UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

In re Bystolic Antitrust Litigation	Case No. 1:20-cv-05735-LJL
This Document Relates To: ALL END-PAYOR ACTIONS	

END-PAYOR PLAINTIFFS' CONSOLIDATED CLASS ACTION COMPLAINT AND JURY DEMAND

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Plaintiffs, the Mayor and City Council of Baltimore ("City of Baltimore"), UFCW Local 1500 Welfare Fund ("Local 1500"), Teamsters Western Region & Local 177 Health Care Plan ("Local 177"), Fraternal Order of Police, Miami Lodge 20, Insurance Trust Fund ("FOP"), Law Enforcement Health Benefits, Inc. ("LEHB"), Teamsters Local No. 1150 Prescription Drug Benefit Plan ("Local 1150"), and Teamsters Local 237 Welfare Fund and Teamsters Local 237 Retirees' Benefit Fund ("Local 237") (together, City of Baltimore, Local 1500, Local 177, FOP, LEHB, Local 1150 and Local 237 are referred to as "Plaintiffs"), bring this action on behalf of themselves, and all others similarly situated, against Forest Laboratories, Inc., Forest Laboratories, LLC, Forest Laboratories Holdings, Ltd., and Forest Laboratories Ireland Ltd., and their successors AbbVie, Inc. ("AbbVie") and Allergan, Inc., Allergan Sales, LLC, and Allergan USA, Inc. (collectively, "Allergan") (together, Forest Laboratories, Inc., Forest Laboratories, LLC, Forest Laboratories Holdings, Ltd., Forest Laboratories Ireland Ltd., AbbVie, Allergan and Forest are referred to as "Forest"); Hetero USA Inc., Hetero Labs Ltd., and Hetero Drugs Ltd. (collectively, "Hetero"); Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc. (collectively, "Torrent"); Alkem Laboratories Ltd. ("Alkem") and Ascend Laboratories, LLC ("Ascend") (collectively, "Alkem"); Indchemie Health Specialties Private Ltd. ("Indchemie"); Glenmark Generics Inc., USA, Glenmark Generics Ltd., Glenmark Pharmaceuticals Ltd. and Glenmark Pharmaceuticals S.A. (collectively, "Glenmark"); Amerigen Pharmaceuticals, Inc., Amerigen Pharmaceuticals, Ltd. and ANI Pharmaceuticals, Inc. (collectively, "Amerigen"); and Watson Laboratories, Inc. (NV), Watson Laboratories, Inc. (DE), Watson Laboratories, Inc. (NY), Watson Laboratories, Inc. (CT), Watson Pharma, Inc., Watson Pharmaceuticals Inc., Actavis, Inc., Teva Pharmaceutical Industries Ltd., and Teva

Pharmaceuticals USA, Inc. (collectively, "Watson") (together, Hetero, Torrent, Alkem, Indchemie, Glenmark, Amerigen, and Watson are referred to as "Generic Defendants," and Forest and the Generic Defendants are referred to as "Defendants"). These allegations are based on investigations of counsel, publicly available materials and knowledge, information, and belief.

I. INTRODUCTION

1. This case, seeking damages (trebled or multiplied as provided by state law) and declaratory and injunctive relief, arises from the Defendants' illegal scheme to unlawfully exclude competition in the United States and its territories and delay entry of generic substitutes for the branded drug Bystolic. Bystolic is a prescription drug manufactured by Forest and its successors, and approved by the U.S. Food and Drug Administration ("FDA") for the treatment of high blood pressure or hypertension.

2. Specifically, Bystolic, also known as "nebivolol hydrochloride" or "nebivolol HCl," is a "beta blocker." Bystolic blocks the action of certain natural substances in a patient's body on the heart and blood vessels and thereby lowers heart rate, blood pressure, and strain on the heart. Bystolic is one of Forest's key drugs with annual sales reported close to $1 billion.[1]

3. Generic drugs are typically sold at a significant discount from their branded counterparts, enabling consumers and third-party payors to save hundreds of millions of dollars. The only material difference between generic and brand name drugs is their price – generics are typically at least 50-80% less expensive when there are multiple generic competitors on the market. As a result – and well understood by Forest – generic entry is:

[1] IMS Health National Sales Perspectives: Retail & Non-Retail, March 2017.

(a) an opportunity for drug purchasers to obtain enormous cost savings; and (b) a serious threat to the monopoly power and profits of the manufacturer of the corresponding brand name drug, such as Forest.

4. AB-rated generics typically take 80% or more of the sales of a drug molecule from the brand name product within six months of generic entry. These extremely rapid erosion rates of the brand sales are due in large part to a unique feature of the pharmaceutical industry called drug substitution laws, which permit (and in many states require) dispensing pharmacies to substitute available AB-rated generic drugs for a brand drug unless the prescribing physician specifically orders otherwise.

5. Recognizing the huge opportunity for this medication, on or about December 17, 2011, generic drug manufacturers began to file Abbreviated New Drug Applications ("ANDAs") with the FDA seeking approval to market generic nebivolol HCl.

6. But no generic competitor has or will enter the market until September 17, 2021. Instead, Forest engineered a series of unlawful reverse-payment deals (also known as "pay for delay" deals) with each of its would-be generic competitors, specifically, each of the Generic Defendants.

7. From October 2012 through November 2013, Defendants entered into these serial deals pursuant to which each of the Generic Defendants agreed not to compete with Forest or enter the market with its generic version of Bystolic prior to September 17, 2021, unless another Generic Defendant entered the market earlier:

Settling Generic Competitor	Date of Settlement	Agreed Upon Delayed Entry Date
Hetero	October 24, 2012	September 17, 2021
Torrent	November 21, 2012	September 17, 2021
Alkem	November 27, 2012	September 17, 2021
Indchemie	November 27, 2012	September 17, 2021
Glenmark	December 21, 2012	September 17, 2021

Amerigen	July 18, 2013	September 17, 2021
Watson	November 6, 2013	September 17, 2021

8. In exchange, the Generic Defendants received "side-deals," and cash payments from Forest. Each of the payments exceeds $15,000,000 in value. As corporate successors to one or more of the Forest Defendants, Allergan and then AbbVie have continued this illegal scheme and unreasonable restraint of trade in the market for nebivolol HCl.

9. Defendants' unlawful scheme succeeded. Every month of delayed generic competition has allowed Forest to unlawfully maintain many millions of dollars in monopoly profits from Bystolic without generic competition and allowed the Generic Defendants to share in those profits by pocketing large and unjustified payments from Forest for agreeing to delay bringing generic nebivolol HCl to market, all at the expense of Plaintiffs and the proposed End-Payor Class.

10. Forest submitted two patents for listing in the FDA Orange Book under the new drug application for Bystolic: U.S. Patent Nos. 6,545,040 (the "'040 Patent") and 5,759,580 (the "'580 Patent"). Beginning on December 17, 2011,[2] after the Generic Defendants became the first generic manufacturers to seek approval from the FDA to market generic Bystolic, Forest sued each of them, accusing them of infringing the '040 Patent. Forest did not assert the '580 Patent against the Generic Defendants. These suits, filed in mid-March 2012, automatically triggered stays of FDA approval of the generic products

[2] *See*, *e.g.*, November 27, 2015 Letter from FDA to Watson, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/203683Orig1s000ltr.pdf; May 27, 2017 Letter from FDA to Glenmark, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/203821Orig1s000ltr.pdf; June 24, 2015 Letter from FDA to Alkem, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/203741Orig1s000ltr.pdf.

(meaning that, pursuant to the applicable regulatory structure, regardless of the merits of the patent infringement actions, the FDA could not grant final approval to any of the Generic Defendants to launch a generic version of Bystolic before June 18, 2015 absent an earlier favorable decision for the Generic Defendants or a dismissal of the actions). Foreclosing the Generic Defendants from launching has also foreclosed all other generic manufacturers; as the first manufacturers to file for approval for generic Bystolic, the Generic Defendants were eligible to share 180 days of market exclusivity, free from competition from other generic manufacturers once they actually launch their generic versions of Bystolic (other than competition from a generic marketed or authorized to be marketed by Forest, also known as an "authorized generic").

11. Between March 2012 and November 2013, while the stays were in effect, the Generic Defendants fought the patent infringement suits and prepared to bring their generic Bystolic products to market to compete with Forest's branded Bystolic. At least seven of the Generic Defendants would have been ready to launch well before September 17, 2021, the delayed entry date agreed to as a result of the unlawful reverse payment agreement, as each had received final FDA approval to do so as follows:

Manufacturer	ANDA No.	Final Approval Date
Amerigen	203659	April 16, 2015
Alkem	203741	June 24, 2015
Indchemie	203828	July 29, 2015
Watson	203683	November 27, 2015
Glenmark	203821	May 25, 2017
Torrent	203966	March 2, 2018
Hetero	203825	November 3, 2020

12. The Generic Defendants would have succeeded in the patent litigation because the '040 Patent was weak. The '040 Patent litigation likely would have concluded by mid-2015, including all appeals. The Generic Defendants would have won and launched

by the later of: (a) the June 2015 expiration of the litigation stay, or (b) the date their ANDAs were finally approved. But rather than compete with Forest as early as mid-2015 and trigger the predictable reduction in Bystolic brand sales and revenues such competition would cause, each Generic Defendant agreed to accept a reverse payment from Forest to stay off the market until September 17, 2021.

13. The side-deals that Forest provided, and each Generic Defendant entered into, were intended to shield Forest from the risk of competition and to allow each Defendant to share in Forest's monopoly profits. The Generic Defendants readily accepted these exclusionary side-deals to quit the patent fight.

14. On February 18, 2014, Actavis PLC and Forest announced an equity and cash merger.[3] On March 1, 2014, Forest's outside lawyers at Weil, Gotshal & Manges LLP were reviewing Forest's documents as part of their "work on the Actavis merger agreement."[4] On March 4, 2014, Forest's outside lawyers informed Forest in-house counsel Eric Agovino via email (the "Agovino email") that "[b]efore we engage in any discussions with the FTC . . . we think it would be prudent for us to review all of the Bystolic settlement and licensing agreements ***as well as the side agreements with those generic companies***."[5] Agovino replied: "We entered into settlement agreements with the following defendants:

1) Hetero

2) Torrent

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[3] *See* Actavis to Acquire Forest Laboratories, Inc. for ~$25 Billion in an Equity and Cash Transaction, https://www.businesswire.com/news/home/20140218005877/en/Actavis-Acquire-Forest-Laboratories-25-Billion-Equity.

[4] *In re Namenda Direct Purchaser Antitrust Litig.*, 15-cv-07488-CM-RWL (S.D.N.Y. Mar. 7, 2019) (ECF No. 680-44 at 332).

[5] *Id*. (emphasis added).

3) Alkem

4) Indchemie

5) Glenmark

6) Amerigen

7) Actavis [Watson's successor]

All had side-deals (one was struck with Alkem, which is a related company with Indchemie)."[6]

15. Forest's Agreement and Plan of Merger with Actavis PLC (the "Merger Agreement"), dated February 17, 2014, provides additional details. Specifically, in the Merger Agreement Forest disclosed its "material contracts," which are defined to include "any Contract involving the settlement of any action or threatened action (or series of related actions) (A) which will (x) involve payments after the date hereof of consideration in excess of $15,000,000 or (y) impose monitoring or reporting obligations to any other Person outside the ordinary course of business or (B) with respect to which material conditions precedent to the settlement have not been satisfied."[7]

16. Forest listed each of the side-deals as a "material contract" "in connection with the settlement of BYSTOLIC patent dispute."[8]

17. Forest thus has described each of the side-deals set forth below as a "material contract," *i.e.*, it was a "Contract involving the settlement of any action or threatened action (or series of related actions) (A) which will (x) involve payments after the date hereof of

[6] *Id*. (emphasis added).

[7] *In re Namenda Direct Purchaser Antitrust Litig.*, 15-cv-07488-CM-RWL (S.D.N.Y. Mar. 7, 2019) (ECF No. 680-22 at 69).

[8] *Id*.

consideration in excess of $15,000,000 or (y) impose monitoring or reporting obligations to any other Person outside the ordinary course of business or (B) with respect to which material conditions precedent to the settlement have not been satisfied." The respective contracts are as follows:

Generic Defendant	Settlement Agreement
Hetero	"SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Hetero USA Inc. and Hetero Labs Ltd. dated October 24, 2012 . . . together with the FINAL TERM SHEET between Hetero Drugs Ltd. and Forest Laboratories Ireland Ltd. dated October 5, 2012, in connection with the settlement of BYSTOLIC patent dispute."[9]
Torrent	"SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc. dated November 21, 2012 . . . together with the PATENT ASSIGNMENT AGREEMENT between Torrent Pharmaceuticals Ltd and Forest Laboratories Holdings Ltd. dated November 21, 2012, in connection with the settlement of BYSTOLIC patent dispute."[10]
Alkem	"SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Alkem Laboratories Ltd. dated November 27, 2012 . . . together with the TERM SHEET between Alkem Laboratories Ltd., Indchemie Health Specialties Private Ltd., and Forest Laboratories Ireland Ltd. dated November 28, 2012, in connection with the settlement of BYSTOLIC patent dispute."[11]

[9] *In re Namenda Direct Purchaser Antitrust Litig.*, 15-cv-07488-CM-RWL (S.D.N.Y. Mar. 7, 2019) (ECF No. 680-22 at 69).

[10] *Id.* at 179.

[11] *Id.*

Generic Defendant	Settlement Agreement
Indchemie	AMENDMENT NO. 1 TO SETTLEMENT AGREEMENT was executed on January 9, 2013" and "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd, and Indchemie Health Specialties Private Ltd. dated November 27, 2012 . . . together with the TERM SHEET between Alkem Laboratories Ltd, Indchemie Health Specialties Private Ltd, and Forest Laboratories Ireland Ltd. dated November 28, 2012, in connection with the settlement of BYSTOLIC patent dispute."[12]
Glenmark	"SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd, and Glenmark Generics Inc., USA and Glenmark Generics Ltd. dated December 21, 2012 . . . together with the COLLABORATION AND OPTION AGREEMENT between Glenmark Pharmaceuticals S.A. and Forest Laboratories Holdings Ltd. dated December 21, 2012, in connection with the settlement of BYSTOLIC patent dispute."[13]
Amerigen	"SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Amerigen Pharmaceuticals, Inc. and Amerigen Pharmaceuticals, Ltd. dated July 18, 2013 . . . together with the BINDING TERM SHEET COLLABORATION AGREEMENT between Forest Laboratories, Inc. and Amerigen Pharmaceuticals, Ltd. dated July 18, 2013, in connection with the settlement of BYSTOLIC patent dispute."[14]
Watson	"SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Watson Laboratories, Inc. (NV), Watson Laboratories, Inc. (DE), Watson Laboratories, Inc. (NY), Watson Laboratories, Inc. (CT), Watson Pharma, Inc., and Actavis, Inc. dated November 6, 2013 . . . together with (a) the LETTER from Forest Laboratories, Inc. to Moksha8, Inc. dated November 1, 2013 and (b) TERMINATION AND RELEASE AGREEMENT between Actavis, Inc. and Moksha8, Inc. dated November 4, 2013, in connection with the settlement of BYSTOLIC patent dispute."[15]

[12] *Id.*

[13] *Id.*

[14] *Id.* at 180.

[15] *Id.*

18. Forest listed the side-deals in the Merger Agreement because, on information and belief, they "involve payments after the date [t]hereof of consideration in excess of $15,000,000."

19. As Forest acknowledged in the Agovino email, and in the Merger Agreement, the side-deals were entered into as part and parcel of Forest's and the Generic Defendants' patent settlement agreements in the Bystolic patent litigation.

20. In addition to the consideration each Generic Defendant accepted from Forest in the form of a side-deal, Forest "agreed to reimburse certain of the Settling Defendants' legal costs in connection with the patent litigation."[16]

21. Forest's settlement agreements also include what is known as a "contingent launch provision" ("CLP"), or an "acceleration clause." CLPs ensure a settling generic that it will not be competitively disadvantaged should a later settling generic negotiate an earlier licensed entry date or otherwise come to market earlier. Pursuant to the CLPs here, the entry date may be "accelerated" permitting the settling generic to enter the market at the same time as any of its competitors. CLPs ensure settling generic ANDA filers that, if any other ANDA filer somehow makes it to market before the agreed-upon licensed entry date, that ANDA filer's licensed entry date would be accelerated so that it could launch at the same time.

22. When CLPs are used, they generally operate the same way in each ANDA filer's settlement agreement. Under a CLP, the first ANDA filer obtains protection from other first ANDA filers by agreeing to delay the launch of its generic product from the date of settlement until a date certain (here, exactly three months before the expiration of the '040

[16] https://www.sec.gov/Archives/edgar/data/38074/000003807413000014/forest10k2013 htm at 29.

Patent),[17] but *if and only if* all other first ANDA filers follow suit. By entering into their respective agreements, each Generic Defendant and Forest ensured that without regard to the strength of Generic Defendants' challenges to the '040 Patent, Bystolic would have no generic competitors while Forest maintains its unlawfully-generated monopoly profits until at least September 17, 2021, and none of the Generic Defendants would come to market earlier.

23. Reverse-payment agreements like the side-deals in this case delay the entry date of generic drug products beyond the date when competition would ensue in the absence of a reverse payment. As the United States Supreme Court put it, "An unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival. And that fact, in turn, suggests that the payment's *objective* is to maintain supracompetitive prices . . . ." *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2236 (2013).[18] Without the ability to offer or accept an unlawful reverse-payment, Forest and each Generic Defendant would have instead agreed upon earlier licensed entry dates for generic versions of Bystolic. Because of the CLPs, if *just one* Generic Defendant did not take an unlawful payment, and instead insisted on an earlier entry date untainted by a side-deal, *every other* Generic Defendant would enter on that same earlier date.

24. Accordingly, each Generic Defendant had the power to either delay or accelerate generic entry and was therefore the proximate and foreseeable cause of injury to Plaintiffs and the End-Payor Class they seek to represent (defined below). Even if they acted

[17] *Id*.

[18] *See also King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388, 405 (3d Cir. 2015) (The Third Circuit Court of Appeals observed, "when the parties' settlement includes a [payment], the generic also presumably agrees to an early entry date [before patent expiration] that is later than it would have otherwise accepted.").

independently of one another, the Generic Defendants jointly and severally contributed to an indivisible harm because each of their reverse payment agreements caused delay of generic versions of Bystolic in a manner for which there is no reasonable basis for division according to the contribution of each Generic Defendant.[19]

25. But for the anticompetitive reverse-payments, the Generic Defendants would have launched their generic products earlier either: (a) at risk;[20] (b) upon prevailing against Forest in the underlying patent litigation; or (c) via lawful settlement agreements providing for earlier negotiated entry dates untainted by the delay caused by the unlawful reverse-payments.

26. Had any of the above scenarios played out – as would have occurred absent the unlawful reverse-payments – Plaintiffs and the proposed End-Payor Class would have paid substantially less for nebivolol HCl.

27. Defendants' conduct was designed to, did, and continues to: (a) delay the entry of less expensive, AB-rated generic versions of Bystolic; (b) fix, raise, maintain or stabilize the price of nebivolol HCl; and (c) allocate 100% of the United States market for nebivolol HCl to Forest until three months before expiration of the '040 Patent.

28. The Generic Defendants' conspiracies with Forest – as distinguished from growth or development as a consequence of a legally-obtained valid patent, other legally-obtained market exclusivity, a superior product, business acumen, or historical accident –

[19] *See*, *e.g.*, *In re Modafinil Antitrust Litig.*, 837 F.3d 238, 262 n.29 (3d Cir. 2016).

[20] An "at risk" launch occurs when a generic has received final approval from the FDA to market its product but the patent infringement litigation is continuing, and therefore the generic may be "at risk" if it enters the market but later loses the patent litigation.

constituted willful exclusionary conduct that enabled Forest to maintain monopoly power in the nebivolol HCl market.

29. Plaintiffs bring this action as end-payor purchasers of Bystolic, on their own behalf and on behalf of all similarly situated end-payor purchasers. As alleged below, Defendants' unlawful conduct injured Plaintiffs and the End-Payor Class Plaintiffs seek to represent by preventing generic nebivolol HCl manufacturers from entering the market with competing generic products and has cost Plaintiffs and the proposed End-Payor Class hundreds of millions of dollars in overcharge damages.

30. Plaintiffs and the proposed End-Payor Class seek to recover damages, including treble damages, under the state antitrust and consumer protection laws enumerated below, as well as injunctive relief.

II. JURISDICTION AND VENUE

31. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because this is a class action involving common questions of law or fact in which the aggregate amount in controversy exceeds $5,000,000, exclusive of interest and costs; there are more than one hundred members of the Class; and at least one member of the putative Class is a citizen of a state different from that of one of Defendants. This Court also has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1337(a), 1407, 15 U.S.C. §§ 15, 22, and 15 U.S.C. § 26, as Plaintiffs allege claims under Section 16 of the Clayton Act, 15 U.S.C. § 26, for injunctive and equitable relief to remedy Defendants' violations of Sections 1 and 2 of the Sherman Antitrust Act, 15 U.S. C. §§ 1, 2.

