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Superior Court of California
County of Los Angeles

OCT 30 2013

John A. Clarke, Executive Officer/Clerk
By LA TRESE JOHNSON, Deputy

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF LOS ANGELES, CENTRAL DISTRICT

AIDS HEALTHCARE FOUNDATION,

Plaintiff,

vs.

JOHNSON & JOHNSON, a New Jersey corporation, JANSSEN THERAPEUTICS, a Division of JANSSEN PRODUCTS, LP, a New Jersey corporation; JANSSEN BIOTECH, INC, a Pennsylvania corporation; DOES 1-10,

Defendants.

CASE NO. BC 526253

COMPLAINT FOR VIOLATION OF CALIFORNIA UNFAIR COMPETITION LAW, BREACH OF CONTRACT—THIRD-PARTY BENEFICIARY, NEGLIGENCE, UNJUST ENRICHMENT, AND BREACH OF COVENANT OF GOOD FAITH AND FAIR DEALING

Trial Date: None Set
Jury Trial Requested

Plaintiff AIDS Healthcare Foundation ("AHF" or "Plaintiff") alleges as follows:

I. INTRODUCTION

1. AHF is a nonprofit corporation that provides cutting edge medical care and advocacy to people with HIV/AIDS regardless of ability to pay. Among other things, it operates a number of HIV/AIDS outpatient medical clinics and AIDS specialty pharmacies in California. By virtue of its participation in the Ryan White program, AHF qualifies as a "covered entity" under Section 340B of the federal Public Health Services Act (referred to hereinafter as the "340B Program") and is entitled to purchase, at discounted rates, the expensive, critically needed HIV

drugs that AHF provides its patients. The cost savings obtained through the 340B program is essential to AHF's ability to carry out its mission of serving low-income HIV/AIDS patients because AHF uses the money it saves on drugs to prevent people with HIV and AIDS from falling through the safety net by increasing the number of patients it serves, increasing the scope of services offered, and offsetting other operational losses. In other words, the 340B program allows AHF to stretch scarce resources as far as possible, reaching more eligible patients and providing more comprehensive services.

2. On information and belief, Defendants Johnson & Johnson, Janssen Therapeutics, Division of Janssen Products, LP, and Janssen Biotech, Inc. (hereinafter, collectively, "J&J Companies") are inter-related entities operating as pharmaceutical manufacturers from which AHF has purchased the drugs it dispenses to AHF's patients. As explained in more detail below, the J&J Companies are bound by both federal law and contractual obligations to dispense qualifying drugs to covered entities under the 340B Program at discounted rates. AHF brings this action because the J&J Companies have failed to fully satisfy their obligations with respect to drugs they sold to AHF over a period of many years.

3. Defendants DOES 1-10 are entities of unknown origin that have agreed to provide AHF with discounted drugs under the 340B program.

4. The J&J Companies and DOES 1-10 have failed to afford the discounted, 340B Program prices to which AHF is entitled under law and Defendants' contracts.

5. AHF made the J&J Companies aware that it was wrongly charged the non-discounted prices before preparing this lawsuit, but the J&J Companies have refused to reimburse AHF for the excess funds it paid for J&J's drugs. Accordingly, the J&J Companies have forced AHF to seek judicial intervention to obtain the critically needed discounted drug pricing to which AHF is indisputably entitled.

6. AHF brings this action to force the J&J Companies and DOES 1-10 to refund/disgorge the money that AHF overpaid them for drugs that should have been furnished to AHF at discounted rates, but were not. AHF is entitled to this relief based on several legal grounds, including statutory, contractual and equitable theories. The J&J Companies and DOES

1-10 should not be permitted to effectively refuse to comply with their respective obligations under the law with respect to 340B Program covered drugs without consequence and thereby deprive AHF of funds that it would use to benefit the needy patients it serves.

II. JURISDICTION AND VENUE

7. The Court has venue in this case pursuant to, inter alia, California Code of Civil Procedure sections 395 and 395.5.

8. Jurisdiction is proper in the Superior Court. (Cal. Code of Civ. Proc. §88.) The total amount of damages sought in this action exceeds $25,000 and is within the jurisdiction of this Court.

