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

SANDOZ INC. Plaintiff, v. AMGEN INC., AMGEN MANUFACTURING LIMITED LLC, and IMMUNEX CORPORATION, Defendants.	Civil Action No. 2:25-cv-00218

COMPLAINT AND DEMAND FOR JURY TRIAL

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Plaintiff, Sandoz Inc. ("Sandoz"), alleges the following against the defendants, Amgen Inc. and wholly owned subsidiaries Amgen Manufacturing Limited LLC and Immunex Corporation (collectively, "Amgen").

I. INTRODUCTION

1. Sandoz, a pioneer and global leader in providing cost effective generic and biosimilar medicines to patients, brings this case against Amgen for unlawfully extending and entrenching its monopoly for its blockbuster drug, Enbrel® (etanercept), by blocking competition from more cost-effective biosimilar competitors, including Sandoz's etanercept biosimilar, Erelzi®.

2. A biosimilar product is a biological product that is equivalent to an existing FDA-approved biologic product, called a reference product, in terms of safety, efficacy, and quality. Biosimilars offer more affordable treatment options, create competition, support the consistent supply of medicines, and provide cost savings that fuel innovation for new therapies. Biosimilars play a vital role in ensuring a sustainable and competitive US healthcare system.

3. Amgen's anticompetitive exploits began when it unlawfully purchased patent rights from a would-be competitor and used those rights over the following years to engage in a long-running and successful effort to further entrench and extend its monopoly power over etanercept—blocking Sandoz's ability to launch its cheaper biosimilar competitor product and reaping billions in profits while denying purchasers and patients access to the lower prices they would have paid in a competitive market, where Sandoz was able to launch.

4. The pharmaceutical company Immunex launched etanercept under the brand name Enbrel® in 1998. Enbrel® is a biologic medicine used to treat a range of disabling inflammatory diseases, including rheumatoid arthritis, psoriasis, psoriatic arthritis, ankylosing spondylitis, and juvenile idiopathic arthritis.

5. Amgen acquired Immunex and the rights to Enbrel® in 2002, and Enbrel® quickly became Amgen's most profitable pharmaceutical. Despite launching in the United States more than a quarter-century ago, Enbrel® remains Amgen's highest revenue product in the U.S., pulling in a staggering $3.288 billion in 2024—a half decade after Amgen should have faced biosimilar competition from Sandoz, and others. Enbrel®'s extraordinarily high prices—which Amgen has increased nearly every single year—are a result of Amgen's unlawful campaign to block Sandoz from launching its competing product and providing patients access to a cheaper alternative. In total, Amgen and Immunex have amassed more than $86 billion from cumulative worldwide sales of Enbrel®.

6. Amgen's staggering Enbrel® profits for at least the last five years are attributable to its unlawful extension of its once legitimate, patent-protected Enbrel® monopoly by preventing competition from—amongst others—Sandoz's biosimilar Erelzi®. Sandoz launched Erelzi® in Europe in June 2017, immediately driving the price of etanercept down to a fraction of what Amgen was able to charge prior to facing competition. In fact, within just one year of Sandoz's launch in Europe, "the price of Enbrel® in Europe dropped by nearly 50% and biosimilars held 40% of the market share."[1] But because Amgen blocked Sandoz's launch in the United States, U.S. patients suffered and were forced to pay more because there were no competing biosimilars to Enbrel® available to them.

7. Like generics, biosimilar drugs have no meaningful differences in safety or effectiveness from but are significantly less expensive than their brand-name counterparts. But Sandoz, and other would-be competitors of Enbrel®, were blocked by Amgen's unlawful

[1] Staff of House Comm. on Oversight and Reform, 116 Cong., Drug Pricing Investigation, 26 (2020), available at https://oversightdemocrats.house.gov/sites/evo-subsites/democrats-oversight.house.gov/files/Amgen%20Staff%20Report%2010-1-20.pdf.

actions. If not enjoined, Amgen's illegal monopoly will remain in place until at least 2029, at which point Amgen will have enjoyed *three decades* of market exclusivity—far more than patent or antitrust laws permit.

8. Amgen first hatched its anticompetitive plan to extend and entrench its monopoly in 2004. Shortly after acquiring the rights to Enbrel®, Amgen reaped massive profits. By mid-2004, annual sales were approaching $2 billion per year, the FDA had approved the drug for multiple indications and, free of competition, Amgen was able to increase the price of Enbrel® annually without any drop in sales. Amgen enjoyed all the economic perks of a monopolist, and its short- and mid-term Enbrel® projections showed that it would continue to profit handsomely from its supracompetitive pricing.

9. However, the long-term Enbrel® sale projections presented a major problem. The patent portfolio that Amgen had built to protect Enbrel® from competition would not extend beyond 2015, opening the door for biosimilar manufacturers—like Sandoz—to launch competing products and begin to eat away at Amgen's share. By 2015, the Immunex patents that Amgen had acquired would expire, and any additional patents Amgen might be able to obtain were unlikely to keep Sandoz, and other biosimilar manufacturers at bay.

10. At the same time, Amgen faced another threat: a competing drug company, F. Hoffman-La Roche AG ("Roche"), owned some of the key patents and patent applications relating to TNFR fusion proteins, including etanercept (the "Brockhaus Patent Rights"). While Roche had granted Amgen a non-exclusive license to the Brockhaus Patent Rights, nothing prevented Roche from licensing those rights to another drug company seeking to develop a biosimilar to compete with Enbrel® (or from developing a competing product itself)—a threat that would likely be realized once Amgen's own Enbrel® patents expired.

11. Amgen therefore had a choice: accept that its monopoly over its highest ever grossing product would come to a natural end and face competition from lower priced biosimilars—like all other branded biologics—or find a way to scheme the system and take steps to unlawfully extend its monopoly beyond the lawful limits.

12. Amgen chose to scheme. Despite already being ensured more than a decade-long monopoly in the U.S. etanercept market, Amgen sought to maintain, extend, and further entrench its power by buying up exclusive patent rights from Roche that otherwise would have enabled a competitor, like Sandoz, to enter the market at least by 2019 (and as early as 2016). In mid-2004, Amgen obtained an exclusive license to the Brockhaus Patent Rights, thereby extending its arsenal to block biosimilar competition and opening the door to buy itself decades more monopoly power and pricing for Enbrel®.

13. After spending years prosecuting the Brockhaus Patents, Amgen was armed with a reinforced patent portfolio, which it weaponized against Sandoz and other would-be competitors. In 2016, Amgen sued Sandoz to block it from launching its biosimilar etanercept product to compete with Enbrel®. In its lawsuit, Amgen relied on the Brockhaus Patents it had unlawfully acquired, and then prosecuted, suing Sandoz for allegedly infringing those rights and exploiting the strength of its ill-gotten portfolio to unlawfully ensure that Enbrel® would face no competition before 2029. Amgen's goal was clear: block Sandoz and other biosimilar competitors, perpetuate supracompetitive pricing, extend anticompetitive sales of Enbrel® for many more years, and use the additional time to further entrench its Enbrel® monopoly to continue even beyond its additional, and unlawfully obtained, patent protected period.

14. Amgen leveraged its wrongful acquisition of the Brockhaus Patent Rights to block Sandoz from launching its biosimilar etanercept to compete with Enbrel® and drive down

prices for patients until 2029, but Sandoz should have been able to launch Erelzi® as early as 2016, when it obtained FDA approval.

15. At that point, Sandoz already had experience launching biosimilar products. Sandoz received FDA approval for Zarxio (filgrastim-sndz), a biosimilar to another of Amgen's lucrative products, Neupogen, in April 2015 and launched shortly thereafter. Sandoz's Zarxio launch was wildly successful, launching at approximately 15% lower cost than its reference biological product, Neupogen, and eroding Amgen's one-time monopoly of 87% share down to just 67% within only 12 months. Within less than three years of Zarxio's launch, it became the first biosimilar to overtake its reference product in market share, surpassing Neupogen.[2] Zarxio provided approximately $1.6 billion in savings to the US healthcare system from 2016 to Q1 2022, effectively driving down healthcare costs and expanding patient access to essential filgrastim product therapy.

16. And through 2023, Sandoz continued to have commercial success with Zarxio, collecting 50% of the market while Neupogen's share plummeted to just 15%.[3] Sandoz was poised to do the same with Erelzi®, its etanercept biosimilar, which was deemed safe and identical to Enbrel® in all significant ways and approved by the FDA in August 2016. Erelzi® should have been able to launch later that year, or at the latest, by 2019 (when certain Amgen patents expired), but potentially as early as August 16, 2016 (when the FDA granted final approval of Sandoz's aBLA). But Amgen's unlawful and anticompetitive scheme worked to keep Sandoz from bringing it to market and providing pricing relief for millions of American patients and their health insurance payors who have been saddled with the oppressive and

[2] https://www.samsungbioepis.com/upload/attach/SB+Biosimilar+Market+Report+Q1+2024.pdf
[3] *Id.*

supracompetitive pricing of Enbrel®. If not enjoined, Amgen will continue to extract undue profits from purchasers and patients by keeping cheaper biosimilar products off the market through 2029, ensuring nearly three decades of unchecked monopoly power. And with each passing day, Amgen further entrenches its Enbrel® monopoly, including by packaging it in anticompetitive cross-therapeutic rebate bundles, ensuring that payors and Pharmacy Benefit Managers ("PBMs") are so reliant on Amgen's massive rebate bundles that even once Sandoz is permitted to launch Erelzi®, Sandoz's sales will continue to be thwarted by Amgen's anticompetitive actions.

