

**IN UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

In re: Seroquel XR (Extended Release Quetiapine
Fumarate) Antitrust Litigation

Master Dkt. No. 20-1076-CFC

This Document Relates To:

Dkt. No. 21-1744-CFC

HEALTH CARE SERVICE CORPORATION,

Plaintiff,

JURY TRIAL DEMANDED

v.

ASTRAZENECA LP,
ASTRAZENECA PHARMACEUTICALS LP,
ASTRAZENECA UK LIMITED, and
HANDA PHARMACEUTICALS, LLC,

Defendants.

FIRST AMENDED COMPLAINT

TABLE OF CONTENTS

I. NATURE OF THE ACTION1

II. JURISDICTION AND VENUE.....6

III. THE PARTIES7

IV. REGULATORY AND ECONOMIC BACKGROUND.....9

A. The Hatch-Waxman Act and FDA Approval Process9

B. The Economic Model of Prescription Drug Purchases and Sales.....12

C. Authorized Generic (AG) Prescription Drugs.....14

D. Pharmaceutical Manufacturers Collude to Thwart Competition16

V. FACTS23

A. AstraZeneca’s Seroquel XR Patents.....23

B. Handa and Accord file ANDAs for Generic Versions of Seroquel XR...25

C. AstraZeneca files patent litigation.....27

D. Handa’s unadjudicated defenses were meritorious29

E. AstraZeneca enters into the unlawful reverse payment settlements32

VI. MARKET POWER AND DEFINITION45

VII. MARKET EFFECTS.....47

VIII. ANTITRUST IMPACT48

IX. CLAIM ACCRUAL AND/OR TOLLING49

X. CLAIMS FOR RELIEF.....51

XI. PRAYER FOR RELIEF64

XII. JURY DEMAND.....65

Plaintiff Health Care Service Corporation (“HCSC”) brings this civil action against Defendants AstraZeneca Pharmaceuticals LP, AstraZeneca LP, AstraZeneca UK Limited (collectively, “AstraZeneca”), and Handa Pharmaceuticals, LLC (“Handa”) (collectively, “Defendants”). HCSC’s allegations are based on personal knowledge, publicly available and other information and belief.

I. NATURE OF THE ACTION

1. This case arises from Defendants’ illegal scheme to allocate markets and unlawfully impose, maintain, and share monopolistic rents in the U.S. market for Seroquel extended release tablets (“Seroquel XR”). Defendants, along with their co-conspirators, accomplished this scheme by colluding to delay market entry of generic equivalents (“generic quetiapine fumarate”) that compete with AstraZeneca’s branded drug. HCSC seeks damages due to overcharges stemming from Defendant Handa and Par Pharmaceutical, Inc.’s (“Par”) unlawful agreement with Defendant AstraZeneca¹ not to compete in the market for Seroquel XR treatment. As detailed *infra*, in 2012, Handa assigned this unlawful agreement to

¹ Accord is a non-party unnamed co-conspirator that executed an unlawful pay-for-delay scheme with AstraZeneca regarding the 400mg formulation of generic quetiapine fumarate.

its co-conspirator Par, which became a party to the conspiracy by performing the agreement, selling generic Seroquel XR at supracompetitive prices, and sharing these illegal rents with Handa.

2. Seroquel XR is an atypical antipsychotic medicine with antidepressant properties used to treat major depressive disorder, bipolar disease, and schizophrenia.

3. Seroquel XR is a blockbuster drug. Prior to market entry by generics, AstraZeneca's U.S. sales of Seroquel XR approached \$1 billion annually, comprising more than 8 million prescriptions.

4. AstraZeneca has held U.S. Patent No. 4,879,288 (the "'288 Patent"), covering the chemical composition of quetiapine fumarate, the primary chemical compound in both Seroquel XR and its predecessor Seroquel IR, since 1989. With the '288 Patent originally set to expire on March 20, 2007,² AstraZeneca developed Seroquel XR, first approved in the U.S. in May 2007, with sales beginning in November 2007. Underlying AstraZeneca's strategy for Seroquel XR was the recently issued U.S. Patent No. 5,948,437 (the "'437 Patent"), a follow-on patent, which purportedly covered Seroquel XR.

² AstraZeneca eventually received a patent term extension of the '288 Patent as reward for participating in FDA's program incentivizing pediatric testing. All patent and/or regulatory exclusivity for the '288 Patent expired on March 26, 2012.

5. However, the '437 Patent was strategically weak. Unlike the '288 Patent covering the chemical compound of quetiapine fumarate itself, the follow-on '437 Patent merely claimed narrow, very specific formulations. Recognizing opportunity, generic companies developed competing versions.

6. Between June and December of 2008, generic drug manufacturers Handa and Accord filed abbreviated new drug applications (“ANDAs”) with the U.S. Food and Drug Administration (“FDA”), with Paragraph IV certifications attesting that patents related to AstraZeneca’s new drug application (“NDA”) for Seroquel XR are either invalid, unenforceable, or not infringed upon by the generics’ proposed ANDA applications. Accord was the first-filer of the 400mg strength generic. Handa was the first-filer of the 50mg, 150mg, 200mg, and 300mg strength versions. Several additional companies (“Later-Filing Manufacturers”) filed ANDAs thereafter.³

7. In response, AstraZeneca filed twelve suits alleging infringement of the '288 Patent and '437 Patent, all consolidated as related actions in the U.S. District Court for the District of New Jersey.

8. AstraZeneca did not bring the Handa Seroquel Patent Litigation for purposes of securing a judgment on the merits in its favor; rather it brought the

³ As of August 2022, fourteen generic companies in addition to Handa and Accord have filed ANDAs.

case to take advantage of the automatic regulatory stay of thirty months.⁴

AstraZeneca knew that Handa's proposed generic version of extended-release quetiapine fumarate would not infringe the '437 Patent because the '437 Patent narrowly claimed very specific formulations of quetiapine fumarate, each of which requires a "gelling agent." Handa's ANDA, and its own patent underlying its ANDA, successfully designed around the use of AstraZeneca's protected gelling agent, which had been clear to AstraZeneca since it received Handa's paragraph IV notification.

9. Although it triggered the automatic thirty months stay, AstraZeneca's patent infringement suit could not avoid this problem. The District Court quickly recognized that Handa's ANDA did not contemplate the use of a "gelling agent," a conclusion that was apparent after its November 30, 2010 claim construction opinion.⁵ Based on this claim construction, AstraZeneca faced an eventual judgment of noninfringement of the '437 Patent.

⁴ See 21 U.S.C. § 355(j)(5)(B)(iii).

⁵ *AstraZeneca Pharm., LP, et al v. Handa Pharm., LLC, et al.*, Civ. No. 3:10-cv-01835, ECF No. 69, p.7.

10. Meanwhile, on December 9, 2010, the FDA granted tentative approval⁶ to Handa's ANDA for generic Seroquel XR in all strengths.⁷ Additionally, on August 23, 2011, the United States Patent and Trademark Office ("PTO") issued to Handa a patent for its generic quetiapine fumarate.⁸ To obtain its patent, Handa had disclosed AstraZeneca's '288 Patent and '437 Patent as prior art, further signaling that Handa had designed around AstraZeneca's patents.

11. Weeks later in September 2011, to avoid its upcoming defeat and its competitor's impending market entry, AstraZeneca induced Handa to drop its patent challenge and delay launching its generic version with a sizeable and illegal "reverse payment."

12. A reverse payment exists when the patent holder—here, AstraZeneca—pays some amount to the alleged patent infringer—here, Handa⁹—allowing the maintenance of supracompetitive prices and sharing of the illegal

⁶ By statute, the FDA cannot grant final approval until the expiration of the thirty months stay or a favorable judgment of noninfringement or invalidity in the patent suit which triggered the stay.

⁷ See Tentative Approval Letter from Keith Webber, Deputy Director Office of Pharmaceutical Science, FDA, to Maggie Chang, Executive Vice President, Quality Affairs, Handa Pharmaceuticals, LLC, at 1 (Dec. 9, 2010), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2010/090482s000ltr.pdf.

⁸ U.S. Patent No. 8,003,637 ("the Handa '637B Patent").

⁹ As assignee of Handa's ANDA and the Handa Reverse Payment Agreement.

gains.¹⁰ AstraZeneca unlawfully paid Handa/Par to stay out of the market for almost five (5) years.

13. Reverse payments need not come in the form of cash. Here, AstraZeneca's payment with Handa comprised a secret non-compete agreement that AstraZeneca would not launch its own generic version of Seroquel XR (known as an authorized generic, here "AG Seroquel XR") during Handa/Par's 180-day exclusivity period, consideration worth hundreds of millions of dollars. This payment was attractive for both parties to the agreement – it allowed AstraZeneca to continue to charge monopolistic prices for five (5) years unchallenged, and it provided Handa/Par with exclusive rights that were worth more money than the revenue it would have made launching its generic in 2012 and competing against Seroquel XR and AG Seroquel XR. *See infra*.

14. Under the terms of this agreement (the "Handa Reverse Payment Agreement"), Handa/Par promised to, and did, abandon the patent battle and delay marketing of generic Seroquel XR until the agreed-upon date of November 1, 2016.¹¹

¹⁰ The Supreme Court in *F.T.C. v. Actavis*, 133 S. Ct. 2223 (2013) determined that resolving patent infringement litigation by having the plaintiff in the patent litigation make a large and unjustified payment to the allegedly infringing defendant violates federal antitrust law (assuming the other elements are satisfied).

¹¹ Press Release, AstraZeneca, AstraZeneca enters into a settlement agreement with Handa Pharmaceuticals regarding US SEROQUEL XR® patent litigation (Sept. 29, 2011), <https://www.astrazeneca.com/media-centre/press-releases/2011/AstraZeneca-enters-into-a-settlement-agreement-with-Handa-Pharmaceuticals-regarding-US-SEROQUEL-XR-patent-litigation-29092011.html#>.

15. Weeks after inducing the Handa Reverse Payment, on October 5, 2011, before the end of trial, AstraZeneca induced Accord to drop its patent challenge related to the 400mg strength of Seroquel XR and enter into an agreement (the “Accord Reverse Payment Agreement”).¹² On information and belief, the Accord Reverse Payment Agreement contained similar non-compete provisions, mirroring the terms of the Handa Reverse Payment Agreement and, together (collectively, “the Reverse Payment Agreements”), delaying the launch of all strengths of generic quetiapine fumarate.

16. But for the unlawful Reverse Payment Agreements, generic versions of quetiapine fumarate would have launched far earlier than November 1, 2016 and AstraZeneca would have marketed and sold its authorized generic earlier than May 1, 2017. In fact, eleven ANDAs for the generic version of AstraZeneca’s instant release tablets of Seroquel (“Seroquel IR”)—subject only to the ‘288 Patent—were approved on March 27, 2012.¹³ Many of the approved ANDAs from that day—like the ANDAs for Handa’s and Accord’s generics—had received temporary approval

¹² Press Release, Globe News Wire, AstraZeneca Enters Into a Settlement Agreement with Accord Healthcare, Inc. and Intas Pharmaceuticals Ltd regarding US SEROQUEL XR® Patent Litigation (Oct. 5, 2011) <http://www.globenewswire.com/news-release/2011/10/05/232367/0/sv/AstraZeneca-Enters-Into-a-Settlement-Agreement-with-Accord-Healthcare-Inc-and-Intas-Pharmaceuticals-Ltd-regarding-US-SEROQUEL-XR-Patent-Litigation.html>.

¹³ AstraZeneca sued the FDA trying to enjoin the FDA from issuing the ANDAs based on additionally claimed exclusivities. The court denied a temporary restraining order and later entered judgment for the FDA on summary judgment. *See AstraZeneca Pharmaceuticals LP v. Food and Drug Admin.*, 872 F. Supp. 2d 60, 74 (D.D.C. 2012), *aff’d*, 713 F.3d 1134 (D.C. Cir. 2013).

years before. Without the unlawful agreements, one or more generic versions of Seroquel XR (in each strength) would have entered the market earlier through either: (1) patent litigation victory by Handa and/or Accord; (2) at-risk launch(es) by Handa and/or Accord; or (3) agreements that lacked illegal reverse payments.

17. The agreements also delayed entry of Later-Filing Manufacturers, which could not statutorily receive FDA approval of ANDAs before the expiration of the 180-day exclusivity periods enjoyed by first-filers. Through the Reverse Payment Agreements, AstraZeneca delayed the triggering of the exclusivity periods by around five years. Later-Filing Manufacturers would have launched six months after the entry of Handa and Accord or soon thereafter. The presence of additional generics would have resulted in increased competition and concomitant lower prices for extended release quetiapine fumarate.

18. HCSC was injured and sustained damages in the form of overcharges on both brand name and generic forms of Seroquel XR as a direct result of the illegal Reverse Payment Agreements. Through this lawsuit, HCSC seeks to recover damages, including treble damages, under the state antitrust and consumer protection laws identified herein.

II. JURISDICTION AND VENUE

19. This Court has subject matter jurisdiction because the amount in controversy exceeds \$75,000 and there is complete diversity of citizenship. 28 U.S.C. § 1332(a).

20. The Court has personal jurisdiction over each Defendant because Defendants: (i) reside in this District, (ii) are incorporated within this District, and/or (iii) transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of the illegal conduct here alleged throughout the United States, including in this District. Defendants' conduct and conspiracy have been directed at, and have had the intended effect of, causing injury to persons residing in, located in, or doing business throughout the United States, including in this District.

21. This District is an appropriate venue because a substantial part of the events giving rise to Plaintiff's claims occurred within the District. 28 U.S.C. § 1391(b)(2), (3).

III. THE PARTIES

Plaintiff

22. Plaintiff Health Care Service Corporation ("HCSC") is the nation's largest customer-owned health insurer and the fourth largest health insurer overall, with more than 16 million members. It is organized as a Mutual Legal Reserve Company under Illinois law and is an independent licensee of the Blue Cross and

Blue Shield Association (“BCBSA”). Through its operating divisions, HCSC offers BCBSA-branded health plans in Illinois, Montana, New Mexico, Oklahoma, and Texas who serve members throughout the United States. Through its operating divisions and subsidiaries, it also offers a wide variety of health and life insurance products and related services. It is headquartered at 300 E. Randolph Street, Chicago, IL.

23. HCSC indirectly purchased, paid and/or reimbursed for some or all of the purchase price for one or more Seroquel XR and its AB-rated generic equivalent.

24. HCSC, through its operating divisions and subsidiaries, provides, inter alia: (1) Medicare benefits through contracts with the Centers for Medicare and Medicaid Services (“CMS”), for Medicare beneficiaries through a variety of Medicare Advantage plans offered under Part C of Medicare, or prescription drug benefits under Part D of Medicare; and (2) private commercial health insurance plan benefits that cover the medical expenses incurred by plan beneficiaries on an individual or group basis. These benefits include prescription drug coverage under which claims have been, and continue to be, submitted and paid.

