UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

UNITED STATES of AMERICA ex rel.

Keith Schenker,

Plaintiff,

v.

Civil No.:

ISTA PHARMACEUTICALS,

FILED IN CAMERA AND UNDER SEAL

Defendant.

COMPLAINT

Plaintiff-Relator, Keith Schenker, by his attorneys Hodgson Russ LLP, for his Complaint, alleges as follows:

PARTIES

1. Plaintiff-Relator Keith Schenker commences this action for himself and for the United States of America against defendant ISTA Pharmaceuticals, Inc. ("ISTA"). under the qui tam provisions of the False Claims Act, 31 U.S.C. §§ 3729 et seq.

2. Keith Schenker is a resident of the State of New York and an employee of ISTA. Mr. Schenker is employed as a Territory Manager (sales representative) in ISTA's Brooklyn and Queens territory. He began his employment with ISTA on January 2, 2007 and has been an employee in that capacity from January 2, 2007, through the present.

3. While an employee of ISTA, Keith Schenker personally learned information and came in contact with many documents that form the basis of the allegations in this Complaint.

4. Keith Schenker is an "original source" within the meaning of the False Claims Act, 31 U.S.C. § 3730(e)(4)(B), because he is an individual who has direct and independent knowledge of the information on which the allegations in this Complaint are based and has voluntarily provided such information to the United States.

5. Upon information and belief, ISTA Pharmaceuticals is a Delaware corporation with its principal place of business in Irvine, California. ISTA Pharmaceuticals is principally engaged in the marketing and sale of pharmaceuticals including prescription pharmaceuticals falling under the jurisdiction and regulation of the U.S. Food and Drug Administration.

JURISDICTION AND VENUE

6. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. § 1331; 28 U.S.C. §1345; and 31 U.S.C. § 3732.

7. This Court has personal jurisdiction over the defendant pursuant to 31 U.S.C. § 3732(a).

8. The defendant regularly conducts substantial business within the State of New York, maintains permanent employees and offices in the State of New York, and has made and is making significant sales within the State of New York.

9. Venue is proper under 31 U.S.C. § 3732(a) because the defendant can be found and/or transacts business within the Western District of New York and because some of the violations of 31 U.S.C. § 3729 alleged in the complaint occurred within this judicial district.

10. Venue is also proper pursuant to 28 U.S.C. § 1391(b) and (c).

SUMMARY OF THE ACTION

11. This action challenges ISTA's unlawful promotion of the brand name prescription drug Xibrom and the foreseeable consequences of such promotion — the submission of false claims to the United States for reimbursement and/or payment.

12. In or around January 27, 2006, ISTA obtained approval from the FDA to market Xibrom, the brand name for the generic drug bromfenac sodium 0.09%. The FDA approved Xibrom only for the "treatment of postoperative inflammation and the reduction of ocular pain in patients who have undergone cataract extraction." Xibrom has never been approved by the FDA for any other purpose.

13. The FDA prohibits retailers of prescription drugs from promoting or marketing drugs for uses not approved by the FDA (*see* 21 U.S.C. § 331(a), (d), and 21 U.S.C. § 352). Such promotion or advertising for unapproved uses is commonly referred to as "off-label" or "off-indication" selling.

14. Beginning no later than January 2007 and continuing up to the present time (the "Relevant Period"), defendant has sought to increase the sales and market share of Xibrom. To accomplish this objective, the defendant has systematically and aggressively promoted Xibrom for the prevention and treatment of Cystoid Macular Edema ("CME"),[1]

[1] CME or swelling of the macula, typically occurs as a result of disease, injury or more rarely, eye surgery. Fluid collects within the layers of the macula, causing blurred, distorted central vision. CME rarely causes

Footnotes continued on next page.

pre-operative conditions, post-operative conditions not including pain and inflammation associated with cataract surgery, as an aid to securing better surgical results, and for use with high risk patients, such as those suffering from diabetes.

15. The defendant's off-label marketing scheme included, among other things:

- Use of a non-FDA approved study (the Rho Study) as a principle selling point for prescribing Xibrom for use in the prevention and/or treatment of CME;
- An elaborate training program that instructed ISTA sales personnel how to effectively promote Xibrom for the prevention and treatment of CME, pre-operative conditions, post-operative conditions not including pain and inflammation associated with cataract surgery, as an aid to securing better surgical results, and for use with high risk patients, such as those suffering from diabetes.
- Tying the financial success of ISTA's sales personnel directly to their ability to increase sales by successfully promoting Xibrom for off-label uses;
- Regular and continuous sales calls by ISTA sales representatives to physicians whose prescribing behavior demonstrated a pattern of off-label use of Xibrom;
- Widespread distribution of articles by ISTA representatives discussing the efficacy of Xibrom for treatment of CME.