32. This Court has supplemental jurisdiction over state law claims pursuant to 28 U.S.C. § 1367(a).

33. Venue is proper within this District under 15 U.S.C. §§ 15(a), 22, and 28 U.S.C. §§ 1391(b), (c), (d). Defendants transact business within this District and/or have agents in and/or that can be found in this District, and a substantial portion of the affected interstate trade and commerce discussed below was carried out in this District. At the time of the unlawful settlements, Forest was headquartered in this District.

34. Defendants' conduct, as described in this Complaint, was within the flow of, was intended to, and did have a substantial effect on, the interstate commerce of the United States, including in this District.

35. During the Class Period, Forest manufactured, sold and shipped Bystolic at supracompetitive prices in a continuous and uninterrupted flow of interstate commerce. Defendants' anticompetitive conduct had a direct, substantial, and reasonably foreseeable effect on interstate commerce.

36. During the Class Period, each Defendant, or one or more of its affiliates, used the instrumentalities of interstate commerce to join or effectuate their scheme.

37. The Court has personal jurisdiction over each Defendant. Each Defendant has transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of the illegal scheme throughout the United States, including in this District. The scheme has been directed at and has had the intended effect of causing injury to individuals and companies residing in or doing business throughout the United States, including in this District.

38. The Court has personal jurisdiction over each Defendant under 15 U.S.C. § 22 because each Defendant transacts business in this District. This Court has specific personal jurisdiction under CPLR § 302(a) over all Defendants because Forest, from its then-

principal place of business in New York, NY, did all of the following: (a) entered into the agreements containing the challenged reverse payments to each Generic Defendant; (b) made the promised reverse payments to each Generic Defendant; (c) enforced each Generic Defendant's agreement to delay entry of its generic Bystolic in consideration for those reverse payments; (d) sold branded Bystolic at supracompetitive prices made possible by the generic delay those reverse payments to each Generic Defendant purchased; and (e) earned as a result of those sales ill-gotten gains from the delay in generic Bystolic competition that those reverse payments to each Generic Defendant purchased. Moreover, some of the agreements containing the challenged reverse payments direct application of New York law and select a New York forum. Personal jurisdiction also lies under Fed. R. Civ. P. 4(k)(2) over the foreign domiciliary defendants.

III. THE PARTIES

A. Plaintiffs

39. Plaintiff the Mayor and City Council of Baltimore is a municipality located in Baltimore, Maryland. During the Class Period, as defined below, the City of Baltimore purchased, paid, and/or provided reimbursement for some or all of the purchase price of Bystolic for personal and/or household use from pharmacies located in and/or on behalf of members located in California, the District of Columbia, Delaware, Florida, Georgia, Illinois, Indiana, Kentucky, Massachusetts, Maryland, Missouri, North Carolina, Nebraska, New Jersey, Nevada, Pennsylvania, South Carolina, Texas, Virginia and West Virginia. The City of Baltimore paid more than it would have absent Defendants' unlawful anticompetitive scheme to prevent generic entry and was injured as a result of the illegal and wrongful conduct alleged herein. The City of Baltimore purchased, paid and/or provided reimbursement for purchases of Bystolic in Massachusetts for personal use on behalf of its

members and/or beneficiaries. The City of Baltimore intends to continue purchasing, intends to continue purchasing, paying, and/or providing reimbursement for some or all of the purchase price of Bystolic and intends to purchase, pay, and/or provide reimbursement for generic Bystolic when it becomes available and will be injured as a result of Defendants ongoing unlawful conduct.

40. Plaintiff UFCW Local 1500 Welfare Fund is an employee welfare benefits fund with its principal place of business at 425 Merrick Avenue, Westbury, New York. Local 1500 provides nearly 23,000 plan participants with health and welfare benefits and, with 15,000 members, is the largest grocery union in New York. During the Class Period (as defined below), Local 1500 purchased, paid, and/or reimbursed for some or all of the purchase price for Bystolic for personal and/or household use from pharmacies located in and/or on behalf of members located in New York and New Jersey. Local 1500 paid more than it would have absent Defendants' unlawful anticompetitive scheme to prevent generic entry and was injured as a result of the illegal and wrongful conduct alleged herein. Local 1500 intends to continue purchasing, paying, and/or providing reimbursement Bystolic and intends to purchase generic Bystolic when it becomes available and will be injured as a result of Defendants' ongoing unlawful conduct.

41. Plaintiff Teamsters Western Region & Local 177 Health Care Plan is a multiemployer health and welfare plan headquartered in Arizona. Local 177 provides self-funded healthcare coverage to over 40,000 employees and their family members. During the Class Period (as defined below), Local 177 purchased, paid, and/or provided reimbursement for some or all of the purchase price of Bystolic for the personal and/or household use from pharmacies located in and/or on behalf of members located in Alaska, Arizona, California,

Colorado, Florida, Hawaii, Idaho, Illinois, Indiana, Louisiana, Massachusetts, Missouri, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Ohio, Oregon, Pennsylvania, South Carolina, Texas, Utah, Virginia, Washington and Wisconsin. Local 177 paid more than it would have absent Defendants' unlawful anticompetitive scheme to prevent generic entry and was injured as a result of the illegal and wrongful conduct alleged herein. Local 177 intends to continue purchasing, paying, and/or providing reimbursement for some or all of the purchase price of Bystolic and intends to purchase, pay, and/or provide reimbursement for generic Bystolic when it becomes available and will be injured as a result of Defendants' ongoing unlawful conduct.

42. Plaintiff Fraternal Order of Police, Miami Lodge 20, Insurance Trust Fund is a governmental plan established and funded through contributions from the City of Miami and the plan's members, who are current and retired sworn officers from the City of Miami Police Department and their dependents. During the Class Period (as defined below), FOP purchased, paid, and/or provided reimbursement for some or all of the purchase price of Bystolic for the personal and/or household use of its members from pharmacies located in and/or on behalf of members located in Alabama, Florida, Idaho and Texas. FOP paid more than it would have absent Defendants' unlawful anticompetitive scheme to prevent generic entry and was injured as a result of the illegal and wrongful conduct alleged herein. FOP intends to continue purchasing, paying, and/or providing reimbursement for some or all of the purchase price of Bystolic and intends to purchase, pay, and/or provide reimbursement for generic Bystolic when it becomes available and will be injured as a result of Defendants' ongoing unlawful conduct.

43. Plaintiff Law Enforcement Health Benefits, Inc. is a voluntary employee benefits plan organized pursuant to § 501(c) of the Internal Revenue Code to provide health benefits to its eligible participants and beneficiaries. LEHB's members are current and retired sworn Philadelphia Police officers, Deputy Sheriffs, and County Detectives, and their dependents. LEHB was established pursuant to a duly executed Trust Agreement for the purpose of providing medical, surgical, and hospital care or benefits, including dental, optical and prescription drug benefits, to approximately 23,000 beneficiaries and covered spouses and dependents. LEHB maintains its principal place of business in Philadelphia, Pennsylvania. During the Class Period (as defined below), LEHB purchased, paid, and/or provided reimbursement for some or all of the purchase price of Bystolic for the personal and/or household use of its members from pharmacies located in and/or on behalf of members located in California, Florida, New Jersey, Pennsylvania and Tennessee. LEHB paid more than it would have absent Defendants' unlawful anticompetitive scheme to prevent generic entry and was injured as a result of the illegal and wrongful conduct alleged herein. LEHB intends to continue purchasing, paying, and/or providing reimbursement for some or all of the purchase price of Bystolic and intends to purchase, pay, and/or provide reimbursement for generic Bystolic when it becomes available and will be injured as a result of Defendants' ongoing unlawful conduct.

44. Plaintiff Teamsters Local No. 1150 Prescription Drug Benefit Plan maintains its principal place of business in Wallingford, Connecticut. Local 1150 provides prescription drug benefits to its union members, plus their spouses and dependents. During the Class Period (as defined below), Local 1150 purchased, paid, and/or provided reimbursement for some or all of the purchase price of Bystolic for the personal and/or household use of its

members from pharmacies located in and/or on behalf of members located in Alabama, Connecticut and Florida. Local 1150 paid more than it would have absent Defendants' unlawful anticompetitive scheme to prevent generic entry and was injured as a result of the illegal and wrongful conduct alleged herein. Local 1150 intends to continue purchasing, paying, and/or providing reimbursement for some or all of the purchase price of Bystolic and intends to purchase, pay, and/or provide reimbursement for generic Bystolic when it becomes available and will be injured as a result of Defendants' ongoing unlawful conduct.

45. Plaintiffs Teamsters Local 237 Welfare Fund and Teamsters Local 237 Retirees' Benefit Fund ("Local 237") consists of two health and welfare benefit plans and is headquartered and with a principal place of business in New York, New York. Local 237 administers the assets of defined contribution plans formed to provide certain benefits including prescription drug benefits. Local 237 provides health and welfare benefits to active and retired members and participants who reside in numerous locations in the United States. During the Class Period (as defined below), Local 237 purchased, paid, and/or provided reimbursement for some or all of the purchase price of Bystolic for the personal and/or household use of its members from pharmacies located in and/or on behalf of members located in Alabama, Connecticut, Delaware, Florida, Georgia, Illinois, Maryland, Missouri, North Carolina, Nevada, New Hampshire, New Jersey, New York, Ohio, Pennsylvania, Puerto Rico, South Carolina, Texas and Vermont. Local 237 paid more than it would have absent Defendants' unlawful anticompetitive scheme to prevent generic entry and was injured as a result of the illegal and wrongful conduct alleged herein. Local 237 intends to continue purchasing, paying, and/or providing reimbursement for some or all of the purchase price of Bystolic and intends to purchase, pay, and/or provide reimbursement for generic

Bystolic when it becomes available and will be injured as a result of Defendants' ongoing unlawful conduct.

B. Defendants

46. Defendant Forest Laboratories, Inc. is a Delaware corporation having its principal place of business at 909 Third Avenue, New York, New York 10022. The negotiation, execution and enforcement of the unlawful reverse payments challenged herein all took place from Forest Laboratories, Inc.'s New York, NY principal place of business.

47. Defendant Forest Laboratories Ireland, Ltd. is an Irish Corporation with a place of business at Clonshaugh Industrial Estate, Dublin 17, Ireland.

48. Defendant Forest Laboratories Holdings, Ltd. is a Bermudian corporation having a principal place of business at 18 Parliament Street, Hamilton HM 11, Bermuda. In or around February 2006, Defendant Forest Laboratories Ireland, Ltd. changed its name to Forest Laboratories Holdings, Ltd. and changed its residence from Ireland to Bermuda.[21]

49. Defendant Forest Laboratories, LLC is a company organized and existing under the laws of Delaware, with its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054. On July 1, 2014, in a series of transactions, Forest Laboratories, Inc. became a limited liability company named Forest Laboratories, LLC. On July 1, 2014, Actavis PLC ("Actavis") acquired Defendant Forest. On May 17, 2015 Actavis acquired Defendant Allergan, Inc. but maintained the name Allergan for its ongoing operations. Subsequently, on January 1, 2018, Forest Laboratories, LLC was merged with and into Defendant Allergan Sales, LLC, a Delaware limited liability

[21] *See, e.g.*, Notice and Stipulation of Name Change, *Forest Labs., Inc. v. Ivax Pharm., Inc*., No. 03-cv-00891 (D. Del. Feb. 8, 2006) ECF No. 536.

company. As a result of these corporate consolidations, Forest Laboratories, Inc., Forest Laboratories, LLC, Forest Laboratories Holdings, Ltd. and Forest Laboratories Ireland Ltd. are predecessors in interest to Allergan Sales, LLC.

50. Defendant Allergan Sales, LLC is a company organized and existing under the laws of Delaware, with its principal place of business at 5 Giralda Farms, Madison, New Jersey 07940.

51. Defendant Allergan, Inc. is a Delaware corporation with its principal place of business located at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

52. Defendant Allergan USA, Inc. is a Delaware corporation with its principal place of business at 5 Giralda Farms, Madison, New Jersey 07940.

53. Allergan, through its merger with Forest, assumed responsibility for performance of the challenged provisions in the agreements, continued to perform those provisions, and benefited from making sales of Bystolic to Plaintiffs and members of the Class at the supracompetitive prices made possible by the delay that those challenged provisions caused.[22]

54. Upon information and belief, Forest assigned the reverse-payment agreements to Allergan, and Allergan never withdrew from them.

55. Upon information and belief, Allergan joined the ongoing unlawful course of conduct and joined the unlawful reverse-payment agreements – with respect to the

[22] *See*, *e.g.*, Bystolic label, *available at* https://www.dailymed nlm nih.gov/dailymed/fda/ fdaDrugXsl.cfm?setid=8b8ad213-1dc8-454e-a524- 075685c0e1a8&type=display (listing Allergan USA, Inc. as the distributor of Bystolic).

suppression of generic competition for Bystolic. Allergan did not withdraw from those conspiracies and instead continued to participate in them.

56. Defendant AbbVie, Inc. is a corporation organized and existing under the laws of Delaware with its corporate headquarters at 1 North Waukegan Road, North Chicago, Illinois 60064.

57. AbbVie is the corporate successor to Allergan and Forest, having completed its purchase of Allergan on May 8, 2020.

58. Defendant AbbVie, through its merger with Allergan, assumed responsibility for performance of the challenged provisions in the agreements, continued to perform those provisions, and benefited from manufacturing and selling Bystolic at the supracompetitive prices made possible by the delay those challenged provisions produced.

59. Upon information and belief, Allergan assigned the reverse-payment agreements to AbbVie, and AbbVie never withdrew from them.

60. AbbVie joined the ongoing unlawful course of conduct and joined the unlawful reverse-payment agreements – with respect to the suppression of generic competition for Bystolic. AbbVie did not withdraw from those conspiracies and instead continued to participate in them.

61. Defendant Hetero Labs Ltd. is an Indian corporation having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estate, Sanathnagar, Hyderabad - 500018 Andhra Pradesh, India.

62. Defendant Hetero Drugs Ltd. is an Indian corporation having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estate, Sanathnagar, Hyderabad - 500018 Andhra Pradesh, India.

63. Defendant Hetero USA Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1031 Centennial Avenue, Piscataway, NJ 08854. On information and belief, Hetero USA Inc. is a wholly-owned subsidiary of Hetero Labs Ltd. Hetero USA Inc. acts as the agent of Hetero Labs Ltd. and Hetero Drugs Ltd.

64. Defendant Torrent Pharmaceuticals Ltd. is an Indian corporation having a principal place of business at Off. Ashram Road, Ahmedabad - 380 009, Gujarat, India.

65. Defendant Torrent Pharma Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 5380 Holiday Terrace, Suite 40, Kalamazoo, MI 49009. On information and belief, Torrent Pharma Inc. is a wholly- owned subsidiary of Torrent Pharmaceuticals Ltd. Torrent Pharma Inc. acts as the agent of Torrent Pharmaceuticals Ltd.

66. Defendant Alkem Laboratories Ltd. is an Indian company having a place of business at Alkem House, Devashish, Senapati Bapat Marg, Lower Parel (West), Mumbai 400013, Maharashtra, India.

67. Defendant Ascend Laboratories, LLC ("Ascend") is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 339 Jefferson Road, Suite 101 Parsippany, NJ, 07054. On information and belief, Ascend is a United States agent of Alkem. Ascend is a wholly owned subsidiary of Alkem, and is operationally controlled by Alkem. Ascend is in the business of marketing, distributing, and selling, in the State of New York and throughout the United States, pharmaceutical drugs, including generic pharmaceutical drugs manufactured by Alkem. On information and belief, since Alkem's acquisition of Ascend in 2010, Alkem has marketed and sold its generic drugs

in the United States primarily through Ascend, and, but for the services Ascend provides Alkem in New York and throughout the United States, Alkem would have to undertake those services on its own. On information and belief, at Alkem's direction, Ascend has agreed that it will not market or distribute Alkem's generic version of Bystolic until September 17, 2021 when it otherwise would have done so earlier. And Alkem will market its delayed generic version of Bystolic through Ascend and Ascend will sell generic Bystolic at supracompetitive prices, making Ascend a participant in the conspiracy with Alkem and Forest alleged herein.

68. Defendant Indchemie Health Specialties Private Ltd. is an Indian company having a place of business at 510, Shah & Nahar Industrila Estate, Dr. E. Moses Road, Worli-Mumbai 400018, India.

69. Defendant Glenmark Generics Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 750 Corporate Drive, Mahwah, NJ 07430. Glenmark Generics Inc. is the same entity as Glenmark Generics Inc., USA. To the extent Glenmark Generics Inc. is an entity separate and apart from Glenmark Generics Inc., USA, any allegations in this Complaint relating to Glenmark Generics Inc., USA shall apply equally to Glenmark Generics Inc.

70. Defendant Glenmark Generics Ltd. is an Indian company having a place of business at Glenmark House, HDO-Corporate Building, Wing -A, B D Sawant Marg, Chakala, Off Western Express Highway, Mumbai 400099, Maharashtra, India.

71. Defendant Glenmark Pharmaceuticals S.A. is a company organized and existing under the laws of Switzerland, with a principal place of business at 2nd Floor, Swisscom Building, Rue de la Maladiere 23, Neuchâtel, 2000, Switzerland.

72. Defendant Glenmark Pharmaceuticals Ltd. is an Indian corporation having a principal place of business at Glenmark House, HDO-Corporate Building, Wing -A, B D Sawant Marg, Chakala, Off Western Express Highway, Mumbai 400099, Maharashtra, India. On information and belief Glenmark Generics Inc., USA, Glenmark Pharmaceuticals S.A., and Glenmark Generics Ltd. are wholly-owned subsidiaries of, and are controlled by, Glenmark Pharmaceuticals Ltd. On information and belief, Glenmark Generics Inc., USA is the North American division of Glenmark Generics Ltd. On information and belief, Glenmark Generics Inc., USA, Glenmark Pharmaceuticals S.A., Glenmark Generics Ltd., and Glenmark Pharmaceuticals Ltd. have officers and directors in common. On information and belief, Glenmark Generics Inc., USA acts as the agent of Glenmark Generics Ltd., Glenmark Pharmaceuticals S.A., and Glenmark Pharmaceuticals Ltd.

73. Defendant Amerigen Pharmaceuticals Ltd. is a Chinese company having places of business at 197 State Route 18S, Suite 306N, East Brunswick, NJ 08816 and No. 58, Qunxing Yi Road, Suzhou Industrial Park, 215006, China.

74. Defendant Amerigen Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 197 State Route 18S, Suite 306N, East Brunswick, NJ 08816. On information and belief, Amerigen Pharmaceuticals Inc. is a wholly-owned subsidiary of Amerigen Pharmaceuticals Ltd. Amerigen Pharmaceuticals Inc. acts as the agent of Amerigen Pharmaceuticals Ltd.

75. Defendant ANI Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 210 Main Street West, Baudette, MN 56623. On January 8, 2020, ANI Pharmaceuticals, Inc. acquired the U.S. portfolio of 23 generic products from Amerigen Pharmaceuticals Ltd. pursuant to

an Asset Purchase Agreement, dated January 8, 2020. On information and belief, in this transaction, ANI Pharmaceuticals assumed the liabilities of Amerigen Pharmaceuticals Ltd. arising out of the claims asserted in this matter and is thus acting to further the unlawful acts alleged in this Complaint by its agreement.[23]

76. Defendant Watson Pharma, Inc. is a corporation organized and existing under the laws of Delaware, having a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054.

77. Defendant Watson Laboratories, Inc. (NV) is a corporation operating under the name Watson Laboratories, Inc. and is organized and existing under the laws of the State of Nevada. Watson Laboratories, Inc. (NV) has places of business at 132 Business Center Drive, Corona, CA 92880 and Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054.

78. Defendant Watson Laboratories, Inc. (DE) is a corporation operating under the name Watson Laboratories, Inc. and is organized and existing under the laws of the State of Delaware. Watson Laboratories, Inc. (DE) has places of business at 311 Bonnie Circle, Corona, CA 92880 and Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054.

79. Defendant Watson Laboratories, Inc. (NY) is a corporation operating under the name Watson Laboratories, Inc. and is organized and existing under the laws of the State of New York. Watson Laboratories, Inc. (NY) has places of business at 311 Bonnie Circle,

[23] *See* Asset Purchase Agreement by and between Amerigen Pharm. Ltd. and ANI Pharm., Inc. dated Jan. 8, 2020, *available at* https://sec report/Document/0001104659-20-025744/tm205343d1_ex10-24 htm.

Corona, CA 92880 and Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054.

80. Defendant Watson Laboratories, Inc. (CT) is a corporation operating under the name Watson Laboratories, Inc. and is organized and existing under the laws of the State of Connecticut. Watson Laboratories, Inc. (CT) has places of business at 131 West St. Danbury, CT 06810, 311 Bonnie Circle, Corona, CA 92880 and Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054.