25. HCSC, through its operating divisions, also administers health plan benefits for its members and group customers, including self-funded customers that contract with HCSC to administer health insurance benefits on their behalf and

pursue recoveries related to those expenditures. Many of these health plan benefits provide members with prescription drug coverage under which claims have been, and continue to be, submitted and paid. In particular, HCSC offers “Administrative Services Only” (“ASO”) services to self-funded health plans across the United States. HCSC is also pursuing recovery related to those claims.

Defendants

26. Defendant Handa Pharmaceuticals, LLC (“Handa”) is a Delaware limited liability company having its principal place of business at 1732 N. 1st Street, Suite 200, San Jose, California 95112.

27. Defendant AstraZeneca Pharmaceuticals LP is a Delaware limited partnership having its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803.

28. Defendant AstraZeneca LP is a Delaware limited partnership having its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803.

29. Defendant AstraZeneca UK Limited is an English corporation having its principal place of business at 15 Stanhope Gate, London, United Kingdom W1Y 6LN.

30. All three AstraZeneca entities are collectively referred to herein as “AstraZeneca.”

Non-Party Co-Conspirators

31. Non-party Par Pharmaceutical, Inc. (“Par”) is a Delaware corporation having its principal place of business at One Ram Ridge Road, Chestnut Ridge, New York 10977.

32. Non-party Accord Healthcare, Inc. (“Accord”) is a North Carolina corporation having its principal place of business at 1009 Slater Road, Suite 210-B, Durham, North Carolina 27703.

IV. REGULATORY AND ECONOMIC BACKGROUND

A. The Hatch-Waxman Act and FDA Approval Process

33. Under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§301-392 (“FDCA”), a manufacturer of a new drug must obtain approval of the FDA to sell the new drug by filing a New Drug Application (“NDA”). An NDA must include submission of specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents.

34. In 1984, Congress amended the FDCA by enacting the Hatch-Waxman amendments, called the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (“Hatch-Waxman”). The purpose of Hatch-Waxman was to hasten the delivery of inexpensive generic drugs to the market while respecting the patent rights of brand name drug patent holders.

35. To encourage generic entry, Hatch-Waxman established certain procedures that apply when a generic company seeks to market a generic product before the expiration of any patents allegedly covering the branded product. Congress achieved this goal by eliminating the requirement that generic manufacturers file a lengthy and costly NDA to obtain FDA approval for generic versions of existing branded drugs. Instead, under Hatch-Waxman, to obtain approval, a generic company wishing to market a generic version of a drug can file an Abbreviated New Drug Application (“ANDA”) that incorporates the scientific findings of safety and effectiveness included in the brand name drug manufacturer’s original NDA. The generic applicant can secure marketing approval if it shows only that its proposed generic drug is bioequivalent to the brand name drug, *i.e.*, that it will contain the same active ingredient(s), strength, dosage form, and route of administration.

36. Once bioequivalence is demonstrated, the FDA assigns an “AB” rating to the generic, which allows it to be substituted for the branded product at the pharmacy.

37. To protect brand name manufacturers’ ability to enforce their patents against infringement through the ANDA process, Hatch-Waxman also streamlined the patent enforcement process, providing that the FDA could not grant a generic manufacturer final approval to market or sell a generic version of the brand name

drug for up to 30 months if the patent holder initiated a patent infringement lawsuit against the ANDA applicant.

38. When the FDA approves a brand name manufacturer's NDA, Hatch-Waxman allows the brand manufacturer to list in the FDA's book of Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") any patents that the brand manufacturer believes could reasonably be asserted against a generic manufacturer who makes, uses, or sells a generic version of the brand name drug prior to the expiration of the listed patents.

39. To obtain FDA approval of an ANDA (and thus the right to sell a generic version of a brand name drug), a generic manufacturer must certify that the generic drug addressed in its ANDA will not infringe any patents listed in the Orange Book. Under Hatch-Waxman, a generic manufacturer's ANDA must contain one of four certifications:

- that no patent for the brand name drug has been filed with the FDA (a "Paragraph I certification");
- that the patent for the brand name drug has expired (a "Paragraph II certification");
- that the patent for the brand name drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III certification"); or
- that the patent for the brand name drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

40. If a generic manufacturer files Paragraph I or II certifications, the FDA must act on the application within 180 days of receipt. If a generic manufacturer files a Paragraph III certification, the FDA can proceed with the ANDA approval process, with final approval being granted after the expiration of the applicable patents.

41. If a generic manufacturer files a Paragraph IV certification, however, a brand name manufacturer may delay the final FDA approval of the ANDA by suing for patent infringement. Specifically, if the brand name manufacturer initiates a patent infringement action against the generic filer within 45 days of the Paragraph IV certification, the FDA may not grant final approval to the ANDA until the earlier of: (a) 30 months, or (b) issuance of a court decision that the patent is invalid or not infringed by the generic manufacturer's ANDA.

42. During the pendency of the 30-month stay, the FDA may grant "tentative approval" to an ANDA applicant if the FDA determines that the ANDA would qualify for final approval but for the 30-month stay but cannot authorize the generic manufacturer to go to market. Thus, by listing a patent in the Orange Book and filing a suit within 45 days of receiving a Paragraph IV certification regarding the listed patent, a brand name drug manufacturer may delay the date of final approval of the generic drug, and the generic drug's entry into the market.

B. The Economic Model of Prescription Drug Purchases and Sales

43. The marketplace for the sale of prescription pharmaceutical products in the United States is unique. In most industries, the buyer of goods is also the person or entity that selects the goods for purchase. In these markets, when the consumer of goods shares the payment obligation, price has a prominent role in choice. Suppliers, therefore, have an incentive to compete with one another on price.

44. The pharmaceutical marketplace does not work in this way. The person in charge of product selection is the doctor who, due to regulations that control the distribution of these controlled substances, is the only actor able to make therapeutic selections. State laws prohibit pharmacists from dispensing certain drugs to patients unless they can present a prescription written by their physician. The patient and, to a larger extent, his or her insurer, has the obligation to pay for the pharmaceutical product selected by the physician.

45. When a pharmacist receives a prescription for a branded drug and an AB-rated¹⁴ generic version of that drug is available, state laws permit (and often require) the pharmacist to dispense the generic in lieu of the brand. In this way, price is reintroduced to the product selection decision at the pharmacy counter, and

¹⁴ AB-rated generic versions of brand name drugs contain the same active ingredient and are determined by the FDA to be just as safe and effective as their brand name counterparts. Every state either requires or permits that a prescription written for the brand drug be filled with an AB-rated generic.

the pharmaceutical marketplace “disconnect” is lessened. When an AB-rated generic equivalent is introduced, brand manufacturers can no longer exploit the “disconnect,” their monopoly power dissipates, and some of the normal competitive pressures are restored.

46. Because AB-rated generic versions of brand-name drugs contain the same active ingredients and are determined by the FDA to be equally as safe and effective as their branded counterparts, the only material difference between generic drugs and their branded counterparts is price.

47. Typically, generic versions of brand name drugs are priced significantly below their brand name counterparts, posing a grave threat to the bottom lines of brand name drug manufacturers.¹⁵

48. Substitution laws and other institutional features of pharmaceutical distribution and use create the economic dynamic that the launch of AB-rated generics results both in rapid price decline and rapid sales shift from brand to generic purchasing.

49. As additional generic manufacturers enter the market, prices for generic versions of a drug decrease predictably because of competition among

¹⁵ For instance, the first-launched generic manufacturer regularly sets its price at 10-20% less than the reference listed drug branded counterpart during the 180-day exclusivity period. Once additional generic companies enter the market, prices reduce to between 50% to 80% (or more) less than the branded price. The Federal Trade Commission (“FTC”) estimates that about one year after market entry, a generic drug takes over 90% of the branded drug’s unit sales at 15% of the price of the branded drug.

generic manufacturers, and the loss of sales volume by the brand name drug to the corresponding generic accelerates. Generic competition enables purchasers both to purchase generic versions of the brand name drug at a substantially lower price and also to purchase the brand name drug at a reduced net price.

50. Until a generic manufacturer enters the market, there is no bioequivalent generic drug that can substitute for the brand name drug, and therefore the brand name manufacturer can charge supracompetitive prices profitably without material loss to sales volume. As a result, brand name drug manufacturers have an obvious economic motivation to delay the introduction of generic competition into the market.

C. Authorized Generic (AG) Prescription Drugs

51. Hatch-Waxman provides another counter for branded manufacturers to compete with a first generic entering the market: a branded manufacturer can launch its own generic version, called an authorized generic (“AG”), of its branded drug. Authorized generics are FDA approved brand drugs that are marketed as generics by the branded manufacturer.¹⁶ Because the Hatch-Waxman amendments’ 180-day marketing period is only “exclusive” against other ANDA-based products, brand manufacturers can compete by launching an AG. The FTC has found that

¹⁶ FEDERAL TRADE COMN’N AUTHORIZED GENERICS: AN INTERIM REPORT 1 (2009).

the AG is a “very close substitute” for the first-filer’s products and that it ordinarily captures “significant market share at the expense of” the generic.

52. By 2003, the authorized generic strategy was increasingly used by branded manufacturers as a way to recoup revenue upon early generic entry.¹⁷ From 2003 to 2006, there were 19 to 21 authorized generic launches a year.¹⁸ Courts have widely concluded that brand manufacturers can launch an authorized generic without disrupting the market exclusivity contemplated by Hatch-Waxman’s grant of 180-day generic market exclusivity to the first-filed generic.¹⁹

53. Nothing prevents a brand manufacturer from selling an AG at any time. An AG is chemically identical to the brand but sold as a generic, typically through either the brand manufacturer’s subsidiary (if it has one) or through a third-party distributor. An AG is essentially the brand product in a different package.

¹⁷ FEDERAL TRADE COMM’N, AUTHORIZED GENERIC DRUGS: SHORT TERM EFFECTS AND LONG-TERM IMPACT 12 n.4 (2011).

¹⁸ *Id.* at 11.

¹⁹ *See, e.g., Mylan Pharm. v. FDA*, No. 104CV242, 2005 WL 241167, at *7 (N.D.W. Va. Sept. 29, 2005); *Teva Pharm. Indus. v. Crawford*, 410 F.3d 51, 55 (D.C. Cir. 2005).

54. One study notes that “pharmaceutical developers facing competition from generics have large incentives to compete with their own or licensed ‘authorized generics.’”²⁰

55. Brand manufacturers sometimes begin selling AGs even before the first-filer generic enters the market—and temporarily competing against its own patent-conferred monopoly—in order to secure multi-year purchase contracts with direct purchasers and load the generic pipeline at the expense of the first-filer generic.

56. Competition from an AG substantially reduces drug prices and the revenues of the first-filer generic (especially during the 180-day exclusivity period). A study analyzing three examples of AGs found that “[f]or all three products, authorized generics competed aggressively against independent generics on price, and both the authorized and independent generics captured substantial market share from the brand.”²¹

57. Launching AGs is a lucrative market strategy. The FTC found that AGs capture a significant portion of sales, reducing the first-filer generic’s

²⁰ Kevin A. Hassett & Robert J. Shapiro, Sonecon, *The Impact of Authorized Generic Pharmaceuticals on the Introduction of Other Generic Pharmaceuticals* 3 (2007), http://www.sonecon.com/docs/studies/050207_authorizedgenerics.pdf.

²¹ Ernst R. Berndt et al., *Authorized Generic Drugs, Price Competition, and Consumers’ Welfare*, 26 *Health Affairs* 790, 796 (2007).

revenues by about 50% on average.²² The first-filer generic makes much less money when it faces competition from an AG because (1) the AG takes a large share of unit sales away from the first filer; and (2) the presence of the AG causes prices, particularly generic prices, to decrease.

58. Authorized generics are therefore a significant source of price competition. In fact, they are the only potential source of generic price competition during the first-to-file generic's 180-day exclusivity period. All drug industry participants recognize this. PhRma recognizes it.²³ Generic companies recognize it.²⁴ So do brand companies.²⁵

D. Pharmaceutical Manufacturers Collude to Thwart Competition

²² FTC 2011 AG Study at 139.

²³ Brand industry group PhRma sponsored a study that concludes that the presence of an authorized generic causes generic prices to be more than 15% lower as compared to when there is no authorized generic. IMS Consulting, *Assessment of Authorized Generics in the U.S.* (2006), http://208.106.226.207/downloads/IMSAuthorizedGenericsReport_6-22-06.pdf.

²⁴ One generic stated that “[d]ue to market share and pricing erosion at the hands of the authorized [generic], we estimate that the profits for the ‘pure’ generic during the exclusivity period could be reduced by approximately 60% in a typical scenario.” *See* FTC 2011 AG Study at 81. Another generic quantified the fiscal consequences of competing with an authorized generic version of the brand drug Paxil, determining that the authorized generic reduced its first generic's revenues by two-thirds, or by approximately \$400 million. Comment of Apotex Corp. in Support of Mylan Citizen Petition (Mar. 24, 2004), <http://www.fda.gov/ohrms/dockets/dailys/04/apr04/040204/04P=0075-emc00001.pdf>. In 2004, generic company Teva acknowledged that an authorized generic would “severely devalu[e]” its 180 day exclusivity because an authorized generic “effectively transfers much of the profit value from the generic challenger [to the authorized generic]” and “allows the [authorized generic] to seize a significant share of the generic supply chain.” Teva Citizen Petition, Docket No. 2004P-0261/CPI (June 9, 2004), www.fda.gov/ohrms/dockets/dailys/04/June04/061004/04p-0261-cp00001-01-vol1.pdf.

²⁵ Commenting on Teva's FDA petition, AstraZeneca stated: “Teva's petition [to prevent the launch of an authorized generic] is a flagrant effort to stifle price competition – to Teva's benefit and the public's detriment.” Comment of AstraZeneca at 7, Docket No. 2004P-0261 (June 23, 2004), <http://www.fda.gov/ohrms/dockets/dailys/04/June04/062904/062904.htm#04P0261>; Comment of Johnson & Johnson at 1, FDA Docket No. 2004P-0075 (May 11, 2004), <http://www.fda.gov/ohrms/dockets/dailys/04/June04/060404/04p-0075-c00002-vol1.pdf>.

1. Pay for Delay Agreements

59. To prevent the erosion of profits caused by the competition of market entering generics, brand and generic manufacturers sometimes—unlawfully—agree not to compete and instead share monopolistic rents. These illegal agreements cheat consumers, subverting the structure and purpose of the regulatory regime implemented by the Hatch-Waxman Act.

60. In order for such an anticompetitive pact to work, brand and generic manufacturers need a means by which to divide the purchaser savings between themselves. The generic manufacturer will not refrain from competing if it does not share in the ill-gotten gains through some means. Pay-offs from the brand manufacturer are the means by which brand and generic manufacturers divide between themselves the ill-gotten gains that delayed competition makes possible. These unlawful pay-off deals are often referred to as “pay-for-delay,” “exclusion payment,” or “reverse payment” agreements.

61. The brand manufacturer may choose to – unlawfully – pay off only the first filer, even if other generic manufacturers are also lined up to challenge the patents. The first filer’s agreement to delay marketing its drug also prevents other generic manufacturers from marketing their products because the first-filer’s 180-day period of exclusivity is delayed.

