IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TEXARKANA DIVISION

The UNITED STATES OF AMERICA ex rel. LOWER DRUG PRICES FOR CONSUMERS, LLC;

Plaintiff/Relator,

versus

ALLERGAN plc,
FOREST LABORATORIES, LLC
and
FOREST LABORATORIES HOLDINGS, LTD.

Defendants.

Civil Action 5:16cv09

JURY TRIAL DEMANDED

[FILED UNDER SEAL]

FILED IN CAMERA AND UNDER SEAL PURSUANT TO

31 U.S.C. § 3730(b)(2)

DO NOT ENTER ON PACER

DO NOT PUBLICLY DISTRIBUTE

COMPLAINT
INTRODUCTION

1. This is a *qui tam* action brought by Lower Drug Prices for Consumers, LLC (herein "LDPFC" or "Relator") on behalf of the United States of America against Defendant Allergan plc and its wholly-owned subsidiaries, Defendant Forest Laboratories LLC and Defendant Forest Laboratories Holdings, Ltd. (collectively, "Defendants"). Relator seeks to recover on behalf of the United States of America under the federal False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq.*, for damages, civil penalties, and treble damages related to false claims made or caused to be made by Defendants for overpayment and overcharges related to the pharmaceutical drug nebivolol hydrochloride ("nebivolol"), which is marketed and sold in the United States by Defendants under the trade name "Bystolic®".

2. The damages alleged in this action arise from overpayments made directly or indirectly by the United States government with respect to nebivolol (Bystolic), through various federal agencies and programs, including but not limited to: Medicare (Parts B and Part D), Medicaid, the Children's Health Insurance Program (CHIP), Indian Health Services, Prison Health Services, the Veterans Administration, Military Health Systems (MHS), Defense Health Agency / TRICARE, the Coast Guard, and the Federal Bureau of Prisons.

3. As alleged in detail herein, nebivolol (Bystolic) is currently sold in the United States at a false and/or fraudulent price because of Defendants' claim to patent protection over nebivolol (Bystolic) due to their ownership and control of United States Patent No. 6,545,040 (the "'040 Patent," attached to this Complaint as Exhibit J). Since June 2, 2015, the '040 Patent has been the only unexpired patent listed in the Food and Drug Administration's Orange Book of Approved Drug Products with Therapeutic Equivalents ("Orange Book") covering nebivolol

(Bystolic). But for the reasons alleged in detail herein, the '040 Patent is an invalid patent that should never have been issued by the United States Patent and Trademark Office. In the absence of the '040 Patent, other pharmaceutical companies would have quickly entered the market to sell generic versions of nebivolol on or after June 2, 2015 (at the expiration of U.S. Patent No. 5,759,580 – the only other patent listed in the Orange Book as covering nebivolol) – which would have resulted in the end of Defendants' monopoly over nebivolol in the United States and a swift drop in the price for the drug, to no more than 10-20 percent of its current market price. For these reasons, every claim made to the federal government today for payment or reimbursement of nebivolol (Bystolic) is a false claim, and every federal government payment or reimbursement today for nebivolol (Bystolic) is an overpayment.

4. As alleged in detail herein, Defendants know, and have known for many years, that the '040 Patent is invalid. The information disclosed herein as the basis for the invalidity of the '040 Patent is and would have been well-known to any company engaged in new drug research – even prior to the March 23, 1988 alleged priority date of the '040 Patent. Yet Defendants and their predecessors did not disclose this information to the United States Patent and Trademark Office. Defendants have used the '040 Patent to prevent potential generic competitors from entering the market for nebivolol; yet Defendants have taken affirmative steps to prevent the validity of '040 Patent from being adjudicated in the United States. Defendants' activities with respect to the '040 Patent are currently the subject of an antitrust investigation by the United States Federal Trade Commission. In at least the United Kingdom (and, on information and belief, in other foreign jurisdictions), Defendants' foreign counterparts to the '040 Patent have been declared invalid.

5. By virtue of their knowing and intentional activities, Defendants have themselves made false claims to the United States government for payment and/or reimbursement of payments for nebivolol (Bystolic), and have caused others to make similar false claims to the federal government. As a result, the United States of America has suffered and continues to suffer substantial damages as a result of these overcharges and overpayments.