17. Amgen's anticompetitive strategy has proven effective. Gaining control of the Brockhaus Patent Rights allowed Amgen to illegally prolong its U.S. Enbrel® monopoly for at least an additional decade. While Amgen has been able to unlawfully hold back biosimilar competitors, like Sandoz, in the U.S. market, Sandoz launched its etanercept biosimilar in Europe more than *eight years ago*. In the European market, where biosimilars have been competing against Enbrel® since 2016, Enbrel®'s price and share have dropped significantly.[4] As one study focused on European markets explained, "[a] key benefit of biosimilar competition is generating cost-savings. Biosimilar entry may result in price competition leading to price reductions of the originator biologic as well as the whole product line (originator and its biosimilars)."[5]

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[4] *See* Staff of House Comm. on Oversight and Reform, 116 Cong., Drug Pricing Investigation, 26 (2020), available at https://oversightdemocrats.house.gov/sites/evo-subsites/democrats-oversight.house.gov/files/Amgen%20Staff%20Report%2010-1-20.pdf. at 25.

[5] Elif Car, *et al.*, *Biosimilar competition in European markets of TNF-alpha inhibitors: a comparative analysis of pricing, market share and utilization trends*, 14 Frontiers in Pharmacology (April 2023), available at https://www.frontiersin.org/journals/pharmacology/articles/10.3389/fphar.2023.1151764/full.

18. Because of Amgen's unlawful acts, Sandoz has lost out on more than $1 billion in sales of Erelzi® that it would have made but-for Amgen's unlawful and anticompetitive scheme to block Sandoz from bringing a lower priced biosimilar alternative to market. And Sandoz continues to lose out on millions of dollars in sales each month that it remains sidelined by Amgen's illegal activity. If Amgen's conduct is not enjoined, Sandoz's damages will continue to mount for at least five more years until the last patents issued from the Brockhaus Patent Rights expire and Sandoz is finally able to launch its competing biosimilar product.

19. Sandoz alleges violation of federal and state antitrust and related laws and seeks: (i) lost profit damages for the last four years—from April 11, 2021 through the filing of this complaint—during which time Sandoz has been precluded from launching its etanercept biosimilar, which should be trebled under the law, and (ii) injunctive relief to, among other things, enjoin Amgen's exclusive use of the Brockhaus Patent Rights—which would allow Sandoz to launch its biosimilar etanercept product.

II. PARTIES

20. Plaintiff Sandoz Inc. and its affiliates sells generic and biosimilar medicines in the U.S. and across the world. Sandoz is a pioneer and global leader in generic and biosimilar medicines, with a legacy stretching back over 25 years. Sandoz is committed to increasing patient access by bringing high-quality, more affordable biological products to market. Sandoz is incorporated under Delaware law and maintains its principal place of business at 100 College Road West, Princeton, New Jersey.

21. Defendant Amgen Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320.

22. Defendant Amgen Manufacturing Limited LLC is a limited liability company existing under the laws of the Territory of Bermuda, with its principal place of business at Road 31 Km 24.6, Juncos, Puerto Rico 00777. Amgen Manufacturing is a wholly owned subsidiary of Amgen Inc.

23. Defendant Immunex Corporation is a corporation organized and existing under the laws of the State of Washington with its principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320. Amgen Inc. acquired Immunex in July 2002, and Immunex became a wholly owned subsidiary of Amgen Inc.

24. In this complaint, Amgen Inc., Amgen Manufacturing, and Immunex are collectively referred to as "Amgen."

III. JURISDICTION AND VENUE

25. This action alleges violations of Section 2 of the Sherman Act, 15 U.S.C. § 2, and of state antitrust and related laws. This action seeks declaratory and injunctive relief under Sections 7 and 16 of the Clayton Act, 15 U.S.C. §§ 18, 26, and seeks monetary relief pursuant to state laws. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 (federal question), § 1337(a) (antitrust enforcement), and § 1367(a) (supplemental jurisdiction).

26. Venue is proper in this district pursuant to 15 U.S.C. § 22 and 28 U.S.C. § 1391(b) because, during the relevant period, Amgen 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.

27. As alleged below, Sandoz would have sold and made available Erelzi® for patients across the United States, including for patients who are located within this district, including in Norfolk and Virginia Beach.

28. Because of Enbrel®'s high treatment persistence rate and the chronic nature of the diseases it treats, Sandoz anticipates patients would continue to use and purchase Enbrel® for members located in this district and this division.

29. This Court has personal jurisdiction over Amgen. Amgen conducts business throughout the United States, including in this district, and has purposefully availed itself of the laws of the United States.

30. During the relevant period, Amgen manufactured, sold, and shipped Enbrel® in a continuous and uninterrupted flow of interstate commerce, which included sales of Enbrel® in this district, advertisement of Enbrel® in media in this district, monitoring prescriptions of Enbrel® by prescribers within this district, and employment of product detailers in this district, who, as agents of Amgen, marketed Enbrel® to prescribers in this district.

31. Amgen, throughout the United States and including in this district, has transacted business, maintained substantial contracts, or committed overt acts in furtherance of its illegal conduct. Amgen's unlawful conduct has had a direct, substantial, and reasonably foreseeable effect on interstate commerce, including commerce within this district.

32. Aside from sales of Enbrel®, Amgen transacts substantial business in this district, including business related to the promotion and development of Enbrel® and to the unlawful conduct alleged here.

33. Through its unlawful acts, Amgen has substantially affected and continues to substantially affect commerce throughout the United States, causing injury to Sandoz. Amgen, directly and through its agents, has engaged and continues to engage in activities to block Sandoz from launching its competing biosimilar etanercept, drive up brand sales, fix, raise, maintain, and/or stabilize the price of Enbrel® in the United States, and entrench its monopoly position

through anticompetitive and unlawful cross-therapeutic rebate bundling agreements. This conduct has unreasonably restrained trade and adversely affected the market for the direct sale and purchase of etanercept throughout the United States, including in this district, and continues to do so.

IV. REGULATORY AND ECONOMIC BACKGROUND

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

34. Biologics are large, complex molecules derived from living organisms like human cells, animal cells, and microorganisms (e.g., bacteria or yeast) and often produced through biotechnical or other more recently developed methods. They include a wide range of products, including vaccines, gene therapies, blood components, and recombinant proteins. Unlike traditional small-molecule drugs that are chemically synthesized and have a well-defined structure, biologics are complex mixtures that are not easily identified or characterized.

35. While biologics account for only about 2% of prescriptions in the US, they represent a disproportionately large share of pharmaceutical spending at approximately 46%, with the US seeing a 160% increase in spending on biological products from 2013 – 2021.[6]

36. Biologics are licensed under § 351 of the Public Health Service Act (PHSA). To get approval to market a new biologic product, an applicant must submit a biologics license application ("BLA") to the FDA.[7] The FDA may grant the BLA if, among other things, the

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[6] IQVIA Institute for Human Data Science, *Biosimilars in the United States: 2023–2027* at 2–4 (2023), https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/biosimilars-in-the-united-states-2023-2027

[7] 42 U.S.C. § 262(a).

manufacturer has demonstrated that the biologic and its manufacturing processes and facilities meet standards to assure that the product is safe, pure, and potent.[8]

37. A biosimilar is a drug that is highly similar, but not structurally identical to, a brand-name biologic (referred to as the innovator or reference product). Biosimilars have generated approximately $36 billion in health system and patient savings since Sandoz launched the first biosimilar in the US in 2015, with approximately $12.4 billion of these savings being generated in 2023 alone.[9]

38. Before 2010, biosimilars were, like small-molecule brand and generic drugs, approved under the Food, Drug and Cosmetic Act ("FDCA"). But because of the complexity of biologics and the fact that they often require complex, sensitive manufacturing processes, it is not feasible to create an exact duplicate of an existing biologic. Biosimilars therefore could not be approved through the abbreviated pathway for generic small-molecule drugs established by the Hatch-Waxman Act, which requires the sponsor to show the generic has the same active ingredients, strength, dosage form, and route of administration and is bioequivalent to an approved brand-name drug.

39. Recognizing the need for an abbreviated approval process for biosimilars, Congress passed the Biologics Price Competition and Innovation Act ("BPCIA") as part of the Affordable Care Act, signed into law on March 23, 2010. The purpose of the BPCIA was to create a regime for biosimilars, similar to the one created by the Hatch-Waxman Act for generic drugs, in order to promote competition and lower prices in the biologics markets.

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[8] 42 U.S.C. § 262(a)(2)(C)(i)(I).

[9] Association for Accessible Medicines, *The U.S. Generic & Biosimilar Medicines Savings Report at* 1 (September 2024), https://accessiblemeds.org/wp-content/uploads/2025/01/AAM-2024-Generic-Biosimilar-Medicines-Savings-Report.pdf.

40. The BPCIA amended the PHSA to create an abbreviated licensure pathway for biosimilars. Under § 351(k) of the PHSA, a company seeking to market a biosimilar product in the United States must first submit to the FDA an abbreviated biologics license application ("aBLA") with information demonstrating, among other things, biosimilarity to the reference (brand) product based on data from analytical studies, animal studies, and clinical studies. The FDA will grant approval if this data shows the product 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]

41. A biosimilar manufacturer may not submit an aBLA until four years after the reference product is first licensed, and an aBLA may not be approved until twelve years after the reference product is first licensed.[11] Put another way, the manufacturer of a new biologic drug enjoys a statutory twelve-year monopoly over its product without biosimilar competition. Thereafter, biosimilar manufacturers, like Sandoz, are free to compete—subject to lawful patent restraints.

B. Biosimilar competition lowers drug prices.

42. Biosimilar competition is a relatively recent source of healthcare savings. In 2015, Sandoz became the first manufacturer to receive FDA approval for a biosimilar product. Sandoz's pioneer product, Zarxio (filgrastim-sndz), was a biosimilar to Amgen's reference product, Neupogen, an injectable medication used to help reduce the chance of infection due to a low white blood cell count in patients who are receiving certain types of chemotherapy. After launch, the presence of Zarxio drove the price of filgrastim products down significantly. One

[10] 42 U.S.C. § 262(i)(2); *see also* 42 U.S.C. § 262(k)(2)(A).

