UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
NORFOLK DIVISION

CAREFIRST OF MARYLAND, INC., GROUP HOSPITALIZATION AND MEDICAL SERVICES, INC., CAREFIRST BLUECHOICE, INC., and CFA, LLC d/b/a CAREFIRST ADMINISTRATORS, on behalf of themselves and all others similarly situated,

Plaintiffs,

v.

JOHNSON & JOHNSON and JANSSEN BIOTECH, INC.

Defendants.

Civil Action No. _____

JURY TRIAL DEMANDED

CLASS ACTION COMPLAINT

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The plaintiffs, on behalf of themselves and all others similarly situated, for their complaint against defendants Johnson & Johnson and its wholly owned subsidiary Janssen Biotech, Inc., now known as Johnson & Johnson Innovative Medicine (collectively, "J&J"), allege the following based on (a) personal knowledge, (b) the investigation of counsel, and (c) information and belief.

I. INTRODUCTION

1. This civil action alleges that J&J is unlawfully delaying the introduction of biosimilar competition for ustekinumab—a human immunoglobulin G1 (IgG1) monoclonal antibody that treats a range of life-threatening autoimmune diseases, including Crohn's disease, plaque psoriasis, active psoriatic arthritis, and ulcerative colitis, all conditions linked to the IL-12/IL-23 pathway—onto the U.S. market.

2. Since 2009, J&J has manufactured and sold ustekinumab under the brand name Stelara. Stelara has been one of best-selling drugs in the United States for nearly a decade. In 2022 alone, it brought nearly $6.4 billion in U.S. sales and nearly $10 billion worldwide, accounting for about 10% of J&J's entire revenue. During the life of the product to date, J&J has grossed well over $50 billion on sales of Stelara.

3. In recent years, it was widely accepted by both J&J and the pharmaceutical industry in general that J&J would lose exclusivity for U.S. sales of Stelara on September 25, 2023—the date its composition patent for ustekinumab would expire and biosimilar products would then enter the U.S. marketplace.

4. However, J&J has been, and continues to delay biosimilar competition through a series of unlawful acts. To avoid losing exclusivity over Stelara and to maintain its supra-competitive prices, J&J implemented a scheme to unlawfully prolong patent protection for Stelara well beyond September 2023.

5. *First*, between 2019 and 2021 J&J defrauded the United States Patent and Trademark Office (PTO) into incorrectly issuing a method-of-use patent covering use of ustekinumab to treat ulcerative colitis. During prosecution of the application, the patent examiner pointed out that J&J's own 2015 clinical trial testing protocol disclosed the *exact* method-of-use that J&J's application claimed as novel years later. In response, J&J intentionally misled the patent examiner by, among other things, (i) falsely representing to the examiner that the clinical results were unpredictable, (ii) concealing from the examiner public articles (i.e., prior art) that showed ustekinumab had been used to successfully treat ulcerative colitis before the patent application was filed, and (iii) misrepresenting to the examiner that later clinical results could serve as a basis to allow the patent.

6. The examiner relied on J&J's falsehoods and misdirection and issued, incorrectly, the patent. Having acquired the patent by fraud, J&J later used it against companies that were seeking to launch biosimilar versions of Stelara into the U.S. market.

7. *Second*, in 2020—over a decade after it launched Stelara and while it sat atop a monopoly for ustekinumab sales—J&J purchased a biosimilar research company, Momenta, that held patents on manufacturing methods ostensibly helpful in developing bio*similar* versions of compounds like ustekinumab. Of course, the technologies in these patent rights had nothing to do with J&J's development and manufacturing of its ustekinumab product, Stelara. J&J had long ago developed Stelara and had been making and selling it for years, and the patents had no pro-competitive use to J&J for Stelara. Instead, J&J used the Momenta patents against biosimilar companies seeking to compete against J&J. In so doing, J&J turned matters on their head: while the Momenta technologies and patents were intended to facilitate biosimilar approvals and

interchangeability determinations and thus enhance competition, J&J used the patents to block and delay entry of biosimilar products and restrain U.S. biosimilar competition.

8. In late 2022 J&J sued—or, in some cases, threatened suit against—each of the many would-be biosimilar entrants that would soon come to market with competing biosimilar ustekinumab products. In doing so, J&J used both its fraudulently acquired method-of-use patent and its unlawfully acquired Momenta biosimilar manufacturing patents to unlawfully delay competition. J&J knew that it had procured the method-of-use patent covering use of ustekinumab to treat ulcerative colitis through fraud, and it knew that its acquisition of the Momenta biosimilar manufacturing patents was anticompetitive. Nonetheless, it sued (or threatened suit) against its would-be competitors. J&J's goal was not to win litigation; instead, J&J sought to use the unlawfully acquired patents to *delay entry* of would-be biosimilars through settlements that would buy J&J additional exclusivity beyond September 2023.

9. None of J&J's misconduct enjoys *Noerr-Pennington* qualified immunity. The acts of fraudulent acquisition and assertion of the method-of-use patent against would-be biosimilar competitors fall within the *Walker Process* exception. The acquisition of the biosimilar manufacturing patents violates Section 2 of the Sherman Act (and related state laws) and is therefore an independent antitrust violation separate and apart from J&J's later assertion of them in litigation.

10. J&J's scheme worked. J&J used its fraudulently acquired method-of-use patent and its unlawfully procured biosimilar manufacturing patents to extract settlements from each of the would-be biosimilar entrants. These settlements pushed out biosimilar entry for ustekinumab until 2025.

11. Because of these unlawful acts, purchasers of ustekinumab have paid, and continue to pay, supra-competitive prices for ustekinumab. U.S. purchasers of ustekinumab are paying substantially more for the drug than they would if J&J had not engaged in the scheme. During the period of expected delay and impairment of generic competition—September 2023 through early 2025—the overpayments are estimated to exceed $1 billion.

12. J&J sells ustekinumab to a group of authorized distributors, who in turn sell to specialty pharmacies, hospitals, health care providers, infusion therapy providers, who then provide it to patients (who typically pay for the drug using third party payers—also known as end payers—and other forms of payment). Plaintiffs and members of the proposed class are end payers for Stelara. They are the last links in the pharmaceutical distribution chain, and they are being overcharged for ustekinumab due to J&J's violation of law.

13. The complaint alleges violation of federal and state antitrust and related laws. Injunction relief is sought to, among other things, enjoin J&J's use of the fraudulently acquired method-of-use patent and the Momenta technologies (including the Momenta patents). Monetary relief is sought for overcharges caused by the wrongdoing, and, where appropriate, the damages should be doubled or trebled under law.

II. PARTIES

14. The plaintiff CareFirst of Maryland, Inc. (CFMI) is a not-for-profit corporation organized and existing under the laws of the State of Maryland, with a principal place of business at 1501 South Clinton Street, Baltimore, Maryland 21224.

15. The plaintiff Group Hospitalization and Medical Services, Inc. (GHMSI) is a not-for-profit corporation founded pursuant to an act of Congress, with a principal place of business at 840 First Street, NE, Washington, DC 20065.

16. CFMI and GHMSI both do business as CareFirst BlueCross BlueShield, and both are independent licensees of the Blue Cross and Blue Shield Association.

17. In fulfillment of its mission to provide affordable and accessible health benefits to its members, including employees of the federal government residing and/or employed in Maryland, the District of Columbia, and Northern Virginia, CareFirst BlueCross BlueShield indirectly purchases Stelara for members of its private healthcare plans and its Medicare Advantage plans. For Medicare Advantage members that receive Stelara injections from a physician, these purchases are provided as part of Medicare Part B coverage. For Medicare Advantage members that perform their own Stelara injections at home (or receive injections from caregivers at home), these purchases are provided as part of Medicare Part D coverage.

18. CareFirst BlueCross BlueShield has purchased Stelara for its members since before September 26, 2023, and anticipates continuing to purchase Stelara for its members through at least 2025.

19. The plaintiff CareFirst BlueChoice, Inc. (BlueChoice) is a corporation organized and existing under the laws of the District of Columbia, with a principal place of business at 840 First Street, NE, Washington, DC 20065. BlueChoice, an independent licensee of the Blue Cross and Blue Shield Association, provides health benefit plans for employees of the federal government residing and/or employed in Maryland, the District of Columbia, and Northern Virginia.

20. BlueChoice has purchased Stelara for its members since before September 26, 2023, and anticipates continuing to purchase Stelara for its members through at least 2025.

21. The plaintiff CFA, LLC d/b/a CareFirst Administrators (CFA) is a limited liability company organized and existing under the laws of the State of Maryland, with a principal place

of business in 1501 South Clinton Street, Baltimore, Maryland 21224. CFA is an independent licensee of the Blue Cross and Blue Shield Association.

22. CFA operates as a third-party administrator for self-funded health benefit plans in Maryland, the District of Columbia, and Northern Virginia. On behalf of its client plans, CFA indirectly purchases Stelara, has purchased Stelara since before September 26, 2023, and anticipates continuing to purchase Stelara through at least 2025.

23. All plaintiffs (collectively, CareFirst) are indirect subsidiaries of CareFirst, Inc., a corporation organized and existing under the laws of the State of Maryland. Jointly, these plaintiffs provide health insurance or administer health insurance for 3.4 million individuals.

24. CareFirst purchases prescription drugs at third-party pharmacies, like CVS, Walgreens, and Rite Aid, where CareFirst's health plan members have prescriptions filled. CareFirst incurs substantial costs associated with its members' transactions at these third-party pharmacies.

25. The defendant Johnson & Johnson is a corporation organized and existing under the laws of the State of New Jersey, with a principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

26. The defendant Janssen Biotech, Inc. is a corporation organized and existing in Pennsylvania, with a principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey. Janssen Biotech, Inc. is now known as Johnson & Johnson Innovative Medicine.

27. Johnson & Johnson was directly involved in much of the wrongful conduct that gives rise to these claims. Janssen Biotech, Inc., now Johnson & Johnson Innovative Medicine, a wholly owned subsidiary of Johnson & Johnson, wrongfully acquired and owns patents that were used against competitors of Johnson & Johnson, enabling Johnson & Johnson to charge supra-

competitive prices for Stelara. Johnson & Johnson and Janssen Biotech, Inc., now Johnson & Johnson Innovative Medicine, are collectively referred to in this case as J&J.

III. JURISDICTION AND VENUE

28. This action alleges violations of Section 2 of the Sherman Act, 15 U.S.C. § 2, and of state antitrust, consumer protection, and related laws. This action seeks injunctive relief under Section 16 of the Clayton Act, 15 U.S.C. § 26, and seeks monetary relief pursuant to state laws. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 (federal question), § 1332(d)(2) (class action exceeding $5 million), § 1337(a) (antitrust enforcement), and § 1367(a) (supplemental jurisdiction).

29. Venue is proper in this district pursuant to 15 U.S.C. § 22 and 28 U.S.C. §§ 1391(b), (c), and (d) because, during the class period, J&J resided, transacted business, was found, or had agents in this district, and a substantial portion of the alleged activity affecting interstate trade and commerce discussed below has been carried out in this district.

30. This Court has personal jurisdiction over J&J. J&J conducts business throughout the United States, including in this district, and has purposefully availed itself of the laws of the United States. During the class period, J&J manufactured, sold, and shipped Stelara in a continuous and uninterrupted flow of interstate commerce, which included sales of Stelara in this district, advertisement of Stelara in media in this district, monitoring prescriptions of Stelara by prescribers within this district, and employment of product detailers in this district, who as agents of J&J marketed Stelara to prescribers in this district. J&J, throughout the United States and including in this district, has transacted business, maintained substantial contracts, or committed overt acts in furtherance of its illegal scheme. J&J's unlawful conduct had a direct, substantial, and reasonably foreseeable effect on interstate commerce, including commerce within this district.

31. By reason of the unlawful activities alleged herein, J&J substantially affected commerce throughout the United States, causing injury to the plaintiffs and class members. J&J, directly and through its agents, engaged in activities to suppress competition, drive up brand sales, and fix, raise, maintain, and/or stabilize the price of Stelara in the United States. This conduct unreasonably restrained trade and adversely affected the market for the direct sale and purchase of ustekinumab throughout the United States, including in this district.

IV. REGULATORY AND ECONOMIC BACKGROUND

A. The relevant federal regulatory structure encourages competition among pharmaceutical companies.

32. Drugs generally fall into one of two categories: small molecule or biologic.[1] The majority of drugs are small molecule, manufactured using chemical processes. Biologics, in contrast, are derived from biological sources such as animals or microorganisms, and the resulting molecules are larger and sometimes more complex.

33. Biologics, like Stelara, are not new. For example, vaccines are biologics, and the first vaccines were first developed in the late eighteenth century. Another common biologic—insulin—was first isolated in the 1920s. Nonetheless, technological advances in the past few decades have exponentially expanded the number of biologics available.

34. Due to the differences between biologic and small molecule drugs, as well as biologics' more recent proliferation, distinct federal regulatory frameworks govern the approval and sale of (1) new biologics and their copies and (2) new small molecule drugs and their copies.

35. The Food and Drug Administration (FDA) regulates small molecule drugs under the Food, Drug, and Cosmetics Act (FDCA), as amended by the Drug Price Competition and

[1] Biologic drugs are sometimes referred to as biopharmaceuticals.

Patent Term Restoration Act of 1984.[2] Under the FDCA, a drug company must file a New Drug Application (NDA) with the FDA before it can market a new small molecule drug. The first company to market a new small molecule drug usually holds patent or regulatory exclusivity, which prevents competition for a limited time. During this monopolistic period, the first entrant can—and almost always does—charge supra-competitive prices. The theory behind these government-granted exclusivities (indeed, the U.S. patent system in general) is that the promise of monopolistic profits will drive innovation.

36. After the period of exclusivity expires, however, other drug companies are free to sell copies of the first entrant's product, known as generic drugs. Enacted in 1984, the Drug Price Competition and Patent Term Restoration Act—more commonly known as the Hatch-Waxman Act—governs the approval of generic small molecule drugs. Under the Hatch-Waxman Act, generic drug manufacturers must file abbreviated NDAs (ANDAs) with the FDA to obtain approval for their bioequivalent copies of the NDA holder's drug (known as the branded or reference product). Because a generic is an exact copy of the reference drug, it competes solely on price—all other product features are identical. To compete for market share with the established brand, generics typically enter the market at far lower prices.

37. The approval process for new biologic drugs is similar, but not identical, to the pathway for new small molecule drugs. The Biologics Price Competition and Innovation Act (BPCIA)—signed into law as part of the Affordable Care Act in 2010—governs the approval of both new biologics and their copies.[3] Under 42 U.S.C. § 262(a), a biologic manufacturer must

[2] Pub. Law No. 98-417, 98 Stat. 1585 (1984).

[3] 42 U.S.C. § 262, 124 Stat. 808.

submit a Biologic License Application (BLA) to the FDA before it can market its drug.[4] The FDA may grant the BLA if, among other things, the manufacturer has demonstrated that the biologic is "safe, pure, and potent."[5]

38. Because biologics are derived from living matter, copies of the reference biologic are not identical in the same way that small molecule generics are identical to the brand product (reference and generic small molecule drugs share the exact same chemical structure). Nonetheless, copies of biologics, known as biosimilars, have no clinically meaningful differences in safety, purity, or potency as compared to their reference biologics.

39. Like the Hatch-Waxman Act, the BPCIA provides an abbreviated FDA-approval process for biosimilar drugs. Despite certain differences, the goal of this abbreviated approval pathway is the same as that of the Hatch-Waxman Act: to lower drug prices through robust competition.[6]

40. To obtain approval, a biosimilar manufacturer may submit an abbreviated BLA (ABLA) demonstrating that its biosimilar is "highly similar" to the reference product and that

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[4] 42 U.S.C. § 262(a).

[5] 42 U.S.C. § 262(a)(2)(C)(i)(I).

[6] In its February 2009 proposed budget, the Obama Administration emphasized that "[p]rescription drug costs are high and rising" and proposed "accelerate[d] access" with a "legal pathway for generic versions of biologic drugs." OFF. OF MGMT. & BUDGET, EXEC. OFF. OF THE PRESIDENT, A NEW ERA OF RESPONSIBILITY 28 (2009). Similarly, when debating the yet-enacted BPCIA in June 2009, Senator Sherrod Brown explained, "[p]erhaps nowhere [is the need to bring down costs and increase access] more obvious than the area of biopharmaceuticals or so-called biologics . . . . With costs to biologics ranging anywhere from $10,000 to $200,000 per patient per year, biologic treatments pose a significant financial challenge for patients, for insurance companies, for employers who are paying the bills, and for Federal and State governments that are also paying the bills." 155 Cong. Rec. S6793 (daily ed. June 18, 2009). Representative Frank Pallone similarly stated that "[i]f biologics are the future, then we should do everything we can now to control costs while aiding innovation, just like Hatch-Waxman did." *Emerging Health Care Issues: Follow-On Biologic Drug Competition: Hearing Before the Subcomm. on Health of the H. Comm. on Energy & Commerce*, 111th Cong. 2 (2009).

there are no "clinically meaningful differences" between the two in terms of "safety, purity, and potency."[7]

41. A biosimilar manufacturer may not submit an ABLA until four years after the reference product is first licensed, and an ABLA may not be approved until twelve years after the reference product is first licensed.[8] Put another way, the manufacturer of a new biologic enjoys a statutory twelve-year monopoly over its biologic without biosimilar competition. Thereafter, biosimilars are free to compete.

42. Under certain circumstances, the FDA can also designate a biosimilar as "interchangeable" meaning the biosimilar "may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product."[9] Depending on the state's laws, an interchangeable biosimilar may be substituted for the biologic at the

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[7] 42 U.S.C. § 262(i)(2); see also 42 U.S.C. § 262(k)(2)(A). More specifically, the ABLA must contain information showing that:

i. "the biological product is biosimilar to a reference product based upon data derived from [certain kinds of studies];"

ii. "the biological product and reference product utilize the same mechanism or mechanisms of action for the condition or conditions of use prescribed, recommended, or suggested in the proposed labeling, but only to the extent the mechanism or mechanisms of action are known for the reference product;"

iii. "the condition or conditions of use prescribed, recommended, or suggested in the labeling proposed for the biological product have been previously approved for the reference product;"

iv. "the route of administration, the dosage form, and the strength of the biological product are the same as those of the reference product; and"

v. "the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent."

42 U.S.C. § 262(k)(2).

[8] 42 U.S.C. §§ 262(k)(7).

[9] 42 U.S.C. § 262(i)(3).

pharmacy without a new prescription in the same way that generics are.[10] To obtain an interchangeability designation, a biosimilar applicant must submit to the FDA data sufficient to demonstrate that its product "is biosimilar to the reference product[and] can be expected to produce the same clinical results as the reference product in any given patient . . . ."[11]

43. The first biosimilar approved as interchangeable enjoys an exclusivity period. The exclusivity period depends on whether patent infringement litigation pertaining to the biosimilar maker's application for interchangeability already concluded, was ongoing, or was not yet initiated at the time of the interchangeability approval and the date on which the interchangeable biosimilar was first commercially marketed.[12]

B. Generic and biosimilar competition lowers drug prices.

44. The effect of small molecule drug competition on the market is well-established. Once a reference drug's patent(s) expire and the manufacturer faces competition, brand sales plummet as the market moves to the significantly more affordable generic products. Generic entrants will capture 80% or more of the market within the first six months, 90% of the market within a year, and eventually near 100% of the market.

45. The largest price drop for pharmaceutical products occurs when the number of generic competitors rises from one to two. Prices continue to decline as the number of generic manufacturers increase.

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[10] Food & Drug Admin., *Interchangeable Biological Products*, https://www.fda.gov/media/151094/download#:~:text=An%20interchangeable%20biosimilar%20may%20be,substituted%20for%20brand%2Dname%20drugs.

[11] 42 U.S.C. § 262(k)(4).

[12] 42 U.S.C. § 262 (k)(6); Memorandum from Dr. Mustafa Unlu to Dr. Nikolay P. Nikolov (October 3, 2023) (on file with the Food and Drug Administration), https://www.fda.gov/media/173749/download?attachment.

46. These price drops translate into savings for consumers and health plans. According to the U.S. Generic and Biosimilar Medicines Savings report, in 2020, the use of generic and biosimilar drugs saved consumers about *$340 billion*.[13] In 2021, generic and biosimilars competition saved consumers over $373 billion, and an estimated $2.6 trillion in savings over the past 10 years.[14]

47. Biosimilar competition is a relatively recent source of healthcare savings. The FDA approved the first biosimilar in 2015, and, as of November 2023, the FDA had approved only forty-four biosimilars—including an ustekinumab biosimilar, Wezlana, in October 2023. While there are some differences in distribution, pharmacy-counter substitution, and prescription writing practices of biosimilar and generic drugs, the same general principle applies: biosimilar competition, like generic competition, lowers drug prices and saves healthcare dollars. According to the FDA, as of 2021, biosimilars in the United States "launched with initial list prices 15% to 35% lower than comparative list prices of the reference products."[15] And the "average sales price of brand biologics competing with biosimilars has fallen an average [of] 25% since biosimilar launch."[16]

48. Numerous studies have estimated the amount of savings (determined by estimated price reductions, penetration, and the like) resulting from the introduction of biosimilars. A 2014

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[13] ASSOC. FOR ACCESSIBLE MEDICINES, THE U.S. GENERIC & BIOSIMILAR MEDICINES SAVINGS REPORT 8 (2022), https://accessiblemeds.org/resources/reports/2022-savings-report.

[14] *Id.* at 7.

[15] *FDA Approves First Interchangeable Biosimilar Insulin Product for Treatment of Diabetes*, FOOD & DRUG ADMIN. (July 28, 2021), https://www.fda.gov/news-events/press-announcements/fda-approves-first-interchangeable-biosimilar-insulin-product-treatment-diabetes.

[16] ASSOC. FOR ACCESSIBLE MEDICINES, THE U.S. GENERIC & BIOSIMILAR MEDICINES SAVINGS REPORT 24 (2022), https://accessiblemeds.org/resources/reports/2022-savings-report.

Rand review of studies examining individual biosimilars' price impact and market penetration found that in the coming decade, on average, biosimilars would gain a market penetration of 60% and would reduce prices by 35% and would result in about $44 billion in savings over those ten years.[17] The review study also noted that 60% market penetration was a conservative estimate and that the Congressional Budget Office anticipated a 40% price reduction in the long term.[18]

49. Actual savings far exceeded expectations. A more recent Rand review from 2022, projecting U.S. savings from biosimilar entry from 2021-2025, found that total estimated savings from 2014 to 2025 would amount to $102.5 billion, $38.4 billion of which was projected savings from 2021-2025 from expanded biosimilar competition.[19]

50. A 2022 study determined that biosimilar entry resulted in about $13.3 billion in savings since 2015, including $7 billion in 2021 alone.[20] And a third study estimated that biosimilar entry could result in $100 billion in savings between 2020 and 2024.[21] These results were confirmed by the 2022 Rand study published in the American Journal of Managed Care and a 2023 IQVIA study. Assuming a higher biosimilar entry probability ($46.5 billion), higher biosimilar volume share ($48.3 billion), lower biosimilar prices ($52.8 billion), and lower prices

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[17] ANDREW W. MULCAHY ET AL., THE COST SAVINGS POTENTIAL OF BIOSIMILAR DRUGS IN THE UNITED STATES, RAND CORP. 7 & n.17 (2014).

[18] *Id.*

[19] Andrew W. Mulcahy et al., *Projected US Savings from Biosimilars, 2021-2025*, 28 AM. J. MANAGED CARE 329, 331 (2022).

[20] ASSOC. FOR ACCESSIBLE MEDICINES, THE U.S. GENERIC & BIOSIMILAR MEDICINES SAVINGS REPORT 23 (2022), https://accessiblemeds.org/resources/reports/2022-savings-report.

[21] IQVIA INSTITUTE, BIOSIMILARS IN THE UNITED STATES 2020–2024 17 (2020), https://www.iqvia.com/insights/the-iqvia-institute/reports/biosimilars-in-the-united-states-2020-2024.

for reference biologics ($82.4 billion), the study found potential savings could reach $124.2 billion between 2021 and 2025.[22] In 2023, an IQVIA study concluded that savings from biosimilars would balloon to $181 billion between 2023 and 2027.[23]

C. New products may be entitled to a limited period of exclusivity if covered by a valid patent.

51. A drug manufacturer may hold patents covering a biologic drug, its therapeutic uses, and the processes used to manufacture it, among other things. Such patents may constrain an ABLA applicant's ability to market its biosimilar even after the expiration of the BPCIA's twelve-year exclusivity period.

