UNITED STATES DISTRICT COURT EASTERN DISTRICT OF PENNSYLVANIA

CITY OF PROVIDENCE, individually and on behalf of all others similarly situated, Plaintiff,

Case No.

CLASS ACTION COMPLAINT

v.

JURY TRIAL DEMANDED

JOHNSON & JOHNSON and JANSSEN BIOTECH, INC.,

Defendants

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Plaintiff City of Providence ("Plaintiff" or "Providence") brings this action on behalf of itself and all other similarly situated third-party payors and consumers against Johnson & Johnson and Janssen Biotech, Inc. (together, "J&J" or "Defendants"). Based on personal knowledge as to facts pertaining to it, and upon information and belief as to all other matters, Plaintiff alleges as follows.

PRELIMINARY STATEMENT

1. J&J has engaged in an anticompetitive scheme designed to prevent competition to its blockbuster biologic, Remicade (infliximab), thereby raising and maintaining infliximab prices above competitive levels. Remicade, which is used to treat a host of conditions, including rheumatoid arthritis, Crohn's Disease, and ulcerative colitis, is a biologic, which is a unique category of medications that are derived from living organisms. It was first sold in the United States in 1998 and was the only infliximab product on the market until its patents expired in 2016. J&J estimates that 2.6 million patients worldwide take Remicade.¹ At a cost of approximately \$4,000 per infused dose, J&J has enjoyed annual Remicade sales in the U.S. of approximately \$5 billion.²

2. Leveraging its monopoly power, J&J forced health insurance companies and healthcare providers to enter into exclusionary agreements that effectively blocked competition for Remicade, thus causing Plaintiff and Class members to overpay on their infliximab purchases.

3. To date, two Remicade biosimilars (*i.e.*, a generic version of a biologic) have been brought to market. On April 5, 2016, Pfizer, Inc. ("Pfizer"), in partnership with Celltrion, received

¹ REMICADE® (infliximab), https://www.remicade.com/ (last visited Nov 7, 2017).

² Reuters, *J&J says pharma future bright, despite threat to Remicade* (Oct. 18, 2016), *available at* https://www.reuters.com/article/johnsonjohnson-results/update-3-jj-says-pharma-future-bright-despite-threat-to-remicade-idUSL4N1CO3HB/.

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FDA approval for the biosimilar Inflectra (infliximab-dyyb). Pfizer began shipping Inflectra in November 2016 at a 15% discount to the wholesale acquisition cost ("WAC") of Remicade.³ On April 17, 2017, the FDA approved Merck and Samsung Bioepsis' ("Samsung") biosimilar, Renflexis (infliximab-abda). Merck began selling Renflexis in July 2017 at a 35% discount to the list price of Remicade.⁴ Pfizer similarly adjusted its list price on Inflectra in response.⁵

4. Despite offering substantial price discounts, these biosimilars have garnered only a *de minimis* portion of the market as a result of J&J's multi-faceted exclusionary scheme.⁶ One aspect of the scheme involved forcing insurers to enter into agreements that require the insurer to commit not to cover the biosimilars or to do so only on condition that the patient has first tried Remicade and had an unsuccessful experience. For example, Connecticut Health Insurance Provider ConnectiCare's Pharmacy Pre-Authorization Criteria states that it considers Inflectra and Renflexis to be medically necessary only for those patients "who have had an intolerance to, or a treatment failure of, Remicade."⁷ This "first fail" condition effectively means that the insurer will

³ biopharma-reporter.com (2017), *Discount dancers: Pfizer's infliximab matching Merck's new biosimilar rival*, https://www.biopharma-reporter.com/Article/2017/07/26/Pfizer-cuts-biosimilar-price-to-match-Merck-s-new-infliximab-rival.

⁴ Merck & Co., Inc. – Investors, *Merck Announces U.S. Launch of RENFLEXISTM (infliximab-abda)*, a *Biosimilar of Remicade, for All Eligible Indications*, http://investors.merck.com/news/press-release-details/2017/Merck-Announces-US-Launch-of-RENFLEXIS-infliximab-abda-a-Biosimilar-of-Remicade-for-All-Eligible-Indications/default.aspx.

⁵ biopharma-reporter.com (2017), *supra* at note 3.

⁶ See Jonathan Rockoff, *Pfizer Alleges J&J Thwarted Competition to Remicade in Legal Test of Biotech-Drug Companies*, WSJ, Sept. 20, 2017, *available at* https://www.wsj.com/articles/pfizer-files-antitrustlawsuit-alleging-j-j-thwarted-use-of-biosimilar-rival-to-remicade-1505913080; *see also* Dan Stanton, "Remicade Biosimilar: J&J's 'Fear and Loathing' Subdued as Pfizer Slugs It Out," Biopharma-Reporter.com, *available at* https://www.biopharma-reporter.com/Article/2017/09/15/J-J-on-biosimilars-Remicade-erosion-subdued-as-Pfizer-slugs-it-out?nocount (noting that, as of September 2017, J&J's U.S. Remicade sales had declined by a mere 5%).

⁷ ConnectiCare, *Pharmacy Pre-Authorization Criteria, available at* https://www.connecticare.com/providers/PDFs/Pharmacy/Infliximab.pdf.

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never cover Inflectra or Renflexis, because it would be illogical to give a patient who experiences a Remicade treatment failure an identical biosimilar.

5. J&J was able to coerce insurers into accepting exclusionary contract terms of this nature, in part, by threatening to deny rebates to insurers that rejected J&J's exclusivity conditions and by bundling rebates, as described in further detail below. As a result of these tactics, insurers have no choice but to agree to J&J's exclusivity conditions.

6. The exclusivity agreements that are targeted at insurers also have a direct impact on the purchasing decisions of healthcare providers. Infliximab is an infusion product that is administered in a clinical setting. Therefore, healthcare providers purchase the product using their own funds, with the expectation that the provider will be reimbursed by the insurer at the time the product is administered. Given the cost of infliximab products (Remicade costs approximately \$26,000 for a full year of treatment), a healthcare provider will be strongly dissuaded from stocking a product that it fears may not be covered by insurers. Pfizer alleges that providers have overwhelmingly chosen to stock only Remicade rather than risk possible denials of coverage for Inflectra or Renflexis. Thus, providers have declined to purchase Inflectra and Renflexis across the board, even for patients covered by insurance plans that do cover these products.

7. The entry of biosimilars into the market should have caused prices of Remicade to decline. Yet in the first two quarters following the entry of Inflectra, the average sale price ("ASP") *increased.*⁸

⁸ See CMS.gov, Centers for Medicare & Medicaid Services, 2017 ASP Drug Pricing Files, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/2017ASPFiles.html.

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8. As a result of J&J's exploitation of its monopoly power and extensive exclusionary conduct, Plaintiff and the Class have fewer choices and pay more for their infliximab purchases than they otherwise would, but for J&J's anticompetitive conduct.

JURISDICTION AND VENUE

9. Plaintiff brings this action under Section 16 of the Clayton Act, 15 U.S.C. § 26, to obtain equitable and injunctive relief for violations of Section 2 of the Sherman Antitrust Act, 15 U.S.C. § 2. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1337. Plaintiff also asserts claims for damages, restitution, and other relief, under state antitrust, unfair competition, consumer protection and unjust enrichment laws.

10. The Court additionally has subject matter jurisdiction over these state law claims under 28 U.S.C. § 1367 because those claims are so related to the federal claim that they form part of the same case or controversy.

11. The Court further has subject matter jurisdiction over the state law claims by virtue of the Class Action Fairness Act of 2005 ("CAFA"), which amended 28 U.S.C. §§1332 to add a new subsection (d) conferring federal jurisdiction over class actions where, "any member of a class of Plaintiff is a citizen of a State different from any Defendants" and the aggregate amount in controversy exceeds \$5,000,000, exclusive of interest and costs. The \$5,000,000 amount-in-controversy and diversity-of-citizenship requirements of CAFA are satisfied here.

12. Venue is proper in this District under Section 12 of the Clayton Act, 15 U.S.C. §22 and 28 U.S.C. §1391(b) through (d), because Defendants transact business within this District, and/or have agents and/or can be found in this District, and the interstate trade and commerce, hereinafter described, is carried out in this District.

PARTIES

13. Plaintiff City of Providence is a municipal corporation with a principal address of 25 Dorrance Street, Providence, Rhode Island. Providence is a self-insured health and welfare benefit plan that provides reimbursement for some or all of the purchase price of prescription drugs, including infliximab. Providence provided reimbursement for some or all of the purchase price of infliximab for its active and retired public employees and their dependents in Rhode Island, Massachusetts, Florida, and Texas.

14. Defendant J&J is a corporation organized and existing under the laws of New Jersey. J&J's principal place of business in the United States is located at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. J&J was the sole supplier of infliximab, marketed as Remicade, between 1998 and 2016, when Inflectra came on the market.

