UNITED STATES DISTRICT COURT
EASTERN DISTRICT PENNSYLVANIA

VALUE DRUG COMPANY, individually, on behalf of itself and all others similarly situated, Plaintiff, v. TAKEDA PHARMACEUTICALS U.S.A., INC., ENDO PHARMACEUTICALS, INC., PAR PHARMACEUTICAL INC., WATSON LABORATORIES, INC., TEVA PHARMACEUTICAL INDUSTRIES LTD., TEVA PHARMACEUTICALS USA, INC., and AMNEAL PHARMACEUTICALS LLC, Defendants.	Civil Action No. Jury Trial Demanded

CLASS ACTION COMPLAINT

Plaintiff Value Drug Company, on behalf of itself and all others similarly situated, brings this Class Action Complaint against Takeda Pharmaceuticals U.S.A., Inc. ("Takeda"), Endo Pharmaceuticals, Inc. ("Endo"), Watson Laboratories, Inc. (now known as Teva Pharmaceutical Industries, Ltd.) ("Watson"), Amneal Pharmaceuticals LLC ("Amneal"), Teva Pharmaceutical Industries Ltd. ("Teva Ltd."), Teva Pharmaceuticals USA, Inc. ("Teva USA"), and Par Pharmaceutical, Inc. ("Par") (all defendants collectively, "Defendants") and alleges as follows based on: (a) personal knowledge, (b) the investigation of its counsel, and (c) information and belief.

I. NATURE OF THE CASE

1. This case challenges a horizontal conspiracy among all of the Defendants, all of whom were competitors in the market for Colcrys and its AB-rated generics. Parts of the conspiracy masqueraded as a joint venture, but the restraints were, in fact, naked.

2. As of late 2015, Par, Watson and Amneal were set to begin competing against Takeda in the market for 0.6 mg colchicine tablets, over which Takeda enjoyed a monopoly and marketed under the brand name Colcrys. But rather than compete against one another, all four agreed it would be more profitable to conspire not to do so, and to conceal their conspiracy in part in the form of a distribution joint venture between Takeda and Par. Under the joint venture, Par would sell Takeda's product instead of its own, to maintain Takeda's monopoly, restrict output of Par's competing product, allocate 100% of the market to Takeda's product for several years, and share with Takeda in the corresponding monopoly prices, all at the expense of purchasers and patients.

3. Takeda, Par, Watson, and Amneal agreed to the following:

(a) rather than compete Takeda's Colcrys profits down by launching its own generic version of Colcrys alongside Takeda's branded Colcrys and Takeda's "authorized generic" version sold since early 2015 by Takeda's distributor Prasco LLC ("Prasco"), Par would restrict its output of generic Colcrys and instead become a joint venture partner of Takeda and distribute Takeda's "authorized generic" Colcrys in place of Prasco;

(b) to lengthen the period of time that Colcrys and "authorized generic" Colcrys could be sold free from generic competition, Par would not replace Prasco as Takeda's distributor until 2½ years following the inception of the conspiracy;

(c) Par would pay a large royalty to Takeda on "authorized generic" sales, and would keep the prices at which Par was selling Takeda's "authorized generic" at (or at most a small percentage below) the price at which Takeda was selling branded Colcrys, to keep Colcrys profits from being competed down;

(d) rather than create competition among Takeda's branded Colcrys, Takeda's "authorized generic" Colcrys sold by Prasco, Par's generic Colcrys, and then, 180 days after Par started selling, Watson's and Amneal's generic versions of Colcrys, and thereby suffer a corresponding reduction of supracompetitively high Colcrys prices and profits that the four co-conspirators would otherwise share, Watson and Amneal would restrict their output of generic Colcrys for several years, and then would each enjoy a defined period of time to sell their respective generic Colcrys products free from competition from all other would-be generic Colcrys makers; and

(e) rather than allow generic companies other than the co-conspirators to enter the market with their respective generic versions of Colcrys 180 days after Par started selling, and thereby suffer a corresponding reduction of the supracompetitively high Colcrys prices and profits they were sharing, Takeda would enter into licenses with those other generic companies that would delay their entry beyond Watson's and Amneal's agreed periods of competition-free sales, thereby giving the co-conspirators long periods of supracompetitive Colcrys profits.

4. This single conspiracy to restrict output and restrain competition worked as planned from November 24, 2015 until November 25, 2019. First Takeda alone, and then Takeda and Par together, earned and shared supracompetitive profits from the sale of Takeda's branded and "authorized generic" Colcrys. Watson and Amneal withheld their output from the market in anticipation of their defined periods of exclusive generic sales, as agreed. Competition was severely harmed.

