

ORIGINAL
FILED
COM 19 PM 3:51
JAMES H. HENNING
U.S. DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

1 Timothy J. Becker (*Pro Hac to be Filed*)
2 Gregory Sautter (California No. 191866)
3 ZIMMERMAN REED P.L.L.P.
4 651 Nicollet Mall, Suite 501
5 Minneapolis, Minnesota 55402
6 Telephone: (612) 341-0400
7 Email: tjb@zimmreed.com
8 Email: gps@zimmreed.com

9 Jason Thompson (*Pro Hac to be Filed*)
10 Ann K. Mandt (*Pro Hac to be Filed*)
11 CHARFOOS & CHRISTENSEN, P.C.
12 5510 Woodward Avenue
13 Detroit, MI 48202
14 Telephone: (313) 875-8080
15 Email: jthompson@c2law.com
16 Email: akmandt@c2law.com

17 *Attorneys for Plaintiffs*

18 UNITED STATES DISTRICT COURT
19 NORTHERN DISTRICT OF CALIFORNIA

JCS

20 LOCAL 28 SHEET METAL WORKERS,
21 on behalf of itself and all others similarly
22 situated,

23 Plaintiff,

24 vs.

25 ALZA CORPORATION, a California
26 Corporation,

27 Defendant.

Case No. **19-cv-054758**

COMPLAINT

JURY TRIAL DEMANDED

28 **INTRODUCTION**

COMES NOW THE Plaintiff, Local 28 Sheet Metal Workers, on behalf of itself and the two sub-classes of End-Payers as defined below, and by and for its Complaint against Defendant state and alleges as follows:

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

I.

JUDISDICTION AND VENUE

1. This action is brought pursuant to various state antitrust laws and the consumer protection laws of the State of California for damages stemming from Defendant's illegal monopolistic conduct. The Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1391(b) and (c) and 15 U.S.C. § 1332(d), as amended in 2005, and 28 U.S.C. § 1367.

2. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) and (c), 28 U.S.C. § 1407 in that Defendants did business in this judicial district, and on information and belief are incorporated in the State of California.

3. The illegal monopolization and attempt to monopolize the market for Ditropan XL and generic versions of Ditropan XL, as alleged herein, have substantially affected interstate and foreign commerce.

II.

NATURE OF ACTION

4. This is a nationwide class action brought under various state antitrust laws and California's Unfair Business Practice laws seeking damages and other equitable relief arising from the manufacture and marketing of the brand-name drug Ditropan XL, a drug used to remedy urinary incontinence problems. Defendant's unlawful conduct prevented generic versions of Ditropan XL from coming to the United States market, thereby causing injury to Plaintiff and members of the Class. The generic name for Ditropan XL is oxybutynin.

5. Ditropan XL (oxybutynin) is a drug which has been used to treat urinary incontinence since the 1970's. Ditropan XL, and its generic counter-part, were extended release versions of oxybutynin, designed to deliver the drug in a "sustained release" formulation. As a result of the sustained-release version of the drug, it could be administered once per day (as opposed to multiple tablets) over a 24 hour period. Ditropan XL was marketed by Alza Corporation, a subsidiary of Johnson & Johnson.

1 throughout the United States to assist with the treatment of urinary incontinence and
2 other related problems. Through the patent of its product, Alza controlled the
3 overwhelming majority of all extended release oxybutynin, with yearly sales in excess of
4 \$440 million.

5 6. On or about January 22, 2003, Mylan Pharmaceuticals, Inc. (“Mylan”) filed
6 an application with the Food and Drug Administration (“FDA”) requesting approval to
7 manufacture, market, and sell a generic versions of Ditropan XL.

8 7. In response to Mylan’s ANDA application, Defendant commenced a
9 baseless patent infringement action against Mylan in an attempt to thwart production of
10 generic versions of Ditropan from entering the United States market. In its effort to
11 extend its patent Alza misrepresented evidence to the Patent and Trademark Office
12 (“PTO”) to gain approval of a patent for Ditropan XL. Alza’s misrepresentation
13 included, but were not limited to, information supplied to the PTO related to the
14 “dissolution rate” of Ditropan XL which ALZA knew was anticipated by “prior art.”
15 Despite this knowledge, Alza failed to disclose these facts to the PTO thereby leading to
16 approval of the Ditropan XL patent in the form of *U.S. Patent No. 6.124.355* (“the ‘355
17 patent”).

18 8. In response, litigation ensued between Mylan and Alza over the validity of
19 Alza’s ‘355 patent. Ultimately, the District Court for the Northern District of West
20 Virginia concluded that Mylan’s generic product did not infringe upon Alza’s patent and
21 that the ‘355 patent itself was invalid because it was both “obvious” and “anticipated.”

22 9. As a direct and proximate result of Defendant’s unlawful conduct,
23 consumers have been denied the benefits of free and unrestrained competition in the
24 extended release oxybutynin market. More specifically, Plaintiff and members of the
25 Class have been denied the opportunity to choose between the brand name prescription
26 drug and lower priced generic versions by being forced to pay supracompetitive prices.

27 10. Count I is bought by Plaintiffs on behalf of themselves and those Class
28 members who purchased or paid for Ditropan XL and its generic bio-equivalents in

1 Alabama, Alaska, Arizona, California, the District of Columbia, Florida, Hawaii, Iowa,
2 Kansas, Kentucky, Louisiana, Maine, Massachusetts, Michigan, Minnesota, Mississippi,
3 Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, North Dakota,
4 South Dakota, Tennessee, Vermont, West Virginia and Wisconsin (the "Indirect
5 Purchaser States").