52. A patent must claim a novel invention.[24] If the matter claimed in the patent application "was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention," the PTO must deny the application.[25] Prior patents, publications, and other publicly known material before the filing date of the patent are known as "prior art." Over time, prior art accumulates—patents issue, publications reveal new discoveries, and new drugs go on sale.

53. Federal regulation *requires* a patent applicant to be maximally forthcoming with patent examiners regarding relevant prior art. Federal regulation demands that patent prosecutors disclose to patent examiners "all information known to be material to patentability," including

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[22] Andrew W. Mulcahy et al., *Projected US Savings from Biosimilars, 2021-2025*, 28 AM. J. MANAGED CARE 329, 334 (2022).

[23] IQVIA INSTITUTE, BIOSIMILARS IN THE UNITED STATES 2023-2027 (2023), https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/biosimilars-in-the-united-states-2023-2027.

[24] 35 U.S.C. § 102.

[25] 35 U.S.C. § 102(a).

any prior art.[26] Known as the duty of disclosure, good faith, and candor, this requirement applies to each: (1) "inventor named in the application"; (2) "attorney or agent who prepares or prosecutes the application"; and (3) "[e]very other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, the applicant, an assignee, or anyone to whom there is an obligation to assign the application."[27] The purpose of this duty is to ensure that the patent prosecution process unfolds in a non-adversarial manner: the patent examiner is allowed to trust that the applicant has disclosed all relevant prior art, drawing his or her attention to the facts necessary to fairly evaluate the application.

54. Because patents enable a first entrant to exclude competition and charge supra-competitive prices, it is crucial that any patent covering a brand drug or biologic be valid and lawfully obtained.

D. Regulatory frameworks permit challenges to drug patents.

1. The BPCIA patent dance.

55. Like the Hatch-Waxman Act, the BPCIA implicitly acknowledges that a biologic manufacturer may, at times, abuse the patent system to forestall competition. To remedy this problem, the law provides a framework for challenging invalid patents or arguing non-infringement.

56. In general, a patent owner may not file an action for patent infringement until another person "makes, uses, offers to sell, or sells" a product that infringes the patent within the United States.[28] But the Hatch-Waxman Act and the BPCIA enable the patent holder (the brand

[26] 37 C.F.R. § 1.56(a).

[27] 37 C.F.R. § 1.56(c).

[28] 35 U.S.C. § 271(a).

manufacturer) to bring an infringement action before the biosimilar or generic manufacturer begins to sell their allegedly infringing product. Both laws provide that a patent infringement lawsuit may take place prior to the ANDA applicant's or ABLA applicant's launch,[29] and both laws lay out procedures for resolving the ensuing patent action.

57. Under the Hatch-Waxman Act, a brand manufacturer obtains notice that a generic intends to make a product implicating its patents through a notification process involving a public reference manual known as the Orange Book. Brand manufacturers submit a list of the patents they believe cover their drugs to the FDA, who, in turn, lists them in the Orange Book. When a generic drug files an ANDA, it must state whether its generic product will implicate those patents and provide notice of any potential infringement to the brand.

58. An equivalent reference exists for biologic drugs—the "Purple Book." However, unlike the Orange Book, the Purple Book does not contain a definitive list of patents covering the biologic reference product. Instead, the BPCIA lays out a five-step set of pre-litigation exchanges—known as the patent dance—that may culminate in patent litigation if the parties do not resolve their disputes. The BPCIA also provides remedies for such patent infringement, including injunctive relief and damages.[30] These steps unfold as follows.

59. First, no more than twenty days after the FDA notifies an ABLA applicant that its application has been accepted for review, the applicant must provide the ABLA and other confidential information about how its biosimilar is manufactured to the patent holder (i.e., the reference product sponsor).[31] These disclosures enable the patent holder to evaluate the

[29] 35 U.S.C. § 271(e)(2)(C); 42 U.S.C. §§ 262(l)(6), (l)(8), (l)(9)(B)-(C).

[30] 35 U.S.C. § 271(e)(4).

[31] 42 U.S.C. § 262(l)(2)(A).

biosimilar for possible patent infringement.[32] The information the ABLA applicant provides is subject to strict confidentiality rules.[33]

60. Second, the parties exchange information to identify relevant patents and to flesh out the legal arguments that they might raise in future litigation. Within sixty days of receiving the ABLA and manufacturing information, and based on a review of those materials, the reference product sponsor must provide the ABLA applicant with a list of patents for which it believes "a claim of patent infringement could *reasonably* be asserted" against the applicant if it made, used, offered to sell, sold, or imported its biosimilar.[34] This list of patents is sometimes referred to as the 3A list, named for the BPCIA section. The reference product sponsor must also identify any patents on the 3A list that it would be willing to license.[35]

61. Third, within sixty days of receiving the 3A list, under § 262(l)(3)(B), the ABLA applicant must provide to the patent holder, for each patent listed therein, "a detailed statement that describes, on a claim by claim basis, the factual and legal basis of the opinion of the [ABLA] applicant that such patent is invalid, unenforceable, or will not be infringed by the commercial marketing of the" biosimilar or a statement that it "does not intend to begin commercial marketing of the [biosimilar] product before the date that such patent expires . . . ."[36] The ABLA applicant also must respond to the patent holder's offer to license particular patents.[37] The ABLA

[32] 42 U.S.C. § 262(l)(1)(D).

[33] *See* 42 U.S.C. § 262(l)(1)(H).

[34] 42 U.S.C. § 262(l)(3)(A)(i) (emphasis added).

[35] 42 U.S.C. § 262(l)(3)(A)(ii).

[36] 42 U.S.C. § 262(l)(3)(B)(ii).

[37] 42 U.S.C. § 262(l)(3)(B)(iii).

applicant may further provide to the patent holder a list of patents that the ABLA applicant believes are relevant.[38]

62. Fourth, within sixty days of receiving the ABLA applicant's statement pursuant to subsection (3)(B), the patent holder must reply with "a detailed statement" that, for each patent that the ABLA applicant identified as invalid, unenforceable, or not infringed, describes "on a claim by claim basis, the factual and legal basis of the opinion of the reference product sponsor that such patent will be infringed by the commercial marketing of the [biosimilar] and a response to the [ABLA's] statement concerning validity and enforceability . . . ."[39]

63. By the conclusion of step four—which may occur up to 200 days after the ABLA applicant initially obtains FDA acceptance of its application—the parties have identified all patents whose validity, enforceability, and/or infringement either party believes may be at issue. And they have provided detailed explanations as to the bases for their beliefs that each is or is not invalid, unenforceable, and/or infringed.

64. Fifth, the parties negotiate in good faith a list of patents that "shall be the subject of" an ensuing patent infringement action.[40] If they do not agree on a list after fifteen days of negotiating, each party simultaneously exchanges a list of patents that will become the subject of a patent infringement suit.[41] The patent holder cannot select a greater number of patents than the ABLA applicant unless the ABLA applicant selects zero patents.[42] The exchange occurs on a

[38] 42 U.S.C. § 262(l)(3)(B)(i).

[39] 42 U.S.C. § 262(l)(3)(C).

[40] 42 U.S.C. § 262(l)(4)(A).

[41] 42 U.S.C. §§ 262(l)(4)(B), (l)(5).

[42] 42 U.S.C. § 262(l)(5). If the ABLA applicant does not select any patents, the reference product sponsor may list one patent. 42 U.S.C. § 262(l)(5)(B)(ii)(II).

date agreed to by the parties, but no later than five days after the ABLA applicant notifies the patent holder of the number of patents it will select.[43]

65. If the parties comply with all steps of the patent dance, once those steps are complete, the first phase of BPCIA litigation finally begins. Within thirty days of the list exchange, the patent holder "shall bring an action for patent infringement with respect to" each patent either agreed to or on the exchanged lists.[44]

66. Under certain circumstances, the reference product sponsor need not wait to file a lawsuit. First, as stated above, submitting an ABLA constitutes an act of infringement, sometimes referred to as "artificial" infringement, which may result in injunctive relief and damages.[45] Second, if an ABLA applicant fails to provide the ABLA and other required information under subsection (l)(2)(A), the reference product sponsor may bring an action under 28 U.S.C. § 2201 for declaratory judgment of infringement, validity, or enforceability of any patent that claims the relevant biologic product or its use.[46] Third, if the ABLA applicant provides the ABLA and requisite information under subsection (2)(A), but the applicant fails to complete a later step in the patent dance, the reference product sponsor may also bring an action under 28 U.S.C. § 2201 for declaratory judgment of infringement, validity, or enforceability of any patent included in the 3A list.[47]

[43] 42 U.S.C. § 262(l)(5)(B)(i).

[44] 42 U.S.C. §§ 262(l)(6)(A), (B).

[45] 35 U.S.C. § 271(e)(2)(C), (e)(4).

[46] 42 U.S.C. § 262(l)(9)(C).

[47] 42 U.S.C. § 262(l)(9)(B).

67. The BPCIA also requires an ABLA applicant to provide the patent holder at least 180-days' notice before commercially marketing its biosimilar.[48] Upon receiving such notice, the reference product sponsor may file for a preliminary injunction prohibiting the manufacture or sale of the biosimilar until adjudication of the validity, enforcement, and/or infringement of any patent on the reference sponsor's original 3A list or in the ABLA applicant's list provided under subsection (3)(B).[49] The injunctive relief of BPCIA litigation thus concerns all patents that the patent holder alleges are relevant.

68. Once the 180-day notice period has expired, and provided the FDA has approved the ABLA, the ABLA applicant may launch its biosimilar regardless of whether the patent litigation has been resolved. Such a launch is known as an "at-risk" launch. A manufacturer that launches at-risk accepts the possibility that it will have to pay damages to the patent holder if the patents are found valid, enforceable, and infringed.

2. *Inter partes* review.

69. First entrants—both for small molecule and biologic drugs—often obtain patents on their new drugs shortly before they seek FDA approval, during the approval process, or immediately afterward. Patents obtained in this timeframe may claim and cover a genuine technological breakthrough. These original patents become "prior art," limiting the scope of follow-on patents that the manufacturers may obtain. As the number of patent filings for a drug grows, so does the volume of prior art with which the patent applicant must contend. Later-issued patents (should) be narrow and are more difficult to obtain. They are also inherently

[48] 42 U.S.C. § 262(l)(8)(A). The notice need not be after the FDA approves the ABLA applicant's licensure. *Sandoz Inc. v. Amgen Inc.*, 582 U.S. 1, 3 (2017).

[49] 42 U.S.C. § 262(l)(8)(B).

weaker patents, more susceptible to invalidation: predecessor patents in the same family often render them obvious.

70. For decades, drug manufacturers have manipulated the patent system, overwhelming under-resourced PTO patent examiners into issuing meritless patents. A white paper examining federal district court patent cases in Westlaw and LexisNexis from 2007 to 2011 found that, in 86% of cases that reached a decision on the validity of a patent, the patent claims challenged *were invalid and/or not infringed*.[50] The biotechnology field, which includes biologic drugs, has an even higher invalidity rate. An academic paper that examined all substantive decisions rendered by any court in any patent case filed in 2008 and 2009 found that biotechnology patent holders prevailed only *5.6% of the time*.[51] The authors concluded that their "data set suggests that the biotechnology patents that reach a merits ruling overwhelmingly lose."[52] They added that, "[o]f the litigated patents in our data set, biotechnology patents are much more likely to be invalidated than any other type of patent, and they are less likely than average to be infringed."[53]

71. Concerned that invalid patents were being issued and improperly enforced, to the detriment of both innovation and the economy, Congress passed the Leahy-Smith America Invents Act (AIA) in 2011. A centerpiece of the AIA is the *inter partes* review system, which (1)

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[50] MORGAN LEWIS, WHITE PAPER REPORT: U.S. PATENT INVALIDITY STUDY (2012), https://www.morganlewis.com/-/media/files/publication/presentation/speech/smyth_uspatentinvalidity_sept12.pdf?rev=3a7b8e0fd5c0476ba154ee8a9d96a773.

[51] John R. Allison, Mark A. Lemley & David L. Schwartz, *Our Divided Patent System*, 82 U. CHI. L. REV. 1073, 1073, 1097-98 (2015).

[52] *Id.*

[53] *Id.* at 1137.

allows patent challenges through an administrative process that differs from traditional patent litigation and (2) expands the universe of potential patent challengers.

72. The *inter partes* review process enables any member of the public to challenge an issued patent without first committing an act of infringement. A panel of administrative law judges—who possess both specialized legal and technological knowledge—then reviews the validity of the issued patent. These administrative law judges belong to the Patent Trial and Appeals Board (PTAB)—the same board that decides appeals of patent examiner rejections of patent applications. The only limitation on *inter partes* review is that a petitioner may only challenge the validity of a patent on the basis of obviousness or anticipation—a petition cannot be based on other grounds for invalidity, such as inequitable conduct.[54]

73. The PTAB will grant a request for *inter partes* review only if the challenger of the patent shows "a reasonable likelihood that the petitioner would prevail with respect to at least [one] of the claims challenged in the petition."[55] The PTAB must decide the review within one year of the institution date.[56]

74. Although a step in the right direction, *inter partes* review has not cured the problem of invalid patent issuance. In July 2018, Dr. Scott Gottlieb, then-Commissioner of the FDA, observed that biosimilar competition was "anemic because litigation has delayed market access for biosimilar products that are, or shortly will be, available in markets outside the U.S. several years before they'll be available to patients here. These delays can come with enormous

[54] 35 U.S.C. § 311(b).

[55] 35 U.S.C. § 314(a).

[56] 35 U.S.C. § 316(a)(11).

costs for patients and payors."[57] He added that "patent thickets that are purely designed to deter the entry of approved biosimilars are spoiling this sort of competition."[58]

V. FACTS

A. Ustekinumab prevents the inflammatory processes that characterize various autoimmune diseases.

75. Ustekinumab is an FDA-approved biologic that doctors prescribe to treat several life-threatening autoimmune diseases, including moderate to severe plaque psoriasis, active psoriatic arthritis, moderately to severely active Crohn's disease, and moderately to severely active ulcerative colitis. The drug is also FDA-approved to treat pediatric patients six years and older with moderate to severe plaque psoriasis or active psoriatic arthritis.

76. An autoimmune disease is one where the body's external defense system—its immune system—begins to attack the body instead of protecting it. These internal attacks can take various forms, including prolonged inflammatory responses that damage the body's vital organs. Psoriasis, including plaque psoriasis and psoriatic arthritis, is one such inflammatory disease, which effects the body's skin and joints.

77. Crohn's and ulcerative colitis are two other inflammatory autoimmune diseases, characterized by a chronic inflammation of the gastrointestinal tract. Crohn's disease and ulcerative colitis are related diseases—known as inflammatory bowel diseases—with overlapping epidemiological, clinical, and therapeutic characteristics. "While the conditions feature slight clinical and anatomical differences, given their similarities, they can be impossible

[57] *Remarks from FDA Commissioner Scott Gottlieb, M.D., as prepared for delivery at the Brookings Institution on the release of the FDA's Biosimilars Action Plan*, FOOD & DRUG ADMIN. (Jul. 18, 2018), https://www.fda.gov/news-events/press-announcements/remarks-fda-commissioner-scott-gottlieb-md-prepared-delivery-brookings-institution-release-fdas.

[58] *Id.*

to distinguish in patients, and confusion on which condition a patient has occurs in about 30% of patients."[59] Due to their similarities, these inflammatory bowel diseases have historically been treated with the same or similar therapies. Left untreated, they can result in life-threatening damage to the stomach, large and small intestines, oral cavity, anal canal, pharynx, and esophagus.

78. Ustekinumab treats all four inflammatory autoimmune diseases (plaque psoriasis, psoriatic arthritis, Crohn's disease, and ulcerative colitis) by preventing certain proteins from causing inflammation. Ustekinumab is a human immunoglobulin G1 (IgG1) monoclonal antibody. A monoclonal antibody is a laboratory-made protein that mimics an antibody—a type of protein—that the human body naturally produces (i.e., clones of one antibody—monoclonal).

79. Interleukin 12 (IL-12) and Interleukin 23 (IL-23)[60] are two important signaling proteins that regulate the body's immune responses. Those immune responses are triggered when the IL-12 and IL-23 proteins bind to a receptor known as IL-12Rβ1 (the red receptors in the diagram below) at a site known as the p40 subunit therein initiating, or "signaling," an inflammatory response in the gastrointestinal tract.[61]

80. Ustekinumab treats inflammatory bowel diseases (as well the other autoimmune diseases it treats) by attaching to IL-12's and IL-23's common p40 subunit, therein blocking

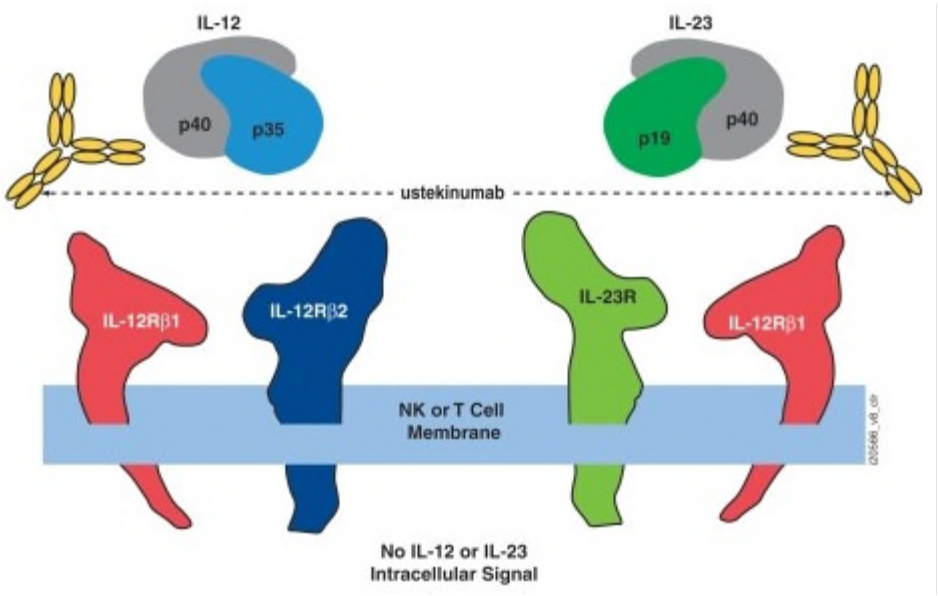
[59] Decl. of Michael S. Epstein, Ex. 1002 at ¶ 35, *Samsung Bioepis Co., Ltd, v. Janssen Biotech, Inc.,* No. IPR2023-01103.

[60] Any class of glycoproteins (proteins with carbohydrate groups—glyco—attached to their polypeptide chain) that white blood cells (leukocytes) produce for regulating immune response are called interleukins.

[61] Jacqueline M. Benson, et al., *Discovery and mechanism of ustekinumab,* 3 MABS 535, 543 (2011).

these proteins from binding to IL-12Rβ1 receptor. By blocking the IL-12 and 23 pathways, ustekinumab prevents the dangerous inflammatory response.[62]

81. In the diagram below, ustekinumab is the yellow protein binding to the grey p40 subunit of the IL-12 or IL-23 proteins, preventing those proteins from binding with the IL-12Rβ1, receptors, depicted in red.[63]



B. J&J obtained a composition patent on ustekinumab and FDA approval for its sale.

82. On August 1, 2001, J&J filed patent application 09/920,262 seeking a patent covering the composition of matter for ustekinumab.

83. On June 7, 2005, the PTO granted the application and issued U.S. Patent No. 6,902,734 (the ’734 patent) covering the composition of ustekinumab. This patent had an expiration date of September 25, 2023.

84. The patent was initially assigned to Centocor, Inc., a subsidiary of Johnson & Johnson, Inc. In 2008, as the result of a merger, the patent was assigned to the merged entity,

[62] *Id.* at 537.

[63] *Id.* at 540, Figure 4.

Centocor Ortho Biotech, Inc. Centocor Ortho Biotech remained a subsidiary of Johnson & Johnson. In 2011, Centocor Ortho Biotech, Inc. changed its name to Janssen Biotech, Inc., and the '734 patent was assigned to Janssen Biotech, Inc. In or around September 2023, Janssen Biotech, Inc. became Johnson & Johnson Innovative Medicine. It does not appear that the '734 was ever assigned to the latter.

85. On September 25, 2009, the FDA approved J&J's Biologic License Application (BLA) No. 125261 to market and sell ustekinumab, under the brand name Stelara, to treat adults with moderate to severe plaque psoriasis. Shortly thereafter, J&J began selling Stelara in the United States.

86. On September 20, 2013, the FDA approved Stelara to treat psoriatic arthritis in adults.

87. On September 23, 2016, the FDA approved Stelara to treat moderately to severely active Crohn's Disease.

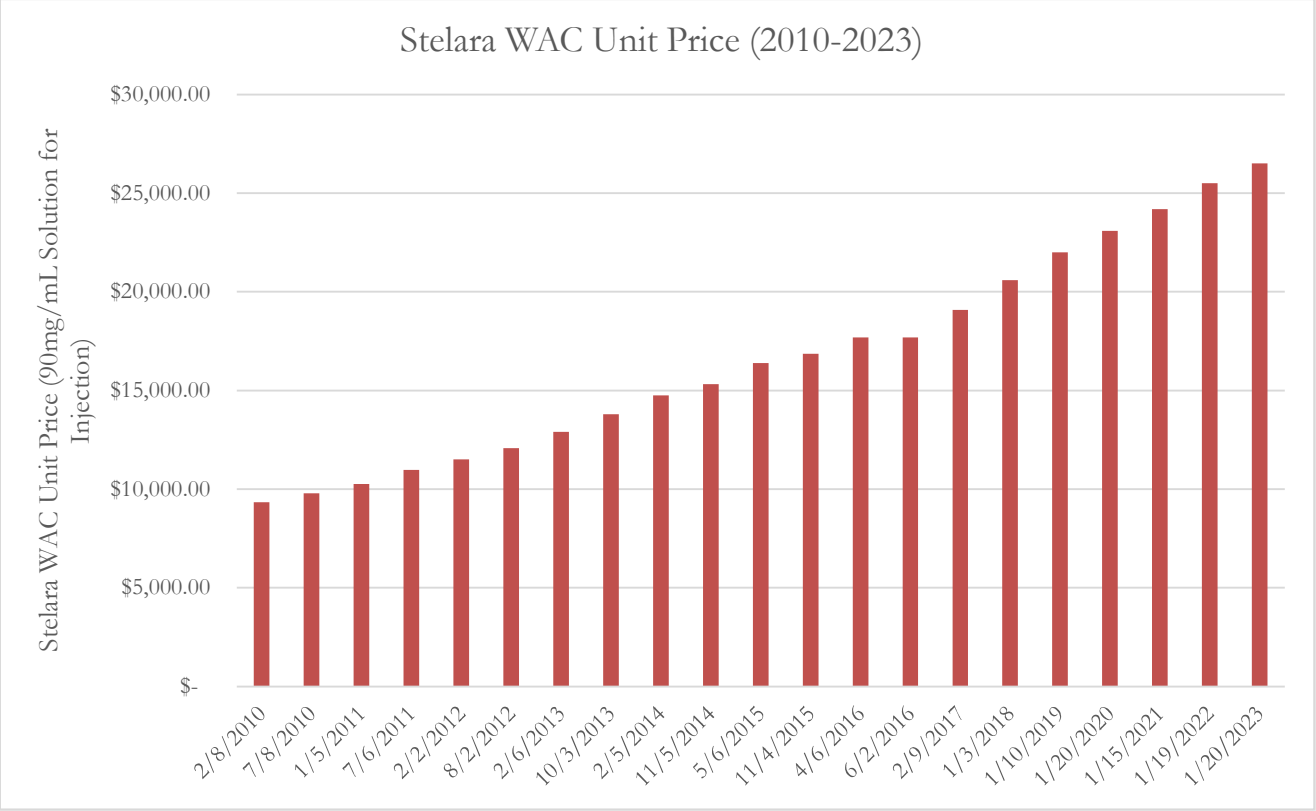
C. J&J marketed and sold Stelara from September 2009 through the present.

88. For at least 14 years—from September 2009 (product launch) to September 25, 2023 (expiration of the '734 patent covering the composition of ustekinumab)—J&J enjoyed exclusive, patent-protected sales of Stelara.