81. Watson Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of Nevada, having places of business at 311 Bonnie Circle, Corona, CA 92880 and 360 Mount Kemble Avenue, Morristown, NJ 07962, and its corporate headquarters at Morris Corporation Center III, 400 Interpace Parkway, Parsippany, NJ 07054.

82. On information and belief, Watson Laboratories, Inc. (NV), Watson Laboratories, Inc. (DE), Watson Laboratories, Inc. (NY), Watson Laboratories, Inc. (CT), and Watson Pharma, Inc. are wholly-owned subsidiaries of Watson Pharmaceuticals, Inc. Watson Laboratories, Inc. (NV), Watson Laboratories, Inc. (DE), Watson Laboratories, Inc. (NY), Watson Laboratories, Inc. (CT), Watson Pharma, Inc. and Watson Pharmaceuticals, Inc. have officers and directors in common.

83. Watson Laboratories, Inc. (NV), Watson Laboratories, Inc. (DE), Watson Laboratories, Inc. (NY), Watson Laboratories, Inc. (CT), and Watson Pharma, Inc. act as agents of Watson Pharmaceuticals, Inc.

84. Actavis, Inc., is a corporation organized and existing under the laws of the State of Nevada with a principal place of business at Morris Corporate Center III, 400

Interpace Parkway, Parsippany, NJ 07054. Watson purchased Actavis, Inc. on October 31, 2012,[24] and the combined companies assumed the Actavis name.[25] Watson is a signatory to the unlawful reverse payment agreement resolving the nebivolol HCl patent litigation between Forest and Watson.

85. Defendant Teva Pharmaceutical Industries Ltd. is an Israeli corporation with a principal place of business at 5 Basel St., Petach Tikva, Israel 4951033.

86. Defendant Teva Pharmaceuticals USA, Inc. is a Delaware corporation with a principal place of business at 400 Interpace Parkway, Parsippany, NJ 07054.

87. Teva Pharmaceutical Industries Ltd. purchased Watson, at the time known as Actavis, on July 26, 2015.[26] As part of the purchase, Teva agreed to adopt "all Liabilities and Claims" of Actavis.[27] Teva Pharmaceuticals USA, Inc. is Teva Pharmaceutical Industries Ltd.'s wholly owned subsidiary, and is responsible for distributing (or forbearing from distributing pursuant to the challenged Watson settlement agreement and side deal) generic Bystolic on behalf of Teva Pharmaceutical Industries Ltd.

88. Defendants' wrongful actions described in this complaint are part of, and were taken in furtherance of the illegal monopolization scheme and restraint of trade alleged herein. These actions were authorized, ordered, and/or undertaken by Defendants' various officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs (or that of their predecessors-in-interest) within the

[24] https://www.biospace.com/article/releases/watson-pharmaceuticals-inc-completes-actavis-acquisition-/.

[25] https://www.prnewswire.com/news-releases/watson-announces-new-name----actavis----for-global-operations-176683401.html.

[26] Master Purchase Agreement dated as of July 26, 2015 by and between Allergan PLC and Teva Pharmaceutical Industries, Ltd., *available at* https://www.sec.gov/Archives/edgar/data/1578845/000156459015006357/agn-ex22_652.htm.

[27] *Id*. at 35.

course and scope of their duties and employment and with their actual, apparent and/or ostensible authority.

IV. ECONOMIC BACKGROUND

89. The marketplace for the sale of prescription pharmaceutical products in the United States is unusual. In most industries, the person who pays for a product is also the person who chooses the product. When the same person has both the payment obligation and the choice of products, the price of the product plays a predominant role in the person's choice of products. Consequently, manufacturers have a strong incentive to lower the price of their products to maintain profitability.

90. The pharmaceutical marketplace, in contrast, is characterized by a "disconnect" between the payment obligation and the product selection. State laws prohibit pharmacists from dispensing certain drugs to patients unless they can present a prescription written by their physician. This prohibition introduces an anomaly into the pharmaceutical marketplace between the payment obligation and the product selection. The patient (or his or her insurer) has the obligation to pay for the pharmaceutical product, but his or her doctor chooses which product the patient will buy.

91. In 1984, Congress sought to ameliorate the "disconnect," by authorizing the manufacture and sale of generic pharmaceuticals under the Hatch-Waxman Act, discussed further below. Now, when a pharmacist receives a prescription for a branded drug and an AB-rated[28] generic version of that drug is available, state laws require the pharmacist to dispense the generic instead of the brand. In this way, price is reintroduced to the product

[28] AB-rated generic versions of brand name drugs contain the same active ingredient and are determined by the FDA to be just as safe and effective as their brand name counterparts. Every state either requires or allows for a prescription written for the brand drug be filled with an AB-rated generic, unless there are "Dispense as Written" instructions to the contrary.

selection decision at the pharmacy counter, and the pharmaceutical marketplace "disconnect" is lessened. When an AB-rated generic equivalent is introduced and not prevented from competing, brand manufacturers can no longer exploit the "disconnect," their monopoly power dissipates and some of the normal competitive pressures are restored.

92. Because AB-rated generic versions of brand-name drugs contain the same active ingredients and are determined by the FDA to be just as safe and effective as their branded counterparts, the only material differences between generic drugs and their branded counterparts are their prices and manufacturers. Because AB-rated generic versions of branded products are commodities that cannot otherwise be differentiated, the primary basis for generic competition is price.

93. Typically, generics are 50% to 80% (or more) less expensive when there are multiple generic competitors on the market for a given brand. Consequently, the launch of an AB-rated generic drug usually results in significant cost savings to all drug purchasers.

94. The combination of these factors — the regulatory interchangeability of AB-rated generics for the brand, state substitution laws, and margin incentives of pharmacies— results in the typical phenomenon that once a brand drug "goes generic," the product swiftly moves from a monopoly priced to a commodity priced item.

95. Generic competition enables all members of the Class to purchase generic versions of the drug at substantially lower prices and to purchase the brand drug at a reduced price.

96. The Hatch-Waxman Act has significantly advanced the rate of generic drug launches while also ushering in an era of historically high profits for drug manufacturers. In 1983, before the Hatch-Waxman Act, only 35% of the top-selling branded drugs with expired

patents had generic alternatives; by 1998, nearly all did. In 1984, annual prescription drug revenue for branded and generic drugs totaled $21.6 billion; by 2009, total annual prescription drug revenue had soared to $300 billion.

97. The Federal Trade Commission ("FTC") estimates that about one year after market entry, a generic drug takes over 90% of the branded drug's unit sales at 15% of the price of the branded drug. As a result, brand manufacturers view competition from generics as a grave threat to their bottom lines.

98. When a branded drug faces generic drug competition, purchasers are able to (a) purchase generic versions of the drug at much lower prices, and/or (b) purchase the branded drug at a reduced price. Until the generic version of a branded drug enters the market, however, there is no bioequivalent generic to substitute for, and compete with, the branded drug, so the brand manufacturer can continue to profitably charge supracompetitive prices.[29] As a result, brand manufacturers, well aware of the rapid erosion of branded drug sales by generics, have a strong incentive to delay the start of generic drug competition. Brand manufacturers often seek to extend their monopolies by any means possible, sometimes even resorting to illegal ones.

V. REGULATORY BACKGROUND

A. The Hatch-Waxman Amendments.

99. The Hatch-Waxman amendments, enacted in 1984, simplified regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file

[29] The price of brand Bystolic has increased substantially over the period from 2015 through 2020. For example, Forest increased the price of the 10 mg tablet of Bystolic by 8.5% in January 2015 and another 8.5% in October 2015, 9% in April 2016, 9% in January 2017, 9.5% in January 2018, 9.5% in January 2019, and 5% in January 2020 – in total increasing the price of the 10 mg tablet of Bystolic by 76% over this period. Forest took nearly identical price increases on the other strengths of Bystolic.

lengthy and costly New Drug Applications ("NDA(s)").[30] A manufacturer seeking approval to sell a generic version of a brand drug may instead file an ANDA. An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's original NDA and must further show that the generic contains the same active ingredient(s), dosage form, route of administration, and strength as the branded drug, and that it is bioequivalent, *i.e.*, absorbed at the same rate and to the same extent as the brand. The FDA assigns generics that meet these criteria relative to their brand counterparts an "AB" rating.

100. The Federal Food, Drug, and Cosmetics Act ("FDCA") and Hatch-Waxman amendments operate on the principle that bioequivalent drug products containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity, and identity are therapeutically equivalent and may be substituted for one another. Bioequivalence demonstrates that the active ingredient of the proposed generic would be present in the blood of a patient to the same extent and for the same amount of time as the brand counterpart.[31]

101. Through the Hatch-Waxman amendments, Congress sought to expedite the entry of less expensive generic competitors to branded drugs, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical manufacturers' incentives to create new and innovative products.

B. Regulatory Exclusivities for New Drugs.

102. In order to promote a balance between new drug innovation and generic drug competition, the Hatch-Waxman amendments also provided for exclusivities (or exclusive

[30] *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355).

[31] 21 U.S.C. § 355(j)(8)(B).

marketing rights) for new drugs. These exclusivities are granted by the FDA upon approval of a drug if statutory requirements are met. These exclusivities are listed in the Orange Book, along with any applicable patents, and can run concurrently with the listed patents.

103. One such exclusivity, New Chemical Entity ("NCE") exclusivity, applies to products containing chemical entities never previously approved by the FDA either alone or in combination. If a product receives NCE exclusivity, the FDA may not accept for review any ANDA for a drug containing the same active moiety for five years from the date of the NDA's approval, unless the ANDA contains a Paragraph IV certification of patent invalidity or non-infringement, in which case an application may be submitted after four years.[32]

104. A drug product may also receive a three-year period of exclusivity if its sponsor submits a supplemental application that contains reports of new clinical investigations (other than bioavailability studies) conducted or sponsored by the sponsor that were essential to approval of the supplemental application. If this exclusivity is granted, the FDA may not approve an ANDA for that drug for three years from the date on which the supplemental application is approved.[33]

105. Regulatory exclusivities are not always absolute bars to generic entry. For example, some can be overcome by carving out information in the label or for other reasons.[34]

C. ANDA Paragraph IV Certifications.

106. Under the Hatch-Waxman amendments, a generic manufacturer's ANDA must contain one of four certifications:

[32] 21 U.S.C. § 355(j)(5)(F)(ii); 21 C.F.R. § 314.108(b)(2).

[33] 21 U.S.C. § 355(j)(5)(F)(iv); 21 C.F.R. § 314.108(b)(2)(5).

[34] *See*, *e.g.*, 21 C.F.R. §§ 314.94(a)(8)(v), 314.127(a)(7); 21 U.S.C. § 355a(o).

a. That no patent for the brand has been filed with the FDA (a "paragraph I certification");

b. That the patent for the brand has expired (a "paragraph II certification");

c. That the patent for the brand will expire on a particular date and the manufacturer does not seek to market its generic before that date (a "paragraph III certification"); or

d. That the patent for the brand is invalid or will not be infringed by the generic manufacturer's proposed product (a "paragraph IV certification").[35]

107. If a generic manufacturer files a paragraph IV certification, a brand manufacturer has the ability to delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement. If the brand manufacturer initiates a patent infringement action against the generic filer within forty-five days of receiving notification of the paragraph IV certification, the FDA will not grant final approval to the ANDA until the earlier of (i) the passage of two-and-a-half years (30 months), or (ii) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA.[36] Until one of those conditions occurs, the FDA may grant "tentative approval," but cannot authorize the generic manufacturer to market its product (*i.e.*, grant final approval). The FDA may grant an ANDA tentative approval when it determines that the ANDA is ready for final approval but for the 30-month stay.

[35] 21 U.S.C. § 355(j)(2)(A)(vii).

[36] 21 U.S.C. § 355(j)(5)(B)(iii). This period is commonly called a "30-month Hatch-Waxman stay" or "30 month stay." The brand/ patent holder can choose to sue the generic after 45 days, including waiting until the generic has launched its product, but, in that event, the brand cannot take advantage of the 30-month stay of FDA approval, and must instead satisfy the showing required to obtain a preliminary injunction to prevent the generic launch.

D. The First Filer's 180-Day Exclusivity Period.

108. Generics may be classified as (i) first-filer generics, (ii) later generic filers, or (iii) authorized generics.

109. To encourage manufacturers to seek approval of generic versions of branded drugs, the Hatch-Waxman amendments grant the first paragraph IV ANDA filer ("first filer") a 180-day exclusivity period to market the generic version of the drug during which time the FDA may not grant final approval to any other generic manufacturer's ANDA for the same brand drug.[37] That is, when a first filer files a substantially complete ANDA with the FDA and certifies that the unexpired patents listed in the Orange Book as covering the brand are either invalid or not infringed by the generic, the FDA cannot approve a later generic manufacturer's ANDA until the first generic has been on the market for 180 days.[38]

110. The 180-day window is often referred to as the first filer's six month or 180-day "exclusivity;" this is a bit of a misnomer because a brand manufacturer (such as the Forest Defendants) can launch an authorized generic ("AG") at any time, manufacturing its AG in accordance with its approved NDA for the branded product but selling at a lower price point. Brand manufacturers frequently launch AGs in response to generic entry in order to recoup some of the sales they would otherwise lose.

111. The Supreme Court has recognized that "this 180-day period of exclusivity can prove valuable, possibly 'worth several hundred million dollars'" to the first filer.[39]

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[37] 21 U.S.C. § 355(j)(5)(B)(iv), (D).

[38] Or, until its first-filer exclusivity has been forfeited. A first filer can forfeit its 180-day exclusivity by, for example, failing to obtain tentative approval from the FDA for its ANDA within 30 months of filing its ANDA. There is no forfeiture here.

[39] *Actavis, Inc.*, 133 S. Ct. at 2229 (quoting C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1579 (2006)).

112. A first filer that informs the FDA it intends to wait until all Orange Book-listed patents expire before marketing its generic does not get a 180-day exclusivity period. Congress created this 180-day period to incentivize generic manufacturers to challenge weak or invalid patents or to invent around such patents by creating non-infringing generics.

E. Patents Are Not Bulletproof.

113. Patents are not bulletproof. Patents are routinely invalidated or held unenforceable, either upon reexamination or *inter partes* proceedings by the United States Patent and Trademark Office ("PTO"), by court decision, or by jury verdict. A patent holder at all times bears the burden of proving infringement.

114. One way that a generic can prevail in patent infringement litigation is to show that its product does not infringe the patent (and/or that the patent holder cannot meet its burden to prove infringement). Another is to show that the patent is invalid or unenforceable.

115. A patent is unenforceable when it claims a product that is patentably distinct from the allegedly infringing product.

116. In these circumstances, the PTO's decision to issue a patent does not substitute for a fact-specific assessment of (i) whether the applicant made intentional misrepresentations or omissions on which the PTO relied in issuing the patent, and (ii) whether a reasonable manufacturer in the patent holder's position would have a realistic likelihood of succeeding on the merits of a patent infringement suit.

117. As a statistical matter, if the parties litigate a pharmaceutical patent infringement suit to a decision on the merits, it is more likely that a challenged patent will be found invalid or not infringed than upheld. The FTC reports that generics prevailed in 73% of Hatch-Waxman patent litigation cases resolved on the merits between 1992 and

2002.[40] An empirical study of all substantive decisions rendered in every patent case filed in 2008 and 2009 similarly reports that when a generic challenger stays the course until a decision on the merits, the generic wins 74% of the time.[41]

F. The Competitive Effects of AB-Rated Generic Competition.

118. AB-rated generics contain the same active ingredient(s) and are determined by the FDA to be just as safe and effective as their branded counterparts. The only material difference between generics and their corresponding brand versions is their price. Because generics are essentially commodities that cannot be therapeutically differentiated, the primary basis for competition between a branded product and its generic version, or between generic versions, is price. Consequently, the launch of a generic usually results in significant cost savings for all drug purchasers, especially end-payor purchasers.

119. Thus, conduct that delays generic entry harms end-payor purchasers (like Plaintiffs and the proposed Class members here) in several ways. One way that end-payor purchasers are harmed (suffer overcharges) is that they are forced to continue purchasing the more expensive branded drug instead of the lower-priced generic equivalent they would have purchased had the generics entered earlier. In addition, conduct that delays generic entry causes end-payor purchasers to pay inflated generic prices because (a) generic prices fall over time, and so generic prices would have been lower if generic competition had started earlier, and (b) brand prices typically increase over time and the generic price is discounted off of the brand price, and so the generic prices would have been lower if the generics had

[40] FTC, *Generic Drug Entry Prior to Patent Expiration: AN FTC Study* vi-vii (2002), https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf.

[41] J. R. Allison, M. A. Lemley & D. L. Schwartz, *Understanding the Realities of Modern Patent Litigation*, 92 Tex. L. Rev. 1769, 1787 (2014) ("[P]atentees won only 164 of the 636 definitive merits rulings, or 26%," and "that number is essentially unchanged" from a decade ago.).

launched earlier, when the brand price was lower (since the generic price would have been discounted off of the lower brand price).

120. Since the passage of the Hatch-Waxman amendments, every state has adopted drug product selection laws that require or allow pharmacies to substitute AB-rated generic equivalents for brand prescriptions (unless the prescribing physician specifically directs that substitutions are not permitted). Substitution laws and other institutional features of pharmaceutical distribution and use create the economic dynamic that the launch of AB-rated generics results both in rapid price decline and rapid sales shift from brand to generic purchasing. Once a generic enters the market, it quickly captures sales of the corresponding brand drug, often 80% or more of the market within the first six months after entry. In a recent study, the FTC found that on average, within a year of generic entry, generics had captured 90% of corresponding brand sales and (with multiple generics on the market) prices had dropped 85%.[42] As a result, competition from generics is viewed by brand manufacturers, such as the Forest Defendants, as a grave threat to their bottom lines.

121. Generic competition enables all purchasers of a drug to (i) purchase generic versions of the drug at substantially lower prices, and/or (ii) purchase the brand at a reduced price.

122. Until a generic version of the brand enters the market, however, there is no bioequivalent drug to substitute for and compete with the brand and the brand manufacturer can therefore continue to profitably charge supracompetitive prices. Brand manufacturers, such as the Forest Defendants, are well aware of generics' rapid erosion of their brand sales.

[42] *See* FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* 8 (2010), https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf ("FTC Pay-for-Delay Study").

Brand manufacturers thus seek to extend their monopoly for as long as possible, sometimes resorting to any means possible—including illegal means—to delay or prevent generic competition.

1. The first AB-rated generic is priced below the brand.

123. Experience and economic research show that the first generic manufacturer to market its product prices it below the prices of its brand counterpart.[43] Every state requires or permits that a prescription written for the brand be filled with an AB-rated generic. Thus, the first generic manufacturer almost always captures a large share of sales from the brand. At the same time, there is a reduction in the average price paid for the drug at issue (brand and AB-rated generic combined).

124. During the 180-day exclusivity period, the first filer is the only ANDA-approved generic manufacturer on the market (though the brand's AG can be, and often is, on the market during the 180-day exclusivity period), and a first-filer generic manufacturer generally makes about 80% of all of the profits that it will ever make on the product.

2. Later generics drive prices down further.

125. Once generic competitors enter the market, the competitive process accelerates, and multiple generic manufacturers typically compete vigorously with each other on price, driving prices down toward the marginal manufacturing costs.[44]

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[43] FTC, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* ii-iii, vi, 34 (2011), https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf ("FTC 2011 AG Study"); FTC Pay-for-Delay Study at 1.

[44] *See, e.g.*, Tracy Regan, *Generic Entry, Price Competition, and Market Segmentation in the Prescription Drug Market*, 26 Int'l J. Indus. Org. 930 (2008); Richard G. Frank, *The Ongoing Regulation of Generic Drugs*, 357 New Eng. J. Med. 1993 (2007); Patricia M. Danzon & Li-Wei Chao, *Does Regulation Drive Out Competition in Pharmaceutical Markets?*, 43 J.L. & Econ. 311 (2000).

126. According to the FDA and the FTC, the greatest price reductions are experienced when the number of generic competitors goes from one to two. In that situation, there are two commodities that compete on price.

127. In a report by the FTC issued at the request of Congress in 2011, the FTC found that generics captured 80% or more of sales in the first six months.[45] In the end, the brand manufacturer's sales decline to a small fraction of their level before generic entry. This is so because, "[a]lthough generic drugs are chemically identical to their branded counterparts, they are typically sold at substantial discounts from the branded price. According to the Congressional Budget Office, generic drugs save consumers an estimated $8 to $10 billion a year at retail pharmacies. Even more billions are saved when hospitals use generics."[46]

G. Pharmaceutical Manufacturers Can Game the Regulatory Structure in Order to Impair Competition.

128. When they do not face generic competition, brand manufacturers can usually sell the branded drug far above the marginal cost of production, generating profit margins in excess of 70% while making hundreds of millions of dollars in sales. The ability to make those kinds of profit margins is what economists call market power. When generics enter the market, however, they quickly take 80% or more of the unit sales. And when multiple generics are in the market, the competition between the generics drives their prices to near the marginal cost of production. This competition puts an end to the brand manufacturer's market power and delivers enormous savings to drug purchasers.