III. PARTIES

AHF

9. Plaintiff AHF is a California nonprofit corporation. Its mission is to provide cutting edge medical care and advocacy to people with HIV/AIDS regardless of ability to pay. Among other things, it operates a number of HIV/AIDS outpatient medical clinics and AIDS specialty pharmacies in California. AHF primarily serves a low income/indigent patient population.

THE J&J COMPANIES

10. On information and belief:

- Defendant Johnson & Johnson is a New Jersey corporation having a principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.
- Defendant Janssen Therapeutics, Division of Janssen Products, LP is a New Jersey corporation having its principal place of business at 1125 Trenton-Harbourton Road, Titusville, NJ (per its website) or 430 Route 22 East, Bridgewater, NJ, 08807 (per its registration on the California Secretary of State website).
- Defendant Janssen Biotech, Inc. is a Pennsylvania corporation having its principal place of business at 800 Ridgeview Road, Horsham, PA 19044.

The J&J Companies control a significant portion of the AIDS (Acquired Immune Deficiency Syndrome) drug market. The J&J Companies also manufacture and market numerous prescription drugs, including drugs used to treat HIV/AIDS patients in the outpatient setting, including but not limited to, Prezista, Intelence, Endurant, and Procrit.

OTHER DEFENDANTS

11. AHF does not know the true names or capacities, whether individual, corporate, associate, or otherwise, of defendant DOES 1-10 and therefore designates those defendants by such fictitious names. Each of the defendants sued herein as a DOE is legally responsible in some manner for the events and happenings referred to and proximately caused the injuries suffered by Plaintiff. AHF will amend this complaint to allege the true names and capacities of these DOES when the same becomes known to AHF.

IV. FACTUAL BACKGROUND

The Federal "340B" Drug Pricing Program

12. Section 602 of the Veterans Health Care Act of 1992 (P.L. 102-585) created what is now commonly known as the "340B Program." This section, codified at 42 United States Code ("U.S.C"). § 256b, *et seq.* ("Section 340B") requires drug manufacturers to provide outpatient drugs to specific entities at a reduced price.

13. The entities eligible to participate in the 340B program are, by and large, nonprofit and governmental safety net medical providers that primarily provide medical care to low income and indigent people. These entities include:

- Federally qualified health centers;
- Black lung clinics;
- Native Hawaiian health centers; and,
- Hemophilia diagnostic centers.

14. AHF is able to participate in the 340B program because it provides medical care to people with HIV/AIDS through grants awarded under the Ryan White CARE Act (42 U.S.C. §§ 300ff *et seq.*,), a federal program designed to provide care to indigent people with HIV/AIDS. 42 U.S.C. § 256b(a)(4)(D), (J). For patients who do not meet 340B program criteria, AHF purchases drugs at retail or pursuant to other contractual arrangements with drug manufacturers.

15. Savings from the 340B program work in two ways. First, entities that pay for and

distribute drugs are able to buy these drugs at a lower price, and thus can either purchase more drugs to provide more services, or utilize the savings to provide other services. Second, for entities that purchase the drugs but are reimbursed by a third party (such as an insurance plan), the 340B program allows for a larger difference between the purchase cost and the reimbursement fee, which creates additional revenue for the nonprofit entity. In these ways, the goal of the 340B Program is met, which is "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), at 12 (1992).

16. 340B participating entities ("Covered Entities") are able to utilize the savings from the 340B program to further their missions as safety net providers. Entities that participate in the 340B program, like AHF, most commonly use the savings to:

- Increase the number of patients served;
- Offset losses from providing services to their patients for less than full compensation;
- Reduce drug prices to patients; and,
- Increase the services provided.

17. Consistent with the foregoing, the 340B Program is a critical mechanism for safety net providers like AHF to serve the healthcare needs of the disadvantaged in their communities.

Administration of the 340B Drug Pricing Program

18. The 340B Program is overseen by the Health Resources and Services Administration ("HRSA"). HRSA is an agency within the United States Department of Health and Human Services ("HHS").

