

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
Miami-Dade Division

CASE NO. 13-21158-CIV-LENARD/GOODMAN

MONICA BARBA and JONATHAN
REISMAN, on behalf of themselves and all
others similarly situated,

Plaintiffs,

v.

SHIRE U.S., INC., a New Jersey
Corporation, SHIRE, LLC, a Kentucky
Limited Liability Company, and DOES 1
through 100, inclusive,

Defendants.

Redacted Version

**MEMORANDUM OF LAW IN SUPPORT OF
PLAINTIFFS' RENEWED MOTION FOR CLASS CERTIFICATION**

TABLE OF CONTENTS

I. INTRODUCTION 1

II. CLASS-WIDE EVIDENCE WILL PROVE PLAINTIFFS’ CASE 1

 A. Shire Knew Its AXR Patent Protection Was Weak 1

 B. Shire’s Own Legal Department Forecasts Generic Entry in 2006-2007 4

 C. Shire Fashions a “3 Way Deal” With Barr/Teva and Impax 5

 D. Shire Pays Impax to Delay Generic Entry of AXR 5

 E. Shire Pays Barr/ Teva to Delay Entry of Generic AXR 7

 F. The Payments Delayed Generic Entry And Injured Consumers 10

 G. Shire’s Unlawful Rebate Agreements Caused Higher Class Copays 11

III. PROPOSED CLASS DEFINITION 12

IV. LAW AND ARGUMENT 12

 A. The Class is Ascertainable 12

 B. Class Certification is Appropriate Under Rule 23(a)..... 13

 1. Joinder is Impracticable 13

 2. Plaintiffs’ Claims Present Common Issues of Law and Fact..... 14

 3. Plaintiffs’ Claims are Typical of Those of the Classes..... 15

 4. Plaintiffs and Counsel Will Adequately Represent the Class..... 16

 C. Class Certification is Appropriate Under Rule 23(b)(3)..... 17

 1. Common Issues of Law or Fact Predominate 17

 a. Defendant’s Violations of The Sherman Act and FAA 19

 (1) Unlawful Restraint Of Trade..... 19

 (2) Monopolization and Attempted Monopolization 20

- (a) Possession of Market Power20
- (b) Causation/Antitrust Impact20
- b. Shire’s Unfair Practices and Deceptive Acts22
- c. Damages Will Be Proven on a Class-Wide Basis.....22
- 2. Class Treatment Is Superior To Other Adjudication Methods24
- V. CONCLUSION.....25

TABLE OF AUTHORITIES

FEDERAL CASES

Allapattah Servs., Inc. v. Exxon Corp. (11th Cir. 2003)
333 F.3d 124822

Amgen Inc. v. Conn. Ret. Plans & Trust Funds (2013)
133 S. Ct. 1184.....18

Babineau v. Fed. Express Corp. (11th Cir. 2009)
F.3d 118322

Bussey v. Macon Cnty. Greyhound Park, Inc. (11th Cir. 2014)
562 F. App’x 78212

Carnegie v. Household Int’l, Inc. (7th Cir. 2004)
376 F.3d 65625

Coastal Fuels Inc., v. Caribbean Petroleum Corp. (1st Cir. 1996)
79 F.3d 18220

Comcast Corp. v. Behrend (2013)
133 S. Ct. 1426.....22, 23

Cox v. Am. Cast Iron Pipe Co. (11th Cir. 1986)
784 F.2d 154614

Evans v. U.S. Pipe & Foundry Co. (11th Cir. 1983)
696 F.2d 92514

FTC v. Actavis, Inc. (2013)
133 S. Ct. 2223.....1, 9

Hawaii v. Standard Oil Co. of Cal. (1972)
405 U.S. 2511

In re Cardizem Antitrust Litig. (E.D. Mich. 2000)
105 F.Supp.2d 61821

In re Flonase Antitrust Litig (2012)
284 F.R.D. 207.....15, 21, 22

In re Neurontin Antitrust Litig. (D.N.J. Jan. 25, 2011)
2011 WL 28611818

In re Nexium Antitrust Litig. (1st Cir. Jan. 21, 2015)
777 F.3d 912

In re Nexium Antitrust Litig. (D. Mass. Nov. 14, 2013)
297 F.R.D. 168.....16, 18, 21

In re Pharm. Indus. Average Wholesale Price Litig. (1st Cir. 2009)
582 F.3d 15623, 25

In re Polyurethane Foam Antitrust Litig. (N.D. Ohio Nov. 17, 2014)
2014 WL 646135523

In re Relafen Antitrust Litig. (D. Mass. May 12, 2004)
221 F.R.D. 26025

In re Scrap Metal Antitrust Litig. (6th Cir. 2008)
527 F.3d 51718

In re Terazosin Hydrochloride Antitrust Litig. (S.D. Fl. 2004)
220 F.R.D. 672.....14, 15, 19, 20, 21, 23, 24

In re Urethane Antitrust Litig. (10th Cir. 2014)
768 F.3d 124518

J. Truett Payne Co. v. Chrysler Motors Corp (1981)
451 U.S. 55719

Karhu v. Vital Pharmaceuticals, Inc. (11th Cir. June 9, 2015)
2015 WL 356072212, 13

Kornberg v. Carnival Cruise Lines, Inc. (11th Cir. 1984)
741 F.2d 133215

Lee v. Life Ins. Co. of N. Am. (D.R.I. 1993)
829 F. Supp. 52919

Little v. T-Mobile USA, Inc.(11th Cir. 2012)
691 F.3d 130212

Mylan Pharms., Inc. v. U.S. FDA (4th Cir. July 5, 2006)
454 F.3d 2702

Natchitoches Parish Hosp. Serv. Dist. v. Tyco Int’l, Ltd. (D. Mass. 2008)
247 F.R.D. 253.....14

Phillips v. Petroleum Co. v. Shutts (1985)
 472 U.S. 79724

Pierson v. Orlando Reg’l Healthcare Sys. (11th Cir. 2012)
 619 F. Supp. 2d 126120

Pottinger v. Miami (S.D. Fla. 1989)
 720 F. Supp. 95513

Sacred Heart Health Sys., Inc. v. Humana Military Healthcare Servs., Inc. (11th Cir. 2010)
 601 F.3d 1159.....24

Shire Lab., LLC v. Barr Pharms. (S.D.N.Y. September 2, 2003)
 1:03-cv-00632-PKC.....3

Shire Lab. Inc. v. Barr Lab., Inc. (S.D.N.Y. Feb. 24, 2003)
 1:03-cv-01219.....3

Shire Lab., LLC v. Impax Lab. (D. Del. December 29, 2003)
 1:03-cv-1164GMS3, 4

Sundance Apts. I, Inc. v. Gen. Elec. Cap. Corp. (S.D. Fla. 2008)
 581 F. Supp. 2d 121518