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[45] FTC 2011 AG Study at 66-67.

[46] *See* Generic Drugs: Questions and Answers, FDA, *available at* https://www.fda.gov/drugs/questions-answers/generic-drugs-questions-answers.

129. Brand and first-filer generic manufacturers have a collective interest in preventing this competition from breaking out. If they work together to prevent or delay competition, they can keep the profit margins on all of the unit sales at 70% and split the resulting excess profits among themselves. They can keep for themselves the enormous savings that competition would have delivered to drug purchasers.

130. A brand manufacturer in the marketplace without competition from generics gets all of the profits on all of the unit sales.

131. When generic entry occurs, the brand manufacturer loses most of the unit sales; generic manufacturers sell most of the units, but at drastically reduced prices; and competition delivers enormous savings to drug purchasers. Competition converts what formerly were excess profits into purchaser savings.

132. To prevent this from happening, brand and generic manufacturers sometimes unlawfully agree to not compete and instead split the purchaser savings between themselves.

133. Figure 1 compares the impact on a brand manufacturer's profits between (i) a situation where it settles a patent lawsuit on the merits (*i.e.*, with only an agreed entry date and without a pay-off to the generic company); and (ii) a situation where it settles the lawsuit with a large, unjustified payment to the generic manufacturer. In the former situation, the agreed generic entry date for the generic is earlier and the brand manufacturer's profits are thus greatly reduced. In the latter situation, the agreed entry date is later and the brand manufacturer's profits increase significantly. Earlier entry may also occur if the generic manufacturer launches its product at risk (*i.e.*, while the litigation is still pending) or prevails in the patent litigation and then launches its product.

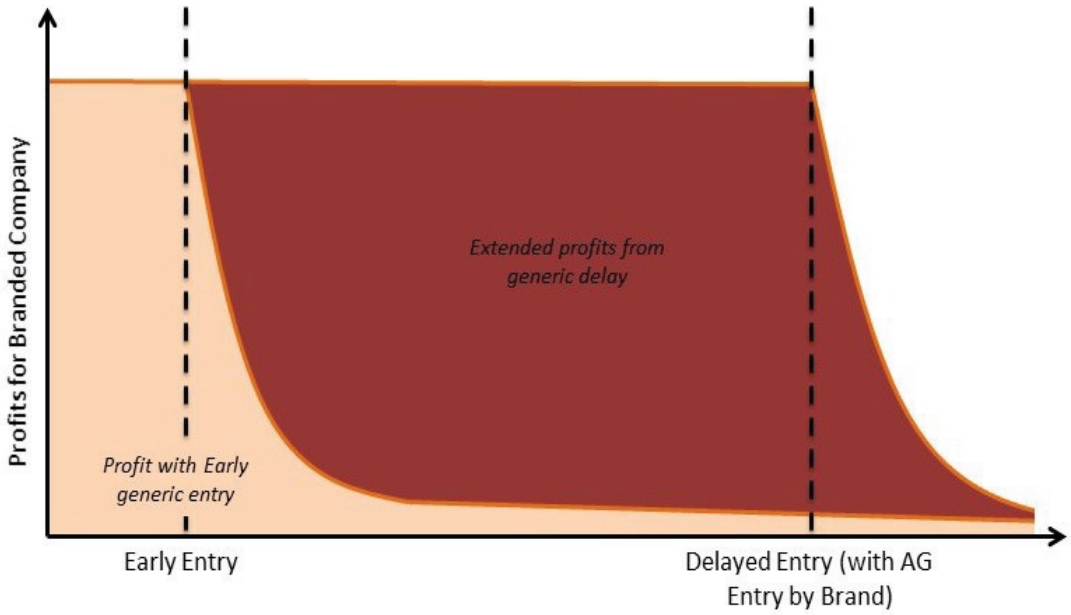

Figure 1: Impact of Delay on Brand Profits

134. In order for such an anticompetitive pact to work, brand and generic manufacturers need a means by which to divide the purchaser savings between themselves. The generic manufacturer will not refrain from competing if it does not share in the ill-gotten gains through some means. Pay-offs from the brand manufacturer are the means by which brand and generic manufacturers divide between themselves the ill-gotten gains that delayed competition makes possible. These unlawful pay-off deals are often referred to as "pay-for-delay," "exclusion payment," or "reverse payment" agreements.

135. The brand manufacturer may choose to – unlawfully – pay off only the first filer, even if other generic manufacturers are also lined up to challenge the patents. The first filer's agreement to delay marketing its drug also prevents other generic manufacturers from marketing their products until at least six months after the first filer launches.

136. Later ANDA filers have more modest financial expectations because they may have little or no expectation of any form of market exclusivity. By the time they enter

the market, there is at least the brand and one other generic on the market (and often a second generic in the form of an AG) and, thus, the drug has already been, or is on its way to being, commoditized.

137. In the absence of an anticompetitive agreement between the brand company and the first filer, later ANDA filers have procompetitive incentives. They are motivated to expend resources to challenge the brand manufacturer's patent(s) (knowing that the first-filer generic is also fighting a patent infringement suit) and to enter the market as early as possible.

138. When an anticompetitive agreement with a first filer is already in place, however, pursuing the litigation to conclusion becomes less attractive to later filers. The later generic manufacturers know that the first filer is not leading the charge against the brand manufacturer's patent(s) (and has sometimes stipulated to the validity or enforceability of the patents as part of an anticompetitive reverse payment agreement). The later generics have to bear the brunt of the litigation costs themselves and, upon prevailing in the patent litigation, expect to face competition from at least the first-filer generic, and typically an authorized generic as well, despite having expended time and resources litigating the infringement case. The first settlement between a brand and first-filer generic (such as the first to file Generic Defendants' and Forest's agreements at issue here) will often provide that, if a later generic filer launches its generic before the delayed date agreed to by the brand and the first filer, the first filer is permitted to launch then as well – greatly reducing the incentive the later filer would otherwise have to continue fighting to enter as soon as possible.

139. Thus, some later generics decide to simply give in to or join the conspiracy between the brand manufacturer and the first-filer generic and agree to drop their challenges

to the brand manufacturer's patent(s) and stay off the market until after entry by the first filer.

140. Pay-for-delay agreements are fundamentally anticompetitive and contrary to the goals of the Hatch-Waxman statutory scheme. In particular, they extend the brand manufacturer's monopoly by blocking access to more affordable generic drugs, forcing purchasers to buy expensive brands at an inflated price instead.

1. Side deals provide a means for manufacturers to share the gains from conspiring.

141. In the past, reverse-payment agreements often took the form of a straight cash payment from the brand name manufacturer to the generic competitor. As these payments attracted regulatory scrutiny, congressional investigations, and class action lawsuits, brand manufacturers and generic competitors have entered into increasingly elaborate agreements in an attempt to mask the fundamentally anticompetitive character of their agreements. For example, the reverse-payment deals that were the subject of the Supreme Court's decision in *Actavis* involved payments allegedly hidden in co-promotion and manufacturing side-deals entered into in connection with settlement of patent litigation over the brand drug AndroGel. Because the profits to be gained by delaying generic competition are so great, however, drug manufacturers retain the incentive to enter into such agreements.

142. Thus side deals are a form of payment actionable under *Actavis* and are anticompetitive.[47]

[47] *See also* A. Edlin *et al*., "Activating Actavis," Antitrust, 28(1), Fall 2013, pp. 16-23, particularly p. 18, also noting that "Ordinarily, a genuinely valuable fee-for-service deal could be kept separate from the settlement to avoid antitrust problems. A degree of skepticism is therefore warranted with regard to complex reverse-payment settlements where the parties justify the large payments by subsidiary consideration."; C.S. Hemphill, "An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition," Columbia L. Rev., 109(4), 2009, pp. 629-687, particularly pp. 666-668, observing that side deals between brand

143. The FTC also agrees that side deals may be suspect and evidence of an antitrust violation. An FTC official has taken the position that contemporaneous side deals prompt "the question of whether the deal is designed to persuade the generic to give up an earlier entry date."[48]

VI. FACTS

A. Basic Chemistry Relating to the Active Pharmaceutical Ingredient in the Drug Product Bystolic.

144. Molecules are composed of atoms (*e.g.*, carbon, nitrogen or hydrogen) that are bonded to each other through the sharing of electrons. The atom carbon forms four bonds and tends to adopt a tetrahedral structure. That three-dimensional arrangement can be envisioned as a tetrahedron with the carbon atom at the center and the four substituents at the four vertices of the tetrahedron.

145. The chemical symbol for a carbon atom is "C." The figure below depicts a carbon atom (labeled as "C") bonded to four different chemical substituents (labeled as "X_1," "X_2," "X_3," and "X_4"). The straight lines from the carbon atom (at the center) to "X_1" and "X_4" are intended to convey that they are in the plane of the page. The solid wedge from the carbon atom to "X_3" is intended to convey that it is coming out of the page towards the reader. The hashed wedge from the carbon atom to "X_2" is intended to convey that it is coming out of the page but away from the reader. Thus, the below figure reflects a three-dimensional tetrahedral structure with a carbon atom at its center.

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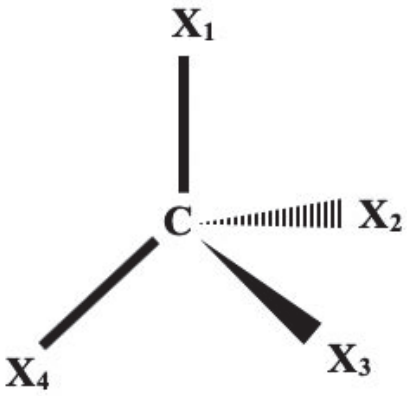
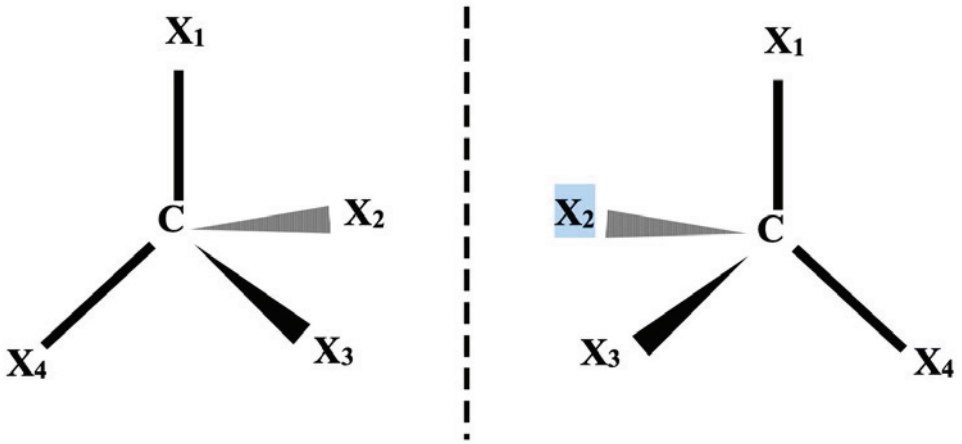
and generic firms are infrequent outside of patent settlements and that "the overall pattern [of the side deals] suggests they provide a disguised means to confer payment." *Id*. at 633.

[48] M. Lipman, "FTC Official Says Patent Settlement Side Deals Suspicious," *Law360*, April 16, 2015, *available at* http://www.law360.com/articles/644134/ftc-official-says-patent-settlement-side-deals-suspicious.



146. When a carbon atom is attached to four different substituents in a tetrahedral arrangement such as that shown above, the substituents can be arranged in either of two conformations, as depicted below, with a mirror line between them. Note that, much like one's left and right hands, these two arrangements (see below) are mirror images of one another. And much like one's left and right hands, they cannot be superimposed on one another by rotation. A carbon atom bonded to four different substituents can thus exist as either of two "stereoisomers" and such a carbon atom is referred to as a "chiral center." Naming conventions exist to distinguish these two stereoisomers from one another, and a commonly used terminology refers to one configuration as the "R" configuration and the other as the "S" configuration.



147. Distinguishing between stereoisomers can be particularly important in biological systems because many active pharmaceutical ingredients ("APIs") in drugs interact with naturally occurring receptors in the human body by fitting into a three-dimensional site on the receptor, much like a left hand fits into a left-handed glove. Just as a left hand would not fit properly into a right- handed glove, the wrong stereoisomer often will not fit into the intended receptor site. Thus, it is not uncommon for one stereoisomer to exhibit a desired pharmacological activity in biological systems while the other does not.

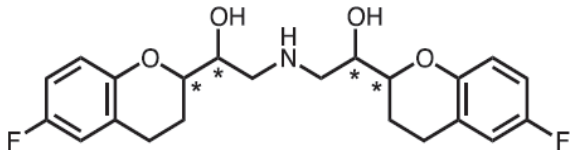
148. Carbon is so ubiquitous in organic chemicals that a carbon atom in chemical structures is often abbreviated as a vertex, rather than as a "C," with the understanding that such vertices are carbon. The chemical symbol for hydrogen is "H" and hydrogen only forms one bond. Because hydrogen is also ubiquitous and the number of chemical bonds that carbon and hydrogen make (*i.e.*, 4 and 1, respectively) is so well known, hydrogen is often omitted from chemical structures and its presence is assumed when a carbon has less than four bonded substituents.

149. Janssen Pharmaceutica ("Janssen"), a subsidiary of Johnson & Johnson, researched the use of nebivolol to treat high blood pressure and heart failure in the 1980s and 1990s. It obtained a series of patents related to this product.

The Bystolic Patents				
U.S. Patent No.	**Application No.**	**First Named Inventor**	**Issue Date**	**Expiry**
4,654,362	06/660355	Van Lommen	March 31, 1987	March 31, 2004
5,759,580	08/669,415	Jans	June 2, 1998	June 2, 2015

6,545,040	07/825,448	Xhonneau	April 8, 2003	December 17, 2021

150. On March 31, 1987, the PTO issued United States Patent No. 4,654,362 ("the '362 Patent"). The '362 Patent disclosed a number of different chemical compounds, including the following chemical compound:



151. The unlabeled vertices above correspond to a carbon atom and each of those carbon atoms (vertices) is connected to other atoms. To the extent a particular carbon atom has less than four bonds depicted, the remainder are hydrogen atoms. With this understanding in mind, each asterisk in the above chemical structure corresponds to a chiral center – *i.e.*, a carbon atom bonded to four different substituents – that can adopt either of two configurations that can be labeled as either an "R" or "S" configuration. As a result, the above chemical structure discloses ten different possible stereoisomers with the following configurations:

1. SRRR	6. SRSS
2. RSSS	7. RSRR
3. SRRS	8. RRSS
4. RSSR	9. SSSS
5. SRSR	10. RRRR

152. On February 21, 2001, Janssen and Mylan entered into a license agreement under which Janssen would manufacture nebivolol and Mylan had exclusive rights to import,

use, and sell nebivolol and to make, use, and sell products containing it within the United States and Canada.[49] Mylan could grant sublicences with prior written approval of Janssen.

153. Mylan filed NDA 21-742, seeking FDA approval of nebivolol under the brand name Bystolic. Forest was, and its successors in interest are now, the holder of NDA No. 21-742 for Bystolic. The active ingredient in Bystolic is a mixture of two of the above ten stereoisomers: the SRRR and RSSS stereoisomers (*i.e.*, nos. 1 and 2, above). The mixture of these two stereoisomers is referred to as nebivolol, and both are present in Bystolic as a hydrochloride salt.

154. On January 6, 2006, Mylan and Forest entered into a development and commercialization agreement. Under the terms of this agreement, Mylan granted Forest a sublicense under the 2001 agreement with Janssen, as well as an exclusive license to some of its own know-how related to nebivolol products. Forest would continue to purchase nebivolol from Janssen until Forest was ready to manufacture nebivolol at its own plant.

155. On March 30, 2012, Forest purchased from Janssen all the patents subject to the 2001 agreement and terminated all the nebivolol agreements among Janssen, Forest and Mylan. During all times relevant to this Complaint, Forest was, and its successor in interest Allergan is, the holder of NDA No. 21-742 for Bystolic.

B. Forest's Bystolic Patents.

156. Forest certified to FDA that the '040 and '580 Patents covered Bystolic, and FDA listed those patents in the Orange Book. The '580 Patent issued on June 2, 1998 and expired seventeen years later, on June 2, 2015. Accordingly, the '580 Patent afforded Forest no protection from generic competition for Bystolic beyond June 2, 2015. Further, some or

[49] *Mylan Inc. v. Comm'r of Internal Revenue*, 111 T.C.M. (CCH) 1199 (T.C. 2016).

all of the Generic Defendants filed Paragraph IV certifications as to the '580 Patent and Forest declined to sue any of the Defendants on that patent.

157. The '040 Patent issued from United States Application Serial No. 07/825,488 ("the '488 Application") filed on January 24, 1992. The '040 Patent issued on April 8, 2003 and is set to expire on December 17, 2021. To understand the impact of prosecution of the '488 Application at the PTO on the scope of the issued claims in the '040 Patent, it is important to understand the effect of the choice of transition in a patent claim. "A patent claim typically has three parts: the preamble, the transition, and the body."[50] "The preamble is an introductory phrase that may summarize the invention, its relation to the prior art, or its intended use or properties."[51] "The transition is a phrase connecting the preamble to the body of the claim. The content of the phrase may indicate whether the elements stated in the body are 'open' or 'closed.'"[52] "The body of the claim is the recitation or listing of the elements and limitations which define the product or process to be encompassed within the patent monopoly."[53]

158. There are three commonly used transitional phrases: "comprising," "consisting of," and "consisting essentially of."[54] These are "terms of art in patent law that 'define the scope of the claim with respect to what unrecited additional components or steps, if any, are excluded from the scope of the claim.'"[55] At one end of the spectrum, the phrase

[50] D. Chisum, CHISUM ON PATENTS § 8.06[1](b) (2003).

[51] *Id*. § 8.06[1](b)[i].

[52] *Id*. § 8.06[1](b)[ii].

[53] *Id*. § 8.06[1](b)[iii].

[54] *Id*. § 8.06[1](b)[ii]; *Conoco, Inc. v. Energy & Envtl. Int'l, L.C.*, 460 F.3d 1349, 1360 (Fed. Cir. 2006).

[55] *Id*. (quoting the Manual of Patent Examining Procedures).

"comprising" signifies that the claim is "open" to the addition of unrecited components or steps.[56] For example, a claim reciting a product "comprising" three ingredients A, B and C encompasses a product composed of A, B, C and D (*i.e.*, the addition of D to the A-B-C combination does not avoid infringement).

159. The originally-filed claims in the application that issued as the '040 Patent employed the open transition "comprising." For example, originally-filed claim 19 covered pharmaceutical compositions "comprising" a "pharmaceutically acceptable carrier" and the SRRR and RSSS stereoisomers of nebivolol. The use of the open transition "comprising" meant that original claim 19 covered formulations having the SRRR and RSSS stereoisomers of nebivolol, even if the formulations also included some or all of the other eight unclaimed stereoisomers of nebivolol. The PTO examiner therefore rejected those claims based upon the prior art '362 Patent described above. The examiner reasoned that the '362 Patent taught mixtures of various of the stereoisomers described above, and thus were covered by pending claim 19.

160. In response, the applicants admitted that the '362 Patent taught "undefined mixtures that may include the presently claimed compounds in admixture with other stereoisomers of the Base Compound. . . ." More specifically, the applicants admitted that "Compound 84 . . . is an undefined mixture of the RSRR, RSSS, SRSS and SRRR isomers, and Compound 87 . . . is an undefined mixture of the RSRS, RSSR, and SRRS isomers." In an attempt to overcome the rejection, the applicants narrowed the claims by substituting new claims utilizing the transition "consisting essentially of" rather than "comprising." In doing so, the applicants emphasized that the purpose of the amendment was to distinguish their

[56] *CIAS, Inc. v. All. Gaming Corp.*, 504 F.3d 1356, 1360 (Fed. Cir. 2007).

claims from the undefined mixtures of other nebivolol isomers disclosed in the Prior Art '362 Patent:

> Claims 18 and 19 have been rewritten as new Claims 25 and 26. Claim 25 recites "A composition consisting essentially of the compound . . .", and Claim 26 recites "A pharmaceutical composition consisting essentially of . . . [the two compounds (a) and (b)]". This amendment is being made to more clearly distinguish the claimed invention over the prior art ['362 Patent] which, as is explained in detail below, discloses undefined mixtures that may include the presently claimed compounds in admixture with other stereoisomers of [nebivolol]. Favorable consideration of the amended claims is respectfully requested.

161. The transition "consisting essentially of" in a patent claim narrows the claim relative to "comprising."[57] "[W]ith respect to a 'consisting essentially of' claim, there is no infringement where the accused product contains additional, unclaimed ingredients that materially affect the basic and novel properties of the invention."[58] Thus, for a claim reciting a product "consisting essentially of" ingredients A, B and C, the addition of unrecited ingredient D will avoid infringement if D has a material effect on the basic and novel properties of the claimed invention.