6 11. Count II is brought pursuant to California's Unfair Competition Law, Cal.
7 Bus. & Prof. Code § 17200 et al. Defendant is a California business, licensed to practice
8 law in the State of California. As such, Defendant maintains a reasonable expectation of
9 being sued in California, under California's laws for its illegal conduct.

10 **III.**

11 **PARTIES**

12 12. Plaintiff Local 28 Sheetmetal Workers Fund is a duly formed Health and
13 Welfare Fund ("The Plan") located in Mineola, New York. During the Class Period as
14 described herein, Plaintiff paid for Ditropan XL which was prescribed for the Plan's
15 members and they have been injured as a result of Defendant's conduct. Plaintiff is a
16 member of both sub-classes defined herein, will adequately represent the interests of the
17 class, and seeks to be certified as the Class Representative of this class.

18 13. Defendant, Alza Corporation ("Alza") is a California Corporation whose
19 principle place of business is 1900 Charkston Road, Mountain View, California. On
20 information and belief, Alza is a corporation in good standing with the State of
21 California.

22 14. Various persons, partnerships, sole proprietors, firms, corporations and
23 individuals not named as defendants in this lawsuit, and individuals, the identities of
24 which are presently unknown, may have participated as co-conspirators with Defendants
25 in the offenses alleged in this Complaint, and have performed acts and made statements
26 in furtherance of the alleged conspiracy to monopolize.

1 IV.

2 **INTERSTATE TRADE AND COMMERCE**

3 15. Defendant's efforts to monopolize and restrain competition in the market
4 for Ditropan XL substantially affected interstate and foreign commerce.

5 16. During all or part of the Class Period, Defendant manufactured and sold
6 substantial amounts of Ditropan XL in a continuous and uninterrupted flow of commerce
7 across state and national lines and throughout the United States. Defendant maintained
8 an exclusive license to market and sell Ditropan XL in the United States.

9 17. In furtherance of its efforts to monopolize and/or restrain competition in the
10 market for Ditropan XL and its generic equivalents, Defendant employed the United
11 States mail and other forms of interstate travel.

12 V.

13 **RELEVANT MARKET**

14 18. During the class period, the relevant market was the manufacture and sale
15 of Ditropan XL, oxybutynin extended release, sold in the United States. The relevant
16 geographic market for Ditropan XL is the United States.

17 19. During the class period, Defendant's share of the relevant market was
18 100%, and Defendant maintained monopoly power in each relevant market during that
19 time period.

20 VI.

21 **MARKET EFFECTS**

22 20. The acts and practices of Defendant, as herein alleged, had the purpose and
23 effect of restraining competition unreasonably and injuring competition by protecting
24 Ditropan XL from generic competition in the relevant market.

25 21. If a generic competitor had been able to enter the relevant market and
26 compete with Defendant, End-Payers such as Plaintiff would have been free to substitute
27 a lower-priced generic for the higher-priced brand name drug and the Class would have
28 paid less for all oxybutynin extended release products, including Ditropan XL.

1 Pharmacists generally are permitted, and in some instances required, to substitute generic
2 drugs for their branded counterparts, unless the prescribing physician has directed that the
3 branded product be dispensed. In addition, there is a ready market for generic products
4 because certain third-party payors of prescription drugs (e.g., managed care plans)
5 encourage or insist on the use of generic drugs whenever possible. A generic product can
6 quickly and efficiently enter the marketplace at substantial discounts, generally leading to
7 a significant erosion of the branded drug's sales within the first year.

8 22. By preventing generic competitors from entering the market, Defendant
9 injured Plaintiff and the other Class members in their business or property by causing
10 them to pay more for Ditropan XL than they otherwise would have paid. Defendant's
11 unlawful conduct deprived Plaintiff and other End-Payors of the benefits of competition
12 that the antitrust laws and California's state consumer protection laws are designed to
13 preserve.

14 VII.

15 FACTUAL ALLEGATIONS

16 A. Federal Regulation of Prescription Drugs

17 1. Brand-name Drugs v. Generic Drugs

18 23. The laws governing pharmaceutical products are meant to balance the
19 competing policy goals of providing new drug inventors an economic return on their
20 investment while also ensuring consumers access to additional and more affordable
21 generic versions of brand name drugs.

22 24. The manufacture, marketing, distribution and sale of prescription drugs is
23 one of the most profitable industries in the United States. The U.S. market accounts for
24 more than 40% of the world's prescription pharmaceutical revenues. The cost of
25 prescription drugs in the United States has been rising at double digit rates for years, and
26 the cost of drugs dispensed in the United States in the most recent year exceeded \$2
27 billion.

1 25. The availability of generic drugs has been one of the most effective means
2 of lowering the cost of prescription drugs. Generic drugs, which also must be approved
3 by the FDA, have the same active chemical composition and provide the same
4 therapeutic effects as the pioneer brand-name drugs upon which they are modeled. The
5 FDA will assign an "AB" rating to generic drugs that are bioequivalent to pioneer or
6 brand-name drugs.

7 26. To be deemed a therapeutic equivalent and assigned an "AB" rating by the
8 FDA, the generic drug must contain the same active ingredient(s); dosage form and route
9 of administration; and strength. If so, the generic drug, as a therapeutic equivalent, can
10 be substituted (and in some instances must be substituted) for the pioneer or brand-name
11 drug at the pharmacy dispensing the drug.