89. Since 2009, J&J has had, and continues to have, monopoly power in the market for ustekinumab in the United States. (Allegations of J&J's monopoly power are later detailed in this complaint).

90. Over those years, J&J grossed over $50 billion in sales of Stelara. Indeed, today, Stelara remains Janssen's best-selling product both in the United States and worldwide, delivering nearly $6.4 billion in net U.S. sales revenue and roughly $9.7 billion in worldwide sales revenue in 2022.

91. J&J capitalized on its monopolist position by raising the price of Stelara twenty times since the product's 2009 launch.



92. In recent years, it was widely expected—by biologic industry followers and by J&J itself—that J&J would lose exclusivity for its Stelara sales in September 2023, i.e., upon expiration of its composition patent and the entry of approved biosimilar products. However, and despite enjoying 14 years of extraordinarily high-priced sales for Stelara yielding many billions of dollars, J&J engaged in unlawful acts to *extend* its monopoly position well beyond the expiration of its compound patent in September 2023.

D. J&J acquired a method of use patent on ustekinumab by fraud to unlawfully extend its monopoly over the drug beyond September 2023.

93. Between 2019 and 2021, J&J defrauded a PTO patent examiner into incorrectly issuing a method-of-use patent covering the use of ustekinumab to treat ulcerative colitis

conditions. The purpose and effect of J&J fraud was to unlawfully extend its monopoly beyond September 2023.

94. To explain the fraud, this complaint first describes the background science and public knowledge that preceded J&J's fraud.

1. In the 2000s, scientists—including those at J&J—documented ustekinumab's ability to treat autoimmune diseases related to the IL-12 and IL-23 proteins, including ulcerative colitis.

95. Since the early 2000s, monoclonal antibodies, like ustekinumab, have been used to treat inflammatory bowel diseases.[64]

96. Research in the early 2000s and 2010s highlighted the role of IL-12 and IL-23 in the pathogenesis of inflammatory bowel disease, including both Crohn's and ulcerative colitis.

97. In 2004, a human study concluded that "a monoclonal antibody against [IL-12] may induce clinical responses and remissions in patients with active Crohn's disease."[65]

98. In 2010, a paper publicized the results of studies where "neutralization of IL-23" was "shown to ameliorate and cure colitis in a number of mouse models of IBD."[66]

[64] Monoclonal antibodies can be recognized by the "mab" at the end of a drug name (mab indicates **m**onoclonal **a**nti**b**ody). For example, infliximab (brand name, Remicade), adalimumab (brand name, Humira), golimumab (brand name, Simponi), vedolizumab (brand name, Entyvio), natalizumab (brand name, Tysabri), and certolizumab (brand name, Cimzia) are all monoclonal antibodies. *See* Decl. of Michael S. Epstein, Ex. 1002 at ¶ 39, *Samsung Bioepis Co., Ltd, v. Janssen Biotech, Inc.*, No. IPR2023-01103.

[65] Peter J. Mannon et al., *Anti-Interleukin-12 Antibody for Active Crohn's Disease*, 351 NEW ENGLAND J. MED. 2069, 2069 (2004), https://pubmed.ncbi.nlm.nih.gov/15537905/.

[66] Philip P. Ahern et al., *Interleukin-23 Drives Intestinal Inflammation through Direct Activity on T Cells*, 33 IMMUNITY 279, 279 (2010), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3078329/.

99. Thus, by 2010, scientists not only understood the value of monoclonal antibody treatment for inflammatory bowel disease generally, but also the importance of using monoclonal antibodies to target the IL-12 and IL-23 proteins to treat these diseases.

100. In 2011, J&J launched three Phase 3 trials studying ustekinumab's impact on Crohn's. In launching these trials, Janssen recognized the potential efficacy of ustekinumab to treat inflammatory bowel diseases. The clinical trials were completed in July 2013, October 2014, and October 2019, respectively, and, unsurprisingly, showed that ustekinumab was effective in treating Crohn's disease. On September 23, 2016, the FDA approved Stelara to treat Crohn's.

101. The research connecting the IL-12 and IL-23 pathways to the treatment of inflammatory bowel disease, the efficacy of ustekinumab in treating Crohn's, and the reality that the same treatments were often effective against both Crohn's and ulcerative colitis inevitably led J&J and researchers worldwide to study the use of ustekinumab to treat ulcerative colitis.

102. In November 2014, researchers in South Africa noted that ulcerative colitis was an "[o]ff-label indication" for ustekinumab/Stelara.[67]

103. On April 2, 2015, J&J announced its proposal for a Phase 3 clinical trial—NCT 236—testing the use of ustekinumab to treat moderately to severely active ulcerative colitis. The study enrolled 961 participants with moderately to severely active ulcerative colitis in a randomized, double-blind two-step study. An eight-week induction study would test participants' responses to intravenous Stelara. Participants who responded to treatment in the induction study would then be enrolled in a forty-four-week maintenance study testing the safety and efficacy of

[67] G. Tarr et al., *Superheroes in autoimmune warfare: Biologic therapies in current SA practice*, 104 S. AFRICAN MED. J. 787, 788 (2014), https://doi.org/10.7196/samj.8947.

subcutaneous Stelara. The inclusion criteria specified that study participants would: (1) have been clinical diagnosed with ulcerative colitis at least three months before screening; (2) have moderately to severely ulcerative colitis; (3) have failed to respond to treatment with biologic therapy (such as other monoclonal antibodies) *or* be naïve to biologic therapy or received biologic therapy without a history of failure and have a current or past history of inadequate treatment (failure) with a series of non-biologic treatments. The study's primary and secondary endpoints drew on global and U.S. definitions of clinical remission and used Mayo scores and measures of endoscopic healing to quantify clinical response.

104. On July 10, 2015, J&J launched NCT 236.

105. On April 20, 2016, in its FDA-approved clinical protocol for NCT 236, J&J explained that while ustekinumab had not been studied to treat ulcerative colitis, "considering the similarities in the genetics and biology of UC and Crohn's disease, *it is reasonable to assume that ustekinumab will also be effective in UC.*"[68] Indeed, J&J relied on the safety results from its Phase 2 studies of ustekinumab to treat Crohn's as a justification for skipping such Phase 2 trials for ulcerative colitis. "Data from completed Phase 2 studies of ustekinumab in Crohn's disease, *along with the shared biology and the similar response to current treatments between Crohn's disease and UC*, provide a substantial scientific and clinical rationale to justify a direct-to-Phase-3 approach to the study of ustekinumab in UC."[69] In short, ulcerative colitis and Crohn's reacted to treatment in such a similar way that J&J's Crohn's trials could be used to justify a "direct-to-

[68] JANSSEN RSCH. & DEV., LLC, CLINICAL PROTOCOL: A PHASE 3, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, PARALLEL-GROUP, MULTICENTER PROTOCOL TO EVALUATE THE SAFETY AND EFFICACY OF USTEKINUMAB INDUCTION AND MAINTENANCE THERAPY IN SUBJECTS WITH MODERATELY TO SEVERELY ACTIVE ULCERATIVE COLITIS 58 (2016), https://classic.clinicaltrials.gov/ProvidedDocs/36/NCT02407236/Prot_000.pdf.

[69] *Id.* at 25.

phase-3 approach" for ulcerative colitis. Based on the similarities between Crohn's and ulcerative colitis, J&J mirrored the dosage for NCT 236 treating ulcerative colitis to the dosage it used in its Phase 3 study treating Crohn's.[70]

106. In addition to NCT 236, other public scientific reports acknowledged the efficacy of ustekinumab to treat ulcerative colitis.

107. On February 11, 2017, researchers in Paris, France issued a case study of two ulcerative colitis patients who were successfully treated with ustekinumab for chronic pouchitis developed after undergoing ileal pouch-anal anastomosis.[71] Acknowledging the known attributes of ustekinumab as (1) "a fully human immunoglobulin [IgG1k] monoclonal antibody that binds the p40 subunit of interleukin [IL]12 and 23 and normalizes IL12- and IL23-mediated signaling" and (2) an effective treatment for Crohn's disease, the study concluded that ustekinumab could effectively treat ulcerative colitis patients experiencing chronic pouchitis refractory to immunosuppressants and anti-TNF treatments.[72]

108. On February 25, 2017, researchers in Santander, Spain reported a retrospective observational study that treated seven patients, two with ulcerative colitis and five with Crohn's, with ustekinumab.[73] The study concluded that "[u]stekinumab is a therapeutic approach for

[70] *Id.* at 58.

[71] My-Linh Tran-Minh et al., *Successful Treatment with Ustekinumab for Chronic Refractory Pouchitis*, 11 J. CROHN'S AND COLITIS 1156, 1156 (2017), https://academic.oup.com/ecco-jcc/article/11/9/1156/2983512.

[72] *Id.*

[73] L. Senra Afonso et al., *CP-202 Ustekinumab treatment in refractory inflammatory bowel disease*, 24 EUR. J. HOSP. PHARMACY (2017), https://ejhp.bmj.com/content/24/Suppl_1/A90.2.

[inflammatory bowel disease] treatment in clinical practice in patients with poor response or intolerance to other biological therapies, especially in patients not responding to anti-TNFα."[74]

109. By April 2017, the Canadian Agency for Drugs and Technologies in Health acknowledged that while ustekinumab was currently only "indicated for plaque psoriasis and psoriatic arthritis," "[t]here is potential for ustekinumab to be used off-label as a treatment option for ulcerative colitis."[75] Put another way, recognizing the efficacy of ustekinumab to treat ulcerative colitis, Canadian doctors were already beginning to prescribe the drug off-label to treat ulcerative colitis.

110. On January 16, 2018, researchers in Munich, Germany published a retrospective data analysis of seventeen ulcerative colitis patients who had received ustekinumab between 2016 and 2017 "after colectomy had been offered to them as only other option."[76] Patients received the ustekinumab protocol used for Crohn's, i.e., "6 mg/kg body weight as an infusion and 90 mg ustekinumab as s.c. [subcutaneous] injection every 8 weeks."[77] The study, led by Dr. Thomas Ochsenkühn, concluded that "[u]stekinumab was effective as [a] rescue medication in therapy-refractory or -intolerant UC in a large IBD referral center. It seems possible that large ongoing trials will confirm our findings and ustekinumab could become a new therapeutic option

[74] *Id.*

[75] CANADIAN AGENCY FOR DRUGS & TECHNOLOGIES, *Issues for Consideration, in* COMMON DRUG REVIEW (2017), https://www.ncbi.nlm.nih.gov/books/NBK476200/?report=printa.

[76] Thomas Ochsenkühn et al., *P759 Ustekinumab as rescue treatment in therapy-refractory or -intolerant ulcerative colitis*, 12 J. CROHN'S & COLITIS S495 (2018), https://academic.oup.com/ecco-jcc/article/12/supplement_1/S495/4808137.

[77] *Id.*

for refractory UC."[78] Dr. Ochsenkühn's paper, thus, explained to the public that ustekinumab could be used to treat ulcerative colitis effectively.

111. On February 1, 2018, researchers in Zurich, Switzerland issued a case study of successful treatment of a patient who developed paradoxical ulcerative colitis with ustekinumab.[79] The article, led by Dr. Antonios Kolios, concluded "[o]ur observation suggests that ustekinumab is an effective treatment option in patients with paradoxical anti-TNF-driven inflammatory reactions like psoriasis or IBD."[80]

112. On August 10, 2018, J&J's NCT 236 Phase 3 clinical trial reached primary completion, i.e., the final data collection for the primary outcome measure.

113. In summary, by August 2018, the scientific literature taught that: (i) ustekinumab treated inflammatory autoimmune diseases by blocking the IL-12 and IL-23 proteins from binding to the receptor that initiated an inflammatory response; (ii) the IL-12 and IL-23 proteins were implicated in the pathogenesis of inflammatory bowel diseases, including Crohn's and ulcerative colitis; (iii) the same treatments were usually effective to treat both Crohn's and ulcerative colitis; (iv) the FDA had years earlier approved Stelara to treat Crohn's, a disease with close etiology to ulcerative colitis; (v) ulcerative colitis patients across the globe *had been successfully treated with ustekinumab*; and (vi) J&J had publicly disclosed its Phase 3 clinical trial plan to confirm the effectiveness of ustekinumab for treatment of ulcerative colitis.

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[78] *Id.*

[79] Antonios G. A. Kolios, et al., *Paradoxical ulcerative colitis during adalimumab treatment of psoriasis resolved by switch to ustekinumab*, 178 BRIT. J. DERMATOLOGY 551 (2018), https://academic.oup.com/bjd/article-abstract/178/2/551/6732166.

[80] *Id.*

114. Thus, by September 2018, J&J believed, and had an objectively sound scientific basis to believe, that ustekinumab was, and would be clinically proven through controlled trials to be, effective in treating ulcerative colitis.

2. J&J misrepresented material facts to the patent examiner and wrongfully obtained a patent for using ustekinumab to treat ulcerative colitis.

115. On September 24, 2019, J&J filed patent application 16/580,509, seeking a method-of-use patent covering ustekinumab to treat moderately to severely active ulcerative colitis. The application claimed a priority date of September 24, 2018. As a result, public knowledge pre-dating September 24, 2018, regarding the ostensible invention in the application—including published medical journal articles, clinical trial protocols, and other publicly available information—could render the application not approvable.

116. A fundamental principle of drug patent law is that once it is publicly known that a drug is effective in treating a particular disease or disorder, later publication of clinical trial results confirming that effectiveness cannot serve as a basis to issue a patent claiming that use for that drug. Rather, those clinical trial results are simply "inherently anticipated" by the earlier disclosure(s).[81] Thus, for years, it was well-established that public disclosure of clinical trials studying a drug's use renders invalid a method-of-use patent later sought for the same use of that drug.

117. By the time J&J submitted its method-of-use patent application and engaged in the ensuing patent prosecution, a reasonable drug patent practitioner representing J&J would have been aware of both (i) the well-established legal rule that public disclosure of Phase 3 clinical plans to study a drug's use can anticipate a later-sought patent on that use of the drug;

[81] *In re Montgomery*, 677 F.3d 1375, 1382 (Fed. Cir. 2012).

and (ii) the fact that J&J's NCT 236 *did anticipate* its later-sought method-of-use patent, covering use of ustekinumab to treat ulcerative colitis.

118. Here, J&J disclosed the protocol for its NCT 236 trial using ustekinumab to treat ulcerative colitis in 2015. Such a protocol was far from merely "an invitation to investigate";[82] it was part of J&J's Phase 3 clinical trial in advance of seeking FDA approval to add ulcerative colitis as an indication for Stelara. Therefore, J&J's NCT 236 inherently anticipated using ustekinumab to treat ulcerative colitis—the very invention J&J claimed in its method-of-use patent application. Although it was publicly known prior to September 24, 2018, that ustekinumab was effective in treating ulcerative colitis, and although J&J believed (based on an objectively sound, scientific basis) that the later Phase 3 clinical trials would show ustekinumab effective in treating ulcerative colitis, J&J nevertheless applied for, and obtained through fraud, a patent on using ustekinumab to treat ulcerative colitis.

a. J&J applied for a secondary patent covering use of ustekinumab to treat ulcerative colitis.

119. On September 24, 2019, J&J filed Patent Application 16/580,509 for a patent claiming the method of using ustekinumab to treat ulcerative colitis.

120. Numerous J&J employees were listed as inventors in Janssen's method-of-use patent application, including Katherine Li (Janssen), Jewel Johans (J&J), Colleen Marano (J&J), Hongyan Zhang (J&J), Christopher O'Brien (Janssen), and Omoniyi Adedokun (Janssen). On the patent application, Johnson & Johnson's address was given as the address for the patent applicant.

[82] *Id.*

121. Two days after filing the method-of-use patent application with the PTO, on September 26, 2019, the same Janssen and J&J employees (along with a few Janssen consultants not listed as inventors) published the results of the NCT 236 study in the New England Journal of Medicine. This article concluded that "[u]stekinumab was more effective than placebo for inducing and maintaining remission in patients with moderate-to-severe" ulcerative colitis.[83]

122. Less than a month later, on October 18, 2019, the FDA approved Stelara for the treatment of adult patients with moderately to severely active ulcerative colitis.

123. In its patent application, J&J acknowledged that "[t]he involvement of the IL-12/23 pathway in the pathogenesis of IBD is well established,"[84] but nevertheless falsely represented that "[p]rior to the present invention, no studies had been conducted with ustekinumab for [ulcerative colitis]."[85] This was untrue. Researchers worldwide had studied the efficacy of ustekinumab to treat ulcerative colitis or complications arising from the same. In the application, J&J also knowingly concealed the Spanish, German, or Swiss studies from the patent examiner.

b. J&J fraudulently prosecuted the later patent for using ustekinumab to treat ulcerative colitis.

124. On July 16, 2020, the patent examiner correctly rejected all the patent application's claims as either anticipated by or obvious over NCT 236, as that study "[taught] the use of [ustekinumab/Stelara] for the instantly claimed purpose," including the method of

[83] Bruce E. Sands et al, *Ustekinumab as Induction and Maintenance Therapy for Ulcerative Colitis*, 381 NEW ENGLAND J. MED. 1201, 1201 (2019), https://www.nejm.org/doi/full/10.1056/NEJMoa1900750.

[84] File for U.S. Patent Application No. 16/580,509 ('307 File Wrapper), Specification dated Sept. 24, 2019, p. 2.

[85] *Id*. at p. 4.

administration and its parameters/endpoints.[86] While certain claims were not taught in NCT 236, those claims were still either anticipated or obvious and, therefore, not patentable. The examiner noted that "where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."[87] The examiner explained that while the clinical trial was "silent regarding the use of the antibody in patients not responsive to other treatments . . . it would have been expected, or it would have been obvious to have used such a novel treatment in those not responding to current (at the time) treatments."[88]

125. On October 5 and 13, 2020, J&J initiated telephone calls with the patent examiner.

126. In the early October calls, J&J misrepresented to the patent examiner that, as of September 2018, "it would not have been obvious"[89]—i.e., that it would have been *surprising*—that ustekinumab would successfully treat ulcerative colitis, as measured by any one of the seven endpoints for ulcerative colitis treatment used in NCT 236. J&J also misrepresented that, in September 2018, it would not have been obvious that there would be a population of patients whose response could be measured in one of these ways.

127. Both statements were knowingly false. In fact, by September 2018, (1) J&J had disclosed detailed plans to conduct NCT 236 (thereby disclosing the method and the likelihood of success of using ustekinumab to treat ulcerative colitis); (2) numerous reports worldwide had

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[86] '307 File Wrapper, Non-Final Rejection dated July 16, 2020, p. 7.

[87] *Id*. (quoting *In re Aller*, 220 F.2d 454, 454 (C.C.P.A. 1955) (internal quotations omitted)).

[88] '307 File Wrapper, Non-Final Rejection dated July 16, 2020, p. 7.

[89] '307 File Wrapper, Examiner Interview Summary Record (PTOL-413) dated Oct. 9, 2020, p. 1.

shown the successful use of ustekinumab to treat ulcerative colitis; and (3) J&J had publicly disclosed clear and rational optimism of achieving success in treating ulcerative colitis with ustekinumab.

128. During the October 2020 calls, J&J also concealed from the patent examiner the fundamental drug patent principle that, when publicly disclosed before the patent's priority date, detailed clinical trial plans describing a method of using a drug to treat a condition inherently anticipate later patent claims covering that method for that drug.

129. On October 16, 2020, J&J filed its response to the examiner's July rejection. In this response, J&J updated the patent application's claims, adding a description of the seven potential endpoint measures used to determine successful treatment of ulcerative colitis.

130. Also in the response, J&J misrepresented that the revised claims were "not anticipated or rendered obvious by the [NCT 236] reference."[90] J&J misrepresented that NCT 236 did not disclose or suggest that treating moderately to severely active ulcerative colitis with ustekinumab would achieve a response as measured by any one of seven known endpoints measures for ulcerative colitis treatment. This statement was false. In fact, the NCT 236 reference did describe the endpoints and fully predicted ustekinumab's likely success on these measures.

131. In its response, J&J also emphasized that the earlier clinical trial protocols "did not include any clinical trial results" before the application's filing date and that J&J first posted the clinical trial results after it filed the application.[91] While this was technically true, it was

[90] '307 File Wrapper, Applicant Arguments/Remarks Made in an Amendment dated Oct. 16, 2020, p. 1.

[91] '307 File Wrapper, Applicant Arguments/Remarks Made in an Amendment dated Oct. 16, 2020, p. 2.

intentionally misleading. As J&J knew, the later-acquired clinical trial results could not overcome invalidity due to inherent anticipation because the details of NCT 236 and its predictable results *were publicly disclosed years before the applicable priority date.* Nonetheless, J&J misrepresented that "[d]ue to the uncertainty of clinical outcomes and the failure of numerous medicines to satisfy designated clinical trial endpoints, the posting of elements of a clinical trial in advance of conduct of the trial do not anticipate or render obvious the subject matter of the claims."[92]

132. In short, J&J responded to the patent examiner's rejection by presenting false and misleading facts and argument regarding how NCT 236 and other prior scientific disclosures did not anticipate that ustekinumab would be successful in treating ulcerative colitis. And, despite having additional opportunities to adhere to its duties of disclosure and candor, J&J did not alert the patent examiner to other relevant prior art.

133. The patent examiner relied upon J&J's knowing and willing false and misleading material representations and omissions. On November 13, 2020, the patent examiner withdrew his earlier objections and filed a notice of allowance and fees due. The examiner did not provide further explanation as to his allowance. Thus, during the patent prosecution, J&J defrauded the patent examiner (and thereby the PTO) and violated its duty of disclosure, good faith, and candor.

134. On March 30, 2021, the PTO issued J&J's method of use patent, Patent No. 10,961,307 (the '307 patent), titled "Methods of Treating Moderately to Severely Active Ulcerative Colitis by Administering an Anti-IL12/IL23 Antibody."[93] Under applicable patent

[92] '307 File Wrapper, Applicant Arguments/Remarks Made in an Amendment dated Oct. 16, 2020, p. 2.

[93] U.S. Patent No. 10,961,307.

law, the '307 patent was set to expire September 24, 2039—*one day shy of 16 years after the original composition patent's expiration date*.

135. In sum, J&J unlawfully acquired the '307 patent by fraud on the PTO. J&J would later use this patent to extend its monopoly in the sale of ustekinumab in the United States beyond September 2023.

E. J&J acquired patents from a biosimilar drugmaker to block entry of competitors to Stelara and unlawfully extend its monopoly beyond September 2023.

136. In 2020, J&J acquired from a biosimilar drug maker several patents that claimed manufacturing methods that ostensibly would be useful in developing biosimilar monoclonal antibody products. Although these technologies were intended *to enhance* biosimilar competition, J&J would later use these patents *to block* entry of biosimilar competitors to J&J's biologic, Stelara, and unlawfully extend its monopoly beyond September 2023.

137. To explain the anticompetitive acquisition, this complaint first describes the background of the acquired biosimilar company.

1. Momenta Pharmaceuticals, Inc. developed and patented technologies to aid in the manufacture of biosimilar drug products to compete with brand biologic drug products.

138. Founded in 2001, Momenta Pharmaceuticals, Inc. was an independent biotechnology company that developed therapeutics for autoimmune diseases. Momenta focused on developing biosimilar and complex generic products, rather than brand products. Towards this end, much of Momenta's work examined methods of manufacturing *biosimilar* antibodies, i.e., such as cell culturing processes that impact attributes of recombinant antibodies in comparison to a reference (or other brand) product. Momenta had developed generic versions of Copaxone and Lovenox and biosimilars for Humira and Eylea.

139. According to J&J, Momenta was "a highly skilled biosimilar manufacturer: its research and development focused on manufacturing antibodies, including enabling biosimilars to more effectively match the reference product."[94]

140. During the manufacturing processes for biosimilar drug products, it is beneficial to control antibody characteristics known as "post-translational modifications," i.e., chemical changes made to an antibody. Even antibodies with identical amino acid sequences can have different post-translational modifications. These post-translational modifications can, in turn, cause otherwise identical antibodies to have different biological properties that can impact their efficacy and safety. If a biosimilar company can control the extent of post-translational modifications (and compare the extent of any changes to a reference product), that company can enhance its ability to produce a biosimilar product that the FDA will approve to compete with the biosimilar's reference product. Simply put, controlling post-translational modifications can be an important aspect of biosimilar development, FDA biosimilar approval, and FDA interchangeability decisions.