15. Defendant Janssen Biotech, Inc. ("Janssen"), a wholly owned subsidiary of J&J, is headquartered in Horsham, Pennsylvania. Janssen co-owns or has licenses to the Remicade patents and performs the marketing for Remicade in the United States.

FACTUAL BACKGROUND AND OVERVIEW OF REGULATORY FRAMEWORK

A. <u>Biologics and biosimilars</u>

16. As explained by the FDA:

Biological products include a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins. Biologics can be composed of sugars, proteins, or nucleic acids or complex combinations of these substances, or may be living entities such as cells and tissues. Biologics are isolated from a variety of natural sources—human, animal, or microorganism—and may be produced by biotechnology methods and other cutting-edge technologies."⁹

⁹ See U.S. Food & Drug Administration, *What Are "Biologics" Questions and Answers*, https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cber/ucm133077.htm (last visited Sept. 18, 2017).

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17. Some of the most important biologic products are proteins, which have the potential to simulate immune responses.¹⁰ Examples of some of the top biologic products in the U.S. include Humira (used to treat rheumatoid arthritis, plaque psoriasis, Crohn's disease, ulcerative colitis, ankylosing spondylitis, psoriatic arthritis, polyarticular juvenile idiopathic arthritis), Rituxan (used to treat Non-Hodgkins lymphoma, chronic lymphocytic leukemia, rheumatoid arthritis), Lantus (used to treat diabetes), Lucentis (used to treat age related macular degeneration), and Avonex (used to treat multiple sclerosis).¹¹

B. The Biologics Price Competition and Innovation Act

18. The Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148, § 7001, 124 Stat. 119, 804 (2010) (the "BPCIA"), was signed into law in 2010 as part of the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119, 804 (2010).¹² FDA procedures for implementing the BPCIA did not become effective until a few years later. As a result, biosimilars have only recently been brought to market, with the first biosimilar receiving FDA approval in 2015.

19. According to the FDA, "the goal of the BPCI Act is similar, in concept, to that of the Drug Price Competition and Patent Term Restoration Act of 1984 (a.k.a. the "Hatch-Waxman Act") which created abbreviated pathways for the approval of drug products under Federal Food,

¹⁰ National Physicians Biologics Working Group, *Biologics: A Different Class of Medications That Makes a Difference for Our Patients, available at*

http://gallery.mailchimp.com/c67da0b816e8460d454282be4/files/NPBWGWhitePaper_1Final.pdf.

¹¹ thebalance.com, *Top 10 Biologic Drugs in the United States*, https://www.thebalance.com/top-biologic-drugs-2663233.

¹² Ude Lu, *Biologics Price Competition and Innovation Act: Striking a Delicate Balance Between Innovation and Accessibility*, 15 Minn. J.L. Sci. & Tech. 613 (2014), *available at* http://scholarship.law.umn.edu/cgi/viewcontent.cgi?article=1074&context=mjlst.

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Drug, and Cosmetic Act (FFD&C Act)."¹³ The FDA further explained that the BPCIA "aligns with the FDA's longstanding policy of permitting appropriate reliance on what is already known about a drug, thereby saving time and resources and avoiding unnecessary duplication of human or animal testing."¹⁴

20. A biosimilar applicant may rely on the clinical studies of the reference listed drug if it can show: (a) that the proposed biosimilar is "highly similar to the reference product notwithstanding minor differences in clinically inactive components"; and (b) that "there are no clinically meaningful differences between [the biosimilar] and the reference product in terms of safety, purity, and potency." 42 U.S.C. § 262(i)(2).

21. Although biosimilars have no clinically meaningful differences in terms of safety, purity, and potency as compared to the originator's biologic, unlike Hatch-Waxman generics, they are not automatically substitutable for the biologic. Thus, if a doctor prescribes the biologic, a pharmacist cannot substitute a biosimilar unless that product has been designated as interchangeable by the FDA and the relevant state law permits substitution of interchangeable biologics. To date, the FDA has not designated any biosimilar as interchangeable. This means that a patient who wishes to receive the biosimilar must have a prescription that specifies the biosimilar (not the biologic) in order to receive the biosimilar.

22. As a result of the BPCIA's regulatory structure (*i.e.*, the lack of automatic substitution), biologic manufacturers can be expected to maintain a substantial portion of their existing patient base, at least in the near term. However, one would not expect the same outcome

¹³ U.S. Food & Drug Administration, *Implementation of the Biologics Competition and Innovation Act of 2009*, https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/ucm215089.htm (last visited Sept. 18, 2017)

¹⁴ Id.

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for new patients, *i.e.*, patients who are placed on infliximab for the first time following entry of biosimilars into the market. Where a physician is prescribing infliximab for the first time, biosimilar manufacturers should be in a better position to compete, as they are lower cost alternatives that have no clinically meaningful differences in terms of safety, purity, and potency as compared to the biologic.

23. Here, J&J has leveraged the fact that existing patients may be less likely to switch to a biosimilar to foreclose competition not only in the market for existing patients but also in the market for patients newly prescribed infliximab. This concept is sometimes referred to as leveraging or tying the contestable demand (*i.e.*, patients newly prescribed infliximab) to the incontestable demand (*i.e.*, existing patients who were taking Remicade prior to the launch of a biosimilar). As a result of this conduct, J&J forestalls biosimilar competition not only as to existing patients, but also as to new patients.

C. <u>Infliximab</u>

24. Infliximab is an artificial antibody that inhibits or prevents activity of the immune system. As a biologic, infliximab is derived from a living organism. It is used to treat a number of conditions, including Crohn's disease, ulcerative colitis, rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, and plaque psoriasis. It must be injected, as the digestive system would destroy it. Thus, infliximab patients must (in most cases) visit clinics, hospitals, or other medical facilities to receive the therapy from healthcare professionals. As a result, patients rarely purchase infliximab themselves at retail pharmacies. Instead, infusion centers, clinics, and hospitals purchase infliximab, and after administration, seek reimbursement from the patient's insurer or other third-party payor, such as Plaintiff.

D. J&J's Remicade

25. J&J introduced the first infliximab product in the United States in 1998 under the brand name Remicade. An estimated 475,000 patients in the U.S. receive at least one dose of Remicade annually. This fact, combined with the cost (approximately \$4,000 per infused dose at list price), makes administering Remicade a major expense item for insurers and healthcare providers. J&J's list price increases for Remicade and other pricing actions have resulted in consistent increases in Remicade's ASP. Indeed, J&J has been able to continue raising the price of Remicade notwithstanding the arrival of Inflectra.

E. <u>Pfizer's Inflectra</u>

26. The South Korean company Celltrion received FDA approval for its Remicade biosimilar Inflectra on April 5, 2016 for treatment of Crohn's Disease, ulcerative colitis, rheumatoid arthritis, ankylosing spondylitis (arthritis of the spine), psoriatic arthritis, and plaque psoriasis. In a press release, Janet Woodcock, M.D., director of FDA's Center for Drug Evaluation and Research reiterated that approval as a biosimilar reflects a determination of "no clinically meaningful differences" from the originator, and stated that "[p]atients and the health care community can be confident that biosimilar products are high quality and meet the agency's rigorous scientific standards."¹⁵

27. On March 6, 2015, Janssen filed a lawsuit against Celltrion and Hospira, Inc. (subsequently acquired by Pfizer), alleging patent infringement.¹⁶ On August 17, 2016, J&J's patent covering the infliximab antibody was ruled invalid by the United States District Court for the District of Massachusetts, a ruling that confirmed that J&J had no valid right to exclude Pfizer

¹⁵ U.S. Food & Drug Administration, *FDA Approves Inflectra, A Biosimilar to Remicade* (Apr.5, 2016), https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm494227.htm.

¹⁶ See Janssen Biotech, Inc., et al. v. Celltrion Healthcare Co., Ltd., et al., Case No. 15-cv-10698 (D. Mass).

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(or other potential biosimilar entrants). The Court held that the antibodies covered by J&J's Remicade patent had been disclosed and claimed in an earlier patent.¹⁷ Just a few months after the District Court's ruling, the U.S. Patent and Trial Appeal Board (of the United States Patent and Trademark Office) issued a final decision in a re-examination of the same patent, holding that the patent was invalid.¹⁸

28. After overcoming these hurdles, and after a 180-day notice period required by the BPCIA, Pfizer began selling Inflectra on November 28, 2016.

29. Other than pediatric ulcerative colitis, for which J&J has Orphan Drug Exclusivity ("ODE"), Inflectra is approved for all the indications for which Remicade is approved. Remicade's ODE ends in September 2018,¹⁹ after which Inflectra (and Renflexis) will be eligible to seek approval for pediatric ulcerative colitis, which indication accounts for less than 5% of overall infliximab utilization.

30. Pfizer introduced Inflectra with a list price 15% lower than Remicade's and, in negotiations with insurers and providers, offered substantial additional price concessions in the form of discounts and/or rebates, which in some instances were more than 40% below Inflectra's list price. Despite these robust price concessions, J&J has maintained its stranglehold on the infliximab market, losing a mere 5% to competition from biosimilars, thus enabling it to maintain prices far above competitive levels.

