic Clomipramine Hcl in this District and throughout the United States.
- 31. All acts alleged in this Complaint to have been done by Defendants were performed by their officers, directors, agents, employees or representatives while engaged in the management, direction, control or transaction of Defendants' business affairs.

# IV. <u>CO-CONSPIRATORS AND AGENTS</u>

- 32. At all relevant times, each Defendant acted in concert, pursuant to a common, unlawful plan and conspired together to fix, raise, maintain, and stabilize the prices and allocate markets and customers, injuring Plaintiff, Class Members and other similarly situated individuals. Each aided and abetted the other. For these reasons, they are jointly and severally liable.
- 33. The acts alleged against Defendants in this Complaint were authorized, ordered, and/or done by their officers, agents, employees, or representatives, while actively engaged in the management and operation of defendants' businesses and affairs.
- 34. Other, presently unidentified firms, corporations, entities and/or individuals, not made defendants in the complaint, participated as co-conspirators with Defendants in the violations alleged in this complaint, and performed acts and made statements in furtherance thereof

conspiracy alleged. Said firms, corporations, entities and/or individuals can be readily identified from documents in Defendants' possession, and will be named in an amended complaint, with leave of the Court, as soon as the relevant information is made available.

## V. INTERSTATE AND INTRASTATE COMMERCE

- 35. Defendants' conduct has taken place within the flow of, and substantially affected the interstate commerce of the United States. By way of example, Defendants used the instrumentalities of interstate commerce, including interstate wires and the U.S. mail, to market, distribute and/or sell substantial quantities of generic Clomipramine Hydrochloride capsules throughout the United States. Defendants also used interstate wires and the U.S. mail to distribute and/or receive sales and/or marketing information, receipts, invoices, statements and payments related to generic Clomipramine Hydrochloride capsules' sales in the United States.
- 36. During the Class Period, Defendants sold substantial quantities of generic Clomipramine Hydrochloride capsules in a continuous and uninterrupted flow of interstate commerce to customers throughout the United States.
- 37. Defendants' anticompetitive conduct has substantial intrastate effects in that, *inter alia*, generic Clomipramine Hydrochloride capsules have been and are offered at higher prices to end-payors inside each respective state than they would have been or would be but for Defendants' conduct. The complete lack of availability of competitive priced generic Clomipramine Hydrochloride capsules directly impacts and disrupts commerce for end-payors within each state.

## VI. <u>FACTUAL ALLEGATIONS</u>

## A. Background Regarding Generic Prescription Drugs

38. "A generic drug is chemically equivalent to its branded counterpart and is generally

marketed by multiple manufacturers under a nonproprietary name; generic drugs can be introduced with the Food and Drug Administration's (FDA) approval after the patent for the branded counterpart has expired." Generics in mature markets often cost as little as 10-15% of the branded drug's price. Defendants manufacture and sell, *inter alia*, generic versions of branded drugs once any applicable patent on the branded drugs expires.

- 39. Once a generic version of a drugs enters the market, the branded drug's market share quickly erodes. Per IMS Health data, generic drugs accounted for 86% of all drugs dispensed in the United States in 2013.<sup>11</sup>
- 40. As additional versions of a particular generic drug enter the market, the price that consumers and third-party payors pay for the drugs drops. In a competitive market, both the branded manufacturer and the older generic manufacturers lower prices in response to the new competitor, as the following FDA chart shows<sup>12</sup>:

<sup>&</sup>lt;sup>9</sup> See Generic Drugs Under Medicare: Part D Generic Drug Prices Declined Overall, but Some Had Extraordinary Price Increases, at 1, GAO-16-706:

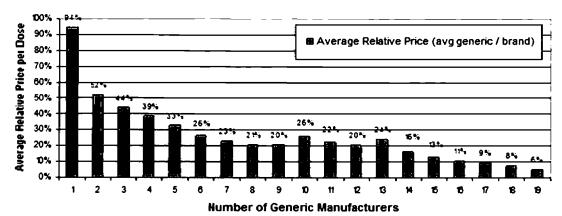
FTC Staff Study, Pay-For-Delay: How Drug Company Pay-Offs Cost Consumers Billions, at 8 (Jan. 2010), available at <a href="http://emmanuelcombe.org/delay.pdf">http://emmanuelcombe.org/delay.pdf</a>.

IMS Institute for Healthcare Informatics, Medicine use and shifting costs of healthcare: A Review of The Use of Medicines in The United States In 2013 (Apr. 2014), at 51, available at

http://www.imshealth.com/en-thought-leadership/quintilesims-institute-reports/use-of-medicines-in-the-us-2013.

FDA, Generic Competition and Drug Prices, <a href="http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm">http://www.fda.gov/AboutFDA/CentersOfficeofMedicalProductsandTobacco/CDER/ucm129385.htm</a>.

#### **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

- 41. Thus, generic drugs lower costs for consumers, in the form of lower copayments and other out-of-pocket costs, and for third-party payers, including private health insurance plans such as Plaintiff.
- 42. Accordingly, generic competition to a branded drug can provide billions of dollars in savings to consumers, pharmacies, other purchasers, private health insurers, health and welfare funds and state Medicaid programs, which reimburse drug purchases for their insureds. A GPhA study found that generic drugs saved the U.S. healthcare system \$1.68 trillion between 2005 and 2014, including \$254 billion in 2014 alone.<sup>13</sup>
- 43. In 1984, Congress enacted the Drug Price and Patent Term Restoration Act of 1984, (the "Hatch-Waxman Act"), partly to assist manufacturers to bring generic drugs to market more quickly. The Hatch-Waxman Act provides an expedited pathway for generic drug companies to obtain Food and Drug Administration (FDA) approval. The Act created a new type of application for a generic drug manufacturer to file, an Abbreviated New Drug Application ("ANDA") in order

<sup>&</sup>lt;sup>13</sup> Generic Pharmaceutical Association, *Generic Drug Savings in the U.S.*, at 1 (2015), http://www.GPhAonline.org/media/wysiwyg/PDF/GPhA\_Savings\_Report\_2015.pdf.

to obtain FDA approval. The ANDA permits a generic drug manufacturer to rely on the branded drug's manufacturer's safety and reliability data. An ANDA applicant must show that its generic drug is bioequivalent to the brand drug. This reliance allows the generic company to forego duplicative and expensive experimentation and having to perform its own clinical trials. The FDA will assign a "Therapeutic Equivalence Code" ranging from "AA" to "BX." An "AB" rating signifies that the approved generic drug is therapeutically equivalent to its branded counterpart.