Valley Drug Co. v. Geneva Pharms., Inc. (11th Cir. 2003)
 350 F.3d 118116

Vega v. T-Mobile USA, Inc. (11th Cir. 2009)
 564 F.3d 125614, 17

Wal-Mart Stores, Inc. v. Dukes (2011)
 131 S. Ct. 2541.....14, 15

Walker v. R.J. Reynolds Tobacco Co. (11th Cir. 2013)
 2013 WL 583201525

Williams v. Mohawk Indus., Inc. (11th Cir. 2009)
 568 F.3d 135014

Williams v. Wells Fargo Bank, N.A. (S.D. Fla. 2012)
 280 F.R.D. 665.....14

Zlotnick v. Premier Sales Group (11th Cir. 2007)
 480 F.3d 128118

STATE CASES

Mack v. Bristol-Myers Squibb Co. (Fla. 1st DCA 1996)
673 So.2d 10019

PNR, Inc. v. Beacon Prop. Mgmt. (Fla. 2003)
842 So.2d 77318, 22

FEDERAL STATUTES

15 U.S.C. §§ 1, 2, & 5.....18

21 U.S.C. § 355(j).....3

Fed. R. Civ. P. 23.....15, 24

STATE STATUTES

Fla. Stat. § 501.20118, 22

Fla. Stat. § 501.204(1).....18

Fla. Stat. § 542.1519

I. INTRODUCTION

This case is about Shire U.S., Inc. and Shire, LLC (“Defendants”/“Shire”)’s decade-long strategy to delay, foreclose and diminish generic competition for Adderall XR (“AXR”). Plaintiffs’ claims under Florida’s Deceptive Trade Practices Act (“FDUPTA”) are by their very nature subject to common proof, and common evidence will prove the illegality of Shire’s conduct and aggregate measure of damages. The Supreme Court has held class treatment in antitrust cases is “definitely preferable” and federal courts across the Country have certified end-payor pharmaceutical antitrust cases such as this one at least ten times. *Hawaii v. Standard Oil Co. of Cal.*, 405 U.S. 251, 266 (1972).¹ Accordingly, the Court should certify a Rule 23(b)(3) class of persons who purchased AXR in Florida from January 1, 2007 through March 31, 2009.

II. CLASS-WIDE EVIDENCE WILL PROVE PLAINTIFFS’ CASE²

A. Shire Knew Its AXR Patent Protection Was Weak

Shire protected AXR with U.S. Patent Nos. 6,322,819 (“819 Patent”) and 6,605,300 (“300 Patent”). Both patents, unless found invalid or non-infringed by a court, expire in October 2018. Casey Dec. ¶ 11, Ex. 3 at SHIREBAR0770301. These patents covered the extended release mechanism, not the active pharmaceutical ingredient (“API”). Such “ancillary” or “evergreen” patents are viewed as offering weaker patent protection than API patents.³

¹ See also Ex. 1 to Casey Dec. ISO Plaintiffs’ Renewed Motion for Class Certification.

² Obtaining discovery from Shire in this case has been hard fought, marked by numerous discovery hearings where Shire has been ordered and re-ordered to produce documents and which ultimately resulted in two trial continuances. As of the February 2014 original class certification motion filing, Defendants had produced only a fraction of the documents produced to date thus requiring Plaintiffs to renew their motion after the production of sufficient fact discovery. Even today, discovery disputes are ongoing.

³ See, e.g., Hemphill & Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. Health Econ. 327 (2012); see also Brief Amici Curiae of 118 Law, Economics, and Business Professors and the American Antitrust Institute in Support of Petitioners at 19, *FTC v. Actavis, Inc., et al.*, 133 S. Ct. 2223 (June 17, 2013) (No. 12-416) (“ancillary [patents]... are less innovative (and so less likely to be valid) and easier to avoid”).

As early as May 2001 (before AXR was approved by FDA and before either of Shire's AXR patents were approved), Shire's internal documents admit the "[REDACTED]" was "[REDACTED]." *Id.* at ¶ 10, **Ex. 4** at SHIREBAR1463783, 788. The answer was a "line extension" in the form of Adderall XR. According to Shire, the primary "Rationale for Development" of AXR (above any clinical benefits to patients) was to "[REDACTED]." *Id.* at 792.

Given that its patents were limited to AXR's release mechanism, Shire was aware its intellectual property (IP) was weak. In its 2001 pre-launch "Adderall XR™ 2002 Brand Plan" timeline, Shire noted [REDACTED] (Shire's loss of regulatory exclusivity) as a "[REDACTED]" and anticipated "[REDACTED]" would enter the market. *Id.* at ¶ 11, **Ex. 5**. A "Key Point" was [REDACTED] "[REDACTED]" In fact, an internal "commercial evaluation" of the AXR product from late 2003 reveals that [REDACTED] [REDACTED]. *Id.* at ¶ 12, **Ex. 6**. Finally, in yet another early-lifecycle planning document, Shire assumed no more than [REDACTED], an admission it planned [REDACTED] [REDACTED]. *Id.* at ¶ 13, **Ex. 7**.

Barr Pharmaceuticals⁴ filed the first AXR Abbreviated New Drug Application ("ANDA") in November 2002, followed by Impax in 2003. FAC ¶¶ 21-22. Since the pre-MMA version of the Hatch-Waxman Act (which applied to Barr/Teva's ANDA) included none of the later-added forfeiture provisions, the only two events triggering a first-filer's 180-day exclusivity were: (1) a "first commercial marketing" by the first-filer;⁵ or (2) "the date of a decision of a court ...

⁴ Barr was acquired by Teva Pharmaceuticals, USA, Inc. and will be referred to as "Barr/Teva."

⁵ "First commercial marketing" means commercial sale of either the first-filer's ANDA product or an authorized generic manufactured and licensed by the NDA-holder. *See, e.g., Mylan Pharms., Inc. v. U.S. FDA*, 454 F.3d 270 (4th Cir. July 5, 2006).

holding the [paragraph IV certification] patent...to be invalid or not infringed[.]” *See* 21 U.S.C. § 355(j)(5)(B)(iv). Thus Barr/Teva as the pre-MMA first-filer enjoyed what the FTC called a generic “bottleneck” or “parked exclusivity” period, whereby generic entry was delayed if Barr/Teva refrained from “commercial marketing” and no district court ruled against Shire’s patents.⁶

Shire brought two patent infringement lawsuits against Barr/Teva in the Southern District of New York regarding the ‘819 and ‘300 patents in February and September of 2003.⁷ In January 2005, Shire filed suit against Impax in the District of Delaware, also alleging infringement of the same patents.⁸ Later, Shire instructed the FTC that it anticipated spending approximately [REDACTED], including costs already spent on fact and expert discovery. Casey Dec. ¶ 14, **Ex. 8** at SHIREBAR2013659.

The most progressed of Shire’s patent infringement litigations was going very poorly for Shire. Impax won a critical Markman Order on February 9, 2005, wherein the court defined claim terms favorably for Impax (which can be case-dispositive for invalidity and non-infringement).⁹ To slow down the case, in March 2005 Shire asked the U.S. Patent Office to “re-issue” its ‘819 and ‘300 patents. (FAC at ¶ 29). Shire claimed it uncovered supposed errors in these patents, but it did not even change any of the 42 claims asserted in the patents, but instead added new claims. (*Id.* at ¶ 30). The District Court noted Shire’s “revolving door” strategy of using baseless administrative procedures to delay the Court.¹⁰

⁶ *See Generic Drug Entry Prior to Patent Expiration: An FTC Study* (July 2002) at 57 (“brand-name and generic companies have entered into agreements that...have had the effect of delaying generic entry by the first generic that otherwise would trigger the running of the 180-day exclusivity, thereby creating bottleneck for any subsequent eligible generic entry.”)

⁷ *See Shire Lab., LLC v. Barr Lab.*, No. 1:03-cv-00632-PKC (S.D.N.Y. filed Sept. 2, 2003); *Shire Lab. Inc. v. Barr Lab., Inc.*, No. 1:03-cv-01219 (S.D.N.Y. Feb. 24, 2003).

⁸ *See Shire Lab., LLC v. Impax Lab.*, No. 1:03-cv-1164GMS (D. Del. filed Dec. 29, 2003).

⁹ *Id.* at D.E.119 (D. Del. Feb. 9, 2005).

¹⁰ *Id.* at D.E.. 230 at *3 (D. Del. Jan. 13, 2006); *see also* FAC ¶¶ 31-33.

On September 12, 2005, Impax moved for summary judgment,¹¹ threatening Shire with the prospect of imminent defeat, which would have constituted a “court decision” triggering Barr’s 180-day exclusivity. In addition, a judgment in favor of Impax would have more than likely sped up resolution of other patent cases, particularly the litigation with Barr/Teva for which trial was, at the time, just around the corner in early 2006.