¹⁷ Andrew Williams, An Inflectra Update – Pfizer Announces Launch of REMICADE Biosimilar, Patent Docs (Oct. 19, 2016), available at http://www.patentdocs.org/2016/10/an-inflectra-update-pfizer-announces-launch-of-remicade-biosimilar.html.

¹⁸ Id.

¹⁹Juwaria Waheed, *Addendum to Primary Clinical Review*, U.S. Food & Drug Administration, *available at*

https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/DevelopmentResources/UCM5102 08.pdf.

F. Samsung's Renflexis

31. Samsung Bioepsis and Merck received FDA approval for their Remicade biosimilar, Renflexis, on April 21, 2-17. Renflexis was approved for all eligible indications, including Crohn's Disease, pediatric Crohn's Disease, ulcerative colitis, rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, and plaque psoriasis.²⁰

32. On May 17, 2017, Janssen filed suit against Samsung Bioepis alleging that Renflexis violates three of its manufacturing process patents.²¹ Samsung Bioepis responded that "[w]e are confident we do not infringe Janssen's patents," and further stated its belief that the suit was filed to delay entry of Renflexis.²²

33. Samsung/Merck began selling Renflexis in July 2017 at a list price of \$753.39, which represented a 35% discount to the list price of Remicade.²³

G. <u>The Importance of Insurance Coverage for Infliximab</u>

34. Most patients who are prescribed Remicade have some form of insurance coverage or qualify for patient assistance. The sources of insurance coverage are (a) private insurance, accounting for about 67 percent of patients nationally, and (b) government insurance programs, accounting for approximately 37 percent. *See* U.S. Bureau of the Census, *Health Insurance Coverage in the United States: 2013* ("2013 Census"), *available at*

²⁰ Merck Press Release, *Merck Announces U.S. Launch of RENFLEXIS (infliximab-abda), a Biosimilar of Remicade, for All Eligible Indications* (July 24, 2017), *available at* http://www.mrknewsroom.com/news-release/corporate-news/merck-announces-us-launch-renflexis-infliximab-abda-biosimilar-remicade-.

²¹ See Janssen Biotech, Inc. v. Samsung Bioepis Co., Ltd., Case No. 17-cv-03524 (D.N.J.).

²² Se Young Lee, *Janssen files suit in U.S. to block sale of Samsung Bioepis' Remicade copy*, Reuters (May 18, 2017), *available at* https://www.reuters.com/article/us-johnson-johnson-samsung-bioepis-lawsu/janssen-files-suit-in-u-s-to-block-sale-of-samsung-bioepis-remicade-copy-idUSKCN18F09G.

²³ See Merck Press Release, supra note 20.

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https://www.census.gov/content/dam/Census/library/publications/2017/demo/p60-260.pdf.²⁴ Insurance coverage and reimbursement are key to the adoption of the product by patients and healthcare providers alike. If a product as expensive as Remicade is not widely reimbursed, it will not be significantly utilized.

35. Remicade is not dispensed in a retail pharmacy but rather administered intravenously in a clinic or other institutional setting. As a result, it is generally included under the "medical benefit" as opposed to the "pharmacy benefit" of most health plans. In the pharmacy benefit setting, physicians prescribe a drug and the patient procures the medication him or herself at the pharmacy, paying for it with a combination of insurance coverage (either private or government-sponsored) and out-of-pocket payment (usually, a co-pay). In the pharmacy benefit context, neither the prescribing physician nor the institution with which the physician is affiliated bears financial risk with respect to the drug selected. This is because the drug is not purchased and stocked in advance by providers at their own cost. Rather, the pharmacy buys the drug, dispenses it, and is reimbursed.

36. In contrast, "medical benefit" products such as Remicade are administered at a clinic or other healthcare provider site, and the provider itself first purchases the drug product for use in the infusion treatment of patients. The provider then later seeks reimbursement for the drug from a third party payer at the time the drug is administered. In this context, the healthcare provider has a strong interest in utilizing drugs that are widely covered by insurance, particularly by the major national commercial health insurers and significant regional insurers. If a drug product is not widely covered, thereby creating a risk that coverage might be denied, providers would be

²⁴ The figures total more than 100% because some patients have more than one type of coverage in a given year. *See* 2013 Census at fn. 2.

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burdened with a potential financial loss for what they paid for the product. Under these circumstances, providers are much less likely to purchase that product.

37. Many of the facilities administering infusion services of the type at issue here are physician-owned. Thus, the physicians themselves have both prescribing authority and a strong financial incentive to avoid products that are not widely covered.

38. As discussed further below, J&J's anticompetitive conduct has blocked market penetration by the biosimilars, Inflectra and Renflexis. As a result, patients have fewer infliximab product choices and they (along with third party payors) pay more on their infliximab purchases than they otherwise would.

DEFENDANTS' EXCLUSIONARY SCHEME

39. In the fall of 2016, as Pfizer prepared to launch the first Remicade biosimilar, J&J publicly touted its "Biosimilar Readiness Plan." For example, during an earnings call, Worldwide Chair for Pharmaceuticals, Juaquin Duato, stated, "We are fully prepared to execute our focused biosimilar readiness plan," including "*developing innovative contracts*." These "innovative contracts" included exclusive dealing arrangements and bundled rebates that operated to exclude competition, as described more fully below. Mr. Duato further touted that "We are confident that we have our readiness plan for our biosimilar launch in the U.S. . . . So we feel well-prepared to face the biosimilar, and as [Chief Financial Officer Dominic Caruso] said, *we are convinced that we will continue to grow our business in the face of biosimilar competition*."²⁵ When asked about J&J's "defense strategy for Remicade," Chief Executive Officer Alex Gorsky went so far as to

²⁵Johnson & Johnson (JNJ) Q3 2016 Results - Earnings Call Transcript (Oct. 18, 2016), available at https://seekingalpha.com/article/4012996-johnson-and-johnson-jnj-q3-2016-results-earnings-call-transcript?part=single.

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say, "I would actually describe it as an offensive approach."²⁶ A central feature of this "offensive strategy" entailed coerced exclusivity agreements with insurers.

40. Exclusionary contracts with insurance companies effectively prevent insurers from providing coverage for biosimilar Inflectra and Renflexis. A key component of this "Biosimilar Readiness Plan" was the extraction of commitments from commercial insurance companies and other insurers to exclude biosimilars from coverage under their plans, making Remicade the exclusive infliximab available to patients covered by those plans. These exclusionary arrangements have taken various forms. Some insurers have entered into contracts with J&J that require the insurer to exclude biosimilars outright from their medical policies and/or drug formularies. In other instances, J&J achieved the same effect by imposing on insurance companies a "first fail" requirement. This is essentially a commitment from the insurer that it will not provide reimbursement for a biosimilar unless the patient has first tried and failed on Remicade. This provision all but ensures that the biosimilar will never be prescribed because, if a patient fails on Remicade, it would be illogical, and indeed contrary to sound medical judgment, for a physician to switch to the therapeutically equivalent biosimilar, which works in exactly the same way. Regardless of their specific form, these contracts all enabled J&J to continue to maintain its monopoly power in the infliximab market.

41. According to Pfizer, J&J has induced most major health insurers, covering at least 70 percent of commercially insured patients in the United States, to adopt these improper contractual exclusivity restrictions, which as described above include outright bans on Inflectra and Renflexis coverage or so-called "fail first" requirements. J&J unlawfully leveraged its

²⁶ Morgan Stanley Global Health Care Conference Call (Sept. 14, 2016), available at https://seekingalpha.com/article/4006218-johnson-and-johnson-jnj-management-presents-morgan-stanley-global-healthcare-brokers?part=single.

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monopoly power and coerced insurance companies into accepting these exclusionary commitments, in part by threatening to deny rebates to insurers that decline J&J's exclusivity commitments. These exclusive dealing arrangements were buttressed by J&J's bundling of rebates across products, effectively tying the rebate on one of J&J's other products to the rebates provided on Remicade purchases.

42. J&J used exclusionary rebates and illegal bundling arrangements with insurance company payers to effectively prevent coverage for any infliximab product other than Remicade. As J&J's Worldwide Chair for Pharmaceuticals Duato explained on an earnings call, "We are fully prepared to execute our focused biosimilar readiness plan," including "developing innovative contracts . . . [to] utilize the full breadth of our portfolio."²⁷ The "full breadth of [J&J's] portfolio" includes drugs such as 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 are widely used. For example, in 2016, sales of Simponi/Simponi Aria and Stelara were \$1.745 billion and \$3.232 billion, respectively.²⁸ J&J has threatened insurers with the loss of rebates on these other drugs, as well as Remicade, if they do not agree to exclude Inflectra and Renflexis from coverage.