- 44. Since passage of the Hatch-Waxman Act, pharmacists are permitted, or required by state law, to substitute a less expensive generically equivalent drug for the brand name version unless requested otherwise by the purchaser or indicated otherwise by the prescriber.
- 45. Defendant Mylan has been marketing generic Clomipramine Hydrochloride capsule products since 1998. Defendants Sandoz and Taro have been marketing generic Clomipramine Hydrochloride capsules products since 1996.

#### B. Consolidation of the Generic Drugs Market

- 46. In theory, a generic drug may be manufactured and marketed by any pharmaceutical manufacturer after receiving an approved ANDA. However, generic drug manufacturers have recently experienced a global wave of consolidations, acquisitions and mergers which have reshaped the market. Pharmaceutical manufacturers, in order to gain market share and maintain profitability, have resulted to buying out their competitors. The result, as is the case here, many generic drugs are produced by only a few manufacturers. There are fewer companies applying for new ANDAs for older generics. Presently, the primary marketers for generic Clomipramine Hydrochloride capsules are Defendants herein.
- 47. Generic Clomipramine Hydrochloride capsules treatments constitute an over \$1 billion market in the United States. This market is dominated by Defendants Mylan, Sandoz and

Taro, which account for ninety-eight percent of the total market in 2014. Consolidation in the industry has affected the number of companies in the generic Clomipramine Hydrochloride market.

48. The consequence of the generic drug industry's consolidation and coordinated pricing activity has been higher prices for consumers. Market consolidation also has resulted in more generic product lines being combined or discontinued, further reducing price competition.

# C. Clomipramine Hydrochloride Price Increases

49. In 2012, the Centers for Medicare and Medicaid Services commissioned a national consulting firm with expertise in Medicare and Medicaid, Myers and Stauffer, to take surveys of pharmacies across the U.S. to determine the average price of prescription drugs. Myers and Stauffer conducts a monthly nationwide survey of retail community pharmacy prescription drug prices and calculates a statistically weighted average price for each drug. The survey evaluates geographic, chain and independent, rural and urban cost variations to arrive at a price for each generic drug surveyed. The National Average Drug Acquisition Cost ("NADAC") is a master list which is updated and published weekly since October 2012. The NADAC thus reflects the actual costs per unit, in this case grams, that drug manufacturers charge for their medications at retail pharmacies across the United States. Medicaid administrators use the NADAC price information to evaluate their reimbursement policies. The table below compares NADAC prices for generic Clomipramine Hydrochloride capsules for each dosage during December 2012, June 2013 and March 2015. These increases were the product of a horizontal agreement among Defendants to increase pricing and restrain competition.

Clomipramine Hydrochloride Capsules NADAC Price Per Gram

Dosage	Dec. 2012 <sup>14</sup>	June 2013 <sup>15</sup>	Mar. 2015 <sup>16</sup>	Increase <sup>17</sup>
25 mg	\$0.243	\$8.87	\$8.45	3,377%
50 mg	\$0.325	\$9.03	\$8.38	2,478%
75 mg	\$0.440	\$0.424	\$8.58	1,850%

Clomipramine Hydrochloride Capsules NADAC Price Per Gram

Dosage	Dec. 2012 <sup>18</sup>	June 2016 <sup>19</sup>	Mar. 2017 <sup>20</sup>	Increase <sup>21</sup>
25 mg	\$0.243	\$8.28	\$6.46	2,558%
50 mg	\$0.325	\$7.69	\$7.32	2,152%
75 mg	\$0.440	\$7.22	\$6.45	1,366%

- 50. The foregoing demonstrates the simultaneous actions by Defendants, which increased the price of generic Clomipramine Hydrochloride capsules by a magnitude of over thirteen hundred to over two thousand five hundred percent from 2012 to the present time.
- 51. Without changes in the market or supply shortages, competition in the market for generic Clomipramine Hydrochloride capsules should have maintained prices at the late 2012 levels. AARP Policy Institute's Rx Price Watch Report notes that retail prices for 115 specialty prescription drugs increased by 10.6 percent on average in 2013, compared with a 1.5 percent inflation rate over the same period. The sudden, unexplained and sustained price increase can be reasonably inferred to be caused by anticompetitive behavior by the generic manufacturers, i.e., illegal collusion among the generic manufacturers to fix, raise, maintain or stabilize the price of

<sup>&</sup>lt;sup>14</sup> CMS, Weekly NADAC Reference File as of 12/27/2012,

available at https://www.medicaid.gov/medicaid/prescription-drugs/survey-of-retail-prices/index.html.

<sup>&</sup>lt;sup>15</sup> CMS, Weekly NADAC Reference File as of 6/27/2013,

available at https://www.medicaid.gov/medicaid/prescription-drugs/survey-of-retail-prices/index.html,

<sup>&</sup>lt;sup>16</sup> CMS, Weekly NADAC Reference File as of 4/18/2015,

available at http://truecostothealthcare.net pharmacy/price/index.

<sup>&</sup>lt;sup>17</sup> Percentage of price increases of December 2012 prices versus March 2015 prices.

<sup>&</sup>lt;sup>18</sup> CMS, Weekly NADAC Reference File as of 12/27/2012,

available at https://www.medicaid.gov/medicaid/prescription-drugs/survey-of-retail-prices index.html.

<sup>&</sup>lt;sup>19</sup> CMS, Weekly NADAC Reference File as of 5/25/2016,

available at https://www.medicaid.gov/medicaid.prescription-drugs/survey-of-retail-prices/index.html.

<sup>&</sup>lt;sup>20</sup> CMS, Weekly NADAC Reference File as of 3/29/2017,

available at https://www.medicaid.gov/medicaid/prescription-drugs/survey-of-retail-prices/index.html.

<sup>&</sup>lt;sup>21</sup> Percentage of price increases of December 2012 prices versus March 2017 prices.

generic Clomipramine Hydrochloride capsules.