62. Pay-for-delay agreements are fundamentally anticompetitive and contrary to the goals of the Hatch-Waxman statutory scheme. In particular, they extend the brand manufacturer's monopoly by blocking access to more affordable generic drugs, forcing purchasers to buy expensive brands instead.

2. No-AG clauses allow manufacturers to share unlawful gains

63. One form of significant value is a promise to temporarily forego the benefits of an authorized generic ("no-AG promise"). With a no-AG promise, the brand manufacturer agrees not to market an authorized generic version of the brand drug for some period of time after the first generic enters. No-AG promises include requirements, such as exclusivity terms or provisions that create an incentive for the brand not to market a competing AG, that effectively amount to a promise not to launch an AG.²⁶

64. Absent a no-AG promise, it almost always makes economic sense for the brand manufacturer to begin marketing an AG as soon as (or sometimes weeks or months before) the first generic enters the marketplace.

65. To prevent an AG from causing this substantial loss of revenues and profits,²⁷ a first-filer generic may be willing to delay its entry into the marketplace

²⁶ See generally FEDERAL TRADE COMM'N, AUTHORIZED GENERIC DRUGS: SHORT TERM EFFECTS AND LONG-TERM IMPACT (2011) (cataloging varieties of anticompetitive no-AG promises).

²⁷ Competition from an AG typically cuts the first filer's revenues by at least half, as the competing generic takes a substantial volume of the unit sales and drives prices lower – delivering commensurate savings to drug purchasers.

in return for the brand manufacturer's agreement to forgo competing with an AG. The additional monopoly profits that the brand manufacturer gains from the delayed onset of generic competition more than makes up for the profits it forgoes by not competing with an AG. The brand manufacturer gains from the delayed onset of generic competition. The first filer gains from the absence of generic competition for the first 180 days of marketing. But drug purchasers lose.

66. The brand and first filer's reciprocal pledges not to compete harm purchasers thrice over. *First*, the pact delays the first filer's entry into the marketplace and thereby extends the time during which the more expensive brand has a monopoly. *Second*, by delaying the first filer's entry (and exclusivity period), the pact also delays the time when other, later, generics enter. *Third*, the pact prevents the brand from marketing an AG during the 180-day exclusivity period, reducing price competition that would otherwise occur between the first filer's generic and the brand's AG.

67. For the first filer, the difference between selling the only generic and competing against an AG for 180 days can amount to tens or even hundreds of millions of dollars, depending on the size of the brand's sales. A no-AG pledge thus has the same economic effect as a pay-off made in cash. As explained by the then-Chairman of the FTC:

Because the impact of an authorized generic on first-filer revenue is so sizable, the ability to promise not to launch an AG is a huge bargaining chip the brand company can use in settlement negotiations with a first-filer generic. It used to be that a brand might say to a generic, “if you go away for several years, I’ll give you \$200 million.” Now, the brand might say to the generic, “if I launch an AG, you will be penalized \$200 million, so why don’t you go away for a few years and I won’t launch an AG.”²⁸

68. Courts agree that no-AG agreements are a form of payment actionable under *Actavis* and are anticompetitive.²⁹

69. For a first ANDA filer (like Handa/Par and Accord) for a brand drug with billions of dollars in annual sales (like Seroquel XR), the difference between selling a generic without having to compete against an AG and selling in competition with an AG can amount to hundreds of millions of dollars. These economic realities are well known in the pharmaceutical industry. No-AG agreements thus allow competitors to benefit from an agreement not to compete

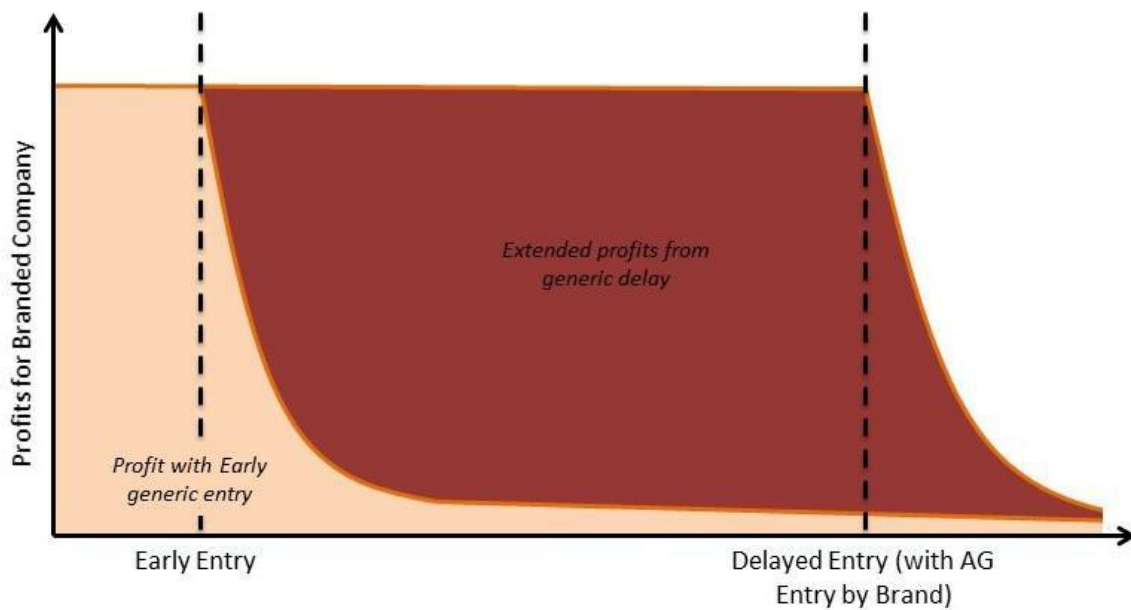
²⁸ Press Release, FTC, Statement of Chairman Jon Leibowitz on the Release of the Commission’s Interim Report on Authorized Generics, (June 24, 2009), <https://www.ftc.gov/sites/default/files/documents/reports/authorized-generics-interim-report-federal-tradecommission/p062105authgenstatementleibowitz.pdf>.

²⁹ See *In re Loestrin 24 Fe Antitrust Litig.*, Nos. 14-2071, 15-1250, 2016 U.S. App. LEXIS 3049, at *25-26 (1st Cir. Feb. 22, 2016); *In re Opana ER Antitrust Litig.*, No. 14 C 10150, 2016 U.S. Dist. LEXIS 16700, at *23-25 (N.D. Ill. Feb. 10, 2016); *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 242 (D. Conn. 2015); *United Food & Commercial Workers Local 1776 & Participating Emp’rs Health & Welfare Fund v. Teikoku Pharma USA, Inc.*, 74 F. Supp. 3d 1052, 1069 (N.D. Cal. 2014); *In re Effexor XR Antitrust Litig.*, No. 11-cv-5479, 2014 U.S. Dist. LEXIS 142206, at *62 (D.N.J. Oct. 6, 2014); *Time Ins. Co. v. AstraZeneca AB*, 52 F. Supp. 3d 705, 709-10 (E.D. Pa. 2014); *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 751 (E.D. Pa. 2014); *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 392 (D. Mass. 2013).

and deny purchasers the consumer surplus that should flow to them from increased competition.

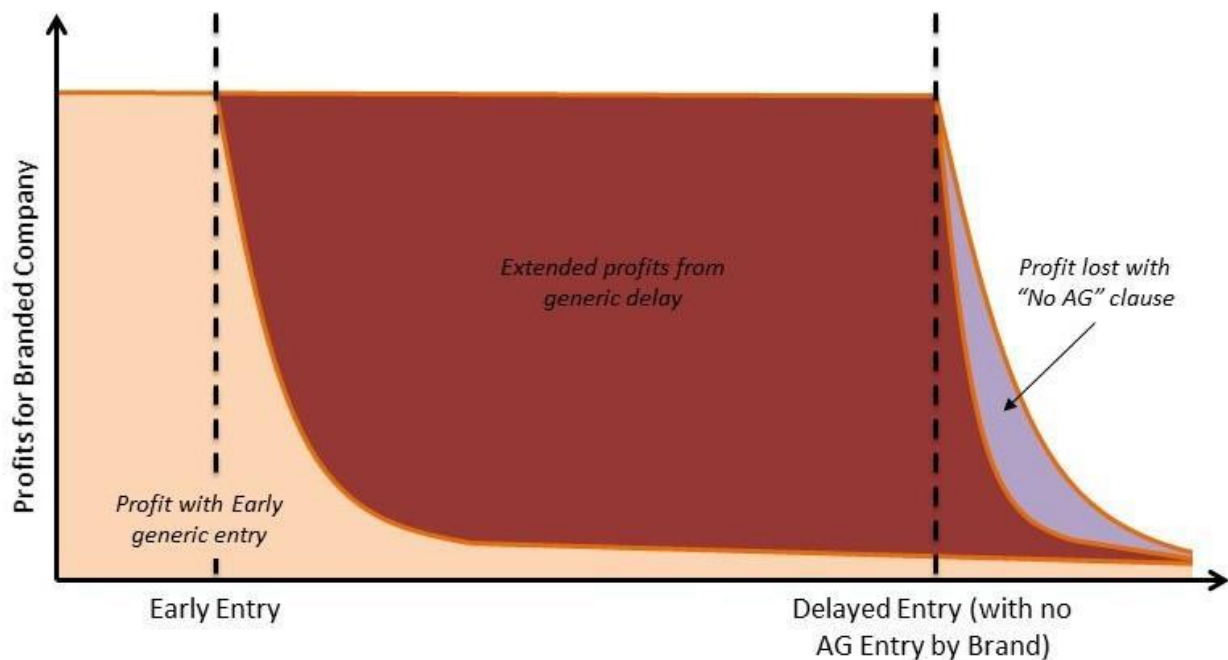
70. Figure 1 compares the impact on a brand manufacturer's profits between (i) a situation where it settles a patent lawsuit on the merits (i.e., with only an agreed entry date and without a pay-off to the generic company); and (ii) a situation where it settles the lawsuit with a large, unjustified payment to the generic manufacturer. In the former situation, the agreed generic entry date for the generic is earlier and the brand manufacturer's profits are thus greatly reduced. In the latter situation, the agreed entry date is later and the brand manufacturer's profits increase significantly. Earlier entry may also occur if the generic manufacturer launches its product at risk (i.e., while the litigation is still pending) or prevails in the patent litigation and then launches its product.

Figure 1: Impact of Delay on Brand Profits



71. Figure 2 depicts what happens when a settlement agreement includes a no-AG promise. The red area shows the brand manufacturer's additional monopoly profits earned during the period of delay. The purple area shows the amount of monopoly profit the brand manufacturer gives up (i.e., shares with the generic).

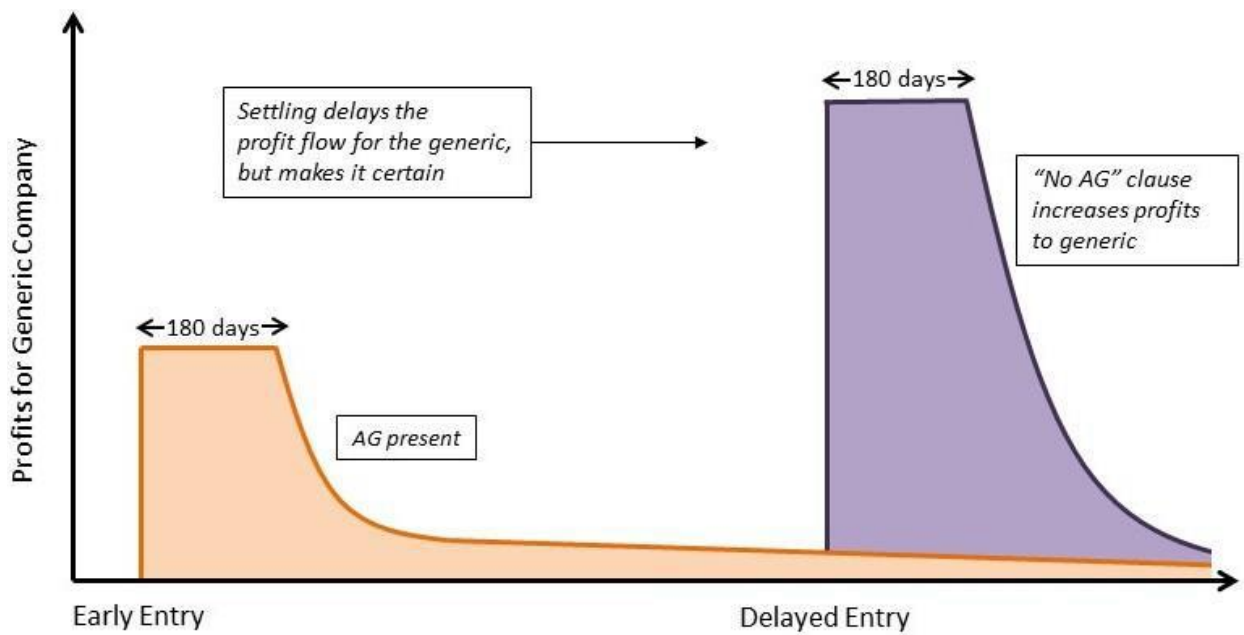
Figure 2: Figure 2: Impact of No-AG clause on brand profits



72. Figure 3 depicts the generic manufacturer's principal considerations in deciding whether to accept a settlement that includes a no-AG promise. Without a settlement, the generic could enter earlier – either when the 30-month stay expires

(“at risk”) or when it wins the litigation. The generic manufacturer’s profits (gross margins) would be high during the 180-day exclusivity period and then fall rapidly as additional generics enter. This profit flow is somewhat uncertain because (1) if the generic launches at risk, it could (theoretically) later be found to infringe a valid patent and (2) it is expected that the brand manufacturer will launch an authorized generic. With a no-AG promise, the profit flow occurs later but is more certain and is larger—roughly twice the size—because the generic manufacturer does not lose half of the market to the brand manufacturer’s authorized generic and can charge a higher price.

Figure 3: Impact of No-AG Promise on Generic’s Profits



73. Pay-offs by means of no-AG clauses usually exceed the value that the first filer could have obtained *even if it had won* the patent infringement litigation. By settling the patent case in exchange for a no-AG payoff, the first filer converts that critical six months into a period of total generic exclusivity that it was not otherwise entitled to, thus doubling its unit sales and making those sales at a higher price.

V. FACTS

A. AstraZeneca's Seroquel XR Patents

74. AstraZeneca Pharmaceuticals LP is the sponsor of NDA No. 22-047, under which the FDA granted approval for extended-release tablets containing various different dosage strengths of the active ingredient 11-[4-[2-(2-hydroxyethoxy)ethyl]-1-piperazinyl] dibenzo [b,f] [1,4] thiazepine fumarate (salt), which is commonly known as quetiapine fumarate. AstraZeneca Pharmaceuticals LP markets these tablets in the United States under the trademark Seroquel® XR.