5. The conspiracy's goals were not fully realized, however. On November 25, 2019, a non-conspiring generic drug company, Mylan Pharmaceuticals Inc. ("Mylan"), disrupted the

conspiracy's aims by launching a generic version of Colcrys, which in turn allowed all other generics to launch, interfering with the planned periods of restricted output to which Takeda, Par, Watson and Amneal had agreed. Nevertheless, each of the co-conspirators, even those that did not ultimately benefit as planned, is jointly and severally liable for the full harm that was in fact caused by the conspiracy.

6. Mylan's launch triggered unfettered competition, including from several non-conspiring generic companies, causing the price of Colcrys and generic Colcrys to quickly fall, and allowing consumers to finally benefit from prices that were about 90% lower than the price at which Takeda's branded and "authorized generic" Colcrys previously were being sold. Absent the conspiracy, this price collapse would have occurred years earlier. Instead, consumers and direct purchasers paid prices for Colcrys that were approximately 1,200% higher than they should have been over that time.

II. PARTIES

7. Plaintiff Value Drug Company is a corporation organized under the laws of the State of Pennsylvania and is located at 195 Theater Drive, Duncansville, Pennsylvania 16635. Value Drug Company, during the Class Period defined below, purchased brand Colcrys directly from Takeda, and generic Colcrys directly from Prasco and Par, at supracompetitive prices and therefore suffered antitrust injury as a result of the anticompetitive conduct alleged herein.

8. Defendant Takeda Pharmaceuticals U.S.A., Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business located at One Takeda Parkway, Deerfield, Illinois 60015.

9. Defendant Endo Pharmaceuticals, Inc. is a Delaware corporation, with its principal place of business at 1400 Atwater Drive, Malvern, PA 19355. Endo is successor-in-interest to Par. On September 28, 2015, Endo completed an acquisition of defendant Par and assumed all of Par's liabilities. Moreover, Endo ratified Par's conduct challenged herein, and reaped illicit benefits from the conspiracy.

10. Defendant Par Pharmaceutical, Inc. is a Delaware corporation with its principal place of business and corporate headquarters at One Ram Ridge Road, Chestnut Ridge, New York 10977.

11. Defendant Watson Laboratories, Inc. is a Nevada corporation having places of business at 311 Bonnie Circle, Corona, CA 92878 and Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054.

12. Defendant Teva Pharmaceutical Industries Ltd. is an Israeli corporation with its principal place of business at 5 Basel St., Petach Tikva, Israel 4951033. Teva Ltd. is successor-in-interest to Watson. On July 26, 2015, Teva Ltd. purchased Watson and, as part of that purchase, assumed all of Watson's liabilities. Moreover, Teva Ltd. ratified Watson's conduct challenged herein.

13. Defendant Teva Pharmaceuticals USA, Inc. is a Delaware corporation with its principal place of business at 400 Interpace Parkway, Parsippany, NJ 07054. Teva Pharmaceuticals USA, Inc. is successor-in-interest to Watson. On July 26, 2015, Teva Pharmaceuticals USA, Inc. purchased Watson and, as part of that purchase, assumed all of Watson's liabilities. Moreover, Teva Pharmaceuticals USA, Inc. ratified Watson's conduct challenged herein.

14. Defendant Amneal Pharmaceuticals, LLC, is a Delaware corporation with its principal place of business at 400 Crossing Boulevard, Third Floor, Bridgewater, NJ, 08807-2863.

III. JURISDICTION AND VENUE

15. This action arises under sections 1 and 2 of the Sherman Act (15 U.S.C. §§ 1, 2) violations of which are made privately actionable through section 4 of the Clayton Act (15 U.S.C. §15(a)), and seeks threefold damages, costs of suit, and reasonable attorneys' fees for the overcharges paid by Plaintiff and members of the proposed class resulting from Defendants' conspiracy and monopolization of the market for Colcrys and its AB-rated generic equivalents. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1337(a), and 15 U.S.C. § 15.

16. Defendants transact business within this district, and they carry out interstate trade and commerce in substantial part in this district and/or have an agent and/or can be found in this district. Venue is therefore appropriate within this district under section 12 of the Clayton Act (15 U.S.C. § 22) and 28 U.S.C. §1391(b) and (c).

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

IV. CLASS ACTION ALLEGATIONS

18. Plaintiff brings this action on behalf of itself and, under Rule 23 of the Federal Rules of Civil Procedure, as representative of a class defined as follows:

> All persons or entities in the United States and its territories and possessions, including the Commonwealth of Puerto Rico, who directly purchased branded or generic Colcrys tablets from Takeda, Prasco, or Par at any time from July 29, 2016 until the effects of Defendants' conduct cease (the "Class").

Excluded from the Class are Defendants, their officers, directors, management, employees, subsidiaries, and affiliates, and all federal governmental entities.