52. The mirror-image price increases has negatively affected both consumers and third-party payers, such as Plaintiff.

# D. Government Investigations.

- 53. During approximately this same period of time that generic Clomipramine Hydrochloride capsules prices increased, prices for a number of other generic drugs also increased dramatically. These increases led to investigations by the House Committee on Oversight and Government Reform, the Subcommittee on Primary Health and Aging, Senate Committee on Health, Education, Labor and Pensions, the Justice Department's ("DOJ") Antitrust Division, the Department of Health and Human Services' Inspector General and the attorneys general of Connecticut, Delaware, Florida, Hawaii, Idaho, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Minnesota, New York, Nevada, North Dakota, Pennsylvania, Ohio, Virginia and Washington State.
- 54. The Congressional investigation revealed that the prices of more than 1,200 generic medications increased an average of 448 percent between July 2013 and June 2014, including generic Clomipramine Hydrochloride capsules.<sup>22</sup>
- 55. After a Senate hearing on February 24, 2015, Rep. Cummings and Sen. Sanders wrote to the U.S. Department of Health & Human Services' Office of the Inspector General ("OIG") asking OIG to investigate how Defendants' price increases affected spending in the Medicare and Medicaid programming.<sup>23</sup> OIG accordingly began to review quarterly average manufacturer prices for the top 200 generic drugs from 2005 to 2014.<sup>24</sup>

<sup>&</sup>lt;sup>22</sup> "Generic Drug Price Sticker Shock Prompts Probe by Congress," ABC News, Nov 21, 2014, By Gillian Mohney. http://dbcnews.go.com/Health/generic-drug-prices-skyrocketing-lawmakers-warn story?id=27060992.

<sup>&</sup>lt;sup>23</sup> http://www.sanders.senate.gov/download/sanders-cummings-letter?inline file.

http://www.sanders.senate.gov/download/oig-letter-to-sen-sanders-4-13-2015?inline\_file.

- 56. The DOJ also launched a probe into alleged price-fixing among generic manufacturers. In November 2014, the DOJ issued grand jury subpoenas to many generic manufacturers requesting documents, information, and testimony relating to "communication or correspondence with any competitor in the sale of generic prescription medications." Impax Laboratories, Inc. was the first to disclose having received a subpoena. In September 2016, Taro Pharmaceuticals, disclosed that it, "as well as two senior officers in its commercial team, received grand jury subpoenas from the [DOJ]," seeking, among other things, "communications with competitors and others regarding the sale of generic pharmaceutical products."
- 57. On December 12, 2016, the DOJ filed criminal informations against Jeffrey Glazer ("Glazer") and Jason Malek, the respective former Chief Executive Officer and President of Heritage Pharmaceutical, Inc. These informations accuse Malek and Glazer of conspiring to "knowingly enter[] into and engag[ing] in a combination and conspiracy other persons and entities engaged in the production and sale of generic pharmaceutical products, including doxycycline hyclate, the primary purpose of which was to allocate customers, rig bids, and fix and maintain prices of doxycycline hyclate sold in the United States."<sup>27</sup>
  - 58. A press release issued by DOJ in conjunction with these filings stated:

"Millions of Americans rely on prescription medications to treat acute and chronic health conditions. By entering into unlawful agreements to fix prices and allocate customers, these two executives sought to enrich themselves at the expense of sick and vulnerable individuals who rely upon access to generic pharmaceuticals as a more affordable alternative to brand-name medicines," said Deputy Assistant Attorney General Brent Snyder of the Justice Department's Antitrust Division. "These charges are an important step in correcting that injustice and in ensuring

<sup>&</sup>lt;sup>25</sup> Impax Laboratories, Inc. Current Report (Form 8-K) (November 3, 2014).

<sup>&</sup>lt;sup>26</sup> Taro, SEC Form 6-K (Sept. 9, 2016), <a href="http://phx.corporate-ir.net/phoenix.zhtml?c-114698&p-irol-SECText&TEXT">http://phx.corporate-ir.net/phoenix.zhtml?c-114698&p-irol-SECText&TEXT</a> <a href="https://ahR0cDovL2FwaS50ZW5rd2l6YXJkl.ni.NvbS9maWxpbmcueG1sP2lwYWdlPTExMTM0MjU">http://ahR0cDovL2FwaS50ZW5rd2l6YXJkl.ni.NvbS9maWxpbmcueG1sP2lwYWdlPTExMTM0MjU</a> wJkRTRVE9MCZTRVE9MCZTUURFU0M9U0VDVEIPTI9FTIRJUkUmc3Vic2lkPTU3.

<sup>&</sup>lt;sup>27</sup> "Information," p. 2 (December 12, 2016) (ECF No. 1) in *United States v. Glazer*, No. 2:16-cr-00506-RBS (E.D. Pa.); "Information," p. 2 (December 12, 2016) (ECF No. 1) in *United States v. Malek*, No. 2:16-cr-00508-RBS (E.D. Pa.).

that generic pharmaceutical companies compete vigorously to provide these essential products at a price set by the market, not by collusion."

"Conspiring to fix prices on widely-used generic medications skews the market, flouts common decency – and very clearly breaks the law," said Special Agent in Charge Michael Harpster of the FBI's Philadelphia Division. "It's a sad state of affairs when these pharmaceutical executives are determined to further pad their profits on the backs of people whose health depends on the company's drugs. The FBI stands ready to investigate and hold accountable those who willfully violate federal antitrust law."

Today's charges are the result of an ongoing federal antitrust investigation into price fixing, bid rigging and other anticompetitive conduct in the generic pharmaceutical industry, which is being conducted by the Antitrust Division's Washington Criminal I Section with the assistance of the FBI's Philadelphia Division, the FBI headquarters' International Corruption Unit, the United States Postal Service Office of Inspector General and the U.S. Attorney's Office for the Eastern District of Pennsylvania.<sup>28</sup>

- 59. On December 14, 2016, the attorneys general ("AG") of twenty states filed a complaint against multiple generic manufacturers of doxycycline hyclate for conspiring to fix the prices and allocate the market for this medication.<sup>29</sup> An amended complaint, filed on March 1, 2017, now includes federal and state antitrust claims by 40 states attorneys general.
- 60. The AG Complaint alleges a "wide-ranging series of conspiracies implicating numerous different drugs and competitors." The Complaint identifies that the conspiracy among multiple generic drug manufacturers is facilitated by direct communications among competitors concerning pricing and market allocation. Defendants attempted to conceal evidence of their communications by deleting texts and other writings. Defendants also had an opportunity to coordinate their price-fixing schemes while attending various trade association meetings or

<sup>&</sup>lt;sup>28</sup> https://www.justice.gov/opa/pr/former-top-generic-pharmaceutical-executives-charged-price-fixing-bid-rigging-and-customer.