[11] 42 U.S.C. § 262(k)(7).

study observed that total annual spending for filgrastim products decreased by 28.1% for Medicare Part B and 22.1% for Medicaid after Zarxio's launch.[12] And Zarxio continues to provide an average patient cost savings of about $132 to $600 compared with the costs of Neupogen.[13]

43. Despite fierce competition from Amgen, Sandoz's Zarxio was immensely successfully, and it became the first biosimilar to surpass its reference product in share, delivering millions of dollars in savings to purchasers and patients.

44. Sandoz has devoted significant resources to stay at the forefront of the biosimilar industry and provide patients with safe and effective biologic products. Sandoz is committed to bringing biosimilars to more patients around the word and has made a strong investment in manufacturing biosimilars, having end-to-end capabilities to ensure the reliable development, manufacturing and supply of industry-leading, quality biosimilars. Sandoz has a robust pipeline of biosimilar products and, as the first company to bring biosimilars to patients in both the U.S. and worldwide, has a proven track record in delivering more cost effective biosimilar medications to patients. Sandoz's biosimilars have provided greater patient access to life-saving medicines, while increasing savings for purchasers and patients across the healthcare system.

45. Still, as of February 2025, the FDA had approved only 68 biosimilars—including 9 Sandoz biosimilar products.[14]

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[12] Jingjing Qian, *Uptake and cost of biosimilar filgrastim among Medicare and Medicaid populations in 2015-2018*, 27 Journal of Managed Care & Specialty Pharmacy 5 (2021), available at https://www.jmcp.org/doi/10.18553/jmcp.2021.27.5.660.

[13] Megan Holsopple, *Biosimlars: Are They Delivering the Cost Savings Promised?*, Pharmacy Times (Feb. 15, 2024), https://www.pharmacytimes.com/view/biosimilars-are-they-delivering-the-cost-savings-promised-.

[14] Biosimilar Product Information, FDA, https://www.fda.gov/drugs/biosimilars/biosimilar-product-information (last visited February 19, 2025).

46. Among the 68 FDA approved biosimilars are two etanercept biosimilars, Sandoz's Erelzi® and Samsung Bioepis's Eticovo, approved in August 2016 and April 2019, respectively.[15]

47. While there are some differences in distribution, pharmacy-counter substitution, and prescription writing practices of biosimilar and generic drugs, the same general economic principle applies: biosimilar competition, like generic competition, lowers drug prices and saves the entire healthcare system 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."[16] According to the 2024 U.S. Generic & Biosimilar Medicines Savings Report, "biosimilars, on average, are priced more than 40 percent lower than the brand biologic[] price at the time of biosimilar launch."[17] And the brand biologics respond to biosimilar entry by lowering their prices to date, "by 33 percent on average."[18]

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

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[15] *Id.*

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

[17] Association for Accessible Medicines, *The U.S. Generic & Biosimilar Medicines Savings Report* at 32 (September 2024), https://accessiblemeds.org/wp-content/uploads/2025/01/AAM-2024-Generic-Biosimilar-Medicines-Savings-Report.pdf.

[18] *Id.*

ten years.[19] 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.[20]

49. Actual savings far exceeded expectations. A more recent Rand review from 2022, projecting U.S. savings from biosimilar entry from 2021 to 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 through 2025 from expanded biosimilar competition.[21]

50. The 2024 U.S. Generic & Biosimilar Medicines Savings Report found that biosimilars generated $36 billion in savings since 2015, including over $12.4 billion in 2023 alone.[22] And a third study estimated that biosimilar entry could result in $100 billion in savings between 2020 and 2024.[23] These results were also confirmed by the 2022 Rand study published in the *American Journal of Managed Car*e 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

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[19] Andrew W. Mulcahy, Zachary Predmore & Soeren Mattke, RAND, *The Cost Savings Potential of Biosimilar Drugs in the United States* at 7 & n.17 (2014), https://www.rand.org/pubs/perspectives/PE127.html.

[20] *Id*.

[21] Andrew W. Mulcahy & Christine Buttorff, *Projected US Savings from Biosimilars, 2021– 2025*, 28 Am. J. Managed Care 329, 331 (2022), https://www.ajmc.com/view/projected-us-savings-from-biosimilars-2021-2025.

[22] Association for Accessible Medicines, *The U.S. Generic & Biosimilar Medicines Savings Report* at 1 (September 2024), https://accessiblemeds.org/wp-content/uploads/2025/01/AAM-2024-Generic-Biosimilar-Medicines-Savings-Report.pdf.

[23] IQVIA, *Biosimilars in the United States: 2020–2024* at 17 (2020), https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/biosimilars-in-the-united-states-2020-2024 ("IQVIA Biosimilars Report").

study found potential savings could reach $124.2 billion between 2021 and 2025.[24] In 2023, an IQVIA study concluded that savings from biosimilars would balloon to $181 billion between 2023 and 2027.[25]

V. FACTS

A. Etanercept is a biologic that reduces the symptoms of inflammatory diseases.

51. Enbrel® is a brand-name biologic approved by the FDA for the treatment of rheumatoid arthritis, plaque psoriasis, psoriatic arthritis, ankylosing spondylitis, and polyarticular juvenile idiopathic arthritis. The active ingredient in Enbrel® is etanercept. It is sold in single-dose prefilled syringes that patients generally self-administer via weekly injections (typically, one 50- mg injection per week).

52. Rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, and plaque psoriasis are autoimmune disorders which result from malfunctions of the body's immune system that cause it to attack its own cells or tissues. These internal attacks can take various forms, including prolonged inflammatory responses that can damage the body's vital organs. As many as 50 million Americans—80% of whom are women—have an autoimmune disease.

53. Rheumatoid arthritis, which affects more than 1.3 million Americans, occurs when the immune system attacks the lining of the joints, leading to chronic inflammation that can cause pain, stiffness, swelling and, over time, bone erosion and joint deformity. It can also cause fatigue, fevers, and loss of appetite and affect the heart, lungs, blood, nerves, eyes, and skin.

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[24] Mulcahy & Buttorff, *supra* note 24, at 234.

[25] IQVIA, *Biosimilars in the United States: 2023–2027* at 29 (2023), https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/biosimilars-in-the-united-states-2023-2027.

54. Plaque psoriasis is a chronic condition in which the immune system causes skin cells to multiply too quickly, causing patches of skin to become scaly and inflamed. Some people with psoriasis develop psoriatic arthritis ("PsA"), which causes pain, swelling, and stiffness of the joints, tendons, and ligaments. Psoriasis also increases the risk of cardiovascular events like heart attack and strokes, mental health problems, certain cancers, Crohn's diseases, diabetes, metabolic syndrome, obesity, osteoporosis, eye inflammation, liver disease, and kidney disease.

55. Ankylosing spondylitis causes inflammation in the joints and ligaments of the spine, resulting in back pain, stiffness, and loss of flexibility. In severe cases, it can cause the vertebrae to fuse, making the spine rigid and inflexible. People with ankylosing spondylitis can suffer from severe, ongoing pain and may also develop inflammatory diseases of the eye, skin, or gut.

56. Juvenile idiopathic arthritis ("JIA") includes several chronic disorders in children involving inflammation of the joints, causing pain, swelling, warmth, stiffness, and loss of motion. While the origins of JIA are not understood, it begins with inflammation caused by overactivation of the immune system. JIA can last for only a few months or years but, in some cases, becomes a lifelong disease requiring treatment into adulthood.

57. The immune system is made up of various cells and antibodies that protect the human body from foreign invaders. Antibodies have two main functions: (1) binding to foreign substances called antigens, preventing the antigens from infecting cells or spreading throughout the body, and (2) recruiting[26] other parts of the immune system to attack antigens.

[26] Antibodies recruit other immune cells by marking the antigens so that immune cells can then recognize and destroy them.

58. One form of antibody is called immunoglobulin G (Ig),[27] which has four subclasses in humans: IgG1, IgG2, IgG3, and IgG4. IgG is protein that consists of two heavy and two light amino acid chains, each of which has variable and constant regions. The constant regions interact with other components of the immune system to elicit a response, while the variable regions bind to antigens.

59. Another component of the immune system is called a cytokine. Cytokines are messenger proteins with a wide range of functions, including initiating immune responses, such as regulating inflammation in the body. One of the dozens of cytokines made by the human body is tumor necrosis factor ("TNF"). TNF is associated with rheumatoid arthritis, PsA, ankylosing spondylitis, and JIA.

60. TNF activates inflammatory pathways by binding to TNF receptors ("TNFRs"). TNFRs have three regions: intracellular, transmembrane, and extracellular. The extracellular portion can be split off to produce a fragment of TNFR that can bind to TNF. There are two distinct TNFRs that exist naturally on cell surfaces: one with a molecular weight of approximately 55 kilodaltons (p55), and another weighing approximately 75 kilodaltons (p75).

61. Etanercept, a fusion protein produced by combining DNA sequences encoding parts of different proteins into one sequence and introducing that sequence into host cells, consists of the extracellular region of a p75 TNFR combined with an IgG1. It works by making a soluble protein that binds to TNR and blocks its interaction with cell surface TNFRs. By rendering TNF biologically inactive, etanercept reduces inflammatory responses in patients with diseases that cause TNF elevation.

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[27] IgG is the most common antibody in the bloodstream making up about 75% of total antibodies in the human body. In addition to IgG, there are four other types of immunoglobulins: IgA, IgM, IgD, and IgE.

B. In the mid-1980s, researchers at Roche and Immunex raced to develop and patent technologies to treat autoimmune conditions.

1. Roche scientists were the first to sequence the p55 TNFR and create TNFR-Ig fusion proteins, paving the way for new treatments.

62. In the mid-1980s, advances in understanding the role of cytokines in inflammatory diseases, along with the development of new molecular tools enabling scientists to study cytokine expression and regulation, generated significant interest in the study of TNR and the potential therapeutic applications of inhibiting its ability to bind to TNFRs.