19. Members of the Class are so numerous that joinder is impracticable. While the exact number of Class members is unknown to Plaintiff, the Class likely numbers greater than 40, and members of the Class are widely dispersed throughout the United States and its territories and possessions, including the Commonwealth of Puerto Rico. The Class is readily identifiable from information and records in the possession of Defendants and Prasco.

20. Plaintiff's claims are typical of the claims of the members of the Class. Plaintiff and all members of the Class were damaged by the same wrongful conduct of Defendants, *i.e.*, they paid artificially inflated prices for brand and generic Colcrys and were deprived of the benefits of competition from less-expensive generic versions of Colcrys as a result of Defendants' wrongful conduct.

21. Plaintiff will fairly and adequately protect and represent the interests of the Class. Plaintiff's interests are coincident with, and not antagonistic to, those of the Class.

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

23. Questions of law and fact common to the members of the Class predominate over questions, if any, that may affect only individual Class members because Defendants have acted

on grounds generally applicable to the entire Class. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

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

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

b. Whether Defendants conspired to restrict output of generic Colcrys;

c. Whether Defendants conspired to maintain Takeda's monopoly power over Colcrys;

d. Whether Takeda and Par's distribution joint venture was a disguise for a naked restraint of competition;

e. Whether Defendants' challenged conduct restrained competition to Colcrys;

f. Whether Defendants' conduct should be evaluated under the *per se* illegality standard, the quick look standard, or under the antitrust rule of reason;

g. Whether Takeda possessed monopoly power with respect to Colcrys;

h. Whether there exist any legitimate procompetitive justifications for some or all of the Defendants' conduct;

i. To the extent such justifications exist, whether there were less restrictive means of achieving them;

j. Whether the Defendants' scheme, in whole or in part, has substantially affected interstate commerce;

k. Whether the Defendants' unlawful conduct was a substantial contributing factor in causing a reduction in competition to Colcrys;

l. whether, and to what extent, Defendants' conduct caused antitrust injury (overcharges) to Plaintiff and the Direct Purchaser Class; and

m. The quantum of overcharges paid by the class in the aggregate.

25. A class action is superior to any other available method for the fair and efficient adjudication of this controversy in that, among other things, such treatment will permit a large number of similarly situated persons and entities to prosecute their common claims in a single

forum simultaneously, efficiently, and without the unnecessary duplication of effort and expense that numerous individual actions would engender.

26. The prosecution of separate actions by individual members of the Class would create a risk of inconsistent or varying adjudications with respect to individual members of the Class. These adjudications would establish incompatible standards of conduct for the Defendants which would, as a practical matter, be dispositive of the claims of the other members not parties to the adjudications or substantially impair or impede their ability to protect their interests.

V. FACTS

A. COLCRYS

27. Colcrys is approved by the Food and Drug Administration ("FDA") for the treatment and prophylaxis (prevention) of gout flares and for the treatment of familial Mediterranean fever ("FMF") in adults and children 4 years or older.

28. Colcrys's active ingredient, colchicine, had been used in the United States for decades before the FDA approval of Colcrys. Before 2006, colchicine was widely available from numerous sources. As a result, before 2006, a colchicine pill cost just $0.09. However, in 2006, the FDA encouraged the pharmaceutical industry to submit New Drug Applications ("NDAs") for previously unapproved drugs to facilitate FDA evaluation of older drug products by contemporary standards.

29. FDA approved Colcrys on July 29, 2009 as the first pharmaceutical product containing colchicine as the sole active ingredient. Since its approval Takeda has charged monopoly prices, realizing annual sales of Colcrys as high as $546 million. By May 2014, Takeda was charging over $5.25 per a tablet of Colcrys, an increase of 5,733.33% over the price in 2006.

B. FDA APPROVAL OF COLCRYS

30. Colchicine is a very old drug that has been used in the treatment of gout for a very long time. It is a naturally occurring substance found in the autumn crocus plant (Colchicum autumnale) and was used by the Ancient Greeks approximately two thousand years ago to treat and prevent symptoms of gout, a type of severe arthritis often characterized by painful "flares" (severe and sudden attacks of pain, redness, inflammation, and tenderness in joints) resulting from the build-up of uric acid. More recently, in 1972, Dr. Stephen Goldfinger reported the successful use of colchicine in treating FMF, a rare, autosomal recessive, auto-inflammatory disease characterized by recurrent and/or chronic inflammation that is concentrated in populations of Mediterranean origin, including Sephardic Jews, Arabs, Turks, and Armenians. Thus, no later than 1972, the uses of colchicine in the treatment and prevention of gout flares and the treatment of FMF were well known and unpatentable.

31. By its own terms, the Food, Drug & Cosmetic Act applies only to "any new drug," and therefore not to old drugs like colchicine. Accordingly, companies marketing colchicine prior to 2006 were not operating pursuant to NDAs. In 2006, however, FDA announced its Unapproved Drugs Initiative under which it planned "to remove unapproved drugs from the market" and bring "all such drugs into the approval process."

