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: All End-Payor Class Actions	**JURY TRIAL DEMANDED**

END-PAYOR PLAINTIFFS' SECOND CONSOLIDATED AMENDED CLASS ACTION COMPLAINT

TABLE OF CONTENTS

Plaintiffs Fraternal Order of Police, Miami Lodge 20, Insurance Trust Fund; Law Enforcement Health Benefits, Inc.; The Mayor and City Council of Baltimore; Pipe Trades Services MN Welfare Fund; Sergeants Benevolent Association Health & Welfare Fund; Welfare Plan of the International Union of Operating Engineers Locals 137, 137A, 137B, 137C, and 137R; and The Uniformed Firefighters' Association of Greater New York Security Benefit Fund and The Retired Firefighters' Security Benefit Fund of the Uniformed Firefighters' Association (collectively "Plaintiffs"), bring this action on behalf of themselves, and all others similarly situated, against AstraZeneca Pharmaceuticals LP, AstraZeneca LP, AstraZeneca UK Limited (collectively, "AstraZeneca"), Handa Pharmaceuticals, LLC ("Handa"), and Par Pharmaceutical, Inc. ("Par")(collectively, "Defendants"). These allegations are based on investigations of counsel, publicly available materials and knowledge, information, and belief.

I. INTRODUCTION

1. This case arises from Defendants' illegal scheme to delay competition in the United States and its territories for Seroquel XR, a prescription medication approved by the U.S. Food and Drug Administration ("FDA") for the treatment of: (1) schizophrenia; (2) acute depressive episodes of bipolar disorder; (3) acute manic or mixed episodes of bipolar disorder in conjunction with other medications; (4) long-term bipolar disorder in conjunction with other medications; and (5) major

depressive disorder in conjunction with other medications for those patients who have not had an adequate response to antidepressant medications. Plaintiffs seek overcharge damages arising from AstraZeneca's unlawful agreements with Handa and Accord Healthcare, Inc. ("Accord") not to compete in the market for Seroquel XR and corresponding generic versions in the United States and its territories. As set forth below, Handa subsequently assigned this unlawful agreement to Par, which performed the agreement, sold generic Seroquel XR at supracompetitive prices, and shared its illegal gains with Handa.

2. Seroquel XR is a dopamine, serotonin, and adrenergic antagonist. As such, it blocks the effects of these neurotransmitters in the brain, resulting in a reduction of symptoms. In patients with schizophrenia, antagonism of the 5-HT_{2A} serotonin receptor in the frontal cortex of the brain relieves the negative symptoms while antagonism of the D_2 dopamine receptor relieves negative symptoms. As of 2016, it was the eighty-sixth most prescribed medication in the United States, with more than 8 million prescriptions and annual sales exceeding $1 billion.

3. Recognizing the huge market for this medication, in 2008, Handa became the first drug manufacturer to file an Abbreviated New Drug Application ("ANDA") (No. 90-482) with the FDA seeking approval to market the 50mg, 150mg, 200mg, and 300mg strengths of generic extended-release quetiapine

fumarate tablets, with Seroquel XR as its Reference Listed Drug.[1] Accord became the first drug manufacturer to file an ANDA (No. 90-681) for the 400mg strength of extended-release quetiapine fumarate tablets, with Seroquel XR as its Reference Listed Drug.[2] Handa later filed an ANDA for the 400mg strength of extended-release quetiapine fumarate.[3]

4. Pursuant to 21 U.S.C. § 355(j)(2)(B), Handa sent AstraZeneca four separate paragraph IV notice letters between July and November 2008.[4] Accord sent AstraZeneca two separate paragraph IV notice letters dated September 5, 2008 and

[1] *See* Final Approval Letter from Carol Holquist, Deputy Director, Office of Regulatory Operations, FDA, to Meredith Selby, Senior Director, Regulatory Affairs, at Par Pharmaceutical Inc., at 2 (May 9, 2017), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/090482Orig1s000ltr.pdf.

[2] *See* Final Approval Letter from Carol Holquist, Deputy Director, Office of Regulatory Operations, FDA, to Sabita Nair, Senior Director, Regulatory Affairs, Accord Healthcare Inc., at 2 (Nov. 1, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/090681Orig1s000TAltr.pdf; FDA, Paragraph IV Patent Certifications (Dec. 1, 2020), https://www.fda.gov/media/133240/download.

[3] *See* Final Approval Letter from Carol Holquist, Deputy Director, Office of Regulatory Operations, FDA, to Meredith Selby, Senior Director, Regulatory Affairs, at Par Pharmaceutical Inc., at 2 (May 9, 2017), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/090482Orig1s000ltr.pdf.

[4] Stipulated Facts ¶ 26, ECF No. 156-1, *AstraZeneca Pharmaceuticals et al. v. Handa Pharmaceuticals LLC*, 3:10-cv-01835-JAP-TJB (D.N.J.) ("Stipulated Facts").

January 23, 2009.[5] In these letters, Handa and Accord each certified that they would seek final FDA approval to launch and market their generic extended-release quetiapine fumarate products prior to the expiration of U.S. Patent No. 5,948,437 (the "'437 Patent"), a follow-on patent, which supposedly covered Seroquel XR. Handa and Accord both claimed that the '437 Patent was invalid and/or would not be infringed by Handa's and Accord's respective proposed generic extended-release quetiapine fumarate products.

5. The '437 Patent was set to expire on May 28, 2017.

6. On July 28, 2008, AstraZeneca filed a complaint against Handa in the United States District Court for the District of New Jersey, alleging that Handa's filing of its ANDA relating to its 200mg, 300mg, and 400mg strengths of generic quetiapine fumarate infringed the '437 patent under 35 U.S.C. § 271(e)(2)(A).[6]

7. On October 28, 2008, AstraZeneca again filed a complaint against Handa in the United States District Court for the District of New Jersey. This time, AstraZeneca alleged that Handa's filing of its ANDA relating to its 50mg strength of generic extended-release quetiapine fumarate infringed the '437 Patent under 35 U.S.C. § 271(e)(2)(A).[7]

[5] *Id.*, ¶ 27.
[6] *Id.*, ¶ 34.
[7] *Id.*, ¶ 35.

8. On December 8, 2008, AstraZeneca filed a third complaint against Handa in the United States District Court for the District of New Jersey, alleging that Handa's filing of its ANDA relating to its 150mg strength of generic extended-release quetiapine fumarate infringed the '437 Patent under 35 U.S.C. § 271(e)(2)(A).[8]

9. The preceding three lawsuits filed by AstraZeneca against Handa were consolidated and are collectively referred to herein as the "Handa Seroquel XR Patent Litigation."

10. AstraZeneca filed two patent infringement lawsuits against Accord on September 26, 2008 and February 10, 2009 in the United States District Court for the District of New Jersey. The complaints both alleged that Accord's filing of its ANDA relating to its 400mg strength of generic extended-release quetiapine fumarate infringed the '437 Patent under 35 U.S.C. § 271(e)(2)(A).[9] These lawsuits are collectively referred to as the "Accord Seroquel XR Patent Litigation."

11. During the course of the Handa Seroquel Patent Litigation, it became apparent that Handa's proposed generic version of the extended-release quetiapine fumarate would not infringe the '437 Patent. The '437 Patent did not broadly claim the chemical compound quetiapine or even its salt quetiapine fumarate. Instead, the

[8] *Id.*, ¶ 36.

[9] *Id.*, ¶¶ 37-38.

'437 Patent narrowly claimed very specific formulations of quetiapine fumarate, each of which requires a "gelling agent." The Honorable Joel A. Pisano, who presided over the Accord Seroquel XR Patent Litigation and the Handa Seroquel XR Patent Litigation, construed "gelling agent" to mean "any substance which forms a gel when in contact with water." But Handa's proposed generic version of Seroquel XR used hydrogenated vegetable oil, which is hydrophobic, not even miscible with water, *i.e.*, it does not form a homogeneous mixture with water, and not a "gelling agent" under the district court's claim construction.

12. The district court issued a claim construction opinion on November 30, 2010, applicable in both the Handa Seroquel XR Patent Litigation and the Accord Seroquel XR Patent Litigation which construed "gelling agent" to mean "any substance which forms a gel when in contact with water."[10] However, Handa's proposed generic version of extended-release quetiapine fumarate used hydrogenated vegetable oil which is hydrophobic and not even miscible with water. Because Handa's proposed generic extended-release quetiapine fumarate does not form a homogenous mixture with water, it is not a "gelling agent" under the district court's claim construction.

[10] *AstraZeneca Pharm., LP, et al vs. Handa Pharm., LLC, et al*, Civ. No. 3:10-cv-01835, Dkt. 69, p.7.

13. On December 9, 2010, the FDA granted tentative approval to Handa's ANDA for generic Seroquel XR in all strengths, determining that Handa's ANDA for generic Seroquel XR was approvable and satisfied all bioequivalence; chemistry, manufacturing, and controls ("CMC"); and labeling requirements.[11] The approval was not final because pursuant to the applicable regulatory structure, AstraZeneca's filing of the Handa Seroquel XR Litigation resulted in an automatic 30-month stay on the ability of the FDA to grant final approval. The 30-month stay period began when AstraZeneca filed its lawsuit in 2008.

14. Based on the district court's claim construction, AstraZeneca was very likely to lose the litigation over the '437 Patent. AstraZeneca faced the distinct possibility of an adverse finding that Handa's proposed generic version of extended-release quetiapine fumarate did not infringe on the '437 Patent. To avoid that outcome, and risk that Handa's proposed generic would not infringe the '437 Patent, AstraZeneca induced Handa to drop its patent challenge and delay launching its generic version with a large "reverse payment" to quit the patent fight and not compete with AstraZeneca for up to five years. A reverse payment occurs when the patent holder—here, AstraZeneca—pays some amount to the alleged patent

[11] *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

infringer—here, Handa. The Supreme Court has 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).

15. On or about September 29, 2011, and after a period of negotiation, AstraZeneca and Handa entered into a settlement agreement concerning Handa's ANDA (the "Handa Non-Compete Agreement").[12] Under the terms of the Handa Non-Compete Agreement, Handa agreed to abandon the patent fight and delay its launch of generic extended-release quetiapine fumarate in the 50mg, 150mg, 200mg, and 300mg strengths until November 1, 2016. Handa also agreed to abandon the patent fight with respect to the 400mg strength as well, even though it did not hold first filer status for that strength. In exchange for Handa's delayed generic launch, AstraZeneca agreed not to compete with Handa by launching an authorized generic Seroquel XR (the brand product packaged and sold as a less-expensive generic, sometimes referred to as an "AG") during Handa's 180-day exclusivity period. Upon information and belief, Handa also acquired the right to obtain generic product

[12] *See US District Court Finds SEROQUEL XR Formulation Patent Valid and Infringed* (Mar. 29, 2012), https://www.businesswire.com/news/home/20120329006628/en/District-Court-Finds-SEROQUEL-XR-Formulation-Patent ("On September 29, 2011, AstraZeneca granted Handa a license to the 5,948,437 patent effective November 1, 2016, or earlier under certain circumstances.").

from AstraZeneca to sell as its own for at least a 180-day period commencing November 1, 2016.

16. But for the Handa Non-Compete Agreement and AstraZeneca's large and unjustified payment, Handa would not have agreed to delay launching generic versions of 50mg, 150mg, 200mg, and 300mg strengths of Seroquel XR until November 1, 2016 (which included delaying its pursuit of final approval for its ANDA regarding these strengths and commercial manufacturing thereof) and AstraZeneca would not have agreed to delay launching an authorized generic in these strengths to compete with Handa's generic product until May 1, 2017. Additional generics would have launched six months after Handa's generic extended-release quetiapine fumarate launch. The presence of additional generics would have resulted in lower prices for extended-release quetiapine fumarate. The purpose and effect of the Handa Non-Compete Agreement was to delay lower-priced generic competition for generic extended-release quetiapine fumarate from an AG in the 50mg, 150mg, 200mg strengths during Handa/Par's 180-day period of generic exclusivity (as described below), thereby generating enormous windfalls for AstraZeneca and Handa (and eventually Par).

17. Handa subsequently assigned this unlawful agreement to Par. Par performed the agreement, sold generic extended-release quetiapine fumarate at supracompetitive prices, and shared the illicit profits with Handa. On October 29,

2012, Par announced that it had acquired Handa's ANDA No. 90-482.[13] 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 product, pursuant to its agreement with Par."[14] 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 co-conspirator 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.

18. On November 1, 2016, Par began selling generic extended-release quetiapine fumarate in the 50mg, 150mg, 200mg, and 300mg strengths and Accord began selling 400mg extended-release quetiapine fumarate.[15]

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[13] *See Par Pharmaceutical Acquires Rights to Market and Distribute Generic Seroquel XR® in the U.S.* (Oct. 29, 2012), https://www.prnewswire.com/news-releases/par-pharmaceutical-acquires-rights-to-market-and-distribute-generic-seroquel-xr-in-the-us-176239031.html.

[14] *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-fda-approval-for-generic-version-of-astrazenecas-seroquel-xr-extended-release-tablets/.

[15] *See e.g.*, OptumRx, Seroquel XR (quetiapine) – First Time Generic, https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/news/rxnews/new-generics/newgenerics_seroquelxr_2016-1102.pdf.

19. On May 1, 2017 (180 days thereafter) AstraZeneca launched authorized generic versions of Seroquel XR in the 50mg, 150mg, 200mg, 300mg and 400mg strengths.[16]

20. Several other generic competitors launched their own versions of generic extended-release quetiapine fumarate in all strengths in or around May 2017.

21. On information and belief, Accord and AstraZeneca entered into a similar agreement to the Handa Non-Compete Agreement, which contained a similar reverse payment from the patent holder, AstraZeneca, to the alleged infringer, Accord, to abandon its patent fight and not compete with AstraZeneca for up to five years. On or about October 5, 2011,[17] prior to the end of any trial, Accord and AstraZeneca entered into an agreement (the "Accord Non-Compete Agreement") pursuant to which Accord agreed to delay its launch of the 400mg strength generic extended-release quetiapine fumarate, for which Accord was the first ANDA filer, until November 1, 2016 and AstraZeneca agreed to not launch an authorized generic

[16] *See* DailyMed, LABEL: QUETIAPINE FUMARATE EXTENDED RELEASE, https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=7283b14f-023d-466f-a7eb-4356803d7c65&audience=consumer (showing AstraZeneca with a May 1, 2017 launch date as an "NDA Authorized Generic").

[17] *AstraZeneca enters into a settlement agreement with Accord Healthcare, Inc. and Intas Pharmaceuticals Ltd regarding US SEROQUEL XR® patent litigation* (Oct. 5, 2011), https://www.astrazeneca.com/media-centre/press-releases/2011/AstraZeneca-enters-into-a-settlement-agreement-with-Accord-Healthcare-Inc-and-Intas-Pharmaceuticals-Ltd-regarding-US-SEROQUEL-XR-patent-litigation-05102011.html#modal-historic-confirmation.

version of the 400mg strength for 180 days thereafter. In accordance with this agreement, Accord in fact did not launch its generic 400mg extended-release quetiapine fumarate product until November 1, 2016 and AstraZeneca did not launch an authorized generic version of Seroquel XR 400mg until May 1, 2017.