12 27. Generic drugs are generally priced substantially below the brand-name
13 drugs to which they are bioequivalent. A 1998 study conducted by the Congressional
14 Budget Office (the "CBO") concluded that generic drugs save consumers and third-party
15 payors between \$8 billion and \$10 billion a year. A report prepared by the Government
16 Accounting Office in August 2000 observed, "Because generic drugs are not patented
17 and can be copied by different manufacturers, they often face intense competition, which
18 usually results in much lower prices than brand-name drugs."

19 28. The Federal Trade Commission ("FTC") estimates that the first generic
20 manufacturer to enter the market typically charges between 70% and 80% of the price of
21 the brand-name drug. As additional manufacturers bring generic versions of the drug to
22 market, the price continues to drop.

23 29. A brand-name drug loses a significant portion of its market share to generic
24 competitors soon after the introduction of generic competition, even if the brand-name
25 manufacture lowers prices to meet competition. The 1998 CBO study estimates that
26 generic drugs capture at least 44% of the brand-name drug's market share in just the first
27 year of sale.

28

1
2
3 **2. Prescriptions for Generic Drugs**

4 30. Generic drugs are drugs that the FDA has found to have the same active
5 chemical composition and provide the same therapeutic effects as the pioneer or brand-
6 name drug.

7 31. If a generic version of a brand-name drug exists and the physician has not
8 specifically indicated on the prescription “DAW” or “dispense as written” (or similar
9 indications, the wording of which varies slightly from state to state), then: (a) for
10 consumers covered by most insurance plans, the pharmacist will substitute the generic
11 drug; and (b) for consumers whose purchases are not covered by insurance plans, the
12 pharmacist will offer the consumer the choice of purchasing the branded drug, or the AB-
13 rated generic at a lower price.

14 32. Once a physician writes a prescription for a brand-name drug such as
15 Ditropan XL, that prescription defines and limits the market to the drug named or its AB-
16 rated generic equivalent. Only drugs which carry the FDA’s AB generic rating may be
17 substituted by a pharmacist for a physician’s prescription for a brand-name drug.

18 **3. New Drug Applications (NDA)**

19 33. The statute regulating the manufacture and distribution of drugs and
20 medical devices in the United States is the Federal Food, Drug and Cosmetic Act, 21
21 U.S.C. § 301 *et seq.* (The “FD&C Act”).

22 34. Under the FD&C Act, approval by the FDA, the governmental body
23 charged with regulation of the pharmaceutical industry, is required before a company
24 may begin selling a new drug in interstate commerce in the United States. 21 U.S.C. §
25 355(a). Premarket approval for a new drug must be sought by filing a new drug
26 application (“NDA”) with the FDA under § 355(b) of the FD&C Act demonstrating that
27 the drug is safe and effective for its intended use.

1 35. New drugs that are approved for sale in the United States by the FDA are
2 typically covered by patents, which provide the patent owner with the right to exclude
3 others from making, using or selling that new drug in the United States for the duration of
4 the patents, plus any extension of the original patent period granted pursuant to the Drug
5 Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355 (“Hatch-
6 Waxman Act”).

7 36. Pursuant to 21 U.S.C. § 355(b), in its NDA the pioneer drug manufacturer
8 must list all patents that claim the drug for which FDA approval is being sought, or that
9 claim a method of using the drug, and with respect to which a claim of patent
10 infringement could reasonably be asserted against an unlicensed manufacturer or seller of
11 the drug.

12 37. Once the NDA is approved, any claimed patents are listed with the NDA in
13 a publication known as the Approved Drug Products With Therapeutic Equivalence
14 Evaluations. The publication is commonly called the “Orange Book.”

15 38. Pursuant to 21 U.S.C. § 355(c)(2), if, after its NDA is approved, the pioneer
16 drug manufacturer is issued a new patent that claims the drug or methods of its use, the
17 company must supplement its NDA by listing such new patent within 30 days of
18 issuance, whereupon the FDA publishes the new patent in a supplement to the Orange
19 Book. The FDA is required to accept as true patent information it obtains from patent
20 holders, such as whether a patent covers a particular drug product. If an unscrupulous
21 patent holder is willing to provide false information to the FDA to delay the onset of
22 generic competition, the FDA is powerless to stop it.

23 39. Once the safety and effectiveness of a new drug is approved by the FDA, it
24 may be used in the United States only under the direction and care of a doctor who writes
25 a prescription specifying the drug, which must be purchased from a licensed pharmacist.
26 Generally, the pharmacist must, in turn, fill the prescription with the drug specified by the
27 physician unless a generic version is available that has been approved by the FDA for
28 substitution as a bioequivalent.

1 **4. Abbreviated New Drug Application (“ANDAs”) For Generic Drugs**

2 40. Congress enacted the Hatch-Waxman Act in 1984 to establish an
3 abbreviated process to expedite and facilitate the development and approval of generic
4 drugs. Consumers benefit from the choice and competition. To effectuate its purpose, the
5 Hatch-Waxman Act permits a generic drug manufacturer to file an Abbreviated New
6 Drug Application (“ANDA”), which incorporates by reference the safety and
7 effectiveness data developed and previously submitted by the manufacturer of the
8 original, pioneer drug.

9 41. The Hatch-Waxman Act permits ANDA applicants to perform all necessary
10 testing, submit an application for approval, and receive tentative approval before the
11 relevant patents expire. Prior to the Hatch-Waxman Act, a generic applicant had to wait
12 until all patents had expired to begin the approval process or otherwise face an
13 infringement suit.