16. Sales of Xibrom have exceeded $7,000,000 for the quarter ending on March 31, 2007.

Footnotes continued from previous page.

a permanent loss of vision, but the recovery is often a slow, gradual process. The majority of patients recover in 2 to 15 months.

17. A large portion of these sales are attributable to the use of Xibrom for the treatment of off-label conditions.

18. Many patients who have been prescribed Xibrom to treat off-label conditions have had their prescriptions paid for, directly or indirectly, by the United States through reimbursement under the Medicaid or Medicare programs.

19. The use of Xibrom for the treatment of CME, for use for pre-cataract surgery, as an aid to securing better surgical results, and for use with high risk patients, such as those suffering from diabetes, is not recognized as a medically accepted indication under applicable federal laws and regulations. Such use is not eligible for coverage under Medicare and Medicaid.

20. Through its off-label marketing and promotion, ISTA knowingly caused medical personnel and pharmacists to submit claims to the United States for payment and/or reimbursement to cover the use of Xibrom for the treatment of the above conditions.

21. The United States has paid these false claims and has therefore suffered substantial financial damages, which have inured to the benefit of the defendants.

ISTA'S ELABORATE OFF-LABEL MARKETING SCHEME

22. Beginning no later than January 2007 and continuing to the present, ISTA has geared its sales and marketing programs to encourage medical personnel to prescribe Xibrom for off-label purposes.

23. ISTA managed an elaborate training program designed to teach ISTA sales representatives how to effectively promote Xibrom for the treatment of CME, pre-operative conditions, post operative conditions other than pain and inflammation associated with cataract surgery, as an aid to securing better surgical results, and for use with high risk patients, such as those suffering from diabetes, none of which are in conformity with the FDA approved use of Xibrom.

24. For example, before a sales representative even begins employment he is expected to memorize voluminous materials bolstering the off-label use of Xibrom, the most notable of which is the Rho study.

25. New sales representatives are provided with flashcards to help them to memorize the results of the Rho study, a study regarding the benefits of using Xibrom in treating CME. CME is a serious sight threatening affliction, which is a rare complication associated with cataract surgery.

26. In January of 2007, ISTA directed its sales representatives to tell physicians that "the use of Xibrom both pre and post cataract surgery reduced the occurrence of CME in cataract surgery patients, and is an effective therapy for post cataract surgery patients suffering from CME." ISTA cites the Rho study to support these claims.

27. Not only is the Rho study not FDA approved, but it is not statistically significant, and provides no evidence that Xibrom is in fact effective for CME prophylaxis or treatment.

28. ISTA is well aware that the Rho study is not statistically significant, and instructed its sales representatives how to respond when a physicians challenge the study. ISTA trains its sales representatives to state that Xibrom's use in the treatment of CME "statistically trends toward superiority."

29. Relator and others were personally drilled regarding the Rho study and how it could be related to the treatment of CME during two separate January 2007 training sessions held in Irvine, California.

30. In February of 2007, ISTA held a plan of action sales meeting in Chicago, Illinois. At least forty sales representatives were present at this meeting. The focal point of this meeting was to encourage sales representatives to market Xibrom to physicians for off-label uses.

31. During the February 2007 meeting, sales representatives were provided with a sheet containing five categories of uses for Xibrom, all of which are off-label. The company referred to these off-label categories of uses depicted on the information sheet as "buckets." These buckets encourage the marketing of Xibrom to treat CME, pre-operative conditions, post operative conditions not including pain and inflammation associated with cataract surgery, as an aid to securing better surgical results, and for use with high risk patients, such as those suffering from diabetes.

32. Throughout the course of this February meeting, and throughout the course of their employment thereafter, ISTA sales representatives were repeatedly encouraged to sell to these "buckets."

33. In fact, during the February 2007 meeting in Chicago, it was noted that the company's top sales representative gained his success by expanding the use of Xibrom in areas other than cataract surgery.