43. J&J's threat to deny Remicade rebates to insurance companies that do not comply with J&J's exclusionary requirements is highly effective because there exists a substantial base of patients across the country who are already controlling their diseases with Remicade. Although biosimilars have no clinically meaningful differences in safety, purity, and potency from the

²⁷ Johnson & Johnson Transcript, *supra* at note 24.

²⁸ Johnson & Johnson, 2016 Annual Report (Form 10-K), at 18 (Feb. 27, 2017), *available at* https://jnj.brightspotcdn.com/88/3f/b666368546bcab9fd520594a6016/2017-0310-ar-bookmarked.pdf

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biologic originator, they cannot (unlike generic drugs under the Hatch-Waxman structure) be substituted for the biologic without the prescriber's prior approval.

44. Although these exclusionary tactics are aimed in the first instance at insurance companies, their anticompetitive effects reverberate throughout the healthcare provider network.

45. The exclusionary conduct targeted at insurers impacted healthcare providers' prescribing and purchasing practices. Infliximab is an infusion product that must be administered in a clinical setting. Healthcare providers, such as hospitals and clinics, must use their own funds to stock the product, relying upon subsequent reimbursement from insurers to recoup their expenses. Given the cost of biologic drugs generally, and Remicade in particular, there is almost no chance that providers will pay for a product that is not widely covered by insurers for fear of stocking a product that will not be reimbursed after the provider administers it to a patient, as even a single unreimbursed dose may cost the provider in excess of \$4,000.

46. Given the widespread gaps in insurance coverage for Inflectra and Renflexis caused by J&J's anticompetitive scheme, providers have overwhelmingly chosen to stock only Remicade, rather than deal with the risk of possible denials of coverage for Inflectra and Renflexis. Thus, providers have declined to purchase Remicade biosimilars across the board, even for patients covered by insurance plans that do cover the product. To further promote the exclusion of biosimilars, J&J has also imposed exclusionary contracts on providers themselves (*e.g.*, clinics, hospitals, etc.).

47. *J&J coerced healthcare providers into exclusionary contracts.* According to Pfizer, following the launch of its competing product Inflectra, J&J began offering large healthcare providers additional rebates and/or discounts on Remicade on the condition that the provider commit to buy Remicade to fulfill all or nearly all of those providers' infliximab needs. Eligibility

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for the rebates hinged on the providers maintaining purchase levels for Remicade at, or very close to, the levels associated with the year prior to Inflectra's launch. As a practical matter, these contracts make Remicade the exclusive infliximab utilized by the participating providers.

48. In addition, one analyst has reported that, "J&J bundled several drugs and medical devices for larger hospitals, making Inflectra less economical."²⁹ Although the bundling of rebates across products is unquestionably a violation of the antitrust laws, it is but one component of a multifaceted scheme by J&J to illegally leverage its monopoly power to effectively exclude biosimilar competition for Remicade.

49. J&J also sought to influence patient decision-making directly by creating

disincentives for the patients to switch to a biosimilar. As explained in a recent article by the

Center for Biosimilars:

[P]atients who hope to achieve cost savings by switching from the reference infliximab to a biosimilar treatment may face disincentives from their health plans. <u>UnitedHealthcare</u>, for example, continues to prefer Remicade to biosimilar treatments, and noted in its July bulletin that patients who want to switch to the biosimilar Renflexis may be required to transition their infusion services to another site of service if they want to continue to receive coverage.³⁰

This tactic was first applied to Inflectra and subsequently to Reflexis:³¹

²⁹ Carly Helfand, *How did Johnson & Johnson beat back Remicade's biosim? Call it the art of the deal* (Jul. 20, 2017), http://www.fiercepharma.com/pharma/what-s-behind-johnson-johnson-s-successful-remicade-defense-and-can-it-last.

³⁰ Kelly Davio, *When Will Patients Benefit from Deepening Infliximab Discounts?*, The Center for Biosimilars (Sept. 5, 2017), *available at* http://www.centerforbiosimilars.com/news/when-will-patients-benefit-from-deepening-infliximab-discounts.

³¹ See United Healthcare Network Bulletin, July 2017, p. 6, available at

https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0ahUKEwjbs6W38KXX AhUD12MKHVNdDccQFggtMAA&url=https%3A%2F%2Fwww.unitedhealthcareonline.com%2Fccmc ontent%2FProviderII%2FUHC%2Fen-

US%2FAssets%2FProviderStaticFiles%2FProviderStaticFilesPdf%2FNews%2FJuly-Interactive-Network-Bulletin-2017.pdf&usg=AOvVaw1wmpfcqXue0luSJTKs5ptW.

Effective Aug. 1, 2017

Renflexis*: For dates of service on or after Aug. 1, 2017, we'll require notification/prior authorization for the specialty medication Renflexis (infliximab-abda). Renflexis is a biosimilar to Remicade*, our preferred infliximab product. Please note, Inflectra was the first infliximab biosimilar product approved by the FDA. It currently requires prior authorization in all places of service. Coverage reviews may include evaluation of the site of service, if requested in an outpatient hospital setting. If coverage is not approved, you and your patient may decide to switch to Remicade, our preferred infliximab product, and/or transition services to an alternate site of service in order for the patient to continue benefit coverage.

50. In addition to the foregoing anticompetitive conduct aimed as insurers, providers, and patients, J&J also attempted to forestall biosimilar entry altogether through the prosecution of sham patent litigation against the biosimilar manufacturers.

51. J&J sought to forestall biosimilar competition altogether by filing lawsuits alleging that the biosimilars Inflectra and Renflexis infringed upon its patents, which patents were ultimately deemed invalid. On March 6, 2015, Janssen filed a lawsuit against Celltrion and Hospira, Inc. (later acquired by Pfizer)³² for patent infringement under 35 U.S.C. §271(e)(2)(C) in the United States District Court for the District of Massachusetts. Janssen Biotech, Inc. v. Celltrion Healthcare Co., Ltd., et al., No. 1:15-cv-10698 (D. Mass.). Janssen asserted claims against Celltrion and Hospira for infringement of six of Janssen's patents covering infliximab, U.S. Patent Nos. 6,284,471 (the "'471 Patent"), 7,223,396, 5,807,715, 7,598,083 (the "'083 Patent"), 6,900,056 (the "'056 Patent"), and 6,773,600 (the "'600 Patent"). Over the course of the litigation, Janssen voluntarily dismissed its claims with respect to all but the '471 Patent, as these other patents expired during the litigation.

52. On August 19, 2016, the District Court entered a partial judgment in favor of Celltrion and Hospira, ruling that the '471 Patent was invalid. *Janssen Biotech, Inc. v. Celltrion*

³² Pfizer acquired Hospira on September 3, 2015. *See* Pfizer Press Release, *available at* https://www.pfizer.com/news/press-release/press-release-detail/pfizer_completes_acquisition_of_hospira.

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Healthcare Co. Inc., No. 15-cv-10698, 2016 WL 4445231 (D. Mass. Aug. 19, 2016). On September 26, 2016, the District Court entered final judgment finding the '471 Patent invalid. *Janssen Biotech, Inc. v. Celltrion Healthcare Co. Inc.*, 210 F. Supp. 3d 244 (D. Mass. 2016). These rulings confirmed that Janssen and J&J had no right to exclude Pfizer (or other potential biosimilar entrants). Furthermore, by these rulings, the District Court concluded that the '471 Patent had been disclosed and claimed in an earlier patent. Janssen filed an appeal to the United States Circuit Court of Appeals for the First Circuit, which appeal remains pending.

53. Then on November 14, 2016, the United States Patent Trial and Appeal Board affirmed a final rejection of the '471 Patent for obviousness-type double patenting in view of two prior patents. *See Ex parte Janssen Biotech, Inc. & N.Y. Univ.*, Appeal 2016-006590 (U.S. P.T.A.B. Nov, 14, 2016).

54. Relatedly, on May 17, 2017, Janssen filed a lawsuit against Samsung, asserting that Renflexis infringed three of Janssen's patents: the '600 Patent, the '056 Patent, and the '083 Patent. *Janssen Biotech, Inc. v. Samsung Bioepis Co., Ltd.*, No. 2:17-cv-03524 (D.N.J.). Notably, by the time Janssen filed its lawsuit against Samsung, Janssen had already stipulated to the dismissal of its claims against Celltrion and Hospira for infringement of the '600 Patent and the '056 Patent; in addition, within weeks of filing its lawsuit against Samsung, Janssen subsequently stipulated to the dismissal of its infringement claims against Celltrion and Hospira regarding the '083 Patent.

55. The voluntary dismissal of most of its patent infringement claims, along with the invalidation of a central Remicade patent at issue in the patent litigation, suggests that Janssen's lawsuits against the above-referenced biosimilar manufacturers lacked a legitimate basis and constituted sham patent litigation intended to impermissibly forestall competition to Remicade.