14 42. The brand-name drug patent owner, upon receiving a Paragraph IV
15 Certification from an ANDA applicant, has 45 days to initiate a patent infringement suit
16 against the applicant. *See* 21 U.S.C. § (j)(5)(5)(iii). If no action is initiated within 45
17 days, the process for FDA approval of the generic product is not delayed by patent issues.
18 However, if a patent infringement suit is brought within the 45-day window, FDA
19 approval of the ANDA is automatically postponed until the earliest of the expiration of
20 the patents, the expiration of 30 months from the patent holder’s receipt of notice of the
21 Paragraph IV Certification, or a final judicial determination of non-infringement.

22 43. The ANDA must include information concerning the applicant’s position
23 *vis-à-vis* the patent that the pioneer drug manufacturer claims applies to the drug.
24 Therefore, the ANDA filer must make one of four certification:

- 25 a. that no patent for the pioneer drug has been filed with the FDA (a
26 “Paragraph I Certification”);
27 b. that the patent for the pioneer drug has expired (a “Paragraph II
28 Certification”);

- 1 c. that the patent for the pioneer drug will expire on a particular date
2 and the generic company does not seek to market its generic product
3 before that date (a “Paragraph III Certification”); or
4 d. that the patent for the pioneer drug is invalid or will not be infringed
5 upon by the proposed generic company’s product (a “Paragraph IV
6 Certification”).

7 21 U.S.C. § 355(j)(2)(A)(vii). In the case of a patent that has not yet expired, the ANDA
8 applicant’s only certification options are Paragraph III or IV Certifications.

9 44. Accordingly, brand-name drug patent holders need only to file a patent
10 infringement lawsuit within 45 days of receipt of Paragraph IV Certification in order to
11 automatically block an ANDA applicant’s generic drug from entering the market for up
12 to 30 months.

13 45. An improper Orange Book listing also has additional anti-competitive
14 effects because the first generic company to file an ANDA with a Paragraph IV
15 Certification is, upon FDA approval, granted a 180-day period of exclusivity in relation
16 to other generic manufacturers. 21 U.S.C. § 355(j)(5)(B)(iv). This 180 day exclusivity
17 against other generic competitors is awarded to the first Paragraph IV filer regardless of
18 whether or not the brand company institutes pre-approval patent infringement litigation in
19 response to the Paragraph IV certification

20 **B. Alza’s Unlawful Monopolist Conspiracy**

21 **1. Alza Commences Sham Litigation**

22 46. Oxybutynin is a drug used to treat urinary incontinence. It was originally
23 developed in the 1970s. In its original form, patients took oxybutynin two to four times
24 per day.

25 47. On September 26, 2000, Alza received a patent from the PTO in the form
26 of *U.S. Patent No. 6,124,355* (“the ‘355 Patent”). The ‘355 Patent covers an extended-
27 release version of oxybutynin called Ditropan XL. Ditropan XL allowed patients to take
28

1 a daily dose of oxybutynin that delivered the drug to the body over a sustained 24 hour
2 period.

3 48. On or about January 22, 2003, Mylan Pharmaceuticals Inc. (“Mylan”) filed
4 an Abbreviated New Drug Application (“ANDA”) with the United States Food and Drug
5 Administration pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the “Paragraph IV”
6 certification). Pursuant to the Hatch-Waxman Act, Mylan’s ANDA noted that its
7 proposed generic version of Ditropan XL was lawful because the generic version: 1) did
8 not infringe upon the ‘355; and/or 2) the ‘355 patent was invalid.

9 49. On or about March 19, 2003, pursuant to the Hatch-Waxman Act, Mylan
10 notified Alza that it had filed an ANDA pursuant to Paragraph IV and that it intended to
11 commercially market a generic version of extended release oxybutynin. On information
12 and belief, Mylan’s letter to Alza set forth in detail the factual and legal basis that: 1)
13 Alza’s ‘355 patent was not valid; and/or 2) alternatively, that its generic version of
14 extended release oxybutynin did not infringe upon the ‘355 patent.

15 50. On May 2, 2003 Alza sued Mylan for infringement of the ‘355 patent in the
16 United States District Court for the Northern District of West Virginia. The case was
17 captioned *Alza Corporation v. Mylan Laboratories, Inc. and Mylan Pharmaceuticals,*
18 *Inc.*, Case No. 1:03CV61 (Keeley). In its Answer, Mylan specifically set forth an
19 Affirmative Defense that, “The ‘355 patent is invalid, unenforceable, and/or not infringed
20 by Mylan Pharmaceuticals’ Proposed Product.” Further, Mylan initiated a Counterclaim
21 against Alza seeking a declaratory judgment that: 1) Alza had “no good faith basis” for
22 contending Mylan’s product infringed on the ‘355 patent; and 2) the ‘355 patent was
23 invalid in part because the ‘355 patent was anticipated by prior art. These defenses
24 would ultimately form the basis for the District Court’s decision more than two years
25 later that Mylan’s proposed product did not infringe upon the ‘355 patent and that the
26 ‘355 patent was invalid.

27 a. *The Morella Patent*
28

1 51. On or about July 19, 1994 the PTO issued *U.S. Patent No. 5,330,776* (“the
2 ‘776 patent” or “Morella”). The Morella patent, issued some six years prior to the ‘355
3 patent, disclosed a “sustained-release pharmaceutical composition include an active
4 ingredient of high solubility in water.” Claim 2 of the patent claimed “genitourinary
5 smooth muscle relaxants” as one of the active ingredients. The Morella application
6 specifically listed “oxybutynin” as “one of two highly soluble genitourinary smooth
7 muscle relaxants.”

8 52. The Morella patent was “prior art” of an extend-release drugs that included
9 oxybutynin. Accordingly, the Morella patent specifically anticipated the ‘355 patent.