34. The keynote speakers at ISTA's February 2007 plan of action meeting were Tom Mitro, the Vice President of Sales, and Steve Lang, the Director of Sales. During that meeting, Mr. Lang and Mr. Mitro focused on encouraging sales representatives to use the Rho study as a sales tool and to market Xibrom aggressively to the off-label "buckets."

35. During the February 7, 2007 meeting, sales representatives were directed to:

- Market Xibrom for long term care;
- Market Xibrom for use in all surgical procedures;
- Market Xibrom as producing better surgical outcomes;
- Market Xibrom for treatment of red eye pain;
- Market Xibrom for treatment of dry eyes;
- Expand the use of Xibrom in areas other than cataract surgery;
- To provide physicians pre-printed prescription pads;
- To provide physicians pre-operative instruction sheets to encourage the pre-operative prescribing of Xibrom;
- To get Xibrom into the "kits" that Allergan and Alcon (other ophthalmic drug manufacturers) were providing to the physicians; and to
- Take physicians out to dinner to evaluate their commitment to prescribing Xibrom

36. ISTA repeatedly encourages sales representatives to utilize three particular sales pitches when meeting with physicians. Those pitches involve: (1) emphasizing the Rho study and the use of Xibrom for treating CME; (2) explaining to doctors that Xibrom is the "Ferrari" of non-steroidal ophthalmic drops and that doctors would get better surgical outcomes by using Xibrom; and (3) suggesting that Xibrom is better for high risk patients such as those with diabetes. Each of these sales pitches suggests the use of Xibrom for off-label purposes, that is, for purposes other than post-cataract surgery pain or inflammation.

37. Sales representatives are encouraged to use a portion of their allotted budget to print pre-operative instruction sheets detailing the pre-operative use of Xibrom, with the hope that the ease of filling out these instruction sheets and providing them to the patients would induce doctors to prescribe Xibrom for pre-op uses.

38. On February 13, 2007, Mr. Schenker received an e-mail from Jennifer Stern, an ISTA representative, providing him with sample pre-op sheets. Pursuant to ISTA's instructions, Mr. Schenker had several pre-op sheets printed.

39. On March 18, 2007, Julie Hess, District Manager for the district of Connecticut and New York, and Mr. Schenker's direct supervisor, sent him an e-mail commending him for investing funds in pre-operative sheets, stating: "I am sure this will help you as you continue to grow your business!"

40. Alcon and Allergan had been in the business of manufacturing eye drops for post-operative cataract surgery long before ISTA became an entrant. These companies, for some time, had been providing ophthalmologists with "kits," which have been described as a

fanny pack filled with eye patches, eye drops and essentially all ophthalmic products that would be needed by a patient for two days after cataract surgery. ISTA Pharmaceuticals does not provide these "kits."

41. Recognizing the power of Alcon and Allergan's market share and the influence of these "kits" in gaining the allegiance of treating physicians, Regional Sales Director Scott Rheault, sent an e-mail containing attachments to the entire Great Lakes region sales staff challenging sales representatives to creatively respond to Allergan and Alcon's marketing.

42. The email from Mr. Rheault specifically directs sales representatives to cite the Rho study when challenged by a physician who argues that Allergan's product Acullar-LS, or Alcon's product, Nevanac, are more effective for the treatment of CME than Xibrom.

43. During ISTA's March 27, 2007 through March 29, 2007 sales meeting, sales representatives were again provided training materials encouraging the use of the Rho study and selling to "buckets."

44. In its April 2007 national sales meeting, ISTA distributed a booklet entitled "ISTA selling simulation customer profiles." This booklet encourages sales representatives to ask various questions in promoting the off-label use of Xibrom. Some of those questions are as follows:

- How do you measure the effectiveness of an NSAID (Non Steroidal Anti Inflammatory Drops) in preventing or treating CME?
- Doctor, has your Allergan rep showed you any head-to-head data in treating CME?

- Doctor, have you seen penetration data showing Acular LS penetrates to the back of the eye?

45. In addition to asking the above questions, the booklet instructs sales representatives to "present Rho data to show Xibrom has excellent data in treating of CME," and to "gain commitment for MD to prescribe Xibrom for all prevention and treatment of CME."

46. The same ISTA booklet instructs sales representatives who encounter a physician reluctant to part with their Allergan "kits" to ask "what would happen to your kit if you prescribed Xibrom?" and further instructs the territory manager to "work with surgical coordinator to place Xibrom 1 ml samples in "kits" after gaining commitment from MD."