32. In 2008, Takeda's predecessor Mutual Pharmaceutical Co., Inc., a subsidiary of United Research Laboratories, Inc. (all referred to collectively as "Takeda" herein) filed three NDAs (*i.e.*, NDA Nos. 22-351, 22-352, and 22-353) for colchicine for the treatment of FMF and the treatment and prophylaxis (*i.e.*, prevention) of gout flares. In 2009, FDA approved these NDAs and granted Takeda's colchicine product a three-year exclusivity for the treatment of

acute gout flares and a seven-year exclusivity for the treatment of FMF. Takeda's final exclusivity expired on July 29, 2016.

C. AB-RATED GENERIC VERSIONS OF BRAND-NAME DRUGS ARE SIGNIFICANTLY LESS EXPENSIVE THAN, AND TAKE SIGNIFICANT SALES DIRECTLY FROM, THE CORRESPONDING BRAND-NAME VERSIONS

33. Competition from lower-priced AB-rated generic drugs saves American consumers billions of dollars a year. These consumer savings mean lower profits for brand drug companies. When robust AB-rated generic entry occurs, the brand company suffers a rapid and steep decline in sales and profits on its corresponding brand drug.

34. The threat of AB-rated generic competition thus creates a powerful incentive for brand companies to protect their revenue streams.

35. When there are many generic competitors, AB-rated generic versions of brand-name drugs are priced significantly below their brand-name counterparts. Because of those lower prices, and aided by institutional features of the pharmaceutical market, AB-rated generic drugs are rapidly and substantially substituted for their more expensive brand-name counterparts.

36. When multiple generic manufacturers enter the market, prices for generic versions of a drug predictably decrease significantly because of competition among the generic manufacturers.

37. An AB rating means that the generic drug is pharmaceutically equivalent and bioequivalent to the corresponding reference-listed brand drug. An AB-rating is particularly significant to a generic manufacturer because, under the Hatch-Waxman Act of 1984, as amended, and all state Drug Product Selection laws, pharmacists may (and in many states, must) substitute an AB-rated generic version of a drug for the brand-name drug automatically at the pharmacy counter, without seeking or obtaining permission from the prescribing physician.

Generic drugs that are not AB-rated, either because they are not pharmaceutically equivalent or not bioequivalent, cannot be automatically substituted by the pharmacist.

38. Robust AB-rated generic competition, facilitated by automatic pharmacy substitution, enables direct purchasers, patients, and insurers to (a) purchase generic versions of brand-name drugs at substantially lower prices, and/or (b) purchase the brand-name drug at reduced prices. However, until generic manufacturers enter the market with their AB-rated generic products, there are no pharmaceutically equivalent and bioequivalent generic drugs which compete with the brand-name drug, and therefore the brand-name manufacturer can continue to charge supracompetitive prices profitably without losing all or a substantial portion of its brand-name sales.

39. The barriers to entry by a generic drug manufacturer are high. Such companies must first formulate a generic version of the brand-name drug; conduct bioequivalence and other studies needed to support an Abbreviated New Drug Application to FDA ("ANDA"); file the ANDA and work with FDA on any issues that arise regarding approval; and invest in manufacturing facilities for the commercialization of the product.

40. As an incentive to spur generic companies to seek approval of generic alternatives to branded drugs, the first generic manufacturer to file an ANDA containing a certification that the generic version does not infringe any valid patent listed in FDA's "Orange Book" against the reference-listed brand drug (a "Paragraph IV certification") gets 180 days of protection from competition from other generic versions of the drug (except the brand's "authorized generic" version).

41. The high profit margins on brand name drugs, and the profit lowering effects of AB-rated generic entry create powerful financial incentives for brand name manufacturers to list

patents in the Orange Book even if such patents are not eligible for listing, and sue any generic competitor that files an ANDA with a Paragraph IV certification even if the competitor's product does not actually infringe the listed patents or the patent is invalid and unenforceable. Brand drug manufacturers do this simply to delay final FDA approval of an ANDA for up to 30 months (the "30-month stay").

D. DEFENDANTS' OUTPUT-RESTRICTION CONSPIRACY

42. In December 2011, Par filed ANDA No. 203976, the first ANDA to seek FDA approval for a generic version of Colcrys. Par certified that all pertinent patents that Takeda listed in the Orange Book under the Colcrys NDA were either invalid or not infringed. As the first generic filer making such a Paragraph IV certification, Par was entitled to a 180-day period of regulatory exclusivity during which the FDA would not approve other generic manufacturers to sell a generic version of Colcrys.

43. Eight other generic companies, including Amneal and Watson, filed ANDAs seeking approval to sell generic versions of Colcrys and made similar Paragraph IV certifications that any listed patents were invalid or not infringed.