22. But for the Accord Non-Compete Agreement and AstraZeneca's large and unjustified payment, Accord would not have delayed launching a generic version of 400mg strength Seroquel XR until November 1, 2016 launch (which included delaying its pursuit of final approval for its ANDA regarding these strengths and commercial manufacturing thereof) and AstraZeneca would not have agreed to delay launching an authorized generic in this strength to compete with Accord's generic product until May 1, 2017. Additional generics would have launched six months after Accord's generic 400mg strength extended-release quetiapine fumarate launch. The presence of additional generics would have resulted in lower prices. The purpose and effect of the Accord Non-Compete agreement was to delay lower-priced generic competition with AstraZeneca's branded Seroquel XR product for up to five years, and to eliminate competition for generic extended-release quetiapine fumarate from an AG during Accord's 180-day period of generic exclusivity, thereby generating enormous windfalls for AstraZeneca and Accord.

23. Because of the unlawful Handa Non-Compete Agreement and Accord Non-Compete Agreement (together, the "Non-Compete Agreements"), no less-expensive generic Seroquel XR was available for Plaintiffs and other Class members (defined below) to purchase in the United States and its territories until November 1, 2016 and, for a period of six months thereafter, there was only one generic available for each strength of Seroquel XR (marketed by Par in the 50mg, 150mg, 200mg, and 300mg strengths and by Accord in the 400mg strength) instead of two which would have driven down the costs of the generics during the 180-day period.

24. But for the unlawful Non-Compete Agreements, one or more generic versions of Seroquel XR (in each strength) would have entered the market much earlier – either following patent litigation victory by Handa and/or Accord, at-risk launche(es) by Handa and/or Accord, or by entering into agreement(s) that did not include unlawful reverse payments from AstraZeneca for delay. Courts have repeatedly recognized that payments for delay result in later generic entry dates than what would otherwise occur. *See, e.g.*, *In re Niaspan Antitrust Litig*., 42 F. Supp. 3d 735, 751-52 (E.D. Pa. 2014). In addition, AstraZeneca would have simultaneously launched authorized generic Seroquel XR (in each strength) when generic entry occurred instead of waiting 180-days (as AstraZeneca actually did). Thus, absent the unlawful Non-Compete Agreements, Plaintiffs and members of the

Class would have been able to satisfy their requirements for extended-release quetiapine fumarate at significantly lower prices substantially earlier.

25. By and through the Non-Compete Agreements, AstraZeneca, Handa/Par, and Accord agreed to divide ill-gotten revenues, both during the period in which Handa/Par and Accord agreed not to launch (*i.e.*, prior to November 1, 2016), and during the first 180 days after Handa/Par and Accord's launches of their respective generics during which AstraZeneca agreed not to launch an authorized generic version of Seroquel XR to compete with Handa/Par's and Accord's respective generic products, all of which resulted in anticompetitive overcharges to Plaintiffs and members of the Class.

26. Plaintiffs bring this action as end-payor purchasers of Seroquel XR and its AB-rated generic equivalents, on their own behalf and on behalf of all similarly situated end-payor purchasers. Defendants' unlawful conduct delayed generic extended-release quetiapine fumarate manufacturers from entering the market with competing generic products and has cost Plaintiffs and end-payor purchasers hundreds of millions of dollars in overcharge damages.

27. Plaintiffs and the proposed Class seek to recover damages, including treble damages, under the state antitrust, consumer protection and unjust enrichment laws enumerated below.

II. JURISDICTION AND VENUE

28. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because this is a class action involving common questions of law or fact in which the aggregate amount in controversy exceeds $5,000,000, exclusive of interest and costs; there are more than one hundred members of the Class; and at least one member of the putative Class is a citizen of a state different from that of one of the Defendants.

29. This Court also has supplemental jurisdiction over state law claims pursuant to 28 U.S.C. § 1367(a).

30. Venue is appropriate within this District under 28 U.S.C. § 1391. Defendants transact business within this District and/or have agents in and/or that can be found in this District, and a portion of the affected interstate trade and commerce discussed below was carried out in this District. Defendants also agreed in earlier motion practice that this district is an appropriate venue.

31. The Court has personal jurisdiction over each of Defendants. Defendants have transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of the illegal scheme throughout the United States, including in this District. The scheme has been directed at and has had the intended effect of causing injury to individuals and companies residing in or doing business throughout the United States, including in this District. Moreover, in earlier

motion practice, Defendants stated that this Court would have personal jurisdiction over them.

III. THE PARTIES

32. Plaintiff Fraternal Order of Police, Miami Lodge 20, Insurance Trust Fund ("FOP") is a governmental plan established and funded through contributions from the City of Miami and the plan's members, who are current and retired sworn officers from the City of Miami Police Department and their dependents. FOP was established pursuant to a duly executed Trust Agreement for the purpose of providing medical, surgical, and hospital care or benefits, including prescription drug benefits, to its members. FOP maintains its principal place of business at 400 NW 2nd Avenue, Miami, Florida, and is a citizen of Florida. FOP 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 in Florida during the Class Period. FOP paid and/or reimbursed more for these products than it would have absent Defendants' anticompetitive conduct to fix, raise, maintain, and stabilize the prices and allocate markets for Seroquel XR.

33. Plaintiff Law Enforcement Health Benefits ("LEHB") is a voluntary employee benefits plan organized pursuant to § 501(c) of the Internal Revenue Code to provide health benefits to its eligible participants and beneficiaries. LEHB's members are current and retired sworn Philadelphia Police officers, Deputy Sheriffs,

and County Detectives, and their dependents. LEHB was established pursuant to a duly executed Trust Agreement for the purpose of providing medical, surgical, and hospital care or benefits, including dental, optical and prescription drug benefits, to approximately 23,000 beneficiaries and covered spouses and dependents. LEHB maintains its principal place of business in Philadelphia, Pennsylvania. LEHB 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 in Arizona, California, Delaware, Florida, Georgia, Illinois, Indiana, Massachusetts, Missouri, New Hampshire, New Jersey, New York, Nevada, Ohio, Pennsylvania, South Carolina, Tennessee, Texas, during the Class Period. LEHB's indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price for Seroquel XR and its AB-rated generic equivalent in Massachusetts for personal use by one or more of its beneficiaries, who are consumers. LEHB paid and/or reimbursed more for these products than it would have absent Defendants' anticompetitive conduct to fix, raise, maintain, and stabilize the prices and allocate markets for Seroquel XR.

34. Plaintiff the Mayor and City Council of Baltimore ("City of Baltimore") is a municipality located in Baltimore, Maryland. The City of Baltimore 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 in California,

Delaware, Florida, Georgia, Illinois, Maryland, Michigan, Missouri, New Hampshire, New Jersey, New York, North Carolina and Pennsylvania during the Class Period. The City of Baltimore paid and/or reimbursed more for these products than it would have absent Defendants' anticompetitive conduct to fix, raise, maintain, and stabilize the prices and allocate markets for Seroquel XR.

35. Plaintiff Pipe Trades Services MN Welfare Fund ("Pipe Trades") is a Taft-Hartley fund authorized under Section 302 (c)(5) of the National Labor Relations Act and an employee welfare benefit plan as defined in Section 3(1) of the Employee Retirement Income Security Act of 1974 ("ERISA"), 29 U.S.C. §1001 *et seq*. Its principal place of business is in White Bear Lake, Minnesota. Pipe Trades is the sponsor of a benefit plan which provides health benefits, including prescription-drug benefits, to plan members, their spouses, and dependents. Pipe Trades 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 in Minnesota during the Class Period. Pipe Trades paid and/or reimbursed more for these products than it would have absent Defendants' anticompetitive conduct to fix, raise, maintain, and stabilize the prices and allocate markets for Seroquel XR.

36. Plaintiff Sergeants Benevolent Association Health & Welfare Fund ("SBA") is located in New York and was established for the purpose of providing prescription drug benefits to active and retired New York City Police Department

Sergeants and their dependents. SBA 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 in Florida, New York, Texas, New Jersey, South Carolina, California, Pennsylvania, Kansas and Indiana during the Class Period. SBA paid and/or reimbursed more for these products than it would have absent Defendants' anticompetitive conduct to fix, raise, maintain, and stabilize the prices and allocate markets for Seroquel XR.

37. Plaintiff the Welfare Plan of the International Union of Operating Engineers Locals 137, 137A, 137B, 137C, and 137R ("IUOE") is a multi-employer health and welfare fund located in Briarcliff Manor, New York. IUOE 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 in New York, Connecticut, South Carolina and Tennessee during the Class Period. IUOE paid and/or reimbursed more for these products than it would have absent Defendants' anticompetitive conduct to fix, raise, maintain, and stabilize the prices and allocate markets for Seroquel XR.

38. Plaintiffs The Uniformed Firefighters' Association of Greater New York Security Benefit Fund and The Retired Firefighters' Security Benefit Fund of the Uniformed Firefighters' Association (collectively "UFA Funds") are health and welfare benefit plans headquartered and with a principal place of business in New,

York, New York. The UFA Funds administer the assets of a defined contribution plan formed by a collective bargaining agreement between the City of New York and the Uniformed Firefighters Association to provide certain benefits including prescription drug benefits. They provide health and welfare benefits to approximately 35,000 beneficiaries who reside in numerous locations in the United States. The UFA Funds 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 in Arizona, California, Colorado, Florida, Illinois, Kentucky, New Jersey, New York, and South Carolina during the Class Period. The UFA Funds paid and/or reimbursed more for these products than it would have absent Defendants' anticompetitive conduct to fix, raise, maintain, and stabilize the prices and allocate markets for Seroquel XR.

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

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

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

42. All three AstraZeneca entities are referred to individually and collectively herein as "AstraZeneca."

43. Defendant Handa Pharmaceuticals, LLC is a California corporation having its principal place of business at 1732 N. 1st Street, Suite 200, San Jose, California 95112.

44. Defendant Par Pharmaceutical, Inc. is a Delaware corporation having its principal place of business at One Ram Ridge Road, Chestnut Ridge, New York 10977.

45. Defendants' wrongful actions described in this Second Consolidated Amended Complaint are part of, and were taken in furtherance of, the illegal monopolization scheme and restraint of trade alleged herein. These actions were authorized, ordered, and/or undertaken by Defendants' various officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs within the course and scope of their duties and employment and with their actual, apparent, or ostensible authority.

IV. ECONOMIC BACKGROUND

46. The marketplace for the sale of prescription pharmaceutical products in the United States is unusual. In most industries, the person who pays for a product is also the person who chooses the product. When the same person has both the payment obligation and the choice of products, the price of the product plays a

predominant role in the person's choice of products. Consequently, manufacturers have a strong incentive to lower the price of their products to maintain profitability.

47. The pharmaceutical marketplace, in contrast, is characterized by a "disconnect" between the payment obligation and the product selection. State laws prohibit pharmacists from dispensing certain drugs to patients unless they can present a prescription written by their physician. This prohibition introduces an anomaly into the pharmaceutical marketplace between the payment obligation and the product selection. The patient (or his or her insurer) has the obligation to pay for the pharmaceutical product, but his or her doctor chooses which product the patient will buy.

48. In 1984, Congress sought to ameliorate the "disconnect," by authorizing the manufacture and sale of generic pharmaceuticals under the Hatch-Waxman Act, discussed further below. Now, when a pharmacist receives a prescription for a branded drug and an AB-rated[18] generic version of that drug is available, state laws permit (and in many cases require) the pharmacist to dispense the generic instead of the brand. In this way, price is reintroduced to the product selection decision at the pharmacy counter, and the pharmaceutical marketplace

[18] 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.

"disconnect" is lessened. When an AB-rated generic equivalent is introduced and not prevented from competing, brand manufacturers can no longer exploit the "disconnect," their monopoly power dissipates, and some of the normal competitive pressures are restored.

49. Because AB-rated generic versions of brand-name drugs contain the same active ingredients and are determined by the FDA to be just as safe and effective as their branded counterparts, the only material differences between generic drugs and their branded counterparts are their prices and manufacturers. Because AB-rated generic versions of branded products are commodities that cannot otherwise be differentiated, the primary basis for generic competition is price.

50. Typically, generics are at least 10% less expensive than their branded counterparts when there is a single generic competitor. They are 50% to 80% (or more) less expensive when there are multiple generic competitors on the market for a given brand. Consequently, the launch of a bioequivalent generic drug usually results in significant cost savings to all drug purchasers.

51. The combination of these factors — the regulatory interchangeability of bioequivalent generics for the brand, state substitution laws, margin incentives of pharmacies, and the like — results in the typical phenomenon that once a brand drug "goes generic," the product swiftly moves from a monopoly priced item to a commodity priced item.

52. Generic competition enables all members of the proposed Class to purchase generic versions of the drug at substantially lower prices and to purchase the brand drug at a reduced price.

53. The Hatch-Waxman Act has significantly advanced the rate of generic drug launches while also ushering in an era of historically high profits for brand drug manufacturers. In 1983, before the Hatch-Waxman Act, only 35% of the top-selling branded drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, annual prescription drug revenue for branded and generic drugs totaled $21.6 billion; by 2009, total annual prescription drug revenue had soared to $300 billion.

54. 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. As a result, brand drug manufacturers view competition from generics as a grave threat to their bottom lines.

55. When a brand drug faces generic drug competition, purchasers are able to (a) purchase generic versions of the drug at much lower prices; and/or (b) purchase the brand drug at a reduced price. Until the generic version of a brand drug enters the market, however, there is no bioequivalent generic to substitute for, and compete with, the branded drug, so the brand manufacturer can continue to profitably charge supracompetitive prices. As a result, brand drug manufacturers, well aware of the

rapid erosion of brand drug sales by generics, have a strong incentive to delay the start of generic drug competition. Brand manufacturers often seek to extend their monopolies by any means possible, sometimes even resorting to illegal ones.

V. REGULATORY BACKGROUND

A. The Hatch-Waxman Amendments.

56. The Hatch-Waxman amendments, enacted in 1984, simplified regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly New Drug Applications ("NDA(s)").[19] A manufacturer seeking approval to sell a generic version of a brand drug may instead file an Abbreviated New Drug Application ("ANDA"). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's original NDA and must further show that the generic contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug, and that it is bioequivalent, *i.e.*, absorbed at the same rate and to the same extent as the brand. The FDA assigns generics that meet these criteria relative to their brand counterparts an "AB" rating.

57. The Federal Food, Drug, and Cosmetics Act ("FDCA") and Hatch-Waxman amendments operate on the principle that bioequivalent drug products

[19] *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355).

containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity, and identity are therapeutically equivalent and may be substituted for one another. Bioequivalence demonstrates that the active ingredient of the proposed generic would be present in the blood of a patient to the same extent and for the same amount of time as the brand counterpart.[20]

58. Through the Hatch-Waxman amendments, Congress sought to expedite the entry of less expensive generic competitors to brand drugs, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical manufacturers' incentives to create new and innovative products.