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56. J&J's exclusionary plan has succeeded in preventing competition from biosimilars, causing Plaintiff and Class members to pay more for infliximab than they otherwise would have. According to Pfizer, virtually no national commercial health insurer provides coverage for Inflectra or Renflexis, except under the spurious "fail first" scenario. Despite some coverage by regional and government plans, Inflectra and Renflexis have secured just 5% percent of total infliximab unit sales in the U.S. to date.

57. As a result of J&J's anticompetitive scheme, Plaintiff and the Class have been denied the benefits of biosimilar competition and have, as a result, paid more for their infliximab purchase than they otherwise would have. Indeed, since the time the FDA approved Inflectra and J&J implemented its publicly-stated plan to block biosimilars, J&J has *raised* the list price of Remicade. This despite the entry of two biosimilars, which are offered at a substantial discount to that of Remicade.

58. In the absence of J&J's anticompetitive conduct, Pfizer (and subsequently Samsung) could have, at a minimum, competed aggressively for those new patients placed on infliximab after the biosimilar launch, which competition would have resulted in lower prices on all infliximab products.

59. As explained in a paper recently published in the International Journal of Industrial Organization, loyalty discounts, like those offered by J&J on Remicade (*i.e.*, large rebates on Remicade and other J&J products and devices in return for a purchaser using Remicade to fulfill all or nearly all of its infliximab needs), result in higher prices paid by all infliximab purchasers:

[T]he incumbent commitment to maintain a loyalty discount softens competition for free buyers. The loyalty discount reduces the incumbent's incentive to compete for free buyers because lowering the price to free buyers requires lowering the price to captive buyers. This, in turn, reduces the entrant's incentive to compete for free buyers with aggressive pricing. This increases prices to free buyers, which inflates prices to captive buyers because their price is based on the loyalty discount from

free buyer prices. Prices are elevated above competitive levels to all buyers, reducing consumer and total welfare.

Professors Einer Elhauge and Abraham L. Wickelgren, *Robust Exclusion and Market Division through Loyalty Discounts*, International Journal of Industrial Organization 43 (2015) 111-121.

J&J HAS MONOPOLY POWER IN THE RELEVANT PRODUCT MARKET

60. Monopoly power is the ability of a single seller to raise prices above the competitive price level without losing significant business.

61. For years before Inflectra's entry, J&J's ASP for Remicade increased, yet Remicade did not lose business. In the last five years alone, Remicade's ASP increased nearly 34% percent. Despite Remicade's price hikes, unit sales of Remicade have actually grown during this period.

62. The introduction of Inflectra and Renflexis has done nothing to erode Remicade's monopoly power: since Inflectra was launched, Remicade's ASP has continued to increase without impacting Remicade's market position. Ten months after Inflectra was introduced, Remicade still accounts for approximately 95% percent of all infliximab sales. Indeed, J&J has confirmed that "biosimilar competition" has had "very little impact" on Remicade.³³

63. The relevant product market consists of Remicade and its biosimilars Inflectra and Renflexis (the "Relevant Product Market"). Remicade currently enjoys a share of approximately 95% of the Relevant Product Market.

64. *Barriers to entry*. Substantial barriers to entry exist to developing biosimilars, including research and development, clinical trials, and obtaining FDA approval. According to

³³ Associated Press, Johnson & Johnson says pricing competition squeezed 1Q sales (Apr. 18, 2017), available at https://abcnews.go.com/amp/Health/wireStory/johnson-johnson-tops-1q-profit-forecasts-net-dips-46859000.

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one source, "It takes 7 to 8 years to develop a biosimilar, at a cost of between \$100 million and \$250 million."³⁴

65. If left unchecked, J&J's conduct will serve as an additional barrier to entry, as potential new entrants will recognize that they will be unable to profitably enter the Relevant Product Market, and therefore will not invest the resources necessary to develop a biosimilar, causing further harm to Plaintiff and the Class.

66. J&J's anticompetitive scheme has led directly to nearly all provider accounts that use infliximab declining to purchase Inflectra or Renflexis at all. Even if some portion of a provider's patient base may be covered, providers are unwilling to risk using Inflectra or Renflexis given the risk of coverage denial caused by J&J's scheme. A single denied claim can cost a provider in excess of \$4,000, whereas the typical provider savings in product acquisition cost for a covered Inflectra claim is approximately \$200-300. Because Remicade is nearly universally covered, providers have taken the "safe" option and stocked Remicade over Inflectra and Renflexis, thus increasing the already-substantial foreclosure caused by J&J's exclusionary contracts. Thus, as a practical matter, J&J's scheme has foreclosed biosimilars from the vast majority of provider accounts using infliximab, the essential channel of distribution for infliximab. And, as noted, in terms of sales, Remicade continues to control approximately 95% of infliximab unit sales.

67. *Geographic market*. The relevant geographic market for the Relevant Product Market alleged herein is the United States of America and its possessions and territories, as these products are marketed and sold on a national basis.

³⁴ Erwin A. Blackstone and P. Fuhr Joseph, *The Economics of Biosimilars*, American Health & Drug Benefits, 2013 Sept.-Oct. 6(8): 469-478, *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4031732/#R6

J&J's CONDUCT HAS STIFLED COMPETITION IN THE RELEVANT PRODUCT MARKET WHILE OFFERING NO OFF-SETTING PROCOMPETITIVE OR LEGITIMATE BUSINESS JUSTIFICATIONS

68. The acts and practices detailed above have caused substantial harm to the competitive process as well as to purchasers, who have been deprived of the principal benefits of competition – more choices and lower prices. The anticompetitive effects of J&J's conduct are evident in its pricing of Remicade since Inflectra's (and more recently Renflexis') entry into the market. Despite the fact that Pfizer has offered substantial discounts and a lower ASP to compete for business with insurers and healthcare providers, J&J has been able to increase the price of Remicade without losing any significant share or volume of sales to Pfizer or Samsung.

69. There is no efficiency or cost-reducing justification for J&J's coercive and exclusionary insurer or provider contract terms. J&J has not achieved improved production costs or economies of scale or scope through its contracting strategies. J&J also has achieved no improvements in the Remicade treatment through its contracting strategies. The intent and effect of J&J's conduct was solely to maintain and strengthen its monopoly position for infliximab and exclude biosimilars from the market.

CLASS ALLEGATIONS

70. Plaintiff brings this action on its own behalf and as representative of two Rule 23(b)(3) classes defined as follows:

The "Antitrust/Consumer Protection Damages Class":

All persons or entities who purchased and/or paid for some or all of the purchase price for infliximab in any form, in Arizona, Arkansas, California, the District of Columbia, Florida, Hawaii, Idaho, Illinois, Iowa, Kansas, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, Pennsylvania, Puerto Rico, Rhode Island, South Dakota, Tennessee, Utah, Vermont, Virginia, West Virginia, or Wisconsin, for consumption by themselves, their families, or their members, employees, insureds,

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participants, or beneficiaries at any time during the period November 28, 2016 through and until the anticompetitive effects of Defendants' unlawful conduct cease;

The "Unjust Enrichment Damages Class":

All persons or entities who purchased and/or paid for some or all of the purchase price for infliximab in any form, in every state and territory in the United States except for Ohio and Indiana, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries at any time during the period November 28, 2016 through and until the anticompetitive effects of Defendants' unlawful conduct cease (the "Unjust Enrichment Damages Class").

The Antitrust/Consumer Protection Damages Class and the Unjust Enrichment Damages

Class shall be collectively termed "the Damages Classes."

71. Plaintiff brings this action on its own behalf and as representative of a Rule 23(b)(2)

class defined as follows:

All persons or entities who purchased and/or paid for some or all of the purchase price for infliximab in any form, in the United States or its territories for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries at any time during the period November 28, 2016 through and until the anticompetitive effects of Defendants' unlawful conduct cease (the "Injunction Class").

72. The following persons or entities are excluded from the Damages Classes and the

Injunction Class (collectively, the "Classes"):

- a. Defendants and their officers, directors, management, employees, subsidiaries, or affiliates;
- b. Government entities, except for government-funded employee benefit plans;
- c. All persons or entities who purchased infliximab for purposes of resale or directly from Defendants or their affiliates;
- d. Fully insured health plans (*i.e.*, plans that purchased insurance from another third-party payor covering 100% of the plan's reimbursement obligations to its members);
- e. "Single flat co-pay" consumers who purchased infliximab only via a fixed dollar co-payment that does not vary on the basis of the purchased drug's

status as branded or generic (e.g., \$20 for both branded and generic drugs); and

f. The judges in this case and any members of their immediate families.

73. Members of the Classes are so numerous that joinder is impracticable. Plaintiff believes the Classes include hundreds of thousands, if not millions, of consumers, and thousands of third-party payors.

74. Plaintiff's claims are typical of the claims of the members of the Classes. Plaintiff and all members of the Classes were damaged by the same wrongful conduct by Defendants, *i.e.*, they paid artificially inflated prices for infliximab products and were deprived of the benefits of competition from less-expensive biosimilars, such as Inflectra and Renflexis, as a result of Defendants' wrongful conduct.