47. The same ISTA booklet instructs sales representatives how to deal with physicians who have very little experience in using Xibrom. Under these circumstances, sales representatives are instructed to probe the physician for any experience they may have had with Xibrom, to encourage the continued use of Xibrom, and encourage the physician to consider using Xibrom for all conditions listed on the "buckets" sheet.

48. On March 7, 2007, Mr. Schenker received a critique from his district manager in the form of a field contact report. In that report, Ms. Hess directed Mr. Schenker to market Xibrom for off-label uses, stating, "remember to move quickly to the business at hand, and focus your call on a specific bucket. Sell and close to the specific 'bucket' and transition to your second product. Doing so will allow you to grow your business and maximize your bonus payout."

49. Encouragement of off-label marketing was repeated as Ms. Hess continued to instruct Mr. Schenker to "tailor your message to the 'bucket' you're going for. . . this will allow you to close for a specific business, and transition smoothly to a second product before running out of time. This habit could pay back multiples in the form of positive sales results."

50. On April 16, 2007, Ms. Hess e-mailed the entire New York district an attachment including the district's expectations of its sales representatives. In that e-mail the sales representatives are encouraged to have the attachment with them at all times.

51. New York District Field Expectations 2007 document specifically states that "successful sales representatives at ISTA excel in these areas. . . clearly communicate product positioning, what 'bucket' are you going for." The expectation sheet also encourages the printing and circulation of pre-op instructional sheets to provide to physicians to encourage the pre-operative prescription of Xibrom.

52. As recent as May 18, 2007, Ms. Hess emailed Mr. Schenker stating, "When at a road block with cataract, sell for reasonable and appropriate use -- dose for that need. 1 or 2 Rx's is still better than zero-to start."

ISTA REAPED GREAT FINANCIAL REWARDS AS A RESULT OF ITS OFF-LABEL MARKETING SCHEME

53. Beginning no later than January 2007 and continuing up to the present, ISTA sales representatives, on a national scale, successfully promoted Xibrom to treat CME, pre-operative conditions, post operative conditions other than pain and inflammation associated with

cataract surgery, as an aid to securing better surgical results, and for use with high risk patients, such as those suffering from diabetes.

54. E-mail and training communications to ISTA sales personnel during the relevant time period indicate that off-label promotion was a nationwide phenomenon, and that high-ranking employees or agents of the company knew and approved of the scheme.

55. During the February 2007 meeting in Chicago, it was noted that the company's top sales representative gained his success by expanding the use of Xibrom in areas other than cataract surgery.

56. In ISTA's April 27, 2007, amended 10-K Securities Exchange Commission filing, it is noted that:

> Bonus achievement by individual ranged from approximately 94% to 96% of target for all Named Executive Officers except for Thomas Mitro. Mr. Mitro's bonus was approximately 108% of target because of his exceptional performance in achieving the sales targets, market share results for Xibrom and Istalol and the building of the sales/marketing infrastructure, including the scale-up of the sales force.

57. This is the same Mr. Mitro who encouraged sales representatives to use the Rho study as a sales tool and to market Xibrom aggressively to the off-label "buckets." The same Mr. Mitro who has suggested that the off –label sale of Xibrom is a vital to being a successful ISTA sales representative.

58. ISTA's Steve Lang projects that the company will exceed net sales/profits targets, gaining $55,000,000 to $60,000,000 in net sales. In its April 30, 2007, 10-Q, quarterly Securities Exchange Commission filing, the company noted that "[r]evenue was approximately

$10.3 million for the three months ended March 31, 2007, as compared to $5.4 million for the three months ended March 31, 2006. The increase in revenue was primarily attributable to the continued growth of Xibrom and Istalol in the marketplace."

59. The lion's share of ISTA's success is based on its successful off-label promotion of Xibrom. The company noted, that:

> We increased our net revenue by 91% in the first quarter of 2007, as compared to the first quarter of 2006. Dollarized total prescriptions for both Xibrom and Istalol grew by 131% to $11.1 million as compared to the first quarter of 2006. In particular, dollarized total prescriptions, as measured by IMS, were (i) $8.6 million for Xibrom in the first quarter of 2007, as compared to $6.8 million in the fourth quarter of 2006...