59. The Hatch-Waxman amendments achieved both goals, advancing substantially the rate of generic product launches and ushering in an era of historically high profit margins for brand pharmaceutical manufacturers. In 1983, before the Hatch-Waxman amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenues for brands and generics totaled $21.6 billion; by 2013, total prescription drug revenues had climbed to more than $329.2 billion, with

[20] 21 U.S.C. § 355(j)(8)(B).

generics accounting for 86% of prescriptions.[21] Generics are dispensed about 95% of the time when a generic form is available.[22]

B. Regulatory Exclusivities for New Drugs.

60. In order to promote a balance between new drug innovation and generic drug competition, the Hatch-Waxman amendments also provided for exclusivities (or exclusive marketing rights) for new drugs. These exclusivities are granted by the FDA upon approval of a drug if statutory requirements are met. These exclusivities are listed in the Orange Book, along with any applicable patents, and can run concurrently with the listed patents.

61. One such exclusivity, New Chemical Entity ("NCE") exclusivity, applies to products containing chemical entities never previously approved by the FDA either alone or in combination. If a product receives NCE exclusivity, the FDA may not accept for review any ANDA for a drug containing the same active moiety for five years from the date of the NDA's approval, unless the ANDA contains a

[21] *See* IMS Institute for Healthcare Informatics, *Medicine Use and Shifting Costs of Healthcare: A Review of the Use of Medicines in the United States in 2013* 30, 51 (2014). https://oversight.house.gov/sites/democrats.oversight.house.gov/files/documents/IMS-Medicine%20use%20and%20shifting%20cost%20of%20healthcare.pdf.

[22] *Id.* at 51.

certification of patent invalidity or non-infringement, in which case an application may be submitted after four years.[23]

62. A drug product may also receive a three-year period of exclusivity if its sponsor submits a supplemental application that contains reports of new clinical investigations (other than bioavailability studies) conducted or sponsored by the sponsor that were essential to approval of the supplemental application. If this exclusivity is granted, the FDA may not approve an ANDA for that drug for three years from the date on which the supplemental application is approved.[24]

63. Regulatory exclusivities are not always absolute bars to generic entry. For example, some can be overcome by carving out information in the label or for other reasons.[25]

C. ANDA Paragraph IV Certifications.

64. To obtain FDA approval of an ANDA, a manufacturer must certify that the generic will not infringe any patents listed in the Orange Book. Under the Hatch-Waxman amendments, a generic manufacturer's ANDA must contain one of four certifications:

a. That no patent for the brand has been filed with the FDA (a "paragraph I certification");

[23] 21 U.S.C. § 355(j)(5)(F)(ii); 21 C.F.R. § 314.108(b)(2).

[24] 21 U.S.C. § 355(j)(5)(F)(iv); 21 C.F.R. § 314.108(b)(2)(5).

[25] *See, e.g.*, 21 C.F.R. §§ 314.94(a)(8)(v), 314.127(a)(7); 21 U.S.C. § 355a(o).

b. That the patent for the brand has expired (a "paragraph II certification");

c. That the patent for the brand will expire on a particular date and the manufacturer does not seek to market its generic before that date (a "paragraph III certification"); or

d. That the patent for the brand is invalid or will not be infringed by the generic manufacturer's proposed product (a "paragraph IV certification").[26]

65. If a generic manufacturer files a paragraph IV certification, a brand manufacturer has the ability to delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement. If the brand manufacturer initiates a patent infringement action against the generic filer within forty-five days of receiving notification of the paragraph IV certification, the FDA will not grant final approval to the ANDA until the earlier of (i) the passage of two-and-a-half years, or (ii) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA.[27] Until one of those conditions occurs, the FDA

[26] 21 U.S.C. § 355(j)(2)(A)(vii).

[27] 21 U.S.C. § 355(j)(5)(B)(iii). This period is commonly called a "30-month Hatch-Waxman stay" or "30 month stay." The brand/ patent holder can choose to sue the generic after 45 days, including waiting until the generic has launched its product, but, in that event, the brand cannot take advantage of the 30-month stay of FDA approval, and must instead satisfy the showing required to obtain a preliminary injunction to prevent the generic launch.

may grant "tentative approval," but cannot authorize the generic manufacturer to market its product (*i.e.*, grant final approval). The FDA may grant an ANDA tentative approval when it determines that the ANDA is ready for final approval but for the 30-month stay.

D. The First Filer's 180-day Exclusivity Period.

66. Generics may be classified as (i) first-filer generics, (ii) later generic filers, or (iii) authorized generics.

67. To encourage manufacturers to seek approval of generic versions of brand drugs, the Hatch-Waxman amendments grant the first paragraph IV ANDA filer ("first filer") a 180-day exclusivity period to market the generic version of the drug, during which the FDA may not grant final approval to any other generic manufacturer's ANDA for the same brand drug.[28] That is, when a first filer files a substantially complete ANDA with the FDA and certifies that the unexpired patents listed in the Orange Book as covering the brand are either invalid or not infringed by the generic, the FDA cannot approve a later generic manufacturer's ANDA until the first generic has been on the market for 180 days.[29]

[28] 21 U.S.C. § 355(j)(5)(B)(iv), (D).

[29] Or, until its first-filer exclusivity has been forfeited. A first filer can forfeit its 180-day exclusivity by, for example, failing to obtain tentative approval from the FDA for its ANDA within 30 months of filing its ANDA. There is no forfeiture here.

68. The 180-day window is often referred to as the first filer's six month or 180-day "exclusivity;" this is a bit of a misnomer, because a brand manufacturer (such as AstraZeneca) can launch an authorized generic ("AG") at any time, manufacturing its AG in accordance with its approved NDA for the branded product but selling at a lower price point. Brand manufacturers frequently launch AGs in response to generic entry in order to recoup some of the sales they would otherwise lose.

69. The Supreme Court has recognized that "this 180-day period of exclusivity can prove valuable, possibly 'worth several hundred million dollars'" to the first filer.[30]

70. A first filer that informs the FDA it intends to wait until all Orange Book-listed patents expire before marketing its generic (paragraph III) does not get a 180-day exclusivity period. Congress created this 180-day period to incentivize generic manufacturers to challenge weak or invalid patents or to invent around such patents by creating non-infringing generics.

E. Patents Are Not Bulletproof.

71. Patents are not bulletproof. Patents are routinely invalidated or held unenforceable, either upon reexamination or *inter partes* proceedings by the United

[30] *FTC v. Actavis, Inc.*, 570 U.S. 136, 133 S. Ct. 2223, 2229 (2013) (quoting C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1579 (2006)).

States Patent and Trademark Office ("PTO"), by court decision, or by jury verdict. A patent holder at all times bears the burden of proving infringement.

72. One way that a generic can prevail in patent infringement litigation is to show that its product does not infringe the patent (and/or that the patent holder cannot meet its burden to prove infringement). Another is to show that the patent is invalid or unenforceable.

73. A patent is unenforceable when it claims a product that is patentably distinct from the allegedly infringing product.

74. In these circumstances, the PTO's decision to issue a patent does not substitute for a fact-specific assessment of (i) whether the applicant made intentional misrepresentations or omissions on which the PTO relied in issuing the patent, and (ii) whether a reasonable manufacturer in the patent holder's position would have a realistic likelihood of succeeding on the merits of a patent infringement suit.

75. As a statistical matter, if the parties litigate a pharmaceutical patent infringement suit to a decision on the merits, it is more likely that a challenged patent will be found invalid or not infringed than upheld. The FTC reports that generics prevailed in 73% of Hatch-Waxman patent litigation cases resolved on the merits between 1992 and 2002.[31] An empirical study of all substantive decisions rendered

[31] FTC, *Generic Drug Entry Prior to Patent Expiration: AN FTC Study* vi-vii (2002), https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf.

in every patent case filed in 2008 and 2009 similarly reports that when a generic challenger stays the course until a decision on the merits, the generic wins 74% of the time.[32]

F. The Competitive Effects of AB-Rated Generic Competition.

76. Generics contain the same active ingredient(s) and are determined by the FDA to be just as safe and effective as their brand counterparts. The only material difference between generics and their corresponding brand versions is their price. Because generics are essentially commodities that cannot be therapeutically differentiated, the primary basis for competition between a branded product and its generic version, or between generic version, is price. Typically, generics are at least 10% less expensive than their brand counterparts when there is a single generic competitor. This discount typically increases to 50% to 80% (or more) when there are multiple generic competitors on the market for a given brand. Consequently, the launch of a generic usually results in significant cost savings for all drug purchasers, especially end-payor purchasers.

77. Since the passage of the Hatch-Waxman amendments, every state has adopted drug product selection laws that either require or permit pharmacies to

[32] John R. Allison, Mark A. Lemley & David L. Schwartz, *Understanding the Realities of Modern Patent Litigation*, 92 Tex. L. Rev. 1769, 1787 (2014) ("[P]atentees won only 164 of the 636 definitive merits rulings, or 26%," and "that number is essentially unchanged" from a decade ago.).

substitute AB-rated generic equivalents for brand prescriptions (unless the prescribing physician specifically directs that substitutions are not permitted). 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. Once a generic hits the market, it quickly captures sales of the corresponding brand drug, often 80% or more of the market within the first six months after entry. In a recent study, the FTC found that on average, within a year of generic entry, generics had captured 90% of corresponding brand sales and (with multiple generics on the market) prices had dropped 85%.[33] As a result, competition from generics is viewed by brand manufacturers, such as AstraZeneca, as a grave threat to their bottom lines.

78. Generic competition enables all purchasers of a drug to (i) purchase generic versions of the drug at substantially lower prices, and/or (ii) purchase the brand at a reduced price.

79. Until a generic version of the brand enters the market, however, there is no bioequivalent drug to substitute for and compete with the brand and the brand manufacturer can therefore continue to profitably charge supracompetitive prices.

[33] *See* FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* 8 (2010), https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf ("FTC Pay-for-Delay Study").

Brand manufacturers, such as AstraZeneca, are well aware of generics' rapid erosion of their brand sales. Brand manufacturers thus seek to extend their monopoly for as long as possible, sometimes resorting to any means possible—including illegal means—to delay or prevent generic competition.

1. The first AB-rated generic is priced below the brand.

80. Experience and economic research show that the first generic manufacturer to market its product prices it below the prices of its brand counterpart.[34] Every state either requires or permits that a prescription written for the brand be filled with an AB-rated generic. Thus, the first generic manufacturer almost always captures a large share of sales from the brand. At the same time, there is a reduction in the average price paid for the drug at issue (brand and AB-rated generic combined).

81. During the 180-day exclusivity period, the first filer is the only ANDA-approved generic manufacturer on the market (though the brand's AG can be, and often is, on the market during the 180-day exclusivity period), a first-filer generic

[34] FTC, Authorized Generic Drugs: Short-Term Effects and Long-Term Impact ii-iii, vi, 34 (2011), https://www.ftc.gov/reports/authorized-generic-drugs-short-term-effects-long-term-impact-report-federal-trade-commission ("FTC 2011 AG Study"); FTC Pay-for-Delay Study at 1. https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf.

manufacturer generally makes about 80% of all of the profits that it will ever make on the product.

2. Later generics drive prices down further.

82. Once generic competitors enter the market, the competitive process accelerates, and multiple generic manufacturers typically compete vigorously with each other on price, driving prices down toward the marginal manufacturing costs.[35]

83. According to the FDA and the FTC, the greatest price reductions are experienced when the number of generic competitors goes from one to two. In that situation, there are two commodities that compete on price. Some typical estimates are that a single generic results in a near term retail price reduction of around 10% as compared to the brand price, but that with two generic entrants the near term retail price reduction is about 50%.

84. In a report by the FTC issued at the request of Congress in 2011, the FTC found that generics captured 80% or more of sales in the first six months.[36] In the end, the brand manufacturer's sales decline to a small fraction of their level before generic entry. This is so because, "[a]lthough generic drugs are chemically

[35] *See, e.g.*, *Generic Competition and Drug Prices*, FTC, https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices; Richard G. Frank, *The Ongoing Regulation of Generic Drugs*, 357 New Eng. J. Med. 1993 (2007); Patricia M. Danzon & Li-Wei Chao, *Does Regulation Drive Out Competition in Pharmaceutical Markets?* 43 J.L. & Econ. 311 (2000).

[36] FTC 2011 AG Study at 66-67.

identical to their branded counterparts, they are typically sold at substantial discounts from the branded price. According to the Congressional Budget Office, generic drugs save consumers an estimated $8 to $10 billion a year at retail pharmacies.

3. Authorized generics, like other generics, compete on price.

85. 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.

86. One study notes that "pharmaceutical developers facing competition from generics have large incentives to compete with their own or licensed 'authorized generics.'"[37]

87. Brand manufacturers sometimes begin selling AGs before the first-filer generic enters the market in order to secure multi-year purchase contracts with direct purchasers and load the generic pipeline at the expense of the first-filer generic.

88. 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,

[37] 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.

authorized generics competed aggressively against independent generics on price, and both the authorized and independent generics captured substantial market share from the brand."[38]

89. The FTC found that AGs capture a significant portion of sales, reducing the first- filer generic's revenues by about 50% on average.[39] The first-filer generic makes much less money when it faces competition from an AG because (i) the AG takes a large share of unit sales away from the first filer; and (ii) the presence of the AG causes prices, particularly generic prices, to decrease.

90. 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.[40] Generic companies recognize

[38] Ernst R. Berndt et al., Authorized Generic Drugs, Price Competition, and Consumers' Welfare, 26 Health Affairs 790, 796 (2007).

[39] FTC 2011 AG Study at 139.

[40] 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.

it.[41] So do brand companies.[42]

G. Pharmaceutical Manufacturers Can Game the Regulatory Structure in Order to Impair Competition.

91. When they do not face generic competition, brand manufacturers can usually sell the brand far above the marginal cost of production, generating profit margins in excess of 70% while making hundreds of millions of dollars in sales. The ability to make those kinds of profit margins is what economists call market power. When generics enter the market, however, they quickly take 80% or more of the unit

[41] 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.

[42] 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#04P026; 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.

sales. And when multiple generics are in the market, the competition between the generics drives their prices to near the marginal cost of production. This competition puts an end to the brand manufacturer's market power and delivers enormous savings to drug purchasers.

92. Brand and first-filer generic manufacturers have a collective interest in preventing this competition from breaking out. If they work together to prevent or delay competition, they can keep the profit margins on all of the unit sales at 70% and split the resulting excess profits among themselves. They can keep for themselves the enormous savings that competition would have delivered to drug purchasers.

93. A brand manufacturer in the marketplace without competition from generics gets all of the profits on all of the unit sales.

94. When generic entry occurs, the brand manufacturer loses most of the unit sales; generic manufacturers sell most of the units, but at drastically reduced prices; and competition delivers enormous savings to drug purchasers. Competition converts what formerly were excess profits into purchaser savings.

95. To prevent this from happening, brand and generic manufacturers sometimes – unlawfully – agree to not compete and instead split the purchaser savings between themselves.

96. 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.