19. Immediate responsibility for oversight of the 340B Program resides in HRSA's Office of Pharmacy Affairs ("OPA"), whose mission is to promote access to clinically and cost effective pharmacy services. OPA also maintains an electronic database of Covered Entities.

Terms of Participation in the 340B Drug Pricing Program

20. Section 340B requires drug manufacturers, including the J&J Companies and DOES 1-10, to participate in the 340B Program as a condition of having their drug charges

reimbursed by the Medicaid program. All, or virtually all, pharmaceutical manufacturers participate in the 340B Program and Medicaid, including the J&J Companies.

21. Under the 340B Program (42 U.S.C. § 256b(a)(1)), manufacturers are required to ensure that Covered Entities pay no more for any product than the 340B ceiling price. The 340B ceiling price is based on the average manufacturer price for the drug under title XIX of the Social Security Act [42 USCS §§ 1396 et seq.] in the preceding calendar quarter, reduced by the statutory Medicaid rebate percentage.

22. Under the 340B Program, drug manufacturers, including the J&J Companies and DOES 1-10, are responsible for ensuring that the prices paid for drugs by Covered Entities are at or below the 340B ceiling price, regardless of whether a 340B Participant purchases from a wholesaler or directly from the manufacturer.

Terms of Contracts Between the Parties

23. Pursuant to its obligations under the 340B Program, the J&J Companies and DOES 1-10 have developed discounted pricing that they extend to Covered Entities for eligible transactions. They make that pricing available to Covered Entities directly or through the Entities' wholesalers.

21. AHF has entered into an agreement with Cardinal Health, Inc. (hereinafter "Cardinal Health") a health care services corporation organized under the laws of Ohio and headquartered at 7000 Cardinal Place, Dublin, OH. Cardinal Health distributes pharmaceuticals nationwide, including drugs manufactured by the J&J Companies and DOES 1-10 that are used in the outpatient setting. Cardinal Health serves as AHF's wholesale pharmaceutical supplier. AHF purchases drugs from the J&J Companies and DOES 1-10 through Cardinal Health and is not able to purchase directly from the manufacturer.

22. Moreover, AHF has registered with the 340B Prime Vendor, Apexus Inc. Apexus operates under a contract with HRSA and is responsible for contracting with drug manufacturers, including the J&J Companies and DOES 1-10, to secure sub-340B ceiling discounts on outpatient drug purchases for public hospitals, community health centers, and other safety-net health care providers electing to join the 340B Program. AHF is informed and believes that Cardinal Health

applies the contracts between Apexus and drug manufacturers to Cardinal Health's clients' accounts to ensure that Cardinal Health's 340B clients receive the benefit of Apexus's sub-ceiling discounts.

23. In order to meet its obligations as AHF's wholesaler, Cardinal Health has entered into contracts with the J&J Companies and DOES 1-10. AHF is informed and believes and thereon alleges that Cardinal Health's contracts with the J&J Companies and DOES 1-10 require the J&J Companies and DOES 1-10 to extend discounted 340B Program drug pricing to Cardinal Health when Cardinal Health is purchasing drugs on behalf of 340B Covered Entities like AHF. AHF also is informed and believes and thereon alleges that Apexus's contracts with the J&J Companies and DOES 1-10 also require the J&J Companies and DOES 1-10 to extend 340B sub-ceiling discounts to Covered Entities registered with the Prime Vendor, and to pass those discounts to the Entities' wholesaler when Covered Entities like AHF purchase drugs covered under Apexus's agreement with the J&J Companies.

24. Under the 340B Program and contracts between (a) the J&J Companies and Apexus and between DOES-10 and Apexus, in Apexus's capacity as the 340B Prime Vendor, and/or (b) the J&J Companies and Cardinal Health, in Cardinal Health's capacity as AHF's wholesaler, the J&J Companies and DOES 1-10 are required to ensure that Covered Entities, i.e., the beneficiaries of the contracts, pay no more for any product than the discounted prices as required by the contracts and Defendants' obligations under the 340B program.