6. LDPFC is a whistleblower that has standing to bring this qui tam action on behalf of the United States of America as alleged in detail herein. Upon first learning that the '040 Patent might be an invalid patent, individuals associated with LDPFC personally began to investigate and gather facts to determine whether or not the '040 Patent is in fact invalid. LDPFC retained attorneys familiar with patent law and patent validity to assist with its investigation. LDPFC also retained technical subject matter experts with specialized knowledge in the fields of cardiovascular science, pharmaceutical new drug research, organic chemistry, and chemical engineering to assist with the investigation. After months of investigation, involving substantial hours of work and substantial monetary resources expended, LDPFC (in connection with its attorneys and experts) came to the inescapable conclusion that the '040 Patent is an invalid patent that should not have been allowed to issue by the United States Patent and Trademark Office, and that should not be listed in the Orange Book.

7. Much of the facts and evidence uncovered by LDPFC during its investigation were not previously presented to or otherwise known by the federal government and its various agencies (including the United States Patent and Trademark Office during the prosecution and examination of the patent application that led to the '040 Patent). The facts and evidence uncovered by LDPFC's investigation include patents and printed publications bearing directly on the invalidity of the '040 Patent; and they also include detailed sworn testimony of LDPFC's

experts (in the form of sworn declarations) providing a synthesis of LDPFC's investigation, and also providing sworn testimony supporting the conclusion that the '040 Patent is invalid.

8. On December 14, 2015 LDPFC became a whistleblower when it provided the results of its investigation to the federal government by instructing its attorney to send the letter that is attached to this Complaint as Exhibit A. Exhibit A was sent to the U.S. Department of Justice, the U.S. Department of Health and Human Services, the Veterans Administration, the Department of Defense, and the Department of Homeland Security. The letter (Exhibit A) provided a detailed explanation of the reasons the '040 Patent is invalid, and it also was accompanied by, *inter alia*: (1) the sworn declarations of Dr. Daniel W. Armstrong (attached as Exhibit B to this Complaint) and Dr. Ronald W. Millard (attached as Exhibit C to this Complaint) and (2) an electronic memory stick containing 53 documents found or created by LDPFC during its investigation and which are listed on the table attached as Exhibit D to this Complaint.

9. On December 22, 2015 LDPFC took further steps as a whistleblower when it filed a Petition for *Inter Partes* review ("IPR") pursuant to 35 U.S.C. § 311, et. seq. in the Patent Trial and Appeal Board of the United States Patent and Trademark Office, seeking to invalidate the '040 Patent using the same facts and evidence uncovered and created during its investigation. A copy of LDPFC's IPR Petition is attached to this Complaint as Exhibit E.

10. As a result of the foregoing activities, LDPFC has standing to bring this Complaint under the FCA on behalf of the United States of America.

11. Pursuant to 31 U.SC. § 3730(b)(2), this complaint must be filed under seal and must remain sealed for a minimum of sixty days without service on the Defendants, to allow the government time to investigate the allegations contained herein and to determine whether the United States of America will intervene to join this action.

THE PARTIES

12. Relator Lower Drug Prices for Consumers LLP ("LDPFC") is a Limited Liability Company organized under the laws of Delaware, with its principal office located at 12 Roszel Road, Suite C-101, Princeton, New Jersey 08540. LDPFC brings this civil action for violations of the federal False Claims Act, 31 U.S.C. § 3729, et seq. on behalf of itself and in its capacity as a relator on behalf of the United States of America pursuant to 31 U.S.C. § 3730(b)(1).

13. On information and belief, Defendant Allergan plc ("Allergan") is an Ireland public limited company having its principal place of business at 1 Grand Canal Square, Docklands, Dublin 2, Ireland and its United States principal place of business at 400 Interpace Parkway, Parsippany, NJ 07054.

14. On information and belief, Defendant Forest Laboratories, LLC is a Delaware limited liability company having a principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054. On information and belief, Forest Laboratories, LLC is the company formerly known as Forest Laboratories, Inc.

15. On information and belief, Defendant Forest Laboratories Holdings, Ltd. is an Irish corporation having a principal place of business as Cumberland House, 1 Victoria Street, Hamilton HM11, Bermuda.

16. In this complaint, Defendant Forest Laboratories, LLC and Defendant Forest Laboratories Holdings, Ltd. are referred to collectively as "Forest Labs" or the "Forest Labs Defendants." On information and belief, the Forest Labs Defendants are subsidiaries of Allergan; and the Forest Labs Defendants (either directly or indirectly) are wholly owned and controlled by Allergan. On information and belief, Allergan exercises complete dominion and control over the activities of the Forest Labs Defendants.