162. The PTO examiner, however, was not persuaded that the use of the "consisting essentially of" transition distinguished the then-pending claims from the '362 Patent. He therefore maintained his rejection of the claims. The applicants for the '040 Patent again argued that it was impossible to tell from the '362 Patent which stereoisomers, and in what amounts, were definitely present in the disclosed mixtures:

> There is no way that one can determine from the teachings of the patent the specific stereoisomeric configuration of [the prior art '362 Patent's] compound Nos. 84 and 87.

[57] *AK Steel Corp. v. Sollac and Ugine*, 344 F.3d 1234, 1239 (Fed. Cir. 2003).

[58] *Yoon Ja Kim v. ConAgra Foods, Inc.*, 465 F.3d 1312, 1320-21 (Fed. Cir. 2006).

The Examiner continued to maintain his rejections and ultimately issued a final rejection of the "consisting essentially of" Claims 25 and 26, as anticipated by the '362 Patent. He also rejected the claims as obvious.

163. The applicants for the '040 Patent appealed the examiner's final anticipation and obviousness rejections to the Board of Patent Appeals and Interferences ("the Board"). In their brief, the applicants continued to argue that it was impossible to say exactly which stereoisomers (and how much of them) were present in Compound 84 of the prior art '362 Patent, but that the "possible" stereoisomers present in unknown amounts were RSRR, RSSS, SRRR and SRSS. During the course of briefing the appeal to the Board, the Examiner dropped the anticipation rejection.

164. The Board nevertheless addressed the anticipation issue and made certain findings and conclusions regarding the relationship between then-pending Claim 26 and Compound 84 of the '362 Patent. Specifically, the Board concluded: [The '362 Patent's] disclosure of compound 84, together with its designation "AB," appears to describe the individual RSSS, SRRR, RSRR and SRSS stereoisomers "just as surely as if they were identified in the reference by name."

165. The Board then determined that the "consisting essentially of" transition in then-pending Claim 26 caused the claim to cover the undefined mixture of isomers in the Prior Art '362 Patent:

> It is well settled that "the phrase 'consisting essentially of' limits the scope of a claim to the specified ingredients and those that do not materially affect the basic and novel characteristic(s) of a composition." Here, a basic and novel characteristic of the pharmaceutical composition of claim 26 is its blood pressure reducing or antihypertensive effect. Thus, claim 26 is open to ingredients that do not materially affect its antihypertensive activity. [The prior art '362 Patent's] antihypertensive compound 84 is a mixture of four stereoisomers: RSSS, SRRR, RSRR and SRSS. Because the RSSR and SRSS

> stereoisomers do not materially affect blood pressure reducing or antihypertensive activity, it appears that they are not excluded from the ***composition of claim 26***. (internal citation omitted and emphasis added).

Accordingly, the Board ordered the Examiner to reconsider his withdrawal of the anticipation rejection based on the Prior Art '362 Patent:

> Specifically, the examiner should consider whether claim 26 'reads on' [the '362 Patent's] compound 84 taking into account the appropriate principles of claim interpretation and the foregoing remarks.

The very clear upshot of the Board's decision was that the claims of the '488 Application were not patentable unless the claims excluded the unclaimed stereoisomers, particularly the RSSR and SRSS stereoisomers.

166. On remand from the Board, the applicants for the '040 Patent did not even attempt to argue against anticipation in view of the Board's opinion. Instead, they further narrowed their claims by replacing "consisting essentially of" with "consisting of," in new Claims 27 and 28. And based on that change, applicants argued that the new "consisting of" limitation excluded the undefined mixture of possible stereoisomers in the '362 Patent: Applicants respectfully submit that the claims, as amended, are patentable over [the prior art '362 Patent].

> Applicants submit that neither a composition consisting of the RSSS enantiomer, nor a composition consisting of the RSSS enantiomer and its enantiomer the SRRR enantiomer, are disclosed in [the '362 Patent]. [The '362 Patent] discloses the base compound, as an undefined mixture of stereoisomers, as compound 84 (designated as "AB") and 87 (designated as "AA"), shown in the table in Col. 21 of the patent.

167. Once again, the applicants expressly noted that "Compound 84 [of the prior art '362 Patent] is an undefined mixture of the RSRR, RSSS, SRSS and SRRR isomers, and Compound 87 [] is an undefined mixture of the RSRS, RSSR, and SRRS isomers." They

argued that the new "consisting of" language excluded compounds containing such additional isomers:

> [I]t is clear that the cited [the '362 Patent] discloses neither a composition consisting of the RSSS enantiomer of the base compound, nor a composition consisting of the RSSS and SRRR enantiomers.

168. And again, applicants did not distinguish their claims based on any particular amount or source of possible unrecited stereoisomers in the "undefined mixture" of the '362 Patent.

169. The phrase "consisting of" is the narrowest of the transitions and it "signifies restriction and exclusion of unrecited steps or components."[59] In light of the Board's reasoning and the applicants' comments and amendments, it is clear that the narrowing amendment was intended to and did exclude the presence of the unclaimed stereoisomers, particularly the RSSR and SRSS stereoisomers (*i.e.*, the claims do not cover formulations containing the unclaimed stereoisomers, especially the RSSR and SRSS stereoisomers).

170. The Examiner then allowed the "consisting of" Claims 27 and 28, which ultimately issued as Claims 2 and 3 of the '040 Patent in 2003.

171. Subsequently, the '040 Patent was subjected to reexamination proceedings and a reexamination certificate issued in 2009.

C. The Generic Defendants File ANDAs for Generic Versions of Bystolic.

172. Alkem, Amerigen, Glenmark, Indchemie, Hetero, Torrent and Watson were the first generic manufacturers to file ANDAs with the FDA containing Paragraph IV certifications regarding the Bystolic patents. In letters granting final approval to their

[59] Manual of Patent Examining Procedures § 2111.03; *Norian Corp. v. Stryker Corp.*, 363 F.3d 1321, 1331 (Fed. Cir. 2004).

ANDAs, the FDA noted that each was "one of the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification for Nebivolol Tablets."[60]

173. Because the Generic Defendants were the first companies to file substantially complete ANDAs with Paragraph IV certifications, they each stood to receive 180 days of marketing exclusivity during which the FDA would not give final approval to any later ANDA filer's generic equivalent of Bystolic.

174. Forest received the Generic Defendants' Paragraph IV notice letters on the following dates:

Manufacturer	Paragraph IV Notice Date
Torrent	February 2, 2012[61]
Indchemie	February 3, 2012[62]
Alkem	February 3, 2012[63]
Watson	February 13, 2012[64]
Amerigen	February 16, 2012[65]
Hetero	February 17, 2012[66]
Glenmark	February 20, 2012[67]

175. Because they contained Paragraph IV certifications, these notice letters were required to include a detailed statement of the factual and legal bases as to why the '040

[60] *See, e.g.*, November 27, 2015 Letter from FDA to Watson, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/203683Orig1s000ltr.pdf; May 27, 2017 Letter from FDA to Glenmark, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/ 203821Orig1s000ltr.pdf; June 24, 2015 Letter from FDA to Alkem, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/203741Orig1s000ltr.pdf.

[61] Complaint ¶ 93, *Forest Labs., Inc. v. Torrent Pharm. Ltd. et al.*, No. 12-cv-05030 (D. Del. Mar. 13, 2012) ECF No. 1.

[62] Complaint ¶ 22, *Forest Labs., Inc. v. Indchemie Health Specialties PVT et al.*, No. 12-cv-01855 (N.D. Ill. Mar. 14, 2012) ECF No. 1.

[63] *Id.* ¶ 38.

[64] Complaint ¶ 108, *Forest Labs., Inc. v. Torrent Pharm. Ltd. et al.*, No. 12-cv-05030 (D. Del. Mar. 13, 2012) ECF No. 1.

[65] *Id.* ¶ 123.

[66] *Id.* ¶ 153.

[67] *Id.* ¶ 138.

Patent (and the '580 Patent, to the extent it was challenged) was invalid, unenforceable, and/or not infringed by their ANDA products. The Paragraph IV notice letters were required to include an offer of confidential access to each Generic Defendant's ANDA under the Hatch-Waxman Act. The notice letters gave rise to a potential cause of action for patent infringement, thereby allowing Forest to file suit against the Generic Defendants under the Hatch- Waxman Act (if Forest otherwise had a basis to sue under Rule 11).

D. The Nebivolol Patent Litigation.

176. On March 13, 2012, in response to their Paragraph IV certification letters, Forest filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Torrent, Watson, Amerigen, Glenmark and Hetero.[68] Despite having received Paragraph IV Certification notice letters from some or all of these companies relating to both the '040 and '580 Patents, Forest chose to assert only the '040 Patent.

177. On March 14, 2012, in response to their Paragraph IV certification letters, Forest filed a patent infringement lawsuit in the United States District Court for the Northern District of Illinois against Indchemie and Alkem.[69] Despite having received Paragraph IV Certification notice letters from both Indchemie and Alkem relating to both the '040 and '580 Patents, Forest chose to assert only the '040 Patent.

178. By order of the Judicial Panel for Multidistrict Litigation, these cases were consolidated into *In re Nebivolol Patent ('040) Litig.*, No. 12-cv-5026 (N.D. Ill. June 12, 2012) ECF No. 1 (hereafter referred to as the "Nebivolol Patent Litigation").

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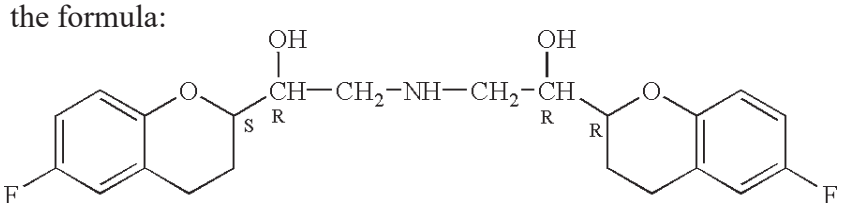
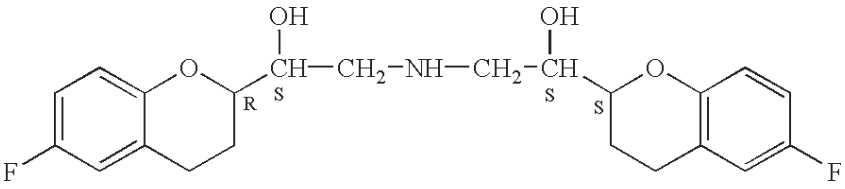
[68] Complaint, *Forest Labs., Inc. v. Torrent Pharm. Ltd. et al.*, No. 12-cv-05030 (D. Del. Mar. 13, 2012) ECF No. 1.

[69] Complaint, *Forest Labs., Inc. v. Indchemie Health Specialties PVT et al.*, No. 12-cv-01855 (N.D. Ill. Mar. 14, 2012) ECF No. 1.

179. Forest could not prevail in the Nebivolol Patent Litigation. The sole independent claim asserted by Forest in the Nebivolol Patent Litigation was claim 2 of the '040 Patent, as shown below:

> 2. A pharmaceutical composition consisting of a pharmaceutically acceptable carrier and, as active ingredients:
>
> (a) the blood pressure reducing compound [2S,αR, 2′R,α′R]-α,α′-[iminobismethylene]bis[6-fluoro-3,4-dihydro-2H-1-benzopyran-2-methanol] having the formula:
>
> 
>
>
> or a pharmaceutically acceptable acid addition salt thereof; and
>
> (b) the compound [2R,αS,2′S,α′S]-α,α′-[iminobismethylene]bis[6-fluoro-3,4- dihydro-2H-1-benzopyran-2-methanol] having the formula:
>
> 
>
>
> or a pharmaceutically acceptable acid addition salt thereof.

'040 Patent at 11:33-12:22. Thus, claim 2 is limited to a pharmaceutical composition consisting of a pharmaceutically acceptable carrier and, as active ingredients, SRRR-nebivolol and RSSS-nebivolol (or pharmaceutically acceptable acid addition salts).

180. The Generic Defendants were well aware of the prosecution history of the '040 Patent and the narrowing amendments the applicants had made. During claim

construction proceedings in the Nebivolol Patent Litigation, they correctly argued that the term "consisting of" in claim 2 of the '040 Patent "excludes any unrecited stereoisomers of nebivolol." The Generic Defendants' generic Bystolic products did not infringe because they included at least small amounts of the unrecited stereoisomers of nebivolol, including the RSSR and SRSS stereoisomers.

181. Early in the Nebivolol Patent Litigation, the Generic Defendants pressed the argument that the "consisting of" transition precluded the use of a plurality of inactive ingredients. Their position was premised on the argument that: (1) a "pharmaceutically acceptable carrier" referred to an individual inactive ingredient in a pharmaceutical formulation; (2) the "consisting of" transition "closed" the claim to unrecited inactive ingredients; and (3) therefore, the claims did not cover formulations having two or more inactive ingredients. At least one other court has construed "pharmaceutically acceptable carrier" to mean "a conventional pharmaceutically acceptable excipient or additive. . . ."[70] To the extent this interpretation applied in the Nebivolol Patent Litigation, the Generic Defendants' products did not infringe for this additional reason.

182. As a result of the foregoing, Forest could not prevail in proving literal infringement of the asserted claims of the '040 Patent. And, in light of the prosecution history of the '040 Patent, Forest could not prevail based on the doctrine of equivalents. In addition, Forest's invalidity defenses concerning the asserted claims of the '040 Patent were weak and it could not have prevailed against the Generic Defendants' invalidity arguments. As the Board explained during the prosecution of the '040 Patent:

> [The '362 Patent's] disclosure of compound 84, together with its designation "AB," appears to describe the individual RSSS, SRRR, RSRR and SRSS

[70] *Schering Corp. v. Mylan Pharm., Inc.*, 2011 U.S. Dist. LEXIS 63825, at *36 (D.N.J. June 15, 2011).

> stereoisomers "just as surely as if they were identified in the reference by name."

The '362 Patent was prior art to the '040 Patent. In light of the '362 Patent's essentially explicit teaching of a mixture of "the individual RSSS, SRRR, RSRR and SRSS stereoisomers" of nebivolol, the asserted compositions in the '040 Patent were anticipated by, or obvious in view of, the prior art, including other pertinent prior art such as Van de Water *et al*., Pharmacological and Hemodynamic Profile of Nebivolol, a Chemically Novel, Potent, and Selective B1-Adrenergic Antagonist, Journal of Cardiovascular Pharmacology, 11, No. 5, 552-563 (1988). Any purported evidence of secondary indicia of nonobviousness was insufficient to overcome the clear *prima facie* obviousness of the claims.

E. Forest Enters into Unlawful Reverse-Payment Agreements with the Generic Defendants.

183. Starting on October 24, 2012, Forest began entering into settlements with Generic Defendants to resolve the Nebivolol Patent Litigation.

184. Forest's internal and external counsel have conceded that each of these settlements also included "side-deals." Indeed, in a March 4, 2014, email between Forest's outside lawyers to Forest in-house counsel Eric Agovino, Agovino informed external counsel that "All [Generic Defendant settlements] had side-deals (one was struck with Alkem, which is a related company with Indchemie)":[71]

[71] *Id*. (emphasis added).

To: 'Malester, Ann'[]; Newborn, Steven[steven.newborn@weil.com]
From: Agovino, Eric
Sent: Tue 3/4/2014 7:47:28 PM
Importance: Normal
Subject: RE: Namenda settlements
Received: Tue 3/4/2014 7:47:00 PM
EXECUTED Forest-Hetero Settlement and License Agreement.pdf
EXECUTED Term Sheet (Hetero).pdf

We entered into settlement agreements with the following defendants:

1) Hetero

2) Torrent

3) Alkem

4) Indchemie

5) Glenmark

6) Amerigen

7) Actavis

All had side deals (one side was struck with Alkem, which is a related company with Indchemie).

Attached are the Hetero agreements.

From: Malester, Ann [mailto:Ann.Malester@weil.com]
Sent: Tuesday, March 04, 2014 9:15 AM
To: Agovino, Eric; Newborn, Steven
Subject: RE: Namenda settlements

Eric,

Before we engage in any discussions with the FTC on the Namenda agreements, we think it would be prudent for us to review all of the Bystolic settlement and licensing agreements as well as the side agreements with those generic companies. Could you put together the same type of information for Bystolic as you sent us for Namenda?

Thanks so much, Ann

185. These side deals were also listed in Forest's Merger Agreement with Actavis PLC as "payments to resolve the material contracts" that "involve payments . . . of consideration in excess of $15,000,000."[72] In addition, Forest also admitted that it reimbursed "certain of the Settling Defendants' legal costs in connection with the patent litigation."[73] Accordingly, Forest paid each Generic Defendant at least $15,000,000 in reverse-payments to resolve the Nebivolol Patent Litigation and induce the Generic Defendants to quit the patent fight. Each Generic Defendant readily accepted these payments to do so.

186. *Hetero*: The Hetero reverse-payment included the "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd[.], and Hetero USA Inc. and Hetero Labs Ltd. dated October 24, 2012," plus a payment allegedly for Forest's saved legal fees and Hetero's expended litigation fees and costs, and a "FINAL TERM SHEET [relating to Nebivolol API] between Hetero Drugs Ltd. and Forest Laboratories Ireland L[imited] dated October 5, 2012, in connection with the settlement of BYSTOLIC patent dispute."[74]

187. Under the Settlement Agreement, Hetero agreed to delay entry of its generic Bystolic product unti

[redacted]

[72] *In re Namenda Direct Purchaser Antitrust Litig.*, 15-cv-07488-CM-RWL (S.D.N.Y. Mar. 7, 2019) (ECF No. 680-22 at 69).

[73] https://www.sec.gov/Archives/edgar/containers/fix010/38074/000003807413000024/R17 htm.

[74] *In re Namenda Direct Purchaser Antitrust Litig.*, 15-cv-07488-CM-RWL (S.D.N.Y. Mar. 7, 2019) (ECF No. 680-22) at 179.

[redacted] The Forest-Hetero Settlement Agreement also contained a CLP, which permitted Hetero to launch its generic version of Bystolic upon the launch a third party generic version of Bystolic.

188. In return for Hetero's agreement to drop its challenge to the '040 patent and to delay marketing its generic Bystolic product, Forest paid Hetero substantial sums. The Settlement Agreement provided, *inter alia*, that [redacted]

189. Prior to the agreement, Forest had been able to obtain sufficient amounts of [redacted] On information and belief, the payments pursuant to [redacted] far exceeded the fair value of any products delivered or services rendered by Hetero, and the agreement itself was nothing more than a

pretextual conduit of cash from Forest to induce Hetero to agree not to compete in the nebivolol HCl market until September 2021.

190. [redacted] The only purpose of such provisions was to limit competition from prospective generic competitors in the nebivolol market.

191. *Torrent*: The Torrent reverse-payment included the "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Torrent Pharmaceuticals Ltd, and Torrent Pharma Inc. dated November 21, 2012," [redacted] and Torrent and Forest executed – on the same day – a "PATENT ASSIGNMENT AGREEMENT between Torrent Pharmaceuticals Ltd and Forest Laboratories Holdings Ltd. dated November 21, 2012, in connection with the settlement of BYSTOLIC patent dispute," pursuant to [redacted].[75]

[75] *In re Namenda Direct Purchaser Antitrust Litig.*, 15-cv-07488-CM-RWL (S.D.N.Y. Mar. 7, 2019) (ECF No. 680-22) at 179.

192. Under the Settlement Agreement, Tonent agreed to delay entry of its generic Bystolic product until [redacted]

The Forest-To1Tent Settlement Agreement also contained a CLP, which permitted Tonent to launch its generic version of Bystolic upon the launch a third paity generic version of Bystolic.

193. fu retmn for Tonent's agreement to drop its challenge to the '040 patent and to delay mai·keting its generic Bystolic, Forest agreed to pay Torrent substantial sums. [redacted]

[redacted]

[redacted] None of the conditions of the milestone payments was difficult to satisfy.

194. Because Forest had manufactured and marketed nebivolol in the United States and other jurisdictions without licenses from Torrent, the Torrent patents had little or no value to Forest. Forest already had all it needed to successfully manufacture and sell Bystolic. On information and belief, Forest knew about Torrent's patents for over eight years before it showed any alleged interest in the patents, and only became interested because the Patent Assignment Agreement was tied to Torrent's agreement to refrain from marketing generic Bystolic until September 2021. On information and belief, the payments pursuant to the Patent Assignment Agreement far exceeded the fair value of any products delivered or services rendered by Torrent, and the agreement itself was nothing more than a pretextual conduit of cash from Forest to induce Torrent not to compete in the nebivolol HCl market until September 2021.

195. *Alkem and Indchemie*: The Alkem and Indchemie reverse-payment included the "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Alkem Laboratories Ltd. dated November 27, 2012," the "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Indchemie Health Specialties Private Ltd. dated November 27, 2012," [redacted], and a "TERM SHEET [relating to Nebivolol drug product] between Alkem Laboratories Ltd., Indchemie Health Specialties Private Ltd., and Forest Laboratories Ireland Ltd. dated November 28, 2012, in connection with the settlement of BYSTOLIC patent dispute."

