UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

In re REMICADE ANTITRUST LITIGATION	Civil Action No. 2:17-cv-4326-JCJ
WALGREEN CO. and THE KROGER CO., Plaintiffs, vs. JOHNSON & JOHNSON and JANSSEN BIOTECH, INC., Defendants.	Civil Action No. _____ JURY TRIAL DEMANDED

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiffs Walgreen Co. and The Kroger Co. bring this civil action against Defendants Johnson & Johnson and Janssen Biotech, Inc. (collectively "J&J" or "Defendants") under the antitrust laws of the United States. For their Complaint, Plaintiffs allege as follows:

I. INTRODUCTION

1. This is a civil antitrust action seeking permanent injunctive relief, treble damages and other relief arising out of Defendants' unlawful exclusion of biosimilar competition to the brand-name drug Remicade, a biologic used to treat certain chronic immune disorders. Remicade has been on the market since 1998. From 1998 to 2016, Remicade was the only drug on the market containing its active ingredient, infliximab. This monopoly position allowed Defendants to sell Remicade at extremely high prices and to generate annual U.S. sales of about $4.8 billion in 2016. For most uses, Remicade sells at approximately $4,000 per infused dose

and about $26,000 for a full year of treatment. Remicade is J&J's best-selling drug and among the best-selling drugs in the world.

2. In 2016, Pfizer Inc. ("Pfizer") received FDA approval to launch and launched a competing biosimilar product, Inflectra. Pfizer sold Inflectra at a 15% discount to the wholesale acquisition cost ("WAC") of Remicade. In 2017, Merck & Co., Inc. ("Merck") received approval to launch and launched another competing biosimilar, Renflexis. Merck began selling Renflexis in July 2017 at a 35% discount to the WAC price of Remicade, a price that Pfizer then matched.

3. Despite offering these large price discounts, Pfizer and Merck have garnered only a *de minimis* share of the infliximab market because of Defendants' exclusionary scheme. Defendants have maintained their monopoly power through exclusionary contracts and bundled discounts that have effectively suppressed competition from Pfizer's and Merck's biosimilar products. Absent that exclusionary conduct, those products would have achieved much higher market shares and Plaintiffs and other purchasers would have received the benefits of that price competition in the form of lower purchase prices.

4. Biologics are genetically engineered proteins derived from human genes and typically administered by injection. They are manufactured in living systems by combining genetic material from multiple sources. Biologics are regulated by the U.S. Food and Drug Administration ("FDA") pursuant to a statute known as the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"). The structure of the BPCIA is similar in concept to that of the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act. Like the Hatch-Waxman Act, which provided for abbreviated approval of generic versions of previously approved branded drugs, the BPCIA created abbreviated means of

obtaining approval for products that are "biosimilar" to previously approved biologics. A product may be shown to be "biosimilar" if is "highly similar" to the previously approved product (known as the reference listed drug, or "RLD"), notwithstanding minor differences in inactive ingredients, such that there are no clinically meaningful differences between the biosimilar product and the reference listed drug in terms of safety, purity and potency.

5. Inflectra and Renflexis are biosimilar to Remicade. Unlike AB-rated generic drugs, biosimilar products cannot automatically be substituted for the reference listed drug at the retail pharmacy. Thus, a pharmacist cannot dispense either of the biosimilar drugs rather than Remicade without calling the physician. The BPCIA contemplates a more stringent classification of biologics and biosimilars—"interchangeable"—that would potentially allow pharmacists to substitute one product for another without physician intervention, but the FDA has only recently published draft guidelines on interchangeability and Pfizer and Merck have not had an opportunity to obtain a determination from the FDA that their infliximab products are interchangeable with Remicade.

6. Within weeks of Inflectra's launch, J&J began to deploy what it referred to as its "Biosimilar Readiness Plan." The core features of the plan were exclusionary contracts, anticompetitive bundled discounts and coercive rebate policies that foreclosed Pfizer's access to the overwhelming majority of potential consumers, despite the lower prices of Inflectra. These measures included the following.