63. A Roche research team led by Dr. Werner Lesslauer made fundamental contributions to the development of TNFR fusion proteins. This Roche team was the first to experimentally prove the existence of two distinct human TNFRs, the p55 and p75, and set out to isolate, purify, sequence, and clone them. In April 1990, the Roche scientists published the amino acid sequences for the p55 TNFR and its encoding DNA. In July 1990, Roche published the same for the p75 TNFR.

64. The Roche scientists were also the first to investigate combining the extracellular regions of TNFRs with portions of immunoglobulins to inhibit inflammatory immune responses and ultimately succeeded in creating fusion proteins using both p55 and p75 TNFRs. While the Roche team's initial fusion protein used IgG3, its experimental work also contemplated the creation of fusion proteins with IgG1 and IgG2.

65. On August 31, 1990, the Roche scientists filed European Patent Application No. 90116707.2 (the "EP '707 Application"), claiming priority[28] to three earlier applications it had

[28] An application that properly claims priority to an earlier-filed patent application receives the filing date of the earlier-filed application, which determines what prior art references can and cannot be asserted against the application during its examination.

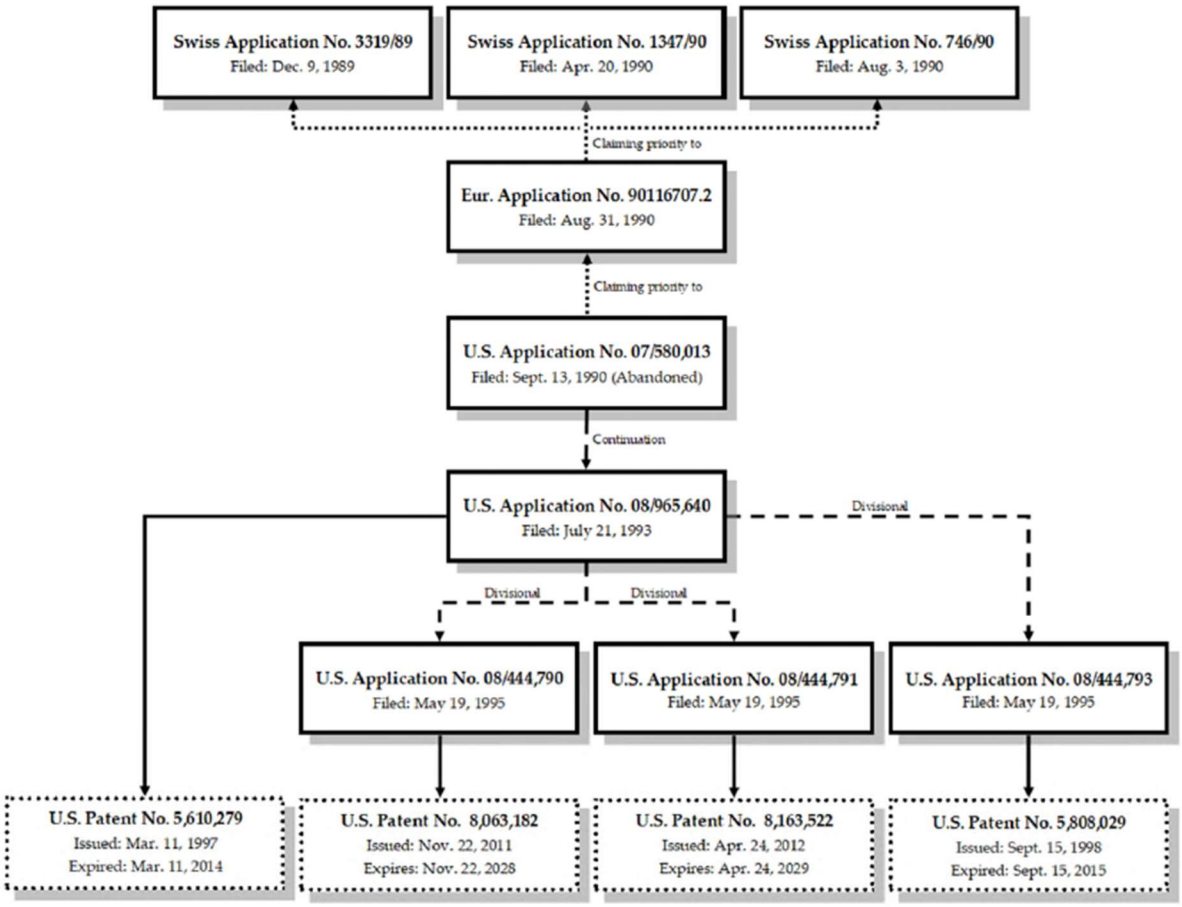
filed in Switzerland,[29] which disclosed and taught the concept of fusing the extracellular regions of the p55 and p75 TNFRs with a specific region of a human IgG heavy chain. The applications in this patent family are referred to herein as the "Brockhaus Patent Applications," the patents that would issue from them are referred to as the "Brockhaus Patents," and the applications and patents and all rights thereto are collectively referred to as the "Brockhaus Patent Rights." The relationships between the Brockhaus Applications and Patents are depicted in Figure 1 below.

66. On September 13, 1990, Roche filed U.S. Patent Application No. 07/580,013 (the "'013 Application"), claiming priority to the EP '707 Application.

67. Roche abandoned the '013 Application and, on July 21, 1993, filed U.S. Application No. 08/095,640 (the "'640 Application") as a continuation. During prosecution, the PTO placed a restriction requirement on the '640 Application: because it claimed multiple distinct inventions (related to the p55 and p75 fusion proteins), Roche would be limited to only one of the claimed inventions unless it elected to pursue only claims related to one of the fusion proteins in the application. Roche decided to pursue claims related to the p55 fusion protein in the '640 Application, which later issued as U.S. Patent No. 5,610,279 (the "'279 Patent"). In order to pursue the non-elected claims, i.e., those related to the p75 fusion protein, Roche was required to file separate divisional applications. Roche therefore filed two divisional applications on May 19, 1995: (1) U.S. Patent Application No. 08/444,790 (the "'790 Application"), which would later issue as U.S. Patent No. 8,063,182, and (2) U.S. Patent Application No. 08/444,791 (the "'791 Application"), which would later issue as U.S. Patent No. 8,163,192.

[29] Swiss Application Nos. 3319/89 (filed September 12, 1989), 746/90 (filed March 8, 1990), and 1347/90 (filed April 20, 1990).

Figure 1. Brockhaus Patent Tree



2. Immunex scientists also develop a p75 TNFR fusion protein.

68. Meanwhile, Immunex was independently researching TNFRs and TNFR fusion proteins, focusing on the p75 TNFR. In May 1990—two months before Roche—Immunex scientists published the amino acid sequence for the p75 and reported that they had isolated a cDNA clone of its receptor.

69. In late 1990, Immunex successfully combined the extracellular portion of a p75 receptor with the hinge-CH2-CH3 portion of a human IgG1—i.e., the fusion protein etanercept, the active ingredient in Enbrel®.

70. Immunex obtained a series of patents directed to etanercept and methods of using etanercept stemming from various continuations-in-part of U.S. Patent Application No. 07/403,241, filed September 5, 1989 (abandoned).

71. On May 10, 1990, Immunex filed U.S. Patent Application No. 07/523,635, which issued as U.S. Patent No. 5,395,760 (the "'760 Patent") on March 7, 1995. Entitled "DNA Encoding Tumor Necrosis Factor-α and -β Receptors," the '760 Patent claims specified isolated DNA sequences that encode soluble human TNFRs, including the p75. It expired on March 7, 2012.

72. On February 8, 1995, Immunex filed U.S. Patent Application No. 08/383,229, which issued as U.S. Patent No. 5,605,690 (the "'690 Patent") on February 25, 1997. The '690 Patent, entitled "Methods of Lowering Active TNF-α Levels in Mammals Using Tumor Necrosis Factor Receptor," claims methods of treating TNF-dependent inflammatory diseases in mammals by administering a TNF antagonist such as a soluble TNFR. It expired on February 25, 2014.

73. On January 27, 1998, Immunex filed U.S. Patent Application No. 08/346,555, which issued as U.S. Patent No. 5,712,155 (the "'155 Patent") on November 29, 1994. Entitled "DNA Encoding Tumor Necrosis Factor-α and -β Receptors," the '155 Patent claims specified isolated DNA sequences that encode soluble human TNFRs, including the p75. It expired on March 7, 2012.

C. Immunex launches Enbrel® and obtains a non-exclusive license to the Brockhaus Patent Rights.

1. The FDA approves Enbrel® as the first TNF inhibitor monotherapy to treat rheumatoid arthritis.

74. On November 2, 1998, the FDA approved Enbrel® for the treatment of moderate to severe rheumatoid arthritis in patients with an inadequate response to one or more disease-

modifying, antirheumatic drugs. Immunex launched Enbrel® in the United States on November 6, 1998.

75. Enbrel® was hailed as a breakthrough in rheumatoid arthritis treatment. Before its launch, the gold standard for rheumatoid arthritis treatment was low-dose methotrexate, which had favorable responses in only 30% of patients and often could not be tolerated for extended periods. More recent rheumatoid arthritis therapies like Remicade and Anakinra were either used in combination with methotrexate or targeted a later disease stage. Enbrel®, therefore, "st[ood] alone as an adult and juvenile rheumatoid arthritis treatment that can be used with or without" methotrexate, including in early stages of the disease, and had "no real competitor."[30]

2. Immunex seeks and gets from Roche a non-exclusive license to the Brockhaus Patent Rights.

76. On November 6, 1998, Immunex launched Enbrel® for the treatment of early and moderate to severely active rheumatoid arthritis. At the time, Immunex neither owned nor had a license to Roche's EP '707 Application teaching the fusion of extracellular regions of p75 TNFRs with a specific region of a human IgG heavy chain.