Shire waited until October 17, 2005, the day before Impax’s summary judgment motions went under submission, to file its first of three Citizen Petitions as a stop-gap to prevent FDA ANDA approval in case Impax prevailed on summary judgment. Casey Dec. ¶ 15, **Ex. 9**. The day after, on October 19, 2005, Shire filed *another* patent suit against both Teva and Impax alleging infringement of Patent No. 6,913,768 (“768 Patent”), which was not even listed in the Orange Book.¹² This lawsuit was objectively and subjectively baseless as neither Barr/Teva nor Impax had infringed Shire’s ‘768 patent as a matter of law. Shire cynically estimated that although [REDACTED]

[REDACTED] Casey Dec. ¶ 8, **Ex. 2** (2006 Adderall XR Strategic Lifecycle Product Plan at SHIREBAR082161).

B. Shire’s Own Legal Department Forecasts Generic Entry in 2006-2007

Internally, Shire knew its AXR patents were at best “uncertain” to withstand litigation. Common evidence will prove Shire planned for generic entry not in 2018 when its patents expired, but as soon as a generic company positioned itself to achieve a patent suit judgment. For example, a September 2005 “Shire Legal Department” presentation titled “[REDACTED] [REDACTED]” estimated a [REDACTED] [REDACTED] Casey Dec. ¶ 16, **Ex. 10** at SHIREBAR738938U-981U. [REDACTED]

¹¹ *Id.* at D.E. 219 (Oct. 18, 2005) (Impax Reply ISO Motion for Summary Judgment).

¹² Under Hatch-Waxman, a generic manufacturer has only infringed a patent if it is listed in the Orange Book. Otherwise, there is no infringement until the generic is actually marketed.

[REDACTED] t.

C. Shire Fashions a “3 Way Deal” With Barr/Teva and Impax

Though Barr was the ‘first-filer’ holding the ‘180-day exclusivity bottleneck’, Shire was threatened by Impax (the second filer)’s litigation progress. Two days after Impax’s summary judgment motions were fully briefed, on October 20, 2005, Shire’s executives internally ‘[REDACTED].’ Casey Dec. ¶ 19, **Ex. 11**. Less than a week later, on October 26, 2005, Shire executive Barbara Deptula met with Barr’s then-President/COO Paul Bisaro, and explained to him that Shire and Barr needed a ‘[REDACTED]. *Id.* at ¶ 20, **Ex. 12**, at SHIREBAR1977859.

D. Shire Pays Impax to Delay Generic Entry of AXR

On January 19, 2006, after swift negotiations, Shire and Impax signed the Settlement & License Agreement for AXR, as well as a Promotional Services Agreement related to Shire’s drug Carbatrol. Casey Dec. ¶¶ 19-20, **Exs. 13, 14**. Despite Shire’s then-statements and current protestations that the deals—executed the same day—are unrelated, common evidence, including Shire’s own documents and admissions, will prove the Carbatrol promotion agreement “resulted” from the Adderall XR patent litigation. *Id.* at ¶¶ 21, **Ex. 15** at SHIREBAR1202889 (Shire’s attorneys acknowledge the “[AXR patent] litigation...resulted in a promotional agreement.”).

First, Shire could have launched an authorized generic AXR through a separate entity and achieved a much more significant royalty than the 50% of net profits it agreed to with Impax. As examples, Shire’s authorized generic deal with its drug Agrylin involved Shire retaining [REDACTED] under similar circumstances, (*Id.* at ¶ 17, **Ex. 11**), and Impax’s CEO Larry Hsu stated his industry-informed opinion that brand company authorized generic (“AG”) agreements contain a “typical [REDACTED] profit split.” *Id.* at ¶ 22, **Ex. 16**. In fact, early in the negotiations with Shire, Impax

internally assumed it would be giving Shire at minimum [REDACTED].
Id. at ¶ 23, **Ex. 17** at IMPAXRSUB00087192.

However, Shire needed to buy off Impax's patent challenge as part of the "3 way deal" with Barr, and Shire thus traded royalty percentage points to Impax as part of that agreement. For example, the 50% profit split on an AG was potentially worth hundreds of millions of dollars to Impax, who—as a later-filer among several other later-filers—only anticipated revenue of [REDACTED] per year from its own ANDA product compared to [REDACTED] as Shire's AG (a fact also recognized by Shire). *Id.* at ¶ 24, **Ex. 18**, at SHIREBAR0002952-953 (Impax "Alone scenario" results in annual NPV of [REDACTED]); *Id.* at ¶ 25, **Ex. 19** (Shire model showing generic entry in April 2006 and Shire-licensed AG contributing [REDACTED] in sales for at least 1.5 years to be split with Impax). Even though an AG was never launched to compete with a Barr ANDA product, Impax nevertheless has made [REDACTED] from sales of its October 2009 AG launch due to Shire's further guarantee of AG supply even in the event Barr/Teva did not settle. But for Impax's settlement with Shire, these [REDACTED] of AXR AG revenue would not have been realized by Impax.

Common evidence demonstrates Shire also paid Impax approximately [REDACTED] for the Carbatrol promotional services (almost [REDACTED] of which was profit to Impax), which required minimal Impax effort as Shire "[REDACTED] [REDACTED], as per the contract. Shire further anticipated paying Impax [REDACTED] on top as "gain share" payments, which was conservative compared to Impax's [REDACTED] estimate. *Id.* at ¶ 26, **Ex. 20**, at IMPAXSUB85694 (*ex post* board presentation reviewing the Impax/ Shire Carbatrol Agreement); *id.* at ¶¶ 27-29, **Exs. 21, 22, 23**. Indeed, even before settlement talks began with

Shire, Impax was shopping around for a contract sales force to promote its then-pending FDA approval product Vadova once approved. As noted by one analyst, the Vadova launch was “Being Funded By Other Peoples [sic] Money.” *Id.* at ¶ 30, **Ex. 24**, at SHIREBAR0003264.

Shire provided [REDACTED] in guaranteed value to Impax, with many more millions in contingent value. Shire’s payments to Impax were well beyond any anticipated future litigation costs as well as far beyond any revenues Impax might have expected to make from its AXR ANDA. These payments were to buy off Impax’s patent challenge and clear the way for a settlement with Barr to delay generic AXR entry.

E. Shire Pays Barr/ Teva to Delay Entry of Generic AXR

Shire then turned its attention to Barr. As early as November 14, 2005, Shire (Deptula) and Barr (Bisaro) had agreed that any deal would contain [REDACTED] with the [REDACTED] in sneer quotes. In other words, the parties agreed there would be payments, just not in the form of cash transfers. Casey Dec. at ¶ 18, **Ex. 12**, at SHIREBAR19778860. Indeed, in an earlier meeting between Ms. Deptula and Mr. Bisaro, Ms. Deptula told Mr. Bisaro “[REDACTED] [REDACTED] by agreeing not to launch a competing authorized generic. She further stated Shire was [REDACTED] [REDACTED]” Casey Dec. at ¶ 44, **Ex. 38**.

One form of payment FTC often challenges are “No Authorized Generic Agreements,” whereby the brand company agrees not to launch an AG to compete during the first-filer’s exclusivity period. Shire informed Barr that Shire [REDACTED], and Shire eventually contractually obligated itself for Impax to launch Shire’s AG in the event Barr did not settle. *Id.* at ¶¶ 18-19, **Exs. 12-13** at SHIREBAR0002151-152. As noted by Shire’s proposals to Barr— [REDACTED]

[REDACTED]

[REDACTED] *Id.* at ¶ 31, **Ex. 25**, at SHIREBAR2219273. Given Shire’s commitment to Impax, Barr would have to agree to a later generic entry date (and thus an extended monopoly for Shire) if it wished to have a complete generic monopoly during the 180 day exclusivity period. As modeled by Shire in numerous documents, the financial impact to Barr of an AG during its exclusivity period ranged from approximately [REDACTED] to [REDACTED]. *See, e.g., id.* at ¶ 25, **Ex. 19**. As negotiated in Section 3.7 of the License Agreement with Barr/Teva, Shire agreed not to launch an AG during Barr’s exclusivity period. Casey Dec. at ¶ 32, **Ex. 26**.

