

**UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

LAW ENFORCEMENT HEALTH
BENEFITS, INC., on behalf of itself
and all others similarly situated,

Plaintiff,

v.

ABBVIE INC., ALLERGAN, INC., ALLERGAN
SALES, LLC, ALLERGAN USA, INC., FOREST
LABORATORIES, INC., FOREST
LABORATORIES HOLDINGS, LTD., FOREST
LABORATORIES IRELAND, LTD., and
FOREST LABORATORIES, LLC,

Defendants.

Civil Action No.

CLASS ACTION COMPLAINT

DEMAND FOR JURY TRIAL

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Plaintiff Law Enforcement Health Benefits, Inc., on behalf of itself and all others similarly situated, brings this Class Action Complaint against AbbVie, Inc. (“AbbVie”); Allergan, Inc., Allergan Sales, LLC, and Allergan USA, Inc. (collectively, “Allergan”); and Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd., Forest Laboratories, LLC, and Forest Laboratories Ireland Ltd. (collectively, “Forest”) (together with AbbVie and Allergan, “Defendants”) for claims under the Sherman Act and various state laws for injunctive relief and to recover damages for the substantial injuries it and others similarly situated have sustained, and continue to sustain, arising from Defendants’ anticompetitive conduct. Plaintiff’s allegations are based on personal knowledge as to Plaintiff and Plaintiff’s own actions and upon the investigation of counsel and on information and belief as to all other matters.

I. INTRODUCTION

1. This case arises from Defendants’ unlawful scheme to delay generic competition in the United States and its territories for the branded drug, Bystolic® (“Bystolic”), a prescription medication containing the active pharmaceutical ingredient nebivolol hydrochloride (or nebivolol HCl) and approved by the U.S. Food and Drug Administration (“FDA”) for the treatment of hypertension.

2. Bystolic is commonly referred to as a “beta blocker” or a beta-adrenergic blocking agent that reduces blood pressure. Beta-blockers block hormone epinephrine (adrenaline) and cause the heart to beat more slowly with less force, thereby lowering blood pressure.

3. Defendant Forest and its successors in interest manufacture, market and sell the branded version of Bystolic, which is a “blockbuster” prescription drug with annual U.S. sales of

\$1 billion.¹ Potential new generic market entrants filed Abbreviated New Drug Applications (“ANDA”) with the United States Food and Drug Administration (the “FDA”) to manufacture, market and sell generic versions of Bystolic on December 17, 2011, as soon as it was possible to do so.² Despite these ANDAs filed nearly nine years ago, no generic competitor has or will enter the market until September 17, 2021.

4. Generic prescription drugs are typically less expensive than their branded counterparts, and perform 99.8% the same as the branded product in order to obtain FDA “bioequivalence” or “AB rated” status to enter the U.S. market. The entry of less expensive generic prescription drugs is critical to reduce costs in the health care industry, saving consumers and health care funds billions of dollars in prescription drug expenditures.³ Generic drugs typically cost 50% less than the branded product and capture 80% or more market share of the branded product within six to nine months of entering the market. This rapid market share erosion is the result of generic substitution laws, which generally require pharmacists to dispense the AB-rated generic product when available. The market share gained by the generic product represents markets share lost by the branded product, causing the branded company of a “blockbuster” drug to lose millions of dollars in sales each day.

5. To avoid or delay these market realities, Defendant Forest entered into a series of unlawful reverse-payment agreements with potential generic competitors, including Hetero,⁴

¹ *Glenmark Pharmaceuticals receives ANDA approval for Nebivolol Tablets, 2.5 mg, 5 mg, 10 mg and 20 mg*, <https://www.glenmarkpharma.com/sites/default/files/Glenmark-receives-ANDA-approval-for-Nebivolol-Tablets%2C2.5-mg%2C5-mg%2C10-mg-and-20-mg.pdf> (May 29, 2017).

² *See, e.g.*, 11/27/2015 Letter from Food and Drug Administration (“FDA”) to Watson, https://www.accessdata.fda.gov/drugsatfda_docs/appltr/2015/203683Orig1s000Ltr.pdf. Case 1:20-cv-05538 Document 1 Filed 07/17/20 Page 2 of 75

³ *Generic Drugs Undergo Rigorous FDA Scrutiny*, U.S. Food & Drug Admin. (Oct. 8, 2014), <https://www.fda.gov/consumers/consumer-updates/generic-drugs-undergo-rigorous-fda-scrutiny>.

⁴ Hetero USA, Inc. and Hetero Labs Ltd. (collectively, “Hetero”)

Torrent,⁵ Alkem,⁶ Indchemie,⁷ Glenmark,⁸ Amerigen⁹ and Watson¹⁰ (collectively, the “Generic Competitors”). From October 2012 through November 2013, Forest entered agreements with the Generic Competitors to: (i) not compete with Forest or enter the market prior to September 17, 2021, unless another generic competitor entered the market earlier; and in exchange, (ii) upon information and belief, provide consideration to the generics through “side-deals” and cash payments. As corporate successors-in-interest to one or more of the Defendants, Allergan and then AbbVie have perpetuated this illegal conduct¹¹ in the market for nebivolol HCl, all at the expense of consumers and health insurers.

6. Beginning on December 17, 2011,¹² Forest filed patent infringement actions against the Generic Competitors that filed ANDA applications, alleging that they infringed on U.S. Patent No. 6,545,040 (the “’040 Patent”), a patent Forest certified as covering Bystolic and successfully submitted for listing in the FDA’s Orange Book. These patent lawsuits, filed in mid-March 2012, automatically triggered 30-month stays under the Hatch-Waxman Act. 21 U.S.C. § 355(j)(5)(B)(iii). The 30-month stays prevented the FDA from granting final approval to any of the Generic Competitors to launch a generic product before June 18, 2015, absent an earlier favorable decision for the Generic Competitors or a dismissal of the actions.

⁵ Torrent Pharmaceuticals Ltd., and Torrent Pharma, Inc. (collectively “Torrent”)

⁶ Alkem Laboratories Ltd. (“Alkem”).

⁷ Indchemie Health Specialties Private Ltd. (“Indchemie”).

⁸ Glenmark Generics Inc., USA, Glenmark Generics Ltd., and Glenmark Pharmaceuticals S.A. (collectively “Glenmark”).

⁹ Amerigen Pharmaceuticals, Inc. and Amerigen Pharmaceuticals, Ltd. (collectively, “Amerigen”).

¹⁰ Watson Pharma, Inc. and Watson Pharmaceuticals, Inc. (“Watson”).

¹¹ *FTC v. Actavis*, 570 U.S. 136 (2013).

¹² *See, e.g.*, 11/27/2015 Letter from FDA to Watson, https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2015/203683Orig1s000Ltr.pdf; 5/27/2017 Letter from FDA to Glenmark, https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2017/203821Orig1s000ltr.pdf; 6/24/2015 Letter from FDA to Alkem, https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2015/203741Orig1s000ltr.pdf.

7. Between March 2012 through November 2013, while the stays were in effect, the Generic Competitors fought the patent infringement lawsuits and prepared to bring their generic Bystolic products to market to compete with Forest's branded Bystolic. At least six of the seven Generic Competitors received final FDA approval to enter the market, as set forth in the table below, meaning they would have been ready to launch well before September 17, 2021.

Manufacturer	ANDA No.	Final Approval Date
Amerigen	203659	4/16/2015
Watson	203683	11/27/2015
Alkem	203741	6/24/2015
Indchemie	203828	7/29/2015
Glenmark	203821	5/25/2017
Torrent	203966	3/2/2018

8. The '040 Patent litigation would likely have concluded by mid-2015, including any appeals, in favor of the generic because the '040 Patent was weak. The Generic Competitors would have won and launched by the later of: (a) June 2015, the expiry of the only other patent that Forest contended covered Bystolic, U.S. Patent No. 5,759,580 (the "580 Patent"), or (b) the date their ANDAs were finally approved. Rather than risk facing competition from the Generic Competitors as early as June 2015 and the subsequent reduction in Bystolic brand sales and revenues, Forest entered into a prototypical "reverse-payment agreement" with the Generic Competitors, sharing monopoly profits to induce them to stay out of the market until September 21, 2021. The result: the pharmaceutical companies won and health insurers and consumers, the intended victims of the anticompetitive scheme, lost by paying supracompetitive prices for years longer than they otherwise would have.

9. On February 18, 2014, Actavis PLC and Forest announced an equity and cash merger.¹³ Forest’s outside lawyers conducted due diligence and reviewed Forest’s documents as part of their “work on the Actavis merger agreement.”¹⁴ On March 4, 2014, Forest’s outside lawyers identified the existence of “side deal” reverse-payment settlements with the generics noting in correspondence with Forest’s in-house counsel 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.*”¹⁵ Forest’s in-house counsel responded:

We entered into settlement agreements with the following defendants:

- 1) Hetero
- 2) Torrent
- 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).¹⁶

¹³ 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>.

¹⁴ *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).

¹⁵ *Id.* (emphasis added).

¹⁶ *Id.* (emphasis added).

10. Forest’s Agreement and Plan of Merger with Actavis PLC (the “Merger Agreement”), dated February 17, 2014, disclosed “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.”¹⁷

11. Forest listed each of the side-deals as a “material contract” “in connection with the settlement of BYSTOLIC patent dispute.” The relevant provisions of the respective contracts are as follows:

(a) **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.”¹⁸

(b) **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

¹⁷ *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) (emphasis added).

¹⁸ *Id.* at 179.

November 21, 2012, in connection with the settlement of BYSTOLIC patent dispute.”¹⁹

- (c) **Alkem/Indchemie:** “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.
- 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.”²⁰
- (d) **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.”²¹

¹⁹ *Id.*

²⁰ *Id.*

²¹ *Id.*

- (e) **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.”²²
- (f) **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.”²³

12. As Forest publicly acknowledged, the side-deals were entered into as part and parcel of Forest’s patent settlement agreements with the Generic Competitors in the Bystolic patent litigation.

²² *Id.* at 180.

²³ *Id.*

13. In addition to the consideration Forest provided each Generic Competitor in the form of a side-deal, Forest “agreed to reimburse certain of the Settling Defendants’ legal costs in connection with the patent litigation.”²⁴

14. Forest also disclosed that its settlement agreements with the Generic Competitors “provide[d] a license to each of the Settling Defendants that will permit them to launch their respective generic versions of Bystolic as of the date that is the later of (a) three calendar months prior to the expiration of the ’040 patent, including any extensions and/or pediatric exclusivities or (b) the date that each Settling Defendant receives final FDA approval of its ANDA, **or earlier in certain circumstances.**”²⁵ The bolded language typically refers to what is known as a “contingent launch provision” (“CLP”), or an “acceleration clause.”

15. 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, 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 enters the market before the agreed-upon licensed entry date, that settling generic’s licensed entry date would be accelerated so that it could launch at the same time.

16. When CLPs are used, they generally operate the same way in each ANDA filer’s settlement agreement. Under a CLP, the first-filing ANDA filer (or, as here, filers) obtains protection from other first filers by agreeing to delay the launch of their generic products from the date of settlement until a date certain (here, exactly three months before the expiration of the

²⁴ <https://www.sec.gov/Archives/edgar/containers/fix010/38074/000003807413000024/R17.htm>.

²⁵ *Id.* (emphasis added).

'040 Patent),²⁶ but *if and only if* all other first-filer generic companies follow suit. By brokering the agreements, Forest ensured that, without regard to the strength of the Generic Competitors' challenges to the '040 Patent, Bystolic would have no generic competitors and Forest would maintain patent-generated monopoly profits until at least September 17, 2021, and none of its generic competitors would come to market earlier.

17. As a direct and proximate result of Defendants' conduct, Plaintiff and other class members have been injured in their business and property. But for Defendants' conduct, they would have been able to purchase less expensive generic Bystolic instead of branded Bystolic at artificially inflated prices.

II. PARTIES

A. Plaintiff

18. Plaintiff Law Enforcement Health Benefits, Inc. ("LEHB" or "Plaintiff") 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. LEHB indirectly purchased, paid and/or provided reimbursement for members purchasing Bystolic in at least New Jersey and Pennsylvania during the Class Period. During the Class Period, LEHB paid more than it would have absent Defendants' unlawful anticompetitive scheme to prevent and delay generic entry and was injured as a result of the illegal and wrongful

²⁶ *Id.*

conduct alleged herein. Plaintiff intends to purchase Bystolic in the future and will be injured if injunctive relief is not granted.

B. Defendants

19. Defendant Forest Laboratories, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 909 Third Avenue, New York, New York 10022.

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

21. 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.²⁷

22. 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, New Jersey 07054. On July 1, 2014, in a series of transactions, Forest Laboratories, Inc. became a limited liability company named Forest Laboratories, LLC.

23. 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 company. As a result of these corporate consolidations, the Forest Defendants are predecessors in interest to Allergan Sales, LLC.

²⁷ See, e.g., Notice and Stipulation of Name Change, *Forest Laboratories, et al. v. Ivax Pharmaceuticals, Inc., et al.*, 03-cv-00891 (D. Del. Feb. 8, 2006) (ECF No. 536).

24. 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.

25. 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.

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

27. 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 indirect sales of Bystolic to Plaintiff and members of the proposed Classes at the supracompetitive prices made possible by the delay those challenged provisions produced.²⁸

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

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

30. 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

²⁸ 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).

60064. AbbVie is the corporate successor to Allergan and Forest, having completed its purchase of Allergan on May 8, 2020.

31. 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 making indirect sales of Bystolic to Plaintiff and members of the proposed Classes at the supracompetitive prices made possible by the delay those challenged provisions produced.

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

33. On information and belief, 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.

C. Co-Conspirators

34. Although not named as a Defendant, Watson Pharma, Inc. was an initiator of and is a participant in the unlawful conspiracy described in this complaint. 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, New Jersey 07054.