JURISDICTION ANDVENUE

17. The legal claims asserted by LDPFC in this complaint arise under the federal False Claims Act, 31 U.S.C. § 3729 *et seq.* This court has original subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331.

18. This Court has personal jurisdiction over each Defendant. Each Defendant has submitted false claims as alleged herein to the federal government, and/or caused others to submit false claims as alleged herein, to the federal government within the State of Texas and within the Eastern District of Texas. Moreover, each Defendant has systematic and continuous contacts with the State of Texas and the Eastern District of Texas by virtue of its extensive commercial activities within the state, including but not limited to its sale of nebivolol (Bystolic) in Texas and the Eastern District of Texas. Furthermore, each Defendant has (either itself or through intermediaries such as sales agents, distributors, wholesalers, and retailers) placed goods into the stream of commerce with the knowledge and expectation that such goods would be sold in Texas and the Eastern District of Texas, including but not limited to nebivolol (Bystolic). On information and belief, each Defendant has engaged in extensive additional activities that subject it to the personal jurisdiction of this Court, and that make the exercise of personal jurisdiction by this Court consistent with requirements of due process.

19. Venue is proper in this district pursuant to 28 U.S.C. § 1391 and 31 U.S.C. § 3732. Each Defendant (either itself or through intermediaries such as sales agents, distributors, wholesalers, and retailers) can be found, resides, transacts business, and/or conducts acts proscribed by 31 U.S.C. § 3729(a)(1) in the Eastern District of Texas.

FACTUAL ALLEGATIONS

The Current Market Price of Nebivolol (Bystolic) is Substantially Inflated Because of the '040 Patent

20. The drug nebivolol hydrochloride ("nebivolol") was approved by the U.S. Food and Drug Administration on or about December 17, 2007 and is listed in the Orange Book. Nebivolol is sold commercially by Defendants in the United States under the trade name "Bystolic."

21. Nebivolol (Bystolic) is known as a "branded" drug, meaning that it is purported to be subject to patent protection, and therefore it is not subject to generic competition in the United States. Currently, Bystolic is the only commercially available form of nebivolol that can be purchased by United States consumers. There are no commercially available generic substitutes. Defendants currently enjoy a monopoly in the commercial market for nebivolol.

22. The Orange Book lists two U.S. patents covering nebivolol – U.S. Patent No. 5,759,580 (the "'580 Patent") and the '040 Patent. The '580 Patent expired on June 2, 2015, meaning that since that date the '040 Patent is the only unexpired United States patent covering nebivolol (Bystolic) and protecting Defendants' monopoly on the nebivolol market.

23. Because the '040 Patent is invalid (as described in detail below), nebivolol should have been available for production and sale by generic pharmaceutical manufacturers when the '580 Patent expired on June 2, 2015. The continued listing of the '040 Patent in the Orange Book and continued assertion by Defendants that the '040 Patent is valid, has precluded and continues to preclude generic competitors from entering the market and providing competing forms of nebivolol to consumers.

24. In fact, several pharmaceutical companies were prepared to begin manufacturing generic forms of nebivolol upon expiration of the '580 Patent. But they were unable to begin

generic production because Forest Labs sued at least seven would-be competitors for infringement of the '040 Patent. The companies sued by Forest Labs, who by all appearances would otherwise have entered the commercial market for nebivolol, included at least: Amerigen Pharmaceuticals; Glenmark Pharmaceuticals; Hetero Labs; Torrent Pharmaceuticals; Watson Laboratories; Alkem Laboratories; and Indchemie Health Specialties. Defendants then settled with each of these companies on terms that both prevented the validity of the '040 Patent from being determined by a court of law, and that also keeps generic nebivolol out of the United States market for many years.

25. On information and belief, Defendants' conduct in settling these patent infringement cases involving the '040 Patent is the subject of an ongoing investigation by the United States Federal Trade Commission for potential anticompetitive activity and/or potential anticompetitive effects.

26. Through their use of the '040 Patent, Defendants have excluded all competitors and have maintained their monopoly in the U.S. market for nebivolol. The resulting absence of price competition results in continued monopoly pricing for nebivolol (Bystolic). On information and belief, Bystolic on average today sells for $108-153 for a 30-day supply. With generic competition, the price of nebivolol would drop quickly and substantially—likely to just 10-20% of the current price within a few months, according to academic and peer-reviewed economic studies on branded and generic pharmaceutical pricing.