7. *Exclusive contracts with insurance company payors.* Insurer decisions about coverage can play an important role in product selection. Although physicians make prescribing decisions based on therapeutic rather than economic factors, if a physician prescribes a product that is not covered by the patient's insurance plan, the patient will be responsible for the full

retail price of the drug (rather than merely a co-pay) and is likely to voice his or her concern to the pharmacist who is asking the patient to pay that price. This is particularly true when the full retail price of a dose of the drug may be $4,000 or more. Under those circumstances, either the pharmacist or the patient will typically ask the physician to prescribe a different drug.

8. Recognizing this, J&J entered into agreements with health insurers under which the insurers agreed not to cover the Pfizer and Merck biosimilar products or to do so only in the rarest of circumstances, thus effectively making Remicade the only covered infliximab. As a result, the biosimilars are either not covered at all or are covered only in "fail first" cases. The "fail first" exception, which purportedly allows a biosimilar infliximab to be used and covered if Remicade has been tried first for a particular patient and has failed to achieve the desired result, is illusory. If Remicade does not work for a particular patient, the physician would not prescribe a biosimilar product that is clinically indistinguishable from Remicade, but would instead turn to a non-infliximab drug. These effectively exclusive contracts have foreclosed Pfizer and Merck from competing for the majority of commercially insured patients in the United States.

9. *Exclusionary rebates and bundling arrangements.* J&J forced most health insurers to enter into the exclusionary contracts described above by conditioning rebates worth (in some cases) tens of millions of dollars per year on the insurer's agreement not to cover biosimilar infliximab drugs or to do so only in unusual circumstances. This financial coercion works because there is a substantial base of patients who are controlling their diseases with Remicade and who are unlikely to switch to a lower-priced biosimilar. Unlike AB-rated generic drugs, which can be substituted automatically for their branded counterparts unless the physician expressly indicates otherwise, biosimilars cannot be substituted for the reference listed drug without the physician's approval. Thus, as a practical matter, the roughly 70% of potential

infliximab patients who are already stable on Remicade are not realistic targets for companies like Pfizer and Merck and are sometimes referred to as "incontestable" patients. The remaining 30% of potential patients are those who are just starting therapy with infliximab and are sometime referred to as "contestable" patients. J&J was able to foreclose competition by threatening to deny rebates to insurers on *all* of their Remicade prescriptions—both the 70% "incontestable" portion and the 30% "contestable" portion—if the insurer covered any biosimilar products. That economic penalty was too great for health insurers to bear.

10. J&J also bundles together rebates on Remicade with rebates on other J&J products, increasing the financial penalty on insurers. In order to offset the loss of these J&J rebates and allow insurers to cover their products without suffering an economic penalty, Pfizer and Merck would have to lower the price of their biosimilar products to unsustainable levels.

11. *Effects of J&J's exclusionary conduct.* As a result of J&J's exclusive contracts, coercive rebates and bundling, Pfizer and Merck have been able to make only *de minimis* inroads into the infliximab market, securing less than 5% of total infliximab unit sales in the United States. The result has been that, even though Pfizer's and Merck's products are significantly less expensive than Remicade and have no clinically meaningful differences from them, the overall price of infliximab has actually increased since the entry of these two additional competitors. Remicade's "average selling price" or "ASP"—a metric defined by federal law that takes into account discounts, rebates and all other price concessions —is higher today than it was before Inflectra's entry. The net effect of J&J's conduct is that buyers of infliximab have fewer choices and pay more than they should. That state of affairs will continue unless and until J&J is enjoined by this Court.

II. PARTIES

12. Plaintiff Walgreen Co. ("Walgreen") is an Illinois corporation having its principal place of business at 200 Wilmot Road, Deerfield, Illinois 60015. Walgreen owns and operates retail stores in several states at which it dispenses prescription drugs, including Remicade, to the public. Walgreen brings this action in its own behalf and as the assignee of AmerisourceBergen Drug Corporation, a pharmaceutical wholesaler, which during the relevant period purchased Remicade directly from Defendants for resale to Walgreen and which has assigned its claims arising out of those purchases to Walgreen.