35. Although not named as a Defendant, Watson Pharmaceuticals, Inc. was an initiator of and is a participant in the unlawful conspiracy described in this complaint. 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, California 92880 and 360 Mount Kemble Avenue, Morristown, New Jersey 07962, and its corporate headquarters at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

36. Although not named as a Defendant, Torrent Pharmaceuticals Ltd. was an initiator of and is a participant in the unlawful conspiracy described in this complaint. Torrent Pharmaceuticals Ltd. is an Indian corporation having a principal place of business at Off. Ashram Road, Ahmedabad - 380 009, Gujarat, India.

37. Although not named as a Defendant, Torrent Pharma Inc. was an initiator of and is a participant in the unlawful conspiracy described in this complaint. 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, Michigan 49009. On information and belief, Torrent Pharma Inc. is a wholly-owned subsidiary of Torrent Pharmaceuticals Ltd. On information and belief, Torrent Pharma Inc. acts as the agent of Torrent Pharmaceuticals Ltd.

38. Although not named as a Defendant, Amerigen Pharmaceuticals Ltd. was an initiator of and is a participant in the unlawful conspiracy described in this complaint. Amerigen Pharmaceuticals Ltd. is a Chinese company having places of business at 197 State Route 18S, Suite 306N, East Brunswick, New Jersey 08816 and No. 58, Qunxing Yi Road, Suzhou Industrial Park, PRC, 215006.

39. Although not named as a Defendant, Amerigen Pharmaceuticals Inc. was an initiator of and is a participant in the unlawful conspiracy described in this complaint. 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, New Jersey 08816. On information and belief, Amerigen Pharmaceuticals Inc. is a wholly-owned subsidiary of Amerigen Pharmaceuticals Ltd. On information and belief, Amerigen Pharmaceuticals Inc. acts as the agent of Amerigen Pharmaceuticals Ltd.

40. Although not named as a Defendant, Glenmark Generics Inc., USA was an initiator of and is a participant in the unlawful conspiracy described in this complaint. 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, New Jersey 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.

41. Although not named as a Defendant, Glenmark Generics Ltd. was an initiator of and is a participant in the unlawful conspiracy described in this complaint. 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.

42. Although not named as a Defendant, Defendant Glenmark Pharmaceuticals Ltd. was an initiator of and is a participant in the unlawful conspiracy described in this complaint. 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 and Glenmark Generics Ltd. are wholly-owned subsidiaries of 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 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. and Glenmark Pharmaceuticals Ltd.

43. Although not named as a Defendant, Hetero Labs Ltd. was an initiator of and is a participant in the unlawful conspiracy described in this complaint. 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.

44. Although not named as a Defendant, Hetero USA Inc. was an initiator of and is a participant in the unlawful conspiracy described in this complaint. 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, New Jersey 08854. On information and belief, Hetero USA Inc. is a wholly-owned subsidiary of Hetero Labs Ltd. On information and belief, Hetero USA Inc. acts as the agent of Hetero Labs Ltd.

45. Although not named as a Defendant, Indchemie Health Specialties Private Ltd. was an initiator of and is a participant in the unlawful conspiracy described in this complaint. 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.

46. Although not named as a Defendant, Alkem Laboratories Ltd. was an initiator of and is a participant in the unlawful conspiracy described in this complaint. 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.

47. All of the Defendants' and unnamed (as defendants) co-conspirators' actions described in this complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by the Defendants' and unnamed co-

conspirators' various officers, agents, employees, or other representatives while actively engaged in the management of the Defendants' and unnamed co-conspirators' affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of the Defendants and unnamed co-conspirators.

III. JURISDICTION AND VENUE

48. 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 Class members, and at least one member of the putative Class is a citizen of a state different from that of one of the Defendants. This Court also has jurisdiction under Section 16 of the Clayton Act, 15 U.S.C. § 26, and Sections 1 and 2 of the Sherman Act 15 U.S.C. §§ 1 and 2.

49. Venue is appropriate within this district under 28 U.S.C. §1391 and Section 12 of the Clayton Act 15 U.S.C. § 22 because, at all relevant times, Defendants transacted business within this district, and the interstate trade and commerce described hereinafter is carried out, in substantial part, in this district. Further, Defendants and/or their agents may be found in this district. Upon information and belief, the anticompetitive agreement emanated from Forest's New York headquarters.

50. 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.

51. During the class period, Forest manufactured, sold and shipped Bystolic in a continuous and uninterrupted flow of interstate commerce. Defendants' anticompetitive conduct had a direct, substantial, and reasonably foreseeable effect on interstate commerce.

52. 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.

53. This Court has personal jurisdiction over each Defendant, because each Defendant has – throughout the United States and including in this District – transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of its illegal scheme and conspiracy. The scheme and conspiracy have been directed at, and have had the intended effect of, causing injury to persons residing in, located in, or doing business throughout the United States, including in this District.

54. This Court has personal jurisdiction over each Defendant under 15 U.S.C. § 22 because each transacts business in this District. Personal jurisdiction lies under Fed. R. Civ. P. 4(k)(2) over the foreign domiciliary defendants.

IV. CLASS ACTION ALLEGATIONS

55. Plaintiff brings this action on behalf of itself and all others similarly situated as a class action under Rules 23(a) and 23(b)(3) of the Federal Rules of Civil Procedure, seeking damages pursuant to the common law of unjust enrichment and the antitrust, unfair competition, unjust enrichment and consumer protection laws of the states listed below (“Damages Class”):

All persons or entities that indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price for Bystolic, other than for resale, in the States, Commonwealths, or Territories of Alabama, Alaska, Arizona, Arkansas, California, Connecticut, the District of Columbia, Florida, Georgia, Hawaii, Idaho, Illinois, Iowa, Kansas, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, Pennsylvania, Puerto Rico, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Vermont, West Virginia, or Wisconsin, at any time during the period from June 2, 2015 through and until the anticompetitive effects of Defendants’ challenged conduct cease (the “Class Period”).

56. Plaintiff brings this action on its own behalf and on behalf of all others similarly situated as a class action under Rules 23(a) and 23(b)(2) of the Federal Rules of Civil Procedure (“Injunctive Relief Class”):

All persons or entities in the United States and its territories that purchased, paid and/or provided reimbursement for some or all of the purchase price for Bystolic, other than for resale at any time during the period from June 2, 2015 through and until the anticompetitive effects of Defendants’ challenged conduct cease (the “Class Period”).

57. The following persons and entities are excluded from the above-defined proposed Classes:

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

(b) All federal and state governmental entities (including state and federal Medicaid programs) except for cities, towns, municipalities or counties with self-funded prescription drug plans;

(c) All persons or entities who purchased Bystolic for purposes of resale or directly from Defendants or their affiliates;

(d) Fully-insured health plans (i.e., health plans that purchased insurance from another third-party payor covering 100 percent 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;

(g) All Counsel of Record; and

(h) All judges assigned to this case and any members of their immediate families.

58. Members of the Classes are so numerous and widely geographically dispersed throughout the United States that joinder of all members of the Classes is impracticable. Moreover, given the costs of complex antitrust litigation, it would be uneconomic for many plaintiffs to bring individual claims and join them together. The identities of members of the Classes will be readily ascertainable through business records kept in regular order.

59. Plaintiff's claims are typical of members of the Classes. Plaintiff and all members of the Classes were damaged by the same wrongful conduct by Defendants. Defendants' anticompetitive conduct deprived members of the Classes of the benefits of competition from less-expensive generic versions of Bystolic, causing them to pay artificially inflated, supracompetitive prices for Bystolic.

60. Plaintiff will fairly and adequately protect and represent the interests of the Classes. The interests of Plaintiff are aligned with, and not antagonistic to, those of the other members of the Classes.

61. Plaintiff is represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation and have particular experience with class action antitrust litigation involving pharmaceutical products.

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

63. Questions of law and fact common to the Classes include:

- (a) Whether the conduct alleged herein constitutes a violation of the antitrust laws;
- (b) Whether Defendants conspired with the Generic Competitors to suppress generic competition to Bystolic;
- (c) Whether Defendants' challenged conduct suppressed generic competition to Bystolic;
- (d) Whether a relevant antitrust market needs to be defined in this case in light of the existence of direct proof of Defendants' power to exclude generic competition and charge supracompetitive prices for Bystolic;
- (e) If a relevant antitrust market needs to be defined, what the definition of the relevant antitrust market for analyzing Defendants' monopoly power is, and whether Defendants had monopoly power in the relevant antitrust market;
- (f) Whether Defendants illegally obtained or maintained monopoly power in the relevant market;
- (g) Whether Defendants' actions were, on balance, unreasonable restraints of trade;
- (h) Whether the Patent Settlements included large and unjustified payments in exchange for promises from the generic manufacturers to delay generic entry;
- (i) Whether the activities of Defendants as alleged herein have substantially affected interstate commerce;
- (j) Whether, and to what extent, Defendants' conduct caused antitrust injury (overcharges) to Plaintiff and the Damages Class; and
- (k) The quantum of overcharge damages paid by the Damages Class in the aggregate.

64. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly-situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.

65. Plaintiff knows of no difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

V. ECONOMIC BACKGROUND

66. 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.

67. 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.

68. 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-rated²⁹ generic version of that drug is available, state laws permit (and in many cases require) the pharmacist to dispense the generic instead of the brand. In this way, price is reintroduced to the product 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.

69. 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.

70. When a single generic competitor enters the market, the generic is typically at least 10% less expensive than its branded counterpart. Once multiple generic competitors enter the market, price drops by 50% to 80% (or more). Consequently, the launch of a bio-equivalent generic drug usually results in significant cost savings to all drug purchasers.

71. The combination of these factors — the regulatory interchangeability of bioequivalent generics for the brand, state substitution laws, margin incentives of pharmacies,

²⁹ 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 permits that a prescription written for the brand drug be filled with an AB-rated generic.

and the like — results in a predictable phenomenon: once a brand drug “goes generic,” the product swiftly moves from a monopoly priced to a commodity priced item.

VI. REGULATORY BACKGROUND

A. The Regulatory Structure for Approval of Drugs

72. Under the Federal Food, Drug, and Cosmetic Act (“FDCA”), a company seeking to market a new drug must obtain the approval of the FDA by filing a New Drug Application (“NDA”). 21 U.S.C. §§ 301-92. An NDA must include specific data concerning the safety and effectiveness of the drug, as well as information on applicable patents. 21 U.S.C. §§ 355(a), (b).

73. When the FDA approves a brand manufacturer’s NDA, the brand manufacturer may list in the FDA’s book of Approved Drug Products with Therapeutic Equivalence Evaluations (called the “Orange Book”) any patent that it certifies (1) claims either the approved drug product or approved methods of using the drug product, and (2) could reasonably be asserted against a generic manufacturer who makes, uses, or sells the drug product without authorization prior to the expiration of the listed patent(s). Relevant patents issued after NDA approval must be listed in the Orange Book within 30 days of issuance. 21 U.S.C. §§ 355(b)(1), (c)(2).

74. The FDA relies completely on the brand manufacturer’s certification about its patents, as the FDA does not have the resources or authority to verify for accuracy or product or its use. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

1. The Hatch-Waxman Amendments

75. The Hatch-Waxman amendments, enacted in 1984, simplified regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file 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 Abbreviated New Drug Application (“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 brand 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.

76. 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

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

78. The Hatch-Waxman amendments achieved both goals, advancing substantially the rate of generic product launches and ushering in an era of historically high profit margins for pharmaceutical manufacturers. In 1983, before the Hatch-Waxman amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984,

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).

prescription drug revenues for brands and generics totaled \$21.6 billion; by 2013, total prescription drug revenues had climbed to more than \$329.2 billion, with generics accounting for 86% of prescriptions.³² Generics are dispensed about 95% of the time when a generic form is available.³³

2. Regulatory Exclusivities for New Drugs

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

62. 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 certification of patent invalidity or non-infringement, in which case an application may be submitted after four years.³⁴

63. 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

³² See IMS Institute for Healthcare Informatics, *Medicine Use and Shifting Costs of Healthcare: A Review of the Use of Medicines in the United States in 2013*, 30, 51 (2014).

³³ *Id.*

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

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.³⁵

79. 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.³⁶

3. ANDA Paragraph IV Certifications

80. To obtain FDA approval of an ANDA, a manufacturer must certify that the generic will not infringe any patents listed in the Orange Book. Under the Hatch-Waxman amendments, a generic manufacturer's ANDA must contain one of four certifications:

- (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").³⁷

81. 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

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

³⁶ *See, e.g.*, 21 C.F.R. §§ 314.94(a)(8)(v), 314.127(a)(7); 21 U.S.C. § 355a(o).

³⁷ 21 U.S.C. § 355(j)(2)(A)(vii).

FDA will not grant final approval to the ANDA until the earlier of (i) the passage of 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.³⁸ 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.

82. 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.

4. The First Filer's 180-day Exclusivity Period

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

84. To encourage manufacturers to seek approval of generic versions of brand 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 the FDA may not grant final approval to any other generic manufacturer's ANDA for the same brand drug.³⁹ 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

³⁸ 21 U.S.C. § 355(j)(5)(B)(iii).

³⁹ 21 U.S.C. § 355(j)(5)(B)(iv), (D).

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.⁴⁰

85. 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 AstraZeneca) 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.

86. 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.⁴¹

87. 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.

B. Patents Are Not Bulletproof

88. 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.

⁴⁰ 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.

⁴¹ *FTC v. Actavis, Inc.*, 570 U.S. 136, 133 (2013) (quoting C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1579 (2006)).

89. 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.

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

91. 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.

92. 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 2002.⁴² 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.⁴³

C. The Competitive Effects of AB-Rated Generic Competition

93. Generics contain the same active ingredient(s) and are determined by the FDA to be just as safe and effective as their brand counterparts. The only material difference between

⁴² 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-patentexpiration-ftc-study/genericdrugstudy_0.pdf.