Shire also paid Barr through artificially low (and short lasting) royalties, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Shire initially demanded a [REDACTED] % royalty, representing to a federal judge that its “bottom line” royalty was [REDACTED] %, and then acceded to [REDACTED] over just six months in response to a Barr red-line counter-proposal. *Id.* at ¶¶ 34, 35, 36, 37, **Exs. 28, 29, 30, 31**. The lower royalty was exchanged for a later license effective date (as Shire’s counsel admitted), and is an unmistakably clear example of Shire giving away significant value in exchange for later generic entry.

Shire also negotiated “other features” including the sale of the Adderall IR brand to Barr in a side-deal executed the same day as the settlement of the AXR patent litigation. Despite internally valuing Adderall IR at [REDACTED] with an operating margin [REDACTED] *Id.*

at ¶ 38, **Ex. 32** (Lutz. Dep. at 125:12-126:12). Shire sold the product to Barr for [REDACTED] (exactly a 50% discount). *Id.* at ¶ 39, **Ex. 33** at SHIREBAR1977948 (Shire's internal valuation); *Id.* at ¶ 40, **Ex. 34**. (Product Acquisition and License Agreement for Adderall IR). To date, Barr has profited more than [REDACTED] from Adderall IR sales, supporting Shire's internal valuations. *Id.* at ¶ 41, **Ex. 35** (Barr/Teva's P&L for 2002 through 2015). This transaction constituted a transfer of \$63 million in value from Shire to Barr.

Finally, Shire also entered into a Women's Health Products Collaboration Agreement with Duramed, Barr/Teva's subsidiary. Shire internally valued the deal as generating [REDACTED] dollars in highly-speculative profits for Shire, but Shire was nevertheless willing to provide an upfront "non-creditable" and "non-reimbursable" [REDACTED] payment (which was made directly to Barr and not Duramed). *Id.* at ¶ 42, **Ex. 36** (August 2006 Product Development and License Agreement at § 7.1); *see also Id.* at ¶ 43, **Ex. 37** (at SHIREBAR 1995417-449) and **Ex. 32** (Lutz Dep. at 114:17-115:18). This represented a disguised but direct transfer of cash in exchange for delaying generic entry of AXR. Shire further agreed to pay Duramed up to [REDACTED] in U.S. development costs over eight years despite not being able to commercialize any of the products in the U.S., and eventually paid approximately [REDACTED] of this amount before buying itself out of the deal in February 2009. *Id.* at ¶ 45, **Ex. 39** (Shire document listing payments to Duramed and Barr/Teva). In fact, the deal was so bad for Shire that, as part of the Termination Agreement in 2009, Shire was required to forgive an additional [REDACTED] in AXR-related debt owed by Barr/Teva.

By these transactions, Shire paid Barr well in excess of [REDACTED], far beyond the [REDACTED] Shire told the FTC it could have expected in total (not just future) litigation costs, easily meeting the Supreme Court's antitrust standard in *Actavis*. *Id.* at ¶ 14, **Ex. 8** at

SHIREBAR2013659. However, from an economics perspective, the deal was a no-brainer. In 2008 alone (when there should have been generic competition), Shire profited [REDACTED] from AXR. *Id.* at ¶ 46, **Ex. 40** (Shire’s P&L for AXR). Thus, the [REDACTED] [REDACTED] return-on-investment) in terms of retained AXR sales.

F. The Payments Delayed Generic Entry And Injured Consumers

As noted by Shire’s in-house counsel, “[REDACTED] [REDACTED] [REDACTED] [REDACTED],” i.e., the date at which generic competition would arrive. Casey Dec. at ¶ 33, **Ex. 27** (Applebaum Dep. at 96:11-13). When AXR first launched, Shire thought that date would occur in [REDACTED]. When Shire was losing its patent litigation, it thought that date would occur in 2006, and sought to negotiate generic entry in 2007-2008. In one Shire internal memo, Shire saw [REDACTED] [REDACTED]. *Id.* at ¶ 47, **Ex. 41** at SHIREBAR2162392 (Shire’s “Adderall XR Forecast Scenarios”). Shire executives wrote in emails to each other that the “best case scenario” for AXR generic entry was [REDACTED]. Shire indeed made a formal proposal to Barr [REDACTED] [REDACTED] *Id.* at ¶ 31, **Ex. 25**, at SHIREBAR2219273 (“[REDACTED]”).

The reverse payment agreements’ anticompetitive aim is best summed up by a question posed in a document found in Ms. Deptula’s files (previously withheld as privileged): “[REDACTED] [REDACTED]” *Id.* at ¶ 48, **Ex. 42**. The answer was quite a lot, and then even more to move the “early launch” even later to April 2009.

Shire’s payments to delay generic entry had a class-wide effect, as all consumers of AXR were required to purchase branded Adderall XR when generic AXR should have been available.

Plaintiffs will use common evidence to prove that but for the illegal agreements, Barr/Teva and other generic manufacturers would have begun manufacturing, marketing and selling generic AXR in the United States no later than January 2007. For example, expert testimony and Shire's internal documents and testimony will prove that, as a result of Shire's anticompetitive conduct, Plaintiffs and Class Members had to pay more money in the form of higher prices or co-pays for "brand name" AXR than they would have paid absent the agreements. Casey Dec. ¶ 59, **Ex. 53** ("Rosenthal Dec.") ¶¶ 15, 16, 29, 30, 32, 50-52. This is because Class Members were deprived of the ability to purchase lower-priced generic equivalents at competitive market prices. *Id.*

G. Shire's Unlawful Rebate Agreements Caused Higher Class Copays

Shire's anticompetitive behavior, including dubious patent challenges and anticompetitive settlements, reduced competition and ensured against a total price collapse. As generic entry approached in April 1, 2009, Shire conceived of a way to retain AXR revenue and at the same time buy more time for Shire's newly patented ADHD drug Vyvanse to gain share before full genericization of AXR. Shire did this by offering significant rebates to third-party payors ("TPPs") to retain brand AXR market share. Employing this strategy, Shire severed the alignment of interests between insured and insurer by offering insurers large rebates, making AXR reimbursement by TPPs cheaper than generic AXR while encouraging and/or requiring TPPs to maintain elevated co-pays for their insureds and disadvantaging generics. Shire required insurers to [REDACTED] As a result of this strategy Shire retained about half of the TPP market. Casey Decl. at ¶ 46, **Ex. 40** (Mark Kuhl Deposition at 29:11-25), instead of losing upwards of 90% of the market as is normally seen with generic erosion in the absence of such unlawful conduct.

III. PROPOSED CLASS DEFINITION

Pursuant to Rules 23(a) and (b)(3), Plaintiffs propose the following Class:

All persons who purchased (for personal or household use) and/or paid for some or all of the purchase price for brand Adderall XR in Florida between January 1, 2007 through March 31, 2009.

Excluded from the Class are: (1) Third Party Payors; (2) Persons and entities who purchased directly from Defendants; (3) Persons and entities who purchased only for resale purposes; (4) “Flat co-pay” “Cadillac Plan” customers who made purchases only via fixed dollar co-payments that do not vary between Adderall XR and its generic equivalent; (5) Patients with insurance coverage including a flat-rate co-pay provision; (6) Governmental entities; (7) Shire, their officers, directors, affiliates, legal representatives, employees, co-conspirators, successors, subsidiaries and assigns, and entities in which Shire has a controlling interest; and, (8) The judges, justices, magistrates or judicial officers presiding over this matter.