196. Under the Settlement Agreements, Alkem and Indchemie agreed to delay entry of their generic Bystolic product until [redacted] The Forest-Alkem Settlement Agreement also contained a CLP, which permitted Alkem to launch its generic version of Bystolic upon the launch a third party generic version of Bystolic.

197. In return for the Alkem/Indchemie agreement to drop challenges to the '040 patent and to delay marketing generic Bystolic, Forest paid Alkem/Indchemie, substantial sums. The Settlement Agreement provided, *inter alia*, that Forest would make [redacted]

[redacted]

198. When the Term Sheet was executed, Forest had not yet submitted its New Drug Application for Byvalson. [redacted]

199. On information and belief, Forest had already been producing sufficient quantities of Bystolic products to meet market demand without any need for additional products or services from Alkem and/or Indchemie. On information and belief, prior to its agreement with Alkem/Indchemie, Forest had expressed no interest to Alkem/Indchemie in the technology or other services (if any) Alkem/Indchemie contributed to the Byvalson product development. On information and belief, the payments pursuant to the Term Sheet far exceeded the fair value of any products delivered or services rendered by Alkem/Indchemie, and the agreement itself was nothing more than a pretextual conduit of cash from Forest to induce Alkem/Indchemie not to compete in the nebivolol HCl market until September 2021.

200. [redacted]

[redacted] The only purpose of such a provision was to limit competition from prospective generic competitors in the nebivolol market.

201. *Glenmark*: The Glenmark reverse-payment included the "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Glenmark Generics Inc., USA and Glenmark Generics Ltd. dated December 21, 2012," [redacted], and a "COLLABORATION AND OPTION AGREEMENT between Glenmark Pharmaceuticals S.A. and Forest Laboratories Holdings Ltd. dated December 21, 2012, in connection with the settlement of BYSTOLIC patent dispute."

202. Under the Settlement Agreement, *inter alia*, Glenmark agreed to delay entry of its generic Bystolic product until [redacted] The Forest-Glenmark Settlement Agreement also contained a CLP, which permitted Glenmark to launch its generic version of Bystolic upon the launch a third party generic version of Bystolic.

203. In return for Glenmark's agreement to drop its challenge to the '040 patent and to delay marketing its generic Bystolic, Forest paid Glenmark substantial sums. [redacted]

204. In addition, pursuant to the "COLLABORATION AND OPTION AGREEMENT," signed the same day as the Settlement Agreement, [redacted]

[redacted]

205. On information and belief, prior to negotiations surrounding the Nebivolol Patent Litigation, [redacted] On further information and belief, the payments under the Collaboration and Option Agreement far exceeded the fair value of any products delivered or services rendered by Glenmark, and the agreement itself was nothing more than a pretextual conduit of cash from Forest to induce Glenmark not to compete in the nebivolol HCl market until September 2021.

206. *Amerigen*: The Amerigen reverse-payment included the "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Amerigen Pharmaceuticals, Inc. and Amerigen Pharmaceuticals, Ltd. dated July 18, 2013," [redacted], and a "BINDING TERM SHEET COLLABORATION AGREEMENT" between Forest Laboratories, Inc. and Amerigen Pharmaceuticals, Ltd. dated July 18, 2013, in connection with the settlement of BYSTOLIC patent dispute."

207. Under the Settlement Agreement, Amerigen agreed to delay entry of its generic Bystolic product until [redacted] The Forest-Amerigen Settlement Agreement also contained a CLP, which

permitted Amerigen to launch its generic version of Bystolic upon the launch a third party generic version of Bystolic.

208. In return for Amerigen's agreement to drop its challenge to the '040 patent and to delay marketing its generic Bystolic, Forest agreed to pay Amerigen substantial sums. [redacted]

209. On information and belief, prior to the nebivolol settlement negotiations with Amerigen, Forest had not expressed any interest in, or attributed any value to Amerigen's products. On further information and belief, the payments under the Collaboration Agreement far exceeded

the fair value of any products delivered or services rendered by Amerigen, and the agreement itself was nothing more than a pretextual conduit of cash from Forest to induce Amerigen not to compete in the nebivolol HCl market until September 2021.

210. *Watson*: The Watson reverse-payment included the "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Watson Laboratories, Inc. (NV), Watson Laboratories, Inc. (DE), Watson Laboratories, Inc. (NY), Watson Laboratories, Inc. (CT), Watson Pharma, Inc., and Actavis, Inc. dated November 6, 2013,"

[redacted] "(a) the LETTER from Forest plus Laboratories, Inc. to Moksha8, Inc. dated November 1, 2013 and (b) TERMINATION AND RELEASE AGREEMENT between [Watson] and Moksha8, Inc. dated November 4, 2013, in connection with the settlement of BYSTOLIC patent dispute."[77]

211. Pursuant to "(a) the LETTER from Forest Laboratories, Inc. to Moksha8, Inc. dated November 1, 2013, and (b) TERMINATION AND RELEASE AGREEMENT between [Watson] and Moksha8, Inc.," Forest paid Watson more than $15,000,000 in exchange for Watson's commitment to delay competition to Bystolic.

212. [redacted]

[77] *In re Namenda Direct Purchaser Antitrust Litig.*, 15-cv-07488-CM-RWL (S.D.N.Y. Mar. 7, 2019) (ECF No. 680-22) at 180.

213. Prior to executing these side deals, Watson and Forest had each entered several agreements with Moksha8. In October 2010, Watson acquired a minority interest in Moksha8 as part of a $30 million investment that included a marketing agreement under which Watson agreed to manufacture and supply select products to Moksha8, which would have exclusive rights to market, sell, and distribute these products in Brazil and Mexico.[78] In October 2012, Watson and Moksha8 agreed to extend Moksha8's rights to commercialize a portfolio of Watson branded generic products in Brazil and Mexico, while also buying out Watson's minority equity position.[79]

214. Around the same time, Forest and Moksha8 entered into a deal whereby Forest extended significant debt financing to Moksha8 over a two-year term and Forest received the option to acquire Moksha8 at the end of the loan's term.[80] Under the loan facility—which itself consisted of three agreements executed between October 22, 2012 and November 30, 2012—Forest committed to providing up to $125 million in debt financing to Moksha8, which was conditioned upon Moksha8 reaching certain business goals.[81]

215. By the time Forest entered into its reverse payment agreement with Watson, Forest had extended approximately $100 million in financing to Moksha8.[82] [redacted]

[78] https://www.genengnews.com/news/watson-invests-30m-in-moksha8-and-forms-marketing-partnership-for-brazil-and-mexico/.

[79] *Id*.

[80] https://www.fiercepharma.com/m-a/forest-ties-up-brazil-s-moksha8-up-to-125m-alliance.

[81] https://www.sec.gov/Archives/edgar/data/38074/000003807414000009/R12 htm.

[82] https://www.sec.gov/Archives/edgar/data/38074/000003807414000009/R12 htm

216. [redacted]

217. [redacted]

a. [redacted]

b. [redacted]

c. [redacted]

d. [redacted]

e. [redacted]

f. [redacted]

g. [redacted]

218. [redacted]

219. The November 2013 agreements entered between Forest, Moksha8, and Watson disguised large payments from Forest to Watson. The agreement themselves were nothing more than a pretextual conduit of cash from Forest to induce Watson not to compete in the nebivolol HCl market until September 2021.

220. The value of each reverse-payment by Forest to each Generic Defendant was in excess of fair value for services provided and/or exceeded Forest's avoided litigation costs.

221. In exchange for these reverse-payments, each Generic Defendant agreed not to compete with Forest in the market for nebivolol HCl, in which Forest had a monopoly, for so long as all others did so also, until September 17, 2021 (a mere three months prior to expiry of the '040 Patent).[83]

222. The purpose and effect of the reverse-payment agreements were to delay Forest from having to face lower-priced generic competition for years.

223. But for the reverse-payment agreements, the Generic Defendants would have been ready, able, and willing to launch their generic versions of Bystolic much earlier.

[83] https://www.sec.gov/Archives/edgar/containers/fix010/38074/000003807413000024/R17 html.

224. Specifically, the Generic Defendants would have launched their less expensive generic versions of Bystolic earlier than September 17, 2021: (a) at risk during pendency of the Nebivolol Patent Litigation; or (b) upon prevailing against Forest in the Nebivolol Patent Litigation; or (c) via lawful, procompetitive settlement agreements providing for earlier negotiated entry dates untainted by the delay caused by the unlawful reverse payments.

225. By operation of the CLPs, if *just one* Generic Defendant launched a generic version of Bystolic prior to September 17, 2021 pursuant to any of the three above scenarios, *all* of the other Generic Defendants would have entered the market.

226. By about October 2012, when Forest and the Generic Defendants began entering into the reverse-payment agreements, Bystolic was generating hundreds of millions of dollars per year in revenues for Forest. Losing a substantial portion of that revenue stream in the event any of the Generic Defendants were to prevail on non-infringement or other defenses – or in the event that Forest had not induced the Generic Defendants with reverse-payments to agree to delay launching generic Bystolic – would have drastically reduced Forest's profits. Thus, Forest had enormous incentives to avoid competition from the Generic Defendants by entering into reverse-payment agreements. Each Generic Defendant also had incentive to accept a reverse payment because (on information and belief) each reverse payment represented more profit than the Generic Defendant would have made by competing with Forest and with the other Defendants because, *inter alia*, the market entry of multiple generics competing on price quickly lowers generic prices toward marginal costs.

227. Forest's willingness to provide large payments to each Generic Defendant, and each Generic Defendant's willingness to accept large payments from Forest in exchange for a multi-year

delay in competition amounted to an agreement between Forest and each Generic Defendant to share the monopoly profits from sales of branded Bystolic at supracompetitive levels.

VII. MONOPOLY POWER AND MARKET DEFINITION

228. As stated above, the pharmaceutical marketplace is characterized by a "disconnect" between product selection and the payment obligation.

229. State laws prohibit pharmacists from dispensing many pharmaceutical products, including Bystolic, to patients without a prescription. The prohibition on dispensing certain products without a prescription creates this disconnect. The patient's doctor chooses which product the patient will buy while the patient (and in most cases his or her insurer) has the obligation to pay for the product.

230. Brand manufacturers, including the Forest Defendants, exploit this price disconnect by employing large sales forces that visit doctors' offices and persuade them to prescribe the brand manufacturers' products. These sales representatives do not advise doctors of the cost of the branded products. Studies show that doctors typically are not aware of the relative costs of branded pharmaceuticals and, even when they are aware of the relative costs, they are largely insensitive to price differences because they do not pay for the products. The result is a marketplace in which price plays a comparatively unimportant role in product selection.

231. The relative unimportance of price in the pharmaceutical marketplace reduces what economists call the price elasticity of demand – the extent to which unit sales go down when price goes up. This reduced-price elasticity, in turn, gives brand manufacturers the ability to raise prices substantially above marginal cost without losing so many sales as to make the price increase unprofitable. The ability to profitably raise prices substantially above marginal costs is what economists and antitrust courts refer to as market power. The result of these pharmaceutical market imperfections and marketing practices is that brand manufacturers gain and maintain

market power with respect to many branded prescription pharmaceuticals, including Bystolic.

232. Forest had and continues to have monopoly power in the market for Bystolic because it has the power to exclude competition and/or raise or maintain the price of nebivolol HCl at supra-competitive levels without losing enough sales to make supra-competitive prices unprofitable, *i.e.*, without losing substantial sales to other products prescribed and/or used for the same purposes as Bystolic.

233. Other drugs that are not AB-rated to Bystolic cannot be substituted automatically for Bystolic by pharmacists, do not exhibit substantial cross-price elasticity of demand with Bystolic, and thus are not economic substitutes for, nor reasonably interchangeable with Bystolic.

234. A small but significant, non-transitory increase to the price of brand Bystolic by Forest would not have caused (and did not cause) a significant loss of sales to non-nebivolol HCl products sufficient to make the price increase unprofitable. Forest has never lowered the price of Bystolic in response to the pricing of any non-nebivolol HCl treatments for high blood pressure. To the contrary, Forest repeatedly raised Bystolic prices without losing substantial sales to other products, even with lower-cost, generic versions of other brand products approved to treat the same indications as Bystolic on the market, including generic Coreg and generic Toprol XL (both beta blockers approved to treat high blood pressure). In fact, Forest substantially increased the WAC price of Bystolic – by more than 60% – over the last five years.

235. Because of its labeling, branded Bystolic is differentiated from all other nebivolol HCl products.

236. Manufacturers attempt to differentiate brand name drugs like Bystolic based on features and benefits (including safety and efficacy), not based on price. Doctors and patients are generally price-insensitive when prescribing and taking prescription drugs like Bystolic. This is

due in part to the presence of insurance that bears much of the cost of prescriptions and other institutional features of the pharmaceutical marketplace. Different patients may respond differently to different drugs and even drugs within its same therapeutic class do not constrain the price of Bystolic. In addition, consumers do not choose prescription drugs directly; they must be prescribed by a physician who does not pay for the drug and may not be aware of its price. This "price disconnect" blunts price competition among different drugs, even if they are prescribed for similar conditions.

237. No non-nebivolol HCl product ever rendered Forest unable to profitably maintain or raise its prices of Bystolic without losing substantial sales.

238. Forest also sold branded Bystolic at [redacted]rices well in excess of marginal costs and in excess of the competitive price, and, therefore, Forest enjoyed high profit margins.

239. Forest also has had, and exercised, the power to exclude generic competition to branded Bystolic.

240. Forest, at all material times, enjoyed high barriers to entry, including regulatory protections and high costs of entry and expansion, which protected branded Bystolic from the forces of price competition.

241. There is direct evidence of market power and anticompetitive effects available in this case sufficient to show Forest's ability to control the price of Bystolic, and to exclude relevant competitors, without the need to show the relevant antitrust markets. The direct evidence consists of, *inter alia*, the following facts: (a) generic Bystolic would have entered the market at a much earlier date, at a substantial discount to branded Bystolic, but for Defendants' anticompetitive conduct; (b) Forest's gross margin on Bystolic (including the costs of ongoing research/development and marketing) at all relevant times was very high; and (c) Forest never

lowered the price of Bystolic to a competitive level in response to the pricing of other branded or generic drugs.

242. To the extent proof of monopoly power by defining a relevant product market is required, Plaintiffs allege that the relevant antitrust market is the market for nebivolol HCl. Forest's market share in the relevant market is 100%, indicating substantial monopoly power. Forest needed to control only branded Bystolic and its AB-rated generic equivalents, and no other products, in order to maintain the price of nebivolol HCl profitably at supracompetitive prices. During the period relevant to this case, Forest has been able to profitably maintain the price of nebivolol HCl well above competitive levels.

243. Only the market entry of competing, AB-rated generic versions would render Defendants unable to profitably maintain their prices for Bystolic without losing substantial sales.

244. "[T]he size of the payment from a branded drug manufacturer to a prospective generic is itself a strong indicator of power-namely, the power to charge prices higher than the competitive level."[84] And a firm that lacks monopoly power is not "likely to pay 'large sums' to induce 'others to stay out of the market'"[85] Forest's anticompetitive reverse payments to the Generic Defendants demonstrate that Forest enjoyed market and/or monopoly power with respect to nebivolol HCl.

245. The United States, the District of Columbia, and the U.S. territories constitute the relevant geographic market.

246. Forest's market share in the relevant market is 100%, indicating substantial monopoly power.

[84] *Actavis*, 133 S. Ct. at 2236 (citations omitted).

[85] *Id*.

VIII. MARKET EFFECTS

247. Forest willfully and unlawfully maintained its market power by engaging in an overarching scheme to exclude competition. Forest designed a scheme to delay competition, to further Forest's anticompetitive purpose of forestalling generic competition against Bystolic. The Generic Defendants cooperated in order to increase their own profits. The reverse payments caused the Generic Defendants to: (a) prevent and delay until September 17, 2021 the entry of less-expensive generic versions of Bystolic in the United States; (b) fix, raise, maintain, or stabilize the price of Bystolic; and (c) allocate to Forest 100% of the U.S. market for Bystolic and its generic equivalents until September 17, 2021. Defendants carried out the scheme with the anticompetitive intent and effect of maintaining supra-competitive prices for nebivolol HCl tablets.

248. But for the unlawful reverse-payment agreements, the Generic Defendants would have begun selling less expensive generic versions of Bystolic much earlier than September 17, 2021. Such sales would have occurred via market entry by any of the Generic Defendants upon a Generic Defendant litigation victory, via an at risk launch during the pendency of the patent litigation, or via a licensed entry in a settlement with Forest that did not include a side-deal or any other unlawful reverse payments from Forest to any Generic Defendant.

249. An increasingly competitive market for Bystolic and its generic equivalents, with lower prices, would have thereafter emerged as additional generic versions of Bystolic (including, on information and belief, an authorized generic version of Bystolic) entered the market. Plaintiffs would have purchased generic Bystolic had it been available.

250. Defendants' acts and practices had the purpose and effect of restraining competition unreasonably and injuring competition by protecting brand Bystolic. These actions allowed Defendants to maintain a monopoly and exclude competition in the market for Bystolic and its AB-rated generic equivalents, to the detriment of Plaintiffs and all other members of the End-

Payor Class.

251. Defendants' exclusionary conduct delayed generic competition and unlawfully enabled Forest to sell Bystolic without further generic competition. Were it not for Defendants' illegal conduct, one or more additional generic versions of Bystolic would have entered the market sooner.

252. Defendants' unlawful concerted action has (a) delayed and suppressed the sale of generic versions of Bystolic in the United States, (b) enabled Forest to sell Bystolic at artificially inflated, supracompetitive prices, and (c) caused Plaintiffs and all Class members to pay more than they would have paid for nebivolol HCl absent this illegal conduct.

253. If generic competitors had not been unlawfully prevented from entering the market earlier and competing in the relevant markets, End-Payor purchasers, such as Plaintiffs and members of the Class, would have paid less for nebivolol HCl by (a) paying lower prices on their remaining brand purchases of Bystolic, (b) substituting purchases of less-expensive generic Bystolic for their purchases of more-expensive branded Bystolic, and/or (c) purchasing generic Bystolic at lower prices sooner.

254. Thus, Defendants' unlawful conduct deprived Plaintiffs and members of the Class of the benefits from the competition that the antitrust laws are designed to ensure.

IX. ANTITRUST IMPACT AND IMPACT ON INTERSTATE COMMERCE

255. During the relevant time period, Forest manufactured, promoted, sold, distributed and /or shipped Bystolic across state and national lines throughout the United States in a continuous and uninterrupted flow of interstate commerce. As a direct result of the unlawful reverse- payment agreements, the Generic Defendants refrained from selling generic versions of Bystolic in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States when they otherwise would have done so. During the relevant time

period, in connection with the purchase and sale of Bystolic, monies as well as contracts, bills and other forms of business communication and transactions were transmitted in a continuous and uninterrupted flow across state lines.

256. During the relevant time period, Plaintiffs and members of the Class purchased substantial amounts of nebivolol HCl indirectly from Forest. As a result of Defendants' illegal conduct, Plaintiffs and members of the Class were compelled to pay, did pay, and continue to pay artificially inflated prices for nebivolol HCl. Those prices were substantially greater than the prices that members of the Class would have paid absent the illegal conduct alleged herein, because: (1) the price of branded Bystolic was artificially inflated by Defendants' illegal conduct, (2) Class members were deprived of the opportunity to purchase lower-priced generic versions of Bystolic sooner, which they would have done had they had the opportunity, and/or (3) the price of generic Bystolic was artificially inflated by Defendants' illegal conduct. The supracompetitive prices were paid at the point of sale, which is where Plaintiffs and the proposed End-Payor Class suffered antitrust impact.

257. As a consequence, Plaintiffs and the members of the Class have sustained substantial damages to their business and property in the form of overcharges. The full amount and forms of components of such damages will be calculated after discovery and upon proof at trial. Commonly used and well-accepted economic models can be used to measure both the extent and the amount of the supracompetitive charges to end payors such as Plaintiffs and the members of the Class.

258. General economic theory recognizes that any overcharge at a higher level of distribution generally results in higher prices at every level below. According to Professor Hovenkamp, "[e]very person at every stage in the chain will be poorer as a result of the monopoly

price at the top." Professor Hovenkamp also acknowledges that "[t]heoretically, one can calculate the percentage of any overcharge that a firm at one distribution level will pass on to those at the next level."[86]

259. Further, the institutional structure of pricing and regulation in the pharmaceutical drug industry assures that overcharges at the higher level of distribution are passed on to end payors. Wholesalers and retailers passed on the inflated prices of Bystolic to Plaintiffs and the Class of end-payors defined herein. Forest's anticompetitive actions enabled it to indirectly charge End-Payors prices in excess of what it otherwise would have been able to charge absent its unlawful actions with the Generic Defendants.

260. The prices were inflated as a direct and foreseeable result of Forest's anticompetitive conduct individually and with each of the Generic Defendants.

261. The inflated prices that the proposed End-Payor Class paid are traceable to, and the foreseeable result of, the overcharges stemming from Defendants' unlawful conduct.