77. Immunex sought and obtained from Roche a license to the "Brockhaus Patent Rights," i.e., all "patents and patent applications that issue from or that claim priority of Swiss Patent Application Nos. 3319/89, 746/90, and/or 1347/90, including, but not limited to, European Application No. 90116707.2 and U.S. Patent Application No. 07/580,013."[31]

78. Roche and Immunex executed a license agreement (the "1998 License Agreement") on September 15, 1999, with an effective date of November 6, 1998 (the date of

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[30] Debra Robertson, *Immunex Takes Premature Step to Guarantee Enbrel Market Share*, 19 Nature Biotech. 108, 109 (Feb. 2001).

[31] License Agreement for Etanercept Among Immunex Corp., Hoffman-La Roche Inc., and F. Hoffman-La Roche Ltd. § 1.2 (Sept. 15. 1999) (attached as Ex. 1).

Enbrel®'s launch). Under the 1998 License Agreement, Roche granted Immunex a co-exclusive license (the "1998 License") under the Brockhaus Patent Rights to make, use, sell, and import etanercept worldwide. "Co-exclusive" meant that Immunex and Roche each had the right to commercialize etanercept worldwide. Roche also had the right to grant co-exclusive rights in each country to (a) one licensee in lieu of or in collaboration with Roche, (b) a single third-party to distribute etanercept within that country in lieu of Roche and its licensee, and (c) a contract manufacturer to manufacture etanercept for use, sale, importation, and/or distribution by Roche and its licensee.[32] In other words, Roche in 1998 maintained the right to manufacture etanercept itself or to allow a non-Immunex third-party to do so.

79. The 1998 License also expressly provided that Roche would retain ownership of the Brockhaus Patent Rights and was responsible at its own discretion for their prosecution and maintenance.[33] Roche also retained the sole right to address infringement of the Brockhaus Patents, including initiating suit, but Immunex agreed to provide reasonable assistance to Roche in taking any such steps and had the right to join any infringement litigation initiated by Roche and to obtain any damages awarded, including lost profits.[34] In other words, Roche in 1998 maintained all core patent rights—the right to prosecute, maintain, and enforce the Brockhaus Patent Rights. This would later change.

80. In exchange for the non-exclusive license grant, Immunex agreed to pay royalties of 4% of its net sales of etanercept products.[35] Roche also received an option to obtain a

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[32] *Id.* § 2.1.

[33] *Id.* §§ 3.1, 3.4.

[34] *Id.* § 3.5.

[35] *Id.* § 5.2.

worldwide, nonexclusive license from Immunex to certain of its patent rights relating to p55 TNFR fusion proteins, subject to certain conditions.[36]

3. Enbrel® is a phenomenal commercial success for Immunex, with $762 million in annual sales by 2001.

81. Enbrel® was an immediate blockbuster, earning Immunex $13 million in U.S. sales in its first few *weeks* on the market. In its 1998 annual report, Immunex touted Enbrel®'s launch as a "key milestone event" and predicted that Enbrel® would "drive a revenue 'step change' for Immunex" that would "provide substantial cash flow and fuel the company's growth."[37]

82. Seeking to expand the Enbrel® market, Immunex sought and, on May 27, 1999, received, FDA approval of Enbrel® for the treatment for polyarticular JIA, making it the first FDA-approved therapy for this indication. Immunex also announced in 1999 that it was conducting pilot studies and clinical trials to investigate the use of Enbrel® for additional indications and partnered with American Home Products Corporation to expand manufacturing capacity. By year end, Enbrel® had become an "unprecedented commercial success for Immunex, with $367 million in U.S. sales."[38]

83. In June 2000, the FDA approved an expanded indication for Enbrel®, adding reduction of the signs and symptoms and delay of the progression of structural damage in patients with moderately to severely active rheumatoid arthritis. It also eliminated the need for

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[36] *Id.* § 2.2.

[37] Immunex Corp., *Annual Report* at 11, 13 (1998), https://digitalcollections.lib.washington.edu/digital/collection/reports/id/24178.

[38] Immunex Corp., *Annual Report* at 23–24 (1999), https://digitalcollections.lib.washington.edu/digital/collection/reports/id/24288.

patients to demonstrate an insufficient response to one or more other rheumatic drugs before starting Enbrel® treatment—allowing more patients to access Enbrel® sooner.

84. Immunex continued "quarter for quarter" to "set new records for sales of Enbrel®."[39] By November 2000, there were more than 1,000 patients on a waiting list for the drug; total sales by year end exceeded $650 million. Sales in 2001 increased 17% to $762 million, cementing Enbrel®'s launch as the most successful ever for a biologic product. As Immunex put it, as a "targeted, potent intervention for inflammation, Enbrel® has changed the practice of rheumatology."[40]

85. Immunex also steadily increased the price of Enbrel®. When Immunex launched Enbrel® in 1998, it set the WAC price at $220 per 50-mg dose ($886 per month). By 2002, Immunex was charging $249 per 50-mg dose ($996 per month).

D. Biotech giant Amgen acquires Immunex and adds Enbrel® to its waning portfolio.

86. In December 2001, Amgen Inc., already the largest biotechnology company in the world, announced that it was buying Immunex for $16 billion in cash and stock—the highest sum *ever paid* for a biotech acquisition.

87. Enbrel® was the key driver of the deal for Amgen, which had not launched a significant new drug in a decade. Sales of its aging blockbusters Epogen (an anemia treatment) and Neupogen (the reference product for Sandoz's biosimilar, Zarxio)—once $1-billion-a-year sellers—were foundering. And ten years of substantial investment in inflammation research had garnered few returns. The FDA had approved Amgen's interleukin-1 inhibitor, Kineret (anakinra), for the treatment of moderate to severe rheumatoid arthritis in November 2001, but

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[39] Immunex Corp., *Annual Report* at 1 (2002), https://www.sec.gov/Archives/edgar/vprr/0202/02029646.pdf.

[40] *Id*.

sales were projected to be (and were) lackluster. Amgen's second-generation TNF inhibitor, pegsunercept, was only in Phase II development. Yet Amgen's new CEO, Kevin Sharer, who took the helm in 2000, had promised investors at least 20% annual growth in sales and earnings per share and revenues of $8–9 billion by 2005.

88. Enbrel® was the solution to Amgen's problems. Amgen executives boasted to investors that Enbrel® had the potential to generate more than $3 billion in annual sales by 2005, and Amgen was "enthusiastic about the long-term potential of Enbrel®."[41]

1. The FTC requires Amgen and Immunex to license certain TNFR patents to prevent an unlawful monopoly in the TNR inhibitor market.

89. Amgen's acquisition of Immunex, and the impact it would have on the market of drugs used to treat immunological conditions, drew immediate antitrust concerns from government agencies and industry watchdogs.

90. The acquisition was subject to review by the Federal Trade Commission (FTC). The FTC's Bureau of Competition is empowered to prevent "acquisitions that are likely to reduce competition and lead to higher prices, lower quality goods or services, or lessen innovation."[42] When the Bureau becomes aware of a merger, "bureau lawyers, along with economists from the FTC's Bureau of Economics, investigate market dynamics" to determine if the merger or acquisition will harm consumers.[43] When deemed necessary, the FTC may take steps before approving the merger or acquisition to protect consumers.

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[41] Andrew Pollack, *Amgen Reports Its Takeover of Immunex*, N.Y. Times, July 17, 2002, https://www.nytimes.com/2002/07/17/business/amgen-reports-its-takeover-of-immunex.html#:~:text=''Some%20of%20the%20things%20we,million%20in%20sales%20last%20year.

[42] FTC, *Merger Review*, https://www.ftc.gov/enforcement/merger-review (last visited July 3, 2024).

[43] *Id*.

91. After reviewing the proposed acquisition, the FTC issued a complaint against Amgen and Immunex stating that the "effects of the Merger, if consummated, may be to lessen competition and to tend to create a monopoly" in violation of federal antitrust law by, *inter alia*, "reducing innovation" and "eliminating potential competition in" the TNF inhibitor market.[44] The complaint noted that Amgen and Immunex were the only two firms in the United States marketing or developing soluble TNF receptor products and two of only five firms developing any type of TNF inhibitors to treat rheumatoid arthritis and other inflammatory diseases.[45] Because of the significant difficulty, cost, and time required to develop TNF inhibitors, the FTC concluded that the consolidation of Amgen's and Immunex's "substantial proprietary rights" in this market could "create large and potentially insurmountable barriers to entry."[46]

92. Amgen and Immunex settled the FTC's antitrust charges by entering a consent order requiring them, *inter alia*, to license certain patents to Serono—a Swiss pharmaceutical company that was "developing a soluble TNF receptor, Onercept, for use in Europe, but [that did] not possess the patent rights necessary to market the product in the United States"[47]—to ensure the continued development of TNF inhibitors for sale in the United States and "to remedy the lessening of competition" in that market that would result from the acquisition.[48]

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[44] Compl. ¶ 25, *In re Amgen Inc. & Immunex Corp.*, Docket No. C-4053 (F.T.C. July 12, 2002).

[45] *Id.* ¶ 20.

[46] *Id.* ¶¶ 22–24.

[47] *Id.* ¶ 20.

[48] Decision & Order at 19, *In re Amgen Inc. & Immunex Corp.*, Docket No. C-4056 (F.T.C. Sept. 3, 2002). Serono's TNF inhibitor, Onercept, was never commercialized.

93. The FTC announced on July 12, 2002, that it would allow the acquisition to proceed under the terms of the consent agreement. The acquisition was completed on July 16, 2002, giving Amgen all rights to Enbrel® in the United States and Canada.

2. Amgen reaps the rewards of its acquisition as Enbrel® becomes one of the most profitable drugs in the world.

94. Once in control of Enbrel®, Amgen immediately set out to maximize its return—and make good on its CEO's promises to investors—by increasing Enbrel® sales, including by obtaining FDA approval to use Enbrel® to treat new immunological conditions and raising Enbrel® prices.

95. Amgen's returns were almost immediate. By December 2002, it had recorded $362.1 million in Enbrel® sales; combined with Immunex's sales for the first half of the year, total 2002 sales of Enbrel® exceeded $770 million. With an estimated 80,000 people taking Enbrel®, supply constraints began impacting sales. To keep up with demand, Amgen immediately built a new Enbrel® manufacturing facility in Rhode Island.