27. Defendants have publicly admitted that the price of nebivolol (Bystolic) would drop substantially in the absence of the '040 Patent. In its most recent Form 10-K filing with U.S. Securities and Exchange Commission, Defendant Allergan stated: "During the next few years, additional products of ours including some of our large revenue drivers, like Bystolic® . . .

will lose patent protection or likely become subject to generic competition. Competition from generic equivalents could result in a material impairment of our intangible assets . . . and may have a material adverse impact on our revenues, financial condition, results of operations and cash flows." Actavis plc (now known as Allergan plc) Form 10-K for the fiscal year ended December 31, 2014 (filed February 18, 2015) at 30. "During the next five years, additional products . . . will lose patent protection, . . . including Bystolic® . . . . Therefore, it is possible that a competitor may launch a generic version of these products at any time, which would result in a significant decline in the product's revenue and profit." *Id.* at 32.

28. The prevailing monopoly price for nebivolol (Bystolic), due solely to the '040 Patent, materially increases the price the United States federal government, directly and indirectly, pays for nebivolol and/or reimburses others who pay for nebivolol. At least the following federal agencies and programs are affected due to the inflated, monopoly pricing for nebivolol (Bystolic) as a result of the '040 Patent:

Agency	Program
Department of Health and Human Services • Center for Medicare and Medicaid Services • Public Health Services	• Medicare • Medicaid • CHIP • Indian Health Services • Prison Health Services
Department of Veterans Affairs	• VA prescription drug purchases and reimbursements
Department of Defense	• Military Health System (MHS) • Defense Health Agency / TRICARE
Department of Homeland Security	• Coast Guard
Department of Justice	• Federal Bureau of Prisons

The Current Market Price for Nebivolol (Bystolic) is a False Price Because the '040 Patent is Invalid and Should Never Have Been Allowed to Issue

29. LDPFC provided a detailed explanation to the federal government of the reasons that each and every claim of the '040 Patent is invalid in the letter that is attached to this Complaint as Exhibit A, and the reasons stated therein are hereby incorporated herein by reference.

30. LDPFC provided to the United States Patent and Trademark Office a further detailed explanation of the reasons that each and every claim of the '040 Patent are invalid in the Petition for *Inter Partes* Review that is attached to this Complaint as Exhibit E, and the reasons stated therein are hereby incorporated into this Complaint by reference. LDPFC anticipates and believes that each and every claim of the '040 Patent will be found to be unpatentable by the Patent Trial and Appeal Board in a final written decision following a full *Inter Partes* Review trial, based on the investigation and whistleblowing activities of LDPFC.

31. The independent claims of the '040 Patent describe and cover particular stereoisomeric forms of the nebivolol molecule. Claim 2 of the '040 Patent covers a combination of the RSSS stereoisomer and the SRRR stereoisomer. Claim 1 covers a purified form of the nebivolol RSSS stereoisomer alone. *See* Exhibit C, Millard Dec. at ¶¶ 72-73. These very same stereoisomers were specifically disclosed as part of Compound 84 of U.S. Patent No. 4,654,362 (the "'362 Patent") – more than four years prior to the earliest priority date of the '040 Patent. *See* Exhibit B, Armstrong Dec. at ¶¶ 58-64; Exhibit F. Compound 84, however, was a mixture that also contained two other stereoisomers of the same molecule (the RSRR and SRSS stereoisomers). *See* Exhibit B, Armstrong Dec. at ¶¶ 58-64.

32. Thus, the technical problem presented by the '040 Patent is nothing more than whether a person of ordinary skill in the art ("POSITA") at the time of the '040 Patent priority

date on March 23, 1988, would be capable of separating and purifying the stereochemical components of the prior art Compound 84 from the '362 Patent. *See* Exhibit B, Armstrong Dec. at ¶ 65. Given this technical problem, the patentability of Claims 1 and 2 of the '040 Patent presents a question that is identical to that addressed by the Federal Circuit Court of Appeals in *Aventis Pharma Deutschland GMBH v. Lupin, Ltd.*, 499 F.3d 1293 (Fed. Cir. 2007).

33. In Aventis, the Federal Circuit held that a patent claiming a compound of purified stereoisomers was obvious and invalid, where those stereoisomers had been disclosed in the prior art as a mixture with other stereoisomers of the same molecule. *See id.* at 1303. Under *Aventis*, the relevant issues in such a case are whether a POSITA would have been motivated to create the purified stereoisomeric forms of the racemic mixture, and whether the POSITA would have been able to carry out the required stereochemical separation without undue experimentation. *See id.* at 1301-1302.

