UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA

CAREFIRST OF MARYLAND, INC., GROUP HOSPITALIZATION AND MEDICAL SERVICES, INC., and CAREFIRST BLUECHOICE, INC., on behalf of themselves and all others similarly situated,

Plaintiffs,

v.

JOHNSON & JOHNSON and JANSSEN BIOTECH, INC.,

Defendants.

Civil Action No. 2:23-cv-00629-JKW-LRL

JURY TRIAL DEMANDED

THIRD AMENDED 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—into 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. In 2023, those earnings rose to nearly $7 billion in U.S. sales and nearly $10.9 billion worldwide. During the life of the product to date, J&J has grossed well over $60 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 then biosimilar products would then enter the U.S. marketplace.

4. However, J&J has been delaying, 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 its patent protection, and therefore its monopoly, over ustekinumab 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 (the '307 patent) covering use of ustekinumab to treat ulcerative colitis. During prosecution of the patent application, the patent examiner discovered that, per federal requirements,[1] J&J had posted on ClinicalTrials.gov several descriptions of its clinical trial testing ustekinumab to treat ulcerative colitis (NCT 236). This J&J trial, NCT 236, disclosed the *exact* method-of-using ustekinumab that J&J's patent application claimed was novel. And the patent examiner properly rejected J&J's patent application in light of J&J's postings on ClinicalTrials.gov. In response to this rejection, J&J made material misrepresentations and omissions to the patent examiner. Among other things, J&J's patent attorney, Eric Dichter: (i) falsely represented to the examiner that the results of J&J's NCT 236 clinical trial were *uncertain* and *unpredictable*; (ii) concealed documents from the *PTO* that J&J had previously submitted to the *FDA* that included material information regarding use of ustekinumab to treat ulcerative colitis and J&J's expectation *that NCT 236 would be successful* (i.e., that ustekinumab would successfully treat ulcerative colitis), including the trial protocol itself; (iii) intentionally omitted published articles (i.e., prior art) that showed ustekinumab *had been used to treat ulcerative colitis successfully* before the patent application was filed; and (iv) intentionally misled the examiner into accepting that he could issue the patent because the clinical results were not available as of the patent's priority date (patent law is clear that a clinical trial plan or protocol can inherently anticipate a claimed invention even where the results of that trial are not yet available).

[1] *See* 42 C.F.R. § 11.22.

6. The examiner justifiably relied on J&J's material misrepresentations and omissions and issued, incorrectly, the '307 patent to which J&J was not entitled. 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 to delay and substantially reduce competition.

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 covered by these patents 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 Momenta patents had no pro-competitive use to J&J for Stelara. Instead, J&J used the Momenta patents *against* biosimilar companies seeking to compete with 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 Amgen, the first would-be biosimilar competitor. It then threatened suit against every other would-be biosimilar entrant that would soon come to market with a competing biosimilar ustekinumab product¶. 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 '307 patent covering use of ustekinumab to treat ulcerative colitis through fraud on the PTO. Nonetheless, it used the Momenta biosimilar manufacturing patents and the '307 patent to sue (or threaten 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* 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. And J&J's acquisition of the Momenta 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 '307 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, with the launch of Wezlana on January 1, 2025, Selarsdi, Pyzchiva, and Yesintek in late February 2025, and Steqeyma and Otulfi in March 2025.

11. Because of J&J's unlawful acts, purchasers of ustekinumab in the United States have paid, and continue to pay, supra-competitive prices for ustekinumab. During the period of expected delay and impairment of biosimilar 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). The 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. Injunctive relief is sought to, among other things, enjoin J&J's use of the fraudulently acquired '307 patent and the Momenta biosimilar manufacturing 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. 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. 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, Northern Virginia, and Hampton Roads, 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. 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, Northern Virginia, and Hampton Roads.

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. 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.

22. 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.

23. 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.

24. 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.

25. 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

26. 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).

27. 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.

28. 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.

29. 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. Indeed, as of the date of this filing, Janssen is recruiting a new pharmaceutical sales representative to be based in Norfolk, Virginia, within this district and this division.

30. As alleged below, CareFirst purchased Stelara for its members who are located within this district and this division, including in Norfolk, Chesapeake, Virginia Beach, Suffolk, and James City County, Virginia.

31. CareFirst anticipates continuing to purchase Stelara for members located in this district and this division, in light of the frequently long-term nature of Stelara regimens. And as further alleged below, ustekinumab therapy to treat moderate-to-severe psoriasis has a persistency rate of about 81.4%.[2]

32. Stelara patient retention in this district and division is supported by easy access to infusion sites. According to the National Infusion Center Association, three infusion centers in Norfolk, Virginia, two centers in Chesapeake, Virginia, and one in Virginia Beach, Virginia administer Stelara infusions.

33. 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

[2] Zhun Cao et al., *Ustekinumab Dosing, Persistence, and Discontinuation Patterns in Patients with Moderate-to-Severe Psoriasis*, 26 J. Dermatolog. Treat. 113, 113 (2014).

scheme. J&J's unlawful conduct had a direct, substantial, and reasonably foreseeable effect on interstate commerce, including commerce within this district.

34. Aside from sales of Stelara, J&J transacts substantial business in this district, including business related to promotion and development of Stelara, and to the unlawful scheme alleged here.

35. J&J's fraudulent prosecution of Patent No. 10,961,307 before the U.S. Patent and Trademark Office, and its defense of *inter partes* reviews numbers IPR2023-01103 and IPR2023-01444 before Patent Trial and Appeal Board, occurred in this district. As alleged below, all three of these proceedings furthered J&J's scheme to unlawfully extend its monopoly in the market for ustekinumab.

36. Further, as of the date of filing the Amended Complaint in this action, J&J was actively recruiting for ten clinical trials within this district and this division, including a "Study to Assess the Long-Term Safety of Ustekinumab Versus Other Biologics in Patients with Crohn's Disease and Ulcerative Colitis" in Portsmouth, Virginia.[3]

37. 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.

[3] *See* Janssen Scientific Affairs, LLC, *A Study to Assess the Long-Term Safety of Ustekinumab Versus Other Biologics in Patients with Crohn's Disease and Ulcerative Colitis*, Global Trialfinder, https://globaltrialfinder.janssen.com/trial/CR108561 (last visited Feb. 5, 2024).

IV. REGULATORY AND ECONOMIC BACKGROUND

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

38. Drugs generally fall into one of two categories: small molecule or biologic.[4] 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.

39. 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.

40. 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.

41. 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 Patent Term Restoration Act of 1984.[5] 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

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

[5] Pub. L. No. 98-417, 98 Stat. 1585 (1984).

government-granted exclusivities (indeed, the U.S. patent system in general) is that the promise of monopolistic profits will drive innovation.

42. 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.

43. 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.[6] Under 42 U.S.C. § 262(a), a biologic manufacturer must submit a Biologic License Application (BLA) to the FDA before it can market its drug.[7] The FDA may grant the BLA if, among other things, the manufacturer has demonstrated that the biologic is "safe, pure, and potent."[8]

44. 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

[6] 42 U.S.C. § 262.

[7] 42 U.S.C. § 262(a).

[8] 42 U.S.C. § 262(a)(2)(C)(i)(I).

(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.

45. 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.[9]

46. 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 there are no "clinically meaningful differences" between the two in terms of "safety, purity, and potency."[10]

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[9] 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).

[10] 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

47. 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.[11] 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.

48. Under certain circumstances, pursuant to the BPCIA, 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."[12] Depending on the relevant state's laws, an interchangeable biosimilar may be substituted for the biologic at the pharmacy without a new prescription in the same way that generics are.[13] 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

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> 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).

[11] 42 U.S.C. § 262(k)(7).

[12] 42 U.S.C. § 262(i)(3).

[13] U.S. FDA, *Interchangeable Biological Products*, https://www.fda.gov/media/151094/download.

[and] can be expected to produce the same clinical result as the reference product in any given patient . . . ."[14]

49. The first biosimilar approved as interchangeable to the reference product enjoys an exclusivity period. The length of the exclusivity period depends on (a) whether, at the time the FDA granted the biosimilar maker's application for interchangeability, any patent infringement litigation related to that application (i) had already concluded, (ii) was ongoing, or (iii) had not yet begun; and (b) the date on which the interchangeable biosimilar was first commercially marketed.[15]

50. In 2019, the FDA issued final guidance to assist applicants in demonstrating that a biosimilar is interchangeable pursuant to the BPCIA.[16]

B. Generic and biosimilar competition lowers drug prices.

51. 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.

52. 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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[14] 42 U.S.C. § 262(k)(4).

[15] 42 U.S.C. § 262(k)(6); Mem. from Dr. Mustafa Unlu to Dr. Nikolay P. Nikolov (Oct. 3, 2023) (on file with the FDA), https://www.fda.gov/media/173749/download?attachment.

[16] FDA, *Considerations in Demonstrating Interchangeability with a Reference Product: Guidance for Industry* 1, 4 (2019).

53. These price drops translate into savings for consumers and health plans. According to the U.S. Generic and Biosimilar Medicines Savings report, in 2022, the use of generic and biosimilar drugs saved consumers about *$408 billion*, which includes $130 billion in Medicare savings, as well as an estimated $2.9 trillion over the past 10 years.[17]

54. Biosimilar competition is a relatively recent source of healthcare savings. The FDA approved the first biosimilar in 2015, and, as of December 2023, the FDA had approved only forty-five 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."[18] According to the 2023 U.S. Generic and Biosimilar Medicines Savings report, "biosimilars, on average, are priced more than 50 percent lower than the brand biologics [sic] price at the time of biosimilar launch."[19] And the "[b]rand biologics respond to biosimilar entry by lowering their prices to date, by 25 percent on average."[20]

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[17] Assoc. for Accessible Medicines, *The U.S. Generic & Biosimilar Medicines Savings Report* 7 (2023), https://accessiblemeds.org/sites/default/files/2023-09/AAM-2023-Generic-Biosimilar-Medicines-Savings-Report-web.pdf.

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

[19] Assoc. for Accessible Medicines, *The U.S. Generic & Biosimilar Medicines Savings Report* 30 (2023), https://accessiblemeds.org/sites/default/files/2023-09/AAM-2023-Generic-Biosimilar-Medicines-Savings-Report-web.pdf.

[20] *Id.*

55. 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 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.[21] 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.[22]

56. 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.[23]

57. The 2023 U.S. Generic and Biosimilar Medicines Savings report found that biosimilars generated $23.6 billion in savings since 2015, including over $9.4 billion in 2022 alone.[24] And a third study estimated that biosimilar entry could result in $100 billion in savings between 2020 and 2024.[25] These results were also confirmed by the 2022 Rand study published

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[21] Andrew W. Mulcahy, Zachary Predmore & Soeren Mattke, Rand Corp., *The Cost Savings Potential of Biosimilar Drugs in the United States* 7 & n.17 (2014).

[22] *Id.*

[23] Andrew W. Mulcahy et al., *Projected US Savings from Biosimilars, 2021-2025*, 28 Am. J. Managed Care 329, 331 (2022).

[24] Assoc. for Accessible Medicines, *The U.S. Generic & Biosimilar Medicines Savings Report* 27 (2023), https://accessiblemeds.org/sites/default/files/2023-09/AAM-2023-Generic-Biosimilar-Medicines-Savings-Report-web.pdf.

[25] IQVIA Inst., *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.

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 for reference biologics ($82.4 billion), the study found potential savings could reach $124.2 billion between 2021 and 2025.[26] In 2023, an IQVIA study concluded that savings from biosimilars would balloon to $181 billion between 2023 and 2027.[27]

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

58. 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.

59. A patent must claim a novel invention.[28] 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 applicant is not entitled to the patent and the PTO must deny the application.[29] Prior patents, publications, and other publicly known material before the filing date of the patent are known as

[26] Andrew W. Mulcahy et al., *Projected US Savings from Biosimilars, 2021-2025*, 28 Am. J. Managed Care 329, 334 (2022).

[27] IQVIA Inst., *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.

[28] 35 U.S.C. § 102.

[29] 35 U.S.C. § 102(a). Even disclosures by the inventor itself, or by one who obtained the subject matter directly from the inventor, provide grounds for denial of the patent application if made more than one year prior to the effective date. *Id.* § 102(b)(1). This provision is defined in MPEP § 2151 as the "one-year grace period."

"prior art." Over time, prior art accumulates—patents issue, publications reveal new discoveries, and new drugs go on sale.

60. The patent examination process is *ex parte*, meaning that the patent examiner engages in a dialogue with the applicant alone. The public, third parties, and even researchers in the same field are not a part of the patent examination process. As a result, the patent process is not an adversarial proceeding, and it lacks the safeguard of adverse parties pushing to present more facts to the examiner.

61. Because the proceedings are *ex parte*, 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 any prior art.[30] 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."[31] 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.

[30] 37 C.F.R. § 1.56(a).

[31] 37 C.F.R. § 1.56(c).

62. Deceiving the PTO, engaging in inequitable conduct, including misleading a patent examiner or giving inaccurate statements during the prosecution, or violating the duty of disclosure renders the patent invalid.

63. In addition, any party presenting (signing, filing, submitting, or advocating for) an application owes the PTO a duty of reasonable inquiry to ensure that all statements made in that application have *evidentiary support* (or, if so identified, are likely to have evidentiary support following further investigation or discovery).[32]

64. Failing to conduct a reasonable inquiry may result in the PTO "(1) striking the offending paper; (2) referring a practitioner's conduct to the Director of Enrollment and Discipline for appropriate action; (3) precluding a party or practitioner from submitting a paper, or presenting or contesting an issue; (4) affecting the weight given to the offending paper; or (5) terminating the proceedings in the Office."[33]

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

66. 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.

[32] 37 C.F.R. § 11.18.

[33] 37 C.F.R. § 11.18(c).

D. Regulatory frameworks permit challenges to drug patents.

67. The existence of one or more patents purporting to cover a drug product does not guarantee a monopoly. Patents are routinely invalidated or held unenforceable, whether through PTO reexamination, PTO *inter partes* proceedings, federal district court rulings of law, or federal district court jury verdicts. A patent holder always bears the burden of proving infringement.