10 53. At all times relevant hereto, including its subsequent infringement action
11 against Mylan, Alza knew, or should have known, that the Morella patent anticipated the
12 ‘355 patent. Despite this knowledge, Alza engaged in an infringement action against
13 Mylan for over two years delaying entry of Mylan’s generic version of oxybutynin into
14 the market.

15 *b. The Biachwal Patent*

16 54. On or about March 21, 1995 the PTO issued *U.S. Patent No. 5,399,359*
17 (“the ‘359 patent” or “Baichwal”). The Baichwal patent encompassed a “24 hour extend-
18 release oral dosage form with 5 mg to 20 mg oxybutynin chloride. The Baichwal patent
19 further taught methods to achieve slower release rates by “modifying the dosage forms”
20 of oxybutynin.

21 55. At the time Alza filed the ‘355 patent it was keenly aware of the Baichwal
22 patent. Specifically, the PTO initially rejected the ‘355 patent as “anticipated” by the
23 Baichwal patent. The Patent Office Examiner specifically noted, “Since the materials
24 taught in the prior art are similar to those of the [‘355 patent], then the physical properties
25 and activity of the composition would be similar to those of the instant claimed invention
26 in the absence of factual evidence to the contrary.”

27 56. Undeterred by the PTO’s filings, Alza went to work to gin-up a method
28 around the PTO’s findings that the Baichwal patent anticipated the ‘355 patent.

1 Ultimately, Alza concocted an argument that the “dissolution rate” of the ‘355 patent was
2 “significantly slower” than that of the Baichwal patent. Based on Alza’s representation,
3 the PTO withdrew the anticipation rejection.

4 57. At the time Alza made this statement to the PTO it knew that its
5 representation to the PTO was, at best, misleading and, at worse, false.

6 58. Prior to receiving approval for the ‘355 patent, a Finnish drug named
7 Cystrin CR was being sold in Finland and throughout Europe. Cystrin CR is a 24 hour
8 controlled release pharmaceutical that administers 10 mg dosages of oxybutynin
9 hydrochloride. Cystrin CR was manufactured pursuant to the examples and teachings
10 set forth in the Baichwal patent.

11 59. On information and belief and at all times relevant hereto, Alza was aware
12 that Cystrin CR, which taught a similar extended release version for oxybutynin to that
13 contained in Ditropan XL, was based on the Baichwal patent. Despite this, Alza failed
14 and/or refused to disclose Cystrin CR to the PTO Examiner. On information and belief,
15 Alza intentionally withheld this information in an effort to secure the ‘355 patent and its
16 illegal monopoly. Specifically, had Alza disclosed that Cystrin CR was an extended
17 release for of oxybutynin, based on the Baichwal patent, the PTO would have continued
18 to reject the ‘355 patent as “anticipated” by the Baichwal patent.

19 60. As a direct and proximate result of Defendant’s lack of candor with the
20 PTO, the ‘355 patent was approved thereby foreclosing the entry of generic versions of
21 extended release oxybutynin onto the market.

22 *c. The Wong Patent*

23 61. On January 21, 1992, some eight years before Alza obtained the ‘355
24 patent, the PTO issued *U.S. Patent No. 5,082,668* (“the ‘668 Patent” or “Wong”). The
25 Wong patent identified a “bilayer osmotic pump dosage form” (“OROS system”) that
26 was subsequently used in the ‘355 patent. Further, the Wong ORSO system identified a
27 drug delivery system over a 24 hour period and included within the patent a description
28 of certain drug types that include oxybutynin.

1 62. On information and belief, at all times relevant hereto, Alza was aware of
2 the Wong patent.

3 63. When read together, the Morella patent, the Baichwal patent and the Wong
4 patent made the '355 patent "obvious" to Alza, or any other person skilled on the art.
5 Specifically, the Morella patent identified oxybutynin as a drug that fell within the release
6 rates set forth in the '355 patent. The Wong patent identified that oxybutynin could be
7 used in connection with an ORSO system, which became the ultimate method used in the
8 '355 patent. And, the Baichwal established a 24 hour extended release for oxybutynin.

9 64. The combination of the Morella patent, Baichwal patent and Wong patent
10 established that the '355 patent was "obvious." In fact, the inventor of the Baichwal
11 patent specifically referenced a prior patent that he obtained which stated, "it would be
12 obvious to one skilled in the art that by varying [the ratio of medicament to hydrophilic
13 material] and/or total weight of the tablet, etc., one can achieve different slow release
14 profiles, and may extend the dissolution of some medicaments to about 24 hours."

15 65. Alza knew that the three patents (Morella, Baichwal and Wong) when read
16 in their totality made the '355 patent obvious. Despite the fact that Alza knew that the
17 '355 patent was both anticipated and obvious it initiated litigation against Mylan to stop
18 Mylan from bring its generic 24 hour extend release version of oxybutynin to the market.

19 66. Alza knew that its litigation against Mylan amounted to little more than a
20 sham to unlawfully and artificially extend the life of the '355 patent. As a direct result,
21 of Alza's illegal monopoly, End-Payers like the Plaintiff and the Class paid artificially
22 inflated costs for extended release oxybutynin.

23
24
25 **2. Monopoly Powers**

26 67. Through the anticompetitive conduct alleged herein, Defendant was able to
27 charge supracompetitive prices for oxybutynin, and thus, by definition, maintained
28 monopoly power with respect to oxybutynin sold in the United States. To the extent that

1 Plaintiff is legally required to prove monopoly power circumstantially by first defining a
2 relevant product market, Plaintiff alleges that the relevant product market is all
3 oxybutynin extend release products – i.e., Ditropan XL (in all its forms and dosage
4 strengths), and bioequivalent oxybutynin products. For the entire period relevant to this
5 case, Defendant has been able to profitably maintain the price of their branded
6 oxybutynin products well above competitive levels.