13. Plaintiff The Kroger Co. ("Kroger") is an Ohio corporation having its principal place of business at 1014 Vine Street, Cincinnati, Ohio 45202. Kroger owns and operates retail stores in several states at which it dispenses prescription drugs, including Remicade, to the public. Kroger brings this action in its own behalf and as the assignee of Cardinal Health, Inc., a pharmaceutical wholesaler, which during the relevant period purchased Remicade directly from Defendants for resale to Kroger and which has assigned its claims arising out of those purchases to Kroger.

14. Defendant Johnson & Johnson is a New Jersey corporation having its principal place of business in New Brunswick, New Jersey. Johnson & Johnson manufactures and markets numerous branded pharmaceutical products, including Remicade, either directly or through subsidiaries.

15. Defendant Janssen Biotech, Inc. ("Janssen") is a Pennsylvania corporation having its principal place of business in Horsham, Pennsylvania. Janssen is a wholly owned subsidiary of Johnson & Johnson. It co-owns or has licenses to certain patents covering Remicade and carries out the marketing of Remicade in the U.S.

16. All of Defendants' actions described in this Complaint were carried out by Defendants' various officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs and within the course and scope of their duties and employment by Defendants, and/or with the actual, apparent, and/or ostensible authority of Defendants.

III. JURISDICTION AND VENUE

17. This action arises under sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, and sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15(a) and 26, to recover permanent injunctive relief, treble damages, costs of suit and reasonable attorneys' fees for the actual and threatened injuries sustained by Plaintiffs resulting from Defendants' unlawful foreclosure of the United States market for infliximab. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1337(a).

18. Defendants transact business within this district and/or have an agent and/or can be found in this district. Venue is appropriate within this district under section 12 of the Clayton Act, 15 U.S.C. § 22 and 28 U.S.C. §1391(b) and (c).

IV. BACKGROUND

A. Characteristics of the Prescription Pharmaceutical Marketplace

19. The marketplace for the sale of prescription pharmaceutical products in the United States suffers from a significant imperfection that brand manufacturers can exploit in order to obtain or maintain market power in the sale of a particular pharmaceutical composition. Markets function best when the person responsible for paying for a product is also the person who chooses which product to purchase. When the same person has both the payment obligation and the choice of products, the price of the product plays an appropriate role in the person's

choice of products and, consequently, the manufacturers have an appropriate incentive to lower the prices of their products.

20. The pharmaceutical marketplace, however, is characterized by a "disconnect" between the payment obligation and the product selection. State laws prohibit pharmacists from dispensing many pharmaceutical products, including Remicade, to patients without a prescription written by a doctor. The prohibition on dispensing certain products without a prescription introduces a disconnect between the payment obligation and the product selection. The patient (and in most cases his or her insurer) has the obligation to pay for the pharmaceutical product, but the patient's doctor chooses which product the patient will buy.

21. Defendants and other brand manufacturers exploit this price disconnect by employing large forces of sales representatives to visit doctors' offices and persuade them to prescribe the manufacturer's products. These sales representatives do not advise doctors of the cost of the branded products. Moreover, studies show that doctors typically are not aware of the relative costs of brand pharmaceuticals and, even when they are aware of the relative costs, they are insensitive to price differences because they do not have to pay for the products. The result is a marketplace in which price plays a less significant role in product selection than in other industries.

B. Biologics

22. Biologics are treatments derived from living systems such as microorganisms or plant or animal cells. Biologics include vaccines, blood and blood products, allergenic extracts, human cells and tissues, gene therapies, and cellular therapies. Although biologics are one of the fastest-growing drug categories in the U.S., they are not new.

23. Biologics tend to target diseases that chemically synthesized drugs cannot. Biologics are available to treat various forms of cancer, Lupus, rheumatoid arthritis, multiple

sclerosis, Crohn's disease, and other disease states. Many biologics face high (and inelastic) demand.

C. The BPCIA

24. Congress has mandated competition in the pharmaceutical industry through legislation like the Hatch-Waxman Act, which created an abbreviated approval process for generic versions of non-biologic branded drugs. Hatch-Waxman allowed generic manufacturers to rely on the originator's safety and efficacy studies and to obtain FDA approval merely by showing bioequivalence to the already approved originator's drug.