<sup>&</sup>lt;sup>29</sup> State of Connecticut v. Aurobindo Pharma USA, Inc., et al., No. 3:16-cv-2056 VLB (D. Conn.).

<sup>&</sup>lt;sup>30</sup> *Id. at* ¶9.

<sup>31</sup> *Id.* at  $\P$ ¶11 – 12.

customer-sponsored conferences.<sup>32</sup> Further opportunities occurred during industry dinners or "Girls Night Out," attended by officers and executives of various generic drug manufacturers, during which the attendees discussed competitively sensitive information.<sup>33</sup> Consequently, the supposed competitors "are often acutely aware of their competition and, more importantly, each other's current and future business plans."<sup>34</sup>

61. The AG Complaint makes it clear that the price increases are not the result of market forces, but are the result of the conspiracy alleged herein, stating:

"Generic drug manufacturers argued publicly that the significant price increases [for generic drugs] were due to a myriad of benign factors, such as industry consolidation, FDA-mandated plant closures, or elimination of unprofitable generic drug product lines. What the Plaintiff States have found through their investigation, however, is that the reason underlying many of these price increases is much more straightforward, and sinister – collusion among generic drug competitors." <sup>35</sup>

## E. Collusion in the Generic Drug Market.

62. The United States' generic Clomipramine Hydrochloride capsules market displays various qualities that place it at risk of collusion and other anticompetitive behavior. Such qualities include: (1) high concentration; (2) high barriers to entry; (3) inelasticity of demand; (4) lack of available product substitutes; and (5) opportunities to conspire.

63. As above, Defendants used various means of direct communications, trade association meetings, including those sponsored by GPhA, customer conferences, industry dinners and girls' nights out as opportunities to meet in furtherance of this conspiracy.

<sup>32</sup> *Id.* at  $\P 49 - 52$ .

<sup>33</sup> *Id.* at  $\P 53 - 60$ .

<sup>&</sup>lt;sup>34</sup> *Id. at* ¶61.

<sup>&</sup>lt;sup>35</sup> *Id. at* ¶6.

- 64. The purpose of these secret, conspiratorial meetings, discussions, and communications was to ensure that all Defendants agreed to participate in, implement, and maintain an unlawful price-fixing and market and customer allocation scheme.
- 65. Further, Defendants deceptively concealed their unlawful activities by mutually agreeing not to divulge the existence of the conspiracy to third parties, including Plaintiff and Class Members. Due to Defendants' conduct, Plaintiff and Class Members could not have known that they were paying an artificially inflated price for generic Clomipramine Hydrochloride capsules. Therefore, Defendants are estopped from asserting any applicable statute of limitations in defense of this action.
- 66. As a result of Defendants' unlawful agreements, Plaintiff and members of the Classes were injured because they paid, and continue to pay, supracompetitive prices for generic Clomipramine Hydrochloride sold in the United States during the Class Period.

#### 1. Concentration in the Market.

- 67. Concentration in a market for goods creates susceptibility for collusion and other anticompetitive conduct. The market for generic Clomipramine Hydrochloride capsules is highly concentrated. Defendants each possess large market shares in their respective markets. The limited number of manufacturers in this market facilitated Defendants' ability to coordinate prices of their generic drugs.
- 68. The market for generic Clomipramine Hydrochloride capsules is mature and Defendants can only compete on price in order to gain market share.

#### 2. High Barriers to Entry.

69. Typically, markets for goods that have high prices attract new competitors who can undercut competition by offering lower prices to the consuming public, thus mitigating effects of

collusion. However, when a market has high barriers to entry, new competitors are less likely to enter the market. Accordingly, high barriers to entry facilitate collusive behavior.

- 70. The market for generic Clomipramine Hydrochloride capsules has high barriers to entry, including regulatory, intellectual property and financial hurdles.
- 71. All generic drug manufacturers must receive FDA approval prior to marketing and selling products. FDA approval requires, inter alia, the preparation and filing of an ANDA, which typically costs at least \$1 million.<sup>36</sup> Bringing a new generic drug to market may cost another \$5 to \$20 million.<sup>37</sup>
- 72. Further, both state and federal law govern the operation of drug manufacturing facilities. Such costs of doing business are another regulatory barrier to entry for potential competitors.
- 73. Intellectual property costs can include acquisition of, and litigation over, patent rights, either through the investigation of whether a drug compound is protected by a valid patent or for establishment of preferred generic treatment under the Hatch-Waxman Act. Transactional costs such as licensing deals can add further layers of costs.
- 74. Finally, generic drug makers also incur large research and development costs, high labor costs to retain employees with specialized skills and knowledge as well as professional certifications suitable for the work required, significant capital outlay for sufficient real estate and equipment, and other corporate financial requirements inherent to the pharmaceutical industry.
- 75. The small number of competitors in the generic Clomipramine Hydrochloride capsules market reflects these high barriers to entry.

<sup>&</sup>lt;sup>36</sup> Testimony of Dr. Scott Gottlieb, Hearing on "Why Are Some Generic Drugs Skyrocketing in Price?" (Nov. 20, 2014), available at <a href="https://www.aci.org/wp-content/uploads/2014/11/Gottlieb-Generic-Drug-Testimony-112014.pdf">https://www.aci.org/wp-content/uploads/2014/11/Gottlieb-Generic-Drug-Testimony-12014.pdf</a>, at 7.

#### 3. Inelastic Demand.

- 76. In economics, elasticity of demand is the sensitivity of supply and demand to changes in one or the other. Price elasticity is defined as the measure of how much the quantity demanded will change if price, a separate factor, changes. When price elasticity of demand is inelastic, prices increase because there will only be a small decrease in demand relative to the price increase, such that the increases make up for the decreases. Accordingly, total revenues rise in a market with price inelasticity of demand, even if raw sales figures go down.
- 77. Perfectly inelastic demand occurs when consumers would pay anything for a good, such as food or water, which is necessary for survival. Colluding entities can profit handsomely from goods that have nearly perfectly inelastic demand because they can charge whatever they wish knowing, first, that consumers will pay whatever price is charged, and second, that the collusion blocks any kind of competition that should serve to lower prices in that market.
- 78. Significantly, Defendants continued to increase prices for generic Clomipramine Hydrochloride capsules even though the number of consumers using it decreased by 4%.<sup>38</sup>
- 79. Accordingly, Defendants have been able to reap materially significant profits as a result of attacking the integrity of the market for generic Clomipramine Hydrochloride capsules, as the market for the drug displays a price inelasticity of demand.