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

8 69. Defendant's market share in the relevant market is and was 100% at all
9 times.

10 70. Defendant's actions are part of, and in furtherance of, the illegal
11 monopolization alleged herein, were authorized, ordered or done by Defendant's officers,
12 agents, employees or representatives while actively engaged in the management of
13 Defendant's affairs.

14 71. Defendant's illegal acts to prevent the introduction and/or dissemination
15 into the U.S. marketplace of any generic version of Ditropan XL resulted in Plaintiff and
16 the Class paying more than they would have paid for extended release oxybutynin, absent
17 Defendant's illegal conduct.

18 **3. Effects on Competition and Damages to Plaintiff and Class**

19 72. Defendant's exclusionary conduct has delayed or prevented the sale of
20 generic oxybutynin in the United States, and unlawfully enabled Defendant to sell
21 Ditropan XL at artificially inflated prices. But for Defendant's illegal conduct, generic
22 competitors would have been able to successfully market generic versions of Ditropan
23 XL capsules by at least May 2, 2003, and additional generic competitors would have
24 entered the market thereafter. Moreover, to the extent that demand for 5 mg and 10 mg
25 extended release oxybutynin tablets would have existed but for Defendant's illegal
26 conduct, generic competitors would have begun marketing generic versions of Ditropan
27 XL at an earlier point in time.

1 Excluded from the Class are all Defendants, their officers, subsidiaries and affiliates; all
2 government entities (except for government-funded employee benefit plans); all persons
3 or entities that purchased Ditropan for purposes of resale, or directly from the Defendant
4 or their affiliates, and the judge in this case and any members of his/her immediate
5 family.

6 76. Plaintiff seeks class certification pursuant to Rule 23(b)(3) of the Federal
7 Rules of Civil Procedure.

8 77. **Numerosity**: The members of the Class are so numerous that joinder of all
9 members is impracticable. Ditropan XL had annual sales in 2004 in excess of \$440
10 million. There were thousands, if not hundreds of thousands, of prescriptions written for
11 the benefit of End-Payers (and/or their members, participants and beneficiaries). The
12 Class members are identifiable, *inter alia*, from information and records that are required
13 by law to be maintained by pharmacies, drugstores, pharmaceutical benefit managers, and
14 managed care organizations.

15 78. **Commonality**: Common questions of law and fact exist as to all members
16 of the Class and predominate over any questions, if any, that may affect only individual
17 members. This is particularly true given the nature of Defendant's conspiracy which was
18 generally applicable to the entire Class, thereby making appropriate relief with respect to
19 the Class as a whole. Such conduct includes the Defendant's exclusionary and anti-
20 competitive efforts: (i) in committing fraud on The United States Patent and Trade
21 Office; (ii) in filing sham litigation; and (iii) converting the relevant market from one
22 confronted with generic competition to one that is not for the sole purpose of
23 monopolizing and attempting to monopolize the market for Ditropan XL.

24 a. Common questions of fact include, but are not limited to:

- 25 (1) whether Defendant maintained or attempted to maintain monopoly
26 power by delaying generic entry;

- 1 (2) whether direct proof of Defendant's monopoly power is available,
2 and if available, whether it is sufficient to prove Defendant's
3 monopoly power without the need to also define a relevant market;
4 (3) whether Defendant intentionally and unlawfully excluded
5 competitors and potential competitors from the market for Ditropan
6 XL and generic bio-equivalents to Ditropan XL; and
7 (4) whether Plaintiff and the Class have been damaged and the
8 aggregate amount of damages.

9 b. Common questions of law include, but are not limited to:

- 10 (1) to the extent a relevant market or markets must be defined, what that
11 definition is or those definitions are;
12 (2) whether Defendant's activities alleged herein have substantially
13 affected interstate commerce;
14 (3) whether Defendant's litigation asserting infringement of the '355
15 patent was baseless; and
16 (4) whether Defendant engaged in sham litigation for the purpose of
17 preventing competition.

18 79. **Typicality:** Plaintiff's claims are typical of the members of the Class, in
19 that Plaintiff purchased and/or paid for Ditropan XL throughout the United States,
20 including the Indirect Purchaser States, during the Class Period. Such purchases and
21 payments were made for consumer consumption of Ditropan XL. Additionally,
22 Plaintiff's claim is typical of the claim of the Class because Alza's conspiracy to effect an
23 illegal monopoly *vis-à-vis* its sham patent litigation applied equally to each and every
24 member of the Class. To that end, all Class members paid inflated cost for oxybutynin
25 extend release tablets due directly to Alza's efforts to deter, delay and/or defeat generic
26 entrants from entering the marketplace. As a direct and proximate result of Alza's
27 conspiracy, Plaintiff and all members of the Class were damaged by the same wrongful
28 conduct of Defendant.

1 80. **Adequacy**: Plaintiff will fairly and adequately protect and represent the
2 interests of the Class. The interest of the Plaintiff is not antagonistic to those of the
3 Class. Further, Plaintiff's attorneys are skilled in the prosecution of complex class action
4 antitrust litigation.