25. AHF relied on the duty of the J&J Companies and DOES 1-10 to comply with 340B, and on its performance under their contracts with Apexus and/or Cardinal Health, of which AHF is the intended beneficiary, to ensure that prices AHF paid for Defendants' drugs did not exceed the required discounted prices.

J&J's Refusal to Afford AHF Discounted Pricing

26. AHF is informed and believes and thereon alleges that it has paid and continues to pay more than the legally required discounted prices for outpatient drugs manufactured and/or distributed by the J&J Companies and DOES 1-10.

27. Between 2005 and 2013, AHF purchased thousands of 340B covered drugs from

the J&J Companies and DOES 1-10, through Cardinal, which should have been governed by the terms of Cardinal Health's and/or Apexus's contracts and arrangements with the J&J Companies and DOES 1-10. AHF discovered through detailed claims analysis, completed in or around May 2013, that it had overpaid the J&J Companies by over $2 million for certain outpatient drugs purchased all the way back to 2005. These drugs were dispensed to patients eligible to receive the discounted drugs under the terms of the 340B Program, and AHF was therefore entitled to the discounted price at the time of the drugs' purchases, but did not receive that price. Rather, AHF received the non-discounted price that applied to non-340B eligible patients.

28. AHF has made attempts to seek redress either by communicating directly with the J&J Companies or through Cardinal Health. For example, on or about May 9, 2013, Cardinal sent an email to the J&J Companies requesting that they reclassify specified drugs purchased at non-340B pricing between 2005 to 2012 as items eligible for 340B pricing, insofar as the drugs were dispensed to eligible 340B patients. Then, on September 20, 2013, representatives from AHF and the J&J Companies met to discuss AHF's request. The J&J Companies wrongfully, oppressively, arbitrarily refused the request. Moreover, on information and belief, AHF alleges that the J&J Companies engage in a practice of deliberately, arbitrarily, oppressively refusing to reclassify transactions of other 340B covered entities who similarly did not receive the 340B price for eligible transactions.

29. Unable to obtain redress from the J&J Companies through informal means, AHF was forced to file this lawsuit to pursue the full amounts it is owed for the improper pricing of drugs AHF purchased from the J&J Companies.

30. In summary, AHF purchased, through Cardinal Health, drugs from the J&J Companies and DOES 1-10. As a result of the conduct of the J&J Companies and DOES 1-10, AHF did not receive the discounted price to which it was lawfully entitled under applicable law and Defendants' contracts with Cardinal Health and/or Apexus for the drugs in question. The J&J Companies were made aware of the incorrect pricing either by AHF or Cardinal Health, on behalf of AHF, and, to date, have refused to retrospectively correct the situation and refund/disgorge to AHF the excess money paid to the manufacturer for the drugs in question.

FIRST CAUSE OF ACTION

For Violation of California Business and Professions Code Sections 17200, *et seq.*

31. AHF reincorporates each of the above-paragraphs as though fully set forth herein.

32. Pursuant to the laws governing the 340B Program and their contractual and other arrangements with Apexus and/or Cardinal Health, the J&J Companies and DOES 1-10 were required to ensure that the price paid for drugs purchased by Covered Entities would be the discounted prices called for under the 340B Program, regardless of whether the Covered Entities purchased the manufacturers' products through a distributor or directly through a manufacturer.

33. AHF is informed and believes and thereon alleges that, as described herein, the J&J Companies and DOES 1-10 have engaged in unfair, unlawful, and/or deceptive schemes to collect inflated charges that exceed the legally mandated and contractually-required 340B prices for outpatient drugs from AHF. The J&J Companies and DOES 1-10 charged AHF substantially more than the discounted rates to which it was entitled on a significant number of prescription drugs purchased for 340B eligible patients. Further, the J&J Companies wrongly and unfairly refused to correct the charges after being informed by AHF that AHF was not afforded certain qualifying drugs at appropriately discounted prices.