25. In 2009, Congress adopted a similar (though not identical) approach to biologics. Under the BPCIA, the FDA is authorized to approve biosimilar versions of originator biologics if it finds that the proposed biosimilar is "highly similar" to the originator product and "there are no clinically meaningful differences between [them] in terms of safety, purity, and potency." 42 U.S.C. § 262(i)(2).

26. Although biosimilars are analogous to generic drugs, they are not automatically substitutable at the pharmacy counter, as AB-rated generics are. The BPCIA provides for a more stringent classification of biosimilars and originator drugs—"interchangeable"—that would allow automatic substitution if such substitution is permitted under the relevant state's law. The FDA only recently published draft guidelines for establishing interchangeability under the BPCIA and, as a result, Pfizer and Merck have not had an opportunity to obtain a designation of interchangeability from the FDA.

D. Infliximab

27. Infliximab is a tumor necrosis factor ("TNF")-inhibiting biologic used to treat a variety of immune system diseases, including Crohn's disease, ulcerative colitis, rheumatoid

arthritis, psoriatic arthritis, ankylosing spondylitis, and plaque psoriasis. Infliximab is produced by a recombinant cell line cultured by continuous perfusion and is purified through a series of steps that includes measures to inactivate and remove viruses. It is an infusion therapy, meaning the drug is administered intravenously through a tube (or catheter). Plaintiffs in this case purchase infliximab and dispense it to patients with an appropriate prescription at their retail pharmacies, including specialty pharmacies.

28. J&J introduced Remicade, the first infliximab product in the U.S., in 1998.

29. An estimated 475,000 patients in the country receive at least one dose of Remicade annually. The average list price of a single dose is approximately $4,000.

E. Pfizer's Inflectra

30. The FDA approved Inflectra on April 5, 2016 after finding "no clinically meaningful differences" between Inflectra and Remicade. On August 17, 2016, the United States District Court for the District of Massachusetts ruled that J&J's patent covering the infliximab antibody was invalid because the alleged invention had not been disclosed and claimed in an earlier patent. Pfizer began selling Inflectra in November 2016. Inflectra is approved for all the same indications as Remicade except pediatric ulcerative colitis, an indication for which J&J qualified for an additional exclusivity period based on its status as an "orphan" indication. That exclusivity is scheduled to expire in September 2018.

31. Pfizer introduced Inflectra with a list price 15% lower than Remicade's and, in negotiations with insurers and providers, offered additional pricing concessions. For some insurance customers, Pfizer committed to ensuring that they would pay a lower unit reimbursement rate for Inflectra than for Remicade.

F. Merck's Renflexis

32. Merck received FDA approval to sell its Remicade biosimilar, Renflexis, on April 21, 2017.

33. Like Inflectra, the drug was approved for the same indications as Remicade except pediatric ulcerative colitis.

34. Merck began selling Renflexis in July 2017 at a list price 35% below the list price of Remicade, a price that Pfizer subsequently matched.

G. Pfizer's Ixifi

35. Pfizer received FDA approval for a third biosimilar, Ixifi, in December 2017, but has not yet launched the drug.

V. OPERATIVE FACTS

A. J&J's Anticompetitive Scheme

36. Notwithstanding their lower price, Inflectra and Renflexis have had virtually no impact on Remicade's monopoly position. J&J has actually increased the price of Remicade since the entry of Inflectra and has nevertheless held both Inflectra and Renflexis to a combined low-single-digit market share. J&J did not achieve this result through competition on the merits, but rather through exclusionary conduct that included exclusive dealing contracts, bundled rebates and other anticompetitive activities designed to foreclose Pfizer and Merck from gaining sales that would otherwise have been expected to go to firms selling an essentially identical product at lower prices.

37. The overwhelming majority of patients who are prescribed Remicade have some form of insurance coverage. The principal sources of insurance coverage are (a) private commercial insurance, accounting for about 60% of insured patients in the U.S., and (b) government insurance programs (principally Medicare and Medicaid), accounting for the

remaining 40%. Patients without any form of insurance must pay the full retail price of the drug out of their own pocket, and only a tiny fraction of the population can afford to do that for a drug as prohibitively expensive as Remicade. Given the ubiquity of insurance, the availability of insurance coverage is key to the acceptance of new drugs that are launched into the U.S. marketplace, particularly in the case of drugs as expensive as Remicade.