141. Momenta's research into methods for preparing biosimilar versions of reference drug products led to its application for patents covering its biosimilar manufacturing technologies. By 2020, Momenta had applied for or obtained four such patents covering methods of using cell culturing processes to target and control features of biosimilar antibodies to assure equivalence to reference products. These patents issued as U.S. Patent No. 8,852,889 (the '889 patent), U.S. Patent No. 9,217,168 (the '168 patent), U.S. Patent No. 9,475,858 (the '858 patent),

[94] First Am. Compl. at ¶ 4, *Janssen Biotech, Inc. v. Amgen Inc.*, C.A. No. 22-1549 (D. Del. Mar. 7, 2023), ECF No. 46.

and U.S. Patent No. 9,663,810 (the '810 patent) (collectively, the Momenta biosimilar manufacturing patents).

142. The Momenta biosimilar manufacturing patents focused methods of modifying the antibody manufacturing process to control two types of post-translational modifications. One—covered by the '168 patent—is a method of controlling "glycans." As with other post-translational modifications, different forms and distributions of glycans can later impact the biological properties of the antibody. As a result, controlling glycans helps ensure biosimilarity. Another—covered by the '858 patent—is a method of controlling "C-terminal variants." Controlling C-terminal variants in antibody manufacturing—i.e., controlling what fraction of the antibodies produced have either zero, one, or two lysines at the end—can help a biosimilar maker not only to achieve close similarity to the reference product, but also meet internal targets and achieve product consistency among its own lots.

143. Together, the '168 patent and the '858 patent describe methods of controlling antibody characteristics by selecting one of two chemicals (arginine or putrescine), in specific amounts, to be used during the antibody manufacturing process in the cell culture medium (i.e., the liquid in which cells grow to express antibodies). Both claim methods of adjusting cell growth media to contain specified amounts of arginine or putrescine to achieve desired characteristics in the resulting antibodies—either adjusting arginine to control C-terminal variants or adjusting putrescine levels to control glycans (specifically, high-mannose glycans and sialylated glycans) to make a biosimilar product. The '168 patent discloses and claims novel methods of cell culture to produce a recombinant antibody, including (among other things) by adding defined amounts of putrescine to the cell culture preparation to affect glycans. The '858 patent discloses and claims novel methods of manipulating a cell culture to produce a

recombinant antibody, including (among other things) using a cell culture that has defined amounts of arginine to affect a particular post-translational modification to the antibody—the distribution of C-terminal variants.[95]

144. In sum, in the years preceding 2020, Momenta had developed technologies to aid in the development, approval, and manufacturing of biosimilar drug products. Use of these technologies, when in proper hands, would encourage biosimilar development, approval, and "interchangeability" determinations.

2. In October 2020, J&J bought Momenta, and along with that, Momenta's biosimilar technologies and patents.

145. On October 1, 2020, J&J acquired Momenta for about $6.5 billion. Through the purchase, J&J bought ownership and control over Momenta's technologies for copying biologic products into biosimilar products, including the four Momenta biosimilar manufacturing patents.

146. At the time of the acquisition, J&J was a monopolist in the market for ustekinumab in the United States.

147. Correct use of the Momenta technologies and biosimilar patents is, as J&J has admitted, of particular use to bios*imilar* developers because those technologies can be used to manufacture products more likely to obtain an "interchangeability" determination from the FDA, i.e., a determination the new biosimilar product is interchangeable with the brand (reference) product. As J&J acknowledges, the Momenta patents "were invented . . . to enable biosimilar manufacturers to better achieve equivalence to the originator product, also called the 'reference

[95] The '889 patent describes methods of producing recombinant antibodies by selecting lysine in specific amounts, to be used during the antibody manufacturing process in the cell culture medium (i.e., the liquid in which cells grow to express antibodies). The '810 patent describes methods of controlling antibody characteristics (fucosylated glycans) by selecting putrescine, in specific amounts, to be used during the antibody manufacturing process in the cell culture medium.

product.'"[96] Regarding one of its would-be competitors, J&J has stated the competitor used the patents to make "as close a copy to STELARA® as possible," taking "full advantage of those inventions, so much so that [the competitor] is seeking not only a biosimilarity designation, but also an 'interchangeability' designation, meaning that the two products can be swapped without the prescribing physician's instruction or consent."[97]

148. However, for J&J, the Momenta biosimilar manufacturing patents are of no pro-competitive use with respect to the approved biologic product, ustekinumab (Stelara). Before acquisition of Momenta, J&J had achieved its monopoly position over ustekinumab without use of Momenta's technologies and the Momenta biosimilar manufacturing patents. J&J had developed Stelara in the 2000s and launched the product back in 2009. For over a decade, J&J had manufacturing processes and procedures in place to ensure product quality and consistency, all without any Momenta technology. As a result, J&J had no need for any of the Momenta biosimilar manufacturing processes in developing, manufacturing, or testing Stelara.

149. Instead, in the hands of J&J, the only ostensible use of the Momenta biosimilar manufacturing patents with respect to ustekinumab is for the anticompetitive purpose of blocking or delaying biosimilar companies from developing and launching products biosimilar to ustekinumab.

150. Indeed, J&J is a company that makes branded biologic products, not biosimilar drug products. The Momenta biosimilar manufacturing patents ostensibly cover manufacturing methods across many potential monoclonal antibody products, not just ustekinumab. As a result,

[96] Mem. in Supp. of J&J Mot. for Prelim. Inj.at 7, *Janssen Biotech, Inc. v. Amgen Inc.*, C.A. No. 22-1549 (D. Del. Mar. 15, 2023), ECF No. 59.

[97] *Id.*

acquisition by J&J of Momenta's biosimilar technologies, including the Momenta biosimilar manufacturing patents, can threaten competition in many monoclonal antibody markets.

151. J&J's acquisition of Momenta's biosimilar manufacturing technologies, including the Momenta biosimilar manufacturing patents, was for the purpose, and has the consequence of, unlawfully extending and maintaining J&J monopoly in the market for ustekinumab in the United States.

152. J&J knowingly and willfully acquired the Momenta biosimilar manufacturing patents to delay competition from would-be ustekinumab biosimilar competitors and to further entrench its ustekinumab monopoly.

153. J&J unlawfully acquired Momenta's biosimilar manufacturing patents to delay or prevent competition from would-be ustekinumab biosimilar competitors.

F. J&J used its fraudulently obtained '307 patent and the unlawfully acquired Momenta biosimilar manufacturing patents to delay competition from would-be ustekinumab biosimilar competitors.

154. J&J and the marketplace expected Stelara to lose exclusivity by September 2023.

155. In or around the late 2010s, several biosimilar manufacturers began developing biosimilar versions of Stelara.

156. J&J and industry experts expected J&J to lose market exclusivity in September 2023 upon expiration of its '734 composition patent. This expectation was reasonable and was based on both the lawful application of J&J's patent and the ability of would-be biosimilars to enter the market.

157. In 10-K filings from fiscal years 2021 and 2022, J&J acknowledged that its "latest expiring United States patent for STELARA (ustekinumab) will expire in September 2023."[98] In

[98] Johnson & Johnson, Annual Report (Form 10-K) at 25 (Feb. 17, 2022); Johnson &

its 2021 10-K, J&J warned that the patent's expiration or loss of market exclusivity "is likely to result in a reduction in sales."[99] In 2022, however, J&J upped its prediction, warning that the patent's expiration or loss of market exclusivity "*will* result in a reduction in sales."[100] These statements were made well *after* the PTO issued the '307 patent in March 2021, which is not set to expire until September 24, 2039.

158. In investor calls and financial filings throughout 2022 and early 2023, J&J repeatedly forecasted loss of exclusivity for Stelara well before 2025.

159. During the October 18, 2022 earnings call, Joseph Wolk, J&J's executive vice president and CFO, reiterated that "the STELARA LOE [loss of exclusivity]. . . is anticipated to occur in the second half of 2023 in the U.S."[101] On the same call, Jennifer Taubert, J&J's executive vice president and worldwide chairperson of pharmaceuticals, acknowledged that the company "anticipate[d] Stelara LOE really in that late-September timeframe or towards the end of" 2023.[102]

160. In early 2023, financial analysts similarly forecasted a loss of exclusivity for Stelara in late 2023. On March 29, 2023, BioPharma Dive reported that due to the imminent expiration of the '734 patent, "[m]any analysts have therefore anticipated biosimilars to Stelara could gain approval and be launched this year or in 2024."[103]

Johnson, Annual Report (Form 10-K) at 25 (Feb. 16, 2023).

[99] Johnson & Johnson, Annual Report (Form 10-K) at 25 (Feb. 17, 2022).

[100] Johnson & Johnson, Annual Report (Form 10-K) at 25 (Feb. 16, 2023) (emphasis added).

[101] *Edited Transcript Q3 2022 Johnson & Johnson Earnings Call*, REFINITIV STREETEVENTS at 6 (October 18, 2022), https://www.investor.jnj.com/files/doc_financials/2022/q3/Final-Q3-2022-Transcript.pdf.

[102] *Id.*

[103] Jonathan Gardner, *Acquired patents aid J&J defense of top-selling drug from biosimilar*

161. During the April 18, 2023 earnings call, Joseph Wolk stated that the company's growth expectations "consider[] the potential composition of matter patent expiry of STELARA, which we currently assume will occur in late 2023 in the United States."[104] Wolk later stated that J&J's "base assumption [is that]. . .in the U.S., STELARA will lose exclusivity in the late third quarter, early fourth quarter of [2023]."[105] Indeed, J&J was "expecting a steeper erosion curve than what was experienced [with REMICADE biosimilars] because [ustekinumab] is a self-administered subcutaneous."[106] Wolk underscored that "[t]here will be multiple competitors on the market at some point, and they may have the affordability of interchangeability."[107] During that earnings call, the expectations regarding J&J's growth in 2023 were based on other drugs in its portfolio. J&J was prepared to lose exclusivity on the sale of ustekinumab.

162. On April 18, 2023, an article in Morningstar forecasted that Stelara biosimilars would "launch in the fourth quarter" of 2023.[108] The analysis explained that Stelara's "self-administration and likely interchangeability with multiple products" would lead Stelara to lose

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challenge, BIOPHARMA DIVE (Mar. 29, 2023), https://www.biopharmadive.com/news/johnson-johnson-stelara-patents-amgen-biosimilar-momenta/646277/.

[104] *Edited Transcript Q1 2023 Johnson & Johnson Earnings Call*, REFINITIV STREETEVENTS at 7 (Apr. 18, 2023), https://johnsonandjohnson.gcs-web.com/static-files/2f3a8bda-b6ac-4e76-80a1-a644f18493ea.

[105] *Id.* at 10.

[106] *Id.*

[107] *Id.*

[108] Damien Conover, *Johnson & Johnson Earnings: Steady Results, but Longer-Term Drug Pressures Mounting*, MORNINGSTAR (Apr. 18, 2023), https://www.morningstar.com/stocks/johnson-johnson-earnings-steady-results-longer-term-drug-pressures-mounting.

market share more rapidly "than the almost midteens annual losses" faced by Remicade after biosimilar approval.[109]

163. On the same day, Reuters published a forecast of Stelara's sales drawing on data from J&J's press releases and Refinitiv data. Reuters explained that Stelara sales were expected to "steep[ly] decline" after loss of U.S. exclusivity in late 2023, falling to an expected $7.44 billion in 2024 and $5.35 billion in 2025 from a forecast of $9.9 billion in 2023.[110]

164. In its Form 10-K for fiscal year 2022, J&J acknowledged that biosimilar applicants were using the BPCIA regulatory framework and the IPR process to challenge patents on biologic reference patents. It noted that in the event the company was unsuccessful "in defending its patents against such challenges, or upon the 'at-risk' launch by the generic or biosimilar firm of its product, [J&J] can lose a major portion of its revenues for the referenced product in a very short period of time."[111]

165. In anticipation of the expiration of the '734 patent, in and around 2022, several would-be biosimilar competitors launched their Phase 3 clinical trials. Indeed, as of August 2023, at least eight pharmaceutical companies had launched such trials (in the U.S. and/or abroad), at least three had filed ABLAs with the FDA, and one had notified J&J that it was prepared to launch in 2023. Table 1 below summarizes these biosimilar filings.

TABLE 1

Applicant	Biosimilar	Phase 3 clinical trials begin	FDA submission

[109] *Id.*

[110] Bhanvi Satija and Manas Mishra, *J&J issues cautious 2023 forecast, shares fall*, REUTERS (Apr. 18, 2023), https://www.reuters.com/business/healthcare-pharmaceuticals/jj-raises-annual-profit-forecast-cancer-drug-strength-2023-04-18/.

[111] Johnson & Johnson, Annual Report (Form 10-K) at 11 (Feb. 17, 2022).

Amgen	ABP 654	Nov. 11, 2020	On or before November 3, 2022
Alvotech and Teva	AVT04	June 3, 2021	January 6, 2023
Formycon/Fresenius Kabi	FYB202	Nov. 9, 2020	Expected Q3 2023
Samsung Bioepis	SB17	July 6, 2021	
Celltrion	CT-P43	January 11, 2021	June 30, 2023
Hikma/Bio-Thera	BAT2206	July 6, 2021	
Intas/Accord, Meiji Seika Pharma/Dong-A	DMB-3115	April 28, 2021	Expected Q3 2023
Biocon	BMAB-1200	June 28, 2022	

1. J&J used its fraudulently obtained ’307 patent and unlawfully acquired Momenta biosimilar manufacturing patents to delay competition from Amgen, a biosimilar competitor.

166. Cognizant that it was about to lose exclusivity over the market for ustekinumab in the United States, in late 2022, J&J used its fraudulently obtained ’307 patent and unlawfully acquired Momenta biosimilar manufacturing patents to forestall biosimilar competition.

167. The first biosimilar competitor J&J blocked was Amgen. On November 11, 2020, Amgen began a Phase 3 clinical trial studying the safety and efficacy of its Stelara biosimilar, ABP 654, to treat plaque psoriasis as compared to ustekinumab. The study was completed on June 3, 2022.

168. On March 24, 2021, Amgen began its Phase 3 interchangeability clinical trial, which studied the similarity and efficacy of “multiple switches between ustekinumab and APB

654 compared with continued use of ustekinumab" in patients with plaque psoriasis.[112] The study was completed on February 28, 2023.

169. On April 18, 2022, Amgen announced positive preliminary results from its initial Phase 3 clinical trial studying the efficacy of ABP 654—its biosimilar version of ustekinumab—as compared to Stelara to treat plaque psoriasis. Amgen reported that the study demonstrated that there was "no clinically meaningful differences between ABP 654 and STELARA."[113]

170. On November 3, 2022, in its third quarter financial report, Amgen announced that it had submitted its Phase 3 clinical trial data regarding the safety and efficacy of ABP 654 as compared to Stelara to the FDA "to support U.S. approval."[114]

171. On November 7, 2022, pursuant to 42 U.S.C. § 262(l)(8)(A), counsel for Amgen informed J&J that it intended to begin marketing ABP 654 not earlier than 180 days from the date of the notice, and that it intended to be ready to start marketing ABP 654 upon receiving FDA approval and for all FDA-approved indications for Stelara.

172. On November 11, 2022, Michael Morin, J&J's legal representative "on Stelara matters,"[115] requested information regarding Amgen's ABLA from Amgen's counsel. Mr. Morin also asked whether Amgen (i) intended to participate in the "patent dance," (ii) would voluntarily

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[112] *A Study to Investigate Interchangeability of ABP 654 for the Treatment of Participants with Moderate to Sever Plaque Psoriasis*, CLINICALTRIALS.GOV, https://clinicaltrials.gov/study/NCT04761627 (Sept. 15, 2023).

[113] *Amgen Announces Positive Top-Line Results from Phase 3 Study of ABP 654, Biosimilar Candidate to Stelara® (Ustekinumab)*, AMGEN (Apr. 18, 2022), https://www.amgen.com/newsroom/press-releases/2022/04/amgen-announces-positive-topline-results-from-phase-3-study-of-abp-654-biosimilar-candidate-to-stelara-ustekinumab.

[114] *Amgen Reports Third Quarter 2022 Financial Results*, AMGEN (Nov. 3, 2022), https://www.amgen.com/newsroom/press-releases/2022/11/amgen-reports-third-quarter-2022-financial-results.

[115] Compl., Ex. K at 2, *Janssen Biotech, Inc. v. Amgen Inc.*, C.A. No. 22-1549 (D. Del. Nov. 29, 2022), ECF No. 1-2.

agree to stay off the market until the '734 composition patent expired on September 25, 2023, and (iii) would agree "to skinny label removing UC from the label until there is a judicial decision" on the '307 method-of-use patent.[116]

173. According to J&J, Amgen refused to provide any of the requested information.

174. On November 29, 2022, J&J sued Amgen for infringement of its '734 composition patent and its '307 method-of-use patent.

175. According to J&J, on December 5, 2022, Amgen provided J&J with a copy of Amgen's ABLA; and on January 4, 2023, Amgen authorized J&J to provide Amgen's confidential ABLA to three experts for evaluation.

176. On January 23, 2023, the parties filed a sealed stipulation and proposed order regarding an agreement as to the '734 composition patent. The contents of this stipulation are not public. The court entered the proposed order on the same date.

177. On February 2, 2023, after its experts ostensibly reviewed Amgen's ABLA, J&J served Amgen with its Section 3A list, which listed the J&J-owned patents that could give rise to patent infringement claims. The list included the '734 composition patent, the '307 method-of-use patent, and the four Momenta biosimilar manufacturing patents that J&J acquired in 2020.

178. About three weeks later, on February 21, 2023, J&J amended its complaint against Amgen, reasserting that Amgen infringed the '734 and '307 patents and adding claims that Amgen's ABP 654 infringed upon the four Momenta biosimilar manufacturing patents. As to the four Momenta patents J&J had acquired, J&J alleged that Amgen "used and is using these patented methodologies [covered by the Momenta biosimilar manufacturing patents] to prepare to commercialize ABP 654, a biosimilar copy of STELARA®—designed to have the same amino

[116] *Id*. at 1.

acid sequence as the active ingredient (ustekinumab) and highly similar physical and biological properties, so it can be sold as a substitute for STELARA®."[117]

179. On March 6, 2023, J&J moved for a preliminary injunction, seeking to enjoin Amgen from launching ABP654 until the court resolved the underlying patent litigation.[118] To obtain this injunctive relief, J&J was required to demonstrate that it was likely to succeed on the merits of its claim that Amgen's biosimilar infringed J&J's patents. Rather than relying on its own '734 composition patent or '307 method-of-use patent—both of which it asserted in its original and amended complaints—J&J relied solely on two of the four Momenta biosimilar manufacturing patents—the '858 and '168 patents.

180. By electing not to rely on the '307 patent, J&J demonstrated its awareness that the patent did not provide a legitimate basis upon which to sue Amgen for patent infringement or seek injunctive relief.

181. On May 22, 2023—the deadline for Amgen to respond to J&J's motion for preliminary injunction—J&J submitted a stipulation of dismissal with prejudice. The following day, the court ordered the case to be dismissed with prejudice.

182. The same day as the dismissal, Amgen announced that the company had reached an agreement with J&J to delay entry of its ABP654 onto the U.S. market until no later than January 1, 2025. This agreement—extracted from Amgen based on J&J's assertion of the fraudulently acquired '307 patent and the unlawfully acquired Momenta patents—provided J&J

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[117] First Am. Compl., ¶¶ 5-7, *Janssen Biotech, Inc. v. Amgen Inc.*, C.A. No. 22-1549 (D. Del. Mar. 7, 2023), ECF No. 46.

[118] J&J Mot. for Prelim. Inj., *Janssen Biotech, Inc. v. Amgen Inc.*, C.A. No. 22-1549 (D. Del. Mar. 6, 2023), ECF Nos. 35-44, 48-56 (redacted versions). J&J initially filed its motion for preliminary injunction on March 1, 2023, but its opening brief in support of its motion was over the page limit and therefore the court denied the motion, granting leave to re-file in compliance with the court's rules. *Id.* at ECF Nos. 24-34, 59-67 (redacted versions).

with *over fifteen more months* of exclusivity over its previous expectation of September 2023 biosimilar entry. Given that J&J had earned nearly $6.4 billion on Stelara in 2022 alone, this fifteen-month period of exclusivity is likely worth at least $8 billion in revenue.

183. On October 31, 2023, the FDA approved Amgen's biosimilar, now known as Wezlana, "as a biosimilar to and interchangeable with Stelara (ustekinumab)" to treat the same indications as Stelara.[119] Based on its settlement agreement with J&J, Amgen will not launch until January 1, 2025.

2. J&J used its fraudulently obtained '307 patent and unlawfully acquired Momenta patents to extract further delays from other would-be biosimilar competitors.

a. The J&J—Samsung Bioepis Settlement.

184. In addition to Amgen, Samsung Bioepis (Samsung) developed an ustekinumab biosimilar called SB17.

185. On June 21, 2023, Samsung filed a petition for *inter partes* review with the Patent Trial and Appeals Board (PTAB) challenging the validity of J&J '307 patent.

186. In its petition, Samsung explained that the PTO should not have issued the '307 method-of-use patent because using ustekinumab to treat ulcerative colitis was anticipated and obvious. Samsung's position mirrors that elaborated earlier in this complaint, i.e., that J&J publicly disclosed use of ustekinumab to treat ulcerative colitis in its 2015 Phase 3 clinical trial protocol.

[119] *FDA Approves Interchangeable Biosimilar for Multiple Inflammatory Diseases*, FOOD & DRUG ADMIN. (Oct. 31, 2023), https://www.fda.gov/news-events/press-announcements/fda-approves-interchangeable-biosimilar-multiple-inflammatory-diseases?utm_medium=email&utm_source=govdelivery.

187. Rather than respond to Samsung's petition, J&J settled with Samsung. On August 3, a little over a month after Samsung filed its IPR, J&J and Samsung filed a joint motion to terminate proceeding, stating that the parties had executed a confidential settlement agreement that resolved all disputes related to the '307 patent. On the same date, the parties also jointly requested that the settlement agreement be treated as confidential.

188. On August 9, 2023, the PTAB granted both requests. In its decision, the PTAB noted that the parties had represented that the filed settlement agreement was a true and complete copy and that it resolved all pending matters between the parties involving the patent at issue.

189. On November 30, 2023, Samsung announced that it had reached a settlement and license agreement with J&J relating to Samsung's launch of its ustekinumab biosimilar, SB17. The parties agreed to an entry date of February 22, 2025.

b. The J&J—Alvotech and Teva Settlement.

190. In August 2020, Alvotech Holdings S.A. (Alvotech) and Teva Pharmaceuticals, Inc. (Teva) entered an exclusive strategic partnership to commercialize certain biosimilars in the United States. One such biosimilar was for ustekinumab, known as AVT04.

191. In May 2022, Alvotech and Teva announced positive results from two clinical studies demonstrating bioequivalence between AVT04 and Stelara. On January 6, 2023, Alvotech and Teva announced that the FDA accepted its ABLA for AVT04 for review and that they anticipated FDA review would be complete in the second half of 2023. On February 9, 2023, Alvotech announced that the European Medicines Agency accepted its Marketing Authorization Application for AVT04.

192. On dates currently unknown but preceding June 12, 2023, officials from J&J and Alvotech/Teva discussed J&J's potential assertion of J&J's intellectual property rights (including the '307 patent and the unlawfully acquired Momenta biosimilar manufacturing patents) against

Alvotech/Teva due to Alvotech/Teva's plans to launch AVT04. At the time, both parties (i) were aware of J&J's efforts in recent months to enforce the '307 patent and the unlawfully acquired Momenta biosimilar manufacturing patents against Amgen, and (ii) Amgen's subsequent agreement to delay entry until January 2025.

193. On June 12, 2023, J&J and Alvotech/Teva announced that they had executed a settlement and licensing agreement with J&J under which Alvotech/Teva agreed to wait to launch AVT04 until no later than February 21, 2025. The agreed launch date for AVT04 is almost 17 months after the '734 patent expired on September 25, 2023.

194. J&J used the '307 patent and the unlawfully acquired Momenta biosimilar manufacturing patents to extract the delayed biosimilar entry date.

c. The J&J—Fresenius Kabi and Formycon AG Settlement.

195. In February 2023, Fresenius Kabi and Formycon AG entered into a global licensing agreement through which Fresenius Kabi would commercialize Formycon's ustekinumab biosimilar, FYB202.