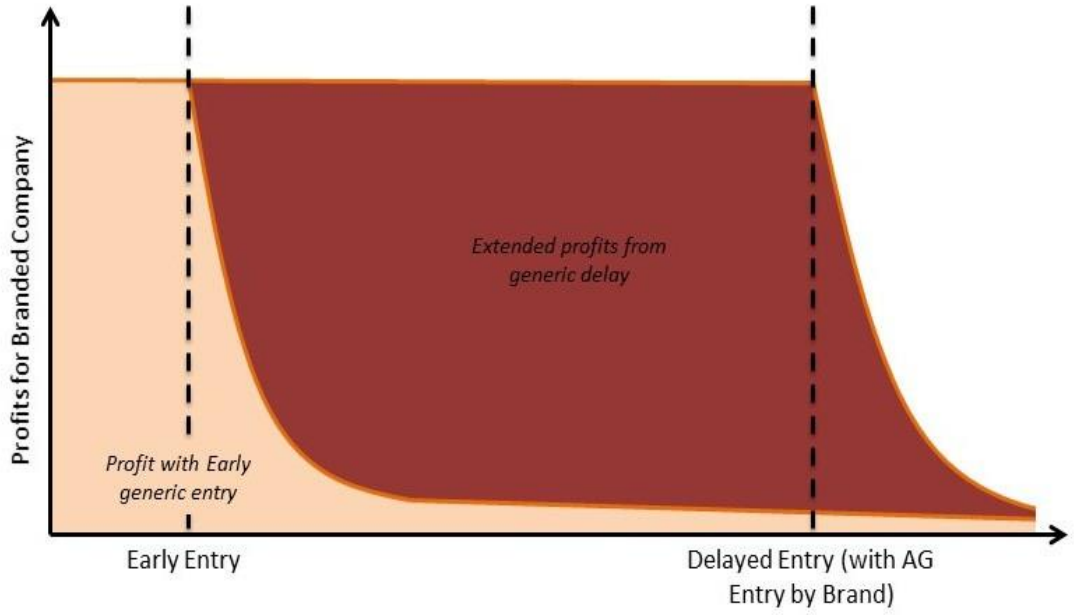

Figure 1: Impact of Delay on Brand Profits

97. 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.

98. 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.

99. Later ANDA filers have more modest financial expectations because they may have little or no expectation of any form of market exclusivity. By the time they enter the market, there is at least the brand and one other generic on the market (and often a second generic in the form of an AG) and, thus, the drug has already been, or is on its way to being, commoditized.

100. In the absence of an anticompetitive agreement between the brand company and the first filer, later ANDA filers have procompetitive incentives. They are motivated to expend resources to challenge the brand manufacturer's patent(s)

(knowing that the first-filer generic is also fighting a patent infringement suit) and to enter the market as early as possible.

101. When an anticompetitive agreement with the first filer is already in place, however, pursuing the litigation to conclusion becomes less attractive to later filers. The later generic manufacturers know that the first filer is not leading the charge against the brand manufacturer's patent(s) (and has sometimes stipulated to the validity or enforceability of the patents as part of an anticompetitive reverse payment agreement). The later generics have to bear the brunt of the litigation costs themselves and, upon prevailing in the patent litigation, expect to face competition from at least the first-filer generic, and typically an authorized generic as well, despite having expended time and resources litigating the infringement case. The first settlement between a brand and first-filer generic (such as the Handa and Accord agreements at issue here) will often provide that, if a later generic filer launches its generic before the delayed date agreed to by the brand and the first filer, the first filer is permitted to launch then as well – greatly reducing the incentive the later filer would otherwise have to continue fighting to enter as soon as possible.

102. Thus, some later generics decide to simply give in to or join the conspiracy between the brand manufacturer and the first-filer generic and agree to drop their challenges to the brand manufacturer's patent(s) and stay off the market until after entry by the first filer.

103. 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.

1. No-AG clauses provide a means for manufacturers to share the gains from conspiring.

104. One form of pay-off, at issue here, is a no-AG promise. With a no-AG promise, the brand manufacturer agrees not to market an AG version of the brand drug for some period of time after the first generic enters.

105. Again, the first filer's ANDA exclusivity does not prohibit the brand manufacturer from marketing its AG under the authority of its NDA. The Hatch-Waxman amendments' 180-day marketing period is "exclusive" only as against other ANDA-based products, not as against the brand manufacturer's NDA-based AG.

106. 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. But competition from an AG has a drastically negative effect on the first-filer generic's revenues. 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.

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

108. The brand and first filer's reciprocal pledges not to compete harm purchasers thrice over. The pact delays the first filer's entry into the marketplace and thereby extends the time during which the more expensive brand is the only product on the market. By delaying the first filer's entry, the pact also delays the time when other, later, generics enter. And the pact prevents the brand from marketing an AG during the 180-day exclusivity period, reducing price competition during that period, particularly price competition that would otherwise occur between the first filer's generic and the brand's AG.

109. 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."[43]

Courts agree that no-AG agreements are a form of payment actionable under Actavis and are anticompetitive.[44]

110. 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

[43] 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-trade- commission/p062105authgenstatementleibowitz.pdf.

[44] *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).

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

111. 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).

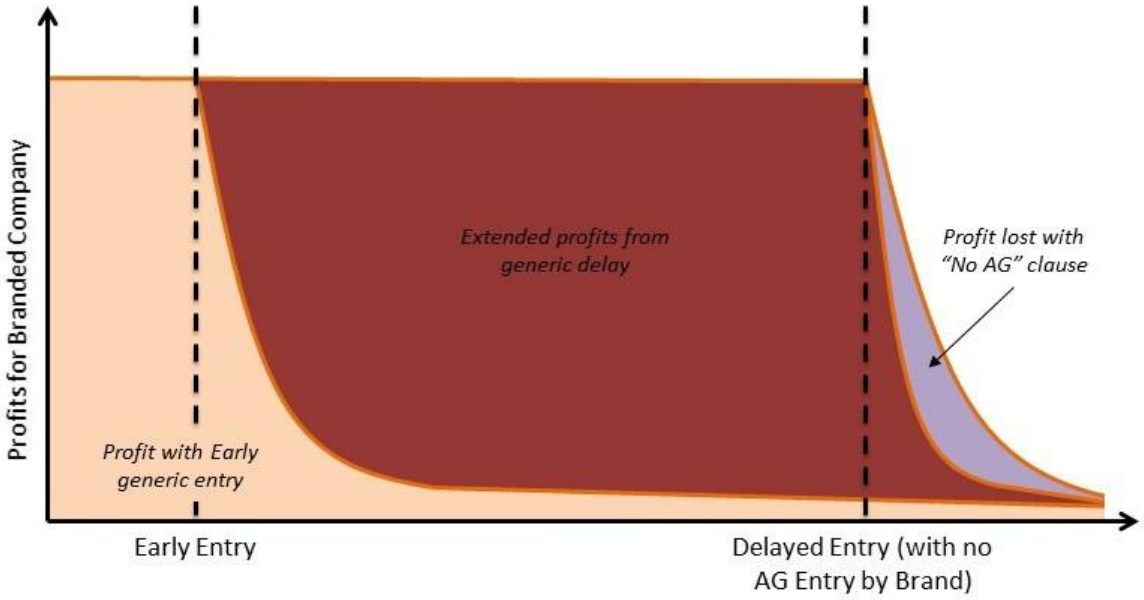

Figure 2: Impact of No-AG clause on brand profits

112. 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 (i) if the generic launches at risk, it could (theoretically) later be found to infringe a valid patent and (ii) 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.

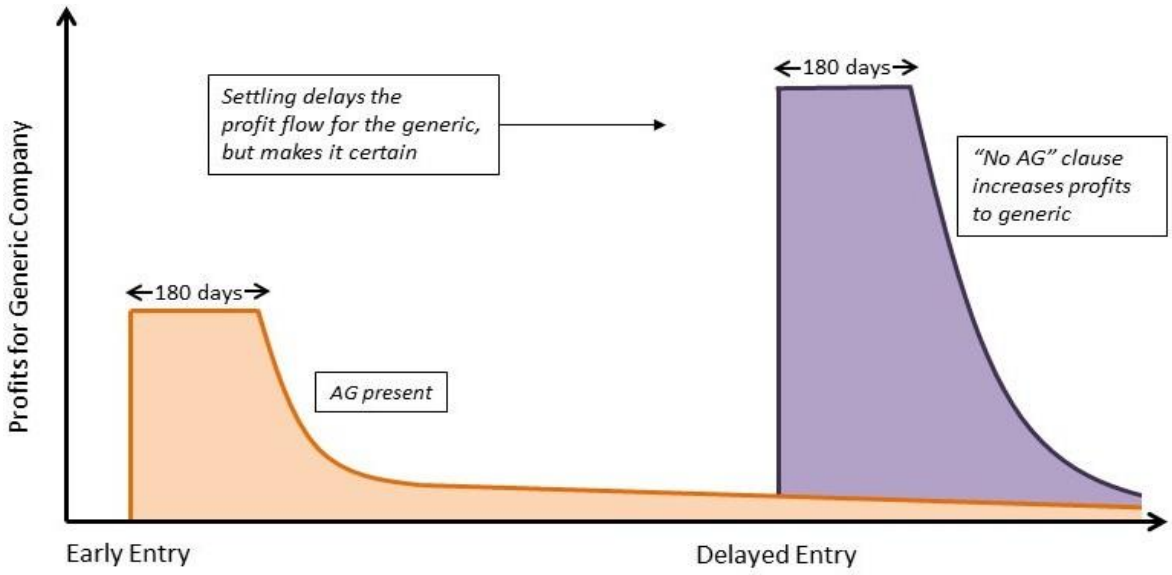

Figure 3: Impact of No-AG Promise on Generic's Profits

113. 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.

H. Regulatory Impact of Pay-for-Delay Agreements on Final Approval.

114. Generic companies that receive payments to delay the market entry of their generics for a period of years have no regulatory or economic incentive to seek final approval for their ANDAs until much closer in time to the agreed-upon, purchased launch date. Their resources are better spent on other ANDAs that have more immediate launch potentials and it is not in their best interest to obtain final approval yet not launch in the near term as it tends to raise anticompetitive red flags. The same is also true concerning the generics' manufacturing of commercial quantities of generic product intended for launch. Given the limited expiration shelf-life of generic drugs – which is usually 24 months -- generic companies have no incentive to obtain ingredients and manufacture commercial quantities of product too far ahead of agreed-upon launch dates.

115. It is also not unusual for generic companies that have entered into pay-for-delay agreements with brand companies to use the interim period of time between the agreement and the delayed entry date to make adjustments to certain aspects of their ANDA that would otherwise not be made or would ordinarily be made post-approval and post-commercial launch.

116. It is also often the case that FDA is made aware of paragraph IV patent litigation settlements between brand and generic companies, as well as the agreed upon entry date. Given the limited resources of FDA, it has no interest in working to grant immediate final approval to ANDA's for generic drugs that are not slated, because of an agreement between the generic and brand companies, to enter the market for several years. Most often, and regardless of its knowledge or lack of knowledge about patent litigation settlements, FDA will simply wait, or even require that generic companies initiate additional, final approval activities nearer in time to the date that the generics know they are eligible or desire to enter the market with their ANDA-based products.

117. In the context of the facts at issue here, after settling with AstraZeneca in 2011 with a generic entry date years ahead in exchange for a reverse payment, Handa (and eventually Par), and Accord had no interest in obtaining, and no need to obtain, final approval of their respective generic Seroquel ANDAs in the near term, and the FDA, likewise, had no interest or need to grant such final approval until the agreed generic launch date was nearing.

118. As concerns Accord, the agreement between AstraZeneca and Accord delayed the launch of Accord's generic Seroquel 400 mg ANDA product until November 1, 2016. Thus, Accord and FDA geared their respective resources towards meeting that date in 2016, not an earlier period of time. Indeed, Accord's

400 mg generic Seroquel ANDA received final approval precisely on November 1, 2016, at which time it entered the market. The timing of final FDA approval was no coincidence, but a direct result of the agreed entry date that AstraZeneca had purchased with its large reverse payment to Accord.

119. As concerns Handa (and Par), AstraZeneca and Handa/Par delayed the launch of Handa's generic Seroquel 50, 150, 200 and 300 mg products until November 1, 2016, and Handa/Par had the additional contractual right and economic incentive to launch and sell generic product as supplied to it by AstraZeneca for at least 180 days at least in part because Handa/Par could avoid manufacturing responsibilities and costs by distributing product supplied by AstraZeneca. Thus, Handa (and Par) had no incentive to seek final approval for its ANDA versions of these milligram strengths until approximately 180-days after November 1, 2016. Handa (and eventually Par) and FDA geared their respective resources towards final approval of its ANDA-based products for May 2017. Par launched less expensive generic versions of 50, 150, 200 and 300 mg on November 1, 2016 with product as supplied by AstraZeneca and thereafter obtained final ANDA approval from FDA for those same milligram strengths in early May 2017. Again, this sequence of events was no coincidence, but a direct result of the agreed entry date that AstraZeneca had purchased with its large reverse payment to Handa.

I. Pay-for-Delay Agreements with First-Filers Can Create Bottlenecks for Later-Filing Generics.

120. An anticompetitive agreement entered into between the brand and the first-filer generic often creates a bottleneck preventing the later ANDA filers from launching, since the later ANDA filers cannot launch earlier than 180 days after the first-filer's launch.

121. Later ANDA filers have more modest financial prospects than the first-filer generic because the later filers have no expectation of any form of market exclusivity, such as the first-filer's 180-day exclusivity. By the time the later ANDA filers enter the market, they typically must compete with the brand, the first-filer, an authorized generic, and other later filers.

122. Nevertheless, in the absence of an anticompetitive agreement between the brand company and the first-filer, the later ANDA filers have procompetitive incentives. They are motivated to enter the market as early as possible because the sooner they enter, the sooner they can earn profits by competing for sales in the market, which results in lower prices.

123. However, later ANDA filers cannot obtain final FDA approval to enter the market until the first-filer's 180-day exclusivity has run or been forfeited. An agreement between the brand and the first-filer that delays the first-filer's entry thus creates a bottleneck that, by delaying the first filer's 180-day exclusivity, consequently delays the later ANDA filers' entry as well.

124. Agreements causing such bottlenecks are fundamentally anticompetitive and are contrary to the goals of the Hatch-Waxman statutory scheme. In particular, they extend the brand manufacturer's monopoly profits by blocking and delaying access to more affordable generic drugs, forcing purchasers to buy the more-expensive brand drug instead.

VI. FACTS

A. AstraZeneca's Seroquel XR Patents.

125. AstraZeneca Pharmaceuticals LP is the holder 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 referred to as quetiapine fumarate. AstraZeneca Pharmaceuticals LP markets these tablets in the United States under the trademark Seroquel® XR.

126. 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 ("PTE") of 1,651 days under 35 U.S.C. 156. Based upon the PTE, the '288 Patent expired on September 26, 2011.

127. 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.

128. AstraZeneca submitted the ’288 and ’437 Patents for listing in the FDA Orange Book under NDA No. 22-047. AstraZeneca Pharmaceuticals LP received pediatric exclusivity[45] 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.

129. 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.

130. 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.

[45] 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.

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.

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

132. 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, 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.

133. Accord filed ANDA No. 90-681 for a generic version of extended-release quetiapine fumarate on June 18, 2008.[46] 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.

134. 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 under 21 U.S.C. 355G)(5)(B)(iv): 180-days of marketing exclusivity during which the FDA would not give final approval to any other ANDA filer's generic equivalent of Seroquel XR (Handa for the 50mg, 150mg, 200mg, 300mg strengths and Accord for the 400mg strength).