34. Under the *Aventis* legal standard, the Millard and Armstrong declarations, along with the additional documents provided to the federal government by LDPFC, demonstrate that the '040 Patent is obvious in light of the prior art and, and is therefore invalid and should not have been issued by the U.S. Patent Office for the reasons set forth below.

35. Prior to 1988, hypertension was widely recognized as a condition with serious public health consequences. In 1985, the pharmaceutical industry estimated that $3.7 billion was spent worldwide annually on antihypertensive medications alone. Cardiovascular drug research had already undergone a significant period of growth beginning in the 1960s, and pharmaceutical companies continued in 1988 to invest heavily in new drug research for potential hypertension drugs. *See* Exhibit C, Millard Dec. at ¶¶32-36.

36. Prior to 1988 the stereoselective aspects of β-blocker drugs were well known. *See* Exhibit C, Millard Dec. at ¶¶59-70; Exhibit B, Armstrong Dec. at ¶ 69. Indeed, β-blockers were considered one of the best examples of the human body's stereoselectivity to pharmaceutical compounds. The benefits of cardioselective β-blockers (*i.e.* selective β-1 antagonists) were well known and highly desired. *See* Exhibit C, Millard Dec. at ¶56. For at least these reasons, a POSITA at the time of the '040 Patent invention would have selected Compound 84 of the '362 Patent as a highly desirable compound of interest for new drug investigation as a potential cardioselective β-blocker drug. *See id.* at ¶¶ 83-84.

37. By 1988, laboratory testing protocols for new drug investigation generally included investigation of individual stereoisomers and racemate pairs of enantiomers when the purified forms could be obtained. *See id.* at ¶¶ 65-70, 85-87. This was particularly true for potential β-blocker drugs given the human body's known stereoselectivity for such compounds. *See id.* For these reasons, a POSITA at the time of the '040 Patent would have been highly motivated to separate Compound 84 of the '362 Patent into its purified stereochemical forms.

38. Also prior to 1988, chromatographic techniques had largely been perfected for performing the required stereochemical separation of Compound 84. *See* Exhibit B, Armstrong Dec. at ¶¶ 40-56, 66. The four stereoisomers of Compound 84 consisted of two sets of racemate enantiomers, the [RSSS, SRRR] pair and the [RSRR, SRSS] pair. These pairs of racemates are diastereomers as to each other, and could easily be separated using conventional chromatography techniques, such as the techniques described in the Handbook of Chromatography (published in 1972). *See* Exhibit G; Exhibit B, Armstrong Dec. at ¶¶ 66, 72, 75-81.

39. A POSITA in March 1988 would have been motivated to separate the racemates of Compound 84 for two reasons: (1) for laboratory testing on the racemates in combination, and

(2) as an intermediate step in the purification of the individual enantiomers. *See* Exhibit C, Millard Dec. at ¶¶ 63, 66-69, 86, 93; Exhibit B, Armstrong Dec. at ¶ 72. The result of combining Compound 84 of the '362 Patent with the chromatography disclosed in the handbook of Chromatography would yield two racemic compounds – one of which would be identical to the [RSSS, SRRR] combination of the '362 Patent. *See* Exhibit B, Armstrong Dec. at ¶¶ 78-79. For these reasons, Claim 2 of the '040 Patent is invalid as obvious in light of the '362 Patent in combination with the Handbook of Chromatography. *See Aventis*, 499 F.3d at 1301.

40. A POSITA at the time of the '040 Patent in 1988 also would have been motivated to further separate the individual racemates produced from the previous step to achieve purified forms of the individual stereoisomers. This would have been done so that each individual stereoisomer could be subjected to new drug laboratory testing. *See* Exhibit C, Millard Dec. at ¶¶ 66-70, 85-87. Prior to 1988, the instruments and technique known as High Performance Liquid Chromatography ("HPLC") had largely been perfected for this purpose. *See* Exhibit B, Armstrong Dec. at ¶¶ 42-56.

41. Two particular publications disclose specific HPLC chiral stationary phase columns that had successfully resolved known β-blocker drugs with a high degree of efficiency. The Okamoto publication (Exhibit H to this Complaint), shows that the enantiomers of five known β-blocker drugs could be separated using chiral HPLC columns based on derivatives of cellulose triphenylcarbamate. *See* Exhibit B, Armstrong Dec. at ¶ 53. The Armstrong publication (Exhibit I to this Complaint) shows that the enantiomers of two known β-blockers could be separated using HPLC chiral columns based on β-cyclodextrin. *See* Exhibit B, Armstrong Dec. at ¶ 54.