IV. LAW AND ARGUMENT

A. The Class is Ascertainable

Although not a Rule 23 prerequisite, courts have also read Rule 23 to contain an implicit, unwritten requirement that a class is “adequately defined and clearly ascertainable.” *Little v. T-Mobile USA, Inc.*, 691 F.3d 1302, 1303-04 (11th Cir. 2012). There is no need to identify individual class members as a prerequisite to certification; rather they must be identifiable by reference to objective criteria permitting class members to be identified in an administratively feasible way. *Karhu v. Vital Pharmaceuticals, Inc.*, No. 14-11648, 2015 WL 3560722 at *3 (11th Cir. June 9, 2015) (unpublished) (citing *Bussey v. Macon Cnty. Greyhound Park, Inc.*, 562 F. App’x 782, 787 (11th Cir. 2014)). The First Circuit recently affirmed a finding of ascertainability in a generic suppression action brought by end-payors where the class was “defined in terms of purchasers of [the drug] during the class period (with some exceptions that also satisfy objective standards).” *In re Nexium Antitrust Litig.*, 777 F.3d 9, 19 (1st Cir. Jan. 21, 2015).

Here, the Class is “sufficiently definite” to enable the Court to determine who fits within

the class definition. *See Pottinger v. Miami*, 720 F. Supp. 955, 957 (S.D. Fla. 1989) (certifying class). The Class is defined with respect to objective criteria: individuals who purchased AXR in Florida during a particular date range. Excluded from the Class are individuals who are also identifiable by “objective standards” such as TPPs, direct purchasers and individuals who purchased AXR with fixed or flat-rate co-pays. At the appropriate time, potential Class Members can come forward as having purchased AXR in Florida from 2007 through April 1, 2009. Unlike the “subjective memory” problems encountered in *Karhu*, which involved an over-the-counter diet pill similar to many other weight loss products on the market at the time and for which purchasers did not save their receipts (2015 WL 3560722 at *1-2, *7), common sense dictates that putative Class Members here will easily recall whether they were prescribed Adderall XR, a once-daily medication that affects how Class Members perform daily functions. They will also recall when they were on it and where they refilled their prescriptions. *See, e.g.*, Barba Dep. at 54:1-58:16, Reisman Dep. at 9:20-24.

If the Court finds it necessary, membership in the class can also be verified with documentation, including Class Members’ own pharmacy, prescription and medical records. *See* Casey Decl. ¶¶ 51, 52, Exs. 45, 46 (Plaintiffs’ prescription records). Additionally, data exists to confirm Class Members’ purchases of AXR during the Class Period. *Id.* at ¶58, Ex. 52 (Declaration of Elan Rubinstein, Pharm.D., MPH (“Rubinstein Dec.”) at ¶¶ 18-36). Class Members may access these records upon request, free of charge. *Id.* at ¶ 37. Accordingly, the proposed Class definition is precise and objective and the Class is ascertainable.

B. Class Certification is Appropriate Under Rule 23(a)

1. Joinder is Impracticable

Rule 23(a)(1) requires members of a class to be “so numerous that joinder of all members

is impracticable.” The Rule does not establish a precise numerical threshold, but parties seeking class certification “must make reasonable estimates that the class to be certified will satisfy the numerosity requirement[.]” *Williams v. Wells Fargo Bank, N.A.*, 280 F.R.D. 665, 672 (S.D. Fla. 2012); *Evans v. U.S. Pipe & Foundry Co.*, 696 F.2d 925, 930 (11th Cir. 1983). Generally, more than 40 Class Members satisfies Rule 23(a)(1). *Cox v. Am. Cast Iron Pipe Co.*, 784 F.2d 1546, 1553 (11th Cir. 1986). The numerosity requirement has been met in similar delayed generic entry pharmaceutical antitrust cases. *See In re Terazosin Hydrochloride Antitrust Litig.*, 220 F.R.D. 672, 685 n.21 (S.D. Fl. 2004) (finding “good faith estimate of the class size” based on sales figures and IMS data sufficient to satisfy numerosity where it included over a thousand people). Based on Shire’s data,¹³ since at least 2008, [REDACTED] of AXR prescriptions were dispensed monthly in Florida. *See* Casey Dec. ¶ 50, **Ex. 44** (Shire-provided Florida prescription data). The sheer size of prescriptions filled during the Class Period makes joinder impracticable.

2. Plaintiffs’ Claims Present Common Issues of Law and Fact

Rule 23(a)(2) requires “questions of law or fact common to the class.” Plaintiffs bear a “relatively light burden” to prove commonality, as it “does not require that all the questions of law and fact raised by the dispute be common or that the common questions of law or fact predominate over individual issues.” *Vega v. T-Mobile USA, Inc.*, 564 F.3d 1256, 1268 (11th Cir. 2009). Rather, “[c]ommonality requires that there be at least one issue whose resolution will affect all or a significant number of the putative Class Members.” *Williams v. Mohawk Indus., Inc.*, 568 F.3d 1350 (11th Cir. 2009). For purposes of Rule 23(a)(2), even a single common question of law or fact will do. *Wal-Mart Stores, Inc. v. Dukes*, 131 S. Ct. 2541, 2551 (2011).

“In the antitrust context courts have held that the existence of an alleged conspiracy or monopoly is a common issue that will satisfy the Rule 23(a)(2) prerequisite.” *Natchitoches*

¹³ Updated data may be available based on ongoing document production by Shire.

Parish Hosp. Serv. Dist. v. Tyco Int'l, Ltd., 247 F.R.D. 253 (D. Mass. 2008) (commonality and typicality satisfied in antitrust action). Common issues include whether defendants had market and/or monopoly power, whether they maintained such power through anticompetitive or unlawful activity, and whether they engaged in anticompetitive activity. *Id.* at 264; *see also* FAC ¶ 146. Each of these common questions will lead to common answers, advancing the litigation for all Class Members “in one stroke.” *Dukes*, 131 S. Ct. at 2551. Since Plaintiffs and the Class’ claims arise out of a common wrong, and Shire’s anticompetitive conduct similarly injured each of them by artificially inflating the price of AXR, Rule 23(a)(2) is satisfied.

3. Plaintiffs’ Claims are Typical of Those of the Classes

Rule 23(a)(3) requires “the claims or defense of the representative parties [to be] typical of the claims or defenses of the class.” “Typicality... does not require identical claims or defenses.” *Kornberg v. Carnival Cruise Lines, Inc.*, 741 F.2d 1332, 1337 (11th Cir. 1984). Rather, typicality “is established if the claims or defenses of the class and the class representative arise from the same event or pattern or practice and are based on the same legal theory.” *Id.* Moreover, “[d]ifferences in the amount of damages between the class representative and other Class Members does not affect typicality.” *Id.*

Once Plaintiffs establish the same unlawful conduct was directed at them and Class Members alike, “the typicality requirement is usually met irrespective of varying fact patterns which underlie the individual claims.” *In re Terazosin*, 220 F.R.D. at 687. All Class Members’ claims “arise from an identical course of conduct—anticompetitive generic suppression—without reference to individual purchasers.” *In re Flonase Antitrust Litig.*, 284 F.R.D. 207, 218 (E.D. Pa. 2012) (indirect purchasers typical where seeking recovery for prescription overcharges based on same legal theory). Whether Shire’s conduct violates FDUTPA and gives rise to the Class Members’ claims will be proven on the same generalized class-wide proof.