135. 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,

[46] *See* Final Approval Letter from Carol Holquist, Deputy Director, Office of Regulatory Operations, FDA, to Sabita Nair, Senior Director, Regulatory Affairs, Accord Healthcare Inc., at 2 (Nov. 1, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/090681Orig1s000TAltr.pdf; FDA, Paragraph IV Patent Certifications (Dec. 1, 2020), https://www.fda.gov/media/133240/download.

2008),[47] 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.[48] The paragraph IV notice letters included certifications that Handa intended to seek final FDA approval to market and to launch its AB-rated generic Seroquel XR products before the expiration of the '437 patent. As required under the Hatch-Waxman Act, the paragraph IV notice letters also 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.

136. Likewise, Accord sent AstraZeneca two separate paragraph IV notice letters dated September 5, 2008 and January 23, 2009.[49] 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 not be infringed," by Accord's generic Seroquel XR products.[50] The paragraph IV notice letters included certifications that Accord intended to seek final FDA approval to market and to launch its AB-rated generic Seroquel XR products before the

[47] Stipulated Facts, ¶ 26.

[48] 21 U.S.C. § 355(j)(2)(B)(iv)(II).

[49] *Id.*, ¶ 27.

[50] 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

expiration of the '437 patent. 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 Commences Patent Litigation - Seroquel XR Patent Litigation.

137. In response to Handa's notice letters dated July 10, 2008 and July 23, 2008, AstraZeneca filed civil action no. 08-cv-3773 in the District of New Jersey on July 28, 2008. In response to Handa's paragraph IV letter dated October 16, 2008, AstraZeneca filed civil action no. 08-cv-5328 in the District of New Jersey on October 28, 2008. In response to Handa's paragraph IV letter dated November 14, 2008, AstraZeneca filed civil action no. 08-cv-5997 in the District of New Jersey on December 8, 2009.

138. In response to Accord's paragraph IV letter dated September 5, 2008, on September 26, 2008, AstraZeneca filed civil action no. 08-cv-04804 against Accord in the District of New Jersey. In response to Accord's paragraph IV letter dated January 23, 2009, AstraZeneca filed civil action no. 09-cv-00619 against Accord in the District of New Jersey on February 10, 2009.

139. In addition to Handa and Accord several other generic drug companies filed subsequent ANDAs seeking approval of generic versions of Seroquel XR ("the Later-Filing Generics"). AstraZeneca subsequently filed seven patent infringement lawsuits relating to generic Seroquel XR against four of the Later-Filing Generics in the District of New Jersey. On April 8, 2010, AstraZeneca filed civil action no. 10-cv-1835 against Anchen Pharmaceuticals, Inc. and Anchen, Inc. (together, "Anchen"). On August 16, 2010, AstraZeneca filed civil action no. 10-cv-4203 against Osmotica Pharmaceutical Corporation ("Osmotica"). Also, on August 16, 2010, AstraZeneca filed civil action no. 10-cv-4205 against Torrent Pharmaceuticals Limited and Torrent Pharma Inc. (together, "Torrent"). On September 28, 2010, AstraZeneca filed civil action no. 10-cv-4971 against Torrent. On October 22, 2010, AstraZeneca filed civil action no. 10-cv-5519 against Mylan Pharmaceuticals, Inc. and Mylan, Inc. (together, "Mylan"). On April 29, 2011, AstraZeneca filed civil action no. 11-cv-2483 against Mylan. Also on April 29, 2011, AstraZeneca filed civil action no. 11-cv-2484 against Osmotica. The foregoing seven patent infringement lawsuits are referred to herein as "the Later-Filer Seroquel XR. Patent Litigation."

140. The Handa Seroquel XR Patent Litigation, the Accord Seroquel XR Patent Litigation, and the Later-Filer Seroquel XR Patent Litigation are referred to collectively as "the Seroquel XR Patent Litigation."

141. 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."[51]

142. On information and belief, the 30-month stay preventing final FDA approval of Handa's ANDA expired at various dates in April 2011, although Handa and AstraZeneca entered into a stipulation that Handa would not seek to enter the market prior to March 26, 2012. On information and belief, the 30-month stay preventing final FDA approval of Accord's ANDA also was set to expire in 2011.

143. On or about September 29, 2011, as further described below, AstraZeneca reached a settlement with Handa resolving the Handa Seroquel XR Patent Litigation. Therefore, some or all of Handa's defenses in the Handa Seroquel XR Patent Litigation were never adjudicated.

144. On or about October 5, 2011, AstraZeneca reached a settlement with Accord resolving the Accord Seroquel XR Patent Litigation. Therefore, on information and belief some or all of Accord's defenses in the Accord Seroquel XR Patent Litigation were never adjudicated.

145. AstraZeneca and the Later-Filing Generics did not settle their litigation prior to trial. The Later-Filer Seroquel XR Patent Litigation proceeded to a bench

[51] *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 vs. Handa Pharm., LLC, et al*, Civ. No. 3:10-cv-01835, Dkt 69, p. 7.

trial in October 2011. At the trial, three of the Later-Filing Generics - namely, Anchen, Osmotica, and Mylan - did not advance a non-infringement defense, 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.[52]

146. The generic Seroquel XR product of the fourth Later-Filing Generic- *i.e.*, Torrent - did not use HPMC but did use a "naturally-occurring hydrophilic polymer" sold under the brand name Viscarin 209 that "hydrates and swells in the presence of water."[53] The district court in the Later-Filer Seroquel XR Patent Litigation 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.[54]

D. Handa's Unadjudicated Defenses Were Meritorious.

147. Unlike the Later-Filing Generics, Handa successfully designed around the '437 Patent by developing a non-infringing product that did not contain a

[52] See *AstraZeneca Pharm., LP*, 2012 WL 1065458, at *8.

[53] *Id.* at *11.

[54] *Id.* at *13.

"gelling agent" as required by each of the claims of the '437 Patent. Instead of using a hydrophilic "gelling agent," Handa's products used a hydrophobic compound known as HVO. Each of the Later-Filing Generics, in contrast, used hydrophilic compounds that formed gels when placed in contact with water. As explained below, 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.

148. 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").

149. Handa disclosed the '288 and '437 Patents as prior art in the applications that led to the Handa '637A Patent and Handa '637B Patent. By issuing the Handa '637A Patent and Handa '637B Patent despite AstraZeneca's '288 and '479 Patents, the examiner necessarily determined that the claimed compositions in

the Handa '637A Patent and in the Handa '637B Patent were patentably distinct from the compositions disclosed and claimed in AstraZeneca's '288 and '479 Patents.

150. As Handa's patents explain, HVO is a "hydrophobic" material that is "nongelling":

> Examples of hydrophobic materials that can be used to form a non-gelling or non-swelling controlled release matrix for the atypical antipsychotic drug include beeswax, white wax, emulsifying wax, hydrogenated vegetable oil, hydrogenated castor oil, icrocrystalline 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.[55]

151. 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

[55] '637A Patent at 6:24-39.

"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, particularly a hydrophilic substance, which forms a gel when in contact with water…"[56]

152. Although Handa settled before trial in the Seroquel XR Patent Litigation, evidence and arguments at the trial for the generics that did not settle 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.[57]

153. During the questioning of AstraZeneca's expert regarding Viscarin 209, the hydrophilicity of the compound was a focal point of the examination:

Q. Can you explain what part of the '437 patent informs you what is contemplated by the word "gel"?

[56] '437 Patent at 2:43-45.

[57] Later-Filer Seroquel XR. Patent Litigation Trial Transcript (Oct. 3, 2011) at 8.

A. Go back to the patent.

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.[58]

154. This questioning, like the text in the '437 Patent itself and AstraZeneca's opening argument, highlight why a hydrophobic compound like the 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.

155. 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 Pay For Delay Settlements.

156. On or about September 29, 2011, AstraZeneca and Handa settled the patent litigation and entered into the Handa Non-Compete Agreement.[59] Under the

[58] *Id*. (Oct. 3, 2011) at 74:7-79:25.

[59] *See US District Court Finds SEROQUEL XR Formulation Patent Valid and Infringed*, https://www.businesswire.com/news/home/20120329006628/en/District-Court-Finds-SEROQUEL-XR-Formulation-Patent (Mar. 29, 2012) ("On September 29, 2011, AstraZeneca granted Handa a license to the 5,948,437 patent effective November 1, 2016, or earlier under certain circumstances.").

terms of the Handa Non-Compete Agreement, Handa agreed to abandon the patent fight and delay its launch of generic extended-release quetiapine fumarate in the 50mg, 150mg, 200mg, and 300mg strengths until November 1, 2016. Handa also agreed to abandon the patent fight with respect to the 400mg strength as well, even though it did not hold first filer status for that strength. 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.

157. On or about October 5, 2011, AstraZeneca and Accord settled the patent litigation and entered into the Accord Non-Compete Agreement[60] pursuant to which Accord agreed to delay its launch of the 400mg strength generic extended-release quetiapine fumarate, for which Accord was the first ANDA filer, until November 1, 2016 and AstraZeneca agreed to not launch an authorized generic version of the 400mg strength for 180 days thereafter. In accordance with this agreement, Accord in fact did not launch its generic 400mg extended-release quetiapine fumarate

[60] *See AstraZeneca enters into a settlement agreement with Accord Healthcare, Inc. and Intas Pharmaceuticals Ltd regarding US SEROQUEL XR® patent litigation* (Oct. 5, 2011), https://www.astrazeneca.com/media-centre/press-releases/2011/AstraZeneca-enters-into-a-settlement-agreement-with-Accord-Healthcare-Inc-and-Intas-Pharmaceuticals-Ltd-regarding-US-SEROQUEL-XR-patent-litigation-05102011.html#modal-historic-confirmation.

product until November 1, 2016 and AstraZeneca did not launch an authorized generic version of Seroquel XR 400mg until May 1, 2017.

158. The purpose and effect of the Handa Non-Compete Agreement and the Accord Non-Compete Agreement was to prevent AstraZeneca from facing competition in the way of lower-priced generic entrants 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.

159. On October 29, 2012, Par announced that it had acquired Handa's ANDA No. 90-482.[61] 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 product, pursuant to its agreement with Par."[62] 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

[61] *See Par Pharmaceutical Acquires Rights to Market and Distribute Generic Seroquel XR® in the U.S.* (Oct. 29, 2012), https://www.prnewswire.com/news-releases/par-pharmaceutical-acquires-rights-to-market-and-distribute-generic-seroquel-xr-in-the-us-176239031.html.

[62] https://handapharma.com/handa-pharmaceuticals-inc-announces-fda-approval-for-generic-version-of-astrazenecas-seroquel-xr-extended-release-tablets/.

became an active participant and co-conspirator 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.

160. It is evident that AstraZeneca always intended to launch an AG to compete with Handa/Par's and Accord's generic Seroquel XR products because AstraZeneca did so on the first day it was allowed to under the terms of the Handa and Accord Non-Compete Agreements.[63] But for the Non-Compete Agreements, AstraZeneca would have launched 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 Non-Compete Agreements, AstraZeneca waited 180 days after the Handa/Par's and Accord's launches to launch a competitive AG generic Seroquel XR.

161. Accord received FDA tentative approval for its ANDA No. 90-0681 on December14, 2010 and final approval on November 1, 2016.[64] Accord's 400mg generic Seroquel XR product would have received final approval before November

[63] DailyMed, LABEL: QUETIAPINE FUMARATE EXTENDED RELEASE, https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=7283b14f-023d-466f-a7eb-4356803d7c65&audience=consumer (showing AstraZeneca with a May 1, 2017 launch date as an "NDA Authorized Generic").

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

1, 2016 absent the Accord Non-Compete Agreement. Handa received tentative approval from FDA on December 9, 2010.[65] Par obtained final FDA approval for ANDA No. 90-482 on May 9, 2017, almost exactly the end of its 180-day exclusivity period.[66] Absent the Handa Non-Compete 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. As a result of the unlawful agreement and agreed upon delayed entry date, Accord and Handa/Par had no incentive to continue to prioritize obtaining final approval. But for the unlawful agreement and corresponding agreed upon delayed entry date, both Accord and Handa/Par would have been incentivized, and would have obtained final approval earlier than they did and entered the market earlier than November 1, 2016.

162. On information and belief, AstraZeneca provided Handa/Par and Accord with licenses under its'437 Patent, and reverse payments in the form of

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

[66] *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-fda-approval-for-generic-version-of-astrazenecas-seroquel-xr-extended-release-tablets/.

agreements not to launch an AG version of Handa/Par's and Accord's respective strengths of generic Seroquel XR. AstraZeneca was motivated to make these payments because it was better than AstraZeneca's risk of an adverse ruling on its patent, which would have caused much earlier generic launch of Seroquel XR.

163. But for the Non-Compete 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: (1) the conclusion of the 30-month stays (or upon termination of the stipulation to delay marketing until March 27, 2012); (2) victory 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. *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").

164. AstraZeneca had huge incentives to avoid competition from Handa/Par and Accord by entering into the Non-Compete Agreements. By the time the Non-

Compete Agreements were executed on or about September 29, 2011, Seroquel XR was generating nearly a billion dollars per year in revenues for AstraZeneca. 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. Therefore, AstraZeneca had enormous incentives to avoid competition from Handa and Accord by entering into the Non-Compete Agreements.

165. It did not make economic sense for AstraZeneca to wait to launch an AG generic Seroquel XR until after Handa/Par's and Accord's 180-day exclusivity period. It would have been more profitable to AstraZeneca to have launched AG Seroquel XR immediately upon Handa/Par's and Accord's launches. 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.

166. On information and belief, 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.

167. The Non-Compete 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.

168. 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]."[67] 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.

169. 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.

170. As discussed above, an AG typically captures approximately 50% of the generic unit sales during the first 180-days of generic marketing. Therefore,

[67] 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-short-termeffects-and-long-term-impact-report-federal-trade-commission.pdf., at ii.

AstraZeneca's promise not to launch an AG Seroquel XR constituted very large payments to Handa/Par and Accord.

171. 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.[68] 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).

172. 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 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 million * 0.9). Therefore, the generic Seroquel XR sales revenue that would have reasonably

[68] Handa Pharmaceuticals Announces Endo Begins Shipping Generic Version of AstraZeneca's SEROQUEL XR® (Nov. 1, 2016), https://handapharma.com/handa-pharmaceuticals-announces-endo-begins-shipping-generic-version-of-astrazenecas-seroquel-xr/.

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been anticipated by Handa/Par during the 180-day exclusivity period without competition from an AG would be approximately $327.96 million.

173. Handa/Par's expectations would have differed dramatically if AstraZeneca had not promised to refrain from competing with authorized generic 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.[69] 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 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.[70] 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 million * 0.5).

[69] FDA, Generic Competition and Drug Prices (current as of Dec. 3, 2020), https://www.fda.gov/about-fda/center-drug-evaluation-and-research/generic-competition-and-drug-prices.