42. A POSITA in March of 1988 would have been motivated to use these techniques to separate the individual enantiomers from the two racemic compounds yielded by the combination of Compound 84 and the conventional chromatography of the Handbook of Chromatography. *See* Exhibit C, Millard Dec. at ¶ 90; Exhibit B, Armstrong Dec. at ¶ 85-87, 96-98. The capabilities of doing so would have been well within the skillset of the POSITA at that time. *See* Exhibit B, Armstrong Dec. at ¶¶ 87-93, 101-106. Using either HPLC chiral column would have resulted in a successful separation of the enantiomers in their optically purified forms, and one of the resulting enantiomers would be the RSSS stereoisomer that is identical to the stereoisomer described by Claim 1 of the '040 Patent. *See id.* For these reasons, Claim 1 of the '040 Patent also is invalid as obvious in light of the '362 Patent in combination with the Handbook of Chromatography (Exhibit G), and in further view of either Okamoto (Exhibit H) or Armstrong (Exhibit I).

43. The previously described chromatographic separations would have been considered ordinary and routine to a POSITA at the time of the '040 Patent in 1988, given the state of the art at the time. At most, these separations would have involved routine and ordinary experimentation for adjusting the chromatographic conditions – the kind of routine experimentation that is inherent to all chromatography. *See* Exhibit B, Armstrong Dec. at ¶ 50. Moreover, the results of the combination of prior art references – the production of purified stereochemical forms of Compound 84 – would not have been an unexpected result. Instead, it would have been the intended and expected result of the combination, as would have been contemplated by a POSITA at the time. *See* Exhibit B, Armstrong Dec. at ¶¶ 73-74, 77, 81, 93, 106; Exhibit C, Millard Dec. at ¶¶ 88-92.

44. The remaining claims of the '040 Patent (Claims 3-6) are dependent claims that add nothing more than trivial limitations that do not independently support patentability. Claim 4 merely states that the recited stereoisomers exist in a 1:1 molar ratio; and Claim 3 states that the RSSS stereoisomer is present in an amount sufficient to potentiate the effects of the other isomer. Both of these characteristics are inherent properties of the claimed compound and therefore cannot support patentability. *See* Exhibit B, Armstrong Dec. at ¶ 80; Exhibit C, Millard Dec. at ¶ 99. Claims 5 and 6 are method claims which require administering the compounds of Claim 2 and Claim 4 in an "effective amount." But the determination of an "effective amount" of the compound is a routine and ordinary step for a POSITA at the time, as explicitly stated in the '040 Patent itself. *See* Exhibit C, Millard Dec. at ¶ 100.

45. For all these reasons, the results of LDPFC's investigation show that the '040 Patent is not valid, it should not have been allowed by the USPTO, and it should not be listed in the Orange Book.

Defendants have Submitted False Claims to the Federal Government, and Have Caused Others to Submit False Claims

46. Various programs of the United States federal government (alleged specifically above) purchase pharmaceutical products directly from Defendants and/or an agent of Defendant. Defendants have submitted claims for payment to the United States federal government, directly or indirectly to the various federal agencies, for payment as a result of these direct purchases of nebivolol (Bystolic).

47. All such claims submitted for payment since June 2, 2015, and continuing to this day, are false claims because they request payment at an inflated and false overprice. By submitting claims for payment at a monopoly price, Defendants are expressly and/or impliedly representing to the federal government that the '040 Patent is a valid patent that supports

Defendants' claim to exclusive rights to sell nebivolol (Bystolic) in the United States, and that supports Defendants' monopoly pricing for the drug. For the reasons previously stated, the express or implied claim that the '040 Patent is a valid patent is a false claim made in support of a false and inflated overprice for the drug.

48. On information and belief, since at least June 2, 2015, Defendants have failed to make statements or take actions required to have the '040 Patent removed from the Orange Book, or to correct previous misstatements that Defendants made to the U.S. Food and Drug Administration that caused the invalid '040 Patent to be listed improperly in the Orange Book with respect to nebivolol.