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

69. A patent is invalid or unenforceable when: (i) the disclosed invention is anticipated and/or obvious in light of earlier prior art—i.e., it is not novel; (ii) its claims are indefinite, lack sufficient written description, or fail to properly enable the claimed invention; (iii) an inventor, an inventor's attorney, or another person involved with the application, with intent to mislead or deceive the PTO, fails to disclose material information, or submits materially false information to the PTO during prosecution; and/or (iv) when a later acquired patent is not patentably distinct from the invention claimed in an earlier patent (and no exception, such as the safe harbor, applies) (referred to as double patenting).

70. An assessment of whether a patent is obvious and therefore invalid is based on the prior art that existed as of the priority date of the claimed invention. "Prior art" refers to patents, published patent applications, and other non-patent sources, such as journal articles, that are publicly available. The "priority date" may be the date of the application for the claimed invention, or it may be an earlier date if, for example, the current patent application is a continuation of an earlier one.

1. The BPCIA Patent Dance

71. 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.

72. 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.[34] But the Hatch-Waxman Act and the BPCIA enable the patent holder (the brand 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,[35] and both laws lay out procedures for resolving the ensuing patent action.

73. 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.

74. 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

[34] 35 U.S.C. § 271(a).

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

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.[36] These steps unfold as follows.

75. 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).[37] These disclosures enable the patent holder to evaluate the biosimilar for possible patent infringement.[38] The information the aBLA applicant provides is subject to strict confidentiality rules.[39]

76. 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.[40] 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.[41]

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[36] 35 U.S.C. § 271(e)(4).

[37] 42 U.S.C. § 262(l)(2)(A).

[38] 42 U.S.C. § 262(l)(1)(D).

[39] *See* 42 U.S.C. § 262(l)(1)(H).

[40] 42 U.S.C. § 262(l)(3)(A)(i) (emphasis added).

[41] 42 U.S.C. § 262(l)(3)(A)(ii).

77. 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 . . . ."[42] The aBLA applicant also must respond to the patent holder's offer to license particular patents.[43] The aBLA applicant may further provide to the patent holder a list of patents that the aBLA applicant believes are relevant.[44]

78. 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 . . . ."[45]

79. 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.

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[42] 42 U.S.C. § 262(l)(3)(B)(ii).

[43] 42 U.S.C. § 262(l)(3)(B)(iii).

[44] 42 U.S.C. § 262(l)(3)(B)(i).

[45] 42 U.S.C. § 262(l)(3)(C).

80. Fifth, the parties negotiate in good faith a list of patents that "shall be the subject of" an ensuing patent infringement action.[46] 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.[47] The patent holder cannot select a greater number of patents than the aBLA applicant unless the aBLA applicant selects zero patents.[48] The exchange occurs on a 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.[49]

81. 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.[50]

82. 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.[51] 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

[46] 42 U.S.C. § 262(l)(4)(A).

[47] 42 U.S.C. §§ 262(l)(4)(B), (l)(5).

[48] 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).

[49] 42 U.S.C. § 262(l)(5)(B)(i).

[50] 42 U.S.C. §§ 262(l)(6)(A), (B).

[51] 35 U.S.C. § 271(e)(2)(C), (e)(4).

relevant biologic product or its use.[52] 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.[53]

83. The BPCIA also requires an aBLA applicant to provide the patent holder at least 180-days' notice before commercially marketing its biosimilar.[54] 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).[55] The injunctive relief of BPCIA litigation thus concerns all patents that the patent holder alleges are relevant.

84. 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.

[52] 42 U.S.C. § 262(l)(9)(C).

[53] 42 U.S.C. § 262(l)(9)(B).

[54] 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).

[55] 42 U.S.C. § 262(l)(8)(B).

2. *Inter Partes* Review

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

86. 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*.[56] 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*.[57] The authors concluded that their "data set suggests that the biotechnology patents that reach a merits ruling overwhelmingly

[56] 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.

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

lose."[58] 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."[59]

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

88. 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.[60]

89. 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

[58] *Id.*

[59] *Id.* at 1137.

[60] 35 U.S.C. § 311(b).

[one] of the claims challenged in the petition."[61] The PTAB must decide the review within one year of the institution date.[62]

90. 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 costs for patients and payors."[63] He added that "patent thickets that are purely designed to deter the entry of approved biosimilars are spoiling this sort of competition."[64]

E. End payers are typically the most efficient enforcer of state antitrust laws.

91. In the pharmaceutical area, direct and indirect (sometimes referred to as "end payer") purchasers and competitors may seek to enforce antitrust laws against drug manufacturers for alleged wrongdoing.

92. *Drug wholesalers as antitrust enforcers*. Over the years, private enforcement of federal antitrust laws has included actions brought by proposed classes of direct purchasers. Direct purchasers of pharmaceuticals are typically drug wholesalers, which purchase drugs from drug manufacturers in bulk and resell them to pharmacies and hospitals. However, several facts of U.S. pharmaceutical wholesaling teach that: (i) drug wholesalers are increasingly unlikely to

[61] 35 U.S.C. § 314(a).

[62] 35 U.S.C. § 316(a)(11).

[63] *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*, FDA (Jul. 18, 2018), https://www.fda.gov/news-events/press-announcements/remarks-fda-commissioner-scott-gottlieb-md-prepared-delivery-brookings-institution-release-fdas.

[64] *Id.*

bring antitrust class actions on behalf of direct purchasers; (ii) wholesalers are especially unlikely to do so with respect to specialty pharmaceuticals; and (iii) wholesalers rarely seek to enforce state antitrust laws. The defendants in this case treat Stelara as a specialty pharmaceutical and distribute the product through distribution agreements that provide significant buy-side revenue to J&J's contracted distributors.

93. *First*, increasing consolidation of U.S. drug wholesalers has led to fewer and fewer wholesalers distributing manufacturers' drug products. While this trend has been underway for quite some time, recent consolidations have created a situation where, even for non-specialty drug products, it is common to have fewer than 30 wholesalers directly purchasing a pharmaceutical product from the drug manufacturer. Indeed, today, 90% of prescription drugs in the United States are distributed by three drug wholesalers: AmerisourceBergen Corporation, Cardinal Health, Inc., and McKesson Corporation. For specialty drugs, the number of direct purchasers is typically much smaller. As a result, use of the class action mechanism can be more challenging (due to the smaller proposed class sizes) than when the number of direct drug purchasers was larger. While direct purchaser cases still are (and should be) certified, in recent years, courts have denied certification of a handful of proposed direct drug purchaser classes based on their ostensible lack of numerosity, and, in the wake of these denials, numerous direct drug purchasers did not file follow-on individual suits. This means that non-class direct drug purchaser actions enforce only some of the anticompetitive harm from the alleged violation. The fact that direct drug purchaser cases challenging delayed generic entry almost always (if not always) begin as class actions further underscores the importance of the class action mechanism to the efficiency of antitrust law enforcement.

94. *Second*, wholesalers increasingly make a considerable amount of their revenues from the "buy side" of drug transactions, i.e., from the side of the transaction with the drug manufacturer. Through payments for services rendered in distribution services agreements and other arrangements, wholesalers can reduce the accounting cost of drugs significantly. Some of these payments look like traditional arrangements between a supplier and wholesaler (e.g., prompt pay discounts, stocking allowances, and the like). But, through distribution service agreements, wholesalers also perform a variety of other services for the manufacturer and, in return, receive buy-side fees and other benefits. Common services include inventory management, meeting service targets with customers, and submitting data to the manufacturer about customer purchasing of the manufacturer's drugs. While specific drug-purchasing decisions are ultimately governed by the needs of the wholesaler's customers, the substantial buy-side revenues direct drug purchasers increasingly earn from the drug manufacturers dampens wholesalers' incentive to bite (i.e., sue) the hand that feeds them.

95. Furthermore, the buy-side economics can be particularly important to direct drug purchasers in the case of specialty drugs. Drug wholesalers compete to be one of the relatively few wholesalers with which a specialty drug manufacturer will contract for the limited distribution network of a specialty drug. Specialty drugs are typically more expensive than non-specialty brand and generic drugs and thus provide the wholesaler an opportunity to earn significant buy-side revenues. As a result, distribution agreements with specialty drug manufacturers can often account for more than *half* of the wholesaler's buy-side gross margin. And total buy-side economics is a significant driver of wholesaler total net revenues. Thus, again, the lucrativeness of specialty pharmaceutical distribution contracts mitigates direct drug purchasers' willingness to sue specialty pharmaceutical producers like J&J.

96. *Third*, direct drug purchasers are not efficient enforcers of *state* antitrust laws. Under the Clayton Act, direct purchasers have a nationwide, treble damages monetary remedy for violations of federal antitrust laws, including the Sherman Act. As a result—and given the similarity of substantive state and federal antitrust law—direct purchasers typically have little incentive to pursue state law damages remedies.

97. In sum, the combination of these factors significantly decreases the likelihood that direct drug purchasers will sue drug manufacturers to vindicate antitrust violations—especially where the higher drug prices that the antitrust violations enable mainly harm end payers (consumers and health insurers).

98. *Biosimilar (and generic) competitors as antitrust enforcers*. Over the years, while there has been some private enforcement of antitrust laws by would-be generic competitors, several features of the pharmaceutical industry and generic/biosimilar entry render would-be generic or biosimilar competitors inefficient enforcers of antitrust laws, particularly with respect to *Walker Process* fraud allegations.

99. *First*, competitor antitrust actions typically seek damages based on valuation of how much the competitor would have earned absent the alleged antitrust violation. And this valuation is typically dwarfed by the much larger damages the wrongdoer's purchasers have suffered by way of overcharges. This is because a generic or biosimilar competitor only seeks to recover its own damages, i.e., the lost profits that it would have been able to earn if allowed onto the market at any earlier date. In contrast, purchasers of medications that are overpriced as a result of anticompetitive conduct seek to recover the amount they overpaid as a result of *all* generic or biosimilar competition being excluded from the market—i.e., the damages incurred by multiple generic manufacturers, not just one, and not simply lost profit. As a result, purchaser

class actions pose a higher risk to brand antitrust violators (via higher potential damages awards) than competitor actions. And competitors have less of a financial incentive to bring such lawsuits (based on their lower potential damages recoveries) than purchasers of overpriced drugs. Thus, while competitors may have some self-interest in enforcing antitrust laws, that interest is typically much less than that of purchaser classes like the one proposed here.

100. *Second*, competitor challenges to brand company patents often prioritize attacks on the patent(s) based on lack of infringement rather than unenforceability (i.e., inequitable conduct or *Walker Process* fraud). This is because, if a competitor wins a lawsuit declaring that its product does not infringe the brand's patents, that lawsuit *only* allows that competitor onto the market. If the competitor wins a lawsuit suit declaring the brand's patent(s) invalid based on inequitable conduct or fraud, then that lawsuit allows *all* competitors to enter the market. And, all things equal, a would-be competitor would prefer to gain market entry for its *own* product only rather than open the market for *all* would-be competitors. Prevailing on a challenge to infringement does the former, while prevailing on an argument that the patent was procured by fraud opens the market for all. As a result, competitor patent challenges often place less emphasis on challenging the patent's overarching enforceability.

101. *Third*, the primary goal of the would-be competitor is market access, not litigating a lawsuit for a damage recovery. As a result, manufacturing competitors who challenge the brand's patents often settle for entry dates that are later than the date they would have been able to come to market absent the asserted patents, but earlier than the entry date the asserted patents allow. In exchange for the negotiated entry date, such settlements require the competitors to release all other claims—including antitrust claims—against the brand manufacturer. Thus,

competitor settlements of patent infringement lawsuits with brand manufacturers typically compromise any potential for enforcement of related antitrust actions.

102. This is particularly true for biosimilar companies. Biosimilar companies make significant investments pursuing aBLA or BLA approval and market access, and they need to recoup those investments through early launch of their product. When faced with actual or threatened litigation by a brand biologic company, biosimilar companies face real-world pressure to settle, regardless of the merits of the litigation. The consequence of this pressure is the biosimilars' abandonment of meritorious claims of anticompetitive behavior by the brand. As a result, especially for biologic drug products, there are strong reasons for competitors not to enforce antitrust laws for strategic business reasons.[65]

103. To date, the FDA has approved seven biosimilar versions of Stelara. The companies responsible for manufacturing and commercializing all seven have reached settlements with J&J. In six of the seven settlements, J&J demanded—and the biosimilar company acceded to granting J&J—a release of all claims. Tellingly, no would-be competitor to J&J for ustekinumab has sought to enforce the antitrust laws. Put another way, the conduct of the biosimilar ustekinumab manufacturers supports the plaintiffs' allegation that biosimilar competitors are not the most efficient enforcers of antitrust claims.

104. *Drug end payers as antitrust enforcers.* Over the years, private enforcement of antitrust laws for alleged violations causing delayed or impaired generic/biosimilar entry and

[65] While in a 2009 decision the Second Circuit remarked—without citing any empirical support—that patent fraud cases are "typically brought as counterclaims in patent infringement suits," *see In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 689 (2d Cir. 2009), two years later the Federal Circuit cut back on the ability of ostensible patent infringers to do so. *See Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011) (stating that this "court now tightens the standards for finding both intent and materiality in order to redirect a doctrine that has been overused to the detriment of the public").

thus higher drug prices has typically included claims brought by drug end payers. As between the three groups of potential private enforcers—direct drug purchasers, competing manufacturers, and end payer purchasers—the empirical, regulatory, and legal fact is that end payers of prescription drugs: (i) are efficient enforcers of antitrust laws; (ii) for biologics and specialty drug products, are likely the most efficient enforcer of antitrust laws; and (iii) as to state antitrust laws, are the most efficient private enforcer group.

105. *First*, in the United States, pharmaceutical end payers are the last stop in the drug payment chain and thus suffer the final legal overcharge. They do not pass on their overcharges to any further downstream party. As a result, no other private enforcers have as clear a claim to ultimate antitrust injury.

106. *Second*, drug end payers are especially efficient enforcers of *state* antitrust laws that provide an "*Illinois Brick* repealer" damages remedy to indirect purchasers. Indeed, courts recognize that end payer enforcement is the very "purpose of *Illinois Brick* repealer statutes."[66]

107. *Third*, drug end payers typically do not have direct product supply arrangements with drug manufacturers. Thus, they do not have the kind of reluctance that direct purchasers would, and do, have about suing drug manufacturers.