⁴³ John R. Allison, Mark A. Lemley & David 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.).

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. Typically, generics are at least 10% less expensive than their brand counterparts when there is a single generic competitor. This discount typically increases to 50% to 80% (or more) when there are multiple generic competitors on the market for a given brand. Consequently, the launch of a generic usually results in significant cost savings for all drug purchasers, especially end-payor purchasers.

94. Since the passage of the Hatch-Waxman amendments, every state has adopted drug product selection laws that either require or permit pharmacies to substitute AB-rated generic equivalents for brand prescriptions (unless the prescribing physician specifically directs that substitutions are not permitted). As a result of substitution laws and other institutional features of pharmaceutical distribution, the launch of AB-rated generics results both in rapid price decline and rapid sales shift from brand to generic purchasing. Once a generic hits 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%.⁴⁴ As a result, competition from generics is viewed by brand manufacturers, such as Forest, as a grave threat to their bottom lines.

95. 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.

⁴⁴ 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”).

96. Once exclusivity is lost and generic entry occurs—an event sometimes referred to as the “patent cliff”—the brand manufacturer can expect a significant drop in profits, as it is forced to either compete by dramatically lowering prices, or accept dramatically lower sales. The tradeoff of longer exclusivity rights in return for quick and effective generic entry after loss of exclusivity was fundamental to the policies and procedures that Congress established in the Hatch-Waxman Act, and embraced by the states in their generic substitution laws. “According to the Congressional Budget Office, generic drugs save consumers an estimated \$8 to \$10 billion a year at retail pharmacies. Billions more are saved when hospitals use generics.”⁴⁵

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

97. 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 Forest, are well aware of generics’ rapid erosion of their brand sales. 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.

98. One way that brand manufacturers game the system, causing an anticompetitive effect, is by paying generic manufacturers to delay entering the market. These agreements not to compete are sometimes referred to as or “pay-for-delay agreements,” and they have long concerned the FTC. Brand and generic manufacturers execute pay-for-delay agreements to take advantage of the regulatory consequences associated with the generic manufacturers’ Paragraph IV certifications.

⁴⁵ *Generic Drugs Undergo Rigorous FDA Scrutiny*, U.S. Food & Drug Admin. (Oct. 8, 2014), <https://www.fda.gov/consumers/consumer-updates/generic-drugs-undergo-rigorous-fda-scrutiny>.

99. In a typical pay-for-delay agreement, the brand manufacturer pays a generic manufacturer to delay or abandon market entry. The brand manufacturer preserves its monopoly by effectively paying some of its monopoly profits to the generic manufacturer, which in turn agrees to delay the market entry of its product. Because of the sharp price drop that would result from generic competition, both the brand and the generic manufacturer can make more money from this arrangement than from competing against each other for increasingly smaller margins.

100. Pay-for-delay agreements often take the form of settlement agreements to end patent infringement suits filed by brand manufacturers when they get notice of an ANDA with a Paragraph IV certification concerning one or more of their patents. Instead of defending their patents in court, as the Hatch-Waxman Act's drafters intended, the brand company pays the generic manufacturer to stay off the market, allowing both companies to benefit from monopoly profits. These agreements are also called "reverse-payment agreement," because the plaintiff pays the defendant to end the suit—the opposite of what normally happens in a civil settlement.

E. Pay-for-Delay Agreements with First-Filers Can Create Bottlenecks for Later-Filing Generics

101. An anticompetitive agreement entered into between the brand and the first-filer generic often creates a bottleneck preventing the later ANDA filers from launching, since the later ANDA filers cannot launch earlier than 180 days after the first-filer's launch.

102. Later ANDA filers have more modest financial prospects than the first-filer generic because the later filers have no expectation of any form of market exclusivity, such as the first-filer's 180-day exclusivity. By the time the later ANDA filers enter the market, they typically must compete with the brand, the first-filer, an authorized generic, and other later filers.

103. Nevertheless, in the absence of an anticompetitive agreement between the brand company and the first-filer, the later ANDA filers have procompetitive incentives. They are

motivated to enter the market as early as possible because the sooner they enter, the sooner they can earn profits by competing for sales in the market, which results in lower prices.

104. However, later ANDA filers cannot obtain final FDA approval to enter the market until the first-filer's 180-day exclusivity has run or been forfeited. An agreement between the brand and the first-filer that delays the first-filer's entry thus creates a bottleneck that, by delaying the first filer's 180-day exclusivity, consequently delays the later ANDA filers' entry as well.

105. Agreements causing such bottlenecks are fundamentally anticompetitive and are contrary to the goals of the Hatch-Waxman statutory scheme. In particular, they extend the brand manufacturer's monopoly profits by blocking and delaying access to more affordable generic drugs, forcing purchasers to buy the more expensive brand drug instead.

VII. FACTUAL ALLEGATIONS

A. Bystolic

106. The FDA approved Bystolic in December 2007. Bystolic is available in four dosage strengths (2.5, 5, 10, and 20mg) and is indicated for the treatment of hypertension.

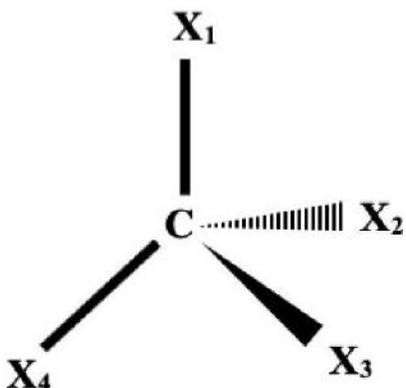
107. Janssen Pharmaceutica ("Janssen") originally held the rights to Bystolic. In 2001, Janssen entered into a license agreement with Mylan Pharmaceuticals ("Mylan") for the rights to Bystolic in the United States and Canada. Mylan obtained consent to further sublicense Bystolic to Forest as part of a January 2006 commercialization and development deal.

108. In March 2012, Forest acquired all intellectual property rights to Bystolic from Janssen for a one-time cash payment of \$357 million. Forest was, and its successor in interest Allergan is, the holder of NDA No. 21-742 for Bystolic.

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

109. 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.

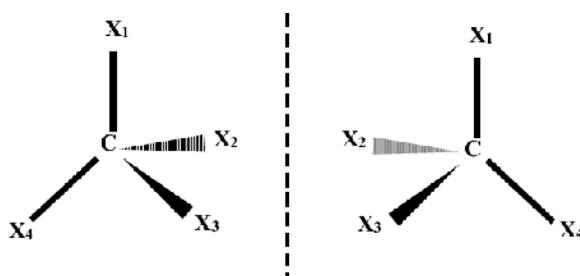
110. The chemical symbol for a carbon atom is “C.” The figure below depicts a carbon atom (labeled as “C”) bonded to four different chemical substituents (labeled as “X1,” “X2,” “X3,” and “X4”).



The straight lines from the carbon atom (at the center) to “X1” and “X4” are intended to convey that they are in the plane of the page. The solid wedge from the carbon atom to “X3” is intended to convey that it is coming out of the page towards the reader. And the hashed wedge from the carbon atom to “X2” is intended to convey that it is coming out of the page but away from the reader. Thus, the above figure reflects a three-dimensional tetrahedral structure with a carbon atom at its center.

111. 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 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.

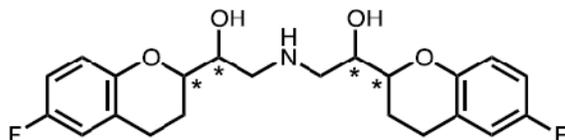


112. Distinguishing between stereoisomers can be particularly important in biological systems because many active pharmaceutical ingredients ("APIs") in drugs interact with naturally occurring receptors in the human body by fitting into a three-dimensional site on the receptor, much like a left hand 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.

113. 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.

114. On March 31, 1987, the United States Patent and Trademark Office (“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:



115. 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 |

116. 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.

C. Forest's Bystolic Patents

117. Forest certified to the FDA that the '040 and '580 Patents covered Bystolic, and FDA listed those patents in the Orange Book. The '580 Patent was 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.

118. The '040 Patent issued from United States Application Serial No. 07/825,488 (“the '488 Application”) was filed on January 24, 1992. To understand the impact of the 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 elements that comprise a patent claim. “A patent claim typically has three parts: the preamble, the transition, and the body.” Donald S. Chisum, CHISUM ON PATENTS § 8.06[1](b) (2003). “The preamble is an introductory phrase that may summarize the invention, its relation to the prior art, or its intended use or properties.” *Id.* § 8.06[1](b)[i]. “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.’” *Id.* § 8.06[1](b)[ii]. “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.” *Id.* § 8.06[1](b)[iii].

119. There are three commonly used transitional phrases: “comprising,” “consisting of,” and “consisting essentially of.” *Id.* § 8.06[1](b)[ii]; *Conoco, Inc. v. Energy & Envtl. Int'l, L.C.*, 460 F.3d 1349, 1360 (Fed. Cir. 2006). 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.” *Id.* (quoting the Manual of Patent Examining Procedures). The choice of transition phrase affects the scope of the patent claim. At one end of the spectrum, the phrase “comprising” signifies that the claim is “open” to the addition of unrecited components of steps *CLAS, Inc. v. Alliance Gaming* 504 F.3d 1356, 1360 (Fed. Cir. 2007). 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).

120. The application of claims that resulted in the '040 Patent, as originally filed, used the transition phrase “comprising.” For example, 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 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 multiple of the stereoisomers described above, and thus were covered by pending claim 19.

121. 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 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.

122. The transition phrase “consisting essentially of” in a patent claim is more narrow than the “comprising.” *AK Steel Corp. v. Sollac and Ugine*, 344 F.3d 1234, 1239 (Fed. Cir. 2003). “[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.” *Yoon Ja Kim v. Conagra Foods, Inc.*, 465 F.3d 1312, 1320-21 (Fed. Cir. 2006). 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.

123. 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.

The Examiner continued to maintain his rejections and ultimately issued a final rejection of Claims 25 and 26 (the “consisting essentially of” claims) as obvious and anticipated by the ’362 Patent.

124. The applicants for the ’040 Patent appealed the examiner’s final obviousness and anticipation 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.

125. 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.”

126. 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 Board's decision made it clear that the claims of the '488 Application were not patentable unless the claims excluded the unclaimed stereoisomers, particularly the RSSR and SRSS stereoisomers.

127. 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.

128. 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.

129. 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.

130. The phrase “consisting of” is the narrowest transition phrase and it “signifies restriction and exclusion of unrecited steps or components.” Manual of Patent Examining Procedures § 2111.03; *Norian Corp. v. Stryker Corp.*, 363 F.3d 1321, 1331 (Fed. Cir. 2004). 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).

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

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

D. The Generic Competitors Challenge the Bystolic Patents

133. Alkem, Amerigen, Glenmark, Indchemie, Hetero, Torrent and Watson were the first generic manufacturers to file ANDAs with the FDA containing Paragraph IV certifications regarding Bystolic patents. In letters granting final approval to their 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.”⁴⁶

134. Because the Generic Competitors 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.

135. Forest received the Generic Competitors’ Paragraph IV notice letters on the following dates:

- Torrent: February 2, 2012⁴⁷
- Indchemie: February 3, 2012⁴⁸
- Alkem: February 3, 2012⁴⁹
- Watson: February 13, 2012⁵⁰
- Amerigen: February 16, 2012⁵¹
- Glenmark: February 20, 2012⁵²
- Hetero: February 17, 2012⁵³

136. 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 Patent 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

⁴⁶ See, e.g., 11/27/2015 Letter from FDA to Watson, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/203683Orig1s000Ltr.pdf; 5/27/2017 Letter from FDA to Glenmark, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/203821Orig1s000ltr.pdf; 6/24/2015 Letter from FDA to Alkem, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/203741Orig1s000ltr.pdf.

⁴⁷ *Forest Laboratories, et al., v. Torrent Pharmaceuticals Ltd. et al.*, 12-cv-05030 (D. Del. Mar. 13, 2012) (ECF No. 1 ¶ 93).

⁴⁸ *Forest Laboratories, et al. v. Indchemie Health Specialties PVT et al.*, 12-cv-01855 (N.D. Ill. Mar. 14, 2012) (ECF No. 1 ¶ 22).

⁴⁹ *Id.* ¶ 38.

⁵⁰ *Forest Laboratories, et al., v. Torrent Pharmaceuticals Ltd. et al.*, 12-cv-05030 (D. Del. Mar. 13, 2012) (ECF No. 1 ¶ 108).

⁵¹ *Id.* ¶ 123.

⁵² *Id.* ¶ 138.

⁵³ *Id.* ¶ 153.

Competitor'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 Competitors under the Hatch-Waxman Act (if Forest otherwise had a basis to sue under Rule 11).

E. The Bystolic Patent Litigation

137. On March 13, 2012, Forest filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Torrent, Watson, Amerigen, Glenmark, and Hetero.⁵⁴

138. On March 14, 2012, Forest filed a patent infringement lawsuit in the United States District Court for the Northern District of Illinois against Indchemie and Alkem.⁵⁵

139. All of these cases were consolidated into multi-district litigation in *In re Nebivolol Patent ('040) Litigation*, 12-cv-5026 (N.D. Ill. June 12, 2012) (ECF No. 1) (hereafter referred to as the "Bystolic Patent Litigation").