262. During the relevant time period, Defendants used various devices to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign wire commerce. All Defendants engaged in illegal activities, as charged in herein, within the flow of, and substantially affecting, interstate commerce.

263. Defendants' conduct was within the flow of, and was intended to have and did have a substantial effect on, interstate commerce of the United States, including in this District.

264. During the Class Period, each Defendant, or one or more of each Defendant's affiliates, used the instrumentalities of interstate commerce to join or effectuate the scheme. The

[86] *See* H. Hovenkamp, FEDERAL ANTITRUST POLICY, THE LAW OF COMPETITION AND ITS PRACTICE (1994) at 624.

scheme in which Defendants participated had a direct, substantial, and reasonably foreseeable effect on interstate commerce.

X. EFFECT ON INTRASTATE COMMERCE

265. During the relevant time period, branded Bystolic, manufactured and sold by Forest, was shipped into each state and was sold to or paid for by End-Payors.

266. During the relevant time period, in connection with the purchase and sale of branded Bystolic, monies exchanged hands and business communications and transactions occurred in each state.

267. Defendants' conduct as set forth in this Complaint had substantial effects on intrastate commerce in that, *inter alia*, retailers within each state were foreclosed from offering cheaper Bystolic and generic Bystolic to members of the End-Payor Class purchasing inside each respective state, and Defendants entered into an unlawful anticompetitive agreements that affected commerce in each state.

XI. CLASS ACTION ALLEGATIONS

268. Plaintiffs bring this action on their own behalf and on behalf of all others similarly situated as a class action under Fed. R. Civ. P. 23(a) and 23(b)(2) and (b)(3), seeking damages pursuant to the antitrust, unfair competition and consumer protection laws of the states listed below, and as representative of an End-Payor Class defined as follows:

> All persons and entities in the United States and its territories who indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price of brand or generic Bystolic from July 17, 2016 through and until the anticompetitive effects of Defendants' challenged conduct cease (the "Class Period").

Excluded from the Class are:

a. Defendants and their counsel, officers, directors, management, employees, subsidiaries, and affiliates;

b. all federal governmental entities;

c. all persons or entities who purchased Bystolic for purposes of resale;

d. fully insured health plans (*i.e.*, health 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 of Bystolic were paid in part by a third-party payor and whose co-payment was the same regardless of the retail purchase price;

f. pharmacy benefit managers; and

g. all judges assigned to this case and any members of their immediate families.

269. Members of the Class are so numerous and widely geographically dispersed throughout the United States and its territories that joinder is impracticable. Plaintiffs believe that there are hundreds of thousands of members of the Class, in an amount to be determined in discovery and at trial. Further, the identities of Class members will be readily ascertainable through business records kept in regular order.

270. Plaintiffs' claims are typical of the claims of members of the Class. Plaintiffs and all members of the Class were damaged by the same wrongful conduct by Defendants, and all paid artificially inflated prices for Bystolic and were deprived of the benefits of competition from less expensive generic versions as a result of Defendants' conduct.

271. Plaintiffs will fairly and adequately protect and represent the interests of the Class. Plaintiffs' interests are coincident with, and not antagonistic to, the Class.

272. Plaintiffs are represented by counsel who are experienced and competent in the prosecution of class action litigation, and who have particular experience with class action litigation involving the pharmaceutical industry.

273. Questions of law and fact common to members of the class predominate over questions, if any, that may affect only individual class members, because Defendants have acted on grounds generally applicable to the entire class. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

274. Questions of law and fact common to the Class include:

a. whether the conduct alleged herein constitutes a violation of the antitrust laws;

b. whether Defendants conspired to suppress generic competition to Bystolic;

c. whether Defendants' anticompetitive scheme suppressed generic competition to Bystolic;

d. whether Defendants' challenged conduct fixed, raised, maintained or stabilized the price of nebivolol HCl;

e. as to those parts of Defendants' challenged conduct for which such justifications may be offered, whether there exist cognizable, non-pretextual procompetitive justifications, which Defendants' challenged conduct was the least restrictive means of achieving, that offset the harm to competition in the markets in which Bystolic is sold;

f. whether a relevant antitrust market needs to be defined in this case in light of the existence of direct proof of Forest's power to exclude generic competition and charge supracompetitive prices for Bystolic;

g. to the extent a relevant antitrust market or markets needs to be defined, what the definition of the relevant antitrust market for analyzing Forest's

monopoly power is, and whether Forest had monopoly power in the relevant antitrust market;

h. whether Forest illegally obtained or maintained monopoly power in the relevant market;

i. whether Defendants' actions were, on balance, unreasonable restraints of trade;

j. determination of a reasonable estimate of the amount of delay Defendants' unlawful monopolistic, unfair, and unjust conduct caused;

k. whether Defendants' scheme, in whole or in part, has substantially affected interstate commerce;

l. whether Forest's compensation to the Generic Defendants was large and unexplained;

m. whether the reverse payment agreement created a bottleneck to further delay generic competition;

n. whether the reverse payment harmed competition;

o. whether Defendants' unlawful monopolistic conduct was a substantial contributing factor in causing some amount of delay of the entry of AB-rated generic Bystolic;

p. whether Defendants' scheme, in whole or in part, and to what extent, caused antitrust injury to the business or property of Plaintiffs and members of the Class in the nature of overcharges; and

q. the quantum of overcharges paid by the Class in the aggregate.

275. Class action treatment is a superior method for the fair and efficient adjudication of this controversy. Among other things, class treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress on claims that might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

276. Plaintiffs know of no difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

XII. COMPLIANCE WITH NOTICE AND DEMAND REQUIREMENTS

277. In accordance with the requirements of Arizona Revised Statute § 44-1415; Hawaii Revised Statute § 480-13.3(a); 815 Illinois Compiled Statutes § 505/10a(d); Nevada Revised Statute § 598A.210(3); New York General Business Law § 340(5); Rhode Island General Laws § 6-36-21; and Utah Code § 76-10-3109, on or about July 27, 2020, counsel sent letters regarding the End-Payor Class Action Complaints against the Forest Defendants to:

a. Mark Brnovich, Attorney General of Arizona;

b. Clare E. Connors, Attorney General of Hawaii;

c. Kwame Raoul, Attorney General of Illinois;

d. Aaron Ford, Attorney General of Nevada;

e. Letitia James, Attorney General of New York;

f. Peter F. Neronha, Attorney General of Rhode Island; and

g. Sean Reyes, Attorney General of Utah;

informing them of the existence of the respective complaints, identifying the relevant state antitrust provisions, and enclosing a copy of the respective complaints.

278. In accordance with the requirements of Arizona Revised Statute § 44-1415; Conn. Gen. Stat. § 35-37; Hawaii Revised Statute § 480-13.3(a); 815 Illinois Compiled Statutes § 505/10a(d); Nevada Revised Statute § 598A.210(3); New York General Business Law § 340(5); Rhode Island General Laws § 6-36-21; and Utah Code § 76-10-3109, on or about Dec. 3, 2020, counsel sent letters regarding this End-Payor Plaintiffs' Consolidated Class Action Complaint to:

a. Mark Brnovich, Attorney General of Arizona;

b. William Tong, Attorney General of Connecticut;

c. Clare E. Connors, Attorney General of Hawaii;

d. Kwame Raoul, Attorney General of Illinois;

e. Aaron Ford, Attorney General of Nevada;

f. Letitia James, Attorney General of New York;

g. Peter F. Neronha, Attorney General of Rhode Island; and

h. Sean Reyes, Attorney General of Utah;

informing them of the existence of the respective complaints, identifying the relevant state antitrust provisions, and identifying new defendants added to the Complaint.

279. On or about July 27, 2020, counsel sent demand letters to the Forest Defendants regarding the End-Payor Class Action Complaints against the Forest Defendants; and on or about Dec. 3, 2020, counsel sent demand letters regarding this End-Payor Plaintiffs' Consolidated Class Action Complaint to counsel of record for, or to the Generic Defendants Amerigen, Alkem, Glenmark, Hetero, Indchemie, Torrent and Watson. These demand letters satisfy the requirements of West Virginia Code § 46A-6-106(c). The demand letters identified the claimants as Plaintiffs

and all end payor purchasers of Bystolic in individual and representative capacities; described the unfair or deceptive acts or practices committed by Defendants' entry into unlawful and anticompetitive settlements; described the injury suffered (increased prices for Bystolic because of the delayed entry of a generic to the market); set forth a demand for relief (treble damages, attorneys' fees, litigation costs, and other available sanctions); and requested an offer to cure within the statutorily prescribed time.

280. On or about July 27, 2020, counsel sent demand letters to the Forest Defendants regarding the End-Payor Class Action Complaints against the Forest Defendants; and on or about Dec. 3, 2020, counsel sent demand letters regarding this End-Payor Plaintiffs' Consolidated Class Action Complaint to counsel of record for, or to the Generic Defendants Amerigen, Alkem, Glenmark, Hetero, Indchemie, Torrent and Watson. These demand letters satisfy the requirements of 10 Me. Rev. Stat. tit. 5 § 213-1-A. The demand letters identified the claimants as Plaintiffs and all end payor purchasers of Bystolic in individual and representative capacities; described the unfair or deceptive acts or practices committed by Defendants' entry into unlawful and anticompetitive settlements; described the injury suffered (increased prices for Bystolic because of the delayed entry of a generic to the market); set forth a demand for relief (actual damages, attorneys' fees, litigation costs, and other available sanctions); and requested an offer to cure.

281. The demand letter requirement of Section 9 of Massachusetts General Laws Annotated Chapter 93A does not apply to Defendants because Defendants have not identified a place of business or assets within Massachusetts. In an abundance of caution, however, Plaintiffs, on behalf of themselves and all others similarly situated, (1) sent the Forest Defendants on or about July 27, 2020 a written demand for relief concerning the claims set forth in the End-Payor Class Action Complaints, and (2) sent to counsel for, or to the Generic Defendants Amerigen, Alkem,

Glenmark, Hetero, Indchemie, Torrent and Watson on or about Dec. 3, 2020, a written demand for relief concerning the claims set forth in this End-Payor Plaintiffs' Consolidated Class Action Complaint. The demand letters identified the claimants as Plaintiffs and all end-payor purchasers of Bystolic, in individual and representative capacities; described the unfair or deceptive acts or practices committed by the Defendants (including their entry into unlawful and anticompetitive settlements); described the injury suffered (increased prices for Bystolic because of the delayed entry of a generic to the market); set forth a demand for relief (treble damages, attorneys' fees, litigation costs, and other available sanctions); and requested an offer to cure within the statutorily prescribed time.

XIII. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELEIF
For Monopolization and Monopolistic Scheme Under State Law
(Against Forest)

282. Plaintiffs incorporate by reference all the allegations above as though fully set forth herein.

283. As described above, Forest has possessed and continues to possess monopoly power nationwide and in each of the United States and its territories in the market for nebivolol HCl. No other manufacturer will sell a competing version of Bystolic before September 17, 2021.

284. At all relevant times, Forest has possessed substantial market power (*i.e.*, monopoly power) in the relevant market. Forest has possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

285. Through its overarching anticompetitive scheme, as alleged above, Forest has willfully maintained its monopoly power in the relevant market using restrictive or exclusionary conduct, rather than by means of greater business acumen or a historic accident, and thereby

injured Plaintiffs and the Class. Forest's anticompetitive conduct was done with the specific intent to maintain its monopoly in the market for Bystolic in the United States.

286. Forest knowingly and intentionally engaged in this anticompetitive scheme to monopolize the nebivolol HCl market as described above. Forest accomplished this scheme by, *inter alia*, (1) allocating to itself 100% of the market for nebivolol HCl in all strengths in the United States until September 17, 2021; (2) entering into illegal agreements which delayed the entry of generic Bystolic in order to lengthen the period in which Forest's brand Bystolic could monopolize the market and make supracompetitive profits; and (3) fixing, raising and maintaining the prices so that Plaintiffs and members of the Class would pay for Bystolic at supracompetitive prices.

287. The goal, purpose, and effect of Forest's scheme were to prevent and delay the sale of nebivolol HCl products in the United States at prices significantly below Forest's prices for Bystolic, thereby effectively preventing the price of nebivolol HCl products from declining dramatically.

288. The goal, purpose and effect of Forest's scheme were also to maintain and extend its monopoly power with respect to nebivolol HCl products. Forest's illegal scheme allowed it to continue charging supracompetitive prices for nebivolol HCl products, without a substantial loss of sales, reaping substantial unlawful monopoly profits.

289. Plaintiffs and members of the Class purchased substantial amounts of Bystolic indirectly from Forest.

290. As a result of Forest's illegal conduct, Plaintiffs and members of the Class were compelled to pay, did pay, and continue to pay, more than they would have paid for their nebivolol HCl requirements absent Forest's illegal conduct. But for Forest's illegal conduct, the Generic

Defendants would have begun selling generic Bystolic sooner, and prices for nebivolol HCl products would have been lower, sooner.

291. Had the Generic Defendants entered the market and lawfully competed with Forest, Plaintiffs and other members of the Class would have substituted lower-priced generic nebivolol HCl products for the higher-priced brand-name Bystolic for some or all of their nebivolol HCl products requirements, and/or would have paid lower net prices on their remaining Bystolic and/or AB-rated bioequivalent purchases.

292. By engaging in the foregoing conduct, Forest intentionally and wrongfully maintained monopoly power in the relevant market and violated the following state antitrust laws:

a. Arizona Rev. Stat. §§ 44-1402 *et seq*., with respect to purchases of Bystolic in Arizona by members of the Class.

b. Cal. Bus. & Prof. Code §§ 16700 and 17200, *et seq*., with respect to purchases of Bystolic in California by members of the Class.

c. Conn. Gen. Stat. § 35-24, *et seq*., with respect to purchases in Connecticut by members of the Class.

d. D.C. Code §§ 28-4503, *et seq*., with respect to purchases of Bystolic in the District of Columbia by members of the Class.

e. Fla. Stat. §§ 501.201, *et seq*., with respect to purchases of Bystolic in Florida by members of the Class.

f. Hawaii Rev. Stat. 480-1, *et seq*., with respect to purchases of Bystolic in Hawaii by members of the Class.

g. Illinois Antitrust Act (740 Illinois Compiled Statutes 10/1, *et seq*.), with respect to purchases of Bystolic in Illinois by members of the Class.

h. Iowa Code §§ 553.5 *et seq*., with respect to purchases of Bystolic in Iowa by members of the Class.

i. Me. Rev. Stat. Ann. 10, §§ 1102, *et seq*., with respect to purchases of Bystolic in Maine by members of the Class.

j. Md. Com'l Law Code Ann. § 11-201, *et seq*., with respect to purchases of Bystolic in Maryland by members of the Class.

k. Mass. Ann. Laws ch. 93A, *et seq*., with respect to purchases of Bystolic in Massachusetts by members of the Class.

l. Mich. Comp. Laws Ann. §§ 445.772, *et seq*., with respect to purchases of Bystolic in Michigan by members of the Class.

m. Minn. Stat. §§ 325D.49, *et seq.*, and Minn. Stat. § 8.31, *et seq*., with respect to purchases of Bystolic in Minnesota by members of the Class.

n. Miss. Code Ann. §§ 75-21-3, *et seq*., with respect to purchases of Bystolic in Mississippi by members of the Class.

o. Mont. Code § 30-14-103, *et seq*., with respect to purchases of Bystolic in Montana by members of the Class.

p. Neb. Code Ann. §§ 59-802, *et seq*., with respect to purchases of Bystolic in Nebraska by members of the Class.

q. Nev. Rev. Stat. Ann. §§ 598A.060, *et seq*., with respect to purchases of Bystolic in Nevada by members of the Class.

r. N.H. Rev. Stat. Ann. §§ 356.11, *et seq*., with respect to purchases of Bystolic in New Hampshire by members of the Class.

s. N.M. Stat. Ann. §§ 57-1-2, *et seq*., with respect to purchases of Bystolic in New Mexico by members of the Class.

t. N.Y. Gen. Bus. Law § 340, *et seq*., with respect to purchases of Bystolic in New York by members of the Class.

u. N.C. Gen. Stat. §§ 75-2.1, *et seq*., with respect to purchases of Bystolic in North Carolina by members of the Class.

v. N.D. Cent. Code §§ 51-08.1-03, *et seq*., with respect to purchases of Bystolic in North Dakota by members of the Class.

w. Or. Rev. Stat. § 646.730, *et seq*., with respect to purchases of Bystolic in Oregon by members of the Class.

x. R.I. Gen. Laws §§ 6-36-5 *et seq*., with respect to purchases of Bystolic in Rhode Island by members of the Class.

y. S.D. Codified Laws §§ 37-1-3.2, *et seq*., with respect to purchases of Bystolic in South Dakota by members of the Class.

z. Tenn. Code Ann. §§ 47-25-101, *et seq*., with respect to purchases of Bystolic in Tennessee by members of the Class.

aa. Utah Code Ann. §§ 76-10-911, *et seq*., with respect to purchases of Bystolic in Utah by members of the Class.

bb. W.Va. Code §§ 47-18-4, *et seq.*, with respect to purchases of Bystolic in West Virginia by members of the Class.

cc. Wis. Stat. §§ 133.03, *et seq*., with respect to purchases of Bystolic in Wisconsin by members of the Class.

293. Plaintiffs and members of the Class have been injured in their business or property by reason of Forest's antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic nebivolol HCl sooner, and (2) paying higher prices for nebivolol HCl products than they would have paid in the absence of Forest's conduct. These injuries are of the type the antitrust laws were designed to prevent, and flow from that which makes Forest's conduct unlawful.

294. Plaintiffs and the proposed Class seek damages and multiple damages as permitted by law for their injuries by Forest's violations of the aforementioned statutes.

SECOND CLAIM FOR RELIEF
For Conspiracy to Monopolize Under State Law
(Against Forest and Hetero; Forest and Torrent; Forest and Alkem; Forest and Indchemie; Forest and Glenmark; Forest and Amerigen; Forest and Watson; and All Defendants)

295. Plaintiffs incorporate by reference all the allegations above as though fully set forth herein.

296. Defendants each committed at least one overt act in furtherance of the conspiracy.

297. The reverse payment Settlement Agreements and side deals entered into by and between Forest each of the Generic Defendants, Hetero, Torrent, Alkem, Indchemie, Glenmark, Amerigen and Watson constituted a continuing illegal contract, combination and conspiracy in restraint of trade under which Forest agreed to pay each Generic Defendant substantial consideration in exchange for the Generic Defendant's agreement to delay bringing its generic version of Bystolic to the market, the purpose and effect of which were to: (1) delay the entry of generic Bystolic in order to lengthen the period in which Forests' branded Bystolic could monopolize the market and make supracompetitive profits; (2) fix, raise and maintain the prices so that Plaintiffs and the Class members would pay for Bystolic at supracompetitive prices; (3)

unlawfully agree to divide a market and delay price reductions and generic competition for Bystolic; (4) allocate to Forest 100% of the U.S. sales of nebivolol HCl until September 17, 2021; and (5) otherwise conspire to unlawfully monopolize and conspire to monopolize the market for nebivolol HCl.

298. As described above, Forest has possessed monopoly power nationwide and in each of the United States in the market for nebivolol HCl. No other manufacturer has sold a competing generic version of Bystolic.

299. Forest and each of the Generic Defendants willfully and unlawfully engaged in a continuing illegal conspiracy to monopolize the nebivolol HCl market by engaging in an anticompetitive scheme to keep generic equivalents from the market—not as a result of providing a superior product, business acumen, or historical accident.

300. Forest and each of the Generic Defendants knowingly and intentionally conspired to monopolize the nebivolol HCl products (*i.e.*, Bystolic in all forms and dosage strengths) and AB-rated bioequivalent nebivolol HCl products market as described above.

301. Each of the reverse-payment Settlement Agreements and side deals between Forest and each of the Generic Defendants was unlawful and Forest's payments to each of the Generic Defendants was large and unjustified. Each of the reverse payment agreements between Forest and each of the Generic Defendants harmed the Class as set forth above.

302. There is and was no legitimate, non-pretextual, procompetitive justification for the reverse-payment agreements between Forest and each of the Generic Defendants that outweighs their harmful effects. Even if there were some conceivable justification, the payments were not necessary to achieve, nor the least restrictive means of achieving, such a purpose.

303. The goal, purpose, and direct and foreseeable effect of Defendants' scheme were to prevent and delay the sale of nebivolol HCl products in the United States and its territories at prices significantly below Forest's prices for Bystolic, thereby effectively preventing the average market price of nebivolol HCl products from declining dramatically.