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[66] *D.R. Ward Constr. Co. v. Rohn & Haas Co.*, 470 F. Supp. 2d 485, 503 (E.D. Pa. 2006). State courts interpreting *Illinois Brick* repealer statutes regularly pronounce that plaintiffs' antitrust standing must be assessed in light of the clear legislative directive to extend recovery to indirect purchasers. *See, e.g.*, *Brown v. Hartford Healthcare Corp.*, No. 03-cv-22-6152239, 2023 WL 7150051, at *6 (Super. Ct. Conn. Oct. 26, 2023) ("[A]n antitrust standing analysis must be consistent with the legislature's rejection of federal antitrust law's prohibition of indirect purchaser claims and the passing-on defense."); *Lorix v. Crompton Corp.*, 736 N.W.2d 619, 629 (Minn. 2007) ("We do not believe that the legislature repudiated *Illinois Brick* and invited indirect purchaser suits only for courts to dismiss those suits on the pleadings based on the very concerns that motivated *Illinois Brick*."); *Knowles v. Visa U.S.A., Inc.*, No. 03-cv-707, 2004 WL 2475284, at *5 (Super. Ct. Me. Oct. 20, 2004) ("Maine's adoption of an *Illinois Brick* repealer further suggests that the court should not deny standing just because plaintiffs are not participants in the actual market where trade was allegedly restrained.").

108. *Fourth*, end payers are often motivated to address restraints of trade that impact important medications given the drugs' medical importance to their members.

109. *Finally*, the empirical fact is that private enforcement of antitrust laws for restraints on pharmaceutical competition is far more often undertaken by purchasers, not competitors. Generics have asserted an antitrust counterclaim in only a single-digit percent of the thousands of Hatch-Waxman patent litigation lawsuits filed against them by brand drug companies. And purchasers assert antitrust claims predicated on *Walker Process* fraud significantly more often than manufacturing competitors.

110. In summary, due to myriad dynamics faced by biosimilar competitors and direct purchasers, these actors are not only unlikely to enforce, but indeed *have not* enforced, antitrust laws based on alleged *Walker Process* violations.

111. In this case, the most efficient enforcer of antitrust laws is the proposed class of Stelara end payers. The plaintiff end payers and their counsel investigated, discovered, developed, and filed the case—no other potential enforcer of the implicated laws did so. And even though this case has been public for many months, no other private enforcer (direct purchaser or biosimilar competitor) or public enforcer (e.g., state attorney general) has filed suit. For this case, the efficient and only enforcer is drug end payers.

V. FACTS

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

112. 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.

113. 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.

114. 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 to distinguish in patients, and confusion on which condition a patient has occurs in about 30% of patients."[67] 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.

115. 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

[67] Decl. of Michael S. Epstein, Ex. 1002 ¶ 35, *Samsung Bioepis Co., Ltd, v. Janssen Biotech, Inc.*, No. IPR2023-01103 (June 21, 2023), Paper No. 1002.

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).

116. Interleukin 12 (IL-12) and Interleukin 23 (IL-23)[68] 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.[69]

117. 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 these proteins from binding to IL-12Rβ1 receptor. By blocking the IL-12 and 23 pathways, ustekinumab prevents the dangerous inflammatory response.[70]

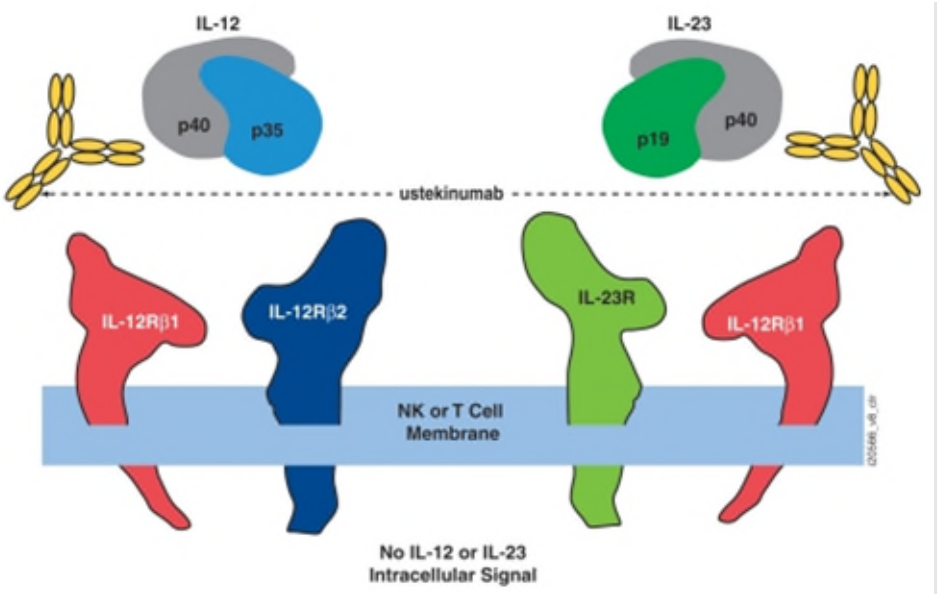
118. In the diagram below, ustekinumab is the yellow protein binding to the grey p40 subunit of the IL-12 or IL-23 proteins, preventing those proteins from binding with the IL-12Rβ1, receptors, depicted in red.[71]

[68] 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.

[69] Jacqueline M. Benson et al., *Discovery and Mechanism of Ustekinumab*, 3 MABS 535, 543 (2011).

[70] *Id.* at 537.

[71] *Id.* at 540 fig. 4.



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

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

120. 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.

121. 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, 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.

122. 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.

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

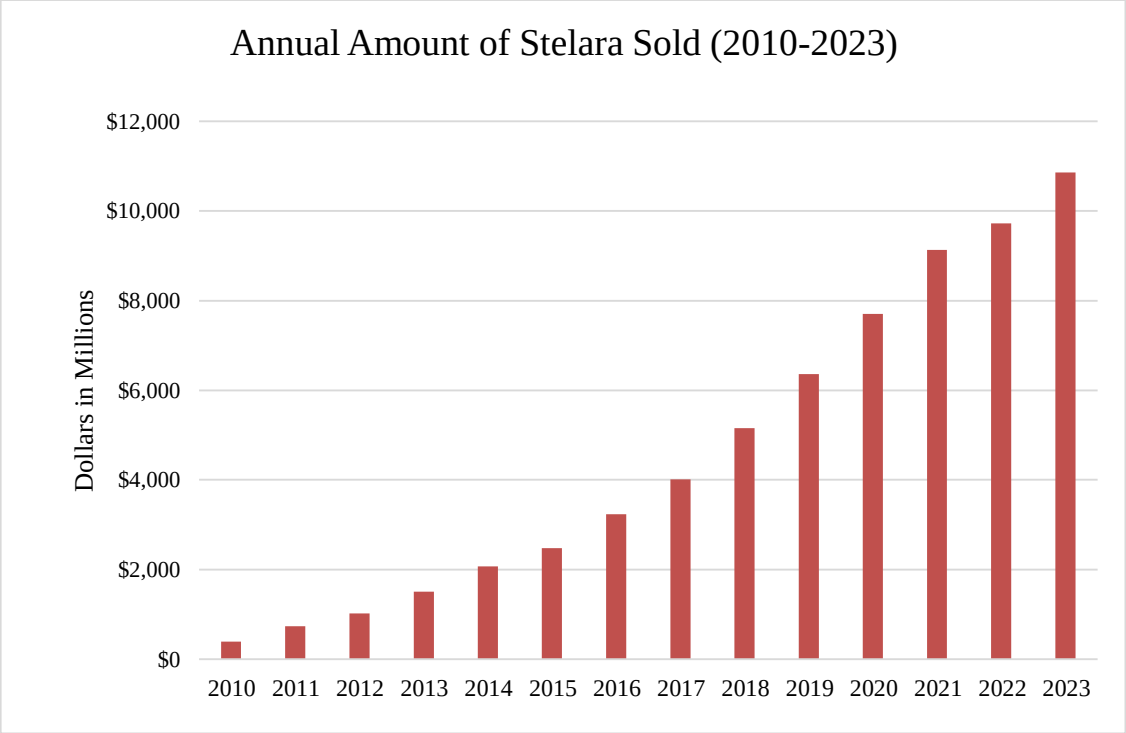
124. On September 23, 2016, the FDA approved Stelara to treat moderately to severely active Crohn's Disease.

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

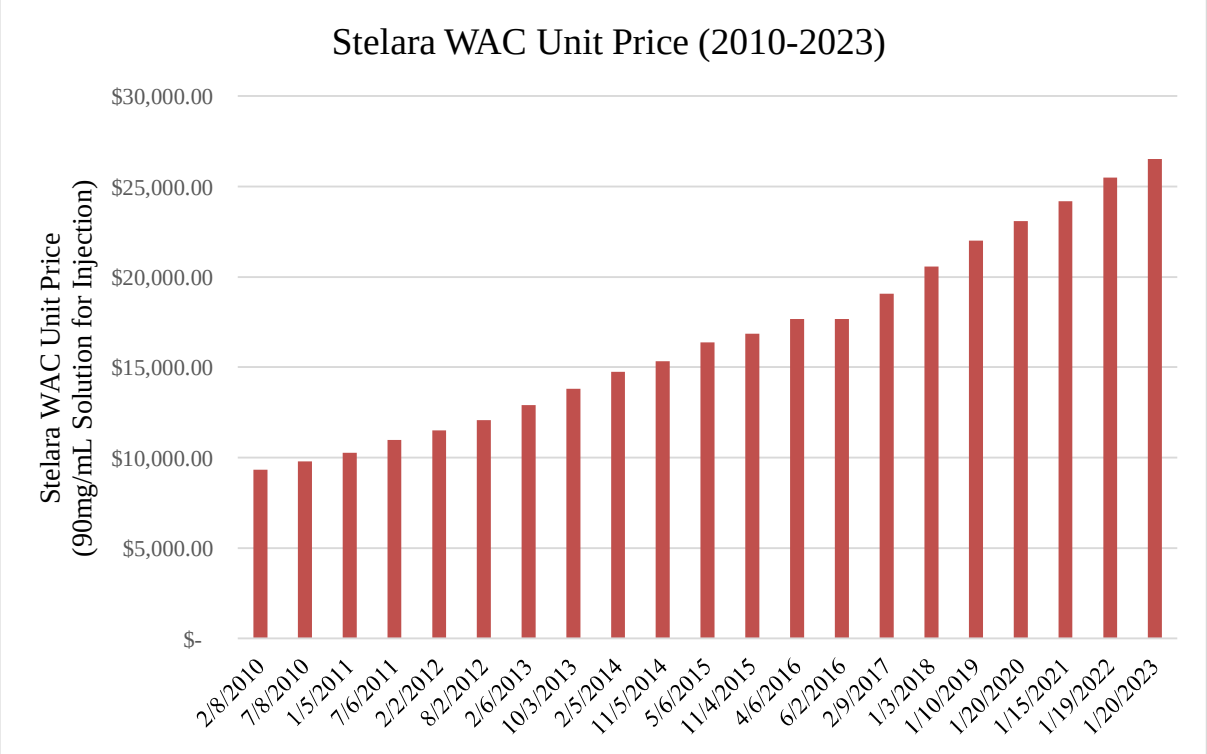
125. For at least 14 years—from September 2009 (product launch) to September 25, 2023 (expiration of the '734 patent covering the composition of ustekinumab)—J&J enjoyed exclusive, patent-protected sales of Stelara.

126. 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).

127. Over those years, J&J grossed over $60 billion in sales of Stelara. Indeed, today, Stelara remains J&J's best-selling product both in the United States and worldwide, delivering nearly $7 billion in net U.S. sales revenue and roughly $10.9 billion in worldwide sales in 2023.



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



129. 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 followed by 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.

130. Between 2019 and 2021, J&J defrauded a PTO patent examiner into incorrectly issuing a method-of-use patent to which J&J was not entitled covering the use of ustekinumab to treat ulcerative colitis conditions. The purpose and effect of J&J's fraud was to unlawfully extend its monopoly beyond September 2023.

131. 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 documented ustekinumab's ability to treat autoimmune diseases related to the IL-12 and IL-23 proteins, including ulcerative colitis.

132. Since the early 2000s, monoclonal antibodies, like ustekinumab, have been used to treat inflammatory bowel diseases.[72]

133. 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.

[72] 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 ¶ 39, *Samsung Bioepis Co., Ltd, v. Janssen Biotech, Inc.*, No. IPR2023-01103 (June 21, 2023), Paper No. 1002.

134. 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."[73]

135. In 2008, Centocor, Janssen's predecessor and also a J&J wholly-owned subsidiary, launched a Phase 2b clinical trial studying the efficacy of ustekinumab in patients with Crohn's.[74] In 2012, several J&J employees and consultants—including an inventor listed on the '307 patent application filed almost seven years later—published an article in the New England Journal of Medicine discussing the positive results of the 2008 Phase 2b study of ustekinumab to treat Crohn's.[75]

136. 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."[76]

137. 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.

138. In 2011, J&J launched three Phase 3 trials studying ustekinumab's impact on Crohn's. In launching these trials, J&J recognized the potential efficacy of ustekinumab to treat inflammatory bowel diseases. The clinical trials were completed in July 2013, October 2014, and

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

[74] *A Study of Safety and Effectiveness of Ustekinumab in Patients with Moderate to Severe Active Crohn's Disease Who Have Been Previously Treated with Anti-TNF Therapy*, ClinicalTrials.gov (Apr. 1, 2013), https://clinicaltrials.gov/study/NCT00771667.

[75] William J. Sandborn et al., *Ustekinumab Induction and Maintenance Therapy in Refractory Crohn's Disease*, 367 New Eng. J. Med. 1519, 1528(2012), https://www.nejm.org/doi/pdf/10.1056/NEJMoa1203572?articleTools=true.

[76] 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/.

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. Shortly thereafter, several J&J employees and consultants—including two inventors listed on the '307 patent application filed three years later—again published an article in the New England Journal of Medicine discussing the successful results.[77]

139. 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.