44. Takeda sued all of the ANDA filers, alleging infringement of the patents purportedly covering Colcrys. Takeda sued Par first, in August of 2013 (the "Par Litigation").

45. Takeda's patents were fatally weak, and had already been found to have not been infringed by Hikma International Pharmaceuticals LLC in litigation regarding another product called Mitigare.

46. Worse for Takeda, the ANDA filers were close to obtaining FDA approval to market generic Colcrys. Par obtained tentative FDA approval to launch its ANDA product in February of 2015. This meant that FDA found Par was ready and able to market its generic

Colcrys product once the 30-month stay (which began when Takeda filed the Par Litigation) had elapsed, or Par prevailed in the Par Litigation, whichever came first.

47. Watson obtained tentative FDA approval to launch its ANDA product in October of 2015. This meant that FDA found Watson was ready and able to market its generic Colcrys product once Par, as the first ANDA filer, had been on the market for 180 days.

48. Amneal would obtain final FDA approval to launch its ANDA product several month later, in September of 2016, and the FDA would approve multiple other ANDA filers throughout the period 2019 through 2021.

49. Knowing how fatally weak its patents purportedly covering Colcrys were, Takeda had anticipated imminent generic competition, and in advance of trial in the Par Litigation, had entered into an agreement with Prasco to distribute, starting in January of 2015, an authorized generic version of Colcrys, to try to lock up generic sales for Takeda and thereby allow Takeda to keep the profits that would have been otherwise lost to generic competitors.

50. Prasco distributed Takeda's authorized generic Colcrys pursuant to Takeda's direction at a price just slightly lower than branded Colcrys.

51. Prasco collected and remitted back to Takeda virtually all of the revenues from sales of authorized generic Colcrys. Authorized generic Colcrys did not reduce Takeda's profits very much at all, therefore. Colcrys prices and Takeda's profits remained at monopoly levels.

52. The market entry of additional generic versions of a brand drug results in increasingly robust price competition and competes down the profits of the branded drug seller, and of the first generic entrant, as the new entrants offer price concessions as they jockey for market share, resulting in substantially lower prices.

53. This would have happened with Colcrys unless Takeda, Par, Watson, and Amneal concertedly took action to prevent it. Takeda was facing the devastation of its Colcrys profits if Par, and then 180 days later Watson and Amneal, entered the market with generic Colcrys. Par was facing the unpleasant prospect of entering, with its generic Colcrys, a market where Takeda, through its distributor Prasco, had already been selling authorized generic Colcrys, which would have forced Par to offer very low prices to dislodge and gain market share, depriving Par of the benefits of its 180-day exclusivity as the first ANDA filer. Watson and Amneal were each facing the unattractive prospect of entering a market where Prasco and Par had already been fighting over market share for 180 days, and therefore of having to offer rock-bottom prices to gain sales and share.

54. Thus, on the eve of trial in the Par Litigation in November of 2015, Takeda, Par, Watson and Amneal agreed to a scheme to restrain price competition to Colcrys by concertedly reducing generic Colcrys output, and agreed to share in the monopoly profits maintained thereby until January of 2024. This single conspiracy had two basic features.

55. First, in addition to entering a settlement agreement resolving the Par Litigation, Takeda and Par entered into a sham joint venture in the form of a distribution agreement that concealed the first part of their output restriction conspiracy. Under the agreement, Par would refrain from launching its generic version of Colcrys, despite having tentative FDA approval. Instead, 2½ years following entry of the agreement (*i.e.*, in July of 2018), instead of competing against Takeda, Par would instead replace Prasco as the distributor of Takeda's authorized generic Colcrys and would remit back to Takeda virtually all of the revenues from sales of authorized generic Colcrys, keeping some of those revenues for itself.

56. Second, in addition to entering into settlement agreements resolving the Par Litigation, Takeda struck agreements with Watson and Amneal, respectively, offering each a defined time, believed to be between 6 and 18 months in duration, to sell generic Colcrys free from competition from all other generic Colcrys sellers, if Watson and Amneal would stay off the market for several years until their defined periods of marketing commenced.

57. The output-restriction agreement among Takeda, Par, Watson, and Amneal contained one escape clause: Par, Watson, and Amneal would refrain from launching their own generic versions of Colcrys only for so long as non-conspirators did so. That is, the co-conspirators agreed that if a non-conspiring seller of generic Colcrys entered the market, Par, Watson, and Amneal could do so, also (the "escape clause"). Par's selling Takeda's authorized generic Colcrys avoided this escape clause. This escape clause, and its necessary implication that the co-conspirators were willing to restrict their own output only so long as non-conspirators were doing so, too, illustrates the interdependence of the promises of the co-conspirators, the existence of the conspiracy, the fact that output restriction was against the unilateral economic interests of the conspirators and was only in their joint conspiratorial interests, and demonstrates the singular nature of the conspiracy.