60. Xibrom is gaining market share, a phenomenon directly linked to the successful off-label marketing of the product.

Count I.

Substantive Violations Of The False Claims Act (31 U.S.C. § 3729(a)(1) and (a)(2))

61. Plaintiff-Relator repeats and re-allege paragraphs 1 through 68 above.

62. Beginning at least as early as January 2007 and continuing up to the present time, the defendant has systematically and aggressively marketed Xibrom for the treatment of CME, pre-operative conditions, post-operative conditions other than pain and inflammation associated with cataract surgery, as an aid to securing better surgical results, and for use with high risk patients, such as those suffering from diabetes.

63. Upon and information and belief, the defendant's sales representatives made false statements to medical personnel about the efficacy of Xibrom for the treatment of CME, pre-operative conditions, post-operative conditions not including pain and inflammation associated with cataract surgery, as an aid to securing better surgical results, and for use with high risk patients, such as those suffering from diabetes.

64. The defendant's off-label marketing and false statements caused medical personnel to prescribe Xibrom for the treatment of CME, pre-operative conditions, post-operative conditions not including pain and inflammation associated with cataract surgery, as an aid to securing better surgical results, and for use with high risk patients, such as those suffering from diabetes.

65. A significant percentage of the patients who have been prescribed Xibrom for treatment of CME, pre-operative conditions, post-operative conditions not including pain and inflammation associated with cataract surgery, as an aid to securing better surgical results, and for use with high risk patients, such as those suffering from diabetes, are persons whose prescriptions are paid for, in whole or in part, by medical assistance programs which are funded by the federal government, such as Medicare and Medicaid.

66. The statutes and regulations establishing the Medicare and Medicaid programs limit coverage to prescription drugs that are used in accordance with a medically accepted indication (*see* 42 U.S.C. § 1396r-8). A medically accepted indication includes any use approved by the FDA or supported by the relevant medical compendia. Xibrom has never been approved by the FDA for the treatment of CME, pre-operative conditions, post-operative

conditions not including pain and inflammation associated with cataract surgery, as an aid to securing better surgical results, and for use with high risk patients, such as those suffering from diabetes, and the use of Xibrom for the treatment of any of the above conditions is not endorsed by the relevant medical compendia.

67. The defendant's off-label marketing of Xibrom and false statements caused medical personnel and pharmacists to submit off-label prescriptions for payment and/or reimbursement through Medicare or Medicaid.

68. The defendants caused these false and/or fraudulent claims to be presented to the United States or its agencies for the express purpose and with the intent that payment would be made for such claims and with full knowledge of their falsity.

69. The United States, through its agents or employees, paid such false and/or fraudulent claims or reimbursed states for paying such false and/or fraudulent claims. At the time of such payment, the United States was unaware of the false and/or fraudulent nature of the claims.

70. The United States has sustained substantial damages by reason of the unlawful marketing and fraudulent conduct of the defendants.

Count II.

False Claims Act Conspiracy
(31 U.S.C. § 3729(a)(3))

71. Plaintiff-Relator repeats and re-allege paragraphs 1 through 78 above.

72. Beginning no later than January 2007 and continuing up to the present time, the defendant has knowingly conspired with others, including their employees and agents, to defraud the United States by causing false or fraudulent claims to be submitted and paid by the United States under Medicare and Medicaid health programs.

73. The United States, through its agencies, paid such false and/or fraudulent claims or reimbursed states for paying such false and/or fraudulent claims.

74. As a result, the United States has sustained substantial damages by reason of the knowing acts and fraudulent conduct of the defendants as described herein.

Jury Demand

75. Plaintiff-Relator demand a jury on all issues and matters triable by a jury herein.

Relief Requested

WHEREFORE, the United States of America ex rel Keith Schenker demand judgment against the defendants as follows:

a) On the first cause of action, for treble damages under 31 U.S.C. § 3729(a)(1) and (2) in an amount to be determined at trial, plus penalties, costs, interest, and attorney's fees;

b) On the second cause of action, for treble damages under 31 U.S.C. § 3729(a)(3) in an amount to be determined at trial, plus penalties, costs, interest, and attorney's fees;

c) On the first and second causes of action, for the damages sustained by the United States of America; and

d) Awarding such other and further relief as this Court deems proper as a matter of law or under the False Claims Act.

Dated: June 11, 2007

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