140. In November 2014, researchers in South Africa noted that ulcerative colitis was an "[o]ff-label indication" for ustekinumab (the Tarr reference).[78]

141. 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—on ClinicalTrials.gov (the 2015 CT posting).

142. According to the 2015 CT posting, 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 subcutaneous Stelara. The inclusion criteria specified that study participants would: (1) have been clinical diagnosed with ulcerative colitis at

[77] Brian G. Feagan et al., *Ustekinumab as Induction and Maintenance Therapy for Crohn's Disease*, 375 New Eng. J. Med. 1946, 1960 (2016), https://www.nejm.org/doi/pdf/10.1056/NEJMoa1602773?articleTools=true.

[78] G.S. 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.

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.

143. As stated in the 2015 CT posting, the induction and maintenance studies' 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. Specifically, they included: (i) global clinical remission defined as Mayo score ≤ 2 points with no individual subscore > 1 and in the US, defined as absolute stool number ≤ 3, a rectal bleeding subscore of 0, and a Mayo endoscopy subscore of 0 or 1**;** (ii) endoscopic healing defined as Mayo endoscopic subscore of 0 or 1; (iii) mean change from baseline in Inflammatory Bowel Disease Questionnaire (IBDQ) score; and (iv) clinical response defined as a decrease from induction baseline in the Mayo score by ≥ 30% and ≥ 3 points, with either a decrease from induction baseline in the rectal bleeding subscore ≥ 1 or a rectal bleeding subscore of 0 or 1.

144. On March 17, 2015, J&J signed and approved the clinical trial protocol for a Phase 3 clinical study of the use of ustekinumab to treat ulcerative colitis (the NCT 236 Protocol). At least two J&J employees who would later be named as inventors of the '307 patent participated in preparing this document.

145. In the NCT 236 Protocol, J&J relied on results from the Crohn's clinical trials to justify going direct-to-Phase 3, representing to the FDA that "[d]ata 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."[79]

146. In the NCT 236 Protocol, J&J further represented to the FDA that "the inflammatory mechanisms at the mucosal level between [ulcerative colitis and Crohn's disease] are largely the same," citing to the Granlund study. J&J also explicitly relied on the Jostins study: "similar conclusions were reached in the genome-wide association study of IBD patients conducted by Jostins and colleagues."[80]

147. In the NCT 236 Protocol, J&J further represented to the FDA that while ustekinumab has not been studied in 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*."[81] It then mirrored the dosage used in the Crohn's trial for the NCT 236 trial: "[t]he doses selected for this Phase 3 protocol for ustekinumab in subjects with UC parallel those being studied in the Phase 3 program for ustekinumab in subjects with Crohn's disease."[82]

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

149. On February 11, 2017, researchers in Paris, France, led by My-Linh Tran-Minh, 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 (the

[79] JNJ-STELARA_002410786 at page 7.

[80] *Id*. at page 25, 114.

[81] *Id*. at page 41 (emphasis added).

[82] *Id*.

Tran-Minh study).[83] 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 Tran-Minh study concluded that ustekinumab could effectively treat ulcerative colitis patients experiencing chronic pouchitis refractory to immunosuppressants and anti-TNF treatments.[84]

150. On February 25, 2017, researchers in Santander, Spain, led by L. Senra Afonso, reported a retrospective observational study that treated seven patients, two with ulcerative colitis and five with Crohn's, with ustekinumab (the "Senra Afonso study").[85] The Senra Afonso study concluded that "[u]stekinumab is a therapeutic approach for [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."[86]

151. 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."[87] Put another way, recognizing the efficacy of ustekinumab to treat

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[83] My-Linh Tran-Minh, Matthieu Allez & Jean-Marc Gornet, *Successful Treatment with Ustekinumab for Chronic Refractory Pouchitis*, 11 J. Crohn's & Colitis 1156, 1156 (2017), *available at* https://academic.oup.com/ecco-jcc/article/11/9/1156/2983512.

[84] *Id.*

[85] L. Senra Afonso et al., *CP-202 Ustekinumab Treatment in Refractory Inflammatory Bowel Disease*, 24 Eur. J. Hosp. Pharmacy (2017), *available at* https://ejhp.bmj.com/content/24/Suppl_1/A90.2.

[86] *Id.*

[87] *Ustekinumab (Stelara)* § 6, *in* Canadian Agency for Drugs & Technologies, *Common Drug Review* (2017), *available at* https://www.ncbi.nlm.nih.gov/books/NBK476200/?report=printa.

ulcerative colitis, Canadian doctors were already beginning to prescribe the drug off-label to treat ulcerative colitis (the Canadian reference).

152. On January 16, 2018, researchers in Munich, Germany, led by Dr. Thomas Ochsenkühn, 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" (the "Ochsenkühn study").[88] 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."[89] The Ochsenkühn study 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 for refractory UC."[90] The Ochsenkühn study thus explained to the public that ustekinumab could be used to treat ulcerative colitis effectively. Dr. Thomas Ochsenkühn presented this study at the European Crohn's and Colitis Organisation (ECCO) conference in February 2018 in Vienna, Austria as well as at the Digestive Disease Week (DDW) conference in June 2018 in Washington, D.C.

153. On February 1, 2018, researchers in Zurich, Switzerland, led by Dr. Antonios Kolios, issued a case study of successful treatment of a patient who developed paradoxical ulcerative colitis with ustekinumab (the "Kolios study").[91] The Kolios study's results suggested

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[88] Thomas Ochsenkühn et al., *P759 Ustekinumab as Rescue Treatment in Therapy-Refractory or -Intolerant Ulcerative Colitis*, 12 J. Crohn's & Colitis S495 (2018), *available at* https://academic.oup.com/ecco-jcc/article/12/supplement_1/S495/4808137.

[89] *Id.*

[90] *Id.*

[91] 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), *available at* https://academic.oup.com/bjd/article-abstract/178/2/551/6732166.

"that ustekinumab is an effective treatment option in patients with paradoxical anti-TNF-driven inflammatory reactions like psoriasis or IBD."[92]

154. 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 measures.

155. By September 2018, the public prior art references 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 in treating 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 was treating ulcerative colitis patients across the globe with ustekinumab in its NCT 236—as shown in the 2017 CT posting on ClinicalTrials.gov.

156. Thus, by September 2018, J&J 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.

157. On September 24, 2018, J&J filed provisional application 62/735,501, describing the allegedly novel invention that would ultimately become the '307 patent.

[92] *Id.*

158. On November 20, 2018, J&J filed its second provisional application, No. 62/769,818, describing the same alleged invention.

159. On September 4, 2019, J&J filed its third provisional application, No. 62/895,774, describing the same alleged invention.

160. On September 24, 2019, J&J filed nonprovisional Patent Application 16/580,509 (the ’509 application), seeking a method-of-use patent covering use of ustekinumab to treat moderately to severely active ulcerative colitis. The application claimed a priority date of September 24, 2018.

161. Public knowledge prior to September 24, 2018 regarding the ostensible invention in the application—including published medical journal articles and other publicly available information—could render the application not approvable. And based on the one-year grace period, disclosures by J&J itself or by a named inventor—including the postings on ClinicalTrials.gov—could provide grounds for denial of the patent application if made prior to September 24, 2017.

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

162. On September 24, 2019, J&J, through its counsel, Eric Dichter, filed the nonprovisional ’509 application for a patent claiming the method of using ustekinumab to treat ulcerative colitis. At the time of filing this patent application, Mr. Dichter had worked as counsel for J&J for about 15 years, including for more than 10 years as Assistant General Counsel. Between 2015 and filing the ’509 application, Mr. Dichter had prosecuted more than a dozen patents on behalf of J&J.

163. Numerous J&J employees were listed as inventors in Janssen’s method-of-use patent application, including Kimberly Shields-Tuttle (Janssen), Katherine Li (Janssen), Jewel

Johanns (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 listed as the address for the patent applicant.

164. Two days after filing the method-of-use patent application with the PTO, on September 26, 2019, many of the same Janssen and J&J employees (along with a few Janssen consultants not listed as inventors) published the results of NCT 236 in the New England Journal of Medicine.[93] Indeed, at the time the article was published, all of the authors currently or previously worked for Johnson & Johnson and/or Janssen. The article concluded that "[u]stekinumab was more effective than placebo for inducing and maintaining remission in patients with moderate-to-severe" ulcerative colitis.[94]

165. 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.

b. J&J fraudulently prosecuted the '307 patent.

166. In its patent application, J&J's counsel, Mr. Dichter, acknowledged that "[t]he involvement of the IL-12/23 pathway in the pathogenesis of IBD is well established," but nevertheless falsely represented that "[p]rior to the present invention, no studies had been conducted with ustekinumab for [ulcerative colitis]."[95] This statement was untrue, and Mr. Dichter violated his duty of reasonable inquiry in failing to make sure it was correct. J&J's

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

[94] *Id.*

[95] File for U.S. Patent Application No. 16/580,509 ('307 File Wrapper), Specification dated Sept. 24, 2019 at 2, 4.

misrepresentations in the ’509 application were material and were specifically intended to deceive the PTO into granting the application and issuing the patent.

167. One or more of the named inventors were aware of the Afonso, Ochsenkühn, Kolios, and/or Tran-Minh studies as well as the Tarr and Canadian references and their importance to the patent application leading to the ’307 patent.

168. One or more of the named inventors of the ’307 patent, patent prosecutors, and other J&J employees closely followed the research and publications of Dr. Afonso, Dr. Ochsenkühn, Dr. Kolios, and Dr. Tran-Minh regarding use of ustekinumab to treat ulcerative colitis specifically and inflammatory bowel disease generally in the years prior to and during the prosecution of the ’307 patent. These prosecutors, inventors, and other J&J employees discussed the importance of this research and circulated it to their colleagues. J&J employees attended conferences where the prior art authors presented the findings of the relevant prior art references. They were aware of the importance of this research to Stelara and the materiality of this research to the ’509 application that led to the ’307 patent.

169. On July 16, 2020, the patent examiner responsible for examining the ’509 application—Robert S. Landsman—issued a non-final rejection of that application. In his rejection, he cited two references, “https://www.ema.europa.eu/en/medicines/human/EPAR/stelara” and “https://clinicaltrials.gov/ct2/show/NCT02407236.” He accessed both from the internet on July 13, 2020. The examiner did not include copies of either website in his rejection.[96]

[96] ’307 File Wrapper, List of References Cited by Examiner dated July 16, 2020.

170. The examiner correctly rejected the '509 application's claims as either anticipated by or obvious over the CT posting, the second reference cited in his rejection.[97] The examiner did not specify which version(s) of the CT posting he reviewed, nor did he include a copy, but his reference to and notes on the CT posting suggest that he saw a webpage titled "Study Details," which provides the details of NCT 236.[98]

171. The examiner explained that the patent application's claims were either anticipated by or obvious over the CT posting, as it "[taught] the use of [ustekinumab/Stelara] for the instantly claimed purpose," including the method of administration and its parameters/endpoints.[99] He noted that while certain claims were not taught in the CT posting, those claims were still either anticipated or obvious and, therefore, not patentable. The examiner further stated 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."[100] Finally, the examiner noted that while the CT posting was "silent regarding the use of the antibody [ustekinumab] 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."[101]

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[97] '307 File Wrapper, Non-Final Rejection dated July 16, 2020 at the page marked 6 in the top righthand corner.

[98] *See* https://web.archive.org/web/20201101225837/https://clinicaltrials.gov/ct2/show/NCT02407236. Again, the last-in-time CT posting available before the one-year grace period cutoff was the CT posting uploaded on September 6, 2017 (the 2017 CT posting). For the purposes of a patent validity analysis, the 2017 CT posting is prior art to the '307 patent.

[99] '307 File Wrapper, Non-Final Rejection dated July 16, 2020 at 1, 7.

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

[101] '307 File Wrapper, Non-Final Rejection dated July 16, 2020 at page 6.

172. Although J&J updated its CT postings over 30 times between its initial 2015 CT posting and the 2017 CT posting, J&J chose not to provide a copy of *any of these postings* to the examiner prior to his July 2020 rejection. In fact, in connection with its September 24, 2019, patent application, J&J made no disclosures *at all* concerning NCT 236.

173. On October 5 and 13, 2020, Mr. Dichter, on behalf of J&J, initiated telephone calls with the patent examiner.

174. During the October 2020 calls, Mr. Dichter (on behalf of J&J) claimed that the CT posting did not inherently anticipate or render obvious the '509 application because the CT posting did not suggest that ustekinumab would be *effective* in treating ulcerative colitis as measured by its endpoints: "Mr. Dichter . . . argued that, while the 'CT' reference may suggest various endpoints, given the nature of Phase 3 clinical trials, *it would not have been obvious that the endpoints would have been met by the claimed antibody*, nor would a specific patient population defined by such endpoints be anticipated."[102] This argument misrepresented clear and directly on point patent law.

175. In *In re Montgomery*, 677 F.3d 1375 (Fed. Cir. 2012), the Federal Circuit clarified that a clinical trial protocol describing use of a drug to treat a particular disease will *inherently anticipate* a patent application claiming that use—rendering it unpatentable under 35 U.S.C. § 102—if the claimed invention inevitably results from the steps disclosed in the clinical trial protocol or description.[103] Put another way, if a clinical trial protocol describes use of a drug to treat a disease, and following that description *inevitably results* in treatment of the disease, then the protocol inherently anticipates a patent claiming use of the drug to treat the disease. That the

[102] '307 File Wrapper, Examiner Interview Summary Record (PTOL-413) dated October 9, 2020 at 1 (emphasis added).

[103] *In re Montgomery*, 677 F.3d 1375, 1380 (Fed. Cir. 2012)

clinical trial *results* were not available at the time the inventor applied for the patent does not matter: "'[n]ewly discovered results of known processes directed to the same purpose are not patentable because such results are inherent.' . . . 'It matters not that those of ordinary skill heretofore may not have recognized the[ ] inherent characteristics of the [prior art].'"[104] Simply put, those clinical trial results are "inherently anticipated" by the earlier disclosure(s).[105] Since its 2012 publication, *In re Montgomery* has remained binding law.