34. AHF is informed and believes and thereon alleges that, as described herein, the conduct of the J&J Companies and DOES 1-10 constitutes unfair competition within the meaning of California Business and Professions Code § 17200, *et seq.*, commonly known as California's "Unfair Competition Law" or "UCL," which prohibits "any unlawful, unfair or fraudulent business act or practice" and "unfair, deceptive, untrue or misleading advertising." Cal. Bus. & Prof. Code § 17200.

35. The UCL forbids all wrongful business activities in any context. Defendants' practices are unlawful and contrary to established public policies. AHF has paid more for drugs than it should have paid in accordance with the 340B Program and, as AHF is informed and believes and thereon alleges, the terms of Defendants' contractual and other arrangements with Apexus and/or Cardinal Health. The impact of Defendants' practices is not mitigated by any justifications, reasons, or motives. Defendants' conduct has no utility when compared to the harm

that its conduct is causing to AHF.

36. As a result of the aforementioned conduct in violation of the UCL, AHF is entitled to equitable relief, including restitution of all charges and disgorgement of profits, attorneys' fees and costs and permanent injunctive relief to prevent such conduct in the future.

SECOND CAUSE OF ACTION

For Breach of Contract – Third-Party Beneficiary

37. AHF reincorporates each of the above paragraphs as though fully set forth herein.

38. Cardinal Health and Defendants, and Apexus and Defendants, entered into contracts for the provision of drugs, including drugs covered under the 340B Program. AHF is informed and believes and thereon alleges that the contractual arrangements between Cardinal Health, Apexus, and Defendants expressly reflect the intention of the contracting parties to directly benefit Covered Entities, like AHF, whether drugs are purchased through a wholesaler or directly from Defendants, by ensuring that the Covered Entities as beneficiaries pay no more than the 340B discounted prices for covered drugs.

39. Although AHF is not a party to the contracts between Cardinal Health, Apexus, and Defendants, it is entitled to damages for breach of contract because Cardinal Health, Apexus, and Defendants intended for AHF, as a 340B Participant, to benefit from these contracts.

40. By agreeing to the terms of its contractual arrangements with Cardinal Health and Apexus, the J&J Companies and DOES 1-10 expressly agreed to sell covered drugs to Covered Entities, including AHF, at discounted prices. AHF is informed and believes and thereon alleges that it was charged substantially more than the discounted prices to which it was entitled on a substantial number of outpatient drugs purchased from the J&J Companies and DOES 1-10.

41. The J&J Companies and DOES 1-10 breached, and continue to breach, their contractual obligations under their contractual arrangements with Apexus and/or Cardinal Health by charging AHF more than the 340B discounted prices for covered drugs and refusing to retrospectively correct the amounts that AHF overpaid for the drugs.

42. AHF is entitled to damages it sustained as a result of Defendants' breach of their contractual obligations, in addition to reasonable costs and attorneys' fees, and other remedies as

the Court may deem appropriate.

43. As a result of Defendants' failure to provide AHF with mandated discount prices for outpatient drugs, AHF has been damaged to its detriment in the principal amount of at least $2 million, plus interest to date.

THIRD CAUSE OF ACTION

For Negligence

44. AHF reincorporates each of the above paragraphs as though fully set forth herein.

45. AHF is informed and believes and thereon alleges that Cardinal Health and Defendants and Apexus and Defendants entered into contractual arrangements calling for drugs purchased on behalf of Covered Entities to be available at discounted rates. AHF is informed and believes and thereon alleges that the contractual arrangements between Cardinal Health, Apexus, and Defendants expressly reflect the intention of the contracting parties to directly benefit Covered Entities, including AHF, whether drugs are purchased through a wholesaler or directly from Defendants, by ensuring that the Covered Entities as beneficiaries pay no more than the required discounted prices for covered drugs.

46. By agreeing to the terms of these contractual arrangements, the J&J Companies and DOES 1-10 had, and continue to have, a duty of care to ensure that they do not charge AHF prices above and beyond the 340B ceiling prices mandated by the contracts for the sale of 340B drugs to Covered Entities.

47. The J&J Companies and DOES 1-10 breached that duty of care by failing to use reasonable care which persons of ordinary prudence would use under similar circumstances to ensure that AHF received outpatient drugs at the required discounted prices.