#### 4. Lack of Available Product Substitutes.

80. As above, generic Clomipramine Hydrochloride is an antidepressant, available by prescription, used to treat OCD. It is used by teenaged and adult patients. Other medications may not be indicated for the patient's condition.

https://www.cms.gov/Research-Statistics-Data-and-Systems: Statistics-Trends-and-Reports/Dashboard/Medicare-Drug-Spending/Drug-Spending/Dashboard.html.

81. The generic Clomipramine Hydrochloride products which Defendants manufacture, while formulated differently in certain cases, are each chemical compounds composed of the same raw materials. As such, the generic Clomipramine Hydrochloride capsules manufactured by Defendants are interchangeable and reasonable substitutes for one another.

# 5. Opportunities to Conspire.

- 82. Defendants' collusive scheme works because each Defendant has constant and continuous opportunities to meet rather than to compete. All Defendants participate in some capacity in GPhA, <sup>39</sup> a leading trade association for generic drug manufacturers and distributors. Defendants' representatives regularly attended meetings of GPhA, including meetings in February and June 2013, and meetings of other trade associations during the Class Period.
- 83. Additionally, Defendants attend industry trade shows and conferences which provide Defendants' representatives the opportunity to interact with each other directly, and discuss their respective businesses and customers. Recreational and social events at these conferences, such as golf outings, lunches, cocktail parties, dinners, and other activities at these trade shows and conferences provide additional opportunities for conspirators to meet with competitors away from the usual business setting. Defendants' representatives use these functions to discuss and share upcoming bids, specific generic drug markets, pricing strategies and pricing terms in their contracts with customers, among other competitively-sensitive information.
- 84. Moreover, the DOJ's grand jury subpoenas and informations also indicate that communications between Defendants were prevalent. The DOJ has stated that "prosecutors are

<sup>&</sup>lt;sup>39</sup> 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."

taking a close look at trade associations as part of their investigation as having been one potential avenue for facilitating the collusion between salespeople at different generic producers."<sup>40</sup>

- 85. The meetings in February and June 2013 provided Defendants with opportunities to collude. Shortly after the meetings, Defendants acted in concert to raise the price of generic Clomipramine Hydrochloride by a dramatic margin. The price increases resulted from Defendants' horizontal price-fixing agreement.
- 86. In this case, Defendants' common membership in GPhA provided them with opportunities to collude by sharing competitive information and collaborating on market strategies with regard to their generic Clomipramine Hydrochloride products.
- 87. Further, Defendants deceptively concealed their unlawful activities by mutually agreeing not to divulge the existence of the conspiracy to third parties, including Plaintiff and Class Members. Due to Defendants' conduct, Plaintiff and Class Members could not have known that they were paying an artificially inflated price for generic Clomipramine Hydrochloride capsules. Therefore, Defendants are estopped from asserting any applicable statute of limitations in defense of this action.

#### VII. <u>EFFECTS ON COMPETITION</u> AND DAMAGES

- 88. Defendants' combination and conspiracy as set forth in this complaint has had the following effects, among others:
  - a. Competition in the market for generic Clomipramine Hydrochloride capsules has been eliminated or substantially reduced;
  - b. Prices for generic Clomipramine Hydrochloride capsules have increased, and run contrary to the typical pricing patterns of generic drugs;

http://www.mergermarket.com/pdf/DoJ-Collusion-Generic-Drug-Prices-2015.pdf.

- c. United States purchasers have been deprived of the benefit of free and open competition on the basis of price in the market for generic Clomipramine Hydrochloride capsules; and
- d. As a direct and proximate result of Defendants' illicit anticompetitive conduct,

  Plaintiff and the Class of end-payors have been injured in their business and

  property in that, during the Class Period, they paid artificially inflated prices for
  generic Clomipramine Hydrochloride.
- 89. As a result of Defendants' conduct as herein alleged, Plaintiff and the Class have been damaged as measured by the full amount of the overcharges that they paid in an amount subject to proof and to be determined at trial.
- 90. The foregoing allegations are likely to have evidentiary support after a reasonable opportunity for discovery.

#### VIII. ANTITRUST IMPACT

- 91. Supracompetitive prices at an upstream level in the chain of distribution ordinarily result in higher prices at every level below. Such is the case here.
- 92. Wholesalers and retailers passed on the supracompetitive prices of generic Clomipramine Hydrochloride capsules to Plaintiff and Class members, who consequently paid overcharges.
- 93. Defendants' anticompetitive conduct enabled them to raise, fix, maintain, and stabilize prices to consumers and third-party payors in excess of the prices Defendants otherwise would have been able to charge absent their anticompetitive conduct.
- 94. The supracompetitive prices paid by Plaintiff and the Class are traceable to, and the direct, proximate, and foreseeable result of, Defendants' illegal concerted pricing policies.

# IX. CLASS ACTION ALLEGATIONS

95. Plaintiffs brings this action on behalf of themselves and as a class action under Rule 23(a) and (b)(2) of the Federal Rules of Civil Procedure, seeking equitable and injunctive relief on behalf of the following class (the "Nationwide Class"):

#### The Injunctive Class:

All persons or entities in the United States and its territories who indirectly purchased, paid, and provided reimbursement for some or all of the purchase price for Albuterol Sulfate tablets, other than for resale, for consumption by itself, its families, or its members, employees, insureds, participants, or beneficiaries, from at least as early as May 1, 2013 through and including the date that the anticompetitive effects of Defendants' unlawful conduct ceased.