38. Not content with its nearly two decades of monopoly profits in the sale of Remicade, J&J implemented a multifaceted scheme to maintain its monopoly after the launch of the Pfizer and Merck biosimilars and ensure that Inflectra (and later Renflexis) would not become viable competitors to Remicade, a scheme embodied in part in its "Biosimilar Readiness Plan." The scheme included exclusionary contracts with health insurers that favored Remicade and excluded biosimilar infliximab products; coercive rebates that forced insurers to accept the terms in those contracts; and bundling arrangements that had a similar impact. The effect of the scheme has been to suppress the normal economic incentive of insurers to encourage the prescription of lower-priced but otherwise equivalent biosimilar drugs.

1. Exclusive Contracts with Health Insurers

39. A centerpiece of J&J's scheme has been to secure contractual commitments from private health insurers that effectively exclude biosimilar products from coverage under those insurers' benefit plans, effectively making Remicade the only infliximab product available to patients covered by those plans.

40. These contractual commitments have taken a variety of forms. Some insurers have agreed to exclude biosimilar infliximab products from coverage altogether. Other contracts have included a provision that the biosimilar would be covered only after a patient tried and failed on Remicade—known as the "fail first" requirement—which virtually ensures that

biosimilars will not be prescribed or reimbursed. If a patient fails on Remicade, a physician would be very unlikely to prescribe a therapeutically equivalent and biosimilar infliximab product, which works in exactly the same way, and would be much more likely to choose a non-infliximab therapy.

41. J&J has induced most of the major health insurers in the United States, covering at least 70% of privately insured patients in the United States, to adopt these exclusionary restrictions. These insurers include the following:

National insurers:

UnitedHealthcare: UnitedHealthcare, with approximately 30.6 million covered commercial patients, adopted the "fail first" requirement.

Anthem: Anthem, with approximately 30.4 million covered commercial patients, excluded Inflectra from coverage.

Aetna: Aetna, with approximately 17.9 million covered commercial patients, adopted a complex set of indication-specific conditions which operate in practice as "fail first" requirements.

Cigna: Cigna, with approximately 13 million covered commercial patients, adopted the "fail first" requirement.

Regional insurers:

HealthNet (Centene): HealthNet, with approximately 12 million covered commercial patients, adopted a complex set of indication-specific conditions which operate in practice as "fail first" requirements.

CareFirst/Blue Cross Blue Shield: CareFirst, with approximately 3.2 million covered commercial patients, adopted the "fail first" requirement.

Blue Cross Blue Shield of North Carolina: BCBS of North Carolina, with approximately 2.7 covered commercial patients, adopted the "fail first" requirement.

Blue Cross Blue Shield of Tennessee: BCBS of Tennessee, with approximately 1.6 million covered commercial patients, adopted the "fail first" requirement.

Blue Cross Blue Shield of Louisiana: BCBS of Louisiana, with approximately 1.6 million covered commercial patients, adopted the "fail first" requirement.

Excellus Blue Cross Blue Shield: Excellus BCBS, with approximately 1.2 million covered commercial patients, adopted the "fail first" requirement.

Independence Blue Cross: Independence Blue Cross, the leading health insurer in Philadelphia, adopted the "fail first" requirement.

42. The exclusive (or effectively exclusive) arrangements described above serve no legitimate purpose and were intended simply to foreclose competition and maintain Remicade's monopoly status in the face of lower-priced competition. There is no medical reason to disfavor biosimilar infliximab products relative to Remicade. Indeed, after Inflectra was approved and before J&J implemented its exclusionary scheme, several health insurers (including at least Aetna, Anthem and UnitedHealthcare) classified Inflectra at parity with Remicade. But this initial state of affairs was short-lived. Shortly after United (the nation's largest health insurer) classified Inflectra at parity with Remicade, it reversed course and classified Remicade as the "preferred" product, while Inflectra would be eligible for reimbursement only in circumstances so limited as to be virtually non-existent. United reversed course because J&J induced it to enter into an exclusive arrangement by threatening to penalize United with the loss of significant rebates unless United agreed to deny coverage to Inflectra.