96. By the time Amgen's acquisition of Immunex was complete, the FDA had approved Enbrel® for the treatment of psoriatic arthritis (PsA). At the time, Enbrel® was the only FDA-approved treatment for PsA. But even while touting that Enbrel® had "the broadest range of indications of any biologic therapy in rheumatic diseases," Amgen set out to obtain even more indications to further bolster sales of the blockbuster.[49] In 2003 and 2004, Amgen succeeded in getting FDA approval for the use of Enbrel® to reduce signs and symptoms of ankylosing spondylitis, to treat moderate to severe plaque psoriasis, and to induce a major

[49] Press Release, Amgen, Amgen Submits Data to FDA Supporting Once-Weekly Dosing of Enbrel (Dec. 23, 2002), https://www.amgen.com/newsroom/press-releases/2002/12/amgen-submits-data-to-fda-supporting-once-weekly-dosing-of-enbrel.

clinical response (i.e., high level of disease control) in active rheumatoid arthritis. Amgen also introduced new dosing regimens and formulations and got approvals for new age groups.

97. With the expanded indications ushering in new patients in the rheumatology and dermatology marketplaces, Enbrel® sales skyrocketed to $1.25 billion in 2003—a 175% increase from the prior year. The 2004 sales increased another 46% to $1.83 billion.

98. As Amgen was expanding Enbrel®'s indication list, it was also raising its price. Every single year post acquisition, Amgen was able to increase what it charged purchasers, payors, and patients for Enbrel®—all without losing sales to other therapeutic alternatives. These high prices set Amgen and Immunex up to enjoy high profit margins from Enbrel® sales.

99. From Enbrel®'s launch in November 1998 through 2004, Immunex and later Amgen reaped monumental benefits from their monopoly in the U.S. etanercept market, enjoying high profit margins generated by supracompetitive pricing and annual price increases. With future sales of Enbrel® projected to exceed $3 billion per year, protecting its golden-goose blockbuster became a crucial priority for Amgen.

100. Amgen went to work to protect its Enbrel® monopoly with a thicket of patents, filing dozens of applications for patents claiming Enbrel® manufacturing processes, formulations, methods of use, and administration devices.[50] But Amgen knew none of these patents were likely to prevent competing biosimilars, including Sandoz, from launching after the

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[50] *See* Jonathan Gardner, *A Three-Decade Monopoly: How Amgen Built a Patent Thicket Around its Top-Selling Drug*, BioPharma Dive (Nov. 1, 2021), https://www.biopharmadive.com/news/amgen-enbrel-patent-thicket-monopoly-biosimilar/609042/; Jeffrey Wu & Claire Wan-Chiung Cheng, *Into the Woods: A Biologic Patent Thicket Analysis*, 19 Chi.-Kent J. Intell. Prop. 93 (2020). A 2018 report found that 72% of the at least 57 applications for patents on Enbrel® were filed after the product was approved and launched. *See* I-Mak, *Overpatented, Overpriced Special Edition: Enbrel* (2020), https://www.i-mak.org/wp-content/uploads/2018/12/i-mak.enbrel.report-2018-11-30F.pdf.

expiration of Amgen's key Enbrel® patents in 2012 (indeed, as explained below, all of these patents were ultimately abandoned in later patent litigation). So, Amgen turned to another strategy: buttressing and entrenching its Enbrel® monopoly by blocking access to patents its competitors could use to launch competing biosimilar products.

E. With patent expiration and biosimilar competition on the horizon, Amgen buys out Roche's remaining Brockhaus Patent Rights.

101. While Amgen had benefited handsomely from its acquisition of Immunex, and thus Enbrel®, it saw a cliff ahead. Absent action, Enbrel® could soon face competition from a competing biosimilar etanercept product launched either directly by Roche or by a competing company that could obtain a license to the Brockhaus Patent Rights (as had been reserved in the 1998 License).

102. In 2004, Amgen undertook to further entrench and extend its monopoly over the U.S. market for etanercept by precluding the use of the Brockhaus Patent Rights by Roche or a Roche assignee and using those rights to keep all others out of the market. In June 2004, Amgen bought out all of the Brockhaus Patent Rights that Roche had retained for itself in the original 1998 License. The transaction made Amgen the exclusive licensee of the Brockhaus Patent Rights, gave it the ability to resume prosecution of any pending Brockhaus Patent Applications, and empowered it to enforce any Brockhaus Patents to exclude competitors from the etanercept market.

103. On June 7, 2004, Amgen and Roche (through Hoffman-La Roche Inc. and F. Hoffman-La Roche Ltd.) signed an agreement titled "Accord & Satisfaction" (the "2004

Exclusive License") concerning the same patent family (the Brockhaus Patent Rights) that was the subject of the 1998 License.[51]

104. The stated purpose of the agreement was "to eliminate the continuing obligations to pay royalties to Roche" pursuant to the 1998 License.[52] Under the 2004 Exclusive License, Roche agreed to waive future royalty payments, and Amgen agreed to make lump sum payments to Roche totaling $150 million.[53]

105. But the 2004 Exclusive License was far more than an agreement to eliminate the headaches of having to pay royalties calculated over time. The agreement also effectuated a significant change in the license rights of Roche's Brockhaus Patent Rights for Amgen and, in doing so, significantly altered the competitive landscape for etanercept.

106. Under the 2004 Exclusive License, Roche granted Amgen a paid-up, irrevocable, exclusive license, with the sole right to grant sublicenses, to the Brockhaus Patent Rights in North America for the commercialization of etanercept.[54] The only reservation of license rights

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[51] *See* Accord & Satisfaction Among Hoffman-La Roche Inc., F. Hoffman-La Roche Ltd., Wyeth, AHP Manufacturing B.V., Amgen Inc. & Immunex Corp. (June 7, 2004) (attached as Ex. 2). Wyeth, a Philadelphia-based pharmaceutical company acquired by Pfizer in 2009, and its wholly owned subsidiary AHP Manufacturing were Amgen's marketing partners for Enbrel®. The agreement granted Wyeth the "exclusive right to distribute products comprising Etanercept outside North America" and the right to "co-promote products comprising Etanercept within North America." *Id.* at 1. Further, the agreement assigned to Wyeth "(a) all right, title and interest in and to all Ex-North America Brockhaus Patents; and (b) the right to sue and recover for any acts of infringement of any Ex-North America Brockhaus Patents." *Id*. at 3.

[52] *Id.* at 1.

[53] *Id.* at 7.

[54] *Id.* at 4 (Article 3.1).

to Roche was for internal, non-clinical research.[55] With respect to patent prosecution, Amgen purchased the right to prosecute patent applications in the U.S. patent family.[56]

107. As of 2004, Amgen controlled the prosecution of the Brockhaus Patent Rights, including pending Brockhaus Patent Applications. The agreement granted Amgen the first right to sue over suspected infringement of the licensed patents at its sole expense and under its sole control—i.e., Amgen had the right to sue other drug companies whose products (like biosimilar etanercept) Amgen believed infringed the patents.[57] Amgen would also keep any award of damages or lost profits resulting from such an infringement suit. Roche was obligated to cooperate in these patent suits, including by participating as a party to the extent required by the court or by providing evidence and testimony in connection with any proceeding affecting the validity of the patents-in-suit.[58] Amgen also had the right to convert its exclusive license to an assignment upon request and upon payment of a relatively trivial sum of $50,000. (If "requested . . . Roche shall execute an assignment of" the patents).[59]

108. As part of the 2004 agreement, Roche retained the secondary right, but not obligation, to sue if Amgen fails to rectify infringement or initiate an action for patent infringement within 180 days after written notification by Roche.[60] The agreement further provides that, once Roche's secondary right to sue is triggered, Roche may, at its sole expense

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[55] *Id.* (Article 3.2).

[56] *Id.* at 5 (Article 3.3).

[57] *Id.* (Article 3.5).

[58] *Id.* (Article 3.4).

[59] *Id.* (Article 3.3).

[60] *Id.* at 6 (Article 3.6).

and under its sole control and direction, initiate suit and may retain the entirety of any award of damages or lost profits as a result of such suit.[61]

109. The description of the 2004 Exclusive License as an "Accord & Satisfaction" is, and appears intended by Amgen to be, misleading. In an accord and satisfaction, parties simply settle a previous unliquidated debt. Roche and Amgen could have accomplished that goal by simply agreeing to a lump sum payment in exchange for future royalties without fundamentally changing the nature of the underlying license rights. But Roche and Amgen did not stop there.

110. The intended and effectuated goal was for Amgen—then a monopolist in the U.S. market for etanercept—to extend and further entrench its monopoly position by foreclosing competition in the U.S. market for etanercept by Roche or another company to which Roche could have assigned the Brockhaus Patent Rights. Through the 2004 Exclusive License, Amgen bought up Roche's U.S. retained rights to a co-exclusive launch of etanercept products and to commercialize any p75 fusion protein and, consequently, procured the ability to use the Brockhaus Patent Rights to preclude competitors from the market.

111. The 2004 Exclusive License was also falsely labeled because, although it moved functional control of the Brockhaus Patent rights in the U.S. to Amgen, it was structured to leave ostensible back-up rights to Roche. This would later enable Amgen to argue in future proceedings, including against Sandoz, that Amgen did not "own" the Brockhaus Patent Rights, and thus the patents that Amgen already did own were not in common ownership with the owner of the Brockhaus Patent Rights (as one observer put it, the agreement "went right up to the line

[61] *Id.* (Article 3.6).

of ownership without actually crossing it"[62]). By doing so, Amgen could seek to extend Enbrel®'s patent protection by layering on later-expiring Brockhaus Patents without running afoul of the legal doctrine of double-patenting.[63]

112. The purpose and effect of Amgen's acquisition of the 2004 Exclusive License was wholly anticompetitive. Amgen already had significant rights to market exclusivity under the BPCIA and its existing patents. It sought to prolong that market exclusivity—and entrench its monopoly—by acquiring patent rights for the entire U.S. market for etanercept, a maneuver prohibited by antitrust laws.