304. The goal, purpose, and direct and foreseeable effect of Defendants' scheme were also to maintain and extend Forest's monopoly power with respect to nebivolol HCl products. The reverse-payment agreements were intended to and did prevent and/or delay generic competition to Bystolic and Defendants' illegal scheme allowed Forest to continue charging supracompetitive prices for nebivolol HCl products, without a substantial loss of sales, reaping substantial unlawful monopoly profits. Specifically, without a reverse payment, each Generic Defendant would have launched its generic version of Bystolic upon receiving final FDA approval (whether before or after a litigation victory), or via a lawful, separate, and independent settlement agreement whereby reasonable parties in the position of Forest and each Generic Defendant would have agreed upon earlier entry dates untainted by delay associated with each unlawful side-deal and other reverse-payments. In addition, by operation of the CLPs, any earlier license date agreed to between each Generic Defendant and Forest would also have applied to all earlier-settling Generic Defendants.

305. Forest and each Generic Defendant, Hetero, Torrent, Alkem, Indchemie, Glenmark, Amerigen and Watson, committed at least one overt act in furtherance of the conspiracy.

306. Plaintiffs and members of the Class purchased substantial amounts of Bystolic indirectly from Forest.

307. As a result of Defendants' illegal conduct, Plaintiffs and members of the Class were compelled to pay, and did pay, and continue to pay, more than they would have paid for their nebivolol HCl requirements absent Defendants' illegal conduct. But for Defendants' illegal

conduct, each Generic Defendants would have begun selling generic Bystolic sooner, and prices for nebivolol HCl products would have been lower, sooner.

308. Had manufacturers of generic Bystolic entered the market and lawfully competed with Forest, Plaintiffs and other members of the Class would have substituted lower-priced generic Bystolic products for the higher-priced branded Bystolic for some or all of their nebivolol HCl products requirements, and/or would have paid lower net prices on their remaining Bystolic and/or AB-rated bioequivalent purchases.

309. But for Defendants' illegal conduct, each Generic Defendant would have begun marketing generic versions of Bystolic well before September 17, 2021, and they would have been able to market such versions more successfully.

310. By engaging in the foregoing conduct, Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of the following state antitrust laws:

a. Arizona Rev. Stat. §§ 44-1402, *et seq.*, with respect to purchases of Bystolic in Arizona by members of the Class.

b. Cal. Bus. & Prof. Code §§ 16700 and 17200, *et seq*., with respect to purchases of Bystolic in California by members of the Class.

c. Conn. Gen. Stat. § 35-24, *et seq*., with respect to purchases in Connecticut by the members of the Class;

d. D.C. Code §§ 28-4503, *et seq*., with respect to purchases of Bystolic in the District of Columbia by members of the Class.

e. Fla. Stat. §§ 501.201, *et seq*., with respect to purchases of Bystolic in Florida by members of the Class, and this conduct constitutes a predicate act under the Florida Deceptive Practices Act.

f. Hawaii Rev. Stat. 480-1, *et seq*., with respect to purchases of Bystolic in Hawaii by members of the Class.

g. Illinois Antitrust Act (740 Illinois Compiled Statutes 10/1, *et seq*.), with respect to purchases of Bystolic in Illinois by members of the Class.

h. Iowa Code §§ 535.5, *et seq*., with respect to purchases of Bystolic in Iowa by members of the Class.

i. Kan. Stat. Ann. §§ 50-101, *et seq*., with respect to purchases of Bystolic in Kansas by members of the Class.

j. Me. Rev. Stat. Ann. 10, §§ 1102, *et seq*., with respect to purchases of Bystolic in Maine by members of the Class.

k. Md. Com'l Law Code Ann. § 11-201, *et seq.*, with respect to purchases of Bystolic in Maryland by members of the Class.

l. Mass. Ann. Laws ch. 93A, *et seq*., with respect to purchases of Bystolic in Massachusetts by members of the Class.

m. Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases of Bystolic in Michigan by members of the Class.

n. Minn. Stat. §§ 325D.49, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to purchases of Bystolic in Minnesota by members of the Class.

o. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases of Bystolic in Mississippi by members of the Class.

p. Mont. Code § 30-14-103, *et seq.*, with respect to purchases of Bystolic in Montana by members of the Class.

q. Neb. Code Ann. §§ 59-802, *et seq.*, with respect to purchases of Bystolic in Nebraska by members of the Class.

r. Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases of Bystolic in Nevada by members of the Class.

s. N.H. Rev. Stat. Ann. §§ 356.11, *et seq.*, with respect to purchases of Bystolic in New Hampshire by members of the Class.

t. N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases of Bystolic in New Mexico by members of the Class.

u. N.Y. Gen. Bus. Law §§ 340, *et seq.*, with respect to purchases of Bystolic in New York by members of the Class.

v. N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases of Bystolic in North Carolina by members of the Class.

w. N.D. Cent. Code §§ 51-08.1-02, *et seq.*, with respect to purchases of Bystolic in North Dakota by members of the Class.

x. Or. Rev. Stat. § 646.730, *et seq*., with respect to purchases of Bystolic in Oregon by members of the Class.

y. R.I. Gen. Laws §§ 6-36-5 *et seq*., with respect to purchases of Bystolic in Rhode Island by members of the Class.

z. S.D. Codified Laws Ann. §§ 37-1-3.2, *et seq.*, with respect to purchases of Bystolic in South Dakota by members of the Class.

aa. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of Bystolic in Tennessee by members of the Class.

bb. Utah Code Ann. §§ 76-10-911, *et seq*., with respect to purchases of Bystolic in Utah by members of the Class.

cc. W.Va. Code §§ 47-18-3, *et seq.*, with respect to purchases of Bystolic in West Virginia by members of the Class.

dd. Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases of Bystolic in Wisconsin by members of the Class.

311. Plaintiffs and members of the Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic Bystolic products, sooner, and (2) paying higher prices for nebivolol HCl products than they would have paid in the absence of Defendants' conduct. These injuries are of the type the antitrust laws were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

312. Plaintiffs and the proposed Class seek damages and multiple damages as permitted by law for their injuries by Defendants' violations of the aforementioned statutes.

THIRD CLAIM FOR RELIEF
Combination and Conspiracy in Restraint of Trade Under State Law (Against Forest and Hetero; Forest and Torrent; Forest and Alkem; Forest and Indchemie; Forest and Glenmark; Forest and Amerigen; Forest and Watson; and All Defendants)

313. Plaintiffs incorporate by reference all the allegations above as though fully set forth herein.

314. Forest and each Generic Defendant, willfully and unlawfully engaged in a continuing illegal contract, combination, and conspiracy to restrain trade in the nebivolol HCl

market by engaging in an anticompetitive scheme to keep generic equivalents from the market and to allocate the market between horizontal competitors.

315. In or about October 24, 2012, Forest and Hetero entered into the Forest/Hetero reverse payment Settlement Agreement and related side deals, together constituting a continuing illegal contract, combination and conspiracy in restraint of trade under which Forest agreed to pay Hetero substantial consideration in exchange for Hetero's agreement to delay bringing its generic version of Bystolic to the market, the purpose and effect of which were to: (1) delay the entry of generic Bystolic in order to lengthen the period in which Forests' branded Bystolic could monopolize the market and make supracompetitive profits; (2) fix, raise and maintain the prices so that Plaintiffs and the Class members would pay for Bystolic at supracompetitive prices; (3) unlawfully agree to divide a market and delay price reductions and generic competition for Bystolic; (4) allocate to Forest 100% of the U.S. sales of nebivolol HCl until September 17, 2021; and (5) otherwise conspire to unlawfully monopolize and conspire to monopolize the market for nebivolol HCl.

316. Subsequently, Forest entered into additional reverse payment Settlement Agreements with Torrent (November 21, 2012); Alkem (November 27, 2012); Indchemie (November 27, 2012); Glenmark (December 21, 2012); Amerigen (July 18, 2013); and Watson (November 6, 2013). And, the reverse payment agreements between Forest and each Generic Defendant each included side deals. Each Settlement Agreement and related side deals constituted a continuing illegal contract, combination and conspiracy in restraint of trade under which Forest agreed to pay Torrent, Alkem, Indchemie, Glenmark, Amerigen and Watson substantial consideration in exchange for their agreement to delay bringing their generic versions of Bystolic to the market, the purpose and effect of which were to: (1) delay the entry of generic Bystolic in

order to lengthen the period in which Forests' brand Bystolic could monopolize the market and make supracompetitive profits; (2) fix, raise, and maintain the prices so that Plaintiffs and Class members would pay for Bystolic at supracompetitive prices; (3) unlawfully agree to divide a market and delay price reductions and generic competition for Bystolic; (4) allocate to Forest 100% of the U.S. sales of nebivolol HCl until September 17, 2021; and (5) otherwise conspire to unlawfully monopolize and conspire to monopolize the market for nebivolol HCl.

317. The agreements between Defendants are horizontal market allocation and price fixing agreements between actual or potential competitors and are illegal *per se* under state antitrust laws.

318. Alternatively, Defendants' agreements are presumptively anticompetitive reverse payment settlements, subject to "quick look" rule of reason scrutiny, because Forest provided substantial consideration in exchange for each Generic Defendants agreement to delay market entrance.

319. Through the agreements, Forest and each of the Generic Defendants joined in an anticompetitive scheme as co-conspirators. The reverse-payment agreements are and were a contract, combination, and/or conspiracy that substantially, unreasonably, and unduly restrained trade in the relevant market, the purpose and effect of which were to: (a) allocate all sales of nebivolol HCl in the United States and its territories to Forest until September 17, 2021; (b) prevent the sale of any generic version of nebivolol HCl in the United States and its territories until September 17, 2021; and (c) fix, raise and/or maintain the price at which the Plaintiffs and all members of the Class would pay for nebivolol HCl.

320. Under Defendants' reverse payment Settlement Agreements and side deals, Forest paid the Generic Competitors financial inducements through large and unexplained payments that

vastly exceed the cost of avoided litigation and are not otherwise explained by the value of any services provided by the Generic Competitors to Defendants (other than Generic Competitors' agreement to delay launching their generic Bystolic). There are no valid, non-pretextual procompetitive business justifications for the settlement agreements, nor for the payments to the Generic Competitors under the settlement agreements. Even if there were some conceivable justification, the settlement agreements and the payments flowing to the Generic Competitors under the agreements, were not reasonably necessary to achieve settlement.

321. In exchange for these payments, the Generic Defendants agreed to, and did, delay introduction of their generic Bystolic in the United States.

322. The anticompetitive consequences of Defendants' reverse payment agreements are sufficiently great and sufficiently unrelated to the settlement of the underlying patent dispute, to amount to an unlawful reverse payment agreement, as evidenced by, *inter alia*, the following:

a. Delaying the entry of generic Bystolic in order to lengthen the period in which Forest's branded Bystolic could monopolize the market and make supracompetitive profits;

b. The agreements created bottlenecks that prevented and delayed generic entry by other generic manufacturers; and

c. There was no countervailing pro-competitive benefits from the agreements.

323. The goal, purpose, and effect of Defendants' scheme were to prevent and delay the sale of nebivolol HCl products in the United States and its territories at prices significantly below Forest's prices for Bystolic, thereby effectively preventing the average market price of nebivolol HCl products from declining dramatically.

324. The goal, purpose and effect of Defendants' scheme were also to maintain and extend Forest's monopoly power with respect to nebivolol HCl products. The illegal scheme allowed Forest to continue charging supracompetitive prices for nebivolol HCl products, without a substantial loss of sales, reaping substantial unlawful monopoly profits.

325. Plaintiffs and members of the Class purchased substantial amounts of Bystolic indirectly from Defendants and/or other manufacturers.

326. As a result of Defendants' illegal conduct, Plaintiffs and members of the Class were compelled to pay, and did pay, more than they would have paid for their nebivolol HCl requirements absent Defendants' illegal conduct. But for Defendants' illegal conduct, the Generic Defendants would have begun selling generic Bystolic sooner, and prices for nebivolol HCl products would have been lower, sooner.

327. By engaging in the foregoing conduct, Defendants intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of the following state antitrust laws:

a. Arizona Rev. Stat. §§ 44-1402, *et seq.*, with respect to purchases of Bystolic in Arizona by members of the Class.

b. Cal. Bus. & Prof. Code §§ 16700 and 17200, *et seq*., with respect to purchases of Bystolic in California by members of the Class.

c. D.C. Code §§ 28-4502, *et seq.*, with respect to purchases of Bystolic in the District of Columbia by members of the Class.

d. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases of Bystolic in Florida by members of the Class.

e. Hawaii Revised Statutes annotated § 480-1, *et seq*., with respect to purchases of Bystolic and in Hawaii by members of the Class.

f. Illinois Antitrust Act (740 Illinois Compiled Statutes 10/1, *et seq*.), with respect to purchases of Bystolic in Illinois by members of the Class.

g. Iowa Code § 553.4, *et seq*., with respect to purchases of Bystolic in Iowa by members of the Class.

h. Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases of Bystolic in Kansas by members of the Class.

i. Me. Rev. Stat. Ann. 10, §§ 1101, *et seq.*, with respect to purchases of Bystolic in Maine by members of the Class.

j. Md. Com'l Law Code Ann. § 11-201, *et seq.*, with respect to purchases of Bystolic in Maryland by members of the Class.

k. Mass. Ann. Laws ch. 93A, *et seq.*, with respect to purchases of Bystolic in Massachusetts by members of the Class.

l. Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases of Bystolic in Michigan by members of the Class.

m. Minn. Stat. §§ 325D.49, *et seq.*, with respect to purchases of Bystolic in Minnesota by members of the Class.

n. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases of Bystolic in Mississippi by members of the Class.

o. Mont. Code § 30-14-201, *et seq.*, with respect to purchases of Bystolic in Montana by members of the Class.

p. Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases of Bystolic in Nebraska by members of the Class.

q. Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases of Bystolic in Nevada by members of the Class.

r. N.H. Revised Statutes § 356:1, *et seq.*, with respect to purchases of Bystolic in New Hampshire by members of the Class.

s. N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases of Bystolic in New Mexico by members of the Class.

t. N.Y. Gen. Bus. Law §§ 340, *et seq.*, with respect to purchases of Bystolic in New York by members of the Class.

u. N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases of Bystolic in North Carolina by members of the Class.

v. N.D. Cent. Code §§ 51-08.1-02, *et seq.*, with respect to purchases of Bystolic in North Dakota by members of the Class.

w. Or. Rev. Stat. § 646.725, *et seq*., with respect to purchases of Bystolic in Oregon by members of the Class.

x. R.I. Gen. Laws § 6-36-4, et seq., with respect to purchases of Bystolic in Rhode Island by members of the Class.

y. S.D. Codified Laws Ann. §§ 37-1-3.1, *et seq.*, with respect to purchases of Bystolic in South Dakota by members of the Class.

z. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of Bystolic in Tennessee by members of the Class.

aa. Utah Code Annotated § 76-10-3103, *et seq*., with respect to purchases of Bystolic in Utah by members of the Class.

bb. W.Va. Code §§ 47-18-3, *et seq.*, with respect to purchases of Bystolic in West Virginia by members of the Class.

cc. Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases of Bystolic in Wisconsin by members of the Class.

328. Plaintiffs and members of the Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced nebivolol HCl generic products sooner, and (2) paying higher prices for nebivolol HCl products than they would have paid in the absence of Defendants' conduct. These injuries are of the type the antitrust laws were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

329. Plaintiffs and the proposed Class seek damages and multiple damages as permitted by law for their injuries by Defendants' violation of the aforementioned statutes.

FOURTH CLAIM FOR RELIEF
Unfair or Deceptive Trade Practices
(Against All Defendants)

330. Plaintiffs incorporate by reference all the allegations above as though fully set forth herein.

331. Defendants engaged in unfair competition, and/or unfair/unconscionable, and/or deceptive acts or practices in violation of the state consumer protection statutes. As a direct and proximate result of Defendants' anticompetitive, deceptive, unfair and/or unconscionable acts or practices, Plaintiffs and Class members were deprived of the opportunity to purchase a less expensive AB-rated generic equivalents and forced to pay higher prices.

332. By engaging in unfair competition, and/or unfair/unconscionable, and/or deceptive acts or practices, Defendants have violated the following state consumer protection statutes:

a. Ark. Code §§ 4-88-101, *et seq*.

b. Cal. Bus. & Prof. Code § 17200, *et seq*.

c. Conn. Gen Stat. Ann. § 35-26, *et seq*.

d. Fla. Stat. § 501.201, *et seq*.

e. Haw. Rev. Stat. §§ 480, *et seq*.

f. Idaho Code §§ 48-601, *et seq*.

g. 815 Ill. Comp. Stat. Ann.§§ 505.1, *et seq*.

h. 5 Me. Rev. Stat. § 207, *et seq*.

i. Mass. Gen. L. Ch. 93A, *et seq*., in that the actions and transactions alleged herein occurred primarily and substantially within Massachusetts, with thousands of end-payors paying substantially higher prices for Bystolic.

j. Mich. Stat. §§ 445.901, *et seq*.

k. Minn. Stat. §§ 325 F. 68, *et seq*., and Minn. Stat. §§ 8.31, *et seq*.

l. Mo. Rev. Stat. §§ 407.020, *et seq.*

m. Mont. Code Ann. §§ 30-14-101, *et seq*.

n. N.C. Gen. Stat. § 75-1, *et seq*.

o. Neb. Rev. Stat. §§ 59-1601, *et seq.*

p. Nev. Rev. Stat. §§ 598.0903, *et seq.*

q. N.H. Rev. Stat. § 358-A:1, *et seq*.

r. N.M. Stat. § 57-12-1, *et seq*.

s. N.Y. Gen. Bus. Law § 349, *et seq*. To the extent New York law so requires, Plaintiffs hereby forgo any minimum or punitive damages in order to preserve the right of New York Class members to recover actual damages by way of a class action.

t. Or. Rev. Stat. §§ 646.605 *et seq*.

u. R.I. Gen. Law § 6-13.1-1, *et seq*.

v. S.D. Codified Laws §§ 37-24-6.

w. Tenn. Code Ann. 47-18-101, *et seq.*

x. Utah Code Ann. §§ 13-11-1, *et seq.*

y. Va. Code §§ 59.1-196, *et seq*.

z. W. Va. Code § 46A-6-101, *et seq*.

333. Plaintiffs and members of the Class have been injured in their business and property by reason of Defendants' anticompetitive, unfair/unconscionable and/or deceptive acts or practices alleged in this Count. Their injury consists of paying higher prices for Bystolic than they would have paid in the absence of these violations. This injury is of the type the state consumer protection statutes were designed to prevent and directly results from Defendants' unlawful conduct.

FIFTH CLAIM FOR RELIEF
Declaratory and Injunctive Relief
(Against All Defendants Under Section 16 of the Clayton Act, 15 U.S.C. § 26 for Defendants' Violations of Sections 1 and 2 of the Sherman Act)

334. Plaintiffs incorporate by reference all the allegations above as though fully set forth herein.

335. At all relevant times, as described herein, Forest has possessed monopoly power nationwide and in each of the United States in the market for nebivolol HCl. But for the

anticompetitive reverse-payments, the Generic Defendants would have launched their generic products earlier.

336. Plaintiffs' allegations as described herein and in the preceding Claims for Relief comprise violations of Sections 1 and 2 of the Sherman Act, in addition to the state laws *supra*.

337. Plaintiffs and the proposed Class request that the Court grant injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26 as may be necessary and appropriate to restore competition in the market for nebivolol HCl.

338. Plaintiffs and the proposed Class, pursuant to Fed. R. Civ. P. 57 and 18 U.S.C. § 2201(a), also seek a declaratory judgment that Defendants' conduct in seeking to prevent competition as described in this action comprises illegal monopolization in violation of Section 2 of the Sherman Act.

XIV. DEMAND FOR JUDGMENT

WHEREFORE, Plaintiffs, on their own behalf and on behalf of the proposed Class, pray for judgment against all Defendants, jointly and severally, and that this Court:

1. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a), (b)(2) and (b)(3), and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the Class, and appoint Plaintiffs as the named representative of the Class;
2. Require specific performance by amending the challenged reverse payment agreements to permit each Defendant to launch its generic version of Bystolic immediately;
3. Enter joint and several judgment against each of Defendants on the all Claims (First through Fifth) above and in favor of Plaintiffs and the Class;

4. Declare that the conduct alleged herein is in violation of Section 1 of the Sherman Act and of the other statutes set forth above;

5. Declare that the conduct alleged herein is in violation of Section 2 of the Sherman Act, and enter permanent injunctive relief:

   a. enjoining Defendants from continuing their illegal conduct;

   b. enjoining Defendants from engaging in future anticompetitive conduct with the purpose or effect of delaying the entry of generic nebivolol HCl or other generic drugs; and

   c. requiring Defendants to take affirmative steps to dissipate the continuing effects of their prior unlawful conduct;

6. Award Plaintiffs and the Class treble damages (*i.e.,* three times overcharges) in an amount to be determined at trial, plus interest, in accordance with law;

7. Award Plaintiffs and the Class their costs of suit, including reasonable attorneys' fees as provided by law; and

8. Award such other and further relief as the Court deems just and proper.

XV. JURY DEMAND

Pursuant to Fed. R. Civ. P. 38(b), Plaintiffs, on behalf of themselves and the proposed Class, demand a trial by jury of all claims and issues so triable.

Dated: December 3, 2020

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