2. Rebate and Bundling Arrangements

43. J&J's scheme has succeeded because health insurers were threatened with the loss of rebates on the large base of existing patients already stabilized on Remicade, amounting to hundreds of thousands of individuals across the country. Given the lack of automatic substitutability of biosimilars for originator drugs, existing Remicade patients who are stable on Remicade are not realistic targets for Inflectra and Renflexis because the physician would have to change the patient's prescription from Remicade to one of the biosimilars and physicians treating patients who are stable on Remicade are unlikely to do so. Thus, the demand for Remicade associated with this existing base of patients is sometimes referred to as "incontestable." In contrast, the demand associated with new patients who are started on infliximab therapy is "contestable." This patient segment accounts for approximately 30% of Remicade prescriptions, and it is the patient segment on which Pfizer and Merck have focused. As the head of J&J's pharmaceuticals business told investors during an October 2016 investor call: "the 70% of patients who are stable on Remicade are highly unlikely to switch."

44. By threatening to withhold rebates on all Remicade prescriptions—prescriptions for the existing patient base and for new ones—J&J has coerced insurers to agree to exclude biosimilars from coverage by bundling the incontestable demand and the contestable demand. Even with the substantial discounts offered by Pfizer and Merck, insurers have agreed to J&J's demands to avoid losing rebates on the substantial base of existing Remicade patients who are not likely to switch to a biosimilar despite the lower price.

45. J&J has further insulated Remicade from competition by bundling rebates for Remicade with rebates on other products in return from commitments by insurers not to cover Inflectra or Renflexis. This has always been a feature of J&J's Biosimilar Readiness Plan. As

J&J's Worldwide Chair for Pharmaceuticals emphasized on an earnings call, J&J was "fully prepared to execute [its] focused biosimilar readiness plan," including "developing innovative contracts . . . [to] utilize the full breadth of [its] portfolio." The "full breadth" of J&J's portfolio includes several drugs for which Pfizer and Merck do not offer a directly competing alternative. These include Simponi (used for rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and ulcerative colitis), Simponi Aria (used for rheumatoid arthritis), and Stelara (used for plaque psoriasis, psoriatic arthritis and Crohn's disease). These products generated approximately $1.7 billion (Simponi/Simponi Aria) and $3.2 billion (Stelara) in sales for J&J in 2016, respectively. J&J has threatened insurers with the loss of rebates on these drugs, as well as Remicade, if they provide coverage to the Pfizer and Merck biosimilars.

46. J&J's multi-product bundling, along with its bundling of new patients and existing patients, have amplified the exclusionary effects of J&J's exclusive contracts. Insurers have emphasized to Pfizer that, in order to counteract the effects of J&J's scheme, Pfizer's net price would have to be low enough to offset the loss of J&J's rebates. This is not an economically feasible option for Pfizer. Because of the combined effect of these bundles, Pfizer cannot lower the price of its product to a level that would offset the financial penalties that J&J has threatened to impose on insurers who do not agree to exclusivity. As a result, Pfizer is effectively prohibited from competing for coverage of its infliximab product, and this state of affairs will continue as long as J&J's exclusionary conduct continues.

B. Market Effects of the Scheme

47. J&J's scheme to suppress biosimilar competition to Remicade has allowed it to maintain monopoly power in the sale of infliximab in the United States despite the entry of lower-priced and substantially equivalent products.

48. Pfizer and Merck have extensive experience in the pharmaceutical industry, including experience in obtaining approvals for new drugs and marketing new drugs to physicians. They sell biosimilar versions of Remicade at prices substantially below the price of J&J's drug. Even without automatic substitution, normal competitive dynamics would have resulted either in (a) Remicade losing more than 4-5% of its sales to the lower-priced Inflectra and Renflexis, or (b) J&J lowering the price of Remicade to avoid such a loss of sales. As a result of J&J's anticompetitive scheme, neither of these has occurred. J&J has been able to raise the price of Remicade and at the same time hold the biosimilar products to a combined single-digit market share. By engaging in the conduct described herein, J&J has maintained its monopoly power in the relevant market and has forced Plaintiffs and other purchasers of the drug to pay higher prices for Remicade rather than they would have paid to purchase the less expensive biosimilars.