Here, Barba, Reisman and unnamed Class Members all have claims based on common legal theories: illegal restraint of trade and attempted monopolization in violation of federal and Florida antitrust statutes as well as standalone FDTUPA claims. Indeed, like Class Members, Barba and Reisman suffered overcharge damages on account of Shire's conduct. *See* Casey Dec. ¶51, **Ex. 45** (Monica Barba Deposition ("Barba Dep.") at 14:11-21, 37:3-6)); *Id.* at ¶ 52, **Ex. 46** (Jonathan Reisman Deposition ("Reisman Dep.") at 19:13-14, 33:16-21). By forcing Florida consumers to buy brand AXR, Plaintiffs and the Class suffered damages.

Plaintiffs seek damages for prescription overcharges based on the same theories available to the Class. For example, Reisman, who was insured by Aetna, wanted generic AXR, but was required to purchase branded AXR numerous times prior to April 1, 2009 because no generic equivalent was available as a result of Shire's payments to delay generic entry. (Reisman Dep. at 19:13-15, 17:21-25, 18:5-9; *see also* Barba Dep. at 13:13-19, 14:11-14). These "forced brand purchases" demonstrate Reisman's injuries are identical to Class Members, who were also forced to pay supracompetitive prices for AXR during the Class Period.

4. Plaintiffs and Counsel Will Adequately Represent the Class

Rule 23(a)(4) requires that "the representative parties will fairly and adequately protect the interests of the class." This analysis "encompasses two separate inquiries: (1) whether any substantial conflicts exist between the representatives and the class; and (2) whether the representatives will adequately prosecute the action." *Valley Drug Co. v. Geneva Pharms., Inc.*, 350 F.3d 1181, 1189 (11th Cir. 2003). Both of these factors are met here.

In a similar delayed generic entry case, the court certified a class that included end-payers, even though the named plaintiffs consisted only of union plan sponsors. *See In re Nexium Antitrust Litig.*, 297 F.R.D. 168, 172-73 (D. Mass. Nov. 14, 2013), *aff'd*, 777 F.3d 9 (1st Cir. Jan. 21, 2015) (certifying class of end-payer plaintiffs in antitrust action arising out of delay

in generic marketing). Here, Plaintiffs and Class Members have an identical interest in proving the unlawfulness of Shire's common course of conduct and obtaining redress. Like Barba and Reisman, all Class Members paid supracompetitive prices for AXR in Florida between January 1, 2007 and March 31, 2009 (because they were unable to obtain the generic). (Barba Dep. at 15:14-18; Reisman Dep. at 15:14-18). Barba and Reisman suffered overcharge injuries and have identical incentives to establish Defendants' liability and pursue full recovery individually and for every Class Member at trial. (Barba Dep. at 49:12-19; Reisman Dep. at 48:24-49:1). Plaintiffs have also demonstrated their commitment to pursue their claims on behalf of the Class, as they have been deposed, responded to extensive written discovery and produced relevant documents. Casey Dec. at ¶ 5.

Plaintiffs' attorneys are highly qualified, as they have substantial experience in prosecuting complex litigation cases, including antitrust class actions on behalf of indirect purchasers. Casey Dec. at ¶¶ 6, 53-56, Exs. 47-50. Plaintiffs' counsel have also demonstrated a willingness and ability to dedicate the resources and expertise necessary to fairly and adequately represent a class and successfully manage a class action to its conclusion. *Id.*

C. Class Certification is Appropriate Under Rule 23(b)(3)

Rule 23(b)(3) requires that "questions of law or fact common to the Class Members predominate over any questions affecting only individual members" and "a class action is superior to any other available methods for fairly and efficiently adjudicating the controversy."

1. Common Issues of Law or Fact Predominate

Common issues predominate if they have a "direct impact on every Class Member's effort to establish liability that is more substantial than the impact of individual issues in resolving the claim or claims of each Class Member." *Vega*, 564 F.3d at 1270. Notably, Rule 23(b)(3) simply calls for "a showing that questions common to the class predominate, not that

those questions will be answered, on the merits, in favor of the class.” *Amgen Inc. v. Conn. Ret. Plans & Trust Funds*, 133 S. Ct. 1184, 1191 (2013). Predominance is a test readily met in certain cases alleging violations of the antitrust laws. *See, e.g., In re Nexium*, 297 F.R.D. at 172-73.¹⁴

Plaintiffs’ FAC is based on violations of Florida’s Deceptive and Unfair Trade Practices Act, Fla. Stat. §§ 501.201, *et seq.* (FDUTPA). Section 501.204(1) of the Act declares “unfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce” to be unlawful. Generally, a FDUTPA claim requires: (1) a deceptive act or unfair practice; (2) causation; and (3) damages. *See, e.g., Sundance Apts. I, Inc. v. Gen. Elec. Cap. Corp.*, 581 F. Supp. 2d 1215, 1220 (S.D. Fla. 2008). Under FDUTPA, an act or business practice is “unfair” when it offends established public policy and is immoral, unethical, oppressive, scrupulous, or substantially injurious to consumers. *See PNR, Inc. v. Beacon Prop. Mgmt.*, 842 So. 2d 773 (Fla. 2003). A “deception” occurs when there is “a representation, omission or practice that is likely to mislead the consumer acting reasonably in the circumstances, to the consumers’ detriment.” *Zlotnick v. Premier Sales Group*, 480 F.3d 1281, 1284 (11th Cir. 2007).

Plaintiffs’ First and Second Causes of Action are predicated on Defendants’ underlying violations of antitrust laws. Specifically, Plaintiffs allege Defendants’ violations of Sections 1, 2 and 5(a)(1) of the Sherman Act, 15 U.S.C. §§ 1, 2, 5(a)(1) constitute unconscionable and unfair acts in violation of FDUTPA. (FAC ¶¶ 156-191). Similarly, Plaintiffs’ Third Cause of Action is

¹⁴ *See also In re Urethane Antitrust Litig.*, 768 F.3d 1245 (10th Cir. 2014) (affirming certification in antitrust action and denying decertification where “there were two common questions that could yield common answers at trial: the existence of a conspiracy and the existence of impact”); *In re Neurontin Antitrust Litig.*, MDL No. 1279, 2011 WL 286118, at *6 (D.N.J. Jan. 25, 2011) (“proof of this [antitrust] violation focuses on the defendant’s conduct, not on the conduct of individual Class Members, and is therefore well suited for class treatment.”); *In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 535 (6th Cir. 2008) (noting predominance is “readily met” in certain antitrust cases “because proof of the *conspiracy* is a common question that is thought to predominate over the other issues of the case”).

premised on Defendants' violations of the Florida Antitrust Act, Fla. Stat. §§ 542.15, *et seq.* ("FAA").¹⁵ (*Id.* at ¶¶ 192-205). Plaintiffs' Fourth and Fifth Causes of Action are not premised on violations of the Sherman Act or FAA, but rather, allege Defendants' conduct constitutes unfair and deceptive practices in violation of FDUTPA. (*Id.* at ¶¶ 206-226). At this juncture, Plaintiffs need only show the common issues involved in proving the elements of their claims on a class-wide basis predominate over any individual ones. They do.

a. **Defendant's Violations of The Sherman Act and FAA**

Generally, a claim based upon an antitrust conspiracy theory raises three ultimate issues to be proven at trial: (1) the existence of a contract, combination or conspiracy in restraint of trade, or unlawful monopoly or attempted monopoly (liability); (2) injury-in-fact (antitrust injury); and (3) the extent of injury (damages). *In re Terazosin Hydrochloride*, 220 F.R.D. at 695 (citing *J. Truett Payne Co. v. Chrysler Motors Corp.*, 451 U.S. 557, 562 (1981)). Whether Shire's conduct violated the Sherman Act or the FAA, and whether such Sherman Act or FAA violations amount to FDUTPA violations, are susceptible to proof using common evidence.