176. By the time J&J submitted and prosecuted the '509 application, a reasonable patent attorney representing J&J would have been aware of (i) *Montgomery* and its holding that public disclosure of Phase 3 clinical plans to study a drug's use can inherently anticipate a later-sought patent on that use; and (ii) the fact that J&J's prior art CT postings *did anticipate* its later-sought '307 patent covering the use of ustekinumab to treat ulcerative colitis.

177. Here, J&J first disclosed the parameters of NCT 236 on ClinicalTrials.gov in 2015. It then updated this posting over 30 times before submitting the '509 application to the PTO, including dozens of times *after NCT 236 began* in July 2015. These CT postings—especially the 2017 CT posting—were far more than "an invitation to investigate" or an "an abstract theory."[106] Like the HOPE clinical trial protocol at issue in *Montgomery*, even J&J's 2015 description of NCT 236 on ClinicalTrials.gov (the 2015 CT posting) represented "an advanced stage of testing designed to secure regulatory approval."[107] Its 2017 CT posting described a clinical trial that was already underway. Therefore, J&J's 2017 CT posting

[104] *Id.* at 1381 (quoting *Bristol-Myers Squibb Co. v. Ben Venue Lab'ys, Inc.*, 246 F.3d 1368, 1376 (Fed. Cir. 2001) and *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1350 (Fed. Cir. 2002)).

[105] *Id.* at 1381-82.

[106] *Id.* at 1382.

[107] *Id.*

inherently anticipated the invention J&J claimed in the '307 patent—use of ustekinumab to effectively treat ulcerative colitis. And attorney Dichter's misrepresentation to the contrary was material and made with the specific intent to deceive the PTO.

178. On October 16, 2020, Mr. Dichter filed J&J's response to the examiner's July rejection (response). In the response, J&J amended the patent application's claim 1, adding a description of seven potential endpoint measures. Under the revised claim, any one of these endpoints could be used to determine successful treatment of ulcerative colitis.[108]

179. With its response, J&J filed its first Information Disclosure Statement (IDS). Although one or more of the named inventors, the patent prosecutors, and other J&J employees who were substantially involved in preparing and/or prosecuting the '509 application were aware of the relevant prior art articles, J&J did not submit *any* of them with this IDS. The relevant prior art articles include: the Afonso, Ochsenkühn, Kolios, Jostins, Granlund, Bradbury, Downs, and/or Nakajima studies, as well as the 2017 CT posting.[109]

180. And despite the fact that the examiner's July 2020 rejection put J&J on notice of the materiality of NCT 236 to the examiner's analysis, J&J's sole disclosure related to NCT 236 was a printout of *only the cover page of the clinical trial website*:

[108] '307 File Wrapper, Claims dated October 16, 2020 at 2.

[109] '307 File Wrapper, Information Disclosure Statement dated October 16, 2020. J&J submitted a second IDS on November 9, 2020. It too did not contain any of the relevant prior art articles. '307 File Wrapper, Information Disclosure Statement dated November 9, 2020.

A Study to Evaluate the Safety and Efficacy of Ustekinumab Induction and Maintenance Therapy in Participants With Moderately to Severely Active Ulcerative Colitis (UNIFI)

ClinicalTrials.gov Identifier: NCT02407236

Recruitment Status : Active, not recruiting
First Posted : April 2, 2015
Results First Posted : December 23, 2019
Last Update Posted : October 1, 2020

Sponsor:
Janssen Research & Development, LLC

Information provided by (Responsible Party):
Janssen Research & Development, LLC

This printout appears to have been downloaded on October 16, 2020—the day J&J responded to the examiner's rejection.[110]

181. J&J also concealed the following documents related to NCT 236 from the examiner:

a. Any of the prior art CT postings, including the 2017 CT posting—over 30 of them published to ClinicalTrials.gov between April 2, 2015 and September 24, 2017. These versions described the progress NCT 236. The examiner found the CT posting on his own;

b. The NCT 236 Protocol J&J submitted to the FDA on March 17, 2015, and its amendments thereto (submitted on July 14, 2015 and April 20, 2016, respectively). In all three versions of the NCT 236 Protocol, J&J relies on the similarities between ulcerative colitis and Crohn's disease, including citations to Jostins and Granlund, to argue that ustekinumab would effectively 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*."[111]

182. Despite its failure to disclose *any* of these material NCT 236 documents to the patent examiner, J&J's October 16, 2020 IDS *did* include a clinical trial protocol for a *different* clinical trial: a multicenter, randomized, double-blind, placebo-controlled study of ustekinumab in subjects with active systemic *lupus* erythematosus (NCT0239061). This lupus protocol was approved in January 2017, *after* J&J submitted the NCT 236 Protocol and its amendments to the FDA.[112]

183. J&J's October 16, 2020 response

184. to the patent examiner repeated the same misrepresentations Mr. Dichter made during his calls with the examiner earlier that month.Mr. J&J misrepresented that "*[d]ue to the*

[110] '307 File Wrapper at 928 (Non Patent Literature dated October 16, 2020).

[111] JNJ-STELARA_002410786 at page 41 (emphasis added).

[112] '307 File Wrapper at 422 (Non Patent Literature dated October 16, 2020).

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."[113] This claim runs directly contrary to the representations J&J made to the FDA and other health authorities that given the similarities between ulcerative colitis and Crohn's disease, and ustekinumab's efficacy in treating Crohn's, *it was reasonable to assume that ustekinumab would effectively treat ulcerative colitis*. Put simply, J&J told the FDA an assumption was reasonable and then turned around and told the PTO that assumption was unreasonable.

185. J&J also misrepresented that the 2015 CT posting—in contrast to the '509 patent application—was "limited to certain elements describing the clinical trial [NCT 236] to be performed."[114] This statement was false: the majority of the clinical endpoints (measures of treatment efficacy) that J&J added to claim 1 of the '509 application were the same as clinical endpoints described in the 2015 CT posting.

186. The October 16, 2020 response also emphasized that before the '509 patent's priority date, the CT posting "did not include any clinical trial results" and that J&J first posted the clinical trial results after it filed the application in September 2019.[115] While this was technically true, it was intentionally misleading. As Mr. Dichter and J&J knew, the later-acquired clinical trial results could not overcome invalidity due to inherent anticipation because the inherent result of NCT 236 was effective treatment of ulcerative colitis. And the prior art CT postings sufficiently disclosed use of ustekinumab to treat ulcerative colitis. J&J presaged the

[113] '307 File Wrapper, Applicant Arguments/Remarks Made in an Amendment dated October 16, 2020 at page 9.

[114] *Id.*

[115] *Id.*

outcome of NCT 236 repeatedly to the FDA and other regulatory authorities. Prior case studies demonstrated that ustekinumab could effectively treat ulcerative colitis. And ustekinumab's efficacy in treating Crohn's provided grounds to assume that the drug would also treat ulcerative colitis.

187. Thus, during the prosecution of the '509 application, Mr. Dichter, the inventors, and other J&J employees substantively involved in preparing and/or prosecuting that application (on behalf of J&J) defrauded—with the specific intent to deceive—the patent examiner (and thereby the PTO) in violation of their duty of disclosure, good faith, and candor.

188. The patent examiner relied upon J&J's knowing and willful false and misleading representations and omissions. These misrepresentations and omissions were material. On November 13, 2020, the patent examiner withdrew his earlier objections and filed a notice of allowance. The examiner did not provide further explanation as to his allowance.

189. On March 30, 2021, the PTO issued J&J's method of use patent as 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."[116]

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

c. J&J's misrepresentations and omissions were material.

191. If Mr. Dichter, the '307 patent's named inventors, and the other J&J employees substantively involved in preparing and/or prosecuting the '509 application had not made such misrepresentations and/or omissions, the PTO would not have issued the '307 patent.

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

192. This reality is evidenced, in part, by the fact that the patent examiner initially rejected the patent application as either anticipated by or obvious over the CT posting and then changed his mind after the October 2020 calls and J&J's written response to the rejection.

193. The materiality of J&J's actions are also evidenced by recent events relating to J&J's continuing patent application No. 18/383,310 (the '310 application) covering substantially similar claims as the '307 patent.[117]

194. J&J filed the '310 application on October 24, 2023, just under one month after J&J's ustekinumab composition patent expired on September 25, 2023. The '310 application named the same eight inventors as the '307 patent, and the owner/assignee was also Janssen Biotech, Inc.

195. On January 16, 2025, Robert S. Landsman—the same patent examiner who issued the '307 patent—issued a non-final rejection, denying all claims of the '310 application as obvious over the CT posting.[118] The examiner also rejected the claims as obvious over the CT posting in view of the Ochsenkühn study—which J&J had finally submitted by this time—and the Stelara label.[119]

196. As to anticipation, the examiner stated the only reason the CT posting "does not anticipate the instant claims is due to the fact that it does not teach the exact dosages based on

[117] The '310 application is a continuation of Patent Application No. 17/174,201 (filed February 11, 2021), which in turn was a divisional of the '509 application, which became the '307 patent. Patent Application No. 18/383,310, Specification dated October 24, 2023 at 1.

[118] Patent Application No. 18/383,310, Non-Final Rejection dated January 16, 2025 at page 5. Like in the examiner's rejection of the '307 patent, the examiner did not specify which version of the CT posting he relied on in this rejection.

[119] *Id*. at 7; Patent Application No. 18/383,310, Information Disclosure Statement dated October 24, 2023 at 3.

subject weight in claim 1(a)"[120]—a claim limitation that was unique to the '310 application and *not* included in the '307 patent. (By this statement, the examiner acknowledged the '307 patent was invalid as anticipated by the CT posting). In addition, while the examiner did not reject the claims in the '310 application due to anticipation, he included in his rejection *two pages' worth* of legal arguments from one of the *inter partes* review petitions (IPRs) regarding the '307 patent.[121] Those arguments included a full description and analysis of *In re Montgomery*, including the IPR's characterization that it "addressed this exact issue"—i.e., whether the CT posting anticipated the '307 patent despite its results being posted after the priority date.[122]

197. Following this rejection (and about a month after Mr. Dichter was deposed in the instant case), Mr. Dichter requested an interview with the the PTO. J&J obtained the '307 patent by convincing the examiner that the results of NCT 236 were uncertain and unpredictable. This representation was false, and both the '307 patent inventors and J&J employees responsible for prosecuting the patent knew it. The patent examiner (and therefore, the PTO) reasonably relied on J&J's misrepresentations and omissions and issued the '307 patent as a result.

198. In addition, separate from J&J's fraudulent conduct, the '307 patent was invalid as obvious in light of the relevant prior art and inherently anticipated by the 2017 CT posting.

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

199. 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

[120] Patent Application No. 18/383,310, Non-Final Rejection dated January 16, 2025 at 5.

[121] *Id*. at 7-9.

[122] *Id*.

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.

200. 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.

201. 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.

202. 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."[123]

203. During the manufacturing processes for biosimilar drug products, it is beneficial to control antibody characteristics known as "post-translational modifications," i.e., changes made to an antibody towards the end of its creation. 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

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

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 in antibody biosimilars can be an important aspect of biosimilar development, FDA biosimilar approval, and FDA interchangeability decisions.

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

205. 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 and '810 patents—is a method of controlling "glycans" or sugar trees. 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 with the reference product. Another—covered by the '858 and '889 patents—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.

206. Together, the Momenta biosimilar manufacturing patents describe methods of controlling antibody characteristics by selecting one of three chemicals (lysine/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). All four patents claim methods of adjusting cell growth media to contain specified amounts of lysine/arginine or putrescine to achieve the desired characteristics in the resulting antibodies—either adjusting lysine/arginine levels to control C-terminal variants or adjusting putrescine levels to control glycans (specifically, high-mannose glycans and sialylated glycans) to make a biosimilar product.

207. 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.

208. 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.

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

210. Correct use of the Momenta biosimilar patents is, as J&J has admitted, of particular use to *biosimilar* developers because those technologies can be used to manufacture

products more likely to obtain an "interchangeability" determination from the FDA, i.e., a determination that 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 product.'"[124] 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."[125]

211. 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 acquiring Momenta, J&J had achieved its monopoly position over ustekinumab without using 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.

212. 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.

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

[125] *Id.*

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

214. J&J's acquisition of the Momenta biosimilar manufacturing patents has the consequence of unlawfully extending and maintaining J&J's monopoly in the market for ustekinumab in the United States.

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

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.

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

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

218. 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.

219. 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."[126] In

[126] 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."[127] 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."[128] 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.

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

221. 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."[129] 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]".[130]

222. 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."[131]

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

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

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

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

[130] *Id*.

[131] Jonathan Gardner, *Acquired Patents Aid J&J Defense of Top-Selling Drug from Biosimilar Challenge*, BioPharma Dive (Mar. 29, 2023), https://www.biopharmadive.com/news/johnson-johnson-stelara-patents-amgen-biosimilar-momenta/646277/.

223. 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."[132] 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]."[133] Indeed, J&J was "expecting a steeper erosion curve than what was experienced [with REMICADE biosimilars] because [ustekinumab] is a self-administered subcutaneous."[134] Wolk underscored that "[t]here will be multiple competitors on the market at some point, and they may have the affordability of interchangeability."[135] 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.

224. On April 18, 2023, an article in Morningstar forecasted that Stelara biosimilars would "launch in the fourth quarter" of 2023.[136] The analysis explained that Stelara's "self-administration and likely interchangeability with multiple products" would lead Stelara to lose market share more rapidly "than the almost midteens annual losses" faced by Remicade after biosimilar approval.[137]

225. 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

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

[133] *Id*. at 10.

[134] *Id.*

[135] *Id*.

[136] 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.

[137] *Id*.

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.[138]

226. 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."[139]

227. 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 four had filed aBLAs with the FDA, and at least one had notified J&J that it was prepared to launch in 2023. Table 1 below summarizes these biosimilar filings.

[138] Bhanvi Satija & 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/.