5 81. **Predominance**: The central allegations in this case revolve around Alza's
6 illegal monopolistic conspiracy. Accordingly, the quantum of evidence required to
7 establish Alza's culpability does not vary from Class member to Class member. These
8 issues predominate over all other issues and include, but are not limited to: 1) whether
9 Alza engaged in sham litigation to defend the '355 patent; 2) whether Alza's sham
10 litigation resulted in formation of an illegal monopoly; and 3) whether "the addition or
11 subtraction of any of the plaintiffs to or from the class [has] a substantial effect on the
12 substance of quantity of the evidence offered" to establish liability.

13 82. **Superiority**: Class action treatment is a superior method for the fair and
14 efficient adjudication of the controversy, in that, among other things, such treatment will
15 permit a large number of similarly situated persons to prosecute their common claims in a
16 single forum simultaneously, efficiently, and without the unnecessary duplication of
17 evidence, effort, and expense that numerous individual actions would engender. The
18 benefits of proceeding through the class mechanism, including providing injured persons
19 or entities with a method for obtaining redress for claims that it might not be practicable
20 to pursue individually, substantially outweigh any difficulties that may arise in
21 management of this class action.

22 83. **Manageability**: Manageability will not be an impediment to certifying this
23 case as a class action. Adequate procedures will be available not only to identify the
24 potential class members, but also to determine the amount of overcharge damages to
25 which each member of the class is entitled. This is particularly true because: 1) federal
26 and state laws require certain organization (whom are customers of Defendant) including,
27 pharmacies, drug stores, pharmacy benefit managers and managed care organizations;
28

1 and 2) the amount of overcharge can be determined *vis-à-vis* excerpt testimony in a
2 method that is generally applicable to the Class.

3 **IX.**

4 **FIRST CAUSE OF ACTION**

5 **FOR COMPENSATORY AND MULTIPLE DAMAGES UNDER THE**
6 **ANTITRUST STATUTES OF THE INDIRECT PURCHASER STATES**

7 84. Plaintiffs repeat and reallege the proceeding and subsequent paragraphs as
8 though set forth herein.

9 85. Defendant's conduct described herein constitutes unlawful acts of
10 monopolization and attempts to monopolize under the antitrust laws of the Indirect
11 Purchaser States, as follows:

- 12 a. Alabama: The aforementioned practices of Defendant was in
13 violation of the Alabama Code § 6-5-60, *et seq.*;
- 14 b. Alaska: The aforementioned practices of Defendant was in violation
15 of Alaska Stat. 45.50.580(a) & (b);
- 16 c. Arizona: The aforementioned practices by Defendant was in
17 violation of the Arizona Uniform State Antitrust Act, Ariz. Re. Stat.
18 §§ 44-1401, *et seq.*, and the Constitution of the State of Arizona,
19 Article 14, § 15;
- 20 d. California: The aforementioned practices by Defendants were and
21 are in violation of the Cartwright Act, Cal. Bus. & Prof. Code §§
22 16700, *et seq.*;
- 23 e. District of Columbia: The aforementioned practices by Defendants
24 were and are in violation of the District of Columbia Antitrust Act,
25 D.C. Code §§ 28-4501, *et seq.*;
- 26 f. Florida: The aforementioned practices by Defendants were and are
27 in violation of the Florida Antrust Act, Fla. Stat. Ann. §§ 542.15, *et*
28 *seq.*;

- 1 g. Hawaii: The aforementioned practices by Defendants were and are
2 in violation of the Hawaii Revised Statutes §§ 480-2, 480-3, and
3 480-4;
- 4 h. Iowa: The aforementioned practices by Defendants were and are in
5 violation of the Iowa Competition Law, Iowa Code §§ 553.4, 553.5
6 (1997);
- 7 i. Kansas: The aforementioned practices by Defendants were and are
8 in violation of the Kansas Monopolies and Unfair Trade Act, Kan.
9 Stat. Ann. §§ 50-101, *et seq.*;
- 10 j. Kentucky: The aforementioned practices by Defendants were and
11 are in violation of the Kentucky Consumer Protection Act, Ky. Rev.
12 Stat. Ann. §§367.110, *et seq.*;
- 13 k. Louisiana: The aforementioned practices by Defendants were and
14 are in violation of the Louisiana Monopolies Law, La. Rev. Stat.
15 Ann. §§ 51:121, *et seq.*;
- 16 l. Maine: The aforementioned practices by Defendants were and are in
17 violation of the Maine Monopolies and Profiteering Statutes, Me.
18 Rev. Stat. Ann. Tit. 10, §§ 1101, *et seq.*;
- 19 m. Massachusetts: The aforementioned practices by Defendants were
20 and are in violation of the Massachusetts Antitrust Act, Mass. Gen.
21 Laws, ch. 93;
- 22 n. Michigan: The aforementioned practices by Defendants were and
23 are in violation of the Michigan Antitrust Reform At. Mich. Comp.
24 Laws §§ 445.771, *et seq.*;
- 25 o. Minnesota: The aforementioned practices by Defendants were and
26 are in violation of the Minnesota Antitrust Law of 1971, Minn. Stat.
27 §§ 325D.49, *et seq.*;
- 28