VI. INTERSTATE COMMERCE

49. The drugs at issue in this case are sold in interstate commerce. Defendants' unlawful activities, as alleged above, have occurred in, and have had a substantial impact on, interstate commerce.

VII. MARKET POWER AND MARKET DEFINITION

50. At all relevant times, J&J had monopoly power in the relevant market—the market for the sale of infliximab in the United States—because it had the power to raise and/or maintain the price of the drug at supracompetitive levels without losing substantial sales. For years before Inflectra's entry, J&J repeatedly raised the price of Remicade without losing business. Absent J&J's exclusionary conduct, the availability of lower-priced biosimilar drugs would have led insurance companies and other third-party payors to encourage physicians to prescribe Pfizer's and Merck's products for the 30% of Remicade patients who are considered

"contestable," thereby significantly curtailing J&J's monopoly power. As a result of J&J's exclusionary conduct, no such curtailment has occurred.

51. J&J has continued to raise the price of Remicade even after the introduction of Inflectra and Renflexis, without losing significant sales, demonstrating that it continues to have monopoly power. Remicade's market share remains above 95%.

52. For clinical reasons, among others, physicians and patients prefer infliximab to other products designed to treat the relevant conditions.

53. By controlling the supply of Remicade and excluding or suppressing biosimilars to Remicade, J&J was able to maintain a supracompetitive price for Remicade without losing significant sales.

54. The only drugs that could have constrained the price (or sales) of Remicade absent J&J's exclusionary conduct are biosimilar infliximab products such as Inflectra and Renflexis, and even those drugs are imperfect economic substitutes. As explained above, the selection of a product to prescribe is made by the physician, not the patient, and physicians typically do not make prescribing decisions on the basis of price. As also explained above, biosimilars, unlike AB-rated generics, are not automatically substitutable for the reference listed drug. Thus, for the majority of Remicade patients who are stable on Remicade, Inflectra and Renflexis did not pose a substantial competitive threat. However, for the minority of Remicade patients who are starting treatment on infliximab, Inflectra and Renflexis did pose a substantial competitive threat to Remicade's monopoly position, and J&J recognized the threat. Absent J&J's exclusionary conduct, Inflectra and Renflexis would have taken sales away from Remicade or forced J&J to lower the price of Remicade to avoid such a loss of sales.

55. J&J knew that entry of biosimilar versions of Remicade would be a significant market event. From 1998 to 2016, other branded drugs that can be used to treat the relevant conditions entered the market but did not take sales from Remicade or cause J&J to lower its price. J&J knew that, in contrast to those drugs, the entry of biosimilar products had the potential to substantially curtail J&J's monopoly unless J&J implemented exclusionary measures.

56. At all relevant times, J&J has sold Remicade at prices well in excess of marginal costs, and in excess of the competitive price, and has enjoyed high profit margins.

57. J&J, at all relevant times, enjoyed high barriers to entry with respect to competition in the relevant product market and high costs of entry and expansion.

58. Until 2016, J&J's market share in the relevant market was 100%. Even after the entry of both Inflectra and Renflexis, J&J's market share has remained above 95%.

VIII. EFFECT ON COMPETITION AND CONTINUING INJURY TO PLAINTIFFS

59. J&J's anticompetitive conduct has had the purpose and effect of restraining competition unreasonably and injuring competition by protecting Remicade from biosimilar competition. As a result of that conduct, Plaintiffs and other purchasers of the drug have been deprived of the benefits of the free and open competition that the antitrust laws are intended to foster.

60. J&J's anticompetitive conduct is ongoing and threatens continuing loss and injury to Plaintiffs unless enjoined by this Court. The exclusionary agreements between J&J and health insurers described above are continuing agreements and will continue to foreclose competition for as long as they remain in effect. Moreover, J&J has every reason to renew and extend these agreements in the future. Plaintiffs continue to pay substantial sums of money to make purchases of Remicade that would be purchases of the less expensive Pfizer and Merck

biosimilars but for J&J's unlawful and exclusionary conduct. Absent intervention by this Court, J&J's exclusionary conduct will continue to foreclose competition in the relevant market and Plaintiffs will continue to be overcharged.