(1) **Unlawful Restraint Of Trade**

To state a claim for unreasonable restraint of trade, "a plaintiff must allege three elements: (1) the existence of a contract, combination or conspiracy; (2) that the agreement unreasonably restrained trade under the per se or rule of reason analysis; and (3) that the restraint affected interstate commerce." *Lee v. Life Ins. Co. of N. Am.*, 829 F. Supp. 529, 535 (D.R.I. 1993), *aff'd*, 23 F.3d 14 (1st Cir. 1994). This District has acknowledged "courts repeatedly have held that the existence of a conspiracy is the predominant issue in price fixing cases, warranting certification of the class even where significant individual issues are present." *In re Terazosin*

¹⁵ Indirect purchasers cannot assert FAA claims, but they may state claims under FDUTPA. *See Mack v. Bristol-Myers Squibb Co.*, 673 So.2d 100, 103, 107-08 (Fla. 1st DCA 1996).

Hydrochloride, 220 F.R.D. at 695). These elements focus almost exclusively on Defendants' conduct, including the impact of, and motive behind, Shire's reverse payment agreements.

(2) Monopolization and Attempted Monopolization

“[C]laims of monopolization are generally proven by demonstrating: (1) possession of monopoly power in the relevant market; and (2) the willful acquisition or maintenance of that power by competitive or exclusionary means.” *In re Terazosin Hydrochloride*, 220 F.R.D. at 695-96. To prove attempted monopolization, Plaintiffs must prove: “(1) that the defendant has engaged in predatory or anticompetitive conduct with (2) a specific intent to monopolize and (3) a dangerous probability of achieving monopoly power.” *Pierson v. Orlando Reg'l Healthcare Sys.*, 619 F. Supp. 2d 1261, 1280 (11th Cir. 2012). As with Plaintiffs' claims for unlawful restraint of trade, the elements of these claims focus almost entirely on Shire's (1) sham Citizen Petitions; (2) supply agreement breaches; and, (3) payments to Barr/Teva and Impax.

(a) Possession of Market Power

This District has held “the definition of the relevant market for determining market power is a question common to all Class Members, and is one that will predominate over any individualized inquiries.” *In re Terazosin Hydrochloride*, 220 F.R.D. at 696. Plaintiffs can also establish Shire possessed market power, for purposes of their restraint of trade and monopolization claims, through common evidence. Plaintiffs can establish such market power directly (by showing supracompetitive prices) or circumstantially (by showing AXR has a dominant share in a relevant market). *Coastal Fuels Inc. v. Caribbean Petroleum Corp.*, 79 F.3d 182, 196-97 (1st Cir. 1996). Both types of proof will involve an analysis of common evidence, including market data and aggregate economic patterns.

(b) Causation/Antitrust Impact

Plaintiffs must also demonstrate common proof can be used to establish antitrust impact

due to Shire's conduct. *In re Terazosin Hydrochloride*, 220 F.R.D. at 696. Courts in the Eleventh Circuit have recognized a presumption of antitrust impact when the defendant has market power and is alleged to have conspired with its competition. *Id.* at 696-97. As stated above, these questions will be litigated with common proof, and thus a presumption of antitrust impact may also arise through common proof. *In re Cardizem Antitrust Litig.*, 105 F. Supp. 2d 618, 649 (E.D. Mich. 2000) (“[T]he ultimate conclusion as to what that evidence proves is for the jury.”). Even if no presumption applies, Plaintiffs will present ample common evidence, premised on market data and expert testimony, to support this element at trial.

Courts routinely certify indirect purchaser pharmaceutical antitrust class actions, including Florida subclasses, after considering arguments regarding Plaintiffs' ability to demonstrate antitrust impact on a class-wide basis. *In re Terazosin Hydrochloride*, 220 F.R.D. at 696-97 (“fact of antitrust injury is susceptible to common proof”); see *In re Nexium*, 297 F.R.D. at 172-73 (accepting end-payors' argument in generic suppression case that “long-standing precedent [] show that common antitrust impact predominates over any individual differences in damages incurred”); *Flonase*, 284 F.R.D. at 225 (“Indirect Purchasers have demonstrated that they can establish impact to this class of consumers...through class-wide evidence.”).

Evidence of common Class impact includes proof that: (1) prices for AXR were higher than they would have been absent Defendants' conduct; and (2) a substantial number of Class Members purchased and/or paid for their AXR at a supracompetitive price. Proof of widespread antitrust impact within the Class can be relatively easily accomplished through well-accepted methodologies and using actual historical data of how the AXR market dynamics would have changed had generic entry come earlier, and had the generics been adequately supplied after

generic entry. *See* Rosenthal Dec. at ¶¶ 38-49. At trial, Dr. Rosenthal will rely on sales and pricing data to make this showing. *Id.* at ¶¶ 36, 37.

b. Shire's Unfair Practices and Deceptive Acts

Plaintiffs' Fourth and Fifth Causes of Action allege FDUTPA violations independent of Defendants' Sherman Act and FAA violations. (FAC ¶¶ 206-226). The acts proscribed by subsection 501.204(1) of FDUTPA include antitrust violations. *In re Flonase Antitrust Litig.*, 815 F. Supp. 2d at 887 (denying summary judgment against indirect purchasers' FDUTPA claim alleging manufacturer engaged in an unfair act or practice by delaying entry of generic Flonase in an attempt to "extend its monopoly and maximize profits at the expense of consumers.").

Here, Plaintiffs intend to prove the numerous side deals with Impax and Teva were reverse payments to delay entry of generic AXR and "offend established public policy" and are "immoral, unethical, oppressive, scrupulous, or substantially injurious to consumers." *PNR, Inc.*, 842 So. 2d at 777. To do so, Plaintiffs will rely on common evidence, including Plaintiffs' experts and Shire's own documents and testimony. Resolution of these issues, all of which focus on Shire's activities, need only be decided once as to the entire Class.

c. Damages Will Be Proven on a Class-Wide Basis

"[Damages c]alculations need not be exact, but at the class certification stage (as at trial), any model supporting a 'plaintiff's damages case must be consistent with its liability case, particularly with respect to the alleged anticompetitive effect of the violation.'" *Comcast Corp. v. Behrend*, 133 S. Ct. 1426, 1433 (2013). "Common issues of fact and law predominate if they have a direct impact on every Class Member's effort to establish liability and on every Class Member's entitlement to... monetary relief." *Babineau v. Fed. Express Corp.*, F.3d 1183, 1191 (11th Cir. 2009). Even "the presence of individualized damages issues does not prevent a finding that the common issues in the case predominate." *Allapattah Servs., Inc. v. Exxon Corp.*, 333

F.3d 1248, 1261 (11th Cir. 2003). Thus damage calculations must match the theory of impact that is presented and accepted for resolution on a class-wide basis. *Comcast*, 133 S. Ct. at 1433.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

“The use of aggregate damages calculations is well established in federal court and implied by the very existence of the class action mechanism itself.” *In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d 156, 197-98 (1st Cir. 2009) (AstraZeneca’s challenge to the aggregate damages methodology “fail[ed] in the starting gate”); accord *In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 534 (6th Cir. 2008). See also *In re Terazosin Hydrochloride*, 220 at 699 (“an aggregate judgment allocation will become an intra-class matter accomplished pursuant to a court-approved plan of allocation”); *In re Polyurethane Foam Antitrust Litig.*, No. 1:10 MD 2196, 2014 WL 6461355, at *44 (N.D. Ohio Nov. 17, 2014) (permitting approximation of aggregate damages proven as a matter of just and reasonable inference in antitrust class action, where damages were “susceptible to computation using a ‘mathematical or formulaic’ calculation.”). Indeed, courts acknowledge in similar cases that antitrust damages can be proven on an aggregate class-wide basis according to well-recognized methodologies such as a “before-during-after” method or a “yardstick” method. Dr. Rosenthal will apply these “widely accepted”

methodologies to this case. *See In re Terazosin Hydrochloride*, 220 F.R.D. at 699 (finding the “before-during-after” or “yardstick” methodologies widely accepted and have been used in numerous other antitrust class actions and collecting cases).