196. On April 25, 2023, Formycon announced that it had successfully completed Phase I and Phase III clinical studies comparing its ustekinumab biosimilar, FYB202, to Stelara in patients with moderate to severe plaque psoriasis. The studies determined that FBY202 was bioequivalent to Stelara in the United Stated (and in the European Union) for "all primary endpoint parameters."[120] Formycon AG and Fresenius Kabi planned to submit for U.S. regulatory approval in the third quarter of 2023, and once approved, Fresenius Kabi would

[120] *Formycon Announces Successful Results of Phase I Clinical Trial for Ustekinumab Biosimilar Candidate FYB202 and Concludes Clinical Development*, FORMYCON (Apr. 25, 2023), https://www.formycon.com/en/blog/press-release/formycon-announces-successful-results-of-phase-i-clinical-trial-for-ustekinumab-biosimilar-candidate-fyb202-and-concludes-clinical-development/.

commercialize FYB202. Formycon CEO, Dr. Stefan Glombitza, stated that the company was "confident that we will provide the authorities with a convincing data package this fall. With FYB202, we can contribute significantly to the treatment options in the growing market segment of inflammatory diseases."[121]

197. On dates currently unknown but preceding August 7, 2023, officials from J&J and Fresenius Kabi/Formycon discussed J&J's potential assertion of J&J's intellectual property rights (including the '307 patent and the unlawfully acquired Momenta biosimilar manufacturing patents) against Kabi/Formycon due to the plans of Kabi/Formycon to launch FYB202. At the time, both parties (i) were aware of J&J's efforts in recent months to enforce the '307 patent and the unlawfully acquired Momenta biosimilar manufacturing patents against Amgen, and (ii) Amgen's subsequent agreement to delay entry until January 2025.

198. On August 7, 2023, Fresenius Kabi and Formycon announced that they had reached a settlement agreement with J&J regarding FYB202. As a result, and subject to FDA approval, Fresenius Kabi agreed to delay launch FYB202 until no later than April 15, 2025. In August 2023, Fresenius announced that it was still on track to submit the ABLA for FYB202 in 2023.

199. The permitted launch date for FYB202 is almost 19 months after the '734 patent expired on September 25, 2023.

200. J&J had used the '307 patent and the unlawfully acquired Momenta biosimilar manufacturing patents to extract the delayed biosimilar entry date.

[121] *Id.*

d. The J&J—Celltrion Settlement.

201. On July 3, 2023, Celltrion announced that it had submitted an ABLA to the FDA for approval of its ustekinumab biosimilar, CT-P43.

202. On dates currently unknown but preceding late August 2023, officials from J&J and Celltrion discussed J&J's potential assertion of J&J's intellectual property rights (including the '307 patent and the unlawfully acquired Momenta biosimilar manufacturing patents) against Celltrion due to the plans of Celltrion to launch CT-P43. At the time, both parties (i) were aware of J&J's efforts in recent months to enforce the '307 patent and the unlawfully acquired Momenta biosimilar manufacturing patents against Amgen, and (ii) Amgen's subsequent agreement to delay entry until January 2025.

203. In late August 2023, Celltrion and J&J executed a settlement agreement under which Celltrion agreed to delay the launch CT-P43 to March 7, 2025, subject to regulatory approval. The permitted launch date for CT-P43 is over 17 months after the '734 patent expired on September 25, 2023.

204. J&J had used the '307 patent and the unlawfully acquired Momenta biosimilar manufacturing patents to extract the delayed biosimilar entry date.

205. All in all, and to date, J&J reached five settlements with would-be biosimilar competitors for agreed-to entry dates ranging from January 1 to April 15, 2025. Table 2 summarizes these settlements and delayed entry dates.

TABLE 2

Applicant	Biosimilar	Settlement date	Agreed-to launch date
Amgen	ABP 654	May 22, 2023	January 1, 2025
Alvotech and Teva	AVT04	June 12, 2023	February 21, 2025

Formycon/Fresenius Kabi	FYB202	August 7, 2023	April 15, 2025
Samsung Bioepis	SB17	Likely on or around August 3, 2023	February 22, 2025
Celltrion	CT-P43	August 25, 2023	March 7, 2025

G. J&J's use of its fraudulently obtained '307 patent and unlawfully acquired Momenta biosimilar manufacturing patents to delay the entry of biosimilar ustekinumab have cost, and continue to cost, purchasers billions of dollars.

206. Since its approval in 2009, Stelara has played an increasingly important role in bolstering J&J's profits. Stelara has been J&J's highest earning product since 2019. That year, the biologic accounted for almost 8% of the company's total revenue. In 2020, J&J sold over $5.2 billion worth of Stelara to U.S. customers. In 2021, over $5.9 billion. In 2022, J&J sold over $6.3 billion in the United States alone and over $9.7 billion globally, accounting for more than 10% of J&J's total revenue. While J&J enjoys exclusivity over the ustekinumab market in the United States, it commands over $17 million per day from the U.S. market alone.

207. As detailed above, J&J's expectation, as of spring 2023, was that it would lose exclusivity over ustekinumab by later that year. In its 10-K filing, for the fiscal year ending January 1, 2023, J&J explained that its "latest expiring United States patent for STELARA (ustekinumab) will expire in September 2023."[122] J&J also reported that the patent's expiration or loss of market exclusivity "*will* result in a reduction in sales."[123]

208. In its 10-Q filing for the first quarter of 2023, filed in April 2023, J&J noted that several pharmaceutical companies had submitted ABLAs for ustekinumab biosimilars and

[122] Johnson & Johnson, Annual Report (Form 10-K) at 25 (Feb. 16, 2023).

[123] *Id*. (emphasis added).

warned that "[i]n the event the Company is not successful in defending its patent claims in related lawsuits," the launch of biosimilars could "potentially result[] in substantial market share and revenue losses."[124]

209. In its 10-Q filing for the second quarter of 2023, filed in July 2023, J&J announced its May 2023 settlement with Amgen and noted that "[a]s a result of the settlement and other agreements with separate third parties, [J&J] does not anticipate the launch of a biosimilar version of STELARA until January 1, 2025."[125]

210. On a July 2023 earnings call, J&J's CEO and Chairman, Joaquin Duato, acknowledged the company's settlements with Amgen and Alvotech, and expressed J&J's expectation that Amgen would launch on January 1, 2025, and Alvotech on February 21, 2025.

211. On the same call, responding to an investor question about possible biosimilar entry before Amgen and the impact of loss of exclusivity on J&J's financial performance, J&J's executive vice president and CFO, Joeseph Wolk, reiterated J&J's assumption that, based on the settlement agreements, they did not expect any biosimilar launch before January 1, 2025. J&J's worldwide vice president of litigation, Erik Haas, added, "From a litigation perspective, I could say that no other biosimilar is better positioned in our view than Amgen or Alvotech would be. So we would not anticipate any other biosimilar having the opportunity or ability to enter the market before those [two]."[126]

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[124] Johnson & Johnson, Quarterly Report (Form 10-Q) at 41 (Apr. 28, 2023).

[125] Johnson & Johnson, Quarterly Report (Form 10-Q) at 49 (July 31, 2023).

[126] *Edited Transcript Q2 2023 Johnson & Johnson Earnings Call*, REFINITIV STREETEVENTS at 12 (July 20, 2023), https://johnsonandjohnson.gcs-web.com/static-files/3d99678b-1313-4418-a75f-26582a10dfc2.

212. J&J used its fraudulently obtained '307 patent and unlawfully acquired Momenta biosimilar manufacturing patents to unlawfully delay the entry of ustekinumab biosimilars and, therefore, the entry of any competition into the ustekinumab market in the United States.

213. If J&J is permitted to improperly maintain its monopoly over the ustekinumab market in the United States until January 1, 2025—an additional 15 months or approximately 463 days beyond the expiration of its '734 composition patent on September 25, 2023—J&J will make over $8 billion.

214. As a result, purchasers of ustekinumab in the United States, including the plaintiffs and class members, have paid, and will continue to pay, supra-competitive prices.

VI. CLASS ALLEGATIONS

215. The plaintiffs, on behalf of themselves and all class members, seek damages, measures as overcharges, trebled, against J&J based on allegations of anticompetitive conduct in the market for ustekinumab in the United States.

216. The plaintiffs bring this action on behalf of themselves and, pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2) and 23(b)(3), as representatives of the class defined as:

> All end payors (including any assignees of such end payors) in the United States and its territories who purchased and/or paid all or part of the purchase price of Stelara from September 26, 2023 until the anticompetitive effects of J&J's conduct cease (class period).

217. Excluded from the class are J&J and any of its officers, directors, management, employees, subsidiaries, and affiliates.

218. Also excluded from the class are: (1) the government of the United States and all agencies thereof and (2) all state or local governments and all agencies thereof.

219. Class members are so numerous and geographically dispersed that joinder of all members is impracticable. Moreover, given the costs of complex antitrust litigation, it would be uneconomic for many plaintiffs to bring individual claims and join them together.

220. The plaintiffs' claims are typical of those of the class members. The same wrongful conduct of J&J damaged the plaintiffs and all class members—i.e., they paid and will pay artificially inflated prices for ustekinumab and were deprived of earlier and more robust competition from cheaper biosimilar versions of ustekinumab because of J&J's wrongful conduct.

221. The plaintiffs will fairly and adequately protect and represent the class's interests. The plaintiffs' interests are coincident with, and not antagonistic to, those of the other class members.

222. Counsel who represent the plaintiffs are experienced in the prosecution of class action antitrust litigation and have robust experience with class action antitrust litigation involving pharmaceutical products.

223. Questions of law and fact common to the class members predominate over questions that may affect only individual class members because J&J has acted on grounds generally applicable to the entire class. This conduct renders appropriate overcharge damages with respect to the class as a whole. Such generally applicable conduct is inherent to J&J's wrongful actions.

224. Questions of law and fact common to the proposed class include:

a. whether J&J willfully and improperly maintained monopoly power over ustekinumab;

b. whether J&J obtained the '307 method-of-use patent by fraud;

c. whether J&J intentionally acquired the Momenta biosimilar manufacturing patents to unlawfully delay competition and to unlawfully maintain its monopoly over ustekinumab;

d. whether J&J unlawfully enforced the fraudulently obtained ’307 patent against would-be biosimilar competitor, Amgen;

e. whether J&J unlawfully used the ’307 patent and Momenta biosimilar manufacturing patents to delay ustekinumab biosimilar competition;

f. whether J&J unlawfully excluded competitors and potential competitors from the market for ustekinumab;

g. whether J&J unlawfully delayed or prevented manufacturers of ustekinumab biosimilars from coming to market in the United States;

h. whether J&J improperly maintained monopoly power by delaying biosimilar entry;

i. whether the law requires a definition of a relevant market when direct proof of monopoly power is available, and if so, the definition of the relevant market;

j. whether J&J’s activities as alleged herein have substantially affected interstate commerce;

k. whether, and if so to what extent, J&J’s conduct caused antitrust injury (i.e., overcharges) to the plaintiffs and the class members; and

l. the quantum of aggregate overcharge damages to the plaintiffs and class members.

225. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. 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, or expense that numerous individual actions would require. The benefits of proceeding through the class mechanism—including providing injured persons or entities with a method for obtaining redress on claims that they could not practicably pursue on an individual basis—substantially outweigh potential difficulties in management of this class action.

226. J&J's anticompetitive conduct has imposed and will continue to impose (unless the plaintiffs obtain equitable relief) a common antitrust injury on the plaintiffs and all class members. J&J's anticompetitive conduct and its relationships with the class members have been substantially uniform. J&J has acted and refused to act on grounds that apply to the class generally, and injunctive and other equitable relief is appropriate respecting the class as a whole.

227. The plaintiffs know of no special difficulty in litigating this action that would preclude its maintenance as a class action.

VII. MARKET POWER AND MARKET DEFINITION

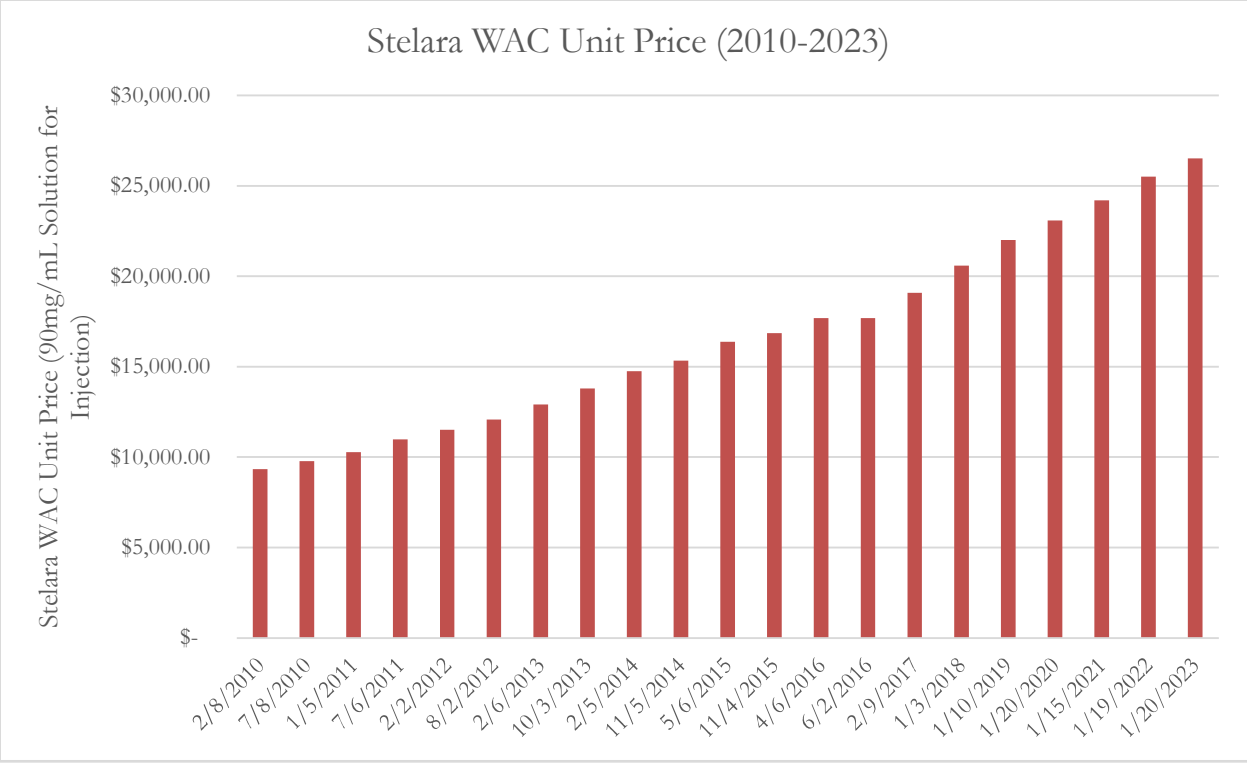
228. The relevant geographic market is the United States and its territories.

229. The relevant product market is ustekinumab.

230. At all times relevant to this civil action, J&J had monopoly power in the market for ustekinumab in the United States.

A. Direct evidence demonstrates J&J's market power.

231. *Supra-competitive prices*. At all times relevant to this civil action, J&J charged supra-competitive prices for Stelara—i.e., prices that were and are markedly higher than it could have been charged had there been biosimilar competition for ustekinumab in the United States. J&J also steadily *increased* the price of Stelara over the years, as shown in the below graphic:



232. From 2009—the entry of Stelara into the U.S. marketplace—to the present, although other biologic products were available in the U.S. to treat ulcerative colitis, Crohn's disease, plaque psoriasis, and psoriatic arthritis, J&J *never* lowered Stelara prices or lost sales volume in response to the pricing of other drugs. Stelara is one of the top ten best-selling drugs in the world, indicating that its sales are not constrained by any other products.

233. *Supra-competitive profits margins.* At all times relevant to this civil action, J&J enjoyed extraordinarily high profit margins from the sale of Stelara.

234. *Combination patent protection and other barriers*. From 2009 (product launch) through September 25, 2023 (expiration of the '734 composition patent), J&J enjoyed legitimate patent protection for ustekinumab. As a result, J&J had the power to exclude competition from ustekinumab biosimilars. In addition, the FDA approval processes for the marketing of biosimilars in the U.S. presented barriers to biosimilar entry.

235. *Lack of interchangeability*. Ustekinumab is not readily interchangeable with other treatments for ulcerative colitis, Crohn's disease, plaque psoriasis, and psoriatic arthritis. Ustekinumab is a unique treatment for these diseases, ostensibly offering advantages over other available treatment for these conditions.

236. First, ustekinumab is the only biologic that functions as an IL-12/23 antagonist, enabling the drug to target a specific inflammatory pathway that other biologics do not. As an IL-12/23 antagonist, ustekinumab occupies a distinctive niche within the treatment options available for ulcerative colitis, Crohn's disease, plaque psoriasis, and psoriatic arthritis. While there are several biologic medications currently indicated to treat ulcerative colitis, Crohn's disease, plaque psoriasis, and psoriatic arthritis (including Humira and Remicade), Stelara is the *only* biologic that specifically targets the IL-12 and IL-23 pathways. The other drugs target different proteins (for example, Remicade and Humira both target the TNF protein).

237. Second, ustekinumab has a significantly more convenient treatment regime. Unlike other biologics in the general therapeutic area which may require weekly or biweekly injections, ustekinumab injections only need to be administered *once every eight to twelve weeks* after the induction dose, depending on the condition it is used to treat. For example, in the first year treating Crohn's or ulcerative colitis, a patient will receive only seven doses of ustekinumab, compared to eight or twenty-seven of other treatments. For psoriatic arthritis and plaque psoriasis, there are only six doses in the first year of treatment with ustekinumab, compared to competitors that require between twelve and sixty-four doses. A treatment schedule that requires injections once every two or three *months* as opposed to every one to two *weeks* is incredibly valuable to patients with chronic illnesses, the majority of which will inject these potent biologics for their entire lives.

238. Ustekinumab's patient adherence rates reflect this reality. One study published in the Journal of Dermatological Treatment found that ustekinumab therapy to treat moderate-to-severe psoriasis has a persistency rate of about 81.4%.[127] The authors identify the convenience of the dosing schedule as a likely cause of the high patient retention rate. Data from the Psoriasis Longitudinal Assessment and Registry (PSOLAR) further underscore patient preference for ustekinumab. Out of the registry's sample of about 3,500 patients who treated their psoriasis with biologic agents, patients who took ustekinumab adhered to their medication regiments longer than patients of any other biologic.[128]

239. J&J has publicly acknowledged—indeed, emphasized—that Stelara is not reasonably interchangeable with other treatments for autoimmune diseases. J&J has stated that "STELARA® represents a breakthrough development in the treatment of such diseases" and that Stelara is a "first-in-kind biologic [that] works by targeting certain proteins—interleukin-12 (IL-12) and interleukin-23 (IL-23)—that patients with autoimmune diseases produce in excess."[129] J&J acknowledges that the mechanism of action is unique in that "STELARA® attaches to those proteins and neutralizes them, thereby reducing the chronic inflammation that is a hallmark of autoimmune diseases."[130] As a result, according to J&J, "STELARA®[is a] novel treatment approach [that] has been particularly useful for patients who fail treatment with other drugs, such

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[127] Zhun Cao et al., *Ustekinumab dosing, persistence, and discontinuation patterns in patients with moderate-to-severe psoriasis,* 26 J. DERMATOLOGICAL TREATMENT 113, 113 (2014).

[128] Murat Borlu, *Ustekinumab,* 56 TURKDERM-TURKISH ARCHIVES DERMATOLOGY & VENEROLOGY 48, 49 (2022), https://jag.journalagent.com/turkderm/pdfs/TURKDERM_56_50_48_51.pdf.

[129] Mem. in Supp. of J&J Mot. for Prelim. Inj. at 8-9, *Janssen Biotech, Inc. v. Amgen Inc.*, C.A. No. 22-1549 (D. Del. Mar. 15, 2023), ECF No. 59.

[130] *Id*. at 9.

as REMICADE®, HUMIRA®, and SIMPONI®, each of which presents safety risks associated with immunosuppression."[131]

240. In its public marketing for Stelara, J&J emphasized that the drug is not reasonably interchangeable with other biologics that treat the diseases for which Stelara is indicated.

241. *Biosimilar competition*. Recent reports regarding biosimilars confirm that biosimilar competition has a significant effect in lowering price among equally effective therapies.

242. Recent biosimilars have achieved high market volume share, reaching more than 60% of a given biologic's volume within the first three years. The introduction of biosimilars frequently leads to higher utilization of the treatment as lower costs improve patient access.

243. Introduction of lower cost biosimilars precipitates reductions in overall drug costs per unit at invoice prices over time. Indeed, such competition typically lowers the per unit cost of both the brand and biosimilar drug. Costs are down between 18% and 50% per unit for drugs with biosimilars.

244. One of J&J's would-be competitors, Amgen, commented in its 2022 Biosimilar Trends report that biosimilar entrants, typically, are successful at taking market share from the reference biologic drug. Amgen's report states: "Biosimilars have gained significant share in the majority of therapeutic areas where they have been introduced."[132] Amgen further remarked "[f]or therapeutic areas with biosimilars launched in the last 3 years, the average share was

[131] *Id*.

[132] AMGEN, 2022 BIOSIMILAR TRENDS REPORT 14 (2022), https://www.amgenbiosimilars.com/commitment/2022-Biosimilar-Trends-Report ("Amgen 2022 Biosimilar Report").

75%," and "[f]or therapeutic areas with biosimilars launched prior to 2019, the average share after 3 years was 39%."[133] J&J has endorsed the accuracy of this report.

245. A 2022 study published in the Journal of the American Medical Association (JAMA) found that "[b]iosimilars in the US that entered the market more recently were estimated to experience a faster uptake (as measured by the market share 1 year after launch). . . ."[134] J&J has endorsed the accuracy of this report.

246. *J&J admissions*. J&J has admitted that biosimilar competition for Stelara would cause it "immediate, substantial, and irreparable harm" because biosimilar competition would lead "PBMs [to] demand renegotiation of the complex web of contracts governing STELARA® on their formularies."[135] According to J&J, the "inevitable result" of such renegotiations would be "long-lasting loss of market share across all indications of STELARA®" and "irreversible price erosion . . . ."[136]

247. This market share loss was not only a general observation by J&J, but also the specific result that J&J forecasted would result from an Amgen biosimilar launch. J&J has stated that "[l]ike all biosimilars attempting to gain market share, [Amgen's biosimilar ustekinumab] will do so by compromising [J&J's] preferred position on the pharmacy and insurance formularies generated by PBMs."[137] As J&J explained, such an action "could trigger PBMs to

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[133] *Id.*

[134] David L. Carl et. al., *Comparison of Uptake and Prices of Biosimilars in the US, Germany, and Switzerland*, 5 JAMA NETWORK OPEN 1, 6 (2022).

[135] Opening Br. in Supp. of J&J Mot. for Prelim. Inj. at 12, *Janssen Biotech, Inc. v. Amgen, Inc.*, C.A. No. 22-1549 (D. Del. Mar. 13, 2023), ECF No. 48.

[136] *Id.* at 16.

[137] Mem. in Supp. of J&J Mot. for Prelim. Inj. at 24, *Janssen Biotech, Inc. v. Amgen, Inc.*, C.A. No. 1:22-cv-01549 (D. Del. Mar. 15, 2023), ECF No. 59.

drop STELARA® from their formularies entirely, replacing it with [Amgen's biosimilar]."[138] J&J has called this effect "pervasive" and has observed that "in a recent report . . . each of the three largest PBMs has previously discontinued coverage of an original reference product entirely in favor of a biosimilar version."[139]

248. The effects of biosimilar competition in the U.S. market for ustekinumab would also have substantial downward pressure on the price of ustekinumab. As J&J has admitted, "Amgen will almost certainly sell [its biosimilar] at a lower price than STELARA®" and "Amgen's own analysis concludes that 'biosimilars typically launch at a discount to reference product [wholesale acquisition cost] and [average sales price].'"[140] Thus, according to J&J, "[p]rice would be the key factor Amgen could use to incentivize PBMs to add [Amgen's biosimilar] to their formularies because. . . [Amgen's biosimilar] does not offer any differentiating characteristics in terms of performance or safety profile."[141]

249. J&J has observed that its would-be competitor, Amgen, previously launched four biosimilars (of other biologics, not Stelara) onto the U.S. market; in each case, Amgen's biosimilar product was priced "at a significant discount—ranging from 15% to 57%—off the wholesale acquisition cost of the reference biologic product."[142] As Amgen has said, the "average sales price . . . is declining, due to competition, for both reference products and

[138] *Id.*

[139] *Id.* (citing Amgen 2022 Biosimilar Report).