61. Plaintiffs have purchased and continue to purchase substantial amounts of Remicade. As a direct result of the illegal conduct alleged herein, Plaintiffs and their assignors have paid and continue to pay prices for infliximab that are substantially greater than the prices they would have paid absent the illegal conduct alleged herein.

62. Plaintiffs' actual and threatened injuries are injuries of the type the antitrust laws were designed to prevent and flow from that which makes Defendants' acts unlawful.

IX. CLAIMS FOR RELIEF

COUNT I: VIOLATION OF 15 U.S.C. § 2 MONOPOLIZATION

63. Plaintiffs incorporate by reference the allegations in paragraphs 1 through 62 above as though fully set forth herein.

64. At all relevant times, J&J possessed monopoly power in the relevant market.

65. Through its overarching anticompetitive scheme, as set forth above, J&J willfully maintained its monopoly power in the relevant market using restrictive or exclusionary conduct, rather than by competing on the merits, and thereby injured Plaintiffs.

66. It was J&J's conscious object to further its dominance in the relevant market by and through the overarching anticompetitive scheme.

67. J&J's scheme has substantially harmed competition.

68. There is and was no cognizable, non-pretextual procompetitive justification for J&J's actions that outweighs the scheme's harmful effects.

69. As a direct and proximate result of J&J's monopolistic conduct, as alleged herein, Plaintiffs have suffered and continue to suffer injury to their business and property in the form of overcharges.

COUNT II: VIOLATION OF 15 U.S.C. § 2
ATTEMPT TO MONOPOLIZE

70. Plaintiffs incorporate by reference the allegations in paragraphs 1 through 62 above as though fully set forth herein.

71. J&J, through its overarching anticompetitive scheme, specifically intended to maintain monopoly power in the relevant market. It was J&J's conscious objective to control prices and/or to exclude competition in the relevant market.

72. The natural and probable consequence of J&J's overarching anticompetitive scheme, which was intended by it and plainly foreseeable to it, was to control prices and exclude competition in the relevant market.

73. There was a substantial and real chance, a reasonable likelihood, and/or a dangerous probability that J&J will succeed in and achieve its goal of maintaining monopoly power in the relevant market.

74. As a direct and proximate result of J&J's attempt to monopolize the relevant market, Plaintiffs have suffered and continue to suffer injury to their business and property in the form of overcharges.

COUNT III: VIOLATION OF 15 U.S.C. § 1
CONSPIRACY IN RESTRAINT OF TRADE

75. Plaintiffs incorporate by reference the allegations in paragraphs 1 through 62 above as though fully set forth herein.

76. As set forth above, the exclusive-dealing and other exclusionary contracts between J&J and health insurers described above have substantially harmed competition in the relevant market.

77. The purpose and effect of those contracts was to maintain J&J's monopoly power in the relevant market.

78. There is no legitimate, nonpretextual, procompetitive business justification for the contracts that outweighs their harmful effect. Even if there were some such conceivable justification, the contracts were not necessary to achieve such a purpose.

79. At all relevant times, J&J possessed market power in the relevant market.

80. As a direct and proximate result of J&J's unlawful conspiracy in restraint of trade, Plaintiffs have suffered and continue to suffer injury to their business and property in the form of overcharges.

X. DEMAND FOR JUDGMENT

WHEREFORE, Plaintiffs pray for judgment against Defendants and for the following relief:

A. A declaration that the conduct alleged herein is in violation of Sections 1 and 2 of the Sherman Act;

B. A permanent injunction enjoining Defendants from continuing their illegal conduct and requiring them to take affirmative steps to dissipate the continuing anticompetitive effects of their prior conduct;

C. An award of Plaintiffs' overcharge damages, in an amount to be determined at trial, trebled;

D. An award of Plaintiffs' costs of suit, including reasonable attorneys' fees as provided by law; and

E. Such other and further relief as the Court deems just and proper.

XI. JURY DEMAND

Plaintiffs demand a trial by jury of all issues so triable.

Dated: June 6, 2018

Respectfully submitted,

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