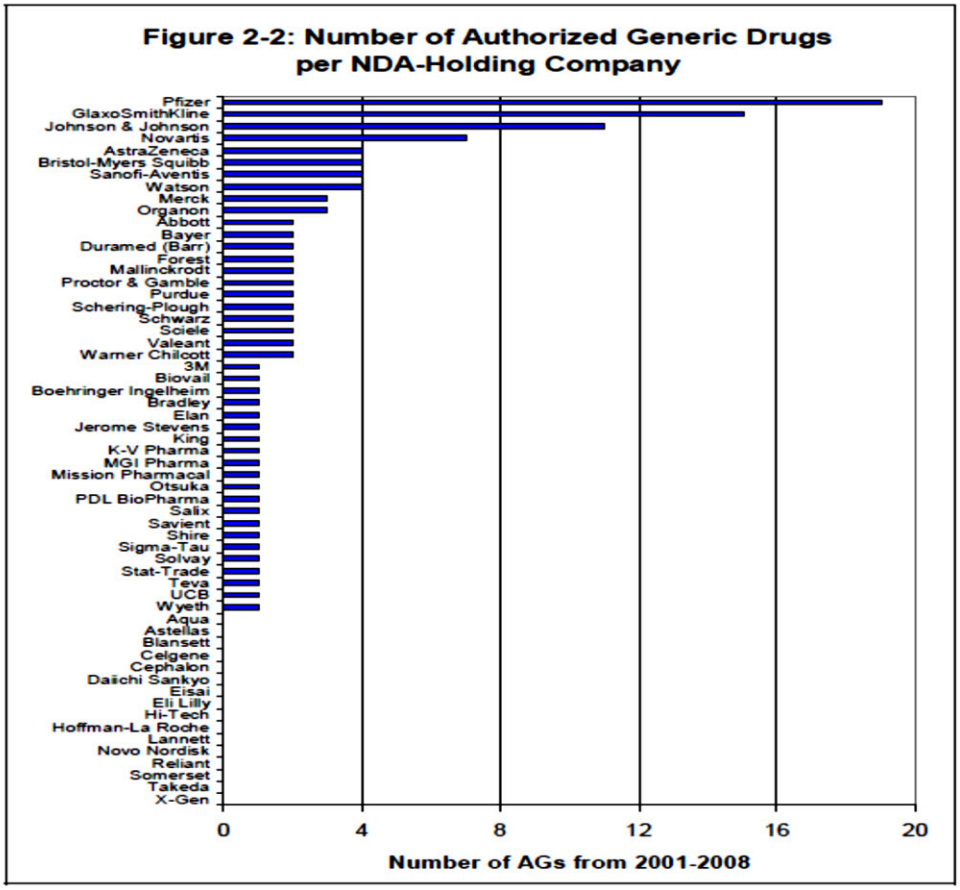
[70] FTC, Authorized Generic Drugs at vi (The Federal Trade Commission has concluded that, when free from competition from an authorized generic, "the first-filer's revenue will approximately double" during the first six months of generic competition, compared to what the first filer would make if it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

174. 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 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.

175. 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.[71]

176. 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.[72]



[71] 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).

[72] 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.").

177. 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.

178. 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.

179. 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.

180. 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.

181. 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 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).

182. 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: during patent litigation (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.[73] At the same time, AstraZeneca would have competed for

[73] As the Supreme Court stated, 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.

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.

183. On information and belief, and based on the fact that several Later-Filing Generics actually launched 180 days after Handa/Par and Accord, several other Later-Filing Generics 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 Later-Filing Generics 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 Later-Filing Generics, would have launched earlier, along with Handa/Par's generic, Accord's generic, and the authorized generic, lowering generic Seroquel XR prices further still.

184. 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

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.

185. 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.

186. 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).

187. But for Defendants' ongoing performance and participation in the Non-Competition 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' ongoing, illegal, anticompetitive conduct, generic versions of Seroquel XR would have become available much earlier, either through: (1) a Handa and/or Accord patent victory; (2) at-risk launch; or (3) agreement(s) that did not include unlawful payments for delay. Plaintiffs and other Class members would have paid lower prices for Seroquel XR and its generic equivalents. Defendants, by their conduct, have injured Plaintiffs and other Class members by causing them to pay millions of dollars in overcharges on their purchases of extended-release quetiapine fumarate.

VII. MARKET POWER AND DEFINITION

188. At all relevant times prior to November 1, 2016, AstraZeneca had and maintained monopoly power in the market for Seroquel XR and its generic equivalents because it had the power to maintain the price of extended-release

quetiapine fumarate at supracompetitive levels without losing sales so as to make the supracompetitive price unprofitable.

189. Direct proof exists that AstraZeneca had monopoly power over the price of extended-release quetiapine fumarate. Such direct evidence includes, among other things, the abnormally-high price-cost margins enjoyed by AstraZeneca prior to entry of generic Seroquel XR and AstraZeneca's ability to profitably maintain the price of Seroquel XR well above competitive levels.

190. Manufacturers attempt to differentiate brand name drugs like Seroquel XR based on features and benefits (including safety and efficacy), not based on price. Doctors and patients are generally price-insensitive when prescribing and taking prescription drugs like Seroquel XR. This is due in part to the presence of insurance that bears much of the cost of prescriptions and other institutional features of the pharmaceutical marketplace. Different patients may respond differently to different drugs and even drugs within its same therapeutic class do not constrain the price of Seroquel XR. In addition, consumers do not choose prescription drugs directly; they must be prescribed by a physician who does not pay for the drug and may not be aware of its price. This "price disconnect" blunts price competition among different drugs, even if they are prescribed for similar conditions.

191. Other drugs that are not AB-rated to Seroquel XR cannot be substituted automatically for Seroquel XR by pharmacists, do not exhibit substantial cross-price

elasticity of demand with Seroquel XR, and thus are not economic substitutes for, nor reasonably interchangeable with, Seroquel XR.

192. Products other than generic Seroquel XR are not economic substitutes for Seroquel XR or its generic equivalents, and the existence of other products used to treat depression, bipolar disorder, schizophrenia, or other illnesses treated by Seroquel XR did not significantly constrain AstraZeneca's pricing of Seroquel XR. On information and belief, AstraZeneca has never lowered the price of Seroquel XR in response to the pricing of other branded or generic drugs (other than generic Seroquel XR). AstraZeneca repeatedly raised Seroquel XR prices, by more than 5% each year, by an average of 1211% per year, over the period from when brand Seroquel XR launched through when generic Seroquel XR launched. Despite these repeated Seroquel XR price increases, Seroquel XR did not lose substantial sales to any product used to treat depression, bipolar disorder, schizophrenia, or other illnesses treated by Seroquel XR (other than generic Seroquel XR, when it launched). In addition, AstraZeneca repeatedly raised Seroquel XR prices without losing substantial sales to other products despite the launches of lower-cost, generic versions of other products approved to treat the same indications as Seroquel XR, including the 2012 launch of generic Seroquel IR (an immediate-release version of the same molecule as Seroquel XR) and the 2015 entry of generic Abilify (another drug approved to treat schizophrenia, depression, and bipolar disorder).

193. AstraZeneca needed to control only the sales of Seroquel XR and its generic equivalents, and no other products, in order to maintain the price of Seroquel XR profitably at supracompetitive prices. Only the market entry of a competing, generic version of Seroquel XR would render AstraZeneca unable to profitably maintain its prices of Seroquel XR without losing substantial sales.

194. To the extent Plaintiffs are legally required to prove monopoly power circumstantially by first defining a relevant product market, the relevant market is Seroquel XR (in all its forms and dosage strengths) and generic Seroquel XR (in all its forms and dosage strengths). The relevant geographic market is the United States.

195. 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 tablets.

196. A small but significant non-transitory price increase above the competitive level for Seroquel XR by AstraZeneca would not cause a loss of sales sufficient to make the price increase unprofitable.

197. At competitive price levels, Seroquel XR does not exhibit significant positive cross-price elasticity of demand with any product other than generic Seroquel XR.

198. AstraZeneca, at all relevant times, enjoyed high barriers to entry with respect to competition to the above-defined relevant product market due to patent and other regulatory protections, and high costs of entry and expansion.

199. During the relevant period, Defendants' anticompetitive conduct has significantly damaged competition and consumers through a reduction of output and higher prices caused by an elimination or reduction of lower cost generic Seroquel XR throughout the United States.

200. AstraZeneca has maintained and exercised the power to exclude and restrict competition to Seroquel XR and its AB-rated generics. AstraZeneca sold Seroquel XR at prices well in excess of marginal costs and substantially in excess of the competitive price, and enjoyed high profit margins.

201. At all relevant times prior to November 1, 2016, AstraZeneca's market share in the relevant market was 100%, implying substantial monopoly power.

VIII. MARKET EFFECTS

202. The Defendants willfully and unlawfully maintained their market power by engaging in an overarching scheme to exclude competition. The Defendants 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. The Defendants carried out the scheme with the

anticompetitive intent and effect of maintaining supra-competitive prices for extended-release quetiapine fumarate ezetimibe tablets.

203. The Defendants' 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 the Defendants to maintain a monopoly and exclude competition in the market for Seroquel XR and its AB-rated generic equivalents, to the detriment of the Plaintiffs and all other members of the End-Payor purchaser Class.

204. The Defendants' 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' 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.

205. The Defendants' illegal acts and conspiracy to delay generic competition for Seroquel XR caused the Plaintiffs and all Class members to pay more than they would have paid for extended-release quetiapine fumarate absent this illegal conduct.

206. If generic competitors had not been unlawfully prevented from entering

the market earlier and competing in the relevant markets, End-Payor purchasers, such as the Plaintiffs and Class members, 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.

207. Thus, the Defendants' unlawful conduct deprived the Plaintiffs and members of the Class of the benefits from the competition that the antitrust laws are designed to ensure.

IX. ANTITRUST IMPACT AND IMPACT ON INTERSTATE COMMERCE

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

209. During the relevant time period, the Plaintiffs and members of the Class purchased substantial amounts of Seroquel XR and/or generic Seroquel XR indirectly from the Defendants. As a result of the Defendants' illegal conduct, the Plaintiffs and the members of the Class were compelled to pay, and did pay, artificially inflated prices for Seroquel XR and generic Seroquel XR. Those prices were substantially greater than the prices that members of the Class would have paid absent the illegal conduct alleged herein, because: (1) the price of brand-name

Seroquel XR was artificially inflated by Defendants' illegal conduct, (2) Class members were 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' illegal conduct. The supracompetitive prices were paid at the point of sale, which is where Plaintiffs and the End-Payor Class suffered antitrust impact.

210. As a consequence, Plaintiffs and members of the Class have sustained substantial damages to their business and property in the form of overcharges. The full amount and forms of components of such damages will be calculated after discovery and upon proof at trial. Commonly used and well-accepted economic models can be used to measure both the extent and the amount of the supracompetitive charge passed through the chain of distribution to end payors such as Plaintiffs and the members of the Class.

211. General economic theory recognizes that any overcharge at a higher level of distribution generally results in higher prices at every level below. *See* Hovenkamp, FEDERAL ANTITRUST POLICY, THE LAW OF COMPETITION AND ITS PRACTICE (1994) at 624. According to Professor Hovenkamp, "[e]very person at every stage in the chain will be poorer as a result of the monopoly price at the top." Professor Hovenkamp also acknowledges that "[t]heoretically, one can

calculate the percentage of any overcharge that a firm at one distribution level will pass on to those at the next level."

212. Further, the institutional structure of pricing and regulation in the pharmaceutical drug industry assures that overcharges at the higher level of distribution are passed on to end payors. Wholesalers and retailers passed on the inflated prices of Seroquel XR and AB-rated generic Seroquel XR to Plaintiffs and the Class of end-payors defined herein. AstraZeneca's anticompetitive actions enabled it to indirectly charge End-Payors prices in excess of what it otherwise would have been able to charge absent its unlawful actions with Handa/Par and Accord.

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

214. The inflated prices the End-Payor Class paid are traceable to, and the foreseeable result of, the overcharges by AstraZeneca and Handa/Par and Accord.

215. During the relevant time period, the Defendants used various devices to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign wire commerce. All the Defendants engaged in illegal activities, as charged in herein, within the flow of, and substantially affecting, interstate commerce.

216. The Defendants' conduct was within the flow of, and was intended to have and did have a substantial effect on, interstate commerce of the United States, including in this District.

217. During the Class Period, each Defendant, or one or more of each Defendant's affiliates, used the instrumentalities of interstate commerce to join or effectuate the scheme. The scheme in which the Defendants participated had a direct, substantial, and reasonably foreseeable effect on interstate commerce.

X. EFFECT ON INTRASTATE COMMERCE

218. During the relevant time period, branded Seroquel XR, manufactured and sold by AstraZeneca, was shipped into each state and was sold to or paid for by End-Payors. Beginning around November 1, 2016, generic Seroquel XR, manufactured and/or sold by Handa/Par and Accord, was shipped into each state and was sold to or paid by End-Payors.

219. During the relevant time period, in connection with the purchase and sale of branded Seroquel XR, money exchanged hands and business communications and transactions occurred in each state. Beginning around November 1, 2016, in connection with the purchase and sale of generic Seroquel XR, money exchanged hands and business communications and transactions occurred in each state.

220. Defendants' conduct as set forth in this Second Consolidated Amended Complaint had substantial effects on intrastate commerce in that, *inter alia*, retailers within each state were foreclosed from offering cheaper Seroquel XR and generic extended-release quetiapine fumarate to End-Payors purchasing inside each respective state, and Defendants entered into an unlawful anticompetitive agreement that affected commerce in each state.

XI. CONTINUING VIOLATION

221. This Complaint alleges a continuing course of conduct (including conduct within the limitations periods), and Defendants' unlawful conduct has inflicted continuing and accumulating harm within the applicable statutes of limitations. Thus, Plaintiffs and the members of the proposed Class can recover for damages that they suffered during any applicable limitations period.

222. As a result, Plaintiffs' and the proposed Class members' claims are timely under all applicable statutes of limitations affecting the Plaintiffs' and the proposed Class members' claims.

XII. CLASS ACTION ALLEGATIONS

223. Plaintiffs bring this action on their own behalf and on behalf of all others similarly situated as a class action under Rules 23(a) and 23(b)(3) of the Federal Rules of Civil Procedure, seeking damages pursuant to the common law of unjust enrichment and the antitrust, unfair competition, and consumer protection

laws of the states listed below (the "Indirect Purchaser States"), and as representative of a class defined as follows:

> All persons and entities in the Indirect Purchaser States and territories who indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price of brand or generic Seroquel XR, other than for resale, at any time during the period from September 5, 2013 through and until the anticompetitive effects of Defendants' challenged conduct cease (the "Class Period").

224. Excluded from the Class are:

a. Defendants and their counsel, officers, directors, management, employees, subsidiaries, and affiliates;

b. all federal governmental entities;

c. all persons or entities who purchased Seroquel XR for purposes of resale;

d. fully insured health plans (*i.e.*, health plans that purchased insurance from another third-party payor covering 100% of the plan's reimbursement obligations to its members);

e. any "flat co-pay" consumers whose purchases of Seroquel XR were paid in part by a third-party payor and whose co-payment was the same regardless of the retail purchase price;

f. pharmacy benefit managers; and

g. all judges assigned to this case and any members of their immediate families.

225. Members of the Class are so numerous and widely geographically dispersed throughout the United States and its territories that joinder is impracticable. Plaintiffs believe that there are hundreds of thousands of members of

the Class, in an amount to be determined in discovery and at trial. Further, the identities of Class members will be readily ascertainable through business records kept in regular order.