48. As a direct and proximate result of Defendants' negligence, AHF suffered damages representing the difference between the prices paid by AHF for various drugs and the discounted prices that should have been charged for those drugs when sold by the J&J Companies or DOES 1-10 to AHF through Cardinal Health.

FOURTH CAUSE OF ACTION

Unjust Enrichment

49. AHF reincorporates each of the above paragraphs as though fully set forth herein.

50. The J&J Companies and DOES 1-10 agreed to sell drugs to AHF at discounted prices as mandated by Defendants' contractual arrangements with Cardinal Health and/or Apexus. The J&J Companies and DOES 1-10 received payment for 340B drugs from AHF and were thereby unjustly enriched to the degree that the prices exceeded the discounted rates that AHF should have been afforded, as required by Defendants' contractual arrangements with Cardinal Health and/or Apexus. The J&J Companies and DOES 1-10 failed to comply with their obligations under these contracts and the 340B Program, generally, to the detriment of AHF by retaining monies to which they are not entitled and that rightfully belong to AHF.

51. If the J&J Companies and DOES 1-10 are permitted to retain such monies collected by its unlawful refusal to afford AHF the 340B discounted prices for eligible 340B transactions, they will be unjustly enriched at the expense of AHF. AHF is entitled to full restitution in the principal amount of at least $2 million plus interest to date.

FIFTH CAUSE OF ACTION

For Breach of Covenant of Good Faith and Fair Dealing

52. AHF reincorporates each of the above paragraphs as though fully set forth herein.

53. Cardinal Health, Apexus and Defendants entered into contractual arrangements for the provision of drugs, including drugs covered by the 340B Program. Contractual arrangements between Cardinal Health and Defendants and/or Apexus and Defendants expressly reflect the intention of the contracting parties to directly benefit Covered Entities, whether drugs are purchased through a wholesaler or directly from Defendants, by ensuring that Covered Entities as beneficiaries pay no more than required discounted prices for covered drugs.

54. By agreeing to the terms of these contractual arrangements, the J&J Companies and DOES 1-10 had, and continue to have, an implied duty of good faith and fair dealing in their performance under the terms of these contractual arrangements, which requires that Defendants charge discounted prices as mandated by the contracts that govern the sale of covered drugs to

Covered Entities.

55. The J&J Companies and DOES 1-10 knowingly breached, and continue to breach, the implied covenant of good faith and fair dealing by failing to perform in good faith the terms of the contractual arrangements, which require that Defendants charge discounted prices for the sale of covered drugs to Covered Entities.

56. As a third-party beneficiary of the contractual arrangements, AHF is entitled to damages it sustained as a result of Defendants' breach of the implied duty of good faith and fair dealing, in addition to reasonable costs and attorneys' fees, and other remedies as the Court may deem appropriate.

57. As a result of Defendants' failure to provide AHF with contractually mandated discounted prices for covered drugs, AHF has been damaged to its detriment in the principal amount of at least $2 million, plus interest to date.

V. DEMAND FOR RELIEF

WHEREFORE, AHF prays for judgment as follows:

1. Requiring Defendants to immediately cease their unlawful acts and practices;

2. Requiring the Defendants to make full restitution of all monies improperly collected from AHF;

3. Granting appropriate injunctive relief pursuant to all causes of action to prevent the practices alleged herein from continuing;

4. Awarding AHF damages to the full extent recoverable by law and in an amount to be proven at trial, plus all applicable interest allowed at the highest applicable interest rate at law under California law;

5. Imposing a constructive trust and ordering Defendants to pay restitution to AHF in the amount it has been overcharged for drugs it purchased as a 340B Participant from Defendants, with interest;

6. For reasonable attorneys' fees pursuant to Code of Civil Procedure section 1021.5, or otherwise to the extent recoverable by law;

7. For punitive damages; and

8. For costs of this proceeding and for such other and further relief as the Court deems just and appropriate.

DATED: October 30, 2013

By: ______________________
SAMANTHA AZULAY Attorney for AIDS HEALTHCARE FOUNDATION