58. This arrangement was beneficial to all of the co-conspirators. In January of 2020, Par asserted that "authorized generic Colcrys is its largest generic product." Par also wrote that "[t]he distribution agreement between Takeda and Par . . . provides powerful incentives to ensure that the parties preserve the two-entrant market." Par even explained the logic behind the output-restriction conspiracy:

> [A market with] a single branded drug (Takeda's Colcrys) and a single generic version (Par's authorized generic) only functions if the market for Colcrys-equivalent colchicine is limited to those two products. [] Although a drug market can maintain price

> stability with a single generic version of a drug on the market, multiple entrants often produce a market-wide price collapse with mass renegotiation and cancellation of supply agreements. [] The distribution agreement between Takeda and Par recognizes this dynamic and provides powerful incentives to ensure that the parties preserve the two-entrant market.

59. Par has asserted that even the entry of a single additional competitor would cause its distribution joint venture with Takeda "to lose approximately $97 million in annual revenue." Par has asserted that with "two or three other generic ANDA filers enter[ing] the market," the joint venture would lose even more, because "[a]s additional generic versions of Colcrys enter the market, Par would be forced to swiftly reduce prices to maintain even a portion of its market share."

60. The conduct among Takeda, Par, Watson, and Amneal only makes economic sense if there was an agreement among the four of them to restrain their respective generic and authorized-generic output and prevent the price collapse that Par so vividly described. Specifically:

(a) absent concerted assurances that Par, Watson, and Amneal would restrict their output of generic Colcrys for several years, it would not be in Takeda's unilateral economic interests to agree to stop distributing authorized generic Colcrys through Prasco;

(b) absent concerted assurances that Takeda would remove Prasco as a distributor of authorized generic Colcrys and that Watson and Amneal would restrict their output for several years, it would not be in Par's unilateral economic interests to agree to restrict its output of its generic Colcrys for several years and to agree to defined periods of sales free from other generic Colcrys competition for Watson and Amneal; and

(c) absent concerted assurances that they would receive defined periods of sales free from other generic Colcrys competition, it would not be in Watson's or Amneal's unilateral economic interests to agree to restrict their output of generic Colcrys for several years after Par's 180-day exclusivity elapsed.

61. Each of Takeda, Par, Watson, and Amneal was a completely involved co-conspirator. Each participated in the formation of the conspiracy, actively and even aggressively supported and furthered it, and was a necessary part and parcel of it.

62. Defendants' conspiracy came to a sudden and unexpected halt in November of 2019, when Mylan launched generic Colcrys.

63. Like many other non-conspiring generic drug companies, Mylan had filed an ANDA with a Paragraph IV certification for generic Colcrys. On or about September 19, 2016 Mylan notified Takeda of its ANDA. Takeda sued Mylan for alleged patent infringement on October 24, 2016. Takeda and Mylan settled their Colcrys patent litigation on November 7, 2017.

64. Takeda's settlement with Mylan permitted Mylan to launch upon a court decision invalidating the patents covering Colcrys.

65. On December 12, 2018, Judge Richard G. Andrews issued an opinion granting a motion by Hikma for summary judgment in patent litigation concerning another product subject to the same patents as Colcrys, which Takeda failed to appeal.

66. On October 28, 2019, Mylan informed Takeda that Mylan intended to immediately launch a generic version of Colcrys, and on November 25, 2019, Mylan launched its generic version of Colcrys, thereby triggering the "escape clause" in Par, Watson, and Amneal's agreements. The output-restriction conspiracy was over.

VI. ANTICOMPETITIVE EFFECTS

67. Defendants' conspiracy severely harmed competition in the market for Colcrys and generic Colcrys, while it lasted and for some time thereafter. It restricted output of generic Colcrys, kept Colcrys prices at supracompetitive levels, and delayed their fall to competitive levels. But for the conspiracy, Par would have launched generic Colcrys under its ANDA in July of 2016 following the expiration of Takeda's exclusivity, followed 180 days later by Watson, Amneal, and several other ANDA filers. Takeda would have kept its authorized generic on the market, distributed by Prasco. The price of Colcrys would have bottomed out to pre-2006 levels nearly instantaneously.

68. Although Watson and Amneal did not get to enjoy the fruits of the conspiracy — because Mylan ended the conspiracy before they could enjoy the periods of reduced competition they were promised in exchange for restricting their output for several years — Defendants' conspiracy was very profitable to both Takeda and Par.

69. By replacing Prasco as Takeda's authorized generic distributor and keeping a share of authorized generic revenues until January of 2024, Par expected to earn approximately $50-80 million more than it would absent the conspiracy (*i.e.*, had it launched its ANDA product on July 29, 2016 alongside Takeda's authorized generic distributed by Prasco and faced additional generic competition after 180 days).