75. AstraZeneca Pharmaceuticals LP is the owner of U.S. Patent No. 4,879,288 (“the ’288 Patent”). The ’288 Patent issued on November 7, 1989 from United States Application No. 07/028,473, which was filed on March 20, 1987. Although the ’288 Patent was originally set to expire on March 20, 2007, it received a patent term extension of 1,651 days under 35 U.S.C. § 156. Based upon the extension, the ’288 Patent expired on September 26, 2011.

76. AstraZeneca UK Limited is the owner of the '437 Patent. The '437 Patent issued on September 7, 1999 from United States Application No. 08/864,306, which was filed on May 28, 1997. The '437 Patent expired on May 28, 2017.

77. AstraZeneca submitted the '288 and '437 patents for listing in the FDA Orange Book under NDA No. 22-047. AstraZeneca Pharmaceuticals LP received pediatric exclusivity³⁰ for NDA No. 22-047, and the pediatric exclusivity associated with the '288 and '437 Patents expired on March 26, 2012 and November 28, 2017, respectively.

78. As the '288 Patent expired on September 26, 2011 and its pediatric exclusivity expired on March 26, 2012, neither the '288 Patent nor its associated pediatric exclusivity could have affected any generic drug company's right, ability or willingness to market a generic version of Seroquel XR after March 26, 2012.

79. To illustrate, on Monday March 27, 2012, the FDA granted final approval to eleven ANDAs for generic versions of AstraZeneca's instant release version of Seroquel, which had only referenced, as here relevant, the '288 Patent.³¹

³⁰ Congress enacted 35 U.S.C. § 355a to incentivize drug developers to conduct studies on their drugs in pediatric patients. Congress established as an incentive, that if the studies were successful, FDA would grant an additional 6-months of regulatory exclusivity running after patent expiration, during which the FDA would not approve generic versions of the studied drug.

³¹ NDA No. 20-639 was approved by the FDA in 1997 and listed the '288 Patent.

80. The '437 Patent contains one independent claim and fourteen dependent claims. Independent claim 1 recites:

A sustained release formulation comprising a gelling agent and 11-[4-[2-(2-hydroxyethoxy) ethyl]-1-piperazinyl]dibenzo-[b,f]I,4]-thiazepine or a pharmaceutically acceptable salt thereof, together with one or more pharmaceutically acceptable excipients.

Each of the fourteen dependent claims in the '437 Patent incorporate the requirements of claim 1, including the requirement for a “gelling agent.” “It is axiomatic that dependent claims cannot be found infringed unless the claims from which they depend have been found to be infringed.” *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1553 (Fed. Cir. 1989). Thus, a generic product or a generic drug company's ANDA that did not contain a “gelling agent” could not infringe the '437 Patent.

B. Handa and Accord file ANDAs for Generic Versions of Seroquel XR

81. Handa and Accord were the first generic manufacturers to file ANDAs with the FDA containing paragraph IV certifications regarding Seroquel XR patents.

82. Handa filed ANDA No. 90-482 for a generic version of extended-release quetiapine fumarate, and amended it four times, between spring and fall of 2008. On information and belief, Handa was the first applicant to file a

substantially complete application containing a paragraph IV certification for the 50mg, 150mg, 200mg, and 300mg strengths, making Handa eligible for 180 days of regulatory exclusivity for those strengths of generic Seroquel XR. Even though Handa's ANDA also included a paragraph IV certification for the 400mg strength, Handa was not the first applicant to file a substantially complete application containing a paragraph IV certification for the 400mg strength.

83. Accord filed ANDA No. 90-681 for a generic version of extended-release quetiapine fumarate on June 18, 2008.³² On information and belief, Accord was the first applicant to file a substantially complete application containing a paragraph IV certification for the 400mg strength of extended-release quetiapine fumarate, making Accord eligible for 180 days of regulatory exclusivity for the 400mg strength of generic Seroquel XR.

84. As the first companies to file substantially complete ANDAs with paragraph IV certifications, Handa and Accord each stood to receive a significant and potentially highly lucrative advantage: 180-days of marketing exclusivity during which the FDA would not give final approval to any other ANDA filer's

³² Paragraph IV Patent Certifications August 22, 2019, <https://www.fda.gov/media/82686/download> (last visited September 9, 2019).

generic equivalent of Seroquel XR (Handa for the 50mg, 150mg, 200mg, 300mg strengths and Accord for the 400mg strength).³³

85. Subsequent to receiving confirmation of receipt from the FDA for its ANDAs, Handa sent four separate paragraph IV notice letters to AstraZeneca of its ANDAs (dated July 10, 2008, July 23, 2008, October 16, 2008, and November 14, 2008), each containing paragraph IV certifications that included a detailed statement of the factual and legal basis as to why the '437 Patent was invalid, unenforceable, and/or not infringed by Handa's ANDA products. As required under the Hatch-Waxman Act, the paragraph IV notice letters included an offer of confidential access to Handa's ANDA. Under the Hatch-Waxman Act, the paragraph IV letters gave rise to an artificial act of patent infringement for purposes of creating standing, thereby allowing AstraZeneca to bring a cause of action for infringement against Handa.

86. Likewise, Accord sent AstraZeneca two separate paragraph IV notice letters dated September 5, 2008 and January 23, 2009.³⁴ Accord's paragraph IV certifications contained (as required by statute) "a detailed statement of the factual and legal basis of the opinion of the applicant that ['437 Patent] is invalid or will

³³ See 21 U.S.C. § 355(j)(5)(B)(iv).

³⁴ Stipulated Facts, ¶ 27, ECF No. 156-1, *AstraZeneca Pharm. et al. v. Handa Pharm. LLC*, 3:10-cv-01835-JAP-TJB (D.N.J.).

not be infringed,” by Accord’s generic Seroquel XR products.³⁵ On information and belief, Accord’s paragraph IV notice letters also included an offer of confidential access to Accord’s ANDA as required under the Hatch-Waxman Act. As explained above, pursuant to the Hatch-Waxman Act, the paragraph IV letters give rise to an artificial act of patent infringement for purposes of creating standing, thereby allowing AstraZeneca to bring a cause of action for infringement against Accord.

C. AstraZeneca files patent litigation

87. In response to Handa’s July 10, 2008, July 23, 2008, October 16, 2008 and November 14, 2008 paragraph IV notice letters, AstraZeneca filed 3 patent infringement cases against Handa in the District of New Jersey on July 28, 2008 (the “Handa Patent Litigation”).

88. In response to Accord’s September 5, 2008 and January 23, 2009 paragraph IV notice letters, AstraZeneca filed 2 patent infringement cases against Accord in the District of New Jersey (the “Accord Patent Litigation”).

89. Other generic drug companies filed subsequent ANDAs seeking approval of generic versions of Seroquel XR. In all, AstraZeneca filed seven patent infringement lawsuits relating to generic Seroquel XR against four of these

³⁵ 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

manufacturers—Anchen Pharmaceuticals, Inc. and Anchen, Inc. (together, “Anchen”); Osmotica Pharmaceutical Corporation (“Osmotica”); Torrent Pharmaceuticals Limited and Torrent Pharma Inc. (together, “Torrent”) and Mylan Pharmaceuticals, Inc. and Mylan, Inc. (together, “Mylan”)—in the District of New Jersey (the “Other Patent Litigation”).

90. The Handa Patent Litigation, the Accord Patent Litigation, and the Other Patent Litigation are collectively referred to as the “Seroquel XR Patent Litigation.”

91. During the Seroquel XR Patent Litigation, the District Court held a *Markman* hearing and construed the term “gelling agent” as “any substance which forms a gel when in contact with water.”³⁶

92. The 30-month stay preventing final FDA approval of Handa’s ANDA expired no later than April 2011. The 30-month stay preventing final FDA approval of Accord’s ANDA expired no later than July 2011.

93. On September 29, 2011, AstraZeneca reached a settlement with Handa of the Handa Patent Litigation.

³⁶ See *AstraZeneca Pharm., LP v. Anchen Pharm., Inc.*, Civ. No. 10-cv-1835, 2012 WL 1065458, at *11 (D.N.J. Mar. 29, 2012); see also, *AstraZeneca Pharm., LP, et al v. Handa Pharm., LLC, et al*, Civ. No. 3:10-cv-01835, Dkt. 69, p. 7.

94. On or about October 5, 2011, AstraZeneca reached a settlement with Accord of the Accord Patent Litigation.

95. AstraZeneca did not settle the Other Patent Litigation prior to trial. Those cases proceeded to a bench trial in October 2011. At the trial, three of the other manufacturers—Anchen, Osmotica, and Mylan—did not defend their cases on the ground of non-infringement, in part because their generic version(s) of Seroquel XR used hydroxypropylmethylcellulose (“HPMC”), the “preferred gelling agent of the ’437 patent”:

The proposed ANDA products of Anchen, Osmotica and Mylan Pharms contain HPMC, the preferred gelling agent of the ’437 patent. Anchen, Mylan and Osmotica have not contested that their proposed ANDA products would infringe various claims of the ’437 patent if those claims are not found to be invalid.³⁷

96. By contrast, Torrent’s generic Seroquel XR product did not use HPMC but instead used a “naturally-occurring hydrophilic polymer” sold under the brand name Viscarin 209 that “hydrates and swells in the presence of water.”³⁸ The District Court concluded that Viscarin 209 was indeed a “gelling agent” under the court’s claim construction, and found that Torrent’s generic Seroquel XR product infringed the ’437 Patent.³⁹

³⁷ See *AstraZeneca Pharm., LP*, 2012 WL 1065458, at *8.

³⁸ *Id.* at *11.

³⁹ *Id.* at *13.

D. Handa's unadjudicated defenses were meritorious

97. Unlike the later-filed generic manufacturers' ANDAs, Handa's ANDA disclosed a product that successfully designed around the '437 Patent by developing a non-infringing product that did not contain a "gelling agent." Instead of using a hydrophilic "gelling agent," Handa's products used a hydrophobic compound known as HVO. Handa obtained a patent on its novel formulation despite the '437 Patent, reflecting the determination of the PTO that Handa's formulation was patentably distinct from the formulation claimed in the '437 Patent.

98. On July 24, 2008, Handa filed United States Provisional Application No. 61/083,270 ("the '270 Application"). On September 5, 2008, Handa filed United States Application Serial No. 12/205,356 ("the '356 Application"), which claimed the benefit of the filing date of the '270 Application. On May 8, 2012, the '356 Application issued as United States Patent No. 8,173,637 ("the Handa '637A Patent"). On March 28, 2011, Handa filed United States Application Serial No. 13/073,873 ("the '873 Application"), which claimed the benefit of the filing date of the '356 and '270 Applications. On August 23, 2011, the '873 Application issued as United States Patent No. 8,003,637 ("the Handa '637B Patent").

99. As Handa's patents explain, HVO is a "hydrophobic" material that is "non gelling":

Examples of hydrophobic materials that can be used to form a nongelling or non-swelling controlled release matrix for the atypical antipsychotic drug include beeswax, white wax, emulsifying wax, hydrogenated vegetable oil, hydrogenated castor oil, microcrystalline wax, cetyl alcohol, stearyl alcohol, free wax acids such as stearic acid, esters of wax acids, propylene glycol mono stearate, glycerol mono stearate, carnauba wax, palm wax, candelilla wax, lignite wax, ozokerite, ceresin wax, lardaceine, China wax and mixtures thereof. Other possible rate controlling excipients useful in the present invention include saturated hydrocarbons having from 25 to 31 carbon atoms, saturated alcohols having from 25 to 31 carbon atoms, saturated monocarboxylic acids having from 25 to 31 carbon atoms, esters obtained from said alcohols and monocarboxylic acids which are described in U.S. Pat. No. 6,923,984, incorporated herein by reference.⁴⁰

100. The district court's claim construction in the Seroquel XR Patent Litigation requires that, *inter alia*, the “gelling agent” interact with “water” to “form[] a gel” (*see supra*); thus, one of the important characteristics in determining whether a particular compound is a “gelling agent” is whether it is “hydrophilic” (*i.e.*, water loving) or “hydrophobic” (*i.e.*, water hating). This is so because “hydrophobic” compounds such as HVO generally do not interact with water. Indeed, the '437 Patent itself indicates that the claimed “gelling agent” must be “hydrophilic”: “The term gelling agent as used herein means any substance,

⁴⁰ '637A Patent at 6:24-39.

particularly a hydrophilic substance, which forms a gel when in contact with water.”⁴¹

101. Although Handa settled before trial in the Seroquel XR Patent Litigation, evidence and arguments at the trial of the other generic manufacturers’ claim show that Handa would have prevailed at trial on its non-infringement defense. During opening arguments, AstraZeneca’s counsel argued that the Viscarin 209 in Torrent's product was “hydrophilic” and interacts substantially with water:

Torrent does not use HPMC. Instead, Torrent uses a commercial carrageenan material called Viscarin GP209. Carrageenan, by way of background, is a naturally-occurring polymer, harvested from, believe it or not, seaweed, like FMC's Viscarin GP209 product is a hydrophilic, that is it's water loving, it hydrates and swells in the presence of the water.⁴²

102. During the direct examination of AstraZeneca’s expert regarding Viscarin 209, the hydrophilicity of the compound was a central part of the examination:

Q. Can you explain what part of the ’437 patent informs you what is contemplated by the word “gel”?

A. Go back to the patent.

⁴¹ ’437 Patent at 2:43-45.

⁴² Trial Transcript, *AstraZeneca Pharmaceuticals LP et al. v. Accord Healthcare, Inc., et al.*, 3:08-cv-04804, ECF No. 207 at 8 (D.N.J. Oct. 3, 2011).

Q. I believe it's tab four.

A. Tab four. In the second column is yellow highlighted materials of the term “gelling agent” as used herein means a substance particularly a hydrophilic substance, which forms a gel when in contact with water and thus, includes such substances as, and it gives a long list of substances which are polymers. The gelling agent is preferably hydroxypropylmethylcellulose.

Q. The patent states it’s particularly a hydrophilic substance. Can you explain to the Court what a hydrophilic gelling agent is?

A. Hydrophilic comes from hydro, water and philic, loves so it’s a material that likes water, has intrinsic positive interaction with water, will tend to hydrate and swell.

Q. So hydrophilic gelling agents will hydrate and swell?

A. They will hydrate and swell....

Q. Now, Dr. Prudhomme, a moment ago when we were looking at the '437 patent, we saw it refers to the use of hydrophilic polymers as gelling agents.

Q. Are carrageenans [i.e., the compounds in Viscarin 209] hydrophilic polymers?

A. Yes, they are.

Q. And what happens to these hydrophilic carrageenan polymers when they come in contact with water?

A. Well, they will tend to hydrate and swell. They also tend to gel.⁴³

103. This questioning, like the text in the '437 Patent itself and

AstraZeneca’s opening argument, highlight why a hydrophobic compound like the

⁴³ Trial Transcript, *AstraZeneca Pharmaceuticals LP et al. v. Accord Healthcare, Inc., et al.*, 3:08-cv-04804, ECF No. 207 at 74-79 (D.N.J. Oct. 3, 2011).

HVO in Handa's products was very unlikely to be found to be a "gelling agent" as required by the claims of the '437 Patent. Additionally, HVO could not have satisfied the requirement for a "gelling agent" under the doctrine of equivalents because HVO is substantially different from the claimed "gelling agent" and further does not satisfy the doctrine of equivalents' function-way-result test.