113. *First*, Amgen had its own patents that it had acquired over the years and used to launch Enbrel® and protect its sales.[64]

114. *Second*, to the extent that Amgen needed a license from Roche to the Brockhaus Patent Rights, Immunex had already acquired those license rights (effective as of the date of Enbrel®'s launch) through the 1998 License, and that license provided co-exclusive rights. Amgen needed nothing further from Roche to be able to commercialize Enbrel® without fear of running afoul of Roche's technology and its related intellectual property.

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[62] Doug Robinson, Dickey & Pierce, P.L.C., *End of The Enbrel Battle: How Amgen Beat Sandoz* (Sept. 8, 2020), https://www.biosimilardevelopment.com/doc/end-of-the-enbrel-battle- how-amgen-beat-sandoz-0001.

[63] The double-patenting doctrine, put simply, prevents the same inventor from obtaining additional years of patent protection by patenting the same thing, or an obvious variant thereof, twice.

[64] *See* U.S. Patent No. 5,606,690; U.S. Patent No. 5,395,760; U.S. Patent No. 5,712,155; U.S. Patent No. 11,491,223; U.S. Patent No. 10,307,483; U.S. Patent No. 8,119,604.

115. *Third*, Amgen was enjoying the twelve-year exclusivity period for etanercept under § 351(k)(7) of the PHSA, which prohibited the FDA from approving any § 351(k) application for a proposed Enbrel® biosimilar until November 2, 2010.[65]

116. Nor was elimination of Roche's co-exclusive rights necessary for the successful development of Enbrel®. Immunex (and later Amgen) had already succeeded in reaching blockbuster sales for years. Despite the retained Roche license rights, Immunex and Amgen had made investments in, and gained a monopoly position in, the U.S. market for etanercept.

117. In sum, Amgen's acquisition of an exclusive license to the Brockhaus Patent Rights was intended to, and did in fact, further maintain, extend, and entrench Amgen's existing etanercept monopoly. The acquisition was anticompetitive with no procompetitive benefits.

F. Amgen uses its exclusive license to the Brockhaus Patent Rights to obtain the '182 and '522 Patents.

118. As a part of the 2004 Exclusive License, Amgen obtained all rights to control the prosecution of the '790 and '791 Applications (i.e., the Roche applications that pursued non-elected claims from the '640 Application, which was subject to a restriction requirement).[66] Amgen immediately set out to finish prosecution of those applications. Amgen notified the PTO

[65] Amgen's BLA No. 103795 for Enbrel® was first licensed by the FDA under § 351(a) of the PHSA on November 2, 1998, and additional supplements for changes and updates to the approved labeling were approved after this date. The dates that are four and 12 years after the date of first licensure of Enbrel® are November 2, 2002, and November 2, 2010, respectively. A licensure of a supplement does not trigger a separate period of exclusivity.

[66] After abandoning the '013 Application, Roche filed the '640 Application as a continuation on July 21, 1993. During prosecution of the '640 Application, the examiner issued a restriction requirement requiring Roche to choose between the p55 and p75 fusion proteins. Roche elected to pursue claims related to the p55 fusion protein only in that application, which issued as the '279 Patent on March 11, 1997. Roche then filed two divisional applications on May 19, 1995— the '790 Application and the '791 Application—to pursue non-elected claims from the '640 Application. *See supra* Section V.B.1 & Figure 1.

that Amgen lawyers would be acting as Roche's representatives in the patent prosecutions in October 2004.

119. The timing and targeting of the Brockhaus Patent prosecutions were no coincidence. The '790 and '791 Applications had been filed on May 19, 1995, a few weeks before a critical statute—the Uruguay Round Agreements of the General Agreement on Tariffs and Trade ("GATT")—took effect.[67] GATT impacted how long patent exclusivity terms would run and how they were calculated. As a result of the GATT amendment, patents that issue from applications filed after June 8, 1995, receive a 20-year term from their effective filing date. Patents claiming priority to applications filed before June 8, 1995, however, are entitled to a term that is the greater of 20 years from the filing date of the application *or* 17 years from the date of patent issuance. The late issuance of any patents from pending Brockhaus Patent Applications that had been filed pre-GATT (in 1995) would be an incredible boon for Amgen.

120. For about seven years, Amgen prosecuted the '790 and '791 Applications.

121. As to the '790 Application, Amgen amended that application twice (in 2005 and 2006). Neither amendment added new matter, the claims were supported by the original specification, and the amendments brought the application into consonance with the earlier PTO

[67] Before June 1995, 35 U.S.C. § 154 provided that the term of a utility or plant patent ended seventeen years from the date of patent grant. To comply with Article 33 of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement resulting from GATT, the United States was required to establish a minimum term for patent protection ending no earlier than twenty years from the date the application was filed. Thus, the Uruguay Round Agreements Act amended 35 U.S.C. § 154 in June of 1995 to change the term of utility and plant patents from ending 17 years from the date of patent grant to ending 20 years from the filing date of the application (or 20 years from the earliest filing date claimed under 35 U.S.C. §§ 120, 121, or 365(c)). With this change, 35 U.S.C. § 154 was also amended to provide for patent term extension in the event that issuance of the application as a patent was delayed due to secrecy order, interference or successful appellate review, subject to a five-year cap on any patent term extension under 35 U.S.C. § 154(b).

restriction requirement. A patent would issue after a successful appeal to the Board of Patent Appeals following an examiner rejection.

122. On November 22, 2011, the PTO approved the ’790 Application and issued the ’182 Patent, entitled “Human TNF Receptor Fusion Protein,” with an expiration of November 22, 2028. The claims in the ’182 Patent (those that Amgen would later assert) define a fusion protein consisting of parts of two different proteins: the extracellular region of p75 fused to all of the domains of the human IgG1 constant region other than the first domain.

123. As to the ’790 Application, Amgen amended that application three times (in 2004, 2007, and 2010) to include several references related to the full amino acid sequence for p75. None of the amendments added new matter, the claims were supported by the original specification, and the amendment brought the application into consonance with the earlier PTO restriction requirement. Like the amendments to the ’182 Patent, these amendments were also triggered by PTO actions, which rejected the ’791 Application for obviousness and insufficient written description. Despite the amendments, the ’791 Application was still rejected, but that rejection was eventually overcome by citing the ’790 Application BPAI Opinion which dealt with similar issues.

124. On April 24, 2012, the PTO issued the ’522 Patent, entitled “Human TNF Receptor,” with an expiration of April 24, 2029. The claims in the ’522 Patent that Amgen would later assert define a method of producing the fusion protein defined in the ’182 Patent.[68] By the time the patents issued, Enbrel® had already been on the U.S. marketplace since 1998, about 13 years. Sales were in the billions of dollars every year. With the pre-GATT filing date permitting

[68] The ’522 Patent issued from the ’791 Application, which (along with the ’790 Application, which issued as the ’182 Patent) was filed on May 19, 1995 as a divisional of the ’640 Application.

an additional 17 years of patent protection, use of these patents would mean Amgen could protect sales of Enbrel® and avoid competition from Sandoz, or any other biosimilar manufacturers, for *more than 30 years*.

125. Soon after the '182 Patent issued, analysts at Sanford C. Bernstein estimated that *this one* patent alone added $6 per share to Amgen's stock price.[69] With approximately 870 million outstanding shares, this single patent issuance potentially added about $5 billion to Amgen's value.

G. Harm to Competition: Amgen uses the '182 and '522 Patents to block Sandoz and Samsung Bioepis from launching cheaper biosimilar etanercept.

126. Since Amgen secured the issuance of the '182 and '522 Patents from Roche's '790 and '791 Applications, it has used them to eliminate competition in the U.S. etanercept market by blocking biosimilar entrants, including Sandoz.

1. Amgen sues Sandoz for infringement of the '182 and '522 Patents, preventing the launch of Erelzi®.

127. Sandoz was the first biosimilar manufacturer to obtain FDA approval to market a biosimilar etanercept product.

128. On September 29, 2015, the FDA accepted Sandoz's aBLA seeking authorization to market Erelzi®.

129. On February 26, 2016, Immunex and Amgen Manufacturing (the two subsidiaries of Amgen), along with Roche, sued Sandoz,[70] asserting infringement of the '182 and '522

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[69] *See* Staff of H. Comm. on Oversight and Reform, *Drug Pricing Investigation: Amgen— Enbrel and Sensipar* at 24 (Oct. 2020), https://oversightdemocrats.house.gov/sites/evo-subsites/democrats-oversight.house.gov/files/Amgen%20Staff%20Report0%2010-1-20.pdf; *see also New Patent Could Be Worth $6 a Share to Amgen*, Forbes, Nov. 28, 2011, www.forbes.com/sites/matthewherper/2011/11/28/new-patent-could-be-worth-6-a-share-to-amgen/#4be44a7a46e1.

[70] *Immunex Corp. v. Sandoz Inc.*, No. 16-cv-1118 (D.N.J.).

Patents as well as three of its own patents, 7,915,225 ("the '225 Patent"), 8,119,605 ("the '605 Patent"), and 8,722,631 ("the '631 Patent") (collectively, the "Psoriasis Patents"). Amgen sought an injunction to prohibit Sandoz from commercializing Erelzi® prior to the expiry of all the patents.

130. Over the course of the litigation, Amgen dropped any claims relating to the Psoriasis Patents, limiting its claims against Sandoz to the '182 and '522 Patents, relying exclusively on the Brockhaus Patents to deny Sandoz access to the etanercept market.

131. On August 11, 2016, and subject to the terms of a confidential stipulation, the court entered a preliminary injunction prohibiting Sandoz from commercializing Erelzi® in the U.S.

132. On August 30, 2016, the FDA approved Erelzi®, but because of Amgen's anticompetitive scheme that resulted in the court issuing an injunction, Sandoz was prevented from launching Erelzi®, despite otherwise being ready, willing, and able to do so, not long after receiving FDA approval.