70. From the absence of AB-rated generic competition for as long as the conspiracy lasted, Takeda earned approximately $1 billion more than it would have had it faced generic competition, even if it had kept Prasco on the market as its authorized generic distributor.

71. For their part, Watson and Amneal each could have expected to earn approximately $12-36 million more during their respective periods as the only generic seller on

the market than they would have earned absent the conspiracy and facing multiple generic competitors.

VII. ANTITRUST IMPACT

72. During the class period, Plaintiff and members of the Class purchased substantial amounts of Colcrys and authorized generic Colcrys from Takeda, Prasco, and Par at supracompetitive prices. As a result of Defendants' conspiracy, and as intended by Defendants, Plaintiff and members of the Class were compelled to pay and did pay artificially inflated prices for their requirements for Colcrys tablets. Those prices were substantially greater than the prices that Plaintiff and members of the Class would have paid absent the conspiracy alleged herein, because, but for the conspiracy, Plaintiff and members of the Class would have paid lower prices for their branded and generic Colcrys requirements.

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

VIII. EFFECT ON INTERSTATE COMMERCE

74. At all material times, Defendants, manufactured, promoted, and sold substantial amounts of brand and generic Colcrys in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States, including its territories, possessions and the Commonwealth of Puerto Rico. During the relevant time period, in connection with the purchase and sale of brand and generic Colcrys, monies as well as contracts, bills and other forms of business communication and transactions were transmitted in a continuous and uninterrupted flow across state lines.

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

IX. MONOPOLY POWER AND RELEVANT MARKET

76. At all relevant times Takeda had monopoly power in a market limited to Colcrys and generic Colcrys, because it had and exercised the power to raise and maintain the price of Colcrys and authorized generic Colcrys tablets at supracompetitive levels without losing substantial sales to other products prescribed and/or used for the same purposes, other than generic Colcrys.

77. A small but significant, non-transitory increase in the price of Colcrys or authorized generic Colcrys would not have caused, and never did cause, a significant loss of sales to products used for the same purposes as Colcrys, other than generic Colcrys.

78. Colcrys and authorized generic Colcrys tablets do not exhibit significant, positive cross-elasticity of demand with respect to price with any product other than generic Colcrys. Indeed, Takeda has repeatedly increased the price of brand Colcrys without losing sales to any other non-Colcrys product.

79. Other drugs that are not AB-rated to Colcrys do not exhibit substantial cross-price elasticity of demand with Colcrys, and thus are not economic substitutes for, nor reasonably interchangeable with, Colcrys.

80. Products other than generic Colcrys are not economic substitutes for Colcrys or authorized generic Colcrys, and the existence of other products used to treat and/or prevent the same conditions as Colcrys did not significantly constrain Takeda's Colcrys or authorized

generic Colcrys pricing. On information and belief, Takeda has never lowered the price of Colcrys or lowered the price of authorized generic Colcrys in response to the pricing of other branded or generic drugs used to treat the same conditions as Colcrys.

81. To the extent Plaintiff is legally required to prove monopoly power circumstantially or indirectly by first defining a relevant product market, the relevant product market is limited to Colcrys and generic Colcrys.

82. The relevant geographic market is the United States and its territories.

83. At all relevant times, Takeda's market share in the relevant market was 100%, implying a substantial amount of monopoly power.

84. Takeda needed to control only Colcrys and generic Colcrys, and no other products, in order to profitably maintain prices at a supracompetitive level. No product other than generic Colcrys ever rendered Takeda unable to profitably raise or maintain the price of Colcrys without losing substantial sales. Only the market entry of an AB-rated generic version of Colcrys would render Takeda unable to profitably maintain its prices of Colcrys and/or authorized generic Colcrys without losing substantial sales.

85. At all relevant times, Takeda enjoyed high barriers to entry with respect to competition to the relevant product market due to patent and other regulatory protections and high costs of entry and expansion.

X. CLAIM ACCRUAL AND/OR TOLLING

86. Plaintiff's Complaint is timely as to all claims accruing within four years of the date of the filing of this Complaint.

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87. Plaintiff's damages claims predating four years before the filing of this Complaint are also timely under the doctrines of equitable tolling, the discovery rule, and fraudulent concealment.

88. These doctrines apply because (1) Defendants concealed from Plaintiff the existence of this cause of action, (2) Plaintiff could not have known about this cause of action until on or after December 2, 2019 when details about the sham joint venture between Takeda and Par began to be made public, and (3) Plaintiff's continuing ignorance was not attributable to lack of diligence on its part.