49. Moreover, the actions taken by Defendants with respect to the '040 Patent have caused others to submit false claims to the federal government for payment or reimbursement of payments made with respect to nebivolol (Bystolic). These other parties include, by way of example only: private insurance companies who provide prescription drug coverage plans under Medicare Part D or other similar federal programs, pharmacy benefit managers, pharmaceutical wholesalers or retail sales agents, health care providers, and others. Defendants' actions with respect to the '040 Patent have caused such parties to submit claims to the federal government (directly or indirectly) for payment or reimbursement of payment for nebivolol (Bystolic) at inflated and false overprices, for the reasons previously stated.

50. Defendants' actions that have caused others to submit false claims to the federal government for nebivolol include, without limitation: (1) failing to supply all relevant information to the United States Patent and Trademark Office during the process of examining and reexamining the '040 Patent; (2) making affirmative statements and taking other actions necessary to have the '040 Patent listed in the Orange Book as covering nebivolol; (3) on an

ongoing basis, failing to take corrective action to have the '040 Patent removed from the Orange Book; (4) using the '040 Patent, by filing lawsuit for patent infringement and otherwise, to exclude potential generic competitors from the United States market for nebivolol; (4) settling '040 Patent infringement lawsuits in a manner intended to prevent the validity of the '040 Patent from being adjudicated by a court of law; and (5) otherwise claiming a right to a monopoly position in the market for nebivolol in the United States and a right to monopoly pricing by virtue of the '040 Patent.

Defendants Have Acted with Knowledge that the '040 Patent is Invalid and that the Market Price for Nebivolol (Bystolic) is a False Price

51. For the reasons stated herein, Defendants have, since well before June 2, 2015, acted with knowledge that the '040 Patent is an invalid patent that should not have been allowed to issue by the United States Patent and Trademark Office, and that should not be listed in the Orange Book as covering nebivolol.

52. The evidence and documents uncovered by LDPFC during its investigation are (and have been for many years) well-known to any company engaged in the business of new drug discovery. The chromatography instruments that would have been used in March 1988 to perform the stereochemical separation of Compound 84 of the '362 Patent are among the most commonly used instruments in pharmaceutical laboratories. *See* Exhibit B, Armstrong Dec. at ¶ 40. The advances in HPLC chromatography the occurred in the late-1970s and early-1980s would have been well known to Defendants even in March 1988; and these facts certainly have been known to the Defendants since prior to June 2, 2015.

53. On or about June 30, 2008, the High Court of Justice, Chancery Division, Patents Court in the United Kingdom declared the UK foreign counterpart patent to the '040 Patent to be invalid and not patentable. On information and belief, courts in other foreign jurisdictions

(including at least Italy) have declared a foreign counterpart to the '040 Patent to be invalid or not patentable. Since well before June 2, 2015, Defendants have been aware that foreign courts have found the subject matter of the '040 Patent and/or similar patent claims to be invalid or not patentable.

54. As previously alleged, the Forest Labs Defendants sued at least seven potential generic nebivolol competitors for infringement of the '040 Patent. On information and belief, some or all of those potential generic competitors compiled and served on Forest Labs detailed invalidity contentions explaining the reasons the '040 Patent is invalid. On information and belief, each potential generic competitor served its invalidity contentions under a Confidential or Highly Confidential designation having the effect of making the invalidity contentions subject to a court protective order and thus keeping the otherwise public invalidity contentions hidden from the public and the federal government. On information and belief, the Forest Labs Defendants cooperated with and/or facilitated the potential generic competitors in designating the invalidity contentions as Confidential or Highly Confidential specifically for the purpose of preventing the general public from discovering the reasons the '040 Patent is invalid. On information and belief, following the service of invalidity contentions by each potential generic competitor, the Forest Labs Defendants settled each patent infringement case on terms that prevented a court of law from adjudicating the validity or invalidity of the '040 Patent. On information and belief, all Defendants (including Defendant Allergan) have been aware of the substance of the aforementioned detailed invalidity contentions, and of the other facts alleged in this paragraph, since at least before June 2, 2015.

55. For at least the reasons alleged herein, Defendants have at all times since at least June 2, 2015 known that the prevailing market price for nebivolol (Bystolic) in the United States

is a false overprice that is maintained solely by the '040 Patent that Defendants know to be invalid.

56. For at least the reasons alleged herein, Defendants have at all times since at least June 2, 2015 known that claims submitted to the federal government (directly or indirectly), by themselves or by third parties, for payment or reimbursement of payments made for nebivolol (Bystolic) are false claims that result in overcharges to the federal government.