104. Had Handa not settled with AstraZeneca, Handa would have prevailed on its noninfringement defense. In addition, on information and belief, Handa had other meritorious defenses.

E. AstraZeneca enters into the unlawful reverse payment settlements

105. On or about September 29, 2011, AstraZeneca and Handa settled the Handa Patent Litigation and entered into the Handa Reverse Payment Agreement.⁴⁴ Under its terms, Handa agreed to abandon the patent fight and delay its launch of generic extended-release quetiapine fumarate in all strengths until November 1, 2016. In exchange for Handa's delayed generic launch, AstraZeneca agreed not to compete with Handa by launching an authorized generic Seroquel XR during Handa's 180-day exclusivity period.

106. On or about October 5, 2011, AstraZeneca and Accord settled the Accord Patent Litigation and entered into the Accord Reverse Payment

⁴⁴ <https://www.astrazeneca.com/media-centre/press-releases/2011/AstraZeneca-enters-into-a-settlement-agreement-with-Handa-Pharmaceuticals-regarding-US-SEROQUEL-XR-patentlitigation-29092011.html#>.

Agreement⁴⁵ pursuant to which Accord agreed to delay its launch of 400mg strength generic extended-release quetiapine fumarate until November 1, 2016. AstraZeneca in turn agreed to not launch an authorized generic version of the 400mg strength for 180 days thereafter.

107. The purpose and effect of the Handa Reverse Payment Agreement and the Accord Reverse Payment Agreement was to prevent AstraZeneca from facing generic competition for up to five years and to allow Handa (and Par) and Accord to sell generic Seroquel XR without competition from an authorized generic during the 180-day exclusivity period.

108. At the time it induced the Reverse Payment Agreements, AstraZeneca's remaining projected litigation costs were significantly less than \$107 million.

109. On October 29, 2012, Par announced that it had acquired Handa's ANDA No. 90- 482.⁴⁶ A press release issued by Handa on May 10, 2017 states, "Par's Quetiapine XR ANDA was developed by Handa and acquired by Par on August 3, 2012. Handa retains the right to a portion of profits from the sale of the

⁴⁵ <http://www.globenewswire.com/news-release/2011/10/05/232367/0/sv/AstraZeneca-Enters-Into-a-Settlement-Agreement-with-Accord-Healthcare-Inc-and-Intas-Pharmaceuticals-Ltd-regarding-US-SEROQUEL-XR-Patent-Litigation.html>.

⁴⁶ 59 <https://www.fdanews.com/articles/150571-par-acquires-seroquel-anda-from-handaexpects-first-filer-exclusivity-upon-2016-launch?v=preview>.

product, pursuant to its agreement with Par.”⁴⁷ By acquiring Handa’s ANDA, acquiring an assignment of the Handa Non-Compete Agreement, agreeing to divide the illicit gains therefrom, performing the delay provisions thereof, and selling generic extended-release quetiapine fumarate at supracompetitive prices, Par became an active participant and coconspirator in the pre-existing conspiracy between Handa and AstraZeneca and Par is, like Handa and AstraZeneca, jointly and severally liable for all harm flowing from it.

110. But for the Non-Compete Agreements, AstraZeneca would have launched an authorized generic Seroquel XR at the same time Handa/Par and Accord launched and competed for generic Seroquel XR with Handa/Par and Accord during their 180-day exclusivity periods. Instead, due to the reverse payment agreements, AstraZeneca waited 180 days after the Handa/Par’s and Accord’s launches to launch a competitive AG generic Seroquel XR.

111. Accord received FDA tentative approval for its ANDA No. 90-0681 on December 14, 2010 and final approval on November 1, 2016.⁴⁸ On information and belief, Accord’s 400mg generic Seroquel XR product would have received final approval before November 1, 2016 absent the Accord Reverse Payment

⁴⁷ <https://handapharma.com/handa-pharmaceuticals-inc-announces-fdaapproval-for-genericversion-of-astrazenecas-seroquel-xr-extended-release-tablets/>.

⁴⁸ See Final Approval Letter from Carol Holquist to Sabita Nair, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/090681Orig1s000TAltr.pdf.

Agreement. Handa received tentative approval from FDA on December 9, 2010.⁴⁹ Par obtained final FDA approval for ANDA No. 90-482 on May 9, 2017, almost exactly the end of its 180-day exclusivity period.⁵⁰ On information and belief, absent the Handa Reverse Payment Agreement, Handa/Par's 50mg, 150mg, 200mg and 300mg strengths of generic Seroquel XR would have received final FDA approval before November 1, 2016. Handa's and Accord's tentative FDA approvals meant that their ANDAs were ready for FDA final approval but for the existence of a patent or regulatory barrier.

112. But for the Reverse Payment Agreements, Handa/Par and Accord would have been ready, willing and able to launch their respective strengths of generic Seroquel XR much earlier. Handa/Par's and Accord's generic Seroquel XR products would have received FDA final approval upon either: (1) the conclusion of the 30-month stays; (2) a favorable decision on patent infringement during litigation by Handa/Par and Accord earlier than November 1, 2016; or (3) a licensed generic Seroquel XR entry date earlier than November 1, 2016 pursuant to an agreement(s) with AstraZeneca that did not include a pay-for-delay payment.

⁴⁹ See Tentative Approval Letter from Keith Webber to Maggie Chang at 1, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2010/090482s000ltr.pdf.

⁵⁰ *Handa Pharmaceuticals, Inc. Announces FDA Approval for Generic Version of AstraZeneca's SEROQUEL XR® Extended Release Tablets* (May 10, 2017), <https://handapharma.com/handa-pharmaceuticals-inc-announces-fdaapproval-for-genericversion-of-astrazenecas-seroquel-xr-extended-release-tablets/>.

See, e.g., King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp., 791 F.3d 388, 405 (3d Cir. 2015) (“when the parties’ settlement includes a [payment], the generic also presumably agrees to an early entry date that is later than it would have otherwise accepted.”); *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d at 751-52 (a reverse payment “is likely to induce the generic to agree to enter the market at a date later than that to which it would otherwise agree”).

113. AstraZeneca had an enormous incentive to avoid competition from Handa/Par and Accord by entering into the reverse payment agreements. By the time the reverse payment agreements in September 2011, Seroquel XR U.S. sales were nearly a billion dollars per year. In the event that Handa/Par and/or Accord were to prevail on non-infringement or other defenses or that AstraZeneca had not induced Handa and/or Accord with pay-for-delay payments to agree not to launch a generic Seroquel XR for five years would have greatly reduced AstraZeneca’s profits.

114. On information and belief, the reverse payment agreements contained confidentiality provisions precluding disclosure of key terms, including AstraZeneca’s promises not to launch an AG of Seroquel XR during Handa/Par’s and Accord’s 180-day exclusivity period. Although the parties made vague public references to their reverse payment agreements, they concealed the agreements’ anticompetitive purpose and terms. No public reference disclosed that AstraZeneca

agreed not to compete with an AG drug during Handa/Par's and Accord's 180-day exclusivity periods.

115. Likewise, the parties' limited disclosures did not reveal that Defendants and their co-conspirators agreed to anticompetitive terms. Knowing the risk that the no-AG terms would be held by a court to be anticompetitive, the parties to the reverse payment agreements deliberately concealed these terms from the public and HCSC, and HCSC remained unaware of the terms of this agreement until class action antitrust lawsuits were filed in August and September 2019.

116. Absent the reverse payment terms, AstraZeneca had no economic rationale to wait to launch an AG generic Seroquel XR until after Handa/Par's and Accord's 180-day exclusivity period. Launching earlier would have been more profitable to AstraZeneca. AstraZeneca only agreed to delay its authorized generic launch until May 1, 2017, 180 days after Handa/Par and Accord launched generic Seroquel XR, as a *quid pro quo* for Handa/Par's and Accord's respective agreements to delay generic Seroquel XR competition until November 1, 2016.

117. As consideration for Handa/Par's and Accord's agreement to forgo selling generic extended-release quetiapine fumarate in competition with AstraZeneca's branded Seroquel XR for up to five years, AstraZeneca agreed to share with Handa/Par and Accord the monopoly profits from sales of branded Seroquel XR in the form of covenants not to compete with Handa/Par's and

Accord's generics with authorized generic Seroquel XR. Instead of competing, which would have resulted in lower prices of both generic and branded Seroquel XR, AstraZeneca agreed and conspired with Handa/Par and with Accord to maintain the prices of extended-release quetiapine fumarate at supracompetitive levels.

118. The reverse payment agreements benefitted Handa/Par and Accord by guaranteeing that they would be the sole generic seller on the market for their respective strengths during their 180-day exclusivity periods, which significantly increased Handa/Par's and Accord's anticipated sales revenues during their exclusivity periods because: (1) Handa/Par and Accord would capture all of the sales that would otherwise have gone to competing AG Seroquel XR, and (2) Handa/Par and Accord would be able to charge significantly higher prices for their generic Seroquel XR products without price competition from competing AG Seroquel.

119. A brand company's launch of a competing authorized generic is extremely costly to any first-filer generic, such as Handa/Par and Accord, because the AG erodes the first-filer's share of the overall generic volume *and* pushes down generic prices. The authorized generic also cuts into the first-filer's long-term "first mover advantage," *i.e.*, the continuing market advantage that can accrue to the first entrant. As the FTC noted in a June 2009 report on authorized generics,

“consumers benefit and healthcare system saves money during the 180-day exclusivity period when an [authorized generic] enters the market, due to the greater discounting that accompanies the added competition provided by the [authorized generic].”⁵¹ Thus, AstraZeneca’s covenants not to launch authorized generic Seroquel XR during Handa/Par’s and Accord’s exclusivity periods were extremely valuable to Handa/Par and Accord.

120. AstraZeneca also sacrificed large profits through its agreements not to launch authorized generics of Handa/Par’s and Accord’s respective strengths of generic Seroquel XR. Absent the unlawful Non-Compete Agreements, it would make economic sense for AstraZeneca to launch AGs during Handa/Par’s and Accord’s 180-day marketing exclusivity periods so that AstraZeneca would retain 50% of the sales that Handa/Par’s and Accord’s less expensive generics otherwise would otherwise capture.

121. As discussed above, an AG typically captures approximately 50% of the generic unit sales during the first 180-days of generic marketing. Therefore, AstraZeneca’s promise not to launch an AG Seroquel XR constituted very large payments to Handa/Par and Accord.

⁵¹ AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACT (“FTC, Authorized Generic Drugs”) (August 2011) at <https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugsshort-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-shortterm-effects-and-long-term-impact-report-federal-trade-commission.pdf>, at ii.

122. The U.S sales of Seroquel XR for the four dosage strengths for which Handa/Par was the first-filer (50mg, 150mg, 200mg, and 300mg strengths) were, and were expected to be, approximately \$911 million for the 12 months ending September 30, 2016.⁵² Therefore, Defendants could assume that 6 months of brand sales would generate revenue of approximately \$455.5 million (half of AstraZeneca's \$911 million in annual Seroquel XR revenue).

123. As discussed above, in the pharmaceutical industry it is common that the generic is expected to take 80% (or more) of the brand sales over the first six months following generic entry. Therefore, approximately \$364.4 million worth of brand sales would be converted to the generic ($\$455.5 \text{ million} * 0.8$) during Handa/Par's 180-day exclusivity period. Also as previously discussed, with only one generic on the market, the generic is typically priced at 90% of the brand, which would result in generic sales of approximately \$327.96 million ($\$364.4 \text{ million} * 0.9$). Therefore, the generic Seroquel XR sales revenue that would have reasonably been anticipated by Handa/Par during the 18-day exclusivity period without competition from an AG would be approximately \$327.96 million.

124. Handa/Par's expectations would have differed dramatically if AstraZeneca had not promised to refrain from competing with authorized generic

⁵² Handa Pharmaceuticals Announces Endo Begins Shipping Generic Version of AstraZeneca's SEROQUEL XR® (Nov. 1, 2016), <https://handapharma.com/announcement-for-generic-shipment/>.

Seroquel XR. According to an FDA study of the effects of additional generic competitors on the generic price, the entry of a second generic drives the average generic price down to 52% of the brand price.⁵³ Thus, while the generics would still take 80% of six months of brand sales, or \$364.4 million, the generic sales value would drop to \$189.488 million ($\$364.4 \text{ million} * 0.52$). And, it would reasonably be expected that those sales would be split evenly (50% / 50%) between Handa/Par and AstraZeneca's AG.⁵⁴ Thus, without the no-AG promise in the Handa Non-Compete Agreement, Handa/Par's sales of generic Seroquel XR during the first 6 months would be expected to be approximately \$94.744 million ($\$189.488 \text{ million} * 0.5$).

125. As a result, the expected value at the time of the Handa Non-Compete Agreement to Handa/Par of the no-AG provision versus facing competition from an AG would have been as much as approximately \$233.216 million, the difference between the amount Handa/Par would reasonably expect to earn as the only generic seller on the market for 180 days following launch and the amount it would reasonably expect to earn if it faced competition from an AG during this

⁵³ <https://www.fda.gov/about-fda/center-drug-evaluation-and-research/generic-competitionanddrug-prices>.

⁵⁴ FTC, Authorized Generic Drugs at vi (The Federal Trade Commission has concluded that, when free from competition from an authorized generic, "the first-filer's revenue will approximately double" during the first six months of generic competition, compared to what the first filer would make if it faced authorized generic competition.).

180-day period (\$327.96 million - \$94.744 million). Thus, AstraZeneca's agreement to not launch an AG for 6 months following Handa/Par's generic launch was a payment to Handa/Par of as much as approximately \$233.216 million. The value of this payment to Handa/Par was tantamount to AstraZeneca handing this amount to Handa/Par in cash.

126. The same math and analysis can be applied to Accord. In exchange for Accord's promise not to launch its generic version of Seroquel XR 400mg strength until November 1, 2016, AstraZeneca promised it would not launch an AG version of Seroquel XR 400mg strength until May 1, 2017. AstraZeneca's sales of the 400mg strength of Seroquel XR in 2015 were and were expected to be about \$421 million. Using the same math as used for Handa/Par, the promise from AstraZeneca to Accord not to compete with an AG during the 180-day exclusivity period was worth about \$107.78 million.⁵⁵

127. It is commonplace for AstraZeneca to compete with first-filers by launching AGs. During the time period from 2001 to 2008, only four companies launched more AGs than AstraZeneca.⁵⁶

⁵⁵ Specifically, Accord's revenues without facing an AG would be expected to be \$421 million * .5 * .8 * .9, or \$151.56 million. Accord's revenues if it competed with an AG would be expected to be \$421 million * .5 * .8 * .52 * .5, or \$43.78 million. The difference is \$107.78 million (\$151.56 million - \$43.78 million).

⁵⁶ FTC, Authorized Generic Drugs at 16 ("For each company, the graph includes all AGs marketed pursuant to the company's NDAs, whether marketed internally (e.g., by a subsidiary), or through an external generic partner.").