2. Class Treatment Is Superior To Other Adjudication Methods

Rule 23(b)(3) requires a class action to be superior to all other methods of dispute resolution. The superiority inquiry focuses on “the relative advantages of a class action suit over whatever other forms of litigation might realistically be available to the plaintiffs.” *Sacred Heart Health Sys., Inc. v. Humana Military Healthcare Servs., Inc.*, 601 F.3d 1159, 1183-84 (11th Cir. 2010). Relevant factors include “(A) the Class Members’ interests in individually controlling the prosecution or defense of separate actions; (B) the extent and nature of any litigation concerning the controversy already begun by or against Class Members; (C) the desirability or undesirability of concentrating the litigation of the claims in the particular forum; (D) the likely difficulties in managing a class action.” Fed. R. Civ. P. 23(b)(3).

First, Class Members have no incentive to control separate actions because they all have common claims and interests. The work of Plaintiffs and their counsel will benefit the entire Class. Moreover, while Class Members’ aggregate damages are large, each Class Member paid only approximately \$10-\$25 per refill for AXR. Casey Dec. at ¶ 57, **Ex. 51** (DeAnna Jones Deposition at 101:23-102:1, Ex. 17). This amount is “simply too insignificant to make the claim worth pursuing for any claimant or attorney, particularly given the enormous expense associated with litigating the complex question whether [Shire’s] conduct was anticompetitive.” *See Fitzpatrick*, 263 F.R.D. at 702 (granting class certification of FDUTPA claims) (citing *Phillips v. Petroleum Co. v. Shutts*, 472 U.S. 797, 809, 105 S. Ct. 2965 (1985)) (claims valued at \$100 mean “most of the plaintiffs would have no realistic day in court if a class action were not available”),

rev'd on other grounds, 635 F.3d 1279 (11th Cir. 2011).¹⁶

Second, Plaintiffs are not aware of any other class actions pending against Defendant on behalf of Florida consumers regarding Shire's anticompetitive conduct.

Third, since Plaintiffs bring their claims under Florida law and seek to represent Florida consumers, concentration of the litigation in this forum is appropriate.

Fourth, prosecuting proposed Class Members' claims in a single action creates far fewer management problems (if any) than the alternative: the prosecution of hundreds or thousands of separate lawsuits. "Courts are generally reluctant to deny class certification based on speculative problems with case management." *Klay*, 382 F.3d at 1273. "[A] class action has to be unwieldy indeed before it can be pronounced an inferior alternative—no matter how massive the fraud or other wrongdoing that will go unpunished if class treatment is denied—to no litigation at all." *Carnegie v. Household Int'l, Inc.*, 376 F.3d 656, 661 (7th Cir. 2004).

As Plaintiffs' Trial Plan demonstrates, this case is manageable as all the key questions relate to Shire's conduct. Casey Dec. ¶ 7, **Ex. 1**. As for damages, Plaintiffs' expert has constructed models for calculating class-wide damages. (Rosenthal Dec. at ¶¶ 38-50). Following a finding of liability at trial, a claims administrator or special master can supervise "prove-up" proceedings, in which Class Members make individual claims.¹⁷ Without class treatment, Shire's anticompetitive conduct will go unchallenged and Class Members will go uncompensated.

V. CONCLUSION

Based on the foregoing, Plaintiffs respectfully request that the Court certify the Class.

¹⁶ See also *In re Relafen Antitrust Litig.*, 221 F.R.D. 260, 288 (D. Mass. May 12, 2004) (small size of claims means interest in prosecuting separate lawsuits "is limited—if not nonexistent.").

¹⁷ See *In re Pharm. Indus. Average Wholesale Litig.*, 582 F.3d at 197, n.33; *In re Nexium*, 297 F.R.D. at 183 ("the possibility of multiple proceedings after a class-wide liability determination hardly offends the rights of any of these litigants") (citing *Walker v. R.J. Reynolds Tobacco Co.*, No. 12-13500, 2013 WL 5832015, at *8-10 (11th Cir. 2013)).

Date: June 19, 2015

Respectfully submitted,
KU & MUSSMAN, PA

By: /s/ Brian Ku
Brian T. Ku, Esq. (Fla. # 610461)
brian@kumusman.com
Louis Mussman, Esq. (Fla # 597155)
Louis@kumusman.com
M. Ryan Casey, Esq. (*Pro Hac Vice*)
ryan@kumusman.com
Ku & Mussman, P.A.
6001 NW 153rd Street, Suite 100
Miami Lakes, Florida 33014
Tel: (305) 891-1322
Fax: (305) 891-4512

-and-

Conlee Whiteley, Esq. (*Pro Hac Vice*)
c.whiteley@kanner-law.com
John R. Davis, Esq. (*Pro Hac Vice*)
j.davis@kanner-law.com
Kanner & Whiteley, LLC
701 Camp Street
New Orleans, Louisiana 70130
Tel: (504) 524-5777
Fax: (504) 524-5763

-and-

Ruben Honik, Esq. (*Pro Hac Vice*)
RHonik@GolombHonik.com
Richard M. Golomb, Esq. (*Pro Hac Vice*)
RGolomb@GolombHonik.com
Kenneth J. Grunfeld, Esq. (*Pro Hac Vice*)
KGrunfeld@GolombHonik.com
GOLOMB & HONIK, P.C.
1515 Market Street, Suite 1100
Philadelphia, PA 19102
Tel: (215) 985-9177
Fax: (215) 985-4169

-and-

Gillian L. Wade, Esq. (*Pro Hac Vice*)
Gwade@milsteinadelman.com
Sara D. Avila, Esq. (*Pro Hac Vice*)
Savila@milsteinadelman.com
MILSTEIN ADELMAN, LLP
2800 Donald Douglas Loop North
Santa Monica, CA 90405
Tel.: (310) 396-9600
Fax: (310) 396-9635

Attorneys for Plaintiffs and the Class

CERTIFICATE OF COMPLIANCE

I HEREBY CERTIFY that on this 19th day of June, 2015, this filing complies with Local Rule 5.1 and this Court's January 29, 2015 Order (Dkt. 173).

By: /s/ Brian Ku
Brian T. Ku, Esq. (Fla. # 610461)

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 19th day of June, 2015, a true and correct copy of the foregoing has been furnished via the Court's ECF system to all counsel listed below:

David A. Zwally
dzwally@flhlaw.com

Edgar H. Haug
ehaug@flhlaw.com

John F. Collins
jcollins@flhlaw.com

Porter F. Fleming
pfleming@flhlaw.com
FROMMER LAWRENCE & HAUG, LLP
745 Fifth Avenue
New York, New York 10151
Tel: (212) 588-0800

Michael F. Brockmeyer
mbrockmeyer@flhlaw.com
FROMMER LAWRENCE & HAUG, LLP

1667 K. Street, NW
Washington, DC 20006
Tel: (202) 292-1530

David S. Shotlander
dshotlander@flhlaw.com
FROMMER LAWRENCE & HAUG, LLP
1667 K. Street NW
Suite 500
Washington, DC 20006
Tel: (202) 292-1530

Eric Christu
echristu@shutts.com
Daniel Barskey
dbarsky@shutts.com
SHUTTS & BOWEN LLP
1000 CityPlace Tower
525 Okeechobee Blvd.
West Palm Beach, Florida 22401
Tel: (561) 650-8518

By: /s/ Brian Ku
Brian T. Ku, Esq. (Fla. # 610461)