[140] *Id.* at 27 (quoting Amgen 2022 Biosimilar Report) (alterations in original).

[141] *Id.*

[142] *Id.*

biosimilars. . . . The prices of most reference products have decreased at a negative [compound annual growth rate] of -4% to -21%."[143] And again, J&J has endorsed the accuracy of that report.

250. J&J has admitted the entry of "Amgen's cut-price biosimilar" would put price pressure on J&J, stating that "PBMs would immediately pressure [J&J] to provide significant price concessions, reducing STELARA®'s net purchase price—the price net of rebates and discounts—to retain its position on formularies."[144] J&J has added that "[b]eyond that immediate price erosion, PBM's continued demands for price concessions would also contribute to an accelerated trajectory of price erosion as more biosimilars eventually come on the market."[145] As J&J has admitted, J&J losses from entry of a biosimilar to Stelara "would be massive, extending beyond mere lost sales, [and] would be considerable even over the short haul."[146]

251. In sum, direct evidence shows that J&J has monopoly power over the sale of ustekinumab in the United States and that entry of a biosimilar ustekinumab would cause significant downward pressure on price, resulting in more affordable and accessible ustekinumab products.

B. Indirect evidence demonstrates J&J's market power.

252. To the extent the plaintiffs are legally required to prove monopoly power through circumstantial evidence by first defining a relevant product market, the relevant product market is the sale of ustekinumab in the United States and has, thus far, consisted solely of Stelara.

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[143] Amgen 2022 Biosimilar Report at 6.

[144] Mem. in Supp. of J&J Mot. for Prelim. Inj. at 27, *Janssen Biotech, Inc. v. Amgen, Inc.*, C.A. No. 1:22-cv-01549 (D. Del. Mar. 15, 2023), ECF No. 59 (citing Amgen 2022 Biosimilar Report).

[145] *Id.*

[146] *Id.* at 26.

Biosimilar versions of ustekinumab will also be in the relevant market once they are available. At all relevant times, J&J's market share in the market was and remains 100%.

253. J&J, at all relevant times, enjoyed high barriers to entry with respect to competition in the product market of ustekinumab due, in large part, to legally and illegally created patent protections.

254. Stelara does not exhibit significant, positive cross-elasticity of demand with any other medication. The existence of non-ustekinumab products that may be used to treat similar indications as ustekinumab did not constrain J&J's ability to raise or maintain Stelara prices without losing substantial sales. As a result, those other drug products do not occupy the same relevant antitrust market as Stelara.

255. J&J needed to control only ustekinumab, and no other products, to maintain a supra-competitive price for Stelara while preserving all or virtually all its sales. Only market entry of a competing, biosimilar ustekinumab would undermine J&J's ability to keep Stelara prices high without losing substantial sales.

256. J&J has admitted that competition from a biosimilar to Stelara is the level of competition that would force J&J to compete based on price or, if it did not, loose significant market share. As J&J had conceded, launch of the Amgen biosimilar "would cause [J&J] to suffer accelerated, long-term loss of market share" by confronting it with "a Hobson's choice: either compete with [Amgen's biosimilar] on price, preserving market share but eviscerating revenues, or keep prices the same and lose market share. Either option would dramatically reduce Janssen's revenue from STELARA® . . . ."[147]

[147] *Id.* at 23.

257. J&J acknowledged that the entry of biosimilar competition to Stelara would "cause a seismic shift in [J&J's] ability to maintain access to STELARA® and its broader portfolio, and result in irretrievable loss of Janssen's STELARA® market share, as well as price erosion, damage to Janssen's R&D, loss of goodwill, and harm to [J&J's] ongoing relationships with payors and customers."[148]

258. Competition from Amgen was particularly threatening to J&J. Amgen had made it clear, publicly, that it intended to seek approval of its biosimilar product as "interchangeable" to Stelara. For example, Amgen reported a "Phase 3 study to support an interchangeability designation in the U.S. for [its Stelara biosimilar] . . . is ongoing, with data readout anticipated in H1 2023." [149] That interchangeability designation would allow Amgen's biosimilar to be substituted for Stelara at the pharmacy level, without physician authorization, enabling Amgen's biosimilar to compete with J&J's Stelara based on price alone.

259. In sum, indirect evidence shows that J&J had monopoly power in an antitrust market of the sale of ustekinumab in the United States.

VIII. MARKET EFFECTS AND CLASS DAMAGES

260. In the absence of the anticompetitive conduct alleged above, multiple manufacturers would have entered the market with ustekinumab biosimilars starting as early as September 26, 2023.

261. Instead, J&J willfully and unlawfully maintained its monopoly power in the market for ustekinumab through the following an anticompetitive scheme: (i) J&J fraudulently

[148] *Id.* at 7.

[149] *Amgen Reports Fourth Quarter Financial Results and Full Year 2022 Financial Results*, AMGEN (Jan. 31, 2023), https://www.amgen.com/newsroom/press-releases/2023/01/amgen-reports-fourth-quarter-and-full-year-2022-financial-results.

obtained the ’307 method-of-use patent; (ii) J&J unlawfully acquired the rights to the Momenta biosimilar manufacturing patents; and (iii) J&J used those patents to delay competition from would-be ustekinumab biosimilar competitors. These acts, individually and in combination, were anticompetitive.

262. J&J’s scheme had, and continues to have, the purpose and effect of preventing biosimilar competition, permitting J&J to maintain supra-competitive monopoly prices for Stelara and enabling J&J to sell Stelara without competition. Absent J&J’s conduct, biosimilar versions of ustekinumab would have been available sooner.

263. Competition among drug manufacturers enables all purchasers of their drugs to buy biosimilar versions of the drugs at substantially lower prices and/or to buy the reference biologic products at reduced prices. Consequently, reference (i.e., brand) biologic manufacturers have a strong incentive to delay biosimilar competition. Purchasers experience substantial cost inflation from that delay.

264. If competition from biosimilar manufacturers had not been restrained and forestalled in the case of ustekinumab, end payers like the plaintiffs and class members would have paid less for ustekinumab by: (i) purchasing, and providing reimbursement for, biosimilar versions of ustekinumab instead of the more expensive Stelara, and (ii) purchasing, and providing reimbursement for, Stelara at lower prices.

265. As a result, J&J’s conduct has forced and will continue to force the plaintiffs and class members to pay more for Stelara and biosimilar ustekinumab than they would have paid absent J&J’s misconduct.

266. CareFirst has purchased Stelara for its members in 45 States and the District of Columbia. Table 3 below identifies the 45 states and the number of purchases in each state.

TABLE 3			
State	**Claims**	**State**	**Claims**
Maryland	18446	Missouri	51
Virginia	1929	Iowa	47
District of Columbia	1231	Louisiana	46
North Carolina	595	Nebraska	45
Pennsylvania	466	Tennessee	39
Delaware	333	New Hampshire	30
Illinois	247	Oregon	29
California	182	West Virginia	28
New York	169	Vermont	25
Florida	156	Connecticut	25
Ohio	154	Kansas	22
Georgia	148	Utah	21
Texas	129	Idaho	20
Michigan	128	Arizona	17
Wisconsin	120	Minnesota	16
New Jersey	116	Indiana	15
South Carolina	99	Kentucky	14
Hawaii	89	Maine	13
Massachusetts	88	Nevada	13
Colorado	86	New Mexico	6
Alabama	78	Oklahoma	3
Arizona	55	Mississippi	2
Washington	51	Montana	2
TOTAL: 25,624			

IX. ANTITRUST IMPACT

267. The effect of J&J's conduct is to net J&J billions of dollars in revenue at the expense of end payers, including the plaintiffs and the class members, who will pay hundreds of millions, if not billions, of dollars in unlawful overcharges.

268. During the relevant period, the plaintiffs and the class members purchased substantial amounts of Stelara indirectly from J&J.

269. As a direct and proximate result of J&J's anticompetitive conduct, the plaintiffs and the class members have paid and will continue to pay supra-competitive prices for ustekinumab because (1) the price of Stelara was and is artificially inflated by J&J's anticompetitive conduct, and (2) the plaintiffs and the class members were and are deprived of the opportunity to purchase lower-priced biosimilar versions of ustekinumab.

270. As a result, the plaintiffs and class members have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount, forms, and components of such damages will be calculated after discovery and upon proof at trial.

271. The overcharges resulting from J&J's conduct are directly traceable through the pharmaceutical distribution chain to the plaintiffs and other class members. J&J first sells Stelara to wholesalers based on Stelara's listed WAC, minus applicable discounts. Wholesalers then sell Stelara to specialty pharmacies, which in turn sell it to consumers. In this short chain of distribution, drug products are not altered or incorporated into other products. Each drug purchase is documented and closely tracked by pharmacies, pharmacy benefit managers, and third-party payers (such as insurers and health and welfare funds). The products and their prices are thus directly traceable from manufacturer to consumer.

X. IMPACT ON INTERSTATE COMMERCE

272. J&J's efforts to monopolize and restrain competition in the market for ustekinumab have substantially affected interstate and foreign commerce.

273. At all material times, J&J manufactured, sold, and shipped substantial amounts of Stelara across state lines in an uninterrupted flow of commerce across state and national lines throughout the United States.

274. At all material times, J&J transmitted funds as well as contracts, invoices, and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Stelara.

275. To further its monopolization and restraint on competition in the market for ustekinumab, J&J used various devices to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign wire commerce. J&J engaged in illegal activities, as charged herein, within the flow of—and substantially affecting—interstate commerce, including in this district.

XI. FEDERAL CLAIMS FOR RELIEF

COUNT ONE

MONOPOLIZATION IN VIOLATION OF SECTION 2 OF THE SHERMAN ACT (15 U.S.C. § 2) SEEKING DECLARATORY AND INJUNCTIVE RELIEF

276. The plaintiffs repeat and incorporate the above paragraphs as though fully set forth herein.

277. At all relevant times, J&J possessed and continues to possess substantial market power (i.e., monopoly power) in the market for ustekinumab in the United States. J&J possessed and continues to possess the power to control prices in, prevent prices from falling in, and exclude competitors from the U.S. market for ustekinumab.

278. J&J's market power is coupled with strong regulatory and contractual barriers to entry.

279. At all relevant times, J&J knowingly, willfully, and improperly maintained its monopoly power in the U.S. market for ustekinumab after September 25, 2023 through restrictive and exclusionary conduct, rather than through growth or development resulting from a superior product, business acumen, or historic accident, and thereby injured the plaintiffs and

class members. J&J's conscious objective was to further its dominance and monopoly power in the market for ustekinumab in the United States.

280. J&J knowingly, willfully, and improperly maintained its monopoly power and harmed competition by:

- fraudulently obtaining the '307 method-of-use patent by withholding relevant information from, and deliberating misrepresenting material information provided to, the patent examiner regarding use of Stelara to treat ulcerative colitis;
- wrongfully acquiring the rights to the Momenta biosimilar manufacturing patents to delay and/or prevent would-be competitors from developing ustekinumab biosimilars and entering the market; and
- knowingly and willingly using the '307 patent and the Momenta biosimilar manufacturing patents to unlawfully delay competition from would-be ustekinumab biosimilar competitors.

281. J&J's monopoly power over ustekinumab should have expired on September 25, 2023, when J&J's '734 ustekinumab composition patent expired. Instead, due to its fraudulently obtained '307 patent, unlawful acquisition of the Momenta biosimilar manufacturing patents, and use of all five patents to unlawfully delay biosimilar competition, J&J's monopoly power will extend an additional fifteen months, until at least January 1, 2025. As a result of J&J's unlawful anticompetitive scheme, no other entity currently sells biosimilar ustekinumab in the United States. This is true even though the FDA already approved Amgen's ustekinumab biosimilar.

282. The goal, purpose, and effect of J&J's overarching anticompetitive scheme was to delay and/or block ustekinumab biosimilars from entering the market, maintain its monopoly in that market, and maintain its supra-competitive prices for Stelara.

283. J&J's anticompetitive scheme substantially harmed competition in the relevant market and was an unreasonable restraint on trade.

284. Had J&J competed on the merits, instead of unlawfully maintaining its monopoly in the market for ustekinumab, one or more ustekinumab biosimilars would have been available by no later than September 26, 2023. The plaintiffs and class members would have substituted the lower-priced ustekinumab biosimilar products for the higher-priced brand Stelara (or purchased Stelara at lower prices) for some or all their ustekinumab requirements. As a result, they would have paid substantially lower prices for ustekinumab.

285. To the extent that J&J is permitted to assert one, there is and was no cognizable, non-pretextual procompetitive justification for its exclusionary conduct that outweighs that conduct's harmful effects. Even if there were some conceivable justifications that J&J were permitted to assert, J&J's conduct is and was broader than necessary to achieve such a purpose.

286. J&J's anticompetitive activities have directly, foreseeably, and proximately caused injury to the plaintiffs and class members throughout the United States. The plaintiffs' and class members' injuries consist of: (a) being denied the opportunity to purchase lower-priced Stelara from J&J; (b) paying higher prices for ustekinumab than they would have paid in the absence of J&J's unfair, illegal, and deceptive conduct; and (c) being denied the opportunity to purchase biosimilar ustekinumab at a price substantially lower than what they were forced to pay for Stelara. These injuries are of the type that the antitrust laws were designed to prevent, and they flow from that which makes J&J's conduct unlawful.

287. The plaintiffs and the class members are the proper entities to bring a case concerning J&J's unlawful anticompetitive scheme.

288. The plaintiffs and class members have been injured, and unless J&J's unlawful conduct is enjoined, the plaintiffs and class members will continue to be injured, in their

businesses and property, as a direct and proximate result of J&J's continuing monopolization in violation of Section 2 of the Sherman Act.

289. Pursuant to Fed. R. Civ. P. 57 and 28 U.S.C. § 2201(a), the plaintiffs and the class members seek a declaratory judgment that J&J's conduct in seeking to prevent competition as described in the preceding paragraphs violates Section 2 of the Sherman Act.

290. Pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, the plaintiffs and class members further seek equitable and injunctive relief to correct for the anticompetitive market effects J&J's unlawful conduct caused and to ensure that similar anticompetitive conduct does not occur in the future.

291. The plaintiffs also seek an order requiring J&J to divest the Momenta biosimilar manufacturing patents to a third party that is not incentivized to use the patents to foreclose competitors from the market for ustekinumab in the United States. Such divesture will ensure that J&J is unable to use the unlawfully acquired Momenta biosimilar manufacturing patents to continue to perpetrate its anticompetitive conduct in the market for ustekinumab in the United States.

COUNT TWO

ATTEMPTED MONOPOLIZATION IN VIOLATION OF SECTION 2 OF THE SHERMAN ACT (15 U.S.C. § 2) SEEKING DECLARATORY AND INJUNCTIVE RELIEF

292. The plaintiffs repeat and incorporate the above paragraphs as though fully set forth herein.

293. At all relevant times, J&J possessed and continues to possess substantial market power (i.e., monopoly power) in the U.S. market for ustekinumab. J&J possessed and continues to possess the power to control prices in, prevent prices from falling in, and exclude competitors from the U.S. market for ustekinumab.

294. Alternatively, if J&J does not already have a monopoly in the market for ustekinumab in the United States, it has attempted to monopolize this market.

295. J&J engaged in predatory or anticompetitive conduct by:

- fraudulently obtaining the '307 method-of-use patent by withholding relevant information from, and deliberating misrepresenting material information provided to, the patent examiner regarding use of Stelara to treat ulcerative colitis;
- wrongfully acquiring the rights to the Momenta biosimilar manufacturing patents to delay and/or prevent would-be competitors from developing ustekinumab biosimilars and entering the market; and
- knowingly and willingly using the '307 patent and the Momenta biosimilar manufacturing patents to unlawfully delay competition from would-be ustekinumab biosimilar competitors.

296. Through its anticompetitive scheme, as alleged above, J&J specifically intended to monopolize the market for ustekinumab in the United States after September 25, 2023. J&J's goal, purpose, and effect was to delay and/or block ustekinumab biosimilars from entering the market, maintain its monopoly in that market, and maintain its supra-competitive prices for Stelara.

297. Based on its current market power in the market for ustekinumab in the United States, there is a dangerous probability that J&J will achieve monopoly power.

298. J&J's attempted monopolization directly, foreseeably, and proximately caused injury to the plaintiffs and class members throughout the United States. The plaintiffs' and class members' injuries consist of: (a) being denied the opportunity to purchase lower-priced Stelara from J&J; (b) paying higher prices for ustekinumab than they would have paid in the absence of J&J's unfair, illegal, and deceptive conduct; and (c) being denied the opportunity to purchase biosimilar ustekinumab at substantially lower prices than what they were forced to pay for J&J's Stelara. These injuries are of the type that the laws of the jurisdictions below were designed to

prevent, and they flow from that which makes J&J's conduct unlawful. The plaintiffs and class members are the proper entities to bring a case concerning J&J's unlawful anticompetitive scheme.

299. The plaintiffs' and class members' allegations comprise a violation of Section 2 of the Sherman Act.

300. Pursuant to Fed. R. Civ. P. 57 and 28 U.S.C. § 2201(a), the plaintiffs and the class members seek a declaratory judgment that J&J's conduct in seeking to prevent competition as described in the preceding paragraphs violates Section 2 of the Sherman Act.

301. Pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, the plaintiffs and class members further seek equitable and injunctive relief to ensure J&J's attempted monopolization does not occur in the future.

302. The plaintiffs also seek an order requiring J&J to divest the Momenta biosimilar manufacturing patents to a third party that is not incentivized to use the patents to foreclose competitors from the market for ustekinumab in the United States. Such divesture will ensure that J&J is unable to use the unlawfully acquired Momenta biosimilar manufacturing patents to attempt to monopolize the market for ustekinumab in the United States in the future.

XII. STATE CLAIMS FOR RELIEF

COUNT THREE

MONOPOLIZATION AND MONOPOLISTIC SCHEME UNDER STATE LAW

303. The plaintiffs repeat and incorporate the above paragraphs as though fully set forth herein.

304. Count Three is pled on behalf of the plaintiffs and class members under the antitrust laws of each jurisdiction identified below.

305. Count Three arises from J&J's exclusionary, anticompetitive scheme that was designed to create and maintain J&J's improper monopoly over ustekinumab and exclude or substantially exclude its biosimilars from the market.

306. The essential elements of each antitrust claim in Count Three are the same. The above-alleged conduct that violates the Sherman Act will, if proven, establish a claim under each of the laws cited below.

307. At all relevant times, J&J possessed and continues to possess substantial market power (i.e., monopoly power) in the market for ustekinumab. J&J possessed and continues to possess the power to control prices in, prevent prices from falling in, and exclude competitors from the U.S. market for ustekinumab.

308. Through its overarching anticompetitive scheme, as alleged above, J&J willfully maintained its monopoly power in the market for ustekinumab in the United States after September 25, 2023 using restrictive or exclusionary conduct, rather than by means of a superior product, business acumen, or historic accident, and thereby injured the plaintiffs and the class members. J&J engaged in its anticompetitive scheme with the specific intent to maintain its monopoly in the market for ustekinumab in the United States.

309. J&J accomplished its anticompetitive scheme by: (i) fraudulently obtaining its '307 method-of-use patent; (ii) wrongfully acquiring the rights to the Momenta biosimilar manufacturing patents; and (iii) using those patents to unlawfully delay competition from would-be ustekinumab biosimilar competitors.

310. The goal, purpose, and effect of J&J's overarching anticompetitive scheme was to delay and/or block ustekinumab biosimilars from entering the market, extend J&J's monopoly in that market, and maintain its supra-competitive prices for Stelara.

311. J&J's anticompetitive scheme substantially harmed competition in the relevant market and was an unreasonable restraint on trade.

312. J&J's anticompetitive scheme directly impacts and disrupts commerce within each jurisdiction below.

313. Had J&J competed on the merits, instead of unlawfully maintaining its monopoly in the market for ustekinumab, one or more ustekinumab biosimilars would have been available no later than September 26, 2023. The plaintiffs and class members would have substituted the lower-priced ustekinumab biosimilars for the higher-priced brand Stelara (or paid less for Stelara) for some or all their ustekinumab requirements. As a result, they would have paid substantially lower prices for ustekinumab.

314. During the class period, Stelara, manufactured and sold by J&J, was shipped into each state and was sold to or paid for by CareFirst and the class.

315. During the class period, in connection with the purchase and sale of Stelara, money changed hands and business communications and transactions occurred in each state.

316. J&J's conduct as set forth in this Complaint had substantial effects on intrastate commerce in that, *inter alia*, retailers within each state were foreclosed from offering cheaper generic Stelara to end payors purchasing inside each respective state. This impairment of competition directly impacts and disrupts commerce within each state.

317. J&J's anticompetitive activities have directly, foreseeably, and proximately caused injury to the plaintiffs and class members throughout the United States. The plaintiffs' and class members' injuries consist of: (a) being denied the opportunity to purchase lower-priced Stelara from J&J; (b) paying higher prices for ustekinumab than they would have paid in the absence of J&J's unfair, illegal, and deceptive conduct; and (c) being denied the opportunity to

purchase biosimilar ustekinumab at prices substantially lower than what they were forced to pay for Stelara. These injuries are of the type that the laws of the jurisdictions below were designed to prevent, and they flow from that which makes J&J's conduct unlawful.

318. The plaintiffs and class members are the proper entities to bring a case concerning J&J's unlawful anticompetitive scheme.

319. The defendants are jointly and severally liable for all damages suffered by the plaintiffs and the class members.

320. By engaging in the foregoing conduct, J&J intentionally and flagrantly maintained its monopoly power over ustekinumab in the United States in violation of the following state laws:

a. Ala. Code § 8-10-3 with respect to the plaintiffs' and class members' purchases in Alabama.

b. Ariz. Arizona Rev. Stat. §§ 44-1401, *et seq*., including Ariz. Rev. Stat. § 44-1403, with respect to the plaintiffs' and class members' purchases in Arizona.

c. Cal. Bus. & Prof. Code §§ 16700, *et seq*., and §§ 17200, et seq., with respect to the plaintiffs' and class members' purchases in California.

d. Conn. Gen. Stat. §§ 35-24, *et seq*., with respect to the plaintiffs' and class members' purchases in Connecticut.

e. D.C. Code §§ 28-4501, *et seq*., with respect to the plaintiffs' and class members' purchases in the District of Columbia.

f. Fla. Stat. §§ 501.201, *et seq*., with respect to the plaintiffs' and class members' purchases in Florida.

g. 740 Ill. Comp. Stat. 10/1, *et seq*., including 740 Ill. Comp. Stat. 10/3, with respect to the plaintiffs' and class members' purchases in Illinois.

h. Iowa Code §§ 553.1 *et seq*., including Iowa Code § 553.5, with respect to the plaintiffs' and class members' purchases in Iowa.

i. Kan. Stat. Ann. §§ 50-101, *et seq*., including Kan. Stat. Ann. § 50-132, with respect to the plaintiffs' and class members' purchases in Kansas.

j. Me. Rev. Stat. Ann. tit. 10, §§ 1101, *et seq.*, including Me. Rev. Stat. Ann. tit. 10, §1102, with respect to the plaintiffs' and class members' purchases in Maine;

k. Md. Code Com. Law § 11-201, *et seq.*, including Md. Code Com. Law § 11-204, with respect to the plaintiffs' and class members' purchases in Maryland.

l. Mich. Comp. Laws Ann. §§ 445.771, *et seq.*, with respect to the plaintiffs' and class members' purchases in Michigan.

m. Minn. Stat. Ann. §§ 325D.49, *et seq.*, including Minn. Stat. Ann. § 325D.52 and Minn. Stat. Ann. § 8.31, *et seq.*, with respect to the plaintiffs' and class members' purchases in Minnesota.

n. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to the plaintiffs' and class members' purchases in Mississippi.

o. Neb. Code Ann. §§ 59-801, *et seq.*, including Neb. Code Ann. § 59-802, with respect to the plaintiffs' and class members' purchases in Nebraska.

p. Nev. Rev. Stat. Ann. §§ 598A.010, *et seq.*, including Nev. Rev. Stat. Ann. § 598A.060, with respect to the plaintiffs' and class members' purchases in Nevada.

q. N.H. Rev Stat. Ann. §§ 356.1, *et seq.*, including N.H. Rev. Stat. Ann. § 356.3, with respect to the plaintiffs' and class members' purchases in New Hampshire.

r. N.M. Stat. Ann. §§ 57-1-1, *et seq.*, including N.M. Stat. Ann. § 57-1-2, with respect to the plaintiffs' and class members' purchases in New Mexico.

s. N.Y. Gen. Bus. Law §§ 340, *et seq.*, with respect to the plaintiffs' and class members' purchases in New York.

t. N.C. Gen. Stat. Ann. §§ 75-1, *et seq.*, including N.C. Gen. Stat. Ann. § 75-2.1, with respect to the plaintiffs' and class members' purchases in North Carolina.

u. N.D. Cent. Code §§ 51-08.1-01, *et seq.*, including N.D. Cent. Code §§ 51-08.1-03, with respect to class members' purchases in North Dakota.

v. Or. Rev. Stat. §§ 646.705, *et seq.*, including Or. Rev. Stat. §§ 646.730, with respect to the plaintiffs' and class members' purchases in Oregon.

w. 10 L.P.R.A. §§ 257, *et seq.*, with respect to class members' purchases in Puerto Rico.

x. R.I. Gen. Laws §§ 6-36-1, *et seq.*, including R.I. Gen. Laws §§ 6-36-5, with respect to class members' purchases in Rhode Island.

y. S.D. Codified Laws §§ 37-1-3.1, *et seq.*, including S.D. Codified Laws §§ 37-1-3.2, with respect to class members' purchases in South Dakota.

z. Tenn. Code Ann §§ 47-25-101, *et seq.*, with respect to the plaintiffs' and class members' purchases in Tennessee.

aa. Utah Code Ann. §§ 76-10-3101, *et seq.*, including Utah Code Ann. §§ 76-10-3104, with respect to purchases in Utah by class members that are Utah residents or citizens.

bb. Vt. Stat. Ann. tit. 9, §§ 2451, *et seq.*, with respect to the plaintiffs' and class members' purchases in Vermont.

cc. W.Va. Code §§ 47-18-1, *et seq.*, including § 47-18-4, with respect to the plaintiffs' and class members' purchases in West Virginia.

dd. Wis. Stat. §§ 133.01, *et seq.*, including Wis. Stat. §§ 133.04, with respect to the plaintiffs' and class members' purchases in Wisconsin.