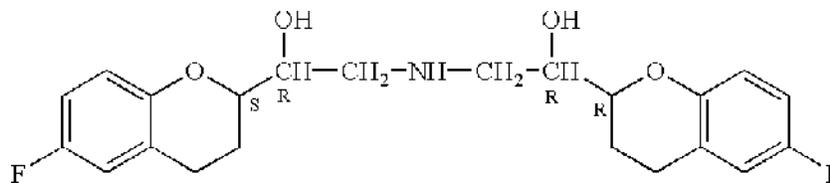
140. Forest could not prevail in the Bystolic Patent Litigation. The sole Patent infringement claim asserted by Forest in the Bystolic Patent Litigation was related to claim 2 from the '040 Patent, shown below:

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:

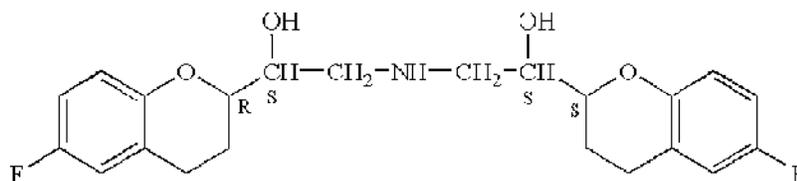
⁵⁴ *Forest Laboratories, et al., v. Torrent Pharmaceuticals Ltd. et al.*, 12-cv-05030 (D. Del. Mar. 13, 2012) (ECF No. 1).

⁵⁵ *Forest Laboratories, et al. v. Indchemie Health Specialties PVT et al.*, 12-cv-01855 (N.D. Ill. Mar. 14, 2012) (ECF No. 1).



or a pharmaceutically acceptable acid addition salt thereof; and

(b) the compound [2R, α S,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. 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).

141. The Generic Competitors 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 Bystolic 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 Competitors’ products did not infringe because they included at least small amounts of the unrecited stereoisomers of nebivolol, including the RSSR and SRSS stereoisomers.

142. Early on in the Bystolic Patent Litigation, the Generic Competitors argued that the “consisting of” transition precluded the patent from covering products using a plurality of inactive ingredients. As explained by the Generic Competitors, a “pharmaceutically acceptable carrier” refers to an individual inactive ingredient in a pharmaceutical formulation and the “consisting of” transition “closed” the claim to unrecited inactive ingredients. Therefore, the

claims did not cover consisting of two or more inactive ingredients. This interpretation is consistent with a court ruling reading “pharmaceutically acceptable carrier” to mean “a conventional pharmaceutically acceptable excipient or additive. . . .” *Schering Corp. v. Mylan Pharms., Inc.*, 2011 U.S. Dist. LEXIS 63825, at *36 (D.N.J. Jun. 15, 2011).

143. Had the Bystolic Patent Litigation concluded, Forest could not have prevailed 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 Generics' 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 stereoisomers “just as surely as if they were identified in the reference by name.”

The '362 Patent was prior art to the '040 Patent. The '362 Patent, as described by the Patent Board, taught through the AB designation that it included a mixture of “the individual RSSS, SRRR, RSRR and SRSS stereoisomers” of nebivolol. Therefore, the asserted compositions in the '040 Patent were anticipated by, or obvious in view of, the prior art, including both the '362 patent and 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, 552563 (1988). Any purported evidence of secondary indicia of nonobviousness was insufficient to overcome the clear prima facie obviousness of the claims.

F. Forest Enters into Unlawful Reverse-Payment Agreements with the Generic Competitors

144. Starting on October 24, 2012, Forest began entering into settlements with Generic Competitors to resolve the Nebivolol Patent Litigation. Forest’s internal and external counsel have conceded that each of these settlements also included “side-deals”:



145. These side-deals were also listed in Forest’s Merger Agreement with Actavis, as “material contracts” that on information and belief “involve payments . . . of consideration in excess of \$15,000,000.”⁵⁶ In addition, Forest has also admitted that it reimbursed “certain of the Settling Defendants’ legal costs in connection with the patent litigation.”⁵⁷ Accordingly, on information and belief, Forest paid each Generic Competitor at least \$15,000,000 (and likely

⁵⁶ *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).

⁵⁷ <https://www.sec.gov/Archives/edgar/containers/fix010/38074/000003807413000024/R17.htm>.

more) in reverse-payments to resolve the Nebivolol Patent Litigation and induce the Generic Competitors to quit the patent fight.

146. 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 payment for Hetero’s expended litigation costs, and a “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.”⁵⁸

147. On information and belief, in addition to the monies Forest paid Hetero for Hetero’s expended litigation costs, pursuant to the “FINAL TERM SHEET,” Forest paid Hetero more than \$15,000,000.

148. 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,” plus payment for Torrent’s expended litigation costs, and 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.”⁵⁹

149. On information and belief, in addition to the monies Forest paid Torrent for Torrent’s expended litigation costs, pursuant to the “PATENT ASSIGNMENT AGREEMENT,” Forest paid Torrent more than \$15,000,000.

150. The **Alkem** reverse-payment included the “SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Alkem Laboratories Ltd. dated November 27, 2012,” plus payment for Alkem’s expended litigation

⁵⁸ *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).

⁵⁹ *Id.*

costs, and a “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.” Alkem and Forest also entered into an “AMENDMENT NO. 1 TO SETTLEMENT AGREEMENT . . . on January 9, 2013.”⁶⁰

151. On information and belief, in addition to the monies Forest paid Alkem for Alkem’s expended litigation costs, pursuant to the Alkem “TERM SHEET,” Forest paid Alkem more than \$15,000,000.

152. The **Indchemie** reverse-payment included the “SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Indchemie Health Specialties Private Ltd. dated November 27, 2012,” plus payment for Indchemie’s expended litigation costs, and a “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.”⁶¹

153. On information and belief, in addition to the monies Forest paid Indchemie for Indchemie’s expended litigation costs, pursuant to the Indchemie “TERM SHEET,” Forest paid Indchemie more than \$15,000,000.

154. 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,” plus payment for Glenmark’s expended litigation costs, and a “COLLABORATION AND OPTION AGREEMENT between

⁶⁰ *Id.*

⁶¹ *Id.*

Glenmark Pharmaceuticals S.A. and Forest Laboratories Holdings Ltd. dated December 21, 2012, in connection with the settlement of BYSTOLIC patent dispute.”⁶²

155. On information and belief, in addition to the monies Forest paid Glenmark for Glenmark’s expended litigation costs, pursuant to the “COLLABORATION AND OPTION AGREEMENT,” Forest paid Glenmark more than \$15,000,000.

156. 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,” plus payment for Amerigen’s expended litigation costs, 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.”⁶³

157. On information and belief, in addition to the monies Forest paid Amerigen for Amerigen’s expended litigation costs, pursuant to the “BINDING TERM SHEET COLLABORATION AGREEMENT,” Forest paid Amerigen more than \$15,000,000.

158. 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,” plus payment for **Watson** expended litigation costs, and “(a) the LETTER from Forest Laboratories, Inc. to Moksha8, Inc. dated November 1, 2013 and (b) TERMINATION AND

⁶² *Id.*

⁶³ *Id.* at 180.

RELEASE AGREEMENT between [Watson] and Moksha8, Inc. dated November 4, 2013, in connection with the settlement of BYSTOLIC patent dispute.”⁶⁴

159. On information and belief, in addition to the monies Forest paid Watson for Watson’s expended litigation costs, pursuant to the “(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.

160. On information and belief, the value of each reverse-payment exceeded Forest’s avoided litigation costs.

161. The agreements also included a CLP or acceleration clause. In exchange for these reverse-payments, each Generic Competitor 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).⁶⁵

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

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

164. Specifically, the Generic Competitors would have launched by the later of: (a) June 2015, which was the expiry of the only other patent that Forest contended covered Bystolic (the ’580 Patent), or (b) the date their ANDAs were finally approved.

⁶⁴ *Id.*

⁶⁵ <https://www.sec.gov/Archives/edgar/containers/fix010/38074/000003807413000024/R17.htm>

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

166. By about October 2012, when Forest and the Generic Competitors 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 Competitors were to prevail on non-infringement or other defenses – or in the event that Forest had not induced the Generic Competitors 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 Competitors by entering into reverse-payment agreements.

167. Forest’s willingness to provide large payments to each Generic Competitor in exchange for a multi-year delay in competition amounted to an agreement to share with the Generic Competitors the monopoly profits from sales of branded Bystolic at supracompetitive levels.

VIII. EFFECTS OF THE SCHEME ON COMPETITION AND DAMAGES TO PLAINTIFF AND THE CLASS

168. U.S. sales of Bystolic were approximately \$1 billion in 2017. Forest received millions of dollars more in sales than it would have achieved absent Defendants’ unlawful scheme to prevent and delay generic competition. Generic Bystolic products would have been priced at a fraction of the cost of brand Bystolic and would have quickly captured the vast majority of the market for nebivolol HCl.

169. Defendants’ unlawful agreement prevented and delayed the sale of generic Bystolic in the United States and unlawfully enabled Forest to sell its branded Bystolic at

artificially inflated prices. But for Defendants' unlawful conduct, generic competitors would have been able to compete, unimpeded, with their own generic versions of Bystolic.

170. Were it not for Defendants' anticompetitive conduct, Plaintiff and other members of the Classes would have purchased lower-priced generic Bystolic instead of the higher-priced brand Bystolic during the Class Period.

171. As a consequence, Plaintiff and other members of the Classes have sustained substantial losses and damage to their business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial.

IX. MONOPOLY POWER AND MARKET DEFINITION

172. Because of the "disconnect" between the payor and the product selector in the pharmaceutical marketplace, brand manufacturers, including Forest, can employ large sales forces that visit doctors' offices and persuade them to prescribe the brand manufacturers' products without regard to cost. These sales representatives do not advise doctors of the cost of the branded products and studies show that doctors typically are not aware of the relative costs of brand pharmaceuticals. Even when prescribing doctors 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.

173. 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.

174. At all relevant times, Defendants had monopoly power over nebivolol HCl products because they had the power to exclude competition and/or raise or maintain the price of the drug they sold as Bystolic at supracompetitive levels without losing enough sales to make supracompetitive prices unprofitable.

175. “[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.”⁶⁶ And a firm that lacks monopoly power is not “likely to pay ‘large sums’ to induce ‘others to stay out of its market.’”⁶⁷

176. A small but significant, non-transitory price increase for Bystolic by Defendants would not have caused a significant loss of sales to non-nebivolol HCl products. Bystolic does not exhibit significant, positive cross-elasticity of demand with respect to price with any non-nebivolol HCl product. Indeed, Defendants have never lowered the price of Bystolic in response to the pricing of any non-nebivolol HCl treatments for high blood pressure. In fact, Defendants substantially increased the price of Bystolic – by more than 60% – over the last five years.

177. Because of its labeling, Bystolic is differentiated from all non-nebivolol HCl products.

178. Defendants needed to control only nebivolol HCl, and no other products, in order to maintain the price of Bystolic profitably at supracompetitive prices. No non-nebivolol HCl product ever rendered Defendants unable to profitably maintain or raise their prices of Bystolic

⁶⁶ *Actavis*, 570 U.S. at 157 (citation omitted).

⁶⁷ *Id.*

without losing substantial sales. 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.

179. Defendants also sold Bystolic at prices well in excess of marginal costs, and in excess of the competitive price, and enjoyed high profit margins.

180. Defendants have had, and exercised, the power to exclude and restrict competition to nebivolol HCl.

181. Defendants, at all relevant times, enjoyed high barriers to entry with respect to competition to the relevant product market due to patent and other regulatory protections and high costs of entry and expansion, which protects brand Bystolic from the forces of price competition.

182. There is direct evidence of market power and anticompetitive effects available in this case sufficient to show Defendants' 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 and at a substantial discount to brand 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 the competitive level in response to the pricing of non-nebivolol HCl product.

183. To the extent proof of monopoly power by defining a relevant product market is required, Plaintiff alleges that the relevant antitrust market is the market for nebivolol HCl.

During the period relevant to this case, Defendants have been able to profitably maintain the price of nebivolol HCl well above competitive levels.

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

185. At all relevant times, Defendants' market share in the relevant market was and remains 100%, providing indirect evidence of their monopoly power.

X. MARKET EFFECTS

186. Defendants willfully and unlawfully maintained their market power by engaging in an overarching scheme to exclude competition. Defendants designed a scheme to prevent and delay competition on the products' merits, in which the Generic Competitors cooperated, to further Forest's anticompetitive purpose of forestalling generic competition against Bystolic. Defendants carried out the scheme with the anticompetitive intent and effect of maintaining supracompetitive prices for nebivolol HCl.

187. The reverse-payments enabled 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 products; and (c) allocate to themselves 100% of the U.S. market for Bystolic and its generic equivalents until September 17, 2021.

188. But for the unlawful reverse-payment agreements, the Generic Competitors would have begun selling a less expensive generic version of Bystolic much earlier than September 17, 2021. Such sales would have occurred via market entry by any of the Generic Competitors upon a Generic Competitor litigation victory, at risk (that is, while the patent litigation remained pending), 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 Competitor.

189. 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 AG version of Bystolic) entered the market. Plaintiff would have purchased generic Bystolic had it been available.

190. Defendants' acts and practices had the purpose and effect of restraining competition unreasonably and injuring competition by protecting brand Bystolic from competition. These actions allowed Defendants to maintain a monopoly and prevent and exclude competition in the market for nebivolol HCl to the detriment of Plaintiff and all other members of the Class.

191. Defendants' exclusionary conduct prevented and 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.

192. Defendants' unlawful concerted action has (a) delayed and suppressed the sale of generic versions of Bystolic in the United States, (b) enabled Defendants to sell Bystolic at artificially inflated, supracompetitive prices, and (c) caused Plaintiff and the Classes to pay supracompetitive prices for nebivolol HCl tablets.

193. Defendants' illegal acts and conspiracy to delay generic competition for Bystolic caused Plaintiff and all members of the Classes to pay more than they would have paid for nebivolol HCl absent this illegal conduct.