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

TABLE 1			
Applicant	**Biosimilar**	**Phase 3 Clinical Trials Begin**	**FDA Submission**
Amgen	ABP 654	November 11, 2020	October 31, 2022
Alvotech/Teva	AVT04	June 3, 2021	October 11, 2022
Formycon/Fresenius Kabi	FYB202	November 9, 2020	September 28, 2023
Samsung Bioepis/ Sandoz	SB17	July 6, 2021	March 30, 2023 and January 29, 2024
Celltrion	CT-P43	January 11, 2021	June 30, 2023
Hikma/Bio-Thera	BAT2206	July 6, 2021	July 24, 2024
Accord BioPharma, Inc./Dong-A ST Co., Ltd./Meiji Seika Pharma Co., Ltd./Intas Pharmaceuticals	DMB-3115	April 28, 2021	On or around October 9, 2023
Biocon	Bmab-1200	June 28, 2022	November 29, 2023

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

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

229. 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.

230. 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.[140] The study was completed on February 28, 2023.

231. 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."[141]

232. On October 31, 2022, Amgen submitted its BLAs to the FDA seeking approval of its ustekinumab biosimilar.

233. 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."[142]

234. 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

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

[141] *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.

[142] *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.

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.

235. On November 11, 2022, Michael Morin, J&J's legal representative "on Stelara matters,"[143] 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 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.[144]

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

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

238. 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.

239. 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.

240. On or about February 2, 2023, Momenta (now a J&J subsidiary) executed an assignment agreement with Janssen under which Momenta assigned all its rights to the Momenta manufacturing patents to Janssen.

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

[144] *Id*. at 1.

241. 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.

242. 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 acid sequence as the active ingredient (ustekinumab) and highly similar physical and biological properties, so it can be sold as a substitute for STELARA®."[145]

243. 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.[146] 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.

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

[146] J&J's Mot. for Prelim. Inj., *Janssen Biotech, Inc. v. Amgen Inc.*, No. 22-cv-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. *See* ECF Nos. 24–34, 59–67 (redacted versions).

244. 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.

245. 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.

246. 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 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.

247. 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.[147] Based on its settlement agreement with J&J, Amgen was not permitted to launch until January 1, 2025. Amgen ultimately launched Wezlana on January 1, 2025.

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

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.

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

249. On March 30, 2023, Samsung filed its BLA with the FDA seeking approval of its ustekinumab biosimilar.

250. 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.

251. In its petition, Samsung explained that J&J was not entitled to 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., among other things, that J&J publicly disclosed the use of ustekinumab to treat ulcerative colitis in the CT posting.

252. 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.

253. 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.

254. On dates currently unknown but preceding July 25, 2023, officials from J&J and Samsung discussed J&J’s potential assertion of J&J’s intellectual property rights (including the ’307 patent, which was knowingly obtained by fraud, and the unlawfully acquired Momenta

biosimilar manufacturing patents) against Samsung due to Samsung's plans to launch SB17. 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.

255. 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.

256. On or about January 29, 2024, Samsung submitted another BLA to the FDA seeking approval of its ustekinumab biosimilar.

257. On July 4, 2024, Samsung's biosimilar product Pyzchiva received final FDA approval as biosimilar and interchangeable to Stelara.

258. Samsung's commercialization partner, Sandoz, will commercialize Pyzchiva in the United States.

259. On February 24, 2025, Samsung launched Pyzchiva.

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

260. 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.

261. 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.

262. On October 11, 2022, Alvotech submitted its BLA to the FDA seeking approval of its ustekinumab biosimilar.

263. On February 9, 2023, Alvotech announced that the European Medicines Agency accepted its Marketing Authorization Application for AVT04.

264. On dates currently unknown but preceding June 9, 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, which J&J knowingly obtained by fraud, 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.

265. 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.

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

267. On April 16, 2024, Alvotech/Teva's biosimilar product Selarsdi received final FDA approval as biosimilar to Stelara.

268. On February 21, 2025, Alvotech/Teva launched Selarsdi.

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

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

270. 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 FYB202 was bioequivalent to Stelara in the United States (and in the European Union) for "all primary endpoint parameters."[148] Formycon and Fresenius planned to submit for U.S. regulatory approval in the third quarter of 2023, and once approved, Fresenius would 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."[149]

271. On dates currently unknown but preceding July 27, 2023, officials from J&J and Fresenius/Formycon discussed J&J's potential assertion of J&J's intellectual property rights (including the '307 patent, which J&J knowingly obtained by fraud, and the unlawfully acquired Momenta biosimilar manufacturing patents) against Fresenius/Formycon due to the plans of Fresenius/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.

272. On August 7, 2023, Fresenius and Formycon announced that they had reached a settlement agreement with J&J regarding FYB202. As a result, and subject to FDA approval,

[148] *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/.

[149] *Id.*

Fresenius 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.

273. On September 28, 2023, Fresenius submitted its BLA to the FDA seeking approval of its ustekinumab biosimilar.

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

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

276. On September 27, 2024, Fresenius/Formycon’s biosimilar product Otulfi received final FDA approval as biosimilar to Stelara.

277. On March 3, 2025, Fresenius/Formycon launched Otulfi.

d. The J&J-Celltrion Settlement.

278. On June 30, 2023, Celltrion submitted its BLA to the FDA seeking approval of its ustekinumab biosimilar, CT-P43.

279. On dates currently unknown but preceding late July 26, 2023, officials from J&J and Celltrion discussed J&J’s potential assertion of J&J’s intellectual property rights (including the ’307 patent, which J&J knowingly obtained by fraud, and the unlawfully acquired Momenta biosimilar manufacturing patents) against Celltrion due to Celltrion’s plans 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.

280. 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.

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

282. On December 17, 2024, Celltrion's biosimilar product Steqeyma received final FDA approval as biosimilar to Stelara.

283. On March 13, 2025, Celltrion launched Steqeyma.

e. The J&J-Accord BioPharma Settlement.

284. On April 28, 2021, Dong-A ST Co., Ltd. (Dong-A), collaborating with Meiji Seika Pharma Co., Ltd., initiated a Phase 3 clinical trial to study the efficacy, safety, pharmacokinetics, and immunogenicity of their ustekinumab biosimilar, DMB-3115, in comparison with Stelara to treat moderate to severe chronic plaque psoriasis.[150]

285. In July 2021, Dong-A entered a global license contract with Intas Pharmaceuticals, Inc., the latter of which planned to commercialize DMB-3115 through its U.S. subsidiary, Accord BioPharma, Inc. (Accord).

286. The Phase 3 clinical trial ended on November 16, 2022.

287. On dates currently unknown but preceding September 20, 2023, officials from J&J and Accord and/or Dong-A discussed J&J's potential assertion of J&J's intellectual property rights (including the '307 patent, which J&J knowingly obtained by fraud, and the unlawfully acquired Momenta biosimilar manufacturing patents) against Accord and/or Dong-A due to their plans to launch DMB-3115. At the time, both parties (i) were aware of J&J's efforts in recent

[150] *Efficacy, Safety, and Immunogenicity of Subcutaneous DMB-3115 Versus Stelara in Patients with Moderate to Severe Chronic Plaque Psoriasis*, ClinicalTrials.gov, https://clinicaltrials.gov/study/NCT04785326.

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.

288. In September 2023, Accord and J&J reached a settlement agreement through which Accord would be permitted to launch DMB-3115 on May 15, 2025, pending FDA approval—over 19 months after the ’734 patent expired on September 25, 2023.

289. On or around October 9, 2023, Accord submitted its BLA to the FDA seeking approval of its ustekinumab biosimilar.

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

291. On January 4, 2024, Accord announced that the FDA had accepted its aBLA for DMB-3115.

292. On January 18, 2024, Dong-A posted its first Phase 3 results.

293. On October 10, 2024, Accord’s biosimilar product Imuldosa received final FDA approval as biosimilar to Stelara.

f. The Biocon Settlement

294. On June 28, 2022, Biocon Biologics UK Ltd. (Biocon Ltd.) initiated a Phase 3 clinical trial to compare the efficacy, safety, immunogenicity, and pharmacokinetics of their ustekinumab biosimilar, Yesintek, Bmab 1200 with Stelara in adults with moderate to severe chronic plaque psoriasis.[151]

[151] *Comparing Efficacy and Safety of Bmab 1200 and Stelara in Patients with Moderate to Severe Chronic Plaque Psoriasis (STELLAR-2),* ClinicalTrials.gov, https://clinicaltrials.gov/study/NCT05335356.

295. On November 22, 2023, Biocon Biologics, Inc. (Biocon), Biocon Ltd.'s wholly owned subsidiary, filed a petition for *inter partes* review with the PTAB challenging the validity of J&J '307 patent.[152]

296. In its petition, Biocon made the same arguments as Samsung did in its *inter partes* review petition filed just five months before—that J&J was not entitled to its '307 patent because using ustekinumab to treat ulcerative colitis was both anticipated and obvious.

297. On November 29, 2023, Biocon submitted its BLA to the FDA seeking approval of its ustekinumab biosimilar.

298. On dates preceding February 27, 2024, officials from J&J and Biocon discussed J&J's potential assertion of J&J's intellectual property rights (including the '307 patent, which J&J knowingly obtained by fraud, and the unlawfully acquired Momenta biosimilar manufacturing patents) against Biocon due to its plans to launch Yesintek. 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.

299. On February 27, 2024, Biocon and J&J reached a settlement agreement through which Biocon would be permitted to launch BMAB 1200 on February 22, 2025, pending FDA approval—almost 17 months after the '734 patent expired on September 25, 2023.

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

301. On or around November 29, 2024, Biocon's biosimilar product Yesintek received final FDA approval as biosimilar to Stelara.

[152] Pet., *Biocon v. Janssen*, IPR2023-01444 (PTAB Nov. 22, 2023), Paper No. 2.

302. On February 24, 2025, Biocon launched Yesintek.

303. All in all, and to date, J&J reached seven settlements with would-be biosimilar competitors for agreed-to entry dates ranging from January 1 to May 15, 2025. In reaching those settlements, J&J used and/enforced the ’307 patent, which it knew it had obtained by fraud, as well as the unlawfully obtained Momenta biosimilar manufacturing patents, against would-be biosimilar competitors. J&J’s use and/or enforcement substantially reduced competition in the market for ustekinumab in the United States. Table 2 summarizes these settlements and delayed entry dates.

TABLE 2

Applicant	Biosimilar	Settlement Date	Agreed-to Launch Date	FDA Approval Date
Amgen	ABP 654	May 19, 2023	January 1, 2025	October 31, 2023
Alvotech and Teva	AVT04	June 9, 2023	February 21, 2025	April 16, 2024
Formycon/ Fresenius Kabi	FYB202	July 27, 2023	April 15, 2025[153]	September 27, 2024
Samsung Bioepis and Sandoz	SB17	July 25, 2023	February 22, 2025	June 28, 2024
Celltrion	CT-P43	July 26, 2023	March 7, 2025	December 17, 2024
Accord BioPharma	DMB-3115	September 20, 2023	May 15, 2025	October 10, 2024

[153] As described further below, Fresenius ultimately launched its ustekinumab biosimilar, Otulfi, on March 3, 2025.

Biocon	BMAB 1200	February 27, 2024	February 22, 2025	On or around December 1, 2024

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.

304. Since its approval in 2009, Stelara has played an increasingly important role in bolstering J&J's profits. From 2019 to 2023, Stelara was J&J's highest earning product. In 2019, 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.

305. 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."[154] J&J also reported that the patent's expiration or loss of market exclusivity "*will* result in a reduction in sales."[155]

306. 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 warned that "[i]n the event the Company is not successful in defending its patent claims in

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

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

related lawsuits," the launch of biosimilars could "potentially result[] in substantial market share and revenue losses."[156]

307. J&J settled with Amgen in May 2023. Just weeks later, analysts predicted that Stelara "could generate sales closer to $10 billion in 2024 dropping to $7.5 billion to $8.5 billion the following year. That would add around $4.6 billion to average estimates for pharmaceutical sales, as long as no biosimilars enter the market before 2025."[157]

308. In its 10-Q filing for the second quarter of 2023, filed in July 2023, J&J announced its 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."[158]

309. 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.

310. 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, Joseph 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.

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

[157] Patrick Wingrove, *Stelara Patent Deal Puts J&J Back on Path to $57 Billion 2025 Revenue Forecast*, Reuters (June 5, 2023), https://www.reuters.com/business/healthcare-pharmaceuticals/stelara-patent-deal-puts-jj-back-path-57-bln-2025-revenue-forecast-2023-06-05/.

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

So we would not anticipate any other biosimilar having the opportunity or ability to enter the market before those [two]."[159]

311. In its January 23, 2024 SEC filing, J&J reported that its 2023 Stelara sales were nearly $7 billion in the U.S and roughly $10.9 billion worldwide.[160]

312. As noted in reporting in January 2023, "[a]nalysts have said the delay in biosimilar launches would make Stelara a larger contributor to J&J's 2024 and 2025 sales than previously anticipated."[161] While Stelara sales are predicted to be about 3% lower in 2024 than they were in 2023—$10.54 billion compared to $10.86 billion—J&J's 2023 fourth quarter sales surpassed analysts' expectations by over 4%—$2.75 billion instead of $2.63 billion.[162] The 2023 fourth quarter started less than one week after September 25, 2023, the date on which J&J and the industry had predicted it would lose market exclusivity.

313. 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.

314. J&J's use of the unlawfully acquired Momenta biosimilar manufacturing patents standing alone was sufficient to delay the entry of ustekinumab biosimilars and, therefore, the entry of any competition into the ustekinumab market in the United States. Indeed, it was the

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

[160] Johnson & Johnson, Current Report (Form 8-K) at 25 (Jan. 23, 2024).

[161] Bhanvi Satija & Patrick Wingrove, *J&J Profit Edges Past Street View After Deals Delay Stelara Competition*, Reuters (Jan. 23, 2024), https://www.reuters.com/business/healthcare-pharmaceuticals/jj-beats-profit-estimates-pharmaceutical-unit-strength-2024-01-23/.

[162] *Id.*

position of J&J itself in its litigation against Amgen that potential infringement of those patents should be sufficient to keep Amgen entirely off the market.