96. Plaintiff also brings this action as a class action, under Fed. R. Civ. P. 23(a) and (b)(3), on behalf of themselves and a class of similarly situated individuals seeking damages arising from Defendants' conduct as described below:

#### The Damages Class:

All persons or entities who indirectly purchased, paid, and provided reimbursement for some or all of the purchase price for generic Clomipramine Hydrochloride capsules manufactured by Defendants and/or their affiliates, other than for resale, for consumption by itself, its families, or its members, employees, insureds, participants, or beneficiaries, from at least as early as June 1, 2013, through and including the date that the anticompetitive effects of Defendants' unlawful conduct ceased, in any of the following states, commonwealths, and territories in the United States: Alabama, Arizona, California, District of Columbia, Florida, Hawaii, Iowa, Kansas, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Mexico, New York, North Carolina, North Dakota, Oregon, Rhode Island, South Dakota, Tennessee, Utah, Vermont, West Virginia, and Wisconsin.

- 97. The following persons or entities are excluded from the Class:
  - a. Defendants and their officers, directors, management, employees, subsidiaries, or affiliates:
  - b. All federal or state governmental entities, excluding cities, towns, or municipalities

- with self-funded prescription drug plans;
- c. All persons or entities who purchased generic Clomipramine Hydrochloride capsules for purposes of resale directly from Defendants and their affiliates;
- d. Fully insured health plans, *i.e.*, plans that purchased insurance from another third-party payor covering 100% of the plan's reimbursement obligations to its members;
- e. Any "flat co-pay" consumers whose purchases were paid in part by a third-party payor and whose co-payment was the same regardless of the retail purchase price;
- f. Pharmacy Benefits Managers; and
- g. All judges assigned to this case and any members of their immediate families.
- 98. The Class members are so numerous that joinder is impracticable. Members of the Class are widely dispersed throughout the country. The Class includes at least hundreds of thousands of consumers and at least thousands of third-party payors.
- 99. Plaintiff's claims are typical of the claims of all Class members. Plaintiff and all Class members were damaged by the same wrongful conduct by Defendants, *i.e.*, they paid artificially inflated prices for generic Clomipramine Hydrochloride capsules, and were deprived of the benefits of competition as a result of Defendants' wrongful conduct.
- 100. Plaintiff will fairly and adequately protect and represent the interests of the Class. Plaintiff's interests are coincident with, and not antagonistic to, those of the Class.
- 101. Plaintiff is represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation, and have particular expertise with class action antitrust litigation in the pharmaceutical industry.
- 102. Questions of law and fact common to the Class members predominate over any questions that may affect only individual Class members, because Defendants have acted on

grounds generally applicable to the entire Class.

- 103. Questions of law and fact common to the Class include:
  - a. whether Defendants violated sections 1 and 3 of the Sherman Act, 15 U.S.C. §§ 1 and 3;
  - b. whether Defendants' combination, conspiracy, or agreement constitutes a violation of the state laws set forth below;
  - whether Defendants conspired to and did suppress competition in the market for generic Clomipramine Hydrochloride capsules;
  - d. whether Defendants' challenged conduct harmed competition in the generic Clomipramine Hydrochloride capsules market;
  - e. whether, and to what extent, Defendants' conduct as alleged herein caused antitrust injury to the business or property of Plaintiff and Class members in the form of overcharges; the quantum of aggregate overcharge damages paid by the class;
  - f. whether Defendants' concealment of their conduct, as alleged in this Complaint, has equitably tolled any statute of limitations so that Defendant is estopped from asserting a statute of limitations defense by virtue of its inequitable conduct; and
  - g. whether Plaintiff and Class members are entitled to injunctive relief to prevent further violation of the Sherman Act sections 1 and 3.
- 104. Class treatment is a superior method for the fair and efficient adjudication of the controversy, because, among other things, class treatment will permit a large number of similarly situated persons to prosecute their common claims in a similar forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including

providing injured persons and entities with a means of obtaining redress on claims that might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in the management of this class action.

- 105. Class treatment also is appropriate under Rule 23(b)(1) and/or (b)(2) because:
  - a. the prosecution of separate actions by individual Class members would create a risk
    of inconsistent or varying adjudications which would establish incompatible
    standards of conduct for Defendants;
  - b. the prosecution of separate actions by individual Class members would create a risk of adjudication of their rights that, as a practical matter, would be dispositive of the interests of other Class members not parties to such adjudications or would substantially impair or impede other Class members' ability to protect their interests; and
  - c. Defendants have acted and refused to act on grounds that apply generally to the Class such that final injunctive relief and/or declaratory relief is warranted with respect to the Class as a whole.
- 106. Plaintiff knows of no difficulty to be encountered in the management of this action that would preclude its maintenance as a class action.

## X. CLAIMS FOR RELIEF

# CLAIM I Violations of Section 1 of the Sherman Act, 15 U.S.C. § 1 (Asserted against all Defendants)

- 107. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.
  - 108. Beginning at least as early as June 1, 2013 to the present (the "Class Period"), the

exact dates being unknown to Plaintiff and the Class and exclusively within the knowledge of Defendants, Defendants, acting in concert, entered into a continuing combination or conspiracy to unreasonably restrain trade and commerce in violation of section 1 of the Sherman Act, 15 U.S.C. § 1, by artificially eliminating or reducing competition in the pricing of generic Clomipramine Hydrochloride capsules in the United States.

- 109. Defendants combined and conspired to raise, fix, maintain or stabilize the prices of generic Clomipramine Hydrochloride in the United States during the Class Period.
- 110. As a result of Defendants' and their co-conspirators' unlawful conduct and acts taken in furtherance of their horizontal price-fixing conspiracy, prices for generic Clomipramine Hydrochloride sold to purchasers in the United States during the Class Period were raised, fixed, maintained or stabilized at artificially inflated levels.
- 111. The combination or conspiracy among Defendants consisted of a continuing agreement, understanding and concerted action among Defendants and their co-conspirators.
- 112. For purposes of formulating and effectuating their combination or conspiracy, Defendants and their co-conspirators engaged in anticompetitive activities, the purpose and effect of which were to artificially fix, raise, maintain, and/or stabilize the prices of generic Clomipramine Hydrochloride capsules. Such activities included: (a) participating in meetings to discuss their respective generic Clomipramine Hydrochloride prices and how they could coordinate their market behavior to restrain trade with regard to their generic drug products; (b) agreeing to coordinate and manipulate the prices and available supply of generic Clomipramine Hydrochloride capsules in a manner that deprived United States purchasers of free and open price competition; and (c) providing pretextual justifications to purchasers and the public to explain the changes in the prices for Defendants' generic Clomipramine Hydrochloride capsules.