75. Plaintiff will fairly and adequately protect and represent the interests of the Classes. Plaintiff's interests are coincident with, and not antagonistic to, those of the Classes.

76. Plaintiff is represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation, and have particular experience with class action antitrust litigation in the pharmaceutical industry.

77. Questions of law and fact common to the members of the Classes 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.

78. Questions of law and fact common to the Damages Classes include:

- a. whether Defendants unlawfully maintained monopoly power through all or part of its overarching scheme;
- b. whether Defendants' anticompetitive scheme suppressed competition from biosimilars, including Inflectra and Renflexis;

- 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 market(s) in which infliximab is sold;
- d. whether direct proof of Defendants' monopoly power is available, and if available, whether it is sufficient to prove Defendants' 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. whether Defendants' scheme, in whole or in part, has substantially affected interstate commerce;
- g. whether Defendants' scheme, in whole or in part, caused antitrust injury to the business or property of Plaintiff and the members of the Damages Classes in the nature of overcharges; and
- h. the quantum of overcharges paid by the Damages Classes in the aggregate.
- 79. Questions of law and fact common to the Injunction Class include:
 - a. whether Defendants unlawfully maintained monopoly power through all or part of its overarching scheme;
 - b. whether Defendants' anticompetitive scheme suppressed competition from biosimilars, such as Inflectra and Renflexis;
 - 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 market(s) in which infliximab is sold;
 - d. whether direct proof of Defendants' monopoly power is available, and if available, whether it is sufficient to prove Defendants' 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. whether Defendants' scheme, in whole or in part, has substantially affected interstate commerce; and
 - g. whether Defendants' scheme, in whole or in part, caused antitrust injury to the business or property of Plaintiff and the Injunction Class.

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80. Class action treatment is a superior method for the fair and efficient adjudication of the controversy in that, among other things, such 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.

81. Plaintiff knows of no difficulty to be encountered in this action that would preclude its maintenance as a class action.

CLAIMS FOR RELIEF

CLAIM I

MONOPOLIZATION AND MONOPOLISTIC SCHEME UNDER STATE LAW

82. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

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

84. Through the overarching anticompetitive scheme, as alleged extensively above, Defendants willfully maintained its monopoly power in the relevant market using restrictive or exclusionary conduct, rather than by means of greater business acumen, and injured Plaintiff and the Classes thereby.

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85. It was Defendants' conscious objective to further their dominance in the relevant market by and through the overarching anticompetitive scheme.

86. Defendants' scheme harmed competition as aforesaid.

87. To the extent Defendants are permitted to assert one, there is and was no cognizable, non-pretextual, procompetitive justification for Defendants' actions comprising the anticompetitive scheme that outweigh the scheme's harmful effects. Even if there were some conceivable such justification that Defendants were permitted to assert, the scheme is and was broader than necessary to achieve such a purpose.

88. As a direct and proximate result of Defendants' illegal and monopolistic conduct, as alleged herein, Plaintiff and the Classes were injured.

89. By engaging in the foregoing conduct, Defendants have intentionally and wrongfully maintained monopoly power in the relevant market in violation of the following state laws:

- a. Arizona Rev. Stat. §§ 44-1401, et seq., with respect to purchases of infliximab in Arizona by members of the Class.
- b. Cal. Bus. & Prof Code §§ 17200, et seq., and California common law with respect to purchases of infliximab in California by members of the Class.
- c. D.C. Code §§ 28-4501, et seq., with respect to purchases of infliximab in the District of Columbia by members of the Class.
- d. Fla. Stat. §§ 501.201, et seq., with respect to purchases of infliximab in Florida by members of the Class.
- e. Hawaii Code §§ 480, et seq., with respect to purchases of infliximab in Hawaii by members of the Class.
- f. 740 Ill. Comp. Stat. 10/3, et seq., with respect to purchases of infliximab in Illinois by members of the Class.
- g. Iowa Code §§ 553.5 et seq., with respect to purchases of infliximab in Iowa by members of the Class.

- h. Kansas Stat. Ann. §§ 50-101, et seq., with respect to purchases of infliximab in Kansas by members of the Class.
- i. Me. Rev. Stat. Ann. 10, §§ 1101, et seq., with respect to purchases of infliximab in Maine by members of the Class.
- j. Mass. Gen. L. Ch. 93A, et seq., with respect to purchases of infliximab in Massachusetts by members of the Class.
- k. Mich. Comp. Laws Ann. §§ 445.771, et seq., with respect to purchases of infliximab in Michigan by members of the Class.
- 1. Minn. Stat. §§ 325D.49, et seq., and Minn. Stat. § 8.31, et seq., with respect to purchases of infliximab in Minnesota by members of the Class.
- m. Miss. Code Ann. §§ 75-21-1, et seq., with respect to purchases of infliximab in Mississippi by members of the Class.
- n. Mo. Rev. Stat. §§ 416.011, et seq., with respect to purchases of infliximab in Missouri by members of the Class.
- o. Neb. Code Ann. §§ 59-801, et seq., with respect to purchases of infliximab in Nebraska by members of the Class.
- p. Nev. Rev. Stat. Ann. §§ 598A.060, et seq., with respect to purchases of infliximab in Nevada by members of the Class.
- q. N.H. Rev. Stat. Ann. §§ 356.1 et seq., with respect to purchases of infliximab in New Hampshire by members of the Class.
- r. N.M. Stat. Ann. §§ 57-1-1, et seq., with respect to purchases of infliximab in New Mexico by members of the Class.
- s. N.Y. Gen. Bus. Law §§ 340, et seq., with respect to purchases of infliximab in New York by members of the Class.
- t. N.C. Gen. Stat. §§ 75-2.1, et seq., with respect to purchases of infliximab in North Carolina by members of the Class.
- u. N.D. Cent. Code §§ 51-08.1-01, et seq., with respect to purchases of infliximab in North Dakota by members of the Class.
- v. Or. Rev. Stat. §§ 646.705, et seq., with respect to purchases of infliximab in Oregon by members of the Class.
- w. 10 L.P.R.A. §§ 257, et seq., with respect to purchases of infliximab in Puerto Rico by members of the Class.

- x. R.I. Gen. Laws §§ 6-36-1 et seq., with respect to purchases of infliximab in Rhode Island by members of the Class.
- y. S.D. Codified Laws §§ 37-1-3.1, et seq., with respect to purchases of infliximab in South Dakota by members of the Class.
- z. Tenn. Code Ann §§ 47-25-101, et seq., with respect to purchases of infliximab in Tennessee by members of the Class.
- aa. Utah code Ann. §§ 76-10-3101, et seq., with respect to purchases of infliximab in Utah by members of the Class.
- bb. Vt. Stat. Ann. 9, §§ 2451, et seq., with respect to purchases of infliximab in Vermont by members of the Class.
- cc. W.Va. Code §§ 47-18-1, et seq., with respect to purchases of infliximab in West Virginia by members of the Class.
- dd. Wis. Stat. §§ 133.01, et seq., with respect to purchases of infliximab in Wisconsin by members of the Class.

CLAIM II

ATTEMPTED MONOPOLIZATION UNDER STATE LAW

90. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

91. Defendants, through their overarching anticompetitive scheme, specifically intended to maintain monopoly power in the relevant market. It was Defendants' conscious objective to control prices and/or to exclude competition in the relevant market.

92. The natural, intended, and foreseeable consequence of Defendants' overarching anticompetitive scheme was to control prices and exclude competition in the relevant market.

93. There was, and continues to be, a dangerous probability that Defendants will succeed in, and achieve their goal, of maintaining monopoly power in the relevant market.

94. As a direct and proximate result of Defendants' illegal and monopolistic conduct, Plaintiff and the Classes were harmed as aforesaid.

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95. By engaging in the foregoing conduct, Defendants have intentionally and

wrongfully attempted to monopolize the relevant market in violation of the following state laws:

- a. Arizona Rev. Stat. §§ 44-1401, et seq., with respect to purchases of infliximab in Arizona by members of the Class.
- b. Cal. Bus. & Prof Code §§ 17200, et seq., and California common law with respect to purchases of infliximab in California by members of the Class.
- c. D.C. Code §§ 28-4501, et seq., with respect to purchases of infliximab in the District of Columbia by members of the Class.
- d. Fla. Stat. §§ 501.201, et seq., with respect to purchases of infliximab in Florida by members of the Class.
- e. Hawaii Code §§ 480, et seq., with respect to purchases of infliximab in Hawaii by members of the Class.
- f. 740 Ill. Comp. Stat. 10/3, et seq., with respect to purchases of infliximab in Illinois by members of the Class.
- g. Iowa Code §§ 553.5 et seq., with respect to purchases of infliximab in Iowa by members of the Class.
- h. Kansas Stat. Ann. §§50-101, et seq., with respect to purchases of infliximab in Kansas by members of the Class.
- i. Me. Rev. Stat. Ann. 10, §§ 1101, et seq., with respect to purchases of infliximab in Maine by members of the Class.
- j. Mass. Gen. L. Ch. 93A, et seq., with respect to purchases of infliximab in Massachusetts by members of the Class.
- k. Mich. Comp. Laws Ann. §§ 445.771, et seq., with respect to purchases of infliximab in Michigan by members of the Class.
- 1. Minn. Stat. §§ 325D.49, et seq., and Minn. Stat. § 8.31, et seq., with respect to purchases of infliximab in Minnesota by members of the Class.
- m. Miss. Code Ann. §§ 75-21-1, et seq., with respect to purchases of infliximab in Mississippi by members of the Class.
- n. Mo. Rev. Stat. §§ 416.010, et seq., with respect to purchases of infliximab in Missouri by members of the Class.
- o. Neb. Code Ann. §§ 59-801, et seq., with respect to purchases of infliximab in Nebraska by members of the Class.