315. Nor would J&J's enforcement of the '307 patent—if not shown to have been fraudulently acquired—serve as a basis to keep biosimilar ustekinumab competitors from the market. For all the reasons previously detailed about how the public record showed lack of invention behind the notion of using ustekinumab for ulcerative colitis, the '307 patent would be held invalid for obviousness and anticipation in any litigation attempting to keep a biosimilar ustekinumab off the market based on infringement of the '307 patent. And because the patent claimed only one of multiples uses of ustekinumab (the least lucrative one), it could not serve to prohibit all uses. J&J documents acknowledge this reality.

316. J&J knew that not only would biosimilar companies have launched on a "skinny label" that carved out the (small usage) ulcerative colitis indication (~10% of market), biosimilars also would have *obtained market share comparable to a launch with the full label*. In October 2021, J&J agreed with the analysis of its consultant, which advised that "Skinny label provides minor benefit to Stelara. Per the Ruxience/Truxima analogue, skinny label on a bs confers little advantage to the reference product," to which J&J's pricing director responded that they "don't disagree with the approach and that it absolutely reflects what we hear in the market research."[163]

317. J&J then incorporated and expanded that analysis in PowerPoints five months later as it forecasted strategies in response to the biosimilar threat, likening the prospect of a market with Stelara biosimilars with skinny labels to the market for the biologic drug Rituxan, seen as a "competitive analog" to Stelara. Rituxan faced biosimilar competition from a biosimilar

[163] JNJ-STELARA_003109188.

with a full label (Truxima) and a skinny label (Ruxience), which carved out an indication for rheumatoid arthritis. Despite the carveout, however, J&J found that the two biosimilars obtained similar market shares, *even on the carved-out indication.*

318. J&J concluded: "Overall, market share is similar between biosimilars with full label vs. skinny label."[164]

319. J&J improperly maintained its monopoly over the U.S. market for ustekinumab until at least January 1, 2025—an additional 14 months or approximately 428 days beyond the FDA's approval of the first ustekinumab biosimilar (Amgen's Wezlana). As a result, J&J made almost $8 billion in U.S. sales.

320. 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.

H. Four months into 2025, J&J continues to use the fraudulently acquired method-of-use patent and the Momenta biosimilar manufacturing patents to foreclose biosimilar competition by suing to stop the launch of a private label biosimilar.

321. Biosimilars compete with biologics not only by launching at lower prices and/or with higher rebates, but also by partnering with pharmacy benefit managers (PBMs) to launch private-label biosimilars. A private label biosimilar is a biosimilar drug that a biosimilar manufacturer (for example, Amgen) makes on behalf of another company—usually a PBM (for example, CVS Health)—and is therefore marketed and sold under the label of the latter company (CVS Health) rather than the original manufacturer (Amgen). Private-labeling allows biosimilars to access a different market channel (a PBMs' full network), thereby increasing competition and lowering prices for payors like the plaintiffs.

[164] JNJ-STELARA_001739020 at slide 56.

322. The launch of private label biosimilars encourages market conversion to biosimilars by giving the private labels preferred formulary status over brand name biologics.

323. For instance, the largest PBMs—CVS Caremark, Express Scripts, and Optum—all partnered with biosimilar companies to launch private label biosimilars of the biologic drug Humira, leading to increased biosimilar conversion and lower prices.

324. For example, for ustekinumab, Amgen has partnered with Optum's new biosimilars-focused private-label subsidiary Nuvaila, launching "Wezlana for Nuvaila," in January 2025.[165]

325. J&J's use of the fraudulently acquired '307 patent and the Momenta biosimilar manufacturing patents to exclude biosimilar competition continues and will continue absent injunction of its unlawful behavior.

326. On February 24, 2025—the same date Samsung Epis launched Pyzchiva—J&J filed a complaint for injunctive relief attempting to prevent Samsung and its commercial partner on the private label (Quallent Pharmaceuticals, an affiliate of Express Scripts) from launching a private label biosimilar. On April 28, 2025, the court denied J&J's motion for preliminary injunction.

327. J&J's attempt to foreclose Samsung's private label launch is baseless. In its complaint, J&J argues that terms in the settlement agreement it extracted from Samsung through assertion of the '307 patent and the Momenta biosimilar manufacturing patents preclude Samsung from entering into the private label partnership. J&J argues that its settlement with

[165] https://aishealth.mmitnetwork.com/blogs/spotlight-on-market-access/optum-s-nuvaila-is-sole-distributor-of-first-stelara-biosimilar-wezlana.

Samsung precludes Samsung from partnering with a second entity (in addition to Sandoz) for Pyzchiva, despite contract language clearly contemplating multiple sublicenses.

328. J&J used the ’307 and Momenta biosimilar manufacturing patents to extract the delayed biosimilar entry date in the Samsung settlement. J&J’s 2025 lawsuit against Samsung is a continuation of its use of these unlawfully acquired patents.

329. In reaching the Samsung patent settlement, J&J used and/or enforced the ’307 patent, which it knew it had obtained through fraud, as well as the unlawfully acquired Momenta biosimilar manufacturing patents. J&J’s use and/or enforcement of these patents substantially reduced and threatens to continue to reduce competition in the market for ustekinumab in the United States.

330. 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 as the plaintiffs and class members will continue to pay, supra-competitive prices.

VI. CLASS ALLEGATIONS

331. 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.

332. 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 classes defined below.

For its Damages Class:

> All Third-Party Payers who indirectly purchased or paid for, as part of a prescription drug benefit, some or all of the purchase

> price for Stelara in the Damages Class States or Territories[166] for personal use by their members, enrollees or beneficiaries, from January 1, 2024 until December 31, 2025 (the "Class Period").

For its Unjust Enrichment Class:

> All Third-Party Payers that indirectly purchased or paid for, as part of a prescription drug benefit, some or all of the purchase price for Stelara in the Unjust Enrichment States or Territories[167] for personal use by their members, enrollees or beneficiaries from January 1, 2024 until December 31, 2025 (the "Class Period").

333. Excluded from each of the classes are: (1) J&J and its subsidiaries and affiliates; (2) federal and state government entities; and (3) Third-Party Payers whose only purchases were made pursuant to any Medicaid plan, whether Fee-for-Service or Managed Medicaid.

334. 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.

335. 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

[166] The Damages Class States and Territories are Alabama, Alaska, Arizona, Arkansas, California, Connecticut, District of Columbia, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Kansas, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, Puerto Rico, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, West Virginia, Wisconsin., and Wyoming.

[167] The Unjust Enrichment Class States and Territories are Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, District of Columbia, Florida, Georgia, Hawaii, Illinois, Iowa, Kansas, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, Puerto Rico, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Vermont, Virginia, West Virginia, Wisconsin, and Wyoming.

competition from cheaper biosimilar versions of ustekinumab because of J&J's wrongful conduct.

336. 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.

337. 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.

338. 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.

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

a. whether J&J willfully and improperly maintained monopoly power over sales of ustekinumab in the United States;

b. whether Mr. Dichter, the named inventors, and other J&J employees substantively involved in preparing or prosecuting the '509 application, on behalf of J&J, made misrepresentations and/or omissions to the PTO with the specific intent to deceive the PTO;

c. whether the misrepresentations and omissions J&J made to the PTO were material to the patent examiner's issuance of the '307 patent;

d. whether Mr. Dichter, the named inventors, and other J&J employees substantively involved in preparing or prosecuting the '307 patent, on behalf of J&J, obtained the '307 method-of-use patent by fraud on the PTO;

a. whether J&J acquired the Momenta biosimilar manufacturing patents and then used them to extend its monopoly over sales of ustekinumab;

b. whether J&J's acquisition and assertion of the Momenta biosimilar manufacturing patents violates antitrust law and caused an antitrust injury;

c. whether J&J knowingly and unlawfully enforced the fraudulently obtained '307 patent against would-be biosimilar competitor, Amgen;

d. whether J&J unlawfully used the '307 patent and Momenta biosimilar manufacturing patents to delay the entry of other biosimilar ustekinumab manufacturers;

e. whether J&J unlawfully delayed or prevented manufacturers of ustekinumab biosimilars from selling ustekinumab on the U.S. market;

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

g. 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;

h. whether J&J's activities as alleged herein have substantially affected interstate commerce;

i. 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

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

340. 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.

341. 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.

342. 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

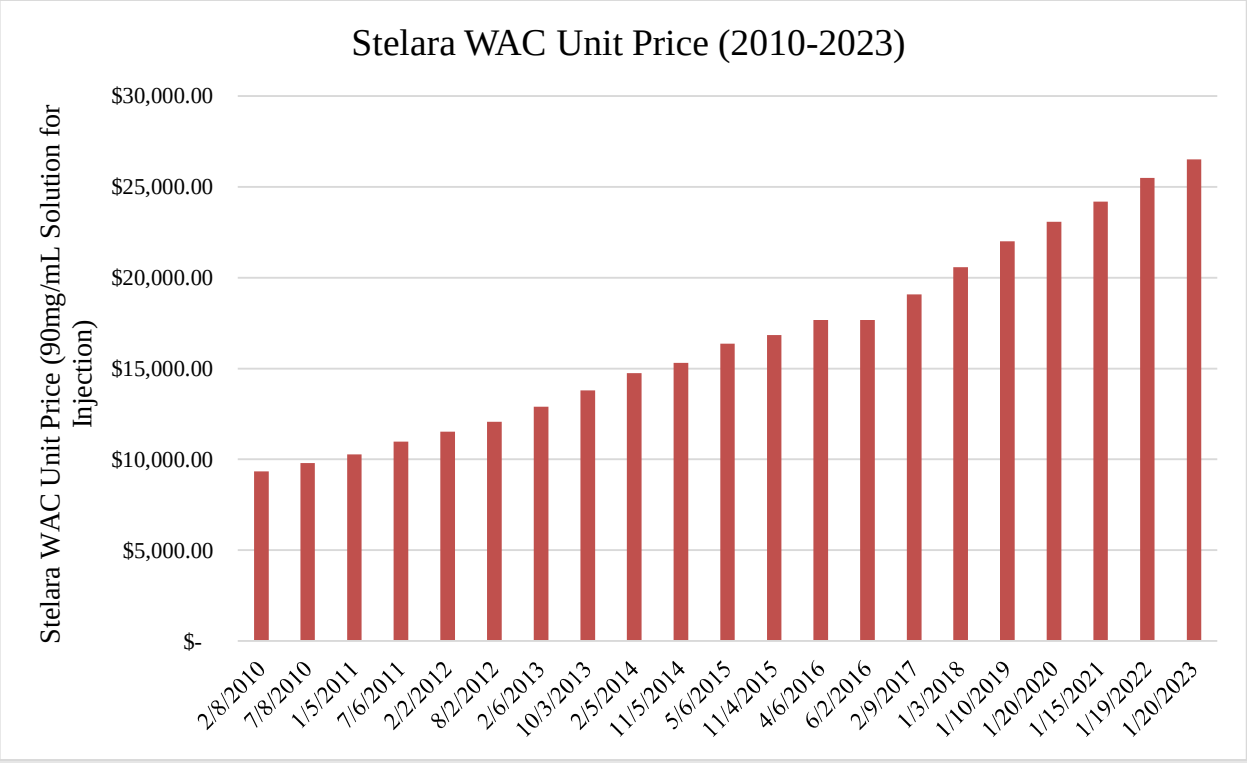
343. The relevant geographic market is the United States and its territories.

344. The relevant product market is ustekinumab.

345. 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.

346. *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:



347. 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.

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

349. *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.

350. *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 treatments for these conditions.

351. 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).

352. 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.

353. 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%.[168] 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 regimens longer than patients of any other biologic.[169]

354. 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."[170] 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."[171] 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

[168] Zhun Cao et al., *Ustekinumab Dosing, Persistence, and Discontinuation Patterns in Patients with Moderate-to-Severe Psoriasis*, 26 J. Dermatolog. Treat. 113, 113 (2014).

[169] Murat Borlu, *Ustekinumab*, 56 Turkderm-Turk. Arch. Dermatol. & Venereol. 48, 49 (2022), https://jag.journalagent.com/turkderm/pdfs/TURKDERM_56_50_48_51.pdf.

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

[171] *Id*. at 9.

as REMICADE®, HUMIRA®, and SIMPONI®, each of which presents safety risks associated with immunosuppression."[172]

355. 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.

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

357. 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.

358. 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.

359. 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."[173] Amgen further remarked "[f]or therapeutic areas with biosimilars launched in the last 3 years, the average share was

[172] *Id*.

[173] 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%."[174] J&J has endorsed the accuracy of this report.

360. 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). . . ."[175] J&J has endorsed the accuracy of this report.

361. *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."[176] 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 . . . ."[177]

362. 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."[178] As J&J explained, such an action "could trigger PBMs to

[174] *Id.*

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

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

[177] *Id.* at 16.

[178] Mem. in Supp. of J&J's Mot. for Prelim. Inj. at 24, *Janssen Biotech, Inc. v. Amgen, Inc.*, 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]."[179] 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."[180]

363. 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].'"[181] 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."[182]

364. 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."[183] As Amgen has said, the "average sales price . . . is declining, due to competition, for both reference products and

[179] *Id.*

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

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

[182] *Id.*

[183] *Id.*

biosimilars. . . . The prices of most reference products have decreased at a negative [compound annual growth rate] of -4% to -21%."[184] And again, J&J has endorsed the accuracy of that report.

365. 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."[185] 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."[186] 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."[187]

366. 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.

367. 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. 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%.

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[184] Amgen 2022 Biosimilar Report at 6.

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

[186] *Id.*

[187] *Id.* at 26.

368. 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.

369. 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.

370. 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.

371. 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, lose 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® . . . ."[188]

372. 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

[188] *Id.* at 23.

erosion, damage to Janssen's R&D, loss of goodwill, and harm to [J&J's] ongoing relationships with payors and customers."[189]

373. 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."[190] 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.

374. 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

375. In the absence of the anticompetitive conduct alleged above, multiple manufacturers would have entered the market with ustekinumab biosimilars starting as early as October 31, 2023.

376. 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 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

[189] *Id.* at 7.

[190] *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.

would-be ustekinumab biosimilar competitors. These acts, individually and in combination, were anticompetitive.

377. 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.

378. 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.

379. 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.

380. 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.

381. 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			

382. These data include purchases of Stelara for CareFirst members in Norfolk, Chesapeake, Virginia Beach, Suffolk, and James City County, Virginia.