128. On information and belief, AstraZeneca has launched authorized generics with respect to at least the following branded drugs: Accolate, Toprol-XL, Novaldex, Entocort EC, Pulmicort, Atacand, Plendil, Prilosec, and Nexium.

129. It is economically rational for a brand manufacturer that intends to compete for generic sales by launching an authorized generic to do so contemporaneously with the first ANDA filer's launch. This is because, during the first-filer's 180-day exclusivity, the only possible competitors for generic sales are the first-filer and the brand's authorized generic. No later-filing generic can launch during this time. As the Third Circuit observed, "Absent a no-AG promise, launching an authorized generic would seem to be economically rational for the brand." *King Drug Co. of Florence, Inc.*, 791 F.3d at 405.

130. Therefore, it would have been economically rational for AstraZeneca to have launched AG Seroquel XR contemporaneously with market entry by Handa/Par and Accord instead of *after* Handa/Par's and Accord's 180-day exclusivity periods. In the absence of the anticompetitive Non-Compete Agreements, AstraZeneca would have done so. Specifically, absent the Handa Non-Compete Agreement, AstraZeneca would have launched authorized generic Seroquel XR in the 50mg, 150mg, 200mg and 300mg strengths contemporaneous with Handa/Par's launch of generic Seroquel SR in these same strengths. Absent the Accord Non-Compete Agreement, AstraZeneca would have launched

authorized generic Seroquel XR in the 400mg strength contemporaneous with Accord's launch of generic Seroquel XR in the 400mg strength.

131. Conversely, if there were no agreements preventing AstraZeneca from launching immediately upon Handa/Par's and Accord's launches, then AstraZeneca's waiting until Handa/Par's and Accord's 180-day exclusivity periods expired to launch authorized generic Seroquel XR was economically irrational. This is because there was no economically rational reason for AstraZeneca to forgo its AG Seroquel XR launches and competition with Handa/Par and Accord during Handa/Par's and Accord's 180-day exclusivity periods. During the 180-day exclusivity period, AstraZeneca was permitted to launch an AG which would only have to compete with a single generic competitor in each strength. But after expiry of Handa/Par's and Accord's 180-day exclusivity periods, other generics could and would launch and AstraZeneca's AG would have to compete with those other generics too. Thus, it only made sense for AstraZeneca to forego its authorized generic launch during Handa/Par's and Accord's 180-day exclusivity periods as part of anticompetitive market-allocation or output-restriction agreements to compensate Handa/Par and Accord for delaying generic Seroquel XR competition.

132. The payments AstraZeneca made to Handa/Par and Accord pursuant to the Non-Compete Agreements no-AG provisions had a cash value of as much as approximately \$233.216 million to Handa/Par and \$107.78 million to Accord. It

was AstraZeneca's intention that these payments would induce Handa/Par and Accord to stay out of the market for Seroquel XR and its generic equivalents in return for sharing monopoly profits, a naked market allocation or output restriction agreement and a per se violation of the antitrust laws. Further, under a rule of reason analysis, the pay-for-delay payments from AstraZeneca to Handa/Par and Accord are large and unjustified, and Defendants and their co-conspirators had no procompetitive justification or other legitimate explanation for the payments. It has been established that there is no conceivable procompetitive justification for a covenant to delay the launch of AG(s).

133. Absent AstraZeneca's unlawful reverse payments to Handa/Par and Accord, any agreement resolving AstraZeneca's patent infringement claim would have resulted in far less (or no) delay of Handa/Par's and Accord's generic Seroquel XR entry, generic competition would have been more robust, and generic prices would have been lower. But for the Non-Compete Agreements, Handa/Par and Accord would have launched their respective strengths of generic Seroquel XR earlier: at risk, following a patent litigation victory, or pursuant to a negotiated entry date as part of an agreement that did not include reverse payments.⁵⁷ At the

⁵⁷ As the Supreme Court determined, brand and generic companies can settle without reverse payments. "They may, as in other industries, settle in other ways, for example, by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point." *FTC. v. Actavis*, 133 S. Ct. at 2237.

same time, AstraZeneca would have competed for generic Seroquel XR sales by immediately launching authorized generic Seroquel XR instead of waiting to launch its authorized generic Seroquel XR for 6 months following Handa/Par's and Accord's generic launches.

134. On information and belief, and based on the fact that several other generic manufacturers actually launched 180 days after Handa/Par and Accord, several other generic manufacturers had agreements with AstraZeneca that permitted entry upon Handa/Par's and Accord's launch, subject to Handa/Par's and Accord's 180-day exclusivity periods. Had Handa/Par and Accord launched their respective strengths of generic Seroquel XR earlier, those other generic manufacturers would have launched earlier as well. But for the bottleneck of generic competition caused by the Non-Compete Agreements, and more specifically by those agreements' foreseeable and intentional effect of causing Handa/Par's and Accord's 180-day exclusivity periods to remain untriggered and thus unelapsed for up to five additional years, until November 1, 2016, one or more other generic manufacturer, would have launched earlier, along with Handa/Par's generic, Accord's generic, and the authorized generic, lowering generic Seroquel XR prices further still.

135. Handa/Par's and Accord's reason that they did not launch earlier than November 1, 2016 had nothing to do with any purported infringement risk flowing

from the '437 Patent. Rather, Handa/Par's and Accord's generic launches were delayed by the anticompetitive Non-Compete Agreements, just as Defendants and their co-conspirators intended. Further, Handa/Par and Accord, as first-time filers for their respective strengths during which no subsequent filer could launch an ANDA version of Seroquel XR. Handa/Par, Accord and AstraZeneca all realized that delaying the generic launches in exchange for no-AG promises would benefit each of them. AstraZeneca was benefitted by continuing to charge monopoly prices for Seroquel XR almost until the expiration of the '437 Patent despite the weakness of the '437 Patent. This is because Handa and Accord were willing to be paid to delay their generic launches, and Handa/Par's and Accord's delay would delay the triggering of the Handa/Par's and Accord's 180-day exclusivity periods, thereby acting as a bottleneck to all Seroquel XR generic competition. Handa/Par and Accord benefitted by obtaining no-AG promises allowing them to be free from AG competition for the first 180-days after their delayed generic Seroquel XR launches.

136. According to publicly available information through the FDA, in addition to first-filers Handa/Par and Accord, at least 12 additional companies filed ANDAs to sell generic Seroquel XR.

137. According to information available publicly through the FDA, many of these entities received final approval on or around the end of Handa/Par's and

Accord's actual 180-day exclusivity periods. These included Pharmadax Inc., IntellipharmaCeutics Corp., Accord (as to the 150mg, 200mg and 300mg strengths), Par (as to the 400mg strength) and Lupin Ltd. These approvals would have been granted earlier if Handa/Par's and Accord's 180-day exclusivity periods had been triggered (and elapsed) earlier as a result of Handa/Par and Accord launching generic Seroquel XR earlier, which would have occurred absent AstraZeneca's payments to Handa/Par and to Accord to delay competition (*i.e.*, absent AstraZeneca's no-AG promises).

138. But for Defendants' and their co-conspirators' ongoing performance and participation in the Non-Compete Agreements, generic competition from AG Seroquel XR, would have occurred earlier, and prices for extended-release quetiapine fumarate would have been lower. But for Defendants' and their co-conspirators' ongoing, illegal, anticompetitive conduct, generic versions of Seroquel XR would have become available much earlier, either through a Handa and/or Accord patent victory, at-risk launch, or agreement(s) that did not include unlawful payments for delay, HCSC would have paid lower prices for Seroquel XR and its generic equivalents.

VI. MARKET POWER AND DEFINITION

139. The relative unimportance of price in the pharmaceutical marketplace reduces what economists call the price elasticity of demand – the extent to which

unit sales go down when price goes up. This reduced-price elasticity, in turn, gives brand manufacturers the ability to raise prices substantially above marginal cost without losing so many sales as to make the price increase unprofitable. The ability to profitably raise prices substantially above marginal costs is what economists and antitrust courts refer to as market power. The result of these pharmaceutical market imperfections and marketing practices is that brand manufacturers gain and maintain market power with respect to many branded prescription pharmaceuticals, including Seroquel XR.

140. Before November 1, 2016, AstraZeneca had monopoly power in the market for Seroquel XR because it had the power to exclude competition and/or raise or maintain the price of extended-release quetiapine fumarate at supracompetitive levels without losing enough sales to make supra-competitive prices unprofitable.

141. A small but significant, non-transitory increase to the price of brand Seroquel XR would not have caused a significant loss of sales sufficient to make the price increase unprofitable.

142. AstraZeneca (and, later, AstraZeneca and Handa/Par and Accord) needed to control only brand Seroquel XR and its AB-rated generic equivalents, and no other products, in order to maintain the price of extended-release quetiapine fumarate profitably at supracompetitive prices. Only the market entry of

competing, AB-rated generic versions would render Defendants and their co-conspirators unable to profitably maintain their prices for Seroquel XR without losing substantial sales.

143. During the 180-day exclusion period, AstraZeneca sold brand Seroquel XR and Handa/Par and Accord sold generic Seroquel XR at prices well in excess of marginal costs and in excess of the competitive price, and, therefore, AstraZeneca and Handa/Par and Accord enjoyed high profit margins.

144. Defendants and their co-conspirators had, and exercised, the power to exclude generic competition to brand Seroquel XR.

145. At all material times, high barriers to entry, including regulatory protections and high costs of entry and expansion, protected branded Seroquel XR from the forces of price competition.

146. There is direct evidence of market power and anticompetitive effects available in this case sufficient to show the Defendants' and their co-conspirators' ability to control the price of Seroquel XR and generic Seroquel XR, and to exclude relevant competitors, without the need to show the relevant antitrust markets. The direct evidence consists of, inter alia, the following facts: (a) generic Seroquel XR would have entered the market at a much earlier date, at a substantial discount to brand Seroquel XR, but for Defendants' and their co-conspirators' anticompetitive conduct; (b) AstraZeneca's gross margin on Seroquel XR

(including the costs of ongoing research/development and marketing) at all relevant times was very high; and (c) AstraZeneca never lowered the price of Seroquel XR to the competitive level in response to the pricing of other brand or generic drugs other than the AB-rated generic Seroquel XR.

147. To the extent proof of monopoly power by defining a relevant product market is required in order to establish any of HCSC's claims, HCSC alleges that the relevant antitrust market is the market for Seroquel XR and its AB-rated generic equivalents.

148. AstraZeneca's anticompetitive reverse payments to Handa/Par and to Accord demonstrate that AstraZeneca enjoyed market and/or monopoly power with respect to extended-release quetiapine fumarate.

149. The United States is the relevant geographic market.

150. AstraZeneca's market share in the relevant market was 100% until November 1, 2016, implying substantial monopoly power.

VII. MARKET EFFECTS

151. Defendants and their co-conspirators willfully and unlawfully engaged in an overarching scheme to exclude competition. Defendants and their co-conspirators designed a scheme to delay competition on the products' merits, to further AstraZeneca's anticompetitive purpose of forestalling generic competition against Seroquel XR, in which Handa/Par and Accord cooperated in order to

increase their own profits. Defendants and their co-conspirators carried out the scheme with the anticompetitive intent and effect of maintaining supra-competitive prices for extended-release quetiapine fumarate ezetimibe tablets.

152. Defendants' and their co-conspirators' acts and practices had the purpose and effect of restraining competition unreasonably and injuring competition by protecting brand Seroquel XR, and later Handa/Par and Accord's generic Seroquel XR, from competition. These actions allowed Defendants and their co-conspirators to maintain a monopoly and exclude competition in the market for Seroquel XR and its AB-rated generic equivalents, to the detriment of HCSC.

153. Defendants' and their co-conspirators' exclusionary conduct delayed generic competition and unlawfully enabled AstraZeneca and Handa/Par and Accord to sell Seroquel XR without further generic competition. Were it not for the Defendants' and their co-conspirators' illegal conduct, one or more additional generic versions of Seroquel XR would have entered the market sooner, and Handa/Par's and Accord's generic would have faced competition during its 180-day exclusivity period from an AstraZeneca authorized generic.

154. Defendants' and their co-conspirators' illegal acts and conspiracy to delay generic competition for Seroquel XR caused HCSC to pay more than it

would have paid for extended-release quetiapine fumarate absent this illegal conduct.

155. If generic competitors had not been unlawfully prevented from entering the market earlier and competing in the relevant markets, HCSC would have paid less for extended-release quetiapine fumarate by (a) paying lower prices on their remaining brand purchases of Seroquel XR, (b) substituting purchases of less expensive generic Seroquel XR for their purchases of more-expensive brand Seroquel XR, and/or (c) purchasing generic Seroquel XR at lower prices sooner.

156. Thus, the Defendants' and their co-conspirators' unlawful conduct deprived HCSC of the benefits from the competition that the antitrust laws are designed to ensure.

VIII. ANTITRUST IMPACT

157. During the relevant time period, Defendants and their co-conspirators manufactured, sold, and shipped generic Seroquel XR across state lines in an uninterrupted flow of interstate commerce.

158. During the relevant time period, HCSC purchased substantial amounts of Seroquel XR and/or generic Seroquel XR indirectly from Defendants and their co-conspirators. As a result of Defendants' and their co-conspirators' illegal conduct, HCSC had to pay, and did pay, artificially inflated prices for Seroquel XR and generic Seroquel XR. Those prices were substantially greater than the prices

that HCSC would have paid absent the illegal conduct alleged herein, because: (1) the price of brand-name Seroquel XR was artificially inflated by Defendants' and their co-conspirators' illegal conduct, (2) Plaintiff was deprived of the opportunity to purchase lower-priced generic versions of Seroquel XR sooner, and/or (3) the price of AB-rated Seroquel XR was artificially inflated by Defendants' and their co-conspirators' illegal conduct. The supracompetitive prices were paid at the point of sale, which is where HCSC suffered its harm.

159. The prices were inflated as a direct and foreseeable result of AstraZeneca's anticompetitive conduct individually and with Handa/Par and Accord.

160. The inflated prices HCSC paid are traceable to, and the foreseeable result of, the overcharges by AstraZeneca and Handa/Par and Accord.

IX. CLAIM ACCRUAL AND/OR TOLLING

161. HCSC's claims are timely as to all claims accruing on or after four years before the date of the filing of this Complaint.

162. HCSC's claims are also timely under the doctrines of equitable tolling, the discovery rule, and continuing violation principles.⁵⁸

⁵⁸ See *In re Effexor Antitrust Litig.*, 337 F. Supp. 3d 435, 452 -53 (D.N.J. 2018); *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 747 (E.D. Pa. 2014).

163. HCSC's claims are tolled under the principles of *American Pipe & Construction Co. v. Utah*, 414 U.S. 538 (1974). In *American Pipe*, the U.S. Supreme Court held that the timely filing of a class action tolls the applicable statute of limitations for all persons encompassed by the class complaint. The Supreme Court clarified the rule in *American Pipe* in *Crown, Cork & Seal Co. Inc. v. Parker*, 462 U.S. 345 (1983). The Supreme Court held that *American Pipe*'s tolling rule is not dependent on intervening in or joining an existing suit; it applies as well to absent class members. *American Pipe* tolling applies, in whole or in part, due to the putative end-payor class action filed on September 5, 2019.⁵⁹

164. Tolling doctrines apply because: (1) Defendants and their co-conspirators concealed the terms of the "no AG" agreements from HCSC, (2) HCSC remained unknowledgeable of the facts which form the bases of its causes of action until on or about August 2, 2019 or later,⁶⁰ and (3) HCSC's continuing lack of knowledge was not attributable to lack of diligence on its part.