194. If generic competitors had not been unlawfully prevented from entering and competing in the relevant market, end-payers, such as Plaintiff and members of the Class, would have paid less for nebivolol HCl by: (a) paying lower prices on their brand purchases of Bystolic,

(b) substituting purchases of less expensive generic Bystolic for their purchases of more expensive brand Bystolic, and/or (c) purchasing generic Bystolic at lower prices sooner.

195. Thus, Defendants' unlawful conduct deprived Plaintiff and the Classes of the benefits of competition that the antitrust laws were designed to ensure.

XI. ANTITRUST IMPACT

196. During the class period, Plaintiff and members of the Classes purchased substantial amounts of Bystolic indirectly from Forest and others at supracompetitive prices. As a result of Defendants' illegal conduct, Plaintiff and members of the Classes were compelled to pay and did pay artificially inflated prices for their nebivolol HCl purchase requirements. Those prices were substantially greater than the prices that Plaintiff and members of the Classes would have paid absent the illegal conduct alleged herein, because: (a) the price of branded Bystolic was artificially inflated by Defendants' illegal conduct; (b) Plaintiff and members of the Classes were deprived of the opportunity to purchase lower-priced generic versions of Bystolic instead of branded Bystolic sooner, which they would have done had they had the opportunity; and/or (c) Plaintiff and members of the Classes would have paid lower prices for generic Bystolic.

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

198. Commonly used and well-accepted economic models can be used to measure both the extent and the amount of the supracompetitive charge passed through the chain of distribution to end-payors such as Plaintiff and members of the Classes.

199. General economic theory recognizes that any overcharge at a higher level of distribution in the chain of distribution for Bystolic results in higher prices at every level below.

Herbert Hovenkamp, FEDERAL ANTITRUST POLICY, THE LAW OF COMPETITION AND ITS PRACTICE (1994) at 624. Professor Herbert Hovenkamp goes on to state that “[e]very person at every stage in the chain will be poorer as a result of the monopoly price at the top.” He 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.”

200. 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 Plaintiff and members of the Class. Further, the delayed entry of generic competition at the direct purchaser level similarly injured end-payors who were equally denied, and continue to be denied, the opportunity to purchase less expensive generic Bystolic.

201. Thus, Defendants’ unlawful conduct deprived Plaintiff and the Classes of the benefits of competition that the antitrust laws were designed to ensure.

202. Defendants’ unlawful anticompetitive conduct alleged herein enabled Forest and others to indirectly charge end-payors prices in excess of what they otherwise would have been able to charge absent their unlawful actions.

203. Prices of Bystolic were artificially inflated as a direct and foreseeable result of Defendants’ anticompetitive conduct.

204. The supracompetitive prices Plaintiff and members of the Classes paid are traceable to, and the direct, proximate, and foreseeable result of, Defendants’ anticompetitive conduct.

205. The overcharges Plaintiff and members of the Classes paid are traceable to, and the direct, proximate, and foreseeable result of, Defendants’ supracompetitive pricing.

XII. INTERSTATE AND INTRASTATE COMMERCE

206. Defendants' anticompetitive conduct has substantially affected intrastate, interstate and foreign commerce.

207. Defendants' anticompetitive conduct has substantial intrastate effects in that, *inter alia*, it deprived wholesalers and retailers within each state of access to less expensive generic Bystolic that they could sell to end-payors within each respective state. The delayed entry of generic Bystolic has directly affected and disrupted commerce for end-payors within each state.

208. During the relevant time period, Bystolic was shipped into each state and end-payors paid for Bystolic in each state.

209. During the relevant time period, Defendants manufactured, promoted, distributed, and/or sold substantial amounts of Bystolic in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States.

210. As a direct result of the unlawful reverse-payment agreements, the Generic Competitors refrained from selling generic versions of Bystolic when they otherwise would have done so.

211. During the relevant time period, in connection with the purchase and sale of Bystolic, Defendants transmitted funds as well as contracts, invoices and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Bystolic.

212. During the relevant time period, various devices were used to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign telephone commerce. The activities of Defendants as alleged in this Complaint were within the flow of, and have substantially affected, intrastate, interstate and foreign commerce.

XIII. FRAUDULENT CONCEALMENT AND CONTINUING VIOLATIONS

A. Defendants Fraudulently Concealed Their Anticompetitive Scheme

213. Due to Defendants' fraudulent concealment of their unlawful conduct, Plaintiff and members of the Classes are entitled to recover damages from the beginning of the Class Period. Plaintiff and members of the Classes had no knowledge of Defendants' unlawful self-concealing scheme and could not have discovered the scheme and conspiracy through the exercise of reasonable diligence.

214. Defendants' scheme was self-concealing, and Defendants employed deceptive tactics and techniques of secrecy to avoid detection of, and to fraudulently conceal, their contract, combination, conspiracy, and scheme.

215. Defendants did not disclose the material terms of their agreements with the Generic Competitors—including the size and value of the payments to the Generic Competitors—in public filings. The earliest Plaintiff was placed on notice of the claims in this complaint was March 2019, when the full February 2014 Forest-Allergan Agreement and Plan of Merger and related internal communications were publicly disclosed in the *In re Namenda Direct Purchaser Antitrust Litigation*, No. 15-cv-7488 (S.D.N.Y.). Publicly disclosed versions of the February 2014 Agreement and Plan of Merger, for example, did not include the Company Disclosure Letter, which identified Defendants' patent settlements with the Generic Competitors as settlement agreements each with consideration of at least \$15 million (but likely more).

216. Because of this failure to disclose, Plaintiff and members of the Classes had no knowledge of the scheme and conspiracy prior to March 2019, when the Agreement and Plan of Merger was fully disclosed; they did not have the facts or information that would have caused a reasonably diligent person to investigate whether a conspiracy existed; and if they would have

had the facts or information to cause them to conduct an investigation, any such investigation would not have revealed the existence of Defendants' unlawful conspiracy.

217. As a result of Defendants' fraudulent concealment, all applicable statutes of limitations affecting Plaintiff's and the Classes' claims have been tolled.

B. Defendants' Continuing Violations of the Antitrust Laws

218. By virtue of Defendants' continued adherence to the unlawful patent settlement agreements with the Generic Competitors, Defendants have reaffirmed and perpetuated their anticompetitive scheme.

219. Defendants' continued sales of Bystolic at monopoly prices in the absence of the competition from Generic Competitors, and each such sale created a claim entitling Plaintiff and members of the Classes relief.

220. Accordingly, Plaintiff's and the Classes' claims are timely.

XIV. CLAIMS FOR RELIEF

**FIRST CLAIM FOR RELIEF
Violation of Section 1 of the Sherman Act
Agreement Not to Compete (15 U.S.C. § 1)**

221. Plaintiff incorporates the allegations set forth above as if fully set forth herein.

222. Plaintiff brings this claim on behalf of the Injunctive Relief Class.

223. Defendants paid the Generic Competitors at least \$15 million, plus consideration in side deals and reimbursement for litigation costs. In exchange for this substantial consideration, the Generic Competitors agreed to drop their patent challenges and not to launch their generic Bystolic products to compete with Bystolic until September 17, 2021.

224. These settlements are unlawful pay-for-delay agreements and illegal contracts, combinations, and conspiracies in restraint of trade. The purposes and effects of these agreements were to: (a) delay and prevent the entry of more affordable generic versions of

Bystolic in the United States; (b) fix, raise, maintain, or stabilize the prices of Bystolic; (c) allocate 100% of the U.S. nebivolol market to Defendants.

225. Defendants implemented the terms of the agreements, and they achieved their intended purpose. As a direct and proximate result of Defendants' anticompetitive conduct, alleged herein, Plaintiff suffered harm in the form of overcharges.

226. There was and is no legitimate, non-pretextual, procompetitive justification for the reverse payments from Forest to the Generic Competitors that outweighs their harmful effect. Even if there were some conceivable justification, the payments were not necessary to achieve that purpose. The payments were far in excess of the amount of saved litigation costs.

227. Plaintiff and members of the Injunctive Relief Class will continue to suffer injury, in the form of overcharges paid for Bystolic, if Defendants' unlawful conduct is not enjoined.

228. Plaintiff and the members of the Injunctive Relief Class therefore seek equitable and injunctive relief under Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable laws, to correct for the anticompetitive market effects caused by Defendants' unlawful conduct, and to assure that similar anticompetitive conduct and effects do not continue or reoccur in the future.

SECOND CLAIM FOR RELIEF
Violation of Section 2 of the Sherman Act
Monopolization and Monopolistic Scheme (15 U.S.C. § 2)

229. Plaintiff incorporates the allegations set forth above as if fully set forth herein.

230. Plaintiff brings this claim on behalf of the Injunctive Relief Class.

231. As described above, throughout the relevant time period Defendants possessed monopoly power nationwide and in each of the state and its territories in the market for nebivolol hydrochloride. No other manufacturer sold a competing version of Bystolic during the relevant time period.

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

233. Through their overarching anticompetitive scheme, as alleged above, Defendants willfully maintained their 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 Plaintiff and the Injunctive Relief Class. Defendants' anticompetitive conduct was done with the specific intent to maintain their monopoly in the market for Bystolic in the United States.

234. Defendants knowingly and intentionally engaged in this anticompetitive scheme to monopolize the nebivolol hydrochloride market as described above. Defendants accomplished this scheme by, inter alia, (1) entering into illegal agreements which delayed the entry of generic Bystolic in order to lengthen the period in which Defendants' brand Bystolic could monopolize the market and make supracompetitive profits; and (2) raising and maintaining prices so that Plaintiff and Injunctive Relief Class members would pay for Bystolic at supracompetitive prices.

235. The goal, purpose, and effect of Defendants' scheme was to prevent and delay the sale of nebivolol hydrochloride in the United States at prices significantly below Defendants' prices for Bystolic, thereby effectively preventing the average market price of nebivolol hydrochloride from declining dramatically while maintaining and extending its monopoly power with respect to nebivolol hydrochloride products.

236. Plaintiff and members of the Injunctive Relief Class purchased substantial amounts of Bystolic indirectly from Defendants.

237. As a result of Defendants' illegal conduct, Plaintiff and members of the Injunctive Relief Class were compelled to pay, and did pay, more than they would have paid for their nebivolol hydrochloride requirements absent Defendants' illegal conduct. But for Defendants' illegal conduct, competitors would have begun selling generic Bystolic during the relevant period, and prices for nebivolol hydrochloride products would have been lower, sooner.

238. Had manufacturers of generic Bystolic entered the market and lawfully competed with Defendants earlier, Plaintiff and other members of the Injunctive Relief Class would have substituted lower-priced generic nebivolol hydrochloride products for the higher-priced brand-name Bystolic for some or all of their nebivolol hydrochloride products requirements, and/or would have paid lower net prices on their remaining Bystolic and/or AB-rated bioequivalent purchases.

239. Plaintiff and members of the Injunctive Relief Class will continue to suffer injury, in the form of overcharges paid for Bystolic, if Defendants' unlawful conduct is not enjoined.

240. Plaintiff and the members of the Injunctive Relief Class therefore seek equitable and injunctive relief under Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable laws, to correct for the anticompetitive market effects caused by Defendants' unlawful conduct, and to assure that similar anticompetitive conduct and effects do not continue or reoccur in the future.

THIRD CLAIM FOR RELIEF
Conspiracy and Combination in Restraint of Trade Under State Law

241. Plaintiff incorporates the allegations set forth above as if fully set forth herein.

242. Plaintiff brings this claim on behalf of the Damages Class.

243. During the Class Period, Defendants and Generic Competitors engaged in a continuing contract, combination or conspiracy with respect to the sale of Bystolic in

unreasonable restraint of trade and commerce, in violation of the various state antitrust statutes set forth below.

244. During the Class Period, Defendants and Generic Competitors entered into illegal contracts, combinations and conspiracies in restraint of trade under which Forest agreed to make large reverse payments to Generic Competitors in exchange for their agreement to delay bringing generic Bystolic to the market until September 17, 2021. The purpose and effect of these reverse-payment agreements were to: (a) allocate to Forest 100% of the U.S. sales of nebivolol HCl until September 17, 2021; (b) delay the availability of generic Bystolic in the United States, thereby protecting Bystolic from any generic competition until September 17, 2021; and (c) fix and maintain, at supracompetitive levels, the price Plaintiff and members of the Classes paid for nebivolol HCl.

245. Defendants and Generic Competitors' reverse-payment agreements were unlawful and the reverse payments were large and unjustified.

246. Defendants and Generic Competitors' reverse-payment agreements harmed Plaintiff and the Classes as set forth above.

247. There is and was no legitimate, non-pretextual, procompetitive justification for the reverse payments from Forest to Generic Competitors that outweighs their harmful effect. Even if there were some conceivable such justification, the payments were not necessary to achieve, nor the least restrictive means of achieving, such a purpose.

248. As a direct, proximate, foreseeable, and intended result of the Defendants' and Generic Competitors' reverse-payment agreements in restraint of trade, as alleged herein, Plaintiff and the Classes were harmed and suffered overcharge damages as aforesaid. Specifically, without a reverse-payment, Generic Competitors would have launched their generic

versions of Bystolic upon receiving final FDA approval, or via a lawful, separate, and independent settlement agreement whereby reasonable parties in the position of Forest and Generic Competitors would have agreed upon earlier entry dates untainted by delay associated with the unlawful side deals and reverse payments. In addition, by operation of the CLPs, any earlier license date agreed to between any Generic Competitor and Forest would also have applied to all earlier-settling Generic Competitors, if any.