- 113. Defendants' concerted anticompetitive acts are illegal *per se*.
- 114. As a direct and proximate result of Defendants' illegal anticompetitive conduct, Plaintiff and the Class of end-payors have been injured in their business and property in that they have paid more for the generic Clomipramine Hydrochloride capsules that they purchased during the Class Period than they otherwise would have paid absent Defendants' wrongful conduct.
- 115. By reason of the foregoing, Plaintiff and the Class are entitled to injunctive relief and a reasonable attorney's fee pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26.

# CLAIM II Violations of Section 3 of the Sherman Act, 15 U.S.C. § 3 (Asserted against all Defendants)

- 116. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.
- 117. Beginning at least as early as June 1, 2013 to the present (the "Class Period"), the exact dates being unknown to Plaintiff and the Class and exclusively within the knowledge of Defendants, Defendants, acting in concert, entered into a continuing combination or conspiracy to unreasonably restrain trade and commerce in violation of section 3 of the Sherman Act, 15 U.S.C. § 3, by artificially eliminating or reducing competition for the pricing of generic Clomipramine Hydrochloride capsules in any territory of the United States or in the District of Columbia.
- 118. Defendants combined and conspired to raise, fix, maintain or stabilize the prices of generic Clomipramine Hydrochloride capsules in any territory of the United States or in the District of Columbia during the Class Period.
- 119. As a result of Defendants' and their co-conspirators' unlawful conduct and acts taken in furtherance of their horizontal price-fixing conspiracy, prices for generic Clomipramine Hydrochloride capsules sold to purchasers in any territory of the United States or in the District of

Columbia during the Class Period were raised, fixed, maintained or stabilized at artificially inflated levels.

- 120. The combination or conspiracy among Defendants consisted of a continuing agreement, understanding and concerted action among Defendants and their co-conspirators.
- 121. For purposes of formulating and effectuating their combination or conspiracy, Defendants and their co-conspirators engaged in anticompetitive activities, the purpose and effect of which were to artificially fix, raise, maintain, and/or stabilize the prices of generic Clomipramine Hydrochloride capsules. Such activities included: (a) participating in meetings to discuss their respective generic Clomipramine Hydrochloride prices and how they could coordinate their market behavior to restrain trade with regard to their generic drug products; (b) agreeing to coordinate and manipulate the prices and available supply of generic Clomipramine Hydrochloride capsules in a manner that deprived United States purchasers of free and open price competition; and (c) providing pretextual justifications to purchasers and the public to explain the changes in the prices for Defendants' generic Clomipramine Hydrochloride capsules.
  - 122. Defendants' concerted anticompetitive acts are illegal per se.
- 123. As a direct and proximate result of Defendants' illegal anticompetitive conduct, Plaintiff and the Class of end-payors have been injured in their business and property in that they have paid more for the generic Clomipramine Hydrochloride capsules that they purchased during the Class Period than they otherwise would have paid absent Defendants' wrongful conduct.
- 124. By reason of the foregoing, Plaintiff and the Class are entitled to injunctive relief and a reasonable attorney's fee pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26.

#### **CLAIM III**

Conspiracy and Combination in Restraint of Trade in Violation of State Laws (Asserted against all Defendants)

- 125. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.
- 126. Beginning at least as early as June 1, 2013 to the present (the "Class Period"), the exact dates being unknown to Plaintiff and the Class and exclusively within the knowledge of Defendants, Defendants, acting in concert, entered into a continuing combination, conspiracy or agreement to unreasonably restrain trade and commerce in restraint of trade, the purpose and effect of which was to fix, raise, maintain or stabilize the price of generic Clomipramine Hydrochloride capsules.
- 127. Defendants implemented the terms of their combination, conspiracy, or agreement and achieved their intended purpose. As a direct and proximate result of Defendants' anticompetitive conduct, as alleged herein, Plaintiff and the Class were harmed as set forth above.
- 128. Defendants' unlawful horizontal combination, conspiracy or agreement harmed competition in the market for generic Clomipramine Hydrochloride capsules.
- 129. There was and is no legitimate or non-pretextual procompetitive justification for Defendants' coordinated price increases that outweighs their harmful effect. Even if there were some conceivable justification, the coordinated price increases were not necessary to achieve that purpose.
- 130. By engaging in the foregoing conduct, Defendants entered a conspiracy and combination in restraint of trade in violation of the following state laws: (a) Ala. Code § 6-5-60, et seq., with respect to purchases in Alabama by members of the Damages Class; (b) Ariz. Rev. Stat. §§ 44-1401, et seq., with respect to purchases in Arizona by members of the Damages Class; (c) Cal. Bus. Code §§ 16700, et seq., and Cal. Bus. Code §§ 17200, et seq., with respect to purchases in California by members of the Damages Class; (d) D.C. Code Ann. §§ 28-4501, et

seq., with respect to purchases in the District of Columbia by members of the Damages Class; (e) Fla. Stat. §§ 501.201, et seq., with respect to purchases in Florida by members of the Damages Class; (f) Hawaii Code § 480, et seq., with respect to purchases in Hawaii by members of the Damages Class; (g) Iowa Code §§ 553 et seq., with respect to purchases in Iowa by members of the Damages Class; (h) Kan. Stat. Ann. §§ 50-101, et seq., with respect to purchases in Kansas by members of the Damages Class; (i) Me. Rev. Stat. Ann. 10, §§ 1101, et seq., with respect to purchases in Maine by members of the Damages Class; (j) Mass. Gen. L. Ch. 93A, et seq., with respect to purchases in Massachusetts by members of the Damages Class; (k) Mich. Comp. Laws Ann. §§ 445.772, et seq., with respect to purchases in Michigan by members of the Damages Class; (1) Minn. Stat. §§ 325D.49, et seq., with respect to purchases in Minnesota by members of the Damages Class; (m) Miss. Code Ann. §§ 75-21-1, et seq., with respect to purchases in Mississippi by members of the Damages Class; (n) Neb. Code Ann. §§ 59-801, et seq., with respect to purchases in Nebraska by members of the Damages Class; (o) Nev. Rev. Stat. Ann. §§ 598A, et seq., with respect to purchases in Nevada by members of the Damages Class; (p) N.M. Stat. Ann. §§ 57-1-1, et seq., with respect to purchases in New Mexico by members of the Damages Class; (q) N.Y. Gen. Bus. L. §§ 340, et seq., with respect to purchases in New York by members of the Damages Class; (r) N.C. Gen. Stat. §§ 75-1, et seq., with respect to purchases in North Carolina by members of the Damages Class; (s) N.D. Cent. Code §§ 51-08.1-01, et seq., with respect to purchases in North Dakota by members of the Damages Class; (t) Or. Rev. Stat. §§ 6.46.705, et seq., with respect to purchases in Oregon by members of the Damages Class; (u) R.I. Gen. Laws §§ 6-36-1 et seq., with respect to purchases in Rhode Island by members of the Damages Class; (v) S.D. Codified Laws Ann. §§ 37-1, et seq., with respect to purchases in South Dakota by members of the Damages Class; (w) Tenn. Code Ann. §§ 47-25-101, et seq., with respect to