- p. Nev. Rev. Stat. Ann. §§ 598A.060, et seq., with respect to purchases of infliximab in Nevada by members of the Class.
- q. N.H. Rev. Stat. Ann. §§ 356.1, et seq., with respect to purchases of infliximab in New Hampshire by members of the Class.
- r. N.Y. Gen. Bus. Law §§ 340, et seq., with respect to purchases of infliximab in New York by members of the Class.
- s. N.M. Stat. Ann. §§ 57-1-1, et seq., with respect to purchases of infliximab in New Mexico by members of the Class.
- t. N.C. Gen. Stat. §§ 75-1, et seq., with respect to purchases of infliximab in North Carolina by members of the Class.
- u. N.D. Cent. Code §§ 51-08.1-03, et seq., with respect to purchases of infliximab in North Dakota by members of the Class.
- v. Or. Rev. Stat. §§ 646.705, et seq., with respect to purchases of infliximab in Oregon by members of the Class.
- w. 10 L.P.R.A. §§ 257, et seq., with respect to purchases of infliximab in Puerto Rico by members of the Class.
- x. R.I. Gen. Laws §§ 6-36-1 et seq., with respect to purchases of infliximab in Rhode Island by members of the Class.
- y. S.D. Codified Laws §§ 37-1-3.1, et seq., with respect to purchases of infliximab in South Dakota by members of the Class.
- z. Utah code Ann. §§ 76-10-3101, et seq., with respect to purchases of infliximab in Utah by members of the Class.
- aa. Vt. Stat. Ann. 9, §§ 2451, et seq., with respect to purchases of infliximab in Vermont by members of the Class.
- bb. Tenn. Code Ann §§ 47-25-101, et seq., with respect to purchases of infliximab in Tennessee by members of the Class.
- cc. W.Va. Code §§ 47-18-1, et seq., with respect to purchases of infliximab in West Virginia by members of the Class.
- dd. Wis. Stat. §§ 133.01, et seq., with respect to purchases of infliximab in Wisconsin by members of the Class.

CLAIM III

UNFAIR AND DECEPTIVE TRADE PRACTICES UNDER STATE LAW

96. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

97. Defendants engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the state consumer protection statutes listed below. As a direct and proximate result of Defendants' anticompetitive, deceptive, unfair, unconscionable, and fraudulent conduct, Plaintiff and class members were deprived of the opportunity to purchase Remicade biosimilars, including Inflectra and Renflexis, and forced to pay higher prices on their infliximab purchases.

98. There was and is a gross disparity between the price that Plaintiff and class members paid and pay for Remicade and the value received, given that lower cost biosimilars, including Inflectra and Renflexis, should be more widely available, and prices for infliximab should be much lower, but for Defendants' unlawful conduct.

99. By engaging in the foregoing conduct, Defendants have engaged in unfair competition or deceptive acts and practices in violation of the following state laws:

- a. Ark. Code §§ 4-88-101, et seq., with respect to purchases of infliximab in Arkansas by members of the Class.
- b. Ariz. Code §§ 44-1255, et seq., with respect to purchases of infliximab in Arizona by members of the Class.
- c. Cal. Bus. & Prof Code §§ 17200, et seq., with respect to purchases of infliximab in California by members of the Class.
- d. D.C. Code §§ 28-3901, et seq., with respect to the purchases of infliximab in the District of Columbia.
- e. Fla. Stat. §§ 501.201, et seq., with respect to purchases of infliximab in Florida by members of the Class.

- f. Idaho Code §§ 48-601, et seq., with respect to the purchases of infliximab in Idaho by members of the Class.
- g. 815 ILCS §§ 505/1, et seq., with respect to the purchases of infliximab in Illinois by members of the Class.
- h. 5 Me. Rev. Stat. §§ 205-A, et seq., with respect to the purchases of infliximab in Maine by members of the Class.
- i. Mass. Gen. L. Ch. 93A, et seq., with respect to purchases of infliximab in Massachusetts by members of the Class.
- j. Mich. Stat. §§ 445.901, et seq., with respect to purchases of infliximab in Michigan by members of the Class.
- k. Minn. Stat. §§ 325F.68, et seq., and Minn. Stat. § 8.31, et seq., with respect to purchases of infliximab in Minnesota by members of the Class.
- 1. Missouri Stat. §§ 407.010, et seq., with respect to purchases of infliximab in Missouri by members of the Class.
- m. Neb. Rev. Stat. §§ 59-1601, et seq., with respect to purchases of infliximab in Nebraska by members of the Class.
- n. Nev. Rev. Stat. §§ 598.0903, et seq., with respect to purchases of infliximab in Nevada by members of the Class.
- o. N.H. Rev. Stat. §§ 358-A, et seq., with respect to purchases of infliximab in New Hampshire by members of the Class.
- p. N.M. Stat. §§ 57-12-1, et seq., with respect to purchases of infliximab in New Mexico by members of the Class.
- q. N.Y. Gen. Bus. Law §§ 349, et seq., with respect to purchases of infliximab in New York by members of the Class.
- r. N.C. Gen. Stat. §§ 75-1, et seq., with respect to purchases of infliximab in North Carolina by members of the Class.
- s. Or. Rev. Stat. §§ 646.605, et seq., with respect to purchases of infliximab in Oregon by members of the Class.
- t. 73 Pa. Stat. Ann. §§ 201-1, et seq., with respect to purchases of infliximab in Pennsylvania by members of the Class.
- u. R.I. Gen. Laws §§ 6-13.1-1, et seq., with respect to purchases of infliximab in Rhode Island by members of the Class

- v. S.D. Code Laws §§ 37-24-1, et seq., with respect to purchases of infliximab in South Dakota by members of the Class.
- w. Utah Code §§13-11-1, et seq., with respect to purchases of infliximab in Utah by member of the Class.
- x. Va. Code Ann. §§ 59.1-196, et seq., with respect to purchases of infliximab in Virginia by members of the Class.
- y. West Virginia Code §§ 46A-6-101, et seq., with respect to purchases of infliximab in West Virginia by members of the Class.

CLAIM IV

INJUNCTIVE RELIEF UNDER SECTION 16 OF THE CLAYTON ACT FOR DEFENDANTS' VIOLATIONS OF SECTION 2 OF THE SHERMAN ACT

100. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

101. Plaintiff's allegations described herein and in claims I through III constitute a violation of Section 2 of the Sherman Act, as well as a violation of the state laws enumerated *supra*.

102. Plaintiff and the members of the proposed Injunction Class seek equitable and injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable laws, to correct for the anticompetitive market effects caused by the unlawful conduct of Defendants, and other relief so as to assure that similar anticompetitive conduct does not reoccur in the future.

CLAIM V

UNJUST ENRICHMENT UNDER STATE LAW

140. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

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141. Defendants have benefited from monopoly profits on the sale of Remicade resulting from the unlawful and inequitable acts alleged in this Complaint.

142. Defendants' financial benefit resulting from their unlawful and inequitable acts is traceable to overpayments for Remicade by Plaintiff and members of the Unjust Enrichment Damages Class.

143. Plaintiff and the Unjust Enrichment Damages Class have conferred upon Defendants an economic benefit, in the nature of profits resulting from unlawful overcharges and monopoly profits, to the economic detriment of Plaintiff and the Unjust Enrichment Damages Class.

144. It would be futile for Plaintiff and the Unjust Enrichment Damages Class to seek a remedy from any party with whom they have privity of contract.

145. It would be futile for Plaintiff and the Unjust Enrichment Damages Class to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which it indirectly purchased Remicade, as they are not liable and would not compensate Plaintiff for unlawful conduct caused by Defendants.

146. The economic benefit of overcharges and monopoly profits derived by Defendants through charging supracompetitive and artificially inflated prices for Remicade is a direct and proximate result of Defendants' unlawful practices.

147. The financial benefits derived by Defendants rightfully belong to Plaintiff and the Unjust Enrichment Damages Class, as Plaintiff and the Unjust Enrichment Damages Class paid anticompetitive and monopolistic prices during the class period, inuring to the benefit of Defendants.