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

- a. Ariz. Rev. Stat. §§ 44-1402, *et seq.*, with respect to purchases of Bystolic in Arizona by members of the Damages Class.
- b. Cal. Bus. and Prof. Code §§ 16720, *et seq.*, with respect to purchases of Bystolic in California by members of the Damages Class.
- c. Conn. Gen. Stat. § 35-26, *et seq.*, with respect to purchases of Bystolic in Connecticut by members of the Damages Class.
- d. D.C. Code §§ 28-4502, *et seq.*, with respect to purchases of Bystolic in the District of Columbia by members of the Damages Class.
- e. Haw. Rev. Stat §§ 480-1, *et seq.*, with respect to purchases of Bystolic in Hawaii by members of the Damages Class.
- f. 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to purchases of Bystolic in Illinois by members of the Damages Class.
- g. Iowa Code §§ 553.4 *et seq.*, with respect to purchases of Bystolic in Iowa by members of the Damages Class.
- h. Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases of Bystolic in Kansas by members of the Damages Class.
- i. Me. Stat. tit. 10 § 1101, *et seq.*, with respect to purchases of Bystolic in Maine by members of the Damages Class.
- j. Md. Code, Com. Law, Section 11-204, *et seq.*, with respect to purchases of Bystolic in Maryland by members of the Damages Class.

- k. Mich. Comp. Laws §§ 445.772, *et seq.*, with respect to purchases of Bystolic in Michigan by members of the Damages Class.
- l. Minn. Stat. §§ 325D.51, *et seq.*, with respect to purchases of Bystolic in Minnesota by members of the Damages Class.
- m. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases of Bystolic in Mississippi by members of the Damages Class.
- n. Neb. Rev. Stat. §§ 59-801, *et seq.*, with respect to purchases of Bystolic in Nebraska by members of the Damages Class.
- o. Nev. Rev. Stat. §§ 598A.060, *et seq.*, with respect to purchases of Bystolic in Nevada by members of the Damages Class.
- p. N.H. Rev. Stat. Ann. §§ 356:2, *et seq.*, with respect to purchases of Bystolic in New Hampshire by members of the Damages Class.
- q. N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases of Bystolic in New Mexico by members of the Damages Class.
- r. N.Y. Gen. Bus. Law §§ 340, *et seq.*, with respect to purchases of Bystolic in New York by members of the Damages Class.
- s. N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases of Bystolic in North Carolina by members of the Damages Class.
- t. N.D. Cent. Code §§ 51-08.1-02, *et seq.*, with respect to purchases of Bystolic in North Dakota by members of the Damages Class.
- u. Or. Rev. Stat. §§ 646.725, *et seq.*, with respect to purchases of Bystolic in Oregon by members of the Damages Class.
- v. P.R. Laws Ann. tit. 10 §§ 258, *et seq.*, with respect to purchases of Bystolic in Puerto Rico by members of the Damages Class.
- w. R.I. Gen. Laws §§ 6-36-4, *et seq.*, with respect to purchases of Bystolic in Rhode Island by members of the Damages Class.
- x. S.D. Codified Laws §§ 37-1-3.1, *et seq.*, with respect to purchases of Bystolic in South Dakota by members of the Damages Class.
- y. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of Bystolic in Tennessee by members of the Damages Class.
- z. Utah Code Ann. §§ 76-10-3104, *et seq.*, with respect to purchases of Bystolic in Utah by members of the Damages Class.

- aa. Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases of Bystolic in Vermont by consumer members of the Damages Class.
- bb. W.Va. Code §§ 47-18-43, *et seq.*, with respect to purchases of Bystolic in West Virginia by members of the Damages Class.
- cc. Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases of Bystolic in Wisconsin by members of the Damages Class.

250. Plaintiff and members of the Damages Class have been injured in their business or property by reason of Defendants' violations of the laws set forth above, in that Plaintiff and members of the Damages Class were: (a) denied the opportunity to purchase lower-priced generic Bystolic; and (b) paid higher prices for Bystolic than they would have paid but for Defendants' unlawful conduct. These injuries are of the type that the above laws were designed to prevent and flow from that which makes Defendants' conduct unlawful.

251. Plaintiff and members of the Damages Class accordingly seek damages and multiple damages as permitted by law for their injuries by Defendants' violations of the aforementioned statutes.

FOURTH CLAIM FOR RELIEF
Monopolization and Monopolistic Scheme Under State Law

252. Plaintiff incorporates the allegations set forth above as if fully set forth herein.

253. Plaintiff brings this claim on behalf of the Damages Class.

254. As described above, at all relevant times prior to September 17, 2021, Defendants had and will continue to have monopoly power in the relevant market.

255. By entering into the reverse-payment agreements with the Generic Competitors, Defendants willfully and intentionally maintained, enhanced, and extended their monopoly power using restrictive or exclusionary conduct, rather than by means of greater business acumen, and injured Plaintiff and the Class thereby. Specifically, Defendants (a) allocated to themselves 100% of the market for nebivolol HCl in all strengths in the United States until

September 17, 2021; (b) delayed the availability of generic versions of Bystolic in the United States, thereby protecting Bystolic from any generic competition until September 17, 2021; and (c) fixed and maintained, at supracompetitive levels, the price Plaintiff and Class members paid for nebivolol HCl.

256. It was Defendants' conscious object to further their dominance in the relevant market by and through the anticompetitive conduct alleged herein.

257. The goal, purpose, and effect of Defendants and the Generic Competitors' reverse-payment agreements was to maintain and extend Defendants' monopoly power in violation of numerous state laws. Forest and the Generic Competitors' reverse-payment agreements were intended to and did prevent and/or delay generic competition to Bystolic and enabled Defendants to continue charging supracompetitive prices for Bystolic without a substantial loss of sales.

258. Defendants and Generic Competitors specifically intended that the reverse-payment agreements would maintain Defendants' monopoly power in the relevant market, and injure Plaintiff and the Class thereby.

259. Defendants and Generic Competitors knowingly and intentionally conspired to maintain, enhance, and extend Defendants' monopoly power in the relevant market.

260. Defendants and Generic Competitors each committed at least one overt act in furtherance of the conspiracy.

261. As a direct, proximate, foreseeable, and intended result of Defendants' monopolistic scheme and concerted monopolistic conduct, as alleged herein, Defendants unlawfully maintained, enhanced, and extended its monopoly power and Plaintiff and the Class were harmed and suffered overcharge damages as a result, as alleged herein. Specifically,

without a reverse-payment, Generic Competitors would have launched their generic versions of Bystolic upon receiving final FDA approval, or via a lawful, separate, and independent settlement agreement whereby reasonable parties in the position of Generic Competitors would have agreed upon earlier entry dates untainted by delay associated with the unlawful side-deals and reverse-payments.

262. All of Forest's corporate successors adopted Defendants' monopolistic scheme and took actions in furtherance thereof.

263. By engaging in the foregoing conduct, Defendants intentionally, willfully, and wrongfully monopolized the relevant market in violation of the following state laws:

- a. Ariz. Rev. Stat. Ann. §§ 44-1402, *et seq.*, with respect to purchases of Bystolic in Arizona by members of the Damages Class.
- b. Cal. Bus. & Prof. Code §§ 16700, *et seq.*, with respect to purchases of Bystolic in California by members of the Damages Class.
- c. Conn. Gen. Stat. §§ 35-27, *et seq.*, with respect to purchases of Bystolic in Connecticut by members of the Damages Class.
- d. D.C. Code §§ 28-4503, *et seq.*, with respect to purchases of Bystolic in the District of Columbia by members of the Damages Class.
- e. Haw. Rev. Stat. §§ 480-1, *et seq.*, with respect to purchases of Bystolic in Hawaii by members of the Damages Class.
- f. 740 Ill. Comp. Stat. 10/1, *et seq.*, with respect to purchases of Bystolic in Illinois by members of the Damages Class.
- g. Iowa Code §§ 553.5, *et seq.*, with respect to purchases of Bystolic in Iowa by members of the Damages Class.
- h. Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases of Bystolic in Kansas by members of the Damages Class.
- i. Me. Stat. tit. 10, § 1102, *et seq.*, with respect to purchases of Bystolic in Maine by members of the Damages Class.
- j. Md. Code, Com Law, Section 11-204(a), *et seq.*, with respect to purchases of Bystolic in Maryland by members of the Damages Class.

- k. Mich. Comp. Laws §§ 445.772, *et seq.*, with respect to purchases of Bystolic in Michigan by members of the Damages Class.
- l. Minn. Stat. §§ 325D.49, *et seq.*, with respect to purchases of Bystolic in Minnesota by members of the Damages Class.
- m. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases of Bystolic in Mississippi by members of the Damages Class.
- n. Neb. Rev. Stat. §§ 59-802, *et seq.*, with respect to purchases of Bystolic in Nebraska by members of the Damages Class.
- o. Nev. Rev. Stat. §§ 598A.060, *et seq.*, with respect to purchases of Bystolic in Nevada by members of the Damages Class.
- p. N.H. Rev. Stat. Ann. §§ 356:11, *et. seq.*, with respect to purchases of Bystolic in New Hampshire by members of the Damages Class.
- q. N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases of Bystolic in New Mexico by members of the Damages Class.
- r. N.Y. Gen. Bus. Law §§ 340, *et seq.*, with respect to purchases of Bystolic in New York by members of the Damages Class.
- s. N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases of Bystolic in North Carolina by members of the Damages Class.
- t. N.D. Cent. Code §§ 51-08.1-02, *et seq.*, with respect to purchases of Bystolic in North Dakota by members of the Damages Class.
- u. Or. Rev. Stat. §§ 646.730, *et seq.*, with respect to purchases of Bystolic in Oregon by members of the Damages Class.
- v. P.R. Laws Ann. tit. 10, §§ 260, *et seq.*, with respect to purchases of Bystolic in Puerto Rico by members of the Damages Class.
- w. R.I. Gen. Laws §§ 6-36-5, *et seq.*, with respect to purchases of Bystolic in Rhode Island by members of the Damages Class.
- x. S.D. Codified Laws §§ 37-1-3.2, *et seq.*, with respect to purchases of Bystolic in South Dakota by members of the Damages Class.
- y. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of Bystolic in Tennessee by members of the Damages Class.
- z. Utah Code Ann. §§ 76-10-911, *et seq.*, with respect to purchases of Bystolic in Utah by members of the Damages Class.

- aa. Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases of Bystolic in Vermont by members of the Damages Class.
- bb. W. Va. Code §§ 47-18-3, *et seq.*, with respect to purchases of Bystolic in West Virginia by members of the Damages Class.
- cc. Wis. Stat. § 133.03, *et seq.*, with respect to purchases of Bystolic in Wisconsin by members of the Damages Class.

264. Plaintiff and members of the Damages Class have been injured in their business or property by reason of Defendants' violations of the laws set forth above, in that Plaintiff and Class members were: (a) denied the opportunity to purchase lower-priced generic Bystolic; and (b) paid higher prices for Bystolic than they would have paid but for Defendants' unlawful conduct. These injuries are of the type that the above laws were designed to prevent and flow from that which makes Defendants' conduct unlawful.

265. Plaintiff and the Damages Class accordingly seek damages and multiple damages as permitted by law for their injuries by Defendants' violations of the aforementioned statutes.

FIFTH CLAIM FOR RELIEF
Conspiracy to Monopolize Under State Law

266. Plaintiff incorporates the allegations set forth above as if fully set forth herein.

267. Plaintiff brings this claim on behalf of the Damages Class.

268. As described above, throughout the relevant time period Defendants have possessed monopoly power nationwide and in each of the United States in the market for nebivolol hydrochloride. No other manufacturer sold a competing version of Bystolic during the relevant time period.

269. Defendants willfully and unlawfully engaged in a continuing illegal conspiracy (or conspiracies) with the Generic Companies to monopolize the nebivolol hydrochloride 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.

270. Defendants knowingly and intentionally conspired to monopolize the Bystolic and AB-rated bioequivalent nebivolol hydrochloride products market as described above. Defendants accomplished this scheme by, among other things, (1) entering into illegal agreements that delayed the entry of generic Bystolic in order to lengthen the period in which Defendants' brand Bystolic could monopolize the market and make supracompetitive profits; (2) raising and maintaining prices so that Plaintiff and Damages Class members would pay for Bystolic at supracompetitive prices; and (3) otherwise conspiring to unlawfully monopolize and conspire to monopolize the market for nebivolol hydrochloride.

271. The goal, purpose, and effect of Defendants' scheme was to prevent and delay the sale of nebivolol hydrochloride products in the United States and its territories at prices significantly below Defendants' prices for Bystolic, thereby effectively preventing the price of nebivolol hydrochloride products from declining dramatically while maintaining and extending its monopoly power with respect to nebivolol hydrochloride products.

272. Plaintiff and members of the Damages Class purchased substantial amounts of Bystolic indirectly from Defendants and/or other manufacturers.

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

274. Had manufacturers of generic nebivolol hydrochloride entered the market and lawfully competed with Defendants, Plaintiff and members of the Damages Class would have substituted lower-priced generic nebivolol hydrochloride products for the higher-priced brand-

name Bystolic for some or all of their nebivolol hydrochloride products requirements, and/or would have paid lower net prices on their remaining Bystolic and/or AB-rated bioequivalent purchases.

275. But for Defendants' illegal conduct, competitors would have begun marketing generic versions of Bystolic during the relevant period.

276. By engaging in the foregoing conduct, Defendants violated the following state antitrust laws:

- a. Ariz. Rev. Stat. Ann. §§ 44-1403, *et seq.*, with respect to purchases of Bystolic in Arizona by members of the Damages Class.
- b. Cal. Bus. & Prof. Code §§ 16720, *et seq.*, with respect to purchases of Bystolic in California by members of the Damages Class.
- c. Conn. Gen. Stat. §§ 35-27, *et seq.*, with respect to purchases of Bystolic in Connecticut by members of the Damages Class.
- d. D.C. Code §§ 28-4503, *et seq.*, with respect to purchases of Bystolic in the District of Columbia by members of the Damages Class.
- e. Haw. Rev. Stat. §§ 480-9, *et seq.*, with respect to purchases of Bystolic in Hawaii by members of the Damages Class.
- f. 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to purchases of Bystolic in Illinois by members of the Damages Class.
- g. Iowa Code §§ 553.5 *et seq.*, with respect to purchases of Bystolic in Iowa by members of the Damages Class.
- h. Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases of Bystolic in Kansas by members of the Damages Class.
- i. Me. Stat. tit. 10, § 1102, *et seq.*, with respect to purchases of Bystolic in Maine by members of the Damages Class.
- j. Md. Code, Com Law, Section 11-204, *et seq.* with respect to purchases of Bystolic in Maryland by members of the Damages Class.
- k. Mich. Comp. Laws §§ 445.773, *et seq.*, with respect to purchases of Bystolic in Michigan by members of the Damages Class.