226. Plaintiffs' claims are typical of the claims of members of the Class. Plaintiffs and all members of the Class were damaged by the same wrongful conduct by Defendants, and all paid artificially inflated prices for Seroquel XR and were deprived of the benefits of competition from less expensive generic versions as a result of Defendants' conduct.

227. Plaintiffs will fairly and adequately protect and represent the interests of the Class. Plaintiffs' interests are coincident with, and not antagonistic to, the Class.

228. Plaintiffs are represented by counsel who are experienced and competent in the prosecution of class action litigation, and who have particular experience with class action litigation involving the pharmaceutical industry.

229. Questions of law and fact common to members of the class predominate over questions, if any, that may affect only individual class members, because Defendants have acted on grounds generally applicable to the entire class. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

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

(a) whether Defendants unlawfully maintained monopoly power through all or part of its overarching scheme;

(b) whether Defendants' anticompetitive scheme suppressed generic competition to Seroquel XR;

(c) as to those parts of Defendants' challenged conduct for which such justifications may be offered, whether there exist cognizable, non-pretextual procompetitive justifications, which Defendants' challenged conduct was the least restrictive means of achieving, that offset the harm to competition in the markets in which Seroquel XR and generic Seroquel XR is sold;

(d) whether direct proof of Defendants' monopoly power is available, and if available, whether it is sufficient to prove AstraZeneca's monopoly power without the need to also define a relevant market;

(e) to the extent a relevant market or markets must be defined, what that definition is, or those definitions are;

(f) determination of a reasonable estimate of the amount of delay Defendants' unlawful monopolistic, unfair, and unjust conduct caused;

(g) whether Defendants' scheme, in whole or in part, has substantially affected interstate commerce;

(h) whether the Defendants' scheme, in whole or in part, has substantially affected intrastate commerce;

(i) whether AstraZeneca and Handa/Par and Accord conspired to delay competition for Seroquel XR;

(j) whether, pursuant to the reverse payment agreement, AstraZeneca's promise not to compete against Handa/Par's and Accord's generic product constituted a payment;

(k) whether AstraZeneca's compensation to Handa/Par and Accord was large and unexplained;

(l) whether the reverse payment agreement created a bottleneck to further delay generic competition for Handa/Par and Accord;

(m) whether the reverse payment harmed competition;

(n) whether before November 1, 2016, AstraZeneca possessed the ability to control prices and/or exclude competition for Seroquel XR;

(o) Whether the Defendants' unlawful monopolistic conduct was a substantial contributing factor in causing some amount of delay of the entry of AB-rated generic Seroquel XR;

(p) whether Defendants' scheme, in whole or in part, caused antitrust injury to the business or property of Plaintiffs and members of the Class in the nature of overcharges; and

(q) the quantum of overcharges paid by the Class in the aggregate.

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

232. Plaintiffs know of no difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

XIII. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELEIF
For Monopolization Under State Law
(Asserted Against AstraZeneca)

233. Plaintiffs incorporate by reference all the allegations above as though fully set forth herein.

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

235. At all relevant times, AstraZeneca possessed substantial market power (*i.e.*, monopoly power) in the relevant market. AstraZeneca possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

236. 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 injured Plaintiffs and the Class. AstraZeneca's anticompetitive conduct was done with the specific intent to maintain its monopoly in the market for Seroquel XR in the United States.

237. AstraZeneca knowingly and intentionally engaged in this anticompetitive scheme to monopolize the extended-release quetiapine fumarate market as described above. 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 Plaintiffs and Class members would pay for Seroquel XR at supracompetitive prices.

238. 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.

239. 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.

240. Plaintiffs and members of the Class purchased substantial amounts of Seroquel XR and/or AB-rated generic equivalents indirectly from AstraZeneca and/or other manufacturers.

241. As a result of AstraZeneca's illegal conduct, Plaintiffs and members of the Class were compelled to pay, and did pay, more than they would have paid for their 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.

242. Had manufacturers of generic extended-release quetiapine fumarate entered the market and lawfully competed with AstraZeneca in a timely fashion, Plaintiffs and other members of the Class 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.

243. By engaging in the foregoing conduct, AstraZeneca violated the following state antitrust laws:

a. AstraZeneca intentionally and wrongfully maintained monopoly power in the relevant market in violation of Arizona Rev. Stat. §§ 44-1403, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in Arizona by Seroquel XR members of the Class.

b. AstraZeneca intentionally and wrongfully maintained monopoly power in the relevant market in violation of Cal. Bus. & Prof. Code §§ 17200, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in California by members of the Class.

c. AstraZeneca intentionally and wrongfully maintained monopoly power in the relevant market in violation of D.C. Code §§ 28-4503, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in the District of Columbia by members of the Class.

d. AstraZeneca intentionally and wrongfully maintained monopoly power in the relevant market in violation of Hawaii Rev. Stat. 480-1, *et seq*. with respect to purchases of Seroquel XR and AB-rated bioequivalents in Hawaii by members of the Class.

e. AstraZeneca intentionally and wrongfully maintained monopoly power in the relevant market in violation of Illinois Antitrust Act (740 Illinois Compiled Statutes 10/1, *et seq*.), with respect to purchases of Seroquel XR and AB-rated bioequivalents in Illinois by members of the Class.

f. AstraZeneca intentionally and wrongfully maintained monopoly power in the relevant market in violation of Iowa Code §§ 553.5 *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in Iowa by members of the Class.AstraZeneca intentionally and

wrongfully maintained monopoly power in the relevant market in violation of Me. Rev. Stat. Ann. 10, §§ 1102, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in Maine by members of the Class.

g. AstraZeneca intentionally and wrongfully maintained monopoly power in the relevant market in violation of Md. Com'l Law Code Ann. § 11-204(a), *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in Maryland by members of the Class.

h. AstraZeneca intentionally and wrongfully maintained monopoly power in the relevant market in violation of Mich. Comp. Laws Ann. §§ 445.773, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in Michigan by members of the Class.

i. AstraZeneca intentionally and wrongfully maintained monopoly power in the relevant market in violation of Minn. Stat. §§ 325D.49, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in Minnesota by members of the Class.

j. AstraZeneca intentionally and wrongfully maintained monopoly power in the relevant market in violation of Miss. Code Ann. §§ 75-21-3, *et*

seq., with respect to purchases of Seroquel XR and AB-rated bioequivalents in Mississippi by members of the Class.

k. AstraZeneca intentionally and wrongfully maintained monopoly power in the relevant market in violation of Mont. Code § 30-14-103, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in Montana by members of the Class.

l. AstraZeneca intentionally and wrongfully maintained monopoly power in the relevant market in violation of Neb. Code Ann. §§ 59-802, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in Nebraska by members of the Class.

m. AstraZeneca intentionally and wrongfully maintained monopoly power in the relevant market in violation of Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in Nevada by members of the Class.

n. AstraZeneca intentionally and wrongfully maintained monopoly power in the relevant market in violation of N.H. Rev. Stat. Ann. §§ 356.11, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in New Hampshire by members of the Class.

o. AstraZeneca intentionally and wrongfully maintained monopoly power in the relevant market in violation of N.M. Stat. Ann. §§ 57-1-2, *et seq.*,

with respect to purchases of Seroquel XR and AB-rated bioequivalents in New Mexico by members of the Class.

p. AstraZeneca intentionally and wrongfully maintained monopoly power in the relevant market in violation of N.Y. Gen. Bus. Law § 340, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in New York by members of the Class.

q. AstraZeneca intentionally and wrongfully maintained monopoly power in the relevant market in violation of N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in North Carolina by members of the Class.

r. AstraZeneca intentionally and wrongfully maintained monopoly power in the relevant market in violation of N.D. Cent. Code §§ 51-08.1-03, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in North Dakota by members of the Class.

s. AstraZeneca intentionally and wrongfully maintained monopoly power in the relevant market in violation of Or. Rev. Stat. § 646.730, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in Oregon by members of the Class.

t. AstraZeneca intentionally and wrongfully maintained monopoly power in the relevant market in violation of R.I. Gen. Laws §§ 6-36-5 *et seq.*,

with respect to purchases of Seroquel XR and AB-rated bioequivalents in Rhode Island by members of the Class.

u. AstraZeneca intentionally and wrongfully maintained monopoly power in the relevant market in violation of S.D. Codified Laws §§ 37-1-3.2, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in South Dakota by members of the Class.

v. AstraZeneca intentionally and wrongfully maintained monopoly power in the relevant market in violation of Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in Tennessee by members of the Class.

w. AstraZeneca intentionally and wrongfully maintained monopoly power in the relevant market in violation of Utah Code Ann. §§ 76-10-911, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in Utah by members of the Class.

x. AstraZeneca intentionally and wrongfully maintained monopoly power in the relevant market in violation of Vt. Stat. Ann. 9, §§ 2453, *et seq*., with respect to purchases of Seroquel XR and AB-rated bioequivalents in Vermont by members of the Class.

y. AstraZeneca intentionally and wrongfully maintained monopoly power in the relevant markets in violation of W.Va. Code §§ 47-18-4,

et seq., with respect to purchases of Seroquel XR and AB-rated bioequivalents in West Virginia by members of the Class.

z. AstraZeneca intentionally and wrongfully maintained monopoly power in the relevant market in violation of Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in Wisconsin by members of the Class.

244. Plaintiffs and members of the Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Claim. Their 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' conduct. These injuries are of the type the antitrust laws were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

245. Plaintiffs and the Class seek damages and multiple damages as permitted by law for their injuries by Defendants' violations of the aforementioned statutes.

Compliance with Notice Requirements

246. In accordance with the requirements of Arizona Revised Statute § 44-1415; Hawaii Revised Statute § 480-13.3(a); 815 Illinois Compiled Statutes §

505/10a(d); Nevada Revised Statute § 598A.210(3); New York General Business Law § 340(5); Rhode Island General Laws § 6-36-21; and Utah Code § 76-10-3109, on September 19, 2019, counsel sent letters by certified mail, return receipt requested, to:

a. Mark Brnovich, Attorney General of Arizona;

b. Clare E. Connors, Attorney General of Hawaii;

c. Kwame Raoul, Attorney General of Illinois;

d. Aaron Ford, Attorney General of Nevada;

e. Letitia James, Attorney General of New York;

f. Peter F. Neronha, Attorney General of Rhode Island; and

g. Sean Reyes, Attorney General of Utah,

informing them of the existence of the Class Action Complaint, identifying the relevant state antitrust provisions, and enclosing a copy of a Class Action Complaint.

SECOND CLAIM FOR RELIEF
For Conspiracy to Monopolize Under State Law
(Asserted Against All Defendants)

247. Plaintiffs incorporate by reference all the allegations above as though fully set forth herein.

248. 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.

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

250. Defendants 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 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 Plaintiffs and Class members 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.

251. The goal, purpose, and effect of Defendants' 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.

252. The goal, purpose and effect of Defendants' scheme was also to maintain and extend its monopoly power with respect to extended-release quetiapine fumarate products. Defendants' 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' scheme allowed Handa/Par and Accord to reap the benefits of reduced generic competition in the United States and to charge supracompetitive prices.

253. Plaintiffs and members of the Class purchased substantial amounts of Seroquel XR and/or AB-rated generic equivalents indirectly from Defendants and/or other manufacturers.

254. As a result of Defendants' illegal conduct, Plaintiffs and members of the Class were compelled to pay, and did pay, more than they would have paid for

their extended-release quetiapine fumarate requirements absent Defendants' illegal conduct. But for Defendants' 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.

255. Had manufacturers of generic extended-release quetiapine fumarate entered the market and lawfully competed with AstraZeneca in a timely fashion, Plaintiffs and other members of the Class 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.

256. But for Defendants' 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.

257. By engaging in the foregoing conduct, Defendants violated the following state antitrust laws:

a. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Arizona Rev. Stat. §§ 44-1402, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in Arizona by members of the Class.

b. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Cal. Bus. & Prof. Code §§ 16700 and 17200, *et seq*., with respect to purchases of Seroquel XR and AB-rated bioequivalents in California by members of the Class.

c. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of D.C. Code §§ 28-4503, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in the District of Columbia by members of the Class.

d. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in Florida by members of the Class, and this conduct constitutes a predicate act under the Florida Deceptive Practices Act.

e. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Hawaii Rev. Stat. 480-1, *et seq*., with respect to purchases of Seroquel XR and AB-rated bioequivalents in Hawaii by members of the Class.

f. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Illinois Antitrust Act

(740 Illinois Compiled Statutes 10/1, *et seq*.), with respect to purchases of Seroquel XR and AB-rated bioequivalents in Illinois by members of the Class.

g. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Iowa Code §§ 535.5, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in Iowa by members of the Class.

h. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in Kansas by members of the Class.

i. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Me. Rev. Stat. Ann. 10, §§ 1102, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in Maine by members of the Class.

j. Defendants intentionally and wrongfully engaged in conspiracy to monopolize the relevant market in violation of Md. Com'l Law Code Ann. § 11-204(a), *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in Maryland by members of the Class.

k. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in Michigan by members of the Class.

l. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Minn. Stat. §§ 325D.49, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in Minnesota by members of the Class.

m. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in Mississippi by members of the Class.

n. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Mont. Code § 30-14-103, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in Montana by members of the Class.

o. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Neb. Code Ann. §§

59-802, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in Nebraska by members of the Class.

p. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in Nevada by members of the Class.

q. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of N.H. Rev. Stat. Ann. §§ 356.11, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in New Hampshire by members of the Class.

r. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in New Mexico by members of the Class.

s. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of N.Y. Gen. Bus. Law §§ 340, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in New York by members of the Class.

t. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of N.C. Gen. Stat. §§ 75-

2.1, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in North Carolina by members of the Class.

u. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of N.D. Cent. Code §§ 51-08.1-02, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in North Dakota by members of the Class.

v. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Or. Rev. Stat. § 646.730, *et seq*., with respect to purchases of Seroquel XR and AB-rated bioequivalents in Oregon by members of the Class.

w. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of R.I. Gen. Laws §§ 6-36-5 *et seq*., with respect to purchases of Seroquel XR and AB-rated bioequivalents in Rhode Island by members of the Class.

x. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of S.D. Codified Laws Ann. §§ 37-1-3.2, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in South Dakota by members of the Class.

y. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in Tennessee by members of the Class.

z. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Utah Code Ann. §§ 76-10-911, *et seq*., with respect to purchases of Seroquel XR and AB-rated bioequivalents in Utah by members of the Class.

aa. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Vt. Stat. Ann. 9, §§ 2453, *et seq*., with respect to purchases of Seroquel XR and AB-rated bioequivalents in Vermont by members of the Class.

bb. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant markets in violation of W.Va. Code §§ 47-18-3, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in West Virginia by members of the Class.

cc. Defendants intentionally and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in Wisconsin by members of the Class.