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148. It would be inequitable under unjust enrichment principles under the law of the District of Columbia and the laws of all states and territories in the United States, except Ohio and Indiana, for Defendants to be permitted to retain any of the overcharges for Remicade derived from Defendants' unfair and unconscionable methods, acts, and trade practices alleged in this Complaint.

149. Defendants are aware of and appreciate the benefits bestowed upon it by Plaintiff and the Unjust Enrichment Damages Class.

150. Defendants should be compelled to disgorge in a common fund for the benefit of Plaintiff and the Unjust Enrichment Damages Class all unlawful or inequitable proceeds it received.

151. A constructive trust should be imposed upon all unlawful or inequitable sums received by Defendants traceable to Plaintiff and the Unjust Enrichment Damages Class.

152. Plaintiff and the Unjust Enrichment Damages Class have no adequate remedy at law.

DEMAND FOR RELIEF

153. WHEREFORE, Plaintiff, on behalf of itself and the proposed Classes, respectfully prays that the Court:

- A. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a) and (b)(3), and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the Classes, and declare Plaintiff the representative of the Classes;
- B. Enter joint and several judgments against Defendants and in favor of Plaintiff and the Classes;

- C. Declare the acts alleged herein to be unlawful under the state statutes set forth above, and the common law of unjust enrichment of the states and territories set forth above;
- D. Permanently enjoin Defendants pursuant to sections 4 and 16 of the Clayton Act, 15 U.S.C.
 §§15(a) and 26, from continuing their unlawful conduct, so as to assure that similar anticompetitive conduct does not continue to occur in the future;
- E. Grant Plaintiff and the Unjust Enrichment Damages Class equitable relief in the nature of disgorgement, restitution, and the creation of a constructive trust to remedy Defendants' unjust enrichment;
- F. Award Plaintiff and the Damages Classes damages as provided by law in an amount to be determined at trial;
- G. Award the Damages Classes damages and, where applicable, treble, multiple, punitive, and/or other damages, in an amount to be determined at trial, including interest;
- H. Award Plaintiff and the Classes their costs of suit, including reasonable attorneys' fees as provided by law; and
- I. Grant such other further relief as is necessary to correct for the anticompetitive market effects caused by Defendants' unlawful conduct, as the Court deems just.

JURY DEMAND

154. Pursuant to Fed. Civ. P. 38, Plaintiff, on behalf of itself and the proposed Classes, demands a trial by jury on all issues so triable.

Dated: November 9, 2017

Respectfully submitted:

s/ Deborah Gross

KAUFMAN, COREN & RESS, P.C. Deborah R. Gross Two Commerce Square, Suite 3900 2001 Market Street Philadelphia, PA 19103

(215) 735-8700 dgross@kcr-law.com

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Case 2:17-cv-05058-JCJ Document 1-4 Filed 11/09/17 Page 1 of 2 CIVIL COVER SHEET

JS 44 (Rev 06/17)

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

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I. (a) PLAINTIFFS				DEFENDANTS		
City of Providence, indivi situated	dually and on behalf c	f all others similarly		Johnson & Johnso	n and Janssen Biotech,	Inc.
(b) County of Residence of	of First Listed Plaintiff	Providence County,	RI	County of Residence	of First Listed Defendant	Morris County, NJ
(EXCEPT IN US PLAINTIFF CASES)					(IN U.S. PLAINTIFF CASES (
				NOTE: IN LAND CC THE TRACT	NDEMNATION CASES, USE T OF LAND INVOLVED	THE LOCATION OF
(c) Atturneys (Firm Name, 2) See Attachment A.	Address, and Telephone Numbe	r)		Attorneys (If Known)		
See Allaciment A.						
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Plaintiff	(U.S. Government	Not a Party)	Citiz	en of This State		
2 U.S Government Defendant	▲ 4 Diversity (Indicate Citizensh	ip of Parties in Item III)	Citiz	en of Another State 🏾 🛣	2 D 2 Incorporated and of Business In	
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& Enforcement of Judgment	Slander	Personal Injury			□ 820 Copyrights	430 Banks and Banking
 151 Medicare Act 152 Recovery of Defaulted 	330 Federal Employers' Liability	Product Liability 368 Asbestos Personal			 830 Patent 835 Patent - Abbreviated 	 450 Commerce 460 Deportation
Student Loans	340 Marine	Injury Product			New Drug Application	470 Racketeer Influenced and Corrupt Organizations
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195 Contract Product Liability	□ 360 Other Personal	Property Damage	1 7.74	Relations 0 Railway Labor Act	□ 864 SSID Title XVI □ 865 RSI (405(g))	 890 Other Statutory Actions 891 Agricultural Acts
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VI. CAUSE OF ACTION	DN Brief description of c	1, 1332, 1337, and	1307			
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VII. REQUESTED IN COMPLAINT:	CHECK IF THIS	IS A CLASS ACTION	(^D	EMAND \$	CHECK YES only JURY JEMAND	if demanded in complaint: : X Yes □No
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ATTACHMENT A

Attorneys for Plaintiff:

KAUFMAN, COREN & RESS, P.C.

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IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

CASE MANAGEMENT TRACK DESIGNATION FORM

CITY OF PROVIDENCE	CIVIL ACTION
v. :	
JOHNSON & JOHNSON and JANSSEN BIOTECH, INC.	NO.
In accordance with the Civil Justice Expense and Del plaintiff shall complete a Case Management Track Des filing the complaint and serve a copy on all defendants. side of this form.) In the event that a defendant doc designation, that defendant shall, with its first appeara the plaintiff and all other parties, a Case Management to which that defendant believes the case should be as	signation Form in all civil cases at the time of (See § 1:03 of the plan set forth on the reverse is not agree with the plaintiff regarding said ince, submit to the clerk of court and serve on Track Designation Form specifying the track
SELECT ONE OF THE FOLLOWING CASE MAN	NAGEMENT TRACKS:
(a) Habeas Corpus – Cases brought under 28 U.S.C. §	2241 through § 2255. ()
(b) Social Security – Cases requesting review of a dec and Human Services denying plaintiff Social Secu	ision of the Secretary of Health rity Benefits. ()
(c) Arbitration – Cases required to be designated for a	rbitration under Local Civil Rule 53.2. ()
(d) Asbestos – Cases involving claims for personal inj exposure to asbestos.	ury or property damage from ()
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(f) Standard Management – Cases that do not fall into any one of the other tracks. ()

11/9/17	Adad Ahr	DEBORAH R. GROSS
Date	Attorney-at-law	Attorney for Plaintiff
_215-735-8700	215-735-5170	DGROSS@KCR-LAW.COM
Telephone	FAX Number	E-Mail Address

(Civ. 660) 10/02

Case 2:17-cv-05058-JCJ Document 1-6 Filed 11/09/17 Page 1 of 2 UNITED STATES DISTRICT COURT

OR THE EASTERN DISTRICT OF PENNSYLVANIA — DESIGNATION FORM to b ssignment to appropriate calendar.			
ddress of Plaintiff: 25 Dorrance Street, Providence, Rhode Islar	<u>10 02903</u>		
ddress of Defendant: One Johnson & Johnson Plaza, New Brunsy	wick, NJ; 800 Ridgeview Dr., Horsnam, PA		
ace of Accident, Incident or Transaction: Montgomery County, PA			
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(Attach two copies of the Disclosure Statement Form in accordance with Fed.R.Civ.P. 7.1(a)	$Y_{es} \square N_{o} \mathring{\Delta}$		
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oes this case involve multidistrict litigation possibilities? ELATED CASE, IF ANY:			
ase Number: 17-cv-04326; 17-cv-04830 Judge J. Curtis Joyner	Date Terminated:		
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Is this case related to property included in an earlier numbered suit pending or within one y	ear previously terminated action in this court?		
	$Yes \square No \square$		
Does this case involve the same issue of fact or grow out of the same transaction as a prior	suit pending or within one year previously terminated		
action in this court?	Yes≱ No□		
. Does this case involve the validity or infringement of a patent already in suit or any earlier	numbered case pending or within one year previously		
terminated action in this court?	Yes No		
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. Is this case a second or successive habeas corpus, social security appeal, or pro se civil righ	the case field by the same individual? Yes No \square		
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8. 🗆 Habeas Corpus	9. D All other Diversity Cases		
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10. □ Social Security Review Cases			
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ARBITRATION CERT			
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□ Pursuant to Local Civil Rule 53.2, Section 3(c)(2) that to the best of my knowledge and	d belief, the damages recoverable in this civil action case exceed the sum o		
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Attorney-at-Law	Attorney I.D.#		
NOTE: A trial fe novo will be a trial by jury only if the			
I certify that, to my knowledge, the within case is not related to any case now pending o	r within one year previously terminated action in this court		
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CIV. 609 (5/2012)			

ClassAction.org

This complaint is part of ClassAction.org's searchable class action lawsuit database and can be found in this post: J&J, Janssen Biotech Pegged with Antitrust Lawsuit Over Pricing of Blockbuster Drug Remicade