- l. Minn. Stat. §§ 325D.52, *et seq.*, with respect to purchases of Bystolic in Minnesota by members of the Damages Class.
- m. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases of Bystolic in Mississippi by members of the Damages Class.
- n. Neb. Rev. Stat. §§ 59-802, *et seq.*, with respect to purchases of Bystolic in Nebraska by members of the Damages Class.
- o. Nev. Rev. Stat. §§ 598A.060, *et seq.*, with respect to purchases of Bystolic in Nevada by members of the Damages Class.
- p. N.H. Rev. Stat. Ann. §§ 356:3, *et seq.*, with respect to purchases of Bystolic in New Hampshire by members of the Damages Class.
- q. N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases of Bystolic in New Mexico by members of the Damages Class.
- r. N.Y. Gen. Bus. Law §§ 340, *et seq.*, with respect to purchases of Bystolic in New York by members of the Damages Class.
- s. N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases of Bystolic in North Carolina by members of the Damages Class.
- t. N.D. Cent. Code §§ 51-08.1-03, *et seq.*, with respect to purchases of Bystolic in North Dakota by members of the Damages Class.
- u. Or. Rev. Stat. §§ 646.730, *et seq.*, with respect to purchases of Bystolic in Oregon by members of the Damages Class.
- v. P.R. Laws Ann. tit. 10, §§ 260, *et seq.*, with respect to purchases of Bystolic in Puerto Rico by members of the Damages Class.
- w. R.I. Gen. Laws §§ 6-36-7 *et seq.*, with respect to purchases of Bystolic in Rhode Island by members of the Damages Class.
- x. S.D. Codified Laws §§ 37-1-3.2, *et seq.*, with respect to purchases of Bystolic in South Dakota by members of the Damages Class.
- y. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of Bystolic in Tennessee by members of the Damages Class.
- z. Utah Code Ann. §§ 76-10-3104, *et seq.*, with respect to purchases of Bystolic in Utah by members of the Damages Class.
- aa. Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases of Bystolic in Vermont by members of the Damages Class.

- bb. W. Va. Code §§ 47-18-4, *et seq.*, with respect to purchases of Bystolic in West Virginia by members of the Damages Class.
- cc. Wis. Stat. § 133.03, *et seq.*, with respect to purchases of Bystolic in Wisconsin by members of the Damages Class.

SIXTH CLAIM FOR RELIEF
Unfair Methods of Competition, and Unfair and Deceptive Acts
in Violation of State Consumer Protection Laws

- 277. Plaintiff incorporates the allegations set forth above as if fully set forth herein.
- 278. Plaintiff brings this claim on behalf of the Damages Class.
- 279. Defendants engaged in unfair competition, and/or unfair, unconscionable, and/or deceptive acts or practices in violation of the state consumer protection statutes listed below.
- 280. As a direct and proximate result of Defendants' anticompetitive, deceptive, unfair, and/or unconscionable acts of practices, Plaintiff and Damages Class members were: (a) denied the opportunity to purchase lower-priced generic Bystolic; and (b) paid higher prices for Bystolic than they would have paid but for Defendants' unlawful conduct.
- 281. The gravity of harm from Defendants' wrongful conduct significantly outweighs any conceivable utility from that conduct. Plaintiff and Damages Class members could not reasonably have avoided injury from Defendants' wrongful conduct.
- 282. There was and is a gross disparity between the price that Plaintiff and the Damages Class members paid for Bystolic and the value they received. Much more affordable generic Bystolic would have been and would be available, and prices for Bystolic would have been and would be far lower, but for Defendants' anticompetitive, unfair, unconscionable, and deceptive conduct.
- 283. By engaging in such conduct, Defendants violated the following consumer protection statutes:

- a. Alaska Stat. Ann. § 45.50.471, *et seq.*, with respect to purchases in Alaska by members of the Damages Class.
- b. Ariz. Rev. Stat. Ann. §§ 44-1521, *et seq.*, with respect to purchases in Arizona by members of the Damages Class.
- c. Ark. Code Ann. §§ 4-88-101, *et seq.*, with respect to purchases in Arkansas by members of the Damages Class.
- d. Cal. Bus. & Prof Code §§ 17200, *et seq.*, with respect to purchases in California by members of the Damages Class.
- e. Conn. Gen. Stat. §§ 42-110b, *et seq.*, with respect to purchases in California by members of the Damages Class.
- f. D.C. Code §§ 28-3901, *et seq.*, with respect to purchases in D.C. by members of the Damages Class.
- g. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases in Florida by members of the Damages Class.
- h. Haw. Rev. Stat. §§ 481-1, *et seq.*, with respect to purchases in Hawaii by members of the Damages Class.
- i. Idaho Code §§ 48-601, *et seq.*, with respect to purchases in Idaho by members of the Damages Class.
- j. 815 Ill. Comp. Stat. 505/1, *et seq.*, with respect to purchases in Illinois by members of the Damages Class.
- k. Kan. Stat. Ann. §§ 50-623, *et seq.*, with respect to purchases in Kansas by members of the Damages Class.
- l. Me. Stat. tit. 5, §§ 207, *et seq.*, with respect to purchases in Maine by members of the Damages Class.
- m. Mass. Gen. Laws ch. 93A, §§ 1, *et seq.*, with respect to purchases in Massachusetts by members of the Damages Class.
- n. Mich. Comp. Laws §§ 445.901, *et seq.*, with respect to purchases in Michigan by members of the Damages Class.
- o. Minn. Stat. §§ 325F.68, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to purchases in Minnesota by members of the Damages Class.
- p. Mo. Rev. Stat. §§ 407.010, *et seq.*, with respect to purchases in Missouri by members of the Damages Class.

- q. Neb. Rev. Stat. §§ 59-1601, *et seq.*, with respect to purchases in Nebraska by members of the Damages Class.
- r. Nev. Rev. Stat. Ann. §§ 598.0903, *et seq.*, with respect to purchases in Nevada by members of the Damages Class.
- s. N.H. Rev. Stat. Ann. §§ 358-A:1, *et seq.*, with respect to purchases in New Hampshire by members of the Damages Class.
- t. N.M. Stat. Ann. §§ 57-12-1, *et seq.*, with respect to purchases in New Mexico by members of the Damages Class.
- u. N.Y. Gen. Bus. Law §§ 349, *et seq.*, with respect to purchases in New York by members of the Damages Class.
- v. N.C. Gen. Stat. §§ 75-1.1, *et seq.*, with respect to purchases in North Carolina by members of the Damages Class.
- w. Or. Rev. Stat. §§ 646.605, *et seq.*, with respect to purchases in Oregon by members of the Damages Class.
- x. R.I. Gen. Laws §§ 6-13.1-1, *et seq.*, with respect to purchases in Rhode Island by members of the Damages Class.
- y. S.C. Code Ann. §§ 39-5-20, *et seq.*, with respect to purchases in South Carolina by Damages Class members.
- z. S.D. Codified Laws §§ 37-24-6, *et seq.*, with respect to purchases in South Dakota by members of the Damages Class.
- aa. Tenn. Code Ann. §§ 47-18-101, *et seq.*, with respect to purchases in Tennessee by members of the Damages Class.
- bb. Utah Code Ann. §§ 13-11-1, *et seq.*, with respect to purchases in Utah by members of the Damages Class.
- cc. Vt. Stat Ann. tit. 9, § 2453, *et seq.*, with respect to purchases in Vermont by members of the Damages Class.
- dd. W. Va. Code §§ 46A-6-101, *et seq.*, with respect to purchases in West Virginia by members of the Damages Class.
- ee. Wis. Stat. § 100.20, *et seq.*, with respect to purchases in Wisconsin by members of the Damages Class.

284. Plaintiff and members of the Damages Class have been injured in their business and property by reason of Defendants' anticompetitive, unfair, unconscionable, and/or deceptive

conduct. 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.

285. On behalf of itself and the Damages Class, Plaintiff seeks all appropriate relief provided for under the foregoing statutes.

SEVENTH CLAIM FOR RELIEF
Unjust Enrichment

286. Plaintiff incorporates the allegations set forth above as if fully set forth herein.

287. Plaintiff brings this claim on behalf of the Damages Class.

288. To the extent required, this claim is pleaded in the alternative to the other claims in this complaint.

289. As a result of their unlawful conduct described above, Defendants have and will continue to be unjustly enriched. Defendants have been unjustly enriched by the receipt of, at a minimum, unlawfully inflated prices and unlawful profits on Bystolic.

290. Defendants' financial benefits are traceable to Plaintiff's and Damages Class members' overpayments for Bystolic.

291. Plaintiff and members of the Damages Class have conferred and continue to confer an economic benefit upon Defendants in the nature of profits resulting from the unlawful overcharges described herein, to the economic detriment of Plaintiff and members of the Damages Class.

292. Defendants have benefited from their unlawful acts and it would be inequitable for Defendants to be permitted to retain any of the ill-gotten gains resulting from the overpayments made by Plaintiff and the members of the Damages Class for Bystolic manufactured by Defendants during the Class Period.

293. It would be futile for Plaintiff and members of the Damages Class to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which they indirectly purchased Bystolic, as those intermediaries are not liable and would not compensate Plaintiff and Damages Class members for Defendants' unlawful conduct.

294. The economic benefit Defendants derived from overcharging Plaintiff and Damages Class members for Bystolic is a direct and proximate result of Defendants' unlawful and anticompetitive practices.

295. The financial benefits Defendants derived are ill-gotten gains that rightfully belong to Plaintiff and members of the Damages Class, who paid and continue to pay artificially inflated prices that inured to Defendants' benefit.

296. It would be inequitable under unjust enrichment principles under the laws of the states described below for Defendants to retain any of the overcharges Plaintiff and members of the Damages Class paid for Bystolic that were derived from Defendants' unfair, anticompetitive and unlawful methods, acts and trade practices.

297. Defendants are aware of and appreciate the benefits that Plaintiff and the members of the Damages Class have bestowed upon them.

298. Defendants should be ordered to disgorge all unlawful or inequitable proceeds they received in a common fund for the benefit of Plaintiff and members of the Damages Class, who collectively have no adequate remedy at law.

299. A constructive trust should be imposed upon all unlawful or inequitable sums Defendants received, which arise from overpayments for of Bystolic by Plaintiff and the Damages Class members.

300. Plaintiff and Damages Class members have no adequate remedy at law.

301. By engaging in the foregoing unlawful or inequitable conduct, which deprived Plaintiff and the Damages Class members of the opportunity to purchase lower-priced generic versions of Bystolic and forced them to pay higher prices for Bystolic, Defendants have been unjustly enriched in violation of the common law of various states and commonwealths, as outlined below:

Alabama

302. Defendants unlawfully overcharged end-payers who made purchases of or reimbursements for Bystolic in Alabama at prices that were higher than they would have been but for Defendants' actions.

303. Plaintiff and members of the Damages Class have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and members of the Damages Class.

304. Defendants accepted and retained the benefits bestowed upon them under inequitable and unjust circumstances arising from unlawful overcharges to Plaintiff and members of the Damages Class.

305. Defendants have benefitted at the expense of Plaintiff and members of the Damages Class from revenue resulting from unlawful overcharges for of Bystolic.

Arizona

306. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for Bystolic in Arizona at prices that were higher than they would have been but for Defendants' actions.

307. Defendants have been enriched by revenue resulting from unlawful overcharges for Bystolic.

308. Plaintiff has been impoverished by the overcharges for Bystolic resulting from Defendants' unlawful conduct.

309. Defendants' enrichment and Plaintiff's impoverishment are connected. Defendants have paid no consideration to any other person for any benefits they received from Plaintiff and members of the Damages Class.

310. There is no justification for Defendants' receipt of the benefits causing their enrichment and Plaintiff's impoverishment, because Plaintiff paid anticompetitive prices that inured to Defendants' benefit, and it would be inequitable for Defendants to retain any revenue gained from their unlawful overcharges.

311. Plaintiff and members of the Damages Class have no remedy at law.

California

312. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for Bystolic in California at prices that were higher than they would have been but for Defendants' actions.

313. Plaintiff and members of the Damages Class have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and Class members.

314. Defendants retained the benefits bestowed upon them under inequitable and unjust circumstances at the expense of Plaintiff and members of the Damages Class.

District of Columbia

315. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for Bystolic in the District of Columbia at prices that were higher than they would have been but for Defendants' actions.

316. Plaintiff and members of the Damages Class have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and members of the Damages Class.

317. Defendants accepted and retained the benefit bestowed upon them under inequitable and unjust circumstances arising from unlawful overcharges to Plaintiff and Damages Class members.

318. Under the circumstances, it would be inequitable and unjust for Defendants to retain such benefits.

Florida

319. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for Bystolic in Florida at prices that were higher than they would have been but for Defendants' actions.

320. Plaintiff and the members of the Damages Class have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and the members of the Damages Class.

321. Defendants appreciated the benefits bestowed upon them by Plaintiff and the members of the Damages Class.

322. It is inequitable for Defendants to accept and retain the benefits received without compensating Plaintiff and the members of the Damages Class.

Georgia

323. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for Bystolic in Georgia at prices that were higher than they would have been but for Defendants' actions.