258. Plaintiffs and members of the Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this claim. Their 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 they would have paid in the absence of Defendants' conduct. These injuries are of the type the antitrust laws were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

259. Plaintiffs and the Class seek damages and multiple damages as permitted by law for their injuries by Defendants' violations of the aforementioned statutes

THIRD CLAIM FOR RELIEF
Combination and Conspiracy in Restraint of Trade
(Asserted Against All Defendants)

260. Plaintiffs incorporate by reference all the allegations above as though fully set forth herein.

261. This claim is pled against all Defendants.

262. Defendants 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.

263. Defendants 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 maintaining the prices so that Plaintiffs and Class members 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.

264. The agreements between Defendants are horizontal market allocation and price fixing agreements between actual or potential competitors and are illegal *per se* under state antitrust laws. Alternatively, this Second Consolidated Amended 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.

265. Alternatively, AstraZeneca's agreements, including its agreement with Handa/Par and Accord, are presumptively anticompetitive reverse payment settlements, subject to "quick look" rule of reason scrutiny, because AstraZeneca provided substantial consideration in exchange for each generic manufacturer's agreement to delay market entrance.

266. 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 the End-Payor Plaintiffs and all members of the proposed End-Payor Class would pay for extended-release quetiapine fumarate.

267. Under the Defendants' 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.

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

269. The anticompetitive consequences of Defendants' 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 was no countervailing pro-competitive benefits from the agreements.

270. The goal, purpose, and effect of Defendants' 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.

271. The goal, purpose and effect of Defendants' 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. Defendants' scheme also allowed Handa/Par and Accord to reap the benefits of reduced generic competition in the United States and to charge supracompetitive prices.

272. Plaintiffs and members of the Class purchased substantial amounts of Seroquel XR and/or AB-rated generic equivalents indirectly from AstraZeneca and/or other manufacturers.

273. As a result of Defendants' illegal conduct, Plaintiffs and members of the Class were compelled to pay, and did pay, more than they would have paid for

their extended-release quetiapine fumarate requirements absent Defendants' illegal conduct. But for Defendants' 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.

274. By engaging in the foregoing conduct, Defendants intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of the following state antitrust laws:

a. Arizona Rev. Stat. §§ 44-1402, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in Arizona by members of the Class.

b. Cal. Bus. & Prof. Code §§ 16700 and 17200, *et seq*., with respect to purchases of Seroquel XR and AB-rated bioequivalents in California by members of the Class.

c. D.C. Code §§ 28-4502, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in the District of Columbia by members of the Class.

d. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in Florida by members of the Class.

e. Hawaii Revised Statutes annotated § 480-1, *et seq*., with respect to purchases of Seroquel XR and AB-rated bioequivalents in Hawaii by members of the Class.

f. Illinois Antitrust Act (740 Illinois Compiled Statutes 10/1, *et seq*.), with respect to purchases of Seroquel XR and AB-rated bioequivalents in Illinois by members of the Class.

g. Iowa Code § 553.4, *et seq*., with respect to purchases of Seroquel XR and AB-rated bioequivalents in Iowa by members of the Class.

h. Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in Kansas by members of the Class.

i. Me. Rev. Stat. Ann. 10, §§ 1101, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in Maine by members of the Class.

j. Md. Com'l Law Code Ann. § 11-204(a), *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in Maryland by members of the Class.

k. Mass. Ann. Laws ch. 93A, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in Massachusetts by members of the Class.

l. Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in Michigan by members of the Class.

m. Minn. Stat. §§ 325D.49, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in Minnesota by members of the Class.

n. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in Mississippi by members of the Class.

o. Mont. Code § 30-14-201, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in Montana by members of the Class.

p. Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in Nebraska by members of the Class.

q. Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in Nevada by members of the Class.

r. N.H. Revised Statutes § 356:1, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in New Hampshire by members of the Class.

s. N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in New Mexico by members of the Class.

t. N.Y. Gen. Bus. Law §§ 340, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in New York by members of the Class.

u. N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in North Carolina by members of the Class.

v. N.D. Cent. Code §§ 51-08.1-02, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in North Dakota by members of the Class.

w. Or. Rev. Stat. § 646.725, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in Oregon by members of the Class.

x. R.I. Gen. Laws § 6-36-4, et seq., with respect to purchases of Seroquel XR and AB-rated bioequivalents in Rhode Island by members of the Class.

y. S.D. Codified Laws Ann. §§ 37-1-3.1, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in South Dakota by members of the Class.

z. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in Tennessee by members of the Class.

aa. Utah Code Annotated § 76-10-3103, *et seq*., with respect to purchases of Seroquel XR and AB-rated bioequivalents in Utah by members of the Class.

bb. W.Va. Code §§ 47-18-3, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in West Virginia by members of the Class.

cc. Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases of Seroquel XR and AB-rated bioequivalents in Wisconsin by members of the Class.

275. Plaintiffs and members of the Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Claim. Their

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 they would have paid in the absence of Defendants' conduct. These injuries are of the type the antitrust laws were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

276. Plaintiffs and the Class seek damages and multiple damages as permitted by law for their injuries by Defendants' violation of the aforementioned statutes.

FOURTH CLAIM FOR RELIEF
Unfair or Deceptive Trade Practices
(Asserted Against All Defendants)

277. Plaintiffs incorporate by reference all the allegations above as though fully set forth herein.

278. Defendants 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' anticompetitive, deceptive, unfair and/or unconscionable acts or practices, Plaintiffs and Class members were deprived of the opportunity to purchase a less expensive AB-rated bioequivalents and forced to pay higher prices.

a. Defendants have engaged in unfair competition, and/or unfair/unconscionable and/or deceptive acts or practices in violation of Ark. Code §§ 4-88-101, *et seq*. Defendants have engaged in unfair competition, and/or unfair/unconscionable and/or deceptive acts or practices in violation of Cal. Bus. & Prof. Code § 17200, *et seq*.

b. Defendants have engaged in unfair competition, and/or unfair/unconscionable and/or deceptive acts or practices in violation of Fla. Stat. § 501.201, *et seq*.

c. Defendants have engaged in unfair competition, and/or unfair/unconscionable and/or deceptive acts or practices in violation of 815 Ill. Comp. Stat. Ann.§§ 505.1, *et seq*.

d. Defendants have engaged in unfair competition, and/or unfair/unconscionable and/or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, *et seq*., in that the actions and transactions alleged herein occurred primarily and substantially within Massachusetts, with thousands of end-payors paying substantially higher prices for Seroquel XR and AB-rated bioequivalents. Plaintiffs and members of the proposed class made purchased, paid and/or provided reimbursement for purchases in Massachusetts for personal use.

e. Defendants have engaged in unfair competition, and/or unfair/unconscionable and/or deceptive acts or practices in violation of Mich. Stat. §§ 445.901, *et seq*.

f. Defendants have engaged in unfair competition, and/or unfair/unconscionable and/or deceptive acts or practices in violation of Minn. Stat. §§ 325 F. 68, *et seq*., and Minn. Stat. §§ 8.31, *et seq*.

g. Defendants have engaged in unfair competition, and/or unfair/unconscionable and/or deceptive acts or practices in violation of Mo. Stat. §§ 407.010, *et seq*.

h. Defendants have engaged in unfair competition, and/or unfair/unconscionable and/or deceptive acts or practices in violation of Neb. Rev. Stat. §§ 59-1601, *et seq.*

i. Defendants have engaged in unfair competition, and/or unfair/unconscionable and/or deceptive acts or practices in violation of Nev. Rev. Stat. §§ 598.0903, *et seq.*

j. Defendants have engaged in unfair competition, and/or unfair/unconscionable and/or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A:1, *et seq*.

k. Defendants have engaged in unfair competition, and/or unfair/unconscionable and/or deceptive acts or practices in violation of N.M. Stat. § 57-12-1, *et seq*.

l. Defendants have engaged in unfair competition, and/or unfair/unconscionable and/or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349, *et seq*. To the extent New York law so requires, Plaintiffs hereby forgo any minimum or punitive damages in order to preserve the right of New York Class members to recover actual damages by way of a class action.

m. Defendants have engaged in unfair competition, and/or unfair/unconscionable and/or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1, *et seq*.

n. Defendants have engaged in unfair competition, and/or unfair/unconscionable and/or deceptive acts or practices in violation of S.D. Codified Laws § 37-24-6.

279. Plaintiffs and members of the Class have been injured in their business and property by reason of Defendants' anticompetitive, unfair/unconscionable and/or deceptive acts or practices alleged in this Count. Their injury consists of paying higher prices for Seroquel XR and/or AB-rated generic bioequivalents than they 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' unlawful conduct.

Compliance With Written Demand Requirements of West Virginia, Maine, and Massachusetts

280. On September 19, 2019, class counsel sent demand letters to Defendants AstraZeneca Pharmaceuticals, LP and AstraZeneca, LP, c/o Executive Director and Chief Executive Officer, Pascal Soriot; AstraZeneca UK Limited; Handa Pharmaceuticals, LLC, c/o President and Chief Executive Officer, Fangyu "Bill" Liu; and Par Pharmaceutical, Inc., c/o, President and Chief Executive Officer Paul V. Campanelli. These demand letters satisfy the requirements of West Virginia Code § 46A-6-106(c). The demand letters, which were sent via certified mail, return receipt requested, identified the claimants as "Plaintiff and all end payor purchasers of Seroquel XR and its AB-rated generic equivalents" in individual and representative capacities; described the unfair or deceptive acts or practices committed by the AstraZeneca and Handa/Par Defendants entry into an unlawful and anticompetitive settlement between AstraZeneca and Handa/Par and AstraZeneca; described the injury suffered (increased prices for Seroquel XR because of the delayed entry of a generic to the market); set forth a demand for relief (treble damages, attorneys' fees, litigation costs, and other available sanctions); and requested an offer to cure within the statutorily prescribed time. The AstraZeneca, and Handa/Par Defendants did not respond with an offer of settlement.

281. On September 19, 2019, class counsel also sent demand letters to Defendants AstraZeneca Pharmaceuticals, LP and AstraZeneca, LP, c/o Executive Director and Chief Executive Officer, Pascal Soriot; AstraZeneca UK Limited; Handa Pharmaceuticals, LLC, c/o President and Chief Executive Officer, Fangyu "Bill" Liu; and Par Pharmaceutical, Inc., c/o, President and Chief Executive Officer Paul V. Campanelli. These demand letters satisfy the requirements of 10 Me. Rev. Stat. tit. 5 § 213-1-A. The demand letters, which were sent via certified mail, return receipt requested, identified the claimants as "Plaintiff and all end payor purchasers of Seroquel XR and its AB-rated generic equivalents" in individual and representative capacities; described the unfair or deceptive acts or practices committed by the AstraZeneca and Handa/Par Defendants entry into an unlawful and anticompetitive settlement between AstraZeneca and Handa/Par and AstraZeneca; described the injury suffered (increased prices for Seroquel XR because of the delayed entry of a generic to the market); set forth a demand for relief (actual damages, attorneys' fees, litigation costs, and other available sanctions); and requested an offer to cure. The AstraZeneca, and Handa/Par Defendants did not respond with an offer of settlement.

282. The demand letter requirement of Section 9 of Massachusetts General Laws Annotated Chapter 93A do not apply to Defendants because Defendants have not identified a place of business or assets within Massachusetts. In an abundance

of caution, however, Plaintiffs, on behalf of themselves and all others similarly situated, served each Defendant (as identified above) with a written demand for relief, on September 19, 2019. The demand letters, which were sent via certified mail, identified the claimants as "Plaintiff and all end payor purchasers of Seroquel XR and its AB-rated generic equivalents" in individual and representative capacities; described the unfair or deceptive acts or practices committed by the Defendants (including the entry into an unlawful and anticompetitive settlement between AstraZeneca and Handa/Par); described the injury suffered (increased prices for Seroquel XR because of the delayed entry of a generic to the market); set forth a demand for relief (treble damages, attorneys' fees, litigation costs, and other available sanctions); and requested an offer to cure within the statutorily prescribed time. The Defendants did not respond with an offer of settlement.

FIFTH CLAIM FOR RELIEF
Unjust Enrichment Under State Law
(Fifty States & the District of Columbia, Except Alaska, Colorado, Connecticut, Delaware, Idaho, Indiana, Louisiana, Michigan, Montana, New Jersey, Ohio, Oklahoma, Oregon, Puerto Rico, South Carolina, Texas,Virginia, Washington, and Wyoming)
(Asserted Against All Defendants)

283. Plaintiffs incorporate by reference all the allegations above as though fully set forth herein.

284. To the extent required, this claim is pleaded in the alternative to the other claims in this Second Consolidated Amended Complaint.

285. As a result of their unlawful conduct described above, Defendants have and will continue to be unjustly enriched. Defendants 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.

286. Defendants' financial benefits are traceable to Plaintiffs' and Class members' overpayments for Seroquel XR and/or its AB-rated generic equivalents.

287. Plaintiffs and Class members have conferred and continue to confer an economic benefit upon Defendants in the nature of profits resulting from the unlawful overcharges described herein, to the economic detriment of Plaintiffs and Class members.

288. Defendants have benefited from their unlawful acts and it would be inequitable for Defendants to be permitted to retain any of the ill-gotten gains resulting from the overpayments made by Plaintiffs and the members of the Class for Seroquel XR and/or its AB-rated generic equivalents manufactured by Defendants during the Class Period.

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

290. The economic benefit Defendants derived from overcharging Plaintiffs and Class members for Seroquel XR and/or its AB-rated generic equivalents is a direct and proximate result of Defendants' unlawful and anticompetitive practices.

291. The financial benefits Defendants derived are ill-gotten gains that rightfully belong to Plaintiffs and Class members, who paid and continue to pay artificially inflated prices that inured to Defendants' benefit.

292. It would be inequitable under unjust enrichment principles under the laws of each state in the United States as well as the District of Columbia, except for Alaska, Colorado, Connecticut, Delaware, Idaho, Indiana, Louisiana, Michigan, Montana, New Jersey, Ohio, Oklahoma, Oregon, Puerto Rico, South Carolina, Texas, Virginia, Washington, and Wyoming, for Defendants to retain any of the overcharges Plaintiffs and Class members 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.

293. Defendants are aware of and appreciate the benefits that Plaintiffs and the Class members have bestowed upon them.

294. Defendants should be ordered to disgorge all unlawful or inequitable proceeds they received in a common fund for the benefit of Plaintiffs and Class members, who collectively have no adequate remedy at law.

295. Plaintiffs and Class members are 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 Plaintiffs and Class members may make claims on a *pro rata* basis.

XIV. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, on their own behalf and on behalf of the proposed Class, pray for judgment against Defendants and that this Court:

1. Determine that this action may be maintained as a class action pursuant to Rules 23(a) and (b)(3) of the Federal Rules of Civil Procedure, and direct that reasonable notice of this action, as provided by Rule 23(c)(2), be given to the Class, and appoint Plaintiffs as the named representatives of the Class;
2. Award Plaintiffs and the Class damages (*i.e.*, three times overcharges) in an amount to be determined at trial, plus interest in accordance with law;
3. Grant Plaintiffs and the Class equitable relief in the nature of disgorgement, restitution, and the creation of a constructive trust to remedy Defendants' unjust enrichment;
4. Award Plaintiffs and the Class their costs of suit, including reasonable attorneys' fees as provided by law; and

5. Award such other and further relief as the Court deems just and proper.

XV. JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiffs, on behalf of themselves and the proposed Class, demand a trial by jury of all issues so triable.

Dated: December 4, 2020

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