89. Until December 2, 2019, Defendants concealed from Plaintiff the existence of its cause of action. Specifically, Defendants concealed from Plaintiff the terms of the joint venture, in particular that it involved a sham joint venture to preserve Takeda's monopoly and reduce output and maintain monopoly pricing for Colcrys.

90. Moreover, the joint venture was inherently self-concealing. It required the Defendants to maintain confidentiality.

91. Plaintiff remained in ignorance of this cause of action until some point within four years of commencement of this action, and Plaintiff's continuing ignorance was not attributable to a lack of diligence on its part.

92. As a result of Defendants' fraudulent concealment, all applicable statutes of limitations for the Plaintiff's and the Class's claims have been tolled. Even absent fraudulent concealment, all applicable statutes of limitations are tolled by the doctrine of equitable estoppel.

93. Alternatively, if the statute of limitations is not tolled, this Complaint alleges a continuing course of conduct (including conduct within the limitations period), and Plaintiff and

members of the Class can recover for damages that they suffered during the limitations period, *i.e.*, within the last four years.

XI. CLAIMS FOR RELIEF

COUNT I
15 U.S.C. § 1
Conspiracy in Restraint of Trade
(Against All Defendants)

94. Plaintiff hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

95. Defendants entered into a single output-restriction conspiracy as detailed above.

96. The conspiracy substantially, unreasonably, and unduly restrained trade in the relevant market, and harmed Plaintiff thereby.

97. Defendants are *per se* liable for the output-restriction conspiracy.

98. Alternatively, Defendants are liable for the conspiracy under a "quick look" and/or rule of reason standard.

99. There is no legitimate, nonpretextual procompetitive justification for the conspiracy that outweighs its harmful effect. Even if there were some conceivable such justification, the conspiracy was broader than necessary to achieve such a purpose.

100. Takeda and Par's agreement to replace Prasco with Par as Takeda's distributor of "authorized generic" Colcrys was a pretextual, sham joint venture that sought to conceal the output-restriction conspiracy and did nothing to contribute to competition, as it merely substituted one distributor with another.

101. As a direct and proximate result of Defendants' conspiracy, as alleged herein, Plaintiff and the Class were harmed as aforesaid.

COUNT II
15 U.S.C. § 2
Monopolization
(Against Takeda Only)

102. Plaintiff hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

103. At all relevant times, Takeda possessed monopoly power in the relevant market.

104. By its conduct as set forth above, Takeda willfully maintained its monopoly power in the relevant market using restrictive or exclusionary conduct, rather than by means of greater business acumen, and injured Plaintiff thereby.

105. It was Takeda's conscious object to further its dominance in the relevant market by and through its conduct set forth above.

106. Takeda's conduct as set forth above constitutes an anticompetitive scheme to maintain monopoly power in the relevant market.

107. The goal, purpose, and/or effect of Takeda's conduct was to maintain and extend Takeda's monopoly power with respect to Colcrys, and share in the unlawful profits derived therefrom. Takeda's conduct to impair generic competition allowed Takeda to continue charging supra-competitive prices for Colcrys and "authorized generic" Colcrys without a substantial loss of sales.

108. As a direct and proximate result of Takeda's monopolistic conduct, as alleged herein, Plaintiff and the Class were harmed as aforesaid.

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COUNT III
15 U.S.C. § 2
Conspiracy to Monopolize
(Against All Defendants)

109. Plaintiff hereby incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

110. Defendants conspired to unlawfully maintain Takeda's monopoly power in the relevant market by agreeing and adhering to the promises comprising the output-restriction conspiracy.

111. Defendants knowingly and intentionally entered into the output-restriction conspiracy.

112. Defendants specifically intended that the conspiracy would maintain Takeda's monopoly power in the relevant market, and injured Plaintiff and the Class thereby.

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

114. As a direct and proximate result of Defendants' concerted monopolistic conduct, as alleged herein, Plaintiff and the Class were harmed as aforesaid.

XII. DEMAND FOR JUDGMENT

Plaintiff, on behalf of itself and the proposed Class, respectfully demand that this Court:

a. Determine that this action may be maintained as a class action pursuant to Federal Rules of Civil Procedure 23(a) and (b)(3), and direct that reasonable notice of this action, as provided by Federal Rule of Civil Procedure 23(c)(2), be given to the Class, and declare the Plaintiff as the representative of the Class;

b. Enter joint and several judgments against the Defendants and in favor of the Plaintiff and the Class;

c. Award the Class damages (*i.e.*, three times overcharges) in an amount to be determined at trial;

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

e. Award such further and additional relief as the case may require and the Court may deem just and proper under the circumstances.

XIII. JURY DEMAND

Pursuant to Fed. R. Civ. P. 38, Plaintiff demands a trial by jury on all issues so triable.

Dated: August 5, 2021

Respectfully submitted,

VALUE DRUG COMPANY

By: _____
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