Relator LDPFC is a Whistleblower that has Standing to Bring this Suit

57. For at least the reasons alleged herein, LDPFC is a whistleblower with standing to bring this action on behalf of the United States government pursuant to 31 U.S.C. § 3730(b).

58. As previously alleged, LDPFC undertook an extensive investigation, incurring significant expenses, in order to uncover and create the evidence presented to the federal government establishing the invalidity of the '040 Patent. These efforts included personal investigation by individuals affiliated with LDPFC, and the retention of attorneys and knowledgeable subject matter experts to assist with the investigation.

59. As shown by the table attached as Exhibit D, most of the documents and evidence uncovered or created by LDPFC during its investigation (and provided by LDPFC to the federal government) were not previously disclosed to the United States Patent and Trademark Office in connection with the examination of the application that led to the '040 Patent, and have not otherwise been known to or considered by the federal government. This is particularly true of Exhibits A, B, C, D, E, G, H and I to this complaint. Thus, this evidence has not been previously publicly disclosed in a manner that would require a dismissal of this action pursuant to 31 U.S.C. § 3730(e)(4)(A).

60. Moreover, with respect to the entirety of LDPFC's investigation and the documents and evidence discovered and created thereby, LDPFC is an original source of that information pursuant to 31 U.S.C. § 3730(e)(4)(B). LDPFC has provided to the federal government knowledge that is independent of and that materially adds to any publicly disclosed allegations or transactions, and LDPFC has voluntarily provided the information to the federal government prior to filing this action. *See* Exhibits A and E.

COUNT I

Violation of the Federal False Claims Act—31 U.S.C. §§ 3729, *et seq.*

61. The allegations of the preceding paragraphs 1 - 60 are hereby incorporated by reference as if alleged in this Count I.

62. Plaintiff / Relator LDPFC is a whistleblower with standing to bring this action on behalf of the United States government pursuant to 31 U.S.C. § 3730(b) for at least the reasons alleged herein.

63. As alleged herein, Defendants (individually and/or in combination with each other) have knowingly presented and/or caused to be presented false or fraudulent claims for payment or approval by the federal government in violation of 31 U.S.C. § 3729(a)(1)(A).

64. As alleged herein, Defendants (individually and/or in combination with each other) have knowingly made, used, and caused to be made or used, a false record or statement material to a false or fraudulent claim in violation of 31 U.S.C. § 3729(a)(1)(B).

65. As a direct and proximate result of Defendants' violations of 31 U.S.C. § 3729(a)(1)(A) and 31 U.S.C. § 3729(a)(1)(B), the federal government of the United States of America has suffered substantial monetary damages in the form of overpayments and reimbursement to others for overpayments made for the pharmaceutical drug nebivolol (Bystolic), in an amount that will be proven at trial.

PRAYER FOR RELIEF

Relator LDPFC respectfully requests this Court to enter judgment in favor of the United States of America and Relator LDPFC, finding that each Defendant has violated the federal False Claims Act, 31 U.S.C. § 3729, *et seq.*, as alleged forth herein, and further requests the following relief be imposed against Defendant:

A. That Defendants each be held liable for actual damages, treble damages, and/or civil penalties between $5,000 and $10,000 for each violation of 31 U.S.C. § 3729(a)(1)(A) and 31 U.S.C. § 3729(a)(1)(B), pursuant to § 3729(a)(1) of the federal False Claims Act; and

B. That this Court award reasonable attorneys' fees, costs and expenses to Relator, which were necessarily incurred in bringing and prosecuting this case, pursuant to 31 U.S.C. §§ 3729(a)(3) and 3730(d); and

C. That this Court award interest, attorney's fees, and other amounts as provided by any other applicable law; and

D. That in the event the United States Government intervenes in this action and takes over its prosecution, the Relator be awarded an amount for bringing this action for the United States of at least 15% but not more than 25% of the proceeds of the action resulting from the trial or settlement of the claim, pursuant to § 3730(d)(1); and

E. That in the event the United States Government does not intervene in this action, the Relator be awarded an amount for collecting the civil penalties and damages for the United States of at least 25% but not more than 30% of the proceeds of the action resulting from the trial or settlement of the claim, pursuant to § 3730(d)(1); and

F. Any further relief that this Court deems just and proper and to which the United States of America and/or LDPFC is entitled.

Date: January 12, 2016

NELSON BUMGARDNER PC

/s/ Donald Puckett

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