165. All applicable statutes of limitations affecting HCSC's claims have been tolled. Principles of continuing violations apply because HCSC continued to

⁵⁹ See *Law Enforcement Health Benefits Inc. v. AstraZeneca Pharms. LP*, Case No. 19-cv-8296 (S.D.N.Y. Sept. 5, 2019).

⁶⁰ The first purchaser antitrust action was filed on August 2, 2019. See *JM Smith Corp., d/b/a Smith Drug Company v. AstraZeneca Pharms. LP, et al.*, Case No. 19-cv-07233 (S.D.N.Y. Aug. 2, 2019).

purchase Seroquel at inflated prices within the last two, three, and four years, which is within the applicable statute of limitations periods. Each such purchase of Seroquel at inflated prices is within the “continuing violations” doctrine.

X. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF For Monopolization Under State Law (against AstraZeneca Defendants only)

166. Plaintiff incorporates by reference all the allegations above as though fully set forth herein.

167. As described above, until at least November 1, 2016, AstraZeneca possessed monopoly power nationwide and in each of the United States in the market for extended-release quetiapine fumarate tablets. No other manufacturer sold a competing version of Seroquel XR before November 1, 2016.

168. At all relevant times, AstraZeneca possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

169. Through its overarching anticompetitive scheme, as alleged above, AstraZeneca willfully maintained its monopoly power in the relevant market using restrictive or exclusionary conduct, rather than by means of greater business acumen or a historic accident, and thereby injuring Plaintiff. AstraZeneca’s

anticompetitive conduct was done with the specific intent to maintain its monopoly in the market for Seroquel XR in the United States.

170. AstraZeneca accomplished this scheme by, *inter alia*, (1) entering into illegal agreements which delayed the entry of generic Seroquel XR in order to lengthen the period in which AstraZeneca's brand Seroquel XR could monopolize the market and make supracompetitive profits; (2) not bringing an authorized generic to market during Handa/Par's and Accord's 180-day generic exclusivity period, thereby allowing Handa/Par and Accord to monopolize the generic market for Seroquel XR during the period, and allowing Handa/Par and Accord to charge supracompetitive profits; and (3) raising and maintaining the prices so that Plaintiff and others would pay for Seroquel XR at supracompetitive prices.

171. The goal, purpose, and effect of AstraZeneca's scheme was to prevent and delay the sale of extended-release quetiapine fumarate tablets products in the United States at prices significantly below AstraZeneca's prices for Seroquel XR, thereby effectively preventing the average market price of extended-release quetiapine fumarate products from declining dramatically.

172. The goal, purpose and effect of AstraZeneca's scheme was also to maintain and extend its monopoly power with respect to extended-release quetiapine fumarate products. AstraZeneca's illegal scheme allowed it to continue charging supracompetitive prices for extended-release quetiapine fumarate

products, without a substantial loss of sales, reaping substantial unlawful monopoly profits.

173. HCSC purchased substantial amounts of Seroquel XR and/or AB-rated generic equivalents indirectly from AstraZeneca and/or other manufacturers.

174. As a result of AstraZeneca's illegal conduct, HCSC was compelled to pay, and did pay, more than it would have paid for extended-release quetiapine fumarate requirements absent AstraZeneca's illegal conduct. But for AstraZeneca's illegal conduct, competitors would have begun selling generic Seroquel XR sooner than they did, and prices for extended-release quetiapine fumarate products would have been lower, sooner.

175. Had manufacturers of generic extended-release quetiapine fumarate entered the market and lawfully competed with AstraZeneca in a timely fashion, HCSC would have substituted lower-priced generic extended-release quetiapine fumarate products for the higher-priced brand-name Seroquel XR for some or all of their extended-release quetiapine fumarate products requirements, and/or would have paid lower net prices on their remaining Seroquel XR and/or AB-rated bioequivalent purchases.

176. By intentionally and wrongfully maintaining monopoly power in the relevant market, AstraZeneca violated the antitrust and competition statutes of all states and territories that may provide any relief for indirect purchasers like HCSC,

with respect to purchases of Seroquel XR and AB-rated bioequivalents made in the corresponding state or territory of the state or territory's statutes below, including but not limited to each of the following such laws:

- a. Az. Rev. Stat. § 44-1403, *et seq.*,
- b. Cal. Bus. & Prof. Code § 17200, *et seq.*,
- c. D.C. Code § 28-4503, *et seq.*,
- d. Hawaii Rev. Stat. 480-1, *et seq.*,
- e. Illinois Antitrust Act (740 Illinois Compiled Statutes 10/1, *et seq.*)
- f. Iowa Code § 535.5, *et seq.*,
- g. Kan. Stat. Ann. § 50-101, *et seq.*,
- h. 10 Me. Rev. Stat. Ann. § 1102, *et seq.*,
- i. Md. Com'l Law Code Ann. § 11-204(a), *et seq.*,
- j. Mich. Comp. Laws Ann. § 445.773, *et seq.*,
- k. Minn. Stat. § 325D.49, *et seq.*, and Minn. Stat. § 8.31, *et seq.*,
- l. Miss. Code Ann. § 75-21-3, *et seq.*,
- m. Mont. Code § 30-14-103, *et seq.*,
- n. Neb. Code Ann. § 59-802, *et seq.*,
- o. Nev. Rev. Stat. Ann. § 598A.060, *et seq.*,
- p. N.H. Rev. Stat. Ann. § 356.11, *et seq.*,
- q. N.M. Stat. Ann. § 57-1-2, *et seq.*,

- r. N.Y. Gen. Bus. Law § 340, *et seq.*,
- s. N.C. Gen. Stat. § 75-2.1, *et seq.*,
- t. N.D. Cent. Code § 51-08.1-03, *et seq.*,
- u. Or. Rev. Stat. § 646.730, *et seq.*,
- v. R.I. Gen. Laws § 6-36-5, *et seq.*,
- w. S.D. Codified Laws Ann. § 37-1-3.2, *et seq.*,
- x. Tenn. Code Ann. § 47-25-101, *et seq.*
- y. Utah Code Ann. § 76-10-911, *et seq.*,
- z. 9 Vt. Stat. Ann. § 2453, *et seq.*,
- aa. W.Va. Code § 47-18-4, *et seq.*,
- bb. Wis. Stat. § 133.03, *et seq.*,

177. HCSC has been injured in its business or property by reason of AstraZeneca's antitrust violations alleged in this Claim. Its injuries consist of: (1) being denied the opportunity to purchase lower-priced generic extended-release quetiapine fumarate, sooner, and (2) paying higher prices for extended-release quetiapine fumarate products than they would have paid in the absence of Defendants' and their co-conspirators' conduct. These injuries are of the type the antitrust laws were designed to prevent, and flow from that which makes Defendants' and their co-conspirators' conduct unlawful.

SECOND CLAIM FOR RELIEF
For Conspiracy to Monopolize Under State Law
(against all Defendants)

178. Plaintiff incorporates by reference all the allegations above as though fully set forth herein.

179. As described above, up to at least November 1, 2016, AstraZeneca possessed monopoly power nationwide and in each of the United States in the market for extended-release quetiapine fumarate tablets. No other manufacturer sold a competing version of Seroquel XR before November 1, 2016.

180. Defendants and their co-conspirators willfully and unlawfully engaged in a continuing illegal conspiracy to monopolize the extended-release quetiapine fumarate by engaging in an anticompetitive scheme to keep generic equivalents from the market—not as a result of providing a superior product, business acumen, or historical accident.

181. Defendants and their co-conspirators knowingly and intentionally conspired to monopolize the extended-release quetiapine fumarate products (*i.e.*, Seroquel XR in all forms and dosage strengths) and AB-rated bioequivalent extended-release quetiapine fumarate products market as described above. Defendants and their co-conspirators accomplished this scheme by, *inter alia*, (1) entering into illegal agreements which delayed the entry of generic Seroquel XR in order to lengthen the period in which AstraZeneca's brand Seroquel XR could

monopolize the market and make supracompetitive profits; (2) conspiring to not bring an authorized generic to market during Handa/Par's and Accord's 180-day generic exclusivity period, thereby allowing Handa/Par and Accord to monopolize the generic market for Seroquel XR during the period, and allowing Handa/Par and Accord to charge supracompetitive profits; (3) raising and maintaining the prices so that HCSC would pay for Seroquel XR at supracompetitive prices; (4) unlawfully agreeing to divide a market and delay price reductions and generic competition for Seroquel XR; and (5) otherwise conspiring to unlawfully monopolize and conspire to monopolize the market for extended-release quetiapine fumarate.

182. The goal, purpose, and effect of Defendants' and their co-conspirators' scheme was to prevent and delay the sale of extended-release quetiapine fumarate tablets products in the United States and its territories at prices significantly below AstraZeneca's prices for Seroquel XR, thereby effectively preventing the average market price of extended-release quetiapine fumarate products from declining dramatically.

183. The goal, purpose and effect of Defendants' and their co-conspirators' scheme was also to maintain and extend its monopoly power with respect to extended-release quetiapine fumarate products. Defendants' and their co-conspirators' illegal scheme allowed AstraZeneca to continue charging

supracompetitive prices for extended-release quetiapine fumarate products, without a substantial loss of sales, reaping substantial unlawful monopoly profits.

Defendants' and their co-conspirators' scheme allowed Handa/Par and Accord to reap the benefits of reduced generic competition in the United States.

184. Plaintiff purchased substantial amounts of Seroquel XR and/or AB-rated generic equivalents indirectly from Defendants and/or other manufacturers.

185. As a result of Defendants' and their co-conspirators' illegal conduct, Plaintiff was compelled to pay, and did pay, more than it would have paid for their extended-release quetiapine fumarate requirements absent Defendants' and their co-conspirators' illegal conduct. But for Defendants' and their co-conspirators' illegal conduct, competitors would have begun selling generic Seroquel XR sooner than they did, and prices for extended-release quetiapine fumarate products would have been lower, sooner.

186. But for Defendants' and their co-conspirators' illegal conduct, competitors would have begun marketing generic versions of Seroquel XR well before November 1, 2016, and they would have been able to market such versions more successfully.

187. HCSC asserts that, by engaging in the foregoing conduct alleged above, including intentionally and wrongfully engaging in a conspiracy to monopolize the relevant market, Defendants and their co-conspirators violated the

antitrust and competition statutes of all states and territories that may provide any relief for indirect purchasers like HCSC, with respect to purchases of Seroquel XR and AB-rated bioequivalents made in the corresponding state or territory of the state or territory's statutes below, including but not limited to each of the following such laws:

- a. Ariz. Rev. Stat. § 44-1402, *et seq.*,
- b. Cal. Bus. & Prof. Code § 16700, *et seq.*, and Cal. Bus. & Prof. Code § 17200, *et seq.*,
- c. D.C. Code § 28-4503, *et seq.*,
- d. Fla. Stat. § 501.201, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in Florida by Plaintiff, and this conduct constitutes a predicate act under the Florida Deceptive Practices Act.
- e. Hawaii Rev. Stat. § 480-1, *et seq.*,
- f. Illinois Antitrust Act (740 Illinois Compiled Statutes 10/1, *et seq.*)
- g. Iowa Code § 535.5, *et seq.*,
- h. Kan. Stat. Ann. § 50-101, *et seq.*,
- i. Me. Rev. Stat. Ann. 10, § 1102, *et seq.*,
- j. Md. Com'l Law Code Ann. § 11-204(a), *et seq.*,
- k. Mich. Comp. Laws Ann. § 445.772, *et seq.*,

- l. Minn. Stat. § 325D.49, *et seq.*, and Minn. Stat. § 8.31, *et seq.*,
- m. Miss. Code Ann. § 75-21-3, *et seq.*,
- n. Mont. Code § 30-14-103, *et seq.*,
- o. Neb. Code Ann. § 59-802, *et seq.*
- p. Nev. Rev. Stat. Ann. § 598A.060, *et seq.*,
- q. N.H. Rev. Stat. Ann. § 356.11, *et seq.*,
- r. N.M. Stat. Ann. § 57-1-2, *et seq.*,
- s. N.Y. Gen. Bus. Law § 340, *et seq.*,
- t. N.C. Gen. Stat. § 75-2.1, *et seq.*,
- u. N.D. Cent. Code § 51-08.1-02, *et seq.*,
- v. Or. Rev. Stat. § 646.730, *et seq.*,
- w. R.I. Gen. Laws §§ 6-36-5, *et seq.*,
- x. S.D. Codified Laws Ann. § 37-1-3.2, *et seq.*,
- y. Tenn. Code Ann. § 47-25-101, *et seq.*
- z. Utah Code Ann. § 76-10-911, *et seq.*,
- aa. 9 Vt. Stat. Ann. § 2453, *et seq.*,
- bb. W.Va. Code § 47-18-3, *et seq.*,
- cc. Wis. Stat. § 133.03, *et seq.*,

188. Plaintiff has been injured in its business or property by reason of Defendants' and their co-conspirators' antitrust violations alleged in this claim. Its

injuries consist of: (1) being denied the opportunity to purchase lower-priced generic extended-release quetiapine fumarate products, sooner, and (2) paying higher prices for extended-release quetiapine fumarate products than it would have paid in the absence of Defendants' and their co-conspirators' conduct. These injuries are of the type the antitrust laws were designed to prevent, and flow from that which makes Defendant's conduct unlawful.

189. Plaintiff seeks damages and multiple damages in an amount in excess of \$50,000 as permitted by law for its injuries by Defendants' and their co-conspirators' violations of the aforementioned statutes.

THIRD CLAIM FOR RELIEF
Combination and Conspiracy in Restraint of Trade
(against all Defendants)

190. Plaintiff incorporates by reference all the allegations above as though fully set forth herein.

191. Defendants and their co-conspirators willfully and unlawfully engaged in a continuing illegal contract, combination, and conspiracy to restrain trade in the extended-release quetiapine fumarate market by engaging in an anticompetitive scheme to keep generic equivalents from the market and to allocate the market between horizontal competitors.

192. Defendants and their co-conspirators accomplished this scheme by, *inter alia*, (1) entering into illegal agreements which delayed the entry of generic

Seroquel XR in order to lengthen the period in which AstraZeneca's brand Seroquel XR could monopolize the market and make supracompetitive profits; (2) illegally agreeing to not bring an authorized generic to market during Handa/Par's and Accord's 180-day generic exclusivity period, thereby allowing Handa/Par and Accord to monopolize the generic market for Seroquel XR during the period, and allowing Handa/Par and Accord to charge supracompetitive profits; (3) raising and/or maintaining the prices so that Plaintiff would pay for Seroquel XR at supracompetitive prices; (4) unlawfully agreeing to divide a market and delay price reductions and generic competition for Seroquel XR; and (5) entering into illegal settlement agreements to cover the terms of the agreement allocating the market for extended-release quetiapine fumarate in the United States and its territories.