- 1 p. Mississippi: The aforementioned practices by Defendant were and
2 are in violation of the Mississippi antitrust statute, Miss. Code Ann.
3 §§ 75-21-1, *et seq.*;
- 4 q. Nebraska: The aforementioned practices by Defendant were and are
5 in violation of the Nebraska Consumer Protection Act, Neb. Rev.
6 Stat. § 59-1601, *et seq.*;
- 7 r. Nevada: The aforementioned practices by Defendants were and are
8 in violation of the Nevada Unfair Trade Practices Act, Nev. Rev.
9 Stat. §§ 598A.010, *et seq.*, and the Nevada Deceptive Trade
10 Practices Act, Nev. Rev. Stat. §§ 598.0903, *et seq.*;
- 11 s. New Jersey: The aforementioned practices by Defendants were and
12 are in violation of the New Jersey Antitrust Act, N.J. Stat. Ann. §§
13 56:9-1, *et seq.*;
- 14 t. New Mexico: The aforementioned practices by Defendants were
15 and are in violation of the New Mexico Antitrust Act, N.M. Stat.
16 Ann. §§ 57-1-1, *et seq.*;
- 17 u. New York: The aforementioned practices by Defendants were and
18 are in violation of the Donnelly Act, N.Y. Gen. Bus. Law §§ 340, *et*
19 *seq.*;
- 20 v. North Carolina: The aforementioned practices by Defendants were
21 and are in violation of North Carolina's antitrust law, N.C. Gen. Stat.
22 §§ 75-1, *et seq.*;
- 23 w. North Dakota: The aforementioned practices by Defendants were
24 and are in violation of North Dakota Antitrust Act, N.D. Cent. Code
25 §§ 51-08.1-01, *et seq.*;
- 26 x. South Dakota: The aforementioned practices by Defendants were
27 and are in violation of South Dakota's antitrust law, S.D. Codified
28 Laws §§ 37-1-3, *et seq.*;

- 1 y. Tennessee: The aforementioned practices by Defendants were and
2 are in violation of Tennessee Trade Practices Act, Tenn. Code Ann.
3 §§ 47-25-101, *et seq.*;
- 4 z. Vermont: The aforementioned practices of Defendants were and are
5 in violation of the Vermont Consumer Fraud Act. Vt. Stat. Ann. Tit.
6 9, §§ 2451, *et seq.*;
- 7 aa. West Virginia: The aforementioned practices by Defendants were
8 and are in violation of the West Virginia Antitrust Act, W.Va. Code
9 §§ 47-18-1, *et seq.*, and the West Virginia Consumer Credit and
10 Protection Act. W. Va. Code §§ 46A-6-101, *et seq.*; and
- 11 bb. Wisconsin: The aforementioned practices by Defendants were and
12 are in violation of the Wisconsin Antitrust Act, Wis. Stat. §§ 133.01,
13 *et seq.*, and the Wisconsin Unfair Trade Practices Act, Wis. Stat. §§
14 100.20, *et seq.*

15 86. As a direct and proximate result of Defendant's violation of the
16 aforementioned statutes, Plaintiff and the Class have been injured in an amount to be
17 proven at trial.

18
19 **SECOND CAUSE OF ACTION**

20 **VIOLATION OF CALIFORNIA'S UNFAIR COMPETITION LAW**

21 **BUSINESS AND PROFESSIONAL CODE § 17200, et. seq.**

22 87. Plaintiff restates and realleges each and every allegation set forth as if
23 stated herein.

24 88. Defendant is a California corporation subject to the laws of the State of
25 California.

26 89. As a California corporation, Defendant has a reasonable likelihood of being
27 sued within the State of California for wrongful conduct that it engages in.

1 90. Defendant's actions constitute unfair and deceptive unlawful practices
2 committed in violation of the Unfair Competition Law, Bus. & Prof. Code §§ 17200, *et*
3 *seq.*

4 91. Defendant violated the "fraudulent" prong of §17200, the "unfair" prong of
5 § 17200 and the "unlawful" prong of § 17200 by engaging in the following conduct (this
6 list is neither meant, nor intended to exhaust and is subject to revision upon completion of
7 discovery):

- 8 a. Defendant misled the PTO by failing to disclose critical
9 information related to the Baichwal and '757 patents of which it was
10 aware. Had Defendant disclosed this information, the PTO would
11 not have approved the '355 Patent;
- 12 b. Defendant misled the PTO into believing that the '355 Patent was
13 not "anticipated" by the Baichwal and/or '757 Patent;
- 14 c. Defendant engaged in sham litigation to defend the '355 patent when
15 it knew, or should have known, that Mylan's generic version of
16 extend release oxybutynin did not infringe upon '355 patent;
- 17 d. Defendant engaged in sham litigation and/or fraudulent conduct
18 when it knew that its extended release product was "obvious" to
19 "one skilled in the art";
- 20 e. Defendant engaged in sham litigation and/or fraudulent conduct
21 when it knew that '355 patent was "anticipated" by "prior art;"
- 22 f. Defendant's conduct was unfair, unlawful or deceptive in that it
23 resulted in artificially inflated costs for oxybutynin extended release
24 products; and
- 25 g. Defendant's conduct was unlawful and/or unfair when it refused to
26 allow generic extracts of oxybutynin chloride extend release into the
27 market.

1 Dated: November 17 2005

2 **ZIMMERMAN REED, P.L.L.P.**

3 

4 Timothy J. Becker (*Pro Hac to be Filed*)
5 Greg Sauter (California No. 191866)
6 651 Nicollet Mall, Suite 501
7 Minneapolis, Minnesota 55402
8 Telephone: (612) 341-0400
9 Email: tgb@zimmreed.com
10 Email: gps@zimmreed.com

11 **CHARFOOS & CHRISTENSEN, P.C.**

12 Jason Thompson (*Pro Hac to be Filed*)
13 Ann K. Mandt (*Pro Hac to be Filed*)
14 5510 Woodward Avenue
15 Detroit, MI 48202
16 Telephone: (313) 875-8080
17 Email: jthompson@c2law.com
18 Email: akmandt@c2law.com

19 *Attorney for the Plaintiff and the Proposed*
20 *Class*