321. As a result of the unlawful and anticompetitive conduct described above, CareFirst and/or members of the class paid artificially inflated prices for Stelara, in each of these listed jurisdictions.

322. Certain States require that a plaintiff comply with specified notice requirements before asserting claims under the States' antitrust statutes. The plaintiffs are in the process of complying with these notice requirements and will amend the complaint to add these additional State law claims at the appropriate time.

COUNT FOUR

ATTEMPTED MONOPOLIZATION UNDER STATE LAW

323. The plaintiffs repeat and incorporate the above paragraphs as though fully set forth herein.

324. Count Four is pled on behalf of the plaintiffs and class members under the antitrust laws of each jurisdiction identified below.

325. Count Four arises from J&J's exclusionary, anticompetitive scheme that was designed to create and maintain J&J's improper monopoly over ustekinumab and exclude or substantially exclude its biosimilars from the market.

326. The essential elements of each antitrust claim in Count Four are the same. The above-alleged conduct that violates the Sherman Act will, if proven, establish a claim under each of the laws cited below.

327. At all relevant times, J&J possessed and continues to possess substantial market power (i.e., monopoly power) in the market for ustekinumab. J&J possessed and continues to possess the power to control prices in, prevent prices from falling in, and exclude competitors from the U.S. market for ustekinumab.

328. Alternatively, if J&J does not already have a monopoly in the market for ustekinumab in the United States, it has attempted to monopolize this market.

329. J&J engaged in predatory or anticompetitive conduct by: (i) fraudulently obtaining its '307 method-of-use patent; (ii) wrongfully acquiring the rights to the Momenta biosimilar manufacturing patents; and (iii) using those patents to unlawfully delay competition from would-be ustekinumab biosimilar competitors.

330. Through its anticompetitive scheme, J&J specifically intended to monopolize the market for ustekinumab in the United States after September 25, 2023 using restrictive or exclusionary conduct, rather than by means of a superior product, business acumen, or historic accident.

331. The goal, purpose, and effect of J&J anticompetitive scheme was to delay and/or block ustekinumab biosimilars from entering the market, extend J&J's monopoly in that market, and maintain its supra-competitive prices for Stelara.

332. Based on its current market power in the market for ustekinumab in the United States, there is a dangerous probability that J&J will achieve monopoly power.

333. During the class period, Stelara, manufactured and sold by J&J, was shipped into each state and was sold to or paid for by CareFirst and the class.

334. During the class period, in connection with the purchase and sale of Stelara, money changed hands and business communications and transactions occurred in each state.

335. J&J's conduct as set forth in this Complaint had substantial effects on intrastate commerce in that, *inter alia*, retailers within each state were foreclosed from offering cheaper biosimilar Stelara to end payors purchasing inside each respective state. This impairment of competition directly impacts and disrupts commerce within each state.

336. J&J's anticompetitive activities have directly, foreseeably, and proximately caused injury to the plaintiffs and class members throughout the United States. The plaintiffs' and class members' injuries consist of: (a) being denied the opportunity to purchase lower-priced Stelara from J&J; (b) paying higher prices for ustekinumab than they would have paid in the absence of J&J's unfair, illegal, and deceptive conduct; and (c) being denied the opportunity to purchase biosimilar ustekinumab at prices substantially lower than what they were forced to pay for Stelara. These injuries are of the type that the laws of the jurisdictions below were designed to prevent, and they flow from that which makes J&J's conduct unlawful.

337. The plaintiffs and class members are the proper entities to bring a case concerning J&J's unlawful anticompetitive scheme.

338. The defendants are jointly and severally liable for all damages suffered by the plaintiffs and the class members.

339. By engaging in the foregoing conduct, J&J intentionally, wrongfully, and flagrantly attempted to monopolize the market for ustekinumab in the United States in violation of the following state laws:

ee. Ala. Code § 8-10-3 with respect to the plaintiffs' and class members' purchases in Alabama.

ff. Ariz. Rev. Stat. Ann. §§ 44-1401, *et seq.*, including Ariz. Rev. Stat. § 44-1403, with respect to the plaintiffs' and class members' purchases in Arizona.

gg. Cal. Bus. & Prof. Code §§ 16700, *et seq.*, and §§ 17200, et seq., with respect to the plaintiffs' and class members' purchases in California.

hh. Conn. Gen. Stat. §§ 35-24, *et seq.*, with respect to the plaintiffs' and class members' purchases in Connecticut.

ii. D.C. Code §§ 28-4501, *et seq.*, with respect to the plaintiffs' and class members' purchases in the District of Columbia.

jj. Fla. Stat. §§ 501.201, *et seq.*, with respect to the plaintiffs' and class members' purchases in Florida.

kk. 740 Ill. Comp. Stat. 10/1, *et seq.*, including 740 Ill. Comp. Stat. 10/3, with respect to the plaintiffs' and class members' purchases in Illinois.

ll. Iowa Code §§ 553.1 *et seq.*, including Iowa Code § 553.5, with respect to the plaintiffs' and class members' purchases in Iowa.

mm. Kan. Stat. Ann. §§ 50-101, *et seq.*, including Kan. Stat. Ann. § 50-132, with respect to the plaintiffs' and class members' purchases in Kansas.

nn. Me. Rev. Stat. Ann. tit. 10, §§ 1101, *et seq.*, including Me. Rev. Stat. Ann. tit. 10, §1102, with respect to the plaintiffs' and class members' purchases in Maine;

oo. Md. Code Com. Law § 11-201, *et seq.*, including Md. Code Com. Law § 11-204, with respect to the plaintiffs' and class members' purchases in Maryland.

pp. Mich. Comp. Laws Ann. §§ 445.771, *et seq.*, with respect to the plaintiffs' and class members' purchases in Michigan.

qq. Minn. Stat. Ann. §§ 325D.49, *et seq.*, including Minn. Stat. Ann. § 325D.52 and Minn. Stat. Ann. § 8.31, *et seq.*, with respect to the plaintiffs' and class members' purchases in Minnesota.

rr. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to the plaintiffs' and class members' purchases in Mississippi.

ss. Neb. Code Ann. §§ 59-801, *et seq.*, including Neb. Code Ann. § 59-802, with respect to the plaintiffs' and class members' purchases in Nebraska.

tt. Nev. Rev. Stat. Ann. §§ 598A.010, *et seq.*, including Nev. Rev. Stat. Ann. § 598A.060, with respect to the plaintiffs' and class members' purchases in Nevada.

uu. N.H. Rev Stat. Ann. §§ 356.1, *et seq.*, including N.H. Rev. Stat. Ann. § 356.3, with respect to the plaintiffs' and class members' purchases in New Hampshire.

vv. N.M. Stat. Ann. §§ 57-1-1, *et seq.*, including N.M. Stat. Ann. § 57-1-2, with respect to the plaintiffs' and class members' purchases New Mexico.

ww. N.Y. Gen. Bus. Law §§ 340, *et seq.*, with respect to the plaintiffs' and class members' purchases in New York.

xx. N.C. Gen. Stat. Ann. §§ 75-1, *et seq.*, including N.C. Gen. Stat. Ann. § 75-2.1, with respect to the plaintiffs' and class members' purchases in North Carolina.

yy. N.D. Cent. Code §§ 51-08.1-01, *et seq.*, including N.D. Cent. Code §§ 51-08.1-03, with respect to class members' purchases in North Dakota.

zz. Or. Rev. Stat. §§ 646.705, *et seq.*, including Or. Rev. Stat. §§ 646.730, with respect to the plaintiffs' and class members' purchases in Oregon.

aaa. 10 L.P.R.A. §§ 257, *et seq.*, with respect to class members' purchases in Puerto Rico.

bbb. R.I. Gen. Laws §§ 6-36-1, *et seq.*, including R.I. Gen. Laws §§ 6-36-5, with respect to class members' purchases in Rhode Island.

ccc. S.D. Codified Laws §§ 37-1-3.1, *et seq.*, including S.D. Codified Laws §§ 37-1-3.2, with respect to class members' purchases in South Dakota.

ddd. Tenn. Code Ann §§ 47-25-101, *et seq.*, with respect to the plaintiffs' and class members' purchases in Tennessee.

eee. Utah Code Ann. §§ 76-10-3101, *et seq.*, including Utah Code Ann. §§ 76-10-3104, with respect to purchases in Utah by Utah residents or citizens who are class members.

fff. Vt. Stat. Ann. tit. 9, §§ 2451, *et seq.*, with respect to the plaintiffs' and class members' purchases in Vermont.

ggg. W.Va. Code §§ 47-18-1, *et seq.*, including § 47-18-4, with respect to the plaintiffs' and class members' purchases in West Virginia.

hhh. Wis. Stat. §§ 133.01, *et seq.*, including Wis. Stat. §§ 133.04, with respect to the plaintiffs' and class members' purchases in Wisconsin.

340. As a result of the unlawful and anticompetitive conduct described above, CareFirst and/or members of the class paid artificially inflated prices for Stelara, in each of these listed jurisdictions.

341. Certain States require that a plaintiff comply with specified notice requirements before asserting claims under the States' antitrust statutes. The plaintiffs are in the process of complying with these notice requirements and will amend the complaint to add these additional State law claims at the appropriate time.

COUNT FIVE

VIOLATIONS OF STATE CONSUMER PROTECTION LAWS

342. The plaintiffs repeat and incorporate the above paragraphs as though fully set forth herein.

343. As described above, J&J engaged in unfair competition or unfair, unconscionable, deceptive, or fraudulent conduct, acts, or practices in violation of the consumer protection statutes set forth below.

344. J&J established, maintained, and/or used a monopoly, or attempted to establish a monopoly, and to restrain trade or commerce in the U.S. market for ustekinumab. A substantial part of this conduct occurred within each jurisdiction identified below. J&J intended to injure competitors and exclude or substantially lessen competition. J&J intended to injure consumers by unlawfully reaping supra-competitive profits.

345. By unlawfully delaying the entry of ustekinumab biosimilars, J&J, as a supplier, engaged in a fraudulent or deceptive act or practice in connection with a consumer transaction.

346. J&J's conduct constitutes consumer-oriented deceptive acts or practices that resulted in consumer injury and broad adverse impact on the public at large. J&J's conduct thereby harmed consumers' interest in an honest marketplace where economic activity is conducted in a competitive manner.

347. J&J withheld material facts and information from the plaintiffs and class members, including that J&J was unlawfully excluding manufacturers of biosimilar ustekinumab from the market and monopolizing the market for ustekinumab (and thereby profiting from the resulting supra-competitive prices that the plaintiffs and class members who purchased or reimbursed purchases of Stelara paid).

348. J&J's conduct was willful and knowing.

349. J&J intended to deceive the plaintiffs and class members regarding the nature of its actions within the stream of commerce in each jurisdiction below.

350. J&J's acts, omissions, misrepresentations, practices, and/or non-disclosures constituted a common, continuous, and continuing course of conduct of unfair competition by means of unfair, unlawful, and/or fraudulent business acts or practices.

351. The plaintiffs and class members purchased (or reimbursed their members for their purchases of) goods, namely ustekinumab, primarily for personal, family, or household purposes.

352. The plaintiffs and class includes, and the plaintiffs administer benefits for, non-profit labor unions and non-profit health and welfare plans whose core mission includes providing health benefits, including prescription drug benefits, to their members and members' spouses and dependents. In carrying out that core mission, those labor unions and health and welfare plans purchase or provide reimbursement for ustekinumab.

353. The plaintiffs and class members who do not profit from purchasing ustekinumab or from reimbursing their members for purchases of ustekinumab are "consumers" under the consumer protection laws of the jurisdictions below.

354. There was and is a gross disparity between the price that the plaintiffs and class members paid for ustekinumab and the value they received, given that less expensive biosimilars should have been available.

355. As a direct and proximate result of J&J's unlawful conduct, the plaintiffs and class members have been injured and are threatened with continued injury.

356. As a direct and proximate result of J&J's unfair, unconscionable, deceptive, and fraudulent conduct in violation of the state consumer protection statutes listed below, the plaintiffs and class members were denied the opportunity to purchase lower-priced ustekinumab biosimilars and paid higher prices for Stelara than they would otherwise have paid.

357. The gravity of harm from J&J's wrongful conduct significantly outweighs any conceivable utility from that conduct. The plaintiffs and class members could not reasonably have avoided injury from J&J's wrongful conduct.

358. J&J's unlawful conduct substantially affected the trade and commerce of each jurisdiction in which ustekinumab was sold.

359. J&J's unfair and deceptive acts described above were knowing and willful, and constitute violations or flagrant violations of the following unfair trade practices and consumer protection statutes[150]:

[150] Following the requisite notices to J&J, the plaintiffs intend to amend this complaint to add claims under the following state statutes:

a. 5 Me. Rev. Stat. §§ 207, *et seq.*, with respect to the plaintiffs' and class members' purchases in Maine.

a. Ariz. Rev. Stat. §§ 44-1521, *et seq.*, with respect to the plaintiffs' and class members' purchases in Arizona.

b. Ark. Code Ann. §§ 4-88-101, *et seq.*, with respect to the plaintiffs' and class members' purchases in Arkansas.

c. Cal. Bus. & Prof. Code §§ 17200, *et seq.*, including §§ 17203 and 17204, with respect to the plaintiffs' and class members' purchases in California.

d. D.C. Code §§ 28-3901, *et seq.*, with respect to the plaintiffs' and class members' purchases in the District of Columbia.

e. Fla. Stat. §§ 501.201, *et seq.*, with respect to the plaintiffs' and class members' purchases in Florida.

f. 815 Ill. Comp. Stat. Ann. §§ 505/1, *et seq.*, with respect to the plaintiffs' and class members' purchases in Illinois.

g. Mich. Comp. Laws Ann. §§ 445.901, *et seq.*, on behalf of the plaintiffs and class members residing or injured in Michigan.

h. Minn. Stat. §§ 325F.68, *et seq.*, with respect to the plaintiffs' and class members' purchases in Minnesota.

i. Mo. Rev. Stat. §§ 407.010, *et seq.*, with respect to the plaintiffs' and class members' purchases in Missouri.

j. Mont. Code, §§ 30-14-101, *et seq.*, with respect to the plaintiffs' and class members' purchases in Montana.

k. Neb. Rev. Stat. §§ 59-1601, *et seq.*, with respect to the plaintiffs' and class members' purchases in Nebraska.

l. Nev. Rev. Stat. §§ 598.0903, *et seq.*, with respect to the plaintiffs' and class members' purchases in Nevada.

m. N.H. Rev. Stat. §§ 358-A:1, *et seq.*, with respect to the plaintiffs' and class members' purchases in New Hampshire.

n. N.M. Stat. Ann. §§ 57-12-1, *et seq.*, with respect to the plaintiffs' and class members' purchases in New Mexico.

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b. Mass. Gen. Laws. Ch. 93A §§ 1, *et seq.*, including Mass. Gen. Laws. Ch. 93A § 9, with respect to the plaintiffs' and class members' purchases in Massachusetts.

o. New York Gen. Bus. Law § 349 with respect to the plaintiffs' and class members' purchases in New York.

p. N.C. Gen. Stat. §§ 75-1.1, *et seq.*, with respect to the plaintiffs' and class members' purchases in North Carolina.

q. Or. Rev. Stat. §§ 646.605, *et seq.*, with respect to the plaintiffs' and class members' purchases in Oregon.

r. R.I. Gen. Laws §§ 6-13.1-1, *et seq.*, with respect to class members' purchases in Rhode Island.

s. S.C. Code §§ 39-5-10, *et seq.*, with respect to the plaintiffs' and class members' purchases in South Carolina.

t. S.D. Codified Laws §§ 37-24-1, *et seq.*, with respect to class members' purchases in South Dakota.

u. Tenn. Code Ann. §§ 47-18-101, *et seq.* with respect to the plaintiffs' and class members' purchases in Tennessee.

v. Utah Code Ann. §§ 13-11-1, *et seq.* with respect to the plaintiffs' and class members' purchases in Utah.

w. Vt. Stat. Ann. tit. 9, §§ 2453, *et seq.*, with respect to the plaintiffs' and class members' purchases in Vermont.

x. Va. Code Ann. §§ 59.1-196, *et seq.* with respect to the plaintiffs' and class members' purchases in Virginia; and

y. West Va. Code §§ 46A-6-101, *et seq.*, with respect to the plaintiffs' and class members' purchases in West Virginia.

360. As a result of the unfair and deceptive conduct described above, CareFirst and/or members of the class paid artificially inflated prices for Stelara, in each of these listed jurisdictions.

361. Certain states require that a plaintiff comply with specified notice requirements before asserting claims under the States' antitrust and/or consumer protection statutes. The plaintiffs are in the process of complying with these notice requirements and will amend the complaint to add any additional State law claims at the appropriate time.

COUNT SIX

UNJUST ENRICHMENT UNDER STATE LAW

362. The plaintiffs repeat and incorporate the above paragraphs as though fully set forth herein.

363. To the extent required, this claim is pled in the alternative to the other claims in this complaint.

364. As a result of its unlawful conduct described above, J&J has and will continue to be unjustly enriched by the receipt of unlawfully inflated prices and unlawful profits from sales of ustekinumab. J&J's financial benefits are traceable to the plaintiffs' and class members' overpayments for ustekinumab. J&J has received a benefit from the class in the form of revenue resulting from unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of J&J and to the economic detriment of the plaintiffs and the class. J&J has benefited from its unlawful acts, and it would be inequitable for J&J to retain any of the ill-gotten gains resulting from the plaintiffs' and class members' overpayments for ustekinumab during the class period.

365. It would be futile for the plaintiffs and class members to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which they indirectly purchased Stelara, as those intermediaries are not liable for, and would not compensate the plaintiffs and class members for, J&J's unlawful conduct.

366. The economic benefit J&J derived from the plaintiffs' and class members' purchases of ustekinumab is a direct and proximate result of J&J's unlawful and anticompetitive practices.

367. The financial benefits J&J derived are ill-gotten gains that rightfully belong to the plaintiffs and class members who paid and continue to pay artificially inflated prices that inured to J&J's benefit.

368. It would be inequitable under unjust enrichment principles under the laws of the jurisdictions identified below for J&J to retain any of the benefits J&J derived from its unfair, anticompetitive, and unlawful methods, acts, and trade practices.

369. J&J is aware of and appreciates the benefits that the plaintiffs and class members have bestowed upon it.

370. J&J should be ordered to disgorge all unlawful or inequitable proceeds it received to a common fund for the benefit of the plaintiffs and class members who collectively have no adequate remedy at law.

371. A constructive trust should be imposed upon all unlawful or inequitable sums J&J received that are traceable to the plaintiffs and class members.

372. By engaging in the unlawful or inequitable conduct described above, which deprived the plaintiffs and class members of the opportunity to purchase lower-priced biosimilar versions of ustekinumab and forced them to pay higher prices for Stelara, J&J has been unjustly enriched in violation of the common law of the following jurisdictions:

1. Alabama

373. J&J unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for ustekinumab in Alabama. The plaintiffs and class members paid higher prices for ustekinumab than they would have paid but for J&J's actions.

374. J&J received money from the plaintiffs and class members as a direct result of the unlawful overcharges and has retained this money.

375. J&J has benefitted at the expense of the plaintiffs and class members from revenue resulting from unlawful overcharges for ustekinumab.

376. It is inequitable for J&J to accept and retain the benefits received without compensating the plaintiffs and class members.

2. Alaska

377. J&J unlawfully profited from overcharges paid by class members who made purchases of or reimbursements for ustekinumab in Alaska. Class members paid higher prices for ustekinumab than they would have paid but for J&J's actions.

378. J&J has received a benefit from class members in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of J&J, to the economic detriment of class members. J&J has received a benefit from class members in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of J&J and to the economic detriment of class members.

379. J&J appreciated the benefits bestowed upon it by class members.

380. J&J accepted and retained the benefits bestowed upon it under inequitable and unjust circumstances arising from unlawful overcharges to class members.

381. Under the circumstances, it would be inequitable for J&J to retain such benefits without compensating class members.

3. Arizona

382. J&J unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for ustekinumab in Arizona. The plaintiffs and class members paid higher prices for ustekinumab than they would have paid but for J&J's actions.

383. J&J has been enriched by revenue resulting from unlawful overcharges for ustekinumab.

384. The plaintiffs and class members have been impoverished by the overcharges for ustekinumab resulting from J&J's unlawful conduct.

385. J&J's enrichment and the impoverishment of the plaintiffs and class members are connected. J&J has paid no consideration to any other person for any benefits it received from the plaintiffs and class members.

386. There is no justification for J&J's receipt of the benefits causing its enrichment and the impoverishment of the plaintiffs and class members because the plaintiffs and class members paid supra-competitive prices that inured to J&J's benefit, and it would be inequitable for J&J to retain any revenue gained from its unlawful overcharges.

387. The plaintiffs and class members have no adequate remedy at law.

4. Arkansas

388. J&J unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for ustekinumab in Arkansas. The plaintiffs and class members paid higher prices for ustekinumab than they would have paid but for J&J's actions.

389. J&J received money from the plaintiffs and class members as a direct result of the unlawful overcharges and have retained this money.

390. J&J has paid no consideration to any other person in exchange for this money.

391. Under the circumstances, it would be inequitable for J&J to retain such benefits without compensating the plaintiffs and the class.

5. California

392. J&J unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for ustekinumab in California. The plaintiffs and class members paid higher prices for ustekinumab than they would have paid but for J&J's actions.

393. J&J has received a benefit from the plaintiffs and the class as a direct result of J&J's fraudulent and misleading conduct and the resulting unlawful overcharges to the class.

394. J&J retained the benefits bestowed upon it under inequitable and unjust circumstances at the expense of the plaintiffs and the class.

395. Plaintiffs and members of the class are entitled to restitution from J&J.

6. Colorado

396. J&J unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for ustekinumab in Colorado. The plaintiffs and class members paid higher prices for ustekinumab than they would have paid but for J&J's actions.

397. J&J has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of J&J and to the economic detriment of the plaintiffs and the class.

398. J&J retained the benefit bestowed upon it under inequitable and unjust circumstances arising from unlawful overcharges to the plaintiffs and the class.

399. Under the circumstances, it would be inequitable and unjust for J&J to retain such benefits without compensating the plaintiffs and class members.

7. Connecticut

400. J&J unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for ustekinumab in Connecticut. The plaintiffs and class members paid higher prices for ustekinumab than they would have paid but for J&J's actions.

401. J&J has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of J&J and to the economic detriment of the plaintiffs and the class.