193. The agreements between Defendants and their co-conspirators are horizontal market allocation and price fixing agreements between actual or potential competitors and are illegal *per se* under state antitrust laws. Alternatively, this Complaint alleges that these agreements are an unreasonable restraint of trade, in violation of state antitrust law, under a "quick look" or "rule of reason" analysis.

194. Alternatively, Handa's agreements with AstraZeneca are presumptively anticompetitive reverse payment settlements, subject to "quick look" rule of reason scrutiny, because AstraZeneca provided substantial consideration in exchange for Handa's agreement to delay market entrance.

195. Through the agreements, AstraZeneca and Handa/Par and Accord joined in an anticompetitive scheme as co-conspirators. The Handa/Par and Accord Delay Agreement are and were a contract, combination and/or conspiracy that substantially, unreasonably, and unduly restrained trade in the relevant market, the purpose and effect of which was to: (a) allocate all sales of extended-release quetiapine fumarate in the United States and its territories to AstraZeneca until November 1, 2016; (b) prevent the sale of any generic version of extended-release quetiapine fumarate in the United States and its territories until November 1, 2016; and (c) fix the price at which HCSC would pay for extended-release quetiapine fumarate.

196. Under Defendants' and their co-conspirators' reverse payment agreement, AstraZeneca paid Handa/Par and Accord financial inducements through large and unexplained payments that vastly exceed the cost of avoided litigation and are not otherwise explained by the value of any services provided by Handa/Par and Accord to AstraZeneca (other than Handa/Par's and Accord's agreement to delay launching its generic Seroquel XR). There are no valid, non-pretextual procompetitive business justifications for the Handa/Par and Accord Delay Agreement, nor for the payments to Handa/Par and Accord under the Agreement. Even if there were some conceivable justification, the Handa/Par and

Accord Delay Agreement, and the payments flowing to Handa/Par and Accord under the Agreement, were not reasonably necessary to achieve it.

197. In exchange for these payments, Handa/Par and Accord agreed to, and did, delay introduction of its generic Seroquel XR in the United States.

198. The anticompetitive consequences of Defendants' and their co-conspirators' reverse payment agreement are sufficiently great and sufficiently unrelated to the settlement of the underlying patent dispute, to amount to an unlawful reverse payment agreement, as evidenced by, *inter alia*, the following:

- a. Delaying the entry of a generic Seroquel XR in order to lengthen the period in which AstraZeneca's brand Seroquel XR could monopolize the market and make supracompetitive profits;
- b. AstraZeneca agreement not to launch an AG during the 180-day exclusivity period worth hundreds of millions of dollars to Handa/Par and Accord;
- c. The agreements created bottlenecks that prevented and delayed generic entry by other generic manufacturers; and
- d. There were no countervailing pro-competitive benefits from the agreements.

199. The goal, purpose, and effect of Defendants' and their co-conspirators' scheme was to prevent and delay the sale of extended-release

quetiapine fumarate products in the United States and its territories at prices significantly below AstraZeneca's prices for Seroquel XR, thereby effectively preventing the average market price of extended-release quetiapine fumarate products from declining dramatically.

200. The goal, purpose and effect of Defendants' and their co-conspirators' scheme was also to maintain and extend AstraZeneca's monopoly power with respect to extended-release quetiapine fumarate products. The illegal scheme allowed AstraZeneca to continue charging supracompetitive prices for extended-release quetiapine fumarate products, without a substantial loss of sales, reaping substantial unlawful monopoly profits.

201. Plaintiff purchased substantial amounts of Seroquel XR and/or AB-rated generic equivalents indirectly from Defendants and/or other manufacturers, including Defendants' co-conspirators, Par and Accord.

202. As a result of Defendants' and their co-conspirators' illegal conduct, Plaintiff was compelled to pay, and did pay, more than it would have paid for its extended-release quetiapine fumarate requirements absent Defendants' and their co-conspirators' illegal conduct. But for Defendants' and their co-conspirators' illegal conduct, competitors would have begun selling generic Seroquel XR sooner than they did, and prices for extended-release quetiapine fumarate products would have been lower, sooner.

203. HCSC asserts that, by engaging in the foregoing conduct alleged above, including intentionally and wrongfully engaging in a combination and conspiracy in restraint of trade, Handa has violated the antitrust and competition statutes of all states and territories that may provide any relief for indirect purchasers like HCSC, with respect to purchases of Seroquel XR and AB-rated bioequivalents made in the corresponding state or territory of the state or territory's statutes below, including but not limited to each of the following such laws:

- a. Ala. Code § 6-5-60, *et seq.*,
- b. Ariz. Rev. Stat. § 44-1402, *et seq.*,
- c. Cal. Bus. & Prof. Code § 16700, *et seq.*,
- d. Conn. Gen. Stat. § 35-24, *et seq.*,
- e. D.C. Code § 28-4503, *et seq.*,
- f. Fla. Stat. § 501.201, *et seq.*,
- g. Hawaii Code § 480-1, *et seq.*,
- h. 740 Ill. Comp. Stat. 10/3, *et seq.*,
- i. Iowa Code § 553.1 *et seq.*,
- j. Kansas Stat. Ann. § 50-101, *et seq.*,
- k. Md. Comm. L. § 11-201, *et seq.*,
- l. 10 Me. Rev. Stat. Ann. § 1101, *et seq.*,
- m. Mich. Comp. Laws Ann. § 445.771, *et seq.*,

- n. Minn. Stat. § 325D.49, *et seq.*,
- o. Miss. Code Ann. § 75-21-1, *et seq.*,
- p. Neb. Code Ann. § 59-801, *et seq.*,
- q. Nev. Rev. Stat. Ann. § 598A.010, *et seq.*,
- r. N.H. Rev. Stat. Ann. § 356.11, *et seq.*,
- s. N.M. Stat. Ann. § 57-1-1, *et seq.*,
- t. N.Y. Bus. Law § 340, *et seq.*,
- u. N.C. Gen. Stat. § 75-1, *et seq.*,
- v. N.D. Cent. Code § 51-08.1-01, *et seq.*,
- w. Or. Rev. Stat. § 646.705, *et seq.*,
- x. 10 L.P.R.A. § 260, *et seq.*,
- y. R.I. Gen. Laws § 6-36-1, *et seq.*,
- z. S.D. Codified Laws § 37-1-3.1, *et seq.*,
- aa. Tenn. Code Ann. § 47-25-101, *et seq.*,
- bb. Utah Code Ann. § 76-10-3101, *et seq.*,
- cc. 9 Vt. Stat. Ann. § 2451, *et seq.*,
- dd. W.Va. Code § 47-18-1, *et seq.*,
- ee. Wis. Stat. § 133.01, *et seq.*.

204. Plaintiff has been injured in its business or property by reason of Defendants' and their co-conspirators' antitrust violations alleged in this Claim. Its

injuries consist of: (1) being denied the opportunity to purchase lower-priced extended-release quetiapine fumarate generic products sooner, and (2) paying higher prices for extended-release quetiapine fumarate products than it would have paid in the absence of Defendants' and their co-conspirators' conduct. These injuries are of the type the antitrust laws were designed to prevent, and flow from that which makes Defendants' and their co-conspirators' conduct unlawful.

205. Plaintiff seeks damages and multiple damages in an amount in excess of \$50,000 as permitted by law for its injuries by Defendants' and their co-conspirators' violations of the aforementioned statutes.

FOURTH CLAIM FOR RELIEF
Unfair or Deceptive Trade Practices
(against all Defendants)

206. Plaintiff incorporates by reference all the allegations above as though fully set forth herein.

207. Defendants and their co-conspirators' engaged in unfair competition, and/or unfair/unconscionable, and/or deceptive acts or practices in violation of the state consumer protection statutes listed below. As a direct and proximate result of Defendants' and their co-conspirators' anticompetitive, deceptive, unfair and/or unconscionable acts or practices, Plaintiff was deprived of the opportunity to purchase a less expensive AB-rated bioequivalents and forced to pay higher prices.

208. Defendants and their co-conspirators have engaged in unfair competition, and/or unfair/unconscionable and/or deceptive acts or practices in violation of the following state statutes:

- a. Ariz. Code § 44-1521, *et seq.*,
- b. Ark. Code § 4-88-101, *et seq.*,
- c. Cal. Bus. & Prof. Code § 17200, *et seq.*
- d. D.C. Code § 28-3901, *et seq.*,
- e. Fla. Stat. § 501.201, *et seq.*
- f. Idaho Code § 48-601, *et seq.*,
- g. 815 Ill. Comp. Stat. Ann. § 505.1, *et seq.*
- h. Kan. Stat. § 50-623, *et seq.*,
- i. 5 Me. Rev. Stat. § 207, *et seq.*,
- j. Mass. Ann. Laws ch. 93A, *et seq.*,
- k. Mich. Stat. § 445.901, *et seq.*,
- l. Minn. Stat. § 325F.68, *et seq.*,
- m. Mo. Stat. § 407.010, *et seq.*,
- n. Neb. Rev. Stat. § 59-1601, *et seq.*,
- o. Nev. Rev. Stat. § 598.0903, *et seq.*,
- p. N.H. Rev. Stat. § 358-A:1, *et seq.*,
- q. N.M. Stat. § 57-12-1, *et seq.*,

- r. N.Y. Gen. Bus. Law § 349, *et seq.*,
- s. N.C. Gen. Stat. § 75-1.1, *et seq.*,
- t. Or. Rev. Stat. § 646.605, *et seq.*,
- u. 73 Pa. Stat. Ann. § 201-1, *et seq.*,
- v. R.I. Gen. Laws § 6-13.1-1, *et seq.*,
- w. S.D. Code Laws § 37-24-1, *et seq.*,
- x. Tenn. Code § 47-18-101, *et seq.*,
- y. Utah Code § 13-11-1, *et seq.*,
- z. Va. Code Ann. § 59.1-196, *et seq.*,
- aa. W. Va. Code § 46A-6-101, *et seq.*,

209. Plaintiff has been injured in its business and property by reason of Defendants' and their co-conspirators' anticompetitive, unfair/unconscionable and/or deceptive acts or practices alleged in this Count. Its injury consists of paying higher prices for Seroquel XR and/or AB rated generic bioequivalents than it would have paid in the absence of these violations. This injury is of the type the state consumer protection statutes were designed to prevent and directly results from Defendants' and their co-conspirators' unlawful conduct.

FIFTH CLAIM FOR RELIEF
Unjust Enrichment Under State Law
(against all Defendants)

210. Plaintiff incorporates by reference all the allegations above as though fully set forth herein.

211. To the extent required, this claim is pleaded in the alternative to the other claims in this Complaint.

212. As a result of their unlawful conduct described above, Defendants and their co-conspirators have and will continue to be unjustly enriched. Defendants and their co-conspirators have been unjustly enriched by the receipt of, at a minimum, unlawfully inflated prices and unlawful profits on Seroquel XR and/or its AB-rated generic equivalents.

213. Defendants' and their co-conspirators' financial benefits are traceable to Plaintiff's overpayments for Seroquel XR and/or its AB-rated generic equivalents.

214. HCSC has conferred and continues to confer an economic benefit upon Defendants and their co-conspirators in the nature of profits resulting from the unlawful overcharges described herein, to the economic detriment of HCSC.

215. Defendants and their co-conspirators have benefited from their unlawful acts and it would be inequitable for Defendants and their co-conspirators to be permitted to retain any of the ill-gotten gains resulting from the overpayments made by HCSC for Seroquel XR and/or its AB-rated generic equivalents manufactured by Defendants and their co-conspirators.

216. It would be futile for HCSC to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which it indirectly purchased Seroquel XR and/or its AB-rated generic equivalents, as those intermediaries are not liable and would not compensate HCSC for Defendants' and their co-conspirators' unlawful conduct.

217. The economic benefit Defendants and their co-conspirators derived is a direct and proximate result of Defendants' and their co-conspirators' unlawful and anticompetitive practices.

218. The financial benefits Defendants and their co-conspirators derived are ill-gotten gains that rightfully belong to HCSC, who paid and continues to pay artificially inflated prices that inure to Defendants' and their co-conspirators' benefit.

219. It would be inequitable under unjust enrichment principles for Defendants and their co-conspirators to retain any of the overcharges HCSC paid for Seroquel XR and/or its AB-rated generic equivalents that were derived from Defendants' unfair, anticompetitive and unlawful methods, acts and trade practices.

220. Defendants and their co-conspirators are aware of and appreciate the benefits that HCSC has bestowed upon them.

221. Defendants should be ordered to disgorge all unlawful or inequitable proceeds they received in a common fund for the benefit of HCSC which has no adequate remedy at law.

222. HCSC is entitled to the amount of Defendants' ill-gotten gains resulting from their unlawful, unjust, and inequitable conduct, and to the establishment of a constructive trust consisting of such amount, from which HCSC can recover.

XI. PRAYER FOR RELIEF

WHEREFORE, HCSC prays for judgment against Defendants and that this Court:

- A. Award it damages (*i.e.*, three times overcharges) in an amount to be determined at trial, plus interest in accordance with law;
- B. Award it equitable relief in the nature of disgorgement, restitution, and the creation of a constructive trust to remedy Defendants' unjust enrichment;
- C. Award it the costs of suit, including reasonable attorneys' fees as provided by law; and
- D. Award it such other and further relief as the Court deems just and proper.

XII. JURY DEMAND

HCSC demands a trial by jury of twelve (12) jurors of all issues so triable.

Dated: September 8, 2022

Respectfully submitted,

/s/ Blake A. Bennett

Blake A. Bennett (#5133)

COOCH AND TAYLOR, P.A.

The Nemours Building

1007 N. Orange Street, Suite 1120

Wilmington, DE 19801

Tel: (302) 984-3889

Email: bbennett@coochtaylor.com

Peter D. St. Phillip (to be admitted *pro hac vice*)

Anthony M. Christina (to be admitted *pro hac vice*)

LOWEY DANNENBERG, P.C.

One Tower Bridge

100 Front Street, Suite 520

West Conshohocken, PA 19428

Tel: (215) 399-4770

Email: pstphillip@lowey.com

achristina@lowey.com

Uriel Rabinowitz (to be admitted *pro hac vice*)

Thomas K. Griffith (to be admitted *pro hac vice*)

LOWEY DANNENBERG, P.C.

44 South Broadway

Suite 1100

White Plains, NY 10601

Tel: (914) 997-0500

Email: urabinowitz@lowey.com
tgriffith@lowey.com

Todd Schneider (to be admitted *pro hac vice*)

Matthew S. Weiler (to be admitted *pro hac vice*)

**SCHNEIDER WALLACE COTTRELL
KONECKY WOTKYNs LLP**

2000 Powell Street, Suite 1400

Emeryville, CA 94608

Tel: (415) 421-7100

Email: tschneider@schneiderwallace.com
mweiler@schneiderwallace.com

Counsel for Health Care Service Corporation