324. Plaintiff and members of the Damages Class have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and members of the Damages Class.

325. Defendants retained the benefits bestowed upon them under unjust circumstances arising from unlawful overcharges to Plaintiff and members of the Damages Class.

326. It is unjust and inequitable for Defendants to retain the benefits received without compensating Plaintiff and members of the Damages Class.

Hawaii

327. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for Bystolic in Hawaii at prices that were higher than they would have been but for Defendants' actions.

328. Plaintiff and members of the Damages Class have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and members of the Damages Class.

329. It is unjust for Defendants to retain the benefits received without compensating Plaintiff and members of the Damages Class.

Illinois

330. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for Bystolic in Illinois at prices that were higher than they would have been but for Defendants' actions.

331. Plaintiff and members of the Damages Class have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and members of the Damages Class.

332. Defendants retained the benefits bestowed upon them under unjust circumstances arising from unlawful overcharges to Plaintiff and members of the Damages Class.

333. It is unjust and inequitable for Defendants to retain the benefits received without compensating Plaintiff and members of the Damages Class.

Iowa

334. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for Bystolic in Iowa at prices that were higher than they would have been but for Defendants' actions.

335. Defendants have been enriched by revenue resulting from unlawful overcharges for Bystolic, which revenue resulted from anticompetitive prices paid by Plaintiff, which inured to Defendants' benefit.

336. Defendants' enrichment has occurred at the expense of Plaintiff and members of the Damages Class.

337. It is against equity and good conscience for Defendants to be permitted to retain the revenue resulting from their unlawful overcharges.

Kansas

338. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for Bystolic in Kansas at prices that were higher than they would have been but for Defendants' actions.

339. Plaintiff and members of the Damages Class have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and members of the Damages Class.

340. Defendants retained the benefits bestowed upon them under unjust circumstances arising from unlawful overcharges to Plaintiff and members of the Damages Class.

341. Defendants were unjustly enriched at the expense of Plaintiff and members of the Damages Class.

Maine

342. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for Bystolic in Maine at prices that were more than they would have been but for Defendants' actions.

343. Plaintiff and members of the Damages Class have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and members of the Damages Class.

344. Defendants retained the benefits bestowed upon them under unjust circumstances arising from unlawful overcharges to Plaintiff and members of the Damages Class.

345. Defendants were aware of and appreciated the benefit bestowed upon them by Plaintiff and members of the Damages Class.

346. Defendants were unjustly enriched at the expense of Plaintiff and members of the Damages Class.

Massachusetts

347. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for Bystolic in Massachusetts at prices that were higher than they would have been but for Defendants' actions.

348. Plaintiff and members of the Damages Class have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and members of the Damages Class.

349. Defendants were aware of or appreciated the benefit conferred upon them by Plaintiff and members of the Damages Class.

350. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiff and members of the Damages Class. Fairness and good conscience require that Defendants not be permitted to retain the revenue resulting from their unlawful overcharges at the expense of Plaintiff and members of the Damages Class.

Michigan

351. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for Bystolic in Michigan at prices that were more than they would have been but for Defendants' actions.

352. Plaintiff and members of the Damages Class have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and members of the Damages Class.

353. Defendants retained the benefits bestowed upon them under unjust circumstances arising from unlawful overcharges to Plaintiff and members of the Damages Class.

354. Defendants were unjustly enriched at the expense of Plaintiff and members of the Damages Class.

Minnesota

355. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for Bystolic in Minnesota at prices that were more than they would have been but for Defendants' actions.

356. Defendants appreciated and knowingly accepted the benefits bestowed upon them by Plaintiff and members of the Damages Class. Defendants have paid no consideration to any other person for any of the benefits they have received from Plaintiff and members of the Damages Class.

357. It is inequitable for Defendants to accept and retain the benefits received without compensating Plaintiff and members of the Damages Class.

Mississippi

358. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for Bystolic in Mississippi at prices that were higher than they would have been but for Defendants' actions.

359. Defendants retain the benefit of overcharges received on the sales of Bystolic, which in equity and good conscience belong to Plaintiff and members of the Damages Class on account of Defendants' anticompetitive conduct.

Missouri

360. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for Bystolic in Missouri at prices that were more than they would have been but for Defendants' actions.

361. Plaintiff and members of the Damages Class have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and members of the Damages Class.

362. Defendants appreciated the benefit bestowed upon them by Plaintiff and members of the Damages Class.

363. Defendants accepted and retained the benefit bestowed upon them under inequitable and unjust circumstances arising from unlawful overcharges to Plaintiff and members of the Damages Class.

Nebraska

364. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for Bystolic in Nebraska at prices that were more than they would have been but for Defendants' actions.

365. Defendants received money from Plaintiff and members of the Damages Class as a direct result of the unlawful overcharges, and have retained this money. Defendants have paid no consideration to any other person in exchange for this money.

366. In justice and fairness, Defendants should disgorge such money and remit the overcharged payments back to Plaintiff and members of the Damages Class.

Nevada

367. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for Bystolic in Nevada at prices that were more than they would have been but for Defendants' actions.

368. Plaintiff and members of the Damages Class have conferred an economic benefit upon Defendants in the nature of revenue resulting from unlawful overcharges for Bystolic.

369. Defendants appreciated the benefits bestowed upon them by Plaintiff and members of the Damages Class, for which they have paid no consideration to any other person.

370. Defendants have knowingly accepted and retained the benefits bestowed upon them by Plaintiff and members of the Damages Class.

371. The circumstances under which Defendants have accepted and retained the benefits bestowed upon them by Plaintiff and members of the Damages Class are inequitable in that they result from Defendants' unlawful overcharges for Bystolic.

New Hampshire

372. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for Bystolic in New Hampshire at prices that were higher than they would have been but for Defendants' actions.

373. Defendants have received a benefit from Plaintiff in the nature of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants.

374. Under the circumstances, it would be unconscionable for Defendants to retain such benefits.

New Mexico

375. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for Bystolic in New Mexico at prices that were higher than they would have been but for Defendants' actions.

376. Defendants have knowingly benefitted at the expense of Plaintiff and members of the Damages Class from revenue resulting from unlawful overcharges for Bystolic.

377. To allow Defendants to retain the benefits would be unjust because the benefits resulted from anticompetitive pricing that inured to Defendants' benefit and because Defendants have paid no consideration to any other person for any of the benefits they received.

New York

378. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for Bystolic in New York at prices that were higher than they would have been but for Defendants' actions.

379. Defendants have been enriched by revenue resulting from unlawful overcharges for Bystolic, which revenue resulted from anticompetitive prices paid by Plaintiff, which inured to Defendants' benefit.

380. Defendants' enrichment has occurred at the expense of Plaintiff and members of the Damages Class.

381. It is against equity and good conscience for Defendants to be permitted to retain the revenue resulting from their unlawful overcharges.

North Carolina

382. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for Bystolic in North Carolina at prices that were higher than they would have been but for Defendants' actions.

383. Plaintiff and members of the Damages Class have conferred an economic benefit upon Defendants in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and members of the Damages Class.

384. Plaintiff did not interfere with Defendants' affairs in any manner that conferred these benefits upon Defendants.

385. The benefits conferred upon Defendants were not gratuitous, in that they comprised revenue created by unlawful overcharges arising from Defendants' actions to delay entry of generic versions of Bystolic to the market.

386. The benefits conferred upon Defendants are measurable, in that the revenue Defendants have earned due to unlawful overcharges are ascertainable by review of sales records and pay-for-delay agreements themselves.

387. Defendants consciously accepted the benefits and continue to do so as of the date of this filing.

North Dakota

388. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for Bystolic in North Dakota at prices that were higher than they would have been but for Defendants' actions.

389. Defendants have been enriched by revenue resulting from unlawful overcharges for Bystolic.

390. Plaintiff has been impoverished by the overcharges for Bystolic resulting from Defendants' unlawful conduct.

391. Defendants' enrichment and Plaintiff's impoverishment are connected. Defendants have paid no consideration to any other person for any benefits they received directly or indirectly from Plaintiff and members of the Damages Class.

392. There is no justification for Defendants' receipt of the benefits causing their enrichment, because Plaintiff paid anticompetitive prices that inured to Defendants' benefit, and it would be inequitable for Defendants to retain any revenue gained from their unlawful overcharges.

393. Plaintiff and members of the Damages Class have no remedy at law.

Oregon

394. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for Bystolic in Oregon at prices that were more than they would have been but for Defendants' actions.

395. Plaintiff and members of the Damages Class have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and members of the Damages Class.

396. Defendants were aware of the benefit bestowed upon them by Plaintiff and members of the Damages Class.

397. It would be inequitable and unjust for Defendants to retain any of the overcharges for Bystolic derived from Defendants' unfair conduct without compensating Plaintiff and Class members.

Pennsylvania

398. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for Bystolic in Pennsylvania at prices that were higher than they would have been but for Defendants' actions.

399. Plaintiff and members of the Damages Class have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and members of the Damages Class.

400. Defendants appreciated the benefit bestowed upon them by Plaintiff and members of the Damages Class.

401. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiff and members of the Damages Class.

Puerto Rico

402. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for Bystolic in Puerto Rico at prices that were higher than they would have been but for Defendants' actions.

403. Defendants have been enriched by revenue resulting from unlawful overcharges for Bystolic.

404. Plaintiff has been impoverished by the overcharges for Bystolic resulting from Defendants' unlawful conduct.

405. Defendants' enrichment and Plaintiff's impoverishment are connected.

406. There is no justification for Defendants' receipt of the benefits causing their enrichment and Plaintiff's impoverishment, because Plaintiff paid anticompetitive prices that inured to Defendants' benefit, and it would be inequitable for Defendants to retain any revenue gained from their unlawful overcharges.

407. Plaintiff and members of the Damages Class have no remedy at law.

Rhode Island

408. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for Bystolic in Rhode Island at prices that were higher than they would have been but for Defendants' actions.

409. Plaintiff and members of the Damages Class have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and members of the Damages Class.

410. Defendants were aware of and/or recognized the benefit bestowed upon them by Plaintiff and the Damages Class members.

411. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiff and members of the Damages Class.

South Dakota

412. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for Bystolic in South Dakota at prices that were higher than they would have been but for Defendants' actions.

413. Plaintiff and members of the Damages Class have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and members of the Damages Class.

414. Defendants were aware of the benefit bestowed upon them by Plaintiff and Damages Class members.

415. Under the circumstances, it would be inequitable and unjust for Defendants to retain such benefits without reimbursing Plaintiff and members of the Damages Class.

Tennessee

416. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for Bystolic in Tennessee at prices that were higher than they would have been but for Defendants' actions.

417. Plaintiff and members of the Damages Class have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and members of the Damages Class.

418. Defendants were aware of or appreciated the benefit bestowed upon them by Plaintiff and members of the Damages Class.

419. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiff and members of the Damages Class.

420. It would be futile for Plaintiff and members of the Damages Class to exhaust all remedies against the entities with which Plaintiff and members of the Damages Class have privity of contract because Plaintiff and members of the Damages Class did not purchase Bystolic directly from any Defendant.

Utah

421. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for Bystolic in Utah at prices that were higher than they would have been but for Defendants' actions.

422. Plaintiff and members of the Damages Class have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and members of the Damages Class.

423. Defendants were aware of or appreciated the benefit bestowed upon them by Plaintiff and members of the Damages Class.

424. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiff and members of the Damages Class.

Vermont

425. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for Bystolic in Vermont at prices that were higher than they would have been but for Defendants' actions.

426. Plaintiff and members of the Damages Class have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and members of the Damages Class.

427. Defendants accepted the benefit bestowed upon them by Plaintiff and members of the Damages Class.

428. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiff and members of the Damages Class.

West Virginia

429. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for Bystolic in West Virginia at prices that were higher than they would have been but for Defendants' actions.

430. Plaintiff and members of the Damages Class have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and members of the Damages Class.

431. Defendants were aware of or appreciated the benefit bestowed upon them by Plaintiff and members of the Damages Class.

432. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiff and members of the Damages Class.

Wisconsin

433. Defendants unlawfully overcharged end-payers, who made purchases of or reimbursements for Bystolic in Wisconsin at prices that were higher than they would have been but for Defendants' actions.

434. Plaintiff and members of the Damages Class have conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of Plaintiff and members of the Damages Class.

435. Defendants appreciated the benefit bestowed upon them by Plaintiff and members of the Damages Class.

436. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiff and members of the Damages Class.

XV. PRAYER FOR RELIEF

437. WHEREFORE, Plaintiff, on behalf of itself and the proposed Classes, prays for judgment against all Defendants, jointly and severally, as follows:

- a. Determine that this action may be maintained as a class action pursuant to Rules 23(a), (b)(2) and (b)(3) of the Federal Rules of Civil Procedure and direct that reasonable notice of this action, as provided by Rule 23(c)(2), be given to the Classes, and appoint Plaintiff as the named representative of the Classes;
- b. Grant injunctive relief that restores Defendants' incentives to compete in the relevant market;
- c. Enter joint and several judgments against each of the Defendants and in favor of Plaintiff and the proposed Classes;
- d. Award Plaintiff and the Damages Class damages (i.e., three times overcharges) in an amount to be determined at trial, plus interest in accordance with law;
- e. Grant Plaintiff and the Injunctive Relief Class equitable relief in the nature of disgorgement, restitution, and the creation of a constructive trust to remedy Defendants' unjust enrichment;
- f. Award Plaintiff and the Classes their costs of suit, including reasonable attorneys' fees, as provided by law; and
- g. Award such further and additional relief as the case may require and the Court may deem just and proper under the circumstances.

XVI. JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff, on behalf of itself and the proposed Classes, demands a trial by jury on all issues so triable.

DATED: July 29, 2020

Respectfully submitted,

/s/ Robert G. Eisler

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Class*