IX. ANTITRUST IMPACT

383. 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.

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

385. 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.

386. 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.

387. Over the course of more than two decades of end payer class litigation concerning delay of generic and biosimilar drug competition in the United States, courts have repeatedly recognized that the quantum of class damages is calculable and need not rely on speculation.

388. Indeed, courts have certified end payer classes in at least 21 generic delay actions.[191] Of the 11 decisions that denied class certification, none held class damages to be overly speculative.[192]

389. 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

[191] *In re Actos Antitrust Litig.*, No. 13-cv-09244, 2024 WL 4345568 (S.D.N.Y. Sept. 30, 2024); *Gov't Emps. Health Ass'n v. Actelion Pharm. Ltd.* (*Tracleer*), No. 18-cv-3560, 2024 WL 4122123 (D. Md. Sept. 6, 2024); *In re Xyrem (Sodium Oxybate) Antitrust Litig.*, No. 20-md-02966, 2023 WL 3440399 (N.D. Cal. May 12, 2023); *In re HIV Antitrust Litig.*, No. 19-cv-02573, 2022 WL 22609107 (N.D. Cal. Sept. 27, 2022); *In re Zetia (Ezetimibe) Antitrust Litig.*, No. 18-md-2836, 2021 WL 3704727 (E.D. Va. Aug. 20, 2021); *In re Opana ER Antitrust Litig.*, MDL No. 2580, 2021 WL 3627733 (N.D. Ill. June 4, 2021); *In re Ranbaxy Generic Drug Application Antitrust Litig.*, 338 F.R.D. 294 (D. Mass. 2021); *In re Namenda Indirect Purchaser Antitrust Litig.*, 338 F.R.D. 527 (S.D.N.Y. 2021); *In re Restasis (Cyclosporine Ophthalmic Emulsion) Antitrust Litig.*, 335 F.R.D. 1 (E.D.N.Y. 2020); *In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Pracs. & Antitrust Litig.*, No. 17-md-2785, 2020 WL 1180550 (D. Kan. Mar. 10, 2020); *In re Loestrin 24 Fe Antitrust Litig.*, 410 F. Supp. 3d 352 (D.R.I. 2019); *Hosp. Auth. of Metro. Gov't of Nashville & Davidson Cty., Tenn. v. Momenta Pharm., Inc.* (*Lovenox*), 333 F.R.D. 390 (M.D. Tenn. 2019); *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, No. 14-md-02503, 2017 WL 4621777 (D. Mass. Oct. 16, 2017); *In re Lidoderm Antitrust Litig.*, No. 14-md-02521, 2017 WL 679367 (N.D. Cal. Feb. 21, 2017); *In re Nexium Antitrust Litig.*, 777 F.3d 9 (1st Cir. 2015); *In re Flonase Antitrust Litig.*, 284 F.R.D. 207 (E.D. Pa. 2012); *Teva Pharm. USA, Inc. v. Abbot Labs* (*TriCor*), 252 F.R.D. 213 (D. Del. 2008); *In re Cipro Cases I & II*, 121 Cal. App. 4th 402 (Cal. Ct. App. 2004); *In re Relafen Antitrust Litig.*, 221 F.R.D. 260 (D. Mass. 2004); *In re Terazosin Hydrochloride*, 220 F.R.D. 672 (S.D. Fla. 2004); *In re Cardizem CD Antitrust Litig.*, 200 F.R.D. 326 (E.D. Mich. 2001).

[192] *In re Lipitor Antitrust Litig.*, MDL No. 2332, 2024 WL 2865074 (D.N.J. June 6, 2024); *In re Niaspan Antitrust Litig.*, 464 F. Supp. 3d 678 (E.D. Pa. 2020); *In re Intuniv Antitrust Litig.*, No. 16-cv-12396, 2019 WL 3947262 (D. Mass. Aug. 21, 2019); *In re Thalomid & Revlimid Antitrust Litig.*, No. 14-cv-6997, 2018 WL 6573118 (D.N.J. Oct. 30, 2018); *In re Asacol Antitrust Litig.*, 907 F.3d 42 (1st Cir. 2018); *In re Wellbutrin XL Antitrust Litig.*, 308 F.R.D. 134 (E.D. Pa. 2015); *Vista Healthplan, Inc. v. Cephalon, Inc.*, No. 06-cv-1833 (*Modafinil*), 2015 WL 3623005 (E.D. Pa. June 10, 2015); *In re Skelaxin (Metaxalone) Antitrust Litig.*, 299 F.R.D. 555 (E.D. Tenn. 2014); *In re Prograf Antitrust Litig.*, No. 11-md-02242, ECF No. 350 (D. Mass. Dec. 17, 2013); *Sheet Metal Workers Local 441 Health & Welfare Plan v. GlaxoSmithKline, PLC* (*Wellbutrin SR*), No. 04-cv-5898, 2010 WL 3855552 (E.D. Pa. Sept. 30, 2010); *In re K-Dur Antitrust Litig.*, MDL No. 1419, 2008 WL 2660723 (D.N.J. Mar. 27, 2008).

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

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

391. 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.

392. 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.

393. 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

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

395. 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.

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

397. 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.

398. J&J knowingly, willfully, and improperly maintained its monopoly power and substantially reduced and harmed competition in the market for ustekinumab in the United States by:

- fraudulently obtaining the '307 method-of-use patent by withholding material information from, and deliberating misrepresenting material information provided to, the patent examiner regarding use of ustekinumab to treat ulcerative colitis;

- wrongfully acquiring the rights to the Momenta biosimilar manufacturing patents, and;

- using and/or enforcing the ’307 patent, which J&J knew it had obtained by fraud on the PTO, and the wrongfully acquired Momenta biosimilar manufacturing patents to unlawfully delay competition from would-be ustekinumab biosimilar competitors, including Amgen, Samsung, Alvotech/Teva, Fresenius/Formycon, Celltrion, and Accord BioPharma..

399. J&J’s monopoly power over ustekinumab should have expired on October 31, 2023, the first date on which the FDA approved a biosimilar version of ustekinumab (Amgen’s Wezlana) and after J&J’s ’734 ustekinumab composition patent expired in September 2023. 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 extended an additional fourteen months, until at least January 1, 2025. As a result of J&J’s unlawful anticompetitive scheme, biosimilar manufacturers were prohibited from selling biosimilar ustekinumab in the United States before January 2025. This is true even though the FDA approved Amgen’s ustekinumab biosimilar in October 2023, as well as other ustekinumab biosimilars shortly thereafter.

400. 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.

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

402. 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 October 31, 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.

403. 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.

404. 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.

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

406. 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.

407. 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.

408. 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.

409. 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.

XII. STATE CLAIMS FOR RELIEF

COUNT TWO

MONOPOLIZATION AND MONOPOLISTIC SCHEME UNDER STATE LAW

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

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

412. Count Two 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.

413. The essential elements of each antitrust claim in Count Two 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.

414. 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.

415. 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.

416. J&J accomplished its anticompetitive scheme by: (i) fraudulently obtaining its '307 method-of-use patent; (ii) wrongfully acquiring the Momenta biosimilar manufacturing patents; and (iii) using the '307 patent, which J&J knew it had obtained by fraud on the PTO, and the wrongfully acquired Momenta biosimilar manufacturing patents to unlawfully delay competition from would-be ustekinumab biosimilar competitors

417. 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.

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

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

420. 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 October 31, 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.

421. 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.

422. 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.

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

424. 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.

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

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

427. 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. Haw. Rev. Stat. §§ 480-13.3, *et seq*., with respect to the plaintiffs' and class members' purchases in Hawaii.

h. 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.

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

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

k. 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;

l. 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.

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

n. 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.

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

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

q. 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.

r. 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.

s. 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.

t. N.Y. Gen. Bus. Law §§ 340, *et seq.*, with respect to the plaintiffs' and class members' purchases in New York.

u. 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.

v. 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.

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

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

y. 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.

z. 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.

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

bb. 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.

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

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

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

428. 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.

COUNT THREE

VIOLATIONS OF STATE CONSUMER PROTECTION LAWS

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

430. 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.

431. 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.

432. 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.

433. 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.

434. 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).

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

436. 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.

437. 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.

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

439. The plaintiffs and class include, 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.

440. 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.

441. 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.

442. 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.

443. 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.

444. 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.

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

446. 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:

a. Ala. Code §§ 8-19-10(e), *et seq.*, with respect to the plaintiffs' and class members' purchases in Alabama.

b. Alaska Stat. §§ 45.50.471, *et seq.*, with respect to class members' purchases in Alaska.

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

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

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

f. Cal. Civ. Code §§ 1750, *et seq.*, with respect to the plaintiffs' and class members' purchases in California.

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

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

i. Ga. Stat. §§ 10-1-390, *et seq.*, with respect to the plaintiffs' and class members' purchases in Georgia.

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

k. Ind. Code Ann. §§ 24-5-0.5-3, *et seq.*, with respect to the plaintiffs' and class members' purchases in Indiana.

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

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

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

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

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

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

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

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

t. N.H. Rev. Stat. §§ 358-A:1, *et seq.*, with respect to the plaintiffs' and class members' purchases in New Hampshire.

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

v. N. Y. Gen. Bus. Law §§ 349, *et seq.*, with respect to the plaintiffs' and class members' purchases in New York.

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

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

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

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

aa. S.D. Codified Laws §§ 37-24-1, *et seq.*, with respect to class members' purchases in South Dakota.

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

cc. Tex. Bus. & Com. Code §§ 17.41, *et seq.*, with respect to the plaintiffs' and class members' purchases in Texas.

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

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

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

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

hh. Wyo. Stat. §§ 40-12-100, *et seq.*, with respect to class members' purchases in Wyoming.

447. 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.

COUNT FOUR

UNJUST ENRICHMENT UNDER STATE LAW

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

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

450. 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.

451. 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.

452. 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.

453. 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.

454. 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.

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

456. 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.

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

458. 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

459. 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.

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

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

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

2. Alaska

463. 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.

464. 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.

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

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

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

3. Arizona

468. 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.

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

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

471. 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.

472. 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.

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

4. Arkansas

474. 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.

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

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

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

5. California

478. J&J unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for ustekinumab in California.[193] The plaintiffs and class members paid higher prices for ustekinumab than they would have paid but for J&J's actions.

479. 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.

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

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

6. Colorado

482. 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.

[193] Affidavit pursuant to Cal. Civ. Code § 1780(d) attached hereto.

483. 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.

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

485. 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

486. 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.

487. 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.

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

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

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

8. Delaware

491. 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.

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

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

494. 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.

495. 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.

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

9. District of Columbia

497. 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.

498. 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.

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

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

10. Florida

501. 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.

502. 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.

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

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

11. Georgia

505. 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.

506. 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.

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

12. Hawaii

508. 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.

509. 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.

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

13. Idaho

511. 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.

512. 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.

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

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

14. Illinois

515. 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.

516. 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.

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

518. 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

519. 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.

520. 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.

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

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

16. Kansas

523. 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.

524. 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.

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

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

17. Kentucky

527. 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.

528. 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.

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

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

18. Louisiana

531. 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.

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

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

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

535. 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.

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

19. Maine

537. 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.

538. 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.

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

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

20. Maryland

541. 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.

542. 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.

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

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

21. Massachusetts

545. 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.

546. 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.

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

548. 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

549. 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.

550. 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.

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

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

23. Minnesota

553. 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.

554. 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.

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

24. Mississippi

556. 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.

557. 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.

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

25. Missouri

559. 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.

560. 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.

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

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

26. Montana

563. 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.

564. 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.

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

27. Nebraska

566. 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.

567. 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.

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

28. Nevada

569. 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.

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

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

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

573. 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

574. 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.

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

30. New Jersey

577. 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.

578. 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.

579. 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.

580. 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.

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

31. New Mexico

582. 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.

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

584. 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

585. 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.

586. 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.

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

588. 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

589. 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.

590. 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.

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

592. 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.

593. 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.

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

34. North Dakota

595. 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.

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

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

598. 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.

599. 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.

600. The class has no remedy at law.

35. Oklahoma

601. 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.

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

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

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

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

36. Oregon

606. 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.

607. 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.

608. J&J was aware of the benefit bestowed upon it by the class.

609. 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

610. 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.

611. 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.

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

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

38. Puerto Rico

614. 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.

615. J&J has been enriched by revenue resulting from unlawful overcharges.

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

617. J&J's enrichment and the class's impoverishment are connected.

618. 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.

619. The class has no remedy at law.

39. Rhode Island

620. 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.

621. 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.

622. J&J was aware of and/or recognized the benefit bestowed upon it by the class.

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

40. South Carolina

624. 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.

625. 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.

626. J&J realized value from the benefit bestowed upon it by the class.

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

41. South Dakota

628. 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.

629. 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.

630. J&J was aware of the benefit bestowed upon it by the class.

631. Under the circumstances, it would be inequitable and unjust for J&J to retain such benefits without reimbursing the class.

42. Tennessee

632. 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.

633. 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.

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

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

636. 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

637. 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.

638. 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.

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

640. 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.

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

44. Utah

642. 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.

643. 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.

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

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

45. Vermont

646. 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.

647. 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.

648. J&J accepted the benefit bestowed upon it by the class.

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

46. Virginia

650. 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.

651. 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.

652. J&J was aware of the benefit bestowed upon it.

653. J&J should reasonably have expected to repay the class.

654. 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.

655. J&J has paid no consideration to any other person for any of the benefits it has received from the class.

47. Washington

656. 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.

657. 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.

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

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

48. West Virginia

660. 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.

661. 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.

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

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

49. Wisconsin

664. 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.

665. 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.

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

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

50. Wyoming

668. 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.

669. 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.

670. 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.

671. 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: October 24, 2025

Respectfully submitted,

/s/William H. Monroe, Jr.

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CERTIFICATE OF SERVICE

I, William H. Monroe, Jr., certify that, on this date, the foregoing document was filed electronically via the Court's CM/ECF system, which will send notice of the filing to all counsel of record, and parties may access the filing through the Court's system.

Dated: October 24, 2025

/s/William H. Monroe, Jr.
William H. Monroe, Jr.