402. J&J has paid no consideration to any other person in exchange for this benefit.

403. J&J retained the benefits bestowed upon it under inequitable and unjust circumstances at the expense of the plaintiffs and class members.

404. Under the circumstances, it would be inequitable and unjust for J&J to retain such benefits.

8. Delaware

405. J&J unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for ustekinumab in Delaware. The plaintiffs and class members paid higher prices for ustekinumab than they would have paid but for J&J's actions.

406. J&J has been enriched by revenue resulting from unlawful overcharges for branded and generic ustekinumab.

407. The plaintiffs and the class have been impoverished by the overcharges for branded and generic ustekinumab resulting from J&J's unlawful conduct.

408. J&J's enrichment and the impoverishment of the plaintiffs and the class are connected. J&J has paid no consideration to any other person for any benefits they received from the plaintiffs and class members.

409. There is no justification for J&J's receipt of the benefits causing its enrichment and the impoverishment of the plaintiffs and the class because the plaintiffs and the class paid supra-competitive prices that inured to J&J's benefit, and it would be inequitable for J&J to retain any revenue gained from its unlawful overcharges.

410. The plaintiffs and the class have no remedy at law.

9. District of Columbia

411. J&J unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for ustekinumab in the District of Columba. The plaintiffs and class members paid higher prices for ustekinumab than they would have paid but for J&J's actions.

412. J&J has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of J&J, to the economic detriment of the plaintiffs and the class.

413. J&J accepted and retained the benefit bestowed upon it under inequitable and unjust circumstances arising from unlawful overcharges to the class.

414. Under the circumstances, it would be inequitable and unjust for J&J to retain such benefits.

10. Florida

415. J&J unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for ustekinumab in Florida. The plaintiffs

and class members paid higher prices for ustekinumab than they would have paid but for J&J's actions.

416. J&J has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of J&J and to the economic detriment of the plaintiffs and the class.

417. J&J appreciated and retained the benefit bestowed upon it by the plaintiffs and class members.

418. It is inequitable and unjust for J&J to accept and retain such benefits without compensating the plaintiffs and class members.

11. Georgia

419. J&J unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for ustekinumab in Georgia. The plaintiffs and class members paid higher prices for ustekinumab than they would have paid but for J&J's actions.

420. J&J has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of J&J and to the economic detriment of the plaintiffs and the class.

421. Under the circumstances, it would be inequitable for J&J to retain such benefits without compensating the plaintiffs and the class.

12. Hawaii

422. J&J unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for ustekinumab in Hawaii. The plaintiffs and class members paid higher prices for ustekinumab than they would have paid but for J&J's actions.

423. J&J has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of J&J and to the economic detriment of the plaintiffs and the class.

424. It is unjust for J&J to retain such benefits without compensating the plaintiffs and the class.

13. Idaho

425. J&J unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for ustekinumab in Idaho. The plaintiffs and class members paid higher prices for ustekinumab than they would have paid but for J&J's actions.

426. J&J has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of J&J and to the economic detriment of the plaintiffs and the class.

427. J&J appreciated the benefit conferred upon it by the class.

428. Under the circumstances, it would be inequitable for J&J to retain such benefits without compensating the class.

14. Illinois

429. J&J unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for ustekinumab in Illinois. The plaintiffs and class members paid higher prices for ustekinumab than they would have paid but for J&J's actions.

430. J&J has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of J&J and to the economic detriment of the plaintiffs and the class.

431. J&J retained the benefits bestowed upon it under unjust circumstances arising from unlawful overcharges to the class.

432. It is against equity, justice, and good conscience for J&J to be permitted to retain the revenue resulting from its unlawful overcharges without compensating the plaintiffs and class members.

15. Iowa

433. J&J unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for ustekinumab in Iowa. The plaintiffs and class members paid higher prices for ustekinumab than they would have paid but for J&J's actions.

434. J&J has been enriched by revenue resulting from unlawful overcharges for ustekinumab, which revenue resulted from anticompetitive prices paid by the class, which inured to J&J's benefit.

435. J&J's enrichment has occurred at the expense of the class.

436. It is against equity and good conscience for J&J to retain such benefits without compensating the class.

16. Kansas

437. J&J unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for ustekinumab in Kansas. The plaintiffs and class members paid higher prices for ustekinumab than they would have paid but for J&J's actions.

438. J&J has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of J&J and to the economic detriment of the plaintiffs and the class.

439. J&J retained the benefits bestowed upon it under unjust circumstances arising from unlawful overcharges to the class.

440. J&J was unjustly enriched at the expense of the plaintiffs and the class members.

17. Kentucky

441. J&J unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for ustekinumab in Kentucky. The plaintiffs and class members paid higher prices for ustekinumab than they would have paid but for J&J's actions.

442. J&J has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of J&J and to the economic detriment of the plaintiffs and the class.

443. J&J appreciated the benefit bestowed upon it by the class.

444. Under the circumstances, it would be inequitable for J&J to retain such benefits without compensating the class.

18. Louisiana

445. J&J unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for ustekinumab in Louisiana. The plaintiffs and class members paid higher prices for ustekinumab than they would have paid but for J&J's actions.

446. J&J has been enriched by revenue resulting from unlawful overcharges for brand and ustekinumab.

447. The plaintiffs and class members have been impoverished by the overcharges for ustekinumab resulting from J&J's unlawful conduct.

448. J&J's enrichment and the impoverishment of the plaintiffs and the class are connected.

449. There is no justification for J&J's receipt of the benefits causing its enrichment and the class's impoverishment because the plaintiffs and the class paid supra-competitive prices that inured to J&J's benefit, and it would be inequitable for J&J to retain any revenue gained from its unlawful overcharges.

450. The plaintiffs and the class have no other remedy at law.

19. Maine

451. J&J unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for ustekinumab in Maine. The plaintiffs and class members paid higher prices for ustekinumab than they would have paid but for J&J's actions.

452. J&J has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of J&J and to the economic detriment of the plaintiffs and the class.

453. J&J was aware of or appreciated the benefit bestowed upon it by the plaintiffs and the class.

454. Under the circumstances, it would be inequitable for J&J to retain such benefits without compensating the class.

20. Maryland

455. J&J unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for ustekinumab in Maryland. The plaintiffs and class members paid higher prices for ustekinumab than they would have paid but for J&J's actions.

456. J&J has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of J&J, to the economic detriment of the plaintiffs and the class.

457. J&J was aware of or appreciated the benefit bestowed upon it by the class.

458. Under the circumstances, it would be inequitable for J&J to retain such benefits without compensating the class.

21. Massachusetts

459. J&J unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for ustekinumab in Massachusetts. The plaintiffs and class members paid higher prices for ustekinumab than they would have paid but for J&J's actions.

460. J&J has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of J&J and to the economic detriment of the plaintiffs and the class.

461. J&J was aware of and/or appreciated the benefit conferred upon it by the class.

462. Under the circumstances, it would be inequitable for J&J to retain such benefits without compensating the class. Fairness and good conscience require J&J not be permitted to retain the revenue resulting from its unlawful overcharges at the expense of the plaintiffs and class members.

22. Michigan

463. J&J unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for ustekinumab in Michigan. The plaintiffs and class members paid higher prices for ustekinumab than they would have paid but for J&J's actions.

464. J&J has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of J&J.

465. J&J retained the benefits bestowed upon it under unjust circumstances arising from unlawful overcharges to the class.

466. J&J was unjustly enriched at the expense of the plaintiffs and the class members.

23. Minnesota

467. J&J unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for ustekinumab in Minnesota. The plaintiffs and class members paid higher prices for ustekinumab than they would have paid but for J&J's actions.

468. J&J appreciated and knowingly accepted the benefits bestowed upon it by the plaintiffs and class members. J&J has paid no consideration to any other person for any of the benefits they have received from the plaintiffs and class members.

469. It would be inequitable for J&J to accept and retain such benefits without compensating the class.

24. Mississippi

470. J&J unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for ustekinumab in Mississippi. The plaintiffs and class members paid higher prices for ustekinumab than they would have paid but for J&J's actions.

471. J&J received money from the class as a direct result of the unlawful overcharges. J&J retains the benefit of overcharges received on the sales of brand ustekinumab, which in equity and good conscience belong to the class on account of J&J's anticompetitive conduct.

472. Under the circumstances, it would be inequitable for J&J to retain such benefits without compensating the class.

25. Missouri

473. J&J unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for ustekinumab in Missouri. The plaintiffs and class members paid higher prices for ustekinumab than they would have paid but for J&J's actions.

474. J&J has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of J&J and to the economic detriment of the plaintiffs and the class.

475. J&J appreciated the benefit bestowed upon it by the class.

476. J&J accepted and retained the benefit bestowed upon it under inequitable and unjust circumstances arising from unlawful overcharges to the class.

26. Montana

477. J&J unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for ustekinumab in Montana. The plaintiffs and class members paid higher prices for ustekinumab than they would have paid but for J&J's actions.

478. The plaintiffs and the class have conferred an economic benefit upon J&J in the form of revenue resulting from unlawful overcharges to the economic detriment of the plaintiffs and the class.

479. Under the circumstances, it would be inequitable for J&J to retain such benefits without compensating the class.

27. Nebraska

480. J&J unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for ustekinumab in Nebraska. The plaintiffs and class members paid higher prices for ustekinumab than they would have paid but for J&J's actions.

481. J&J received money from the class as a direct result of the unlawful overcharges and have retained this money. J&J has paid no consideration to any other person in exchange for this money.

482. In justice and fairness, J&J should disgorge such money and remit the overcharged payments back to the class.

28. Nevada

483. J&J unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for ustekinumab in Nevada. The plaintiffs and class members paid higher prices for ustekinumab than they would have paid but for J&J's actions.

484. The plaintiffs and the class have conferred an economic benefit upon J&J in the form of revenue resulting from unlawful overcharges.

485. J&J appreciated the benefits bestowed upon it by the class, for which it has paid no consideration to any other person.

486. J&J has knowingly accepted and retained the benefits bestowed upon it by the plaintiffs and class members.

487. The circumstance under which J&J has accepted and retained the benefits bestowed on it by the plaintiffs and the class are inequitable in that they result from J&J's unlawful overcharges.

29. New Hampshire

488. J&J unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for ustekinumab in New Hampshire. The plaintiffs and class members paid higher prices for ustekinumab than they would have paid but for J&J's actions.

489. J&J has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of J&J and to the economic detriment of the plaintiffs and the class.

490. Under the circumstances, it would be unconscionable for J&J to retain such benefits.

30. New Jersey

491. J&J unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for ustekinumab in New Jersey. The plaintiffs and class members paid higher prices for ustekinumab than they would have paid but for J&J's actions.

492. J&J has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of J&J and to the economic detriment of the plaintiffs and the class.

493. The benefits conferred upon defendants were not gratuitous, in that they comprised revenue created by unlawful overcharges arising from arising from unlawful overcharges to the plaintiffs and class members.

494. J&J has paid no consideration to any other person for any of the unlawful benefits they received from the plaintiffs and class members with respect to J&J's sales of brand ustekinumab.

495. Under the circumstances, it would be unjust for defendants to retain such benefits without compensating the plaintiffs and class members.

31. New Mexico

496. J&J unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for ustekinumab in New Mexico. The plaintiffs and class members paid higher prices for ustekinumab than they would have paid but for J&J's actions.

497. J&J has knowingly benefitted at the expense of the class from revenue resulting from unlawful overcharges for ustekinumab.

498. To allow J&J to retain the benefits would be unjust because the benefits resulted from anticompetitive pricing that inured to J&J's benefit and because J&J has paid no consideration to any other person for any of the benefits it received.

32. New York

499. J&J unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for ustekinumab in New York. The plaintiffs and class members paid higher prices for ustekinumab than they would have paid but for J&J's actions.

500. J&J has been enriched by revenue resulting from unlawful overcharges for brand ustekinumab, which revenue resulted from anticompetitive prices paid by the class, which inured to J&J's benefit.

501. J&J's enrichment has occurred at the expense of the class.

502. It is against equity and good conscience for J&J to be permitted to retain the revenue resulting from its unlawful overcharges.

33. North Carolina

503. J&J unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for ustekinumab in North Carolina. The plaintiffs and class members paid higher prices for ustekinumab than they would have paid but for J&J's actions.

504. J&J has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of J&J and to the economic detriment of the plaintiffs and the class.

505. The class did not interfere with J&J's affairs in any manner that conferred these benefits upon J&J.

506. The benefits conferred upon J&J were not gratuitous, in that they comprised revenue created by unlawful overcharges arising from J&J's actions in delaying entry of generic versions of ustekinumab to the market and preventing fulsome generic competition in the market for ustekinumab.

507. The benefits conferred on J&J are measurable, in that the revenue J&J has earned due to unlawful overcharges are ascertainable by review of sales records.

508. J&J consciously accepted the benefits conferred upon it and continues to do so as of the date of this filing.

34. North Dakota

509. J&J unlawfully profited from overcharges paid by class members who made purchases of or reimbursements for ustekinumab in North Dakota. Class members paid higher prices for ustekinumab than they would have paid but for J&J's actions.

510. J&J has been enriched by revenue resulting from unlawful overcharges paid by plaintiffs and members of the class.

511. The class has been impoverished by the overcharges for ustekinumab resulting from J&J's unlawful conduct.

512. J&J's enrichment and the class's impoverishment are connected. J&J has paid no consideration to any other person for any benefits it received directly or indirectly from class members.

513. There is no justification for J&J's receipt of the benefits causing its enrichment because the class paid supra-competitive prices that inured to J&J's benefit, and it would be inequitable for J&J to retain any revenue gained from its unlawful overcharges.

514. The class has no remedy at law.

35. Oklahoma

515. J&J unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for ustekinumab in Oklahoma. The plaintiffs and class members paid higher prices for ustekinumab than they would have paid but for J&J's actions.

516. J&J received money from the plaintiffs and class members as a direct result of the unlawful overcharges and have retained this money.

517. J&J has paid no consideration to any other person in exchange for this money.

518. The plaintiffs and class members have no remedy at law.

519. It is against equity and good conscience for J&J to be permitted to retain the revenue resulting from its unlawful overcharges.

36. Oregon

520. J&J unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for ustekinumab in Oregon. The plaintiffs

and class members paid higher prices for ustekinumab than they would have paid but for J&J's actions.

521. J&J has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of J&J and to the economic detriment of the plaintiffs and the class.

522. J&J was aware of the benefit bestowed upon it by the class.

523. Under the circumstances, it would be unjust for J&J to retain any of the overcharges derived from its unfair conduct without compensating the plaintiffs and the class.

37. Pennsylvania

524. J&J unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for ustekinumab in Pennsylvania. The plaintiffs and class members paid higher prices for ustekinumab than they would have paid but for J&J's actions.

525. J&J has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of J&J and to the economic detriment of the plaintiffs and the class.

526. J&J was aware of and/or appreciated the benefit bestowed upon it by the class.

527. Under the circumstances, it would be inequitable for J&J to retain such benefits without compensating the class.

38. Puerto Rico

528. J&J unlawfully profited from overcharges paid by class members who made purchases of or reimbursements for ustekinumab in Puerto Rico. Class members paid higher prices for ustekinumab than they would have paid but for J&J's actions.

529. J&J has been enriched by revenue resulting from unlawful overcharges.

530. The class has been impoverished by the overcharges for ustekinumab resulting from J&J's unlawful conduct.

531. J&J's enrichment and the class's impoverishment are connected.

532. There is no justification for J&J's receipt of the benefits causing its enrichment and the class's impoverishment because the class paid supra-competitive prices that inured to J&J's benefit, and it would be inequitable for J&J to retain any revenue gained from its unlawful overcharges.

533. The class has no remedy at law.

39. Rhode Island

534. J&J unlawfully profited from overcharges paid by class members who made purchases of or reimbursements for ustekinumab in Rhode Island. Class members paid higher prices for ustekinumab than they would have paid but for J&J's actions.

535. J&J has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of J&J and to the economic detriment of the class.

536. J&J was aware of and/or recognized the benefit bestowed upon it by the class.

537. Under the circumstances, it would be inequitable for J&J to retain such benefits without compensating the class.

40. South Carolina

538. J&J unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for ustekinumab in South Carolina. The plaintiffs and class members paid higher prices for ustekinumab than they would have paid but for J&J's actions.

539. The benefits conferred upon J&J were not gratuitous, in that they comprised revenue created by unlawful overcharges arising from unlawful overcharges to the class.

540. J&J realized value from the benefit bestowed upon it by the class.

541. Under the circumstances, it would be inequitable for J&J to retain such benefits without compensating the class.

41. South Dakota

542. J&J unlawfully profited from overcharges paid by class members who made purchases of or reimbursements for ustekinumab in South Dakota. Class members paid higher prices for ustekinumab than they would have paid but for J&J's actions.

543. J&J has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of J&J and to the economic detriment of the class.

544. J&J was aware of the benefit bestowed upon it by the class.

545. Under the circumstances, it would be inequitable and unjust for J&J to retain such benefits without reimbursing the class.

42. Tennessee

546. J&J unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for ustekinumab in Tennessee. The plaintiffs and class members paid higher prices for ustekinumab than they would have paid but for J&J's actions.

547. J&J has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of J&J and to the economic detriment of the plaintiffs and the class.

548. J&J was aware of or appreciated the benefit bestowed upon it by the class.

549. Under the circumstances, it would be inequitable for J&J to retain such benefits without compensating the class.

550. It would be futile for the class to seek a remedy from any party with whom they have privity of contract. J&J has paid no consideration to any other person for any of the unlawful benefits they received indirectly from the class with respect to J&J's sale of ustekinumab. It would be futile for the class to exhaust all remedies against the entities with which the class has privity of contract because the class did not purchase ustekinumab directly from any defendant.

43. Texas

551. J&J unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for ustekinumab in Texas. The plaintiffs and class members paid higher prices for ustekinumab than they would have paid but for J&J's actions.

552. J&J has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of J&J, to the economic detriment of the plaintiffs and class members.

553. J&J was aware of and/or appreciated the benefit bestowed upon it by the plaintiffs and class members.

554. The circumstances under which J&J has retained the benefits bestowed upon it by the plaintiffs and class members are inequitable in that they result from J&J's unlawful conduct.

555. The plaintiffs and class members have no remedy at law.

44. Utah

556. J&J unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for ustekinumab in Utah. The plaintiffs and

class members paid higher prices for ustekinumab than they would have paid but for J&J's actions.

557. J&J has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of J&J and to the economic detriment of the plaintiffs and the class.

558. J&J was aware of and/or appreciated the benefit bestowed upon it by the class.

559. Under the circumstances, it would be inequitable for J&J to retain such benefits without compensating the class.

45. Vermont

560. J&J unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for ustekinumab in Vermont. The plaintiffs and class members paid higher prices for ustekinumab than they would have paid but for J&J's actions.

561. J&J has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of J&J and to the economic detriment of the plaintiffs and the class.

562. J&J accepted the benefit bestowed upon it by the class.

563. Under the circumstances, it would be inequitable for J&J to retain such benefits without compensating the class.

46. Virginia

564. J&J unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for ustekinumab in Virginia. The plaintiffs and class members paid higher prices for ustekinumab than they would have paid but for J&J's actions.

565. J&J has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of J&J and to the economic detriment of the plaintiffs and the class.

566. J&J was aware of the benefit bestowed upon it.

567. J&J should reasonably have expected to repay the class.

568. The benefits conferred upon J&J were not gratuitous, in that they constituted revenue created by unlawful overcharges arising from the J&J's illegal and unfair actions to inflate the prices of ustekinumab.

569. J&J has paid no consideration to any other person for any of the benefits it has received from the class.

47. Washington

570. J&J unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for ustekinumab in Washington. The plaintiffs and class members paid higher prices for ustekinumab than they would have paid but for J&J's actions.

571. J&J has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of J&J and to the economic detriment of the plaintiffs and the class.

572. J&J was aware of and/or appreciated the benefit bestowed upon it by the class.

573. Under the circumstances, it would be inequitable for J&J to retain such benefits without compensating the class.

48. West Virginia

574. J&J unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for ustekinumab in West Virginia. The

plaintiffs and class members paid higher prices for ustekinumab than they would have paid but for J&J's actions.

575. J&J has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of J&J and to the economic detriment of the plaintiffs and the class.

576. J&J was aware of and/or appreciated the benefit bestowed upon it by the class.

577. Under the circumstances, it would be inequitable for J&J to retain such benefits without compensating the class.

49. Wisconsin

578. J&J unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for ustekinumab in Wisconsin. The plaintiffs and class members paid higher prices for ustekinumab than they would have paid but for J&J's actions.

579. J&J has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of J&J and to the economic detriment of the plaintiffs and the class.

580. J&J was aware of and/or appreciated the benefit bestowed upon it by the class.

581. Under the circumstances, it would be inequitable for J&J to retain such benefits without compensating the class.

50. Wyoming

582. J&J unlawfully profited from overcharges paid by class members who made purchases of or reimbursements for ustekinumab in Wyoming. Class members paid higher prices for ustekinumab than they would have paid but for J&J's actions.

583. J&J has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of J&J and to the economic detriment of the class.

584. J&J accepted, used, and enjoyed the benefits bestowed upon it by the class under inequitable and unjust circumstances arising from unlawful overcharges to class members.

585. Under the circumstances, it would be inequitable for J&J to retain such benefits.

DEMAND FOR RELIEF

WHEREFORE, the plaintiffs, on behalf of themselves and the class members, respectfully demand that this Court:

A. Determine that this action may be maintained as a class action pursuant to Rules 23(a), (b)(2), and (b)(3) of the Federal Rules of Civil Procedure; direct that reasonable notice of this action, as provided by Rule 23(c)(2), be provided to the class; and declare the plaintiffs as the class representatives;

B. Grant permanent injunctive relief pursuant to § 16 of the Clayton Act to remedy the ongoing anticompetitive effects of J&J's unlawful monopolization in the market for ustekinumab in the United States;

C. Grant permanent injunctive relief pursuant to § 16 of the Clayton Act to remedy J&J attempted monopolization in the market for ustekinumab in the United States;

D. Order J&J to divest the Momenta biosimilar manufacturing patents to a third party that is not incentivized to use the patents for anticompetitive purposes;

E. Conduct expedited discovery proceedings leading to a prompt trial on the merits before a jury on all claims and defenses;

F. Enter judgment against J&J and in favor of the plaintiffs and the class;

G. Award the class damages (including double or treble damages, where appropriate) in an amount to be determined at trial, plus interest in accordance with law;

H. Award the plaintiffs and the class members their costs of suit, including reasonable attorneys' fees as provided by law; and

I. Award such further and additional relief as is necessary to correct for the anticompetitive market effects J&J's unlawful conduct caused and as the Court may deem just and proper under the circumstances.

JURY DEMAND

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

Dated: December 7, 2023

Respectfully submitted,

/s/ William H. Monroe, Jr.
William H. Monroe, Jr. (VSB No. 27441)
Marc C. Greco (VSB No. 41496)
Kip A. Harbison (VSB No. 38648)
Michael A. Glasser (VSB No. 17651)
GLASSER AND GLASSER, P.L.C.
Crown Center, Suite 600
580 East Main Street
Norfolk, VA 23510
Telephone: (757) 625-6787
Fax: (757) 625-5959
bill@glasserlaw.com
marcg@glasserlaw.com
kip@glasserlaw.com
michael@glasserlaw.com

Thomas M. Sobol *(pro hac vice forthcoming)*
Kristen A. Johnson *(pro hac vice forthcoming)*
Hannah W. Brennan *(pro hac vice forthcoming)*

Rebekah Glickman-Simon *(pro hac vice forthcoming)*
HAGENS BERMAN SOBOL SHAPIRO LLP
One Faneuil Hall Square, 5th Floor
Boston, MA 02109
Tel: (617) 482-3700
Fax: (617) 482-3003
tom@hbsslaw.com
kristenj@hbsslaw.com
hannahb@hbsslaw.com
rebekahgs@hbsslaw.com

Peter D. St. Phillip *(pro hac vice forthcoming)*
Uriel Rabinovitz *(pro hac vice forthcoming)*
Raymond Girnys *(pro hac vice forthcoming)*
Charles Kopel *(pro hac vice forthcoming)*
LOWEY DANNENBERG, P.C.
44 South Broadway, Suite 1100
White Plains, NY 10601
Tel: 914.997.0500
PStPhillip@lowey.com
URabinovitz@lowey.com
Rgirnys@lowey.com
Ckopel@lowey.com