purchases in Tennessee by members of the Damages Class; (x) Utah Code Ann. §§ 76-10-3101, et seq., with respect to purchases in Utah by members of the Damages Class; (y) Vt. Stat. Ann. 9, §§ 2453, et seq., with respect to purchases in Vermont by members of the Damages Class; (z) W.Va. Code §§ 47-18-3, et seq., with respect to purchases in West Virginia by members of the Damages Class; and (aa) Wis. Stat. §§ 133.03, et seq., with respect to purchases in Wisconsin by members of the Damages Class.

- 131. Plaintiff and Class members have been and will continue to be injured in their business or property by reason of Defendants' violations of the laws set forth above, in that Plaintiff and Class members (i) were denied the opportunity to purchase more affordable generic Clomipramine Hydrochloride capsules, and (ii) paid higher prices for generic Clomipramine Hydrochloride capsules than they would have paid but for Defendants' unlawful conduct. Such injuries are of the type that the aforementioned laws were intended to prevent and flow from that which makes Defendants' acts unlawful.
- 132. Plaintiff and the Class are entitled to actual and trebled damages as permitted by law.

# CLAIM IV Violations of State Consumer Protection Statutes (Asserted against all Defendants)

- 133. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.
- 134. Beginning at least as early as June 1, 2013 to the present ("Class Period"), the exact dates being unknown to Plaintiff and the Class and exclusively within the knowledge of Defendants, Defendants, acting in concert, engaged in unfair methods of competition, and unfair and unconscionable acts or practices in the course of trade, with respect to the sale of generic

Clomipramine Hydrochloride capsules in violation of the following state consumer protection and unfair competition statutes: Cal. Bus. & Prof. Code § 17200, et seq.; D.C. Code Ann. § 28-3901, et seq.; Fla. Stat. § 501.201, et seq.; Haw. Rev. Stat. § 480-2, et seq.; Kan. Stat. Ann. § 50-623, et seq.; Mass. Gen. Laws chapter 934 § 1, et seq.; Mich. Comp. Laws § 445.901, et seq.; Miss. Code § 75-24-1, et seq.; Neb. Rev. Stat. § 59-1601, et seq.; N.M. Stat. Ann. § 57-12-1, et seq.; N.C. Gen. Stat. § 75-1.1, et seq.; and Rhode Island Gen. Laws § 6-13.1-1, et seq.

- 135. Defendants agreed to, and did, act unfairly in restraint of commerce by affecting, fixing, controlling and/or maintaining, at artificial and supracompetitive levels, the prices at which generic Clomipramine Hydrochloride capsules were sold, distributed, or obtained and made efforts to conceal their agreements from Plaintiff and the Class.
- 136. Defendants' intentional anticompetitive acts, described above, were intended to and did cause Plaintiff and/or Class members to pay supracompetitive prices for generic Clomipramine Hydrochloride capsules in the states listed above.
- 137. All of Defendants' unlawful and unfair conduct occurred in the course of their business and was part of a generalized course of conduct.
- 138. As a direct and proximate result of the Defendants' unfair methods of competition and unfair and unconscionable trade practices, Plaintiff and the Class have been injured in their business and property in that they paid more for generic Clomipramine Hydrochloride capsules than they otherwise would have paid in the absence of Defendants' unlawful and unfair conduct.
- 139. Plaintiff and the Class are therefore entitled to appropriate relief as provided for by the laws of the states set forth above, including but not limited to damages, injunctive relief, reasonable attorneys' fees, and equitable relief, such as restitution and/or disgorgement of all revenues, earnings, profits, compensation, and benefits Defendants obtained by reason of their

unlawful and unfair conduct.

#### XI. PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of itself and the Class, respectfully requests that the Court:

- A. Determine that this action may be maintained as a class action pursuant to Federal Rules of Civil Procedure 23(a), (b)(l), (b)(2), and (b)(3), and direct that reasonable notice of this action, as provided by Federal Rule of Civil Procedure23(c)(2), be given to the Class, and designate the Plaintiff as the representative of the Class;
- B. Enter joint and several judgments against Defendants and in favor of Plaintiff and the Class;
- C. Award the Class damages and, where applicable, treble, multiple, punitive, and/or other damages, in an amount to be determined at trial, including interest;
- D. Grant Plaintiff and the Class equitable relief in the nature of disgorgement, restitution, and establishment of a constructive trust to remedy Defendants' illegal conduct, including:
  - 1. A judicial determination declaring the rights of Plaintiff and Class members and the corresponding responsibilities of Defendants;
  - 2. A declaration that Defendants are to be financially responsible for the costs and expenses of a Court-approved notice program by mail, broadcast media, and publication designed to give immediate notification to Class members;
  - 3. Disgorgement and/or the imposition of a constructive trust upon Defendants' ill-gotten gains, thereby freezing Defendants' assets, and/or requiring Defendants to pay restitution to Plaintiff and Class members of all funds acquired by means of any act or

practice declared by this Court to violate federal or state statutes or to constitute unfair methods of competition or unfair or unconscionable acts or practices in the course of trade.

E. Award Plaintiff and the Class their costs of suit, including reasonable attorneys' fees as provided for by law.

# XII. <u>DEMAND FOR JURY TRIAL</u>

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff, on behalf of itself and the Class, demands a trial by jury on all issues so triable.

By:

Dated:

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# **ClassAction.org**

This complaint is part of ClassAction.org's searchable class action lawsuit database and can be found in this post: <u>Lawsuit: Pharma Companies Conspired to Fix Generic Drug Prices</u>