133. On September 10, 2018, the court entered an order which stated that commercialization of Sandoz's biosimilar etanercept product would infringe the two Roche Patents (the '182 and '522 Patents).

134. Sandoz and Amgen litigated the infringement claims through trial, and on August 9, 2019, and after a bench trial, the court issued a decision upholding the validity of the '182 and '522 Patents.

135. At trial, Sandoz argued that the specifications in the patents were deficient because they did not sufficiently describe etanercept, convey that Roche had possession of etanercept, or direct a person of ordinary skill in the art ("POSA") to the specific embodiment of

etanercept.[71] Sandoz next argued that Roche never made Sandoz's claimed etanercept fusion protein.[72] Sandoz further argued that Amgen's "decision to take over the prosecution and amend the specifications of the ['790 and '791 Applications] [was] a clear indication that the original specifications as filed by Roche were deficient" and that amendments Amgen made to the specifications constituted "new matter" not previously included in the application. Sandoz lastly argued Amgen's patents were not enabled.[73] Amgen opposed these arguments, and the district court rejected Sandoz's arguments, finding that the material added in the amendments was sufficiently described in the applications as originally filed and that the amendments "did not add new matter."[74]

136. Sandoz appealed that decision to the Federal Circuit, but on July 1, 2020, the Federal Circuit affirmed the district court judgment upholding the validity of the '182 and '522 Patents. On appeal, Sandoz argued Amgen's patents were invalid for "(1) obviousness-type double patenting; (2) failure to meet the written description requirement; and (3) obviousness."[75] Specifically, Sandoz argued "that later amendments show that the Roche inventors did not have possession of the full p75 sequence at the time of invention," but the Federal Circuit held that the district court had not erred in finding that the amendments did not add new matter.[76]

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[71] *Immunex Corp. v. Sandoz Inc.*, 395 F. Supp. 3d 366, 381 (D.N.J. 2019), *aff'd*, 964 F.3d 1049 (Fed. Cir. 2020), *cert. denied sub nom.*, *Sandoz Inc. v. Immunex Corp.*, 141 S. Ct. 2623 (2021)

[72] *Id.* at 386.

[73] *Id.* at 388–89.

[74] *Id.* at 381–90.

[75] *Immunex Corp. v. Sandoz Inc*., 964 F.3d 1049, 1056 (Fed. Cir. 2020), *cert. denied sub nom., Sandoz Inc. v. Immunex Corp.*, 141 S. Ct. 2623 (2021).

[76] *Id.* at 1064.

137. On January 29, 2021, Sandoz filed a petition for *certiorari* to the U.S. Supreme Court, but that petition was denied on May 17, 2021.[77]

138. Amgen succeeded in blocking Sandoz from launching its competing etanercept biosimilar as a direct result of its unlawful acquisition of the Brockhaus Patent Rights.

2. Amgen sues Samsung Bioepis for infringement of the '182 and '522 Patents and blocks the launch of its Enbrel® biosimilar.

139. Ensuring that no competitor could challenge its etanercept monopoly, Amgen followed the exact same playbook after a second potential competitor—Samsung Bioepis Co., Ltd. ("Bioepis")—received FDA approval for its etanercept biosimilar product, Eticovo (etancercept-ykro), on April 25, 2019.

140. Amgen sued Bioepis on April 30, 2019 (the "*Bioepis* case"), alleging infringement of the '182 Patent and the '522 Patent and the same three Psoriasis Patents (the '225, '605, and '631 Patents) that had been asserted against Sandoz. Amgen sought an injunction to prohibit Bioepis from commercializing its biosimilar etanercept prior to the expiry of the patents.

141. On December 23, 2019, Amgen amended its complaint against Bioepis. Amgen (i) maintained the allegations regarding the '182 Patent and the '522 Patent, but (ii) withdrew the allegations regarding the Psoriasis Patents, and (iii) added infringement allegations regarding three other manufacturing patents that were later dismissed.

142. The prior rulings against Sandoz had a significant impact on the *Bioepis* case. On November 3, 2021, Amgen again was able to successfully use the Brockhaus Patent Rights to preclude biosimilar entry when the *Bioepis* court entered judgment in favor of Immunex and

[77] *Sandoz Inc. v. Immunex Corp*., 141 S. Ct. 2623 (2021).

against Bioepis on the claims for infringement of the ’182 and ’522 Patents. Bioepis was permanently enjoined from commercializing in the United States any product containing etanercept. Bioepis was also required to immediately destroy any Bioepis etanercept product that had been imported into the United States. The injunction terminates on April 24, 2029, once both the ’182 Patent and the ’522 Patent expire.

143. Once again, it was Amgen’s monopolistic acquisition of the Brockhaus Patent Rights that allowed Amgen to keep its competitor off the market, extend its Enbrel® monopoly, and harm competition.

H. Amgen’s overt acts to exploit its Enbrel® monopoly: annual price hikes helping the company secure more than $86 billion in net revenues.

144. Amgen capitalized on its monopolist position by continuously raising the per unit price of Enbrel®.

145. A 2020 investigation of Amgen’s pricing of Enbrel® by the House of Representatives’ Committee on Oversight and Reform found that, since acquiring the rights to Enbrel® in 2002, Amgen raised its price 27 times, including by nearly 30% within one 12-month period. By 2020, a 50-mg dose of Enbrel® cost $1,414 per unit, $5,556 per month, or $72,240 a year: a 457% increase from the date Amgen acquired it.

146. Since 2020, Amgen has increased the price of Enbrel® at least six more times, most recently in January 2024. A 50-mg dose of Enbrel® now costs patients as much as $1,850 per month: *more than 650% more* than it cost when launched in 1998.

147. These price increases fueled Amgen’s massive profits from Enbrel® sales. Its Enbrel® revenues increased every year from 2002 to 2016, culminating in $5.72 billion in 2016. One case study found that 100% of Enbrel®’s revenue growth between 2011 and 2021 came

from price increases alone. And despite recent declines in prescription volumes, Amgen has continued to reap billions annually, profiting $3.29 billion in 2024.

148. All told, Amgen has grossed nearly $90 billion in sales of Enbrel®. And Enbrel® remains one of Amgen's best-selling products both in the United States and worldwide, delivering nearly $3.29 billion in total sales in 2024.

I. Amgen uses its exclusive license to the Brockhaus Patent Rights to unlawfully buttress and entrench its monopoly.

149. Amgen has successfully used the rights it acquired under the 2004 Exclusive License—the exclusive license to the Brockhaus Patent Rights, the right to prosecute patents under them, and the right to bring enforcement actions—to unlawfully entrench and strengthen its monopoly, blocking Sandoz's—and all other manufacturers'—biosimilar entry into the U.S. market for etanercept.

150. Were it not for Amgen's unlawful acquisition of those rights, Sandoz would have launched its etanercept biosimilar in the U.S. market no later than 2019. And just as it did with Zarxio, Sandoz would have quickly gained market share, pulling in hundreds of millions of dollars in profits, while simultaneously driving down prices for purchasers and patients. Amgen's ceaseless efforts to thwart competition by Sandoz runs afoul of state and federal antitrust laws.

151. *First*, without Amgen's acquisition of exclusive rights in the 2004 Exclusive License, Roche would have retained the "co-exclusive" right to license the Brockhaus Patent Rights to another competitor—such as Sandoz—or use them itself. Unable (under the law) to sell that highly valuable right to Amgen (a monopolist in the etanercept market), a reasonable company in the position of Roche would have monetized those rights by either launching its own biosimilar product or licensing another to enter the market.

152. *Second*, because Sandoz invested significant time and money into developing and getting FDA approval for Erelzi® in 2016, a reasonable company in Roche's position would not simply sit on valuable, unused patent rights but instead would license them to Sandoz, a world-wide leader in manufacturing successful biosimilar products who had demonstrated a commitment to investing in a competing etanercept biosimilar product. Indeed, Roche already had several long-term manufacturing and other agreements with biosimilar companies.

153. *Third*, were it not for Amgen's unlawful acquisition of the exclusive license to the Brockhaus Patent Rights and the right to prosecute patents under them, the '182 and '522 Patents would likely never have issued or would have issued in a different form. Amgen *relied solely* on the Brockhaus Patent Rights to successfully block Sandoz's biosimilar entry, demonstrating that it was Amgen's intent to use those patent rights when they were acquired to block competitors' entry. Absent Amgen's unlawful acquisition of those rights to buttress and prolong its monopoly, Sandoz could and would have entered the market at least as early as 2019.

154. Sandoz would have launched its etanercept biosimilar, Erelzi®, at least by August 13, 2019 (when the Psoriasis Patents expired), but potentially as early as August 16, 2016 (when the FDA granted final approval of Sandoz's aBLA).

155. In part because of Amgen's prior experience competing against Sandoz's Neupogen biosimilar, Zarxio, Amgen knew that Sandoz's biosimilar entry would have an immediate adverse effect on Enbrel® sales. And once Bioepis was able to launch a second etanercept biosimilar product, with multiple biosimilar entrants, "competition [would] intensif[y] rapidly, resulting in greater net price declines for both the reference and biosimilar products and a greater effect on product sales."[78]

[78] Amgen Inc., Annual Report (Form 10-K) at 18 (Feb. 27, 2024).

156. Amgen itself predicted that Erelzi® and Eticovo would likely have launched at Wholesale Acquisition Cost (WAC) prices 15%–37% lower than that of Enbrel®[79] and captured 20%–25% of the etanercept market within one year of entry[80]—providing approximately $151–467 million in cost savings for the healthcare system in the first year alone.[81] Amgen further predicted that uptake of the etanercept biosimilars would have continued to increase over time, capturing approximately 75% of the market after three years, providing nearly $1 billion in savings to the healthcare system, annually.[82] Had both Sandoz and Bioepis been able to launch by August 13, 2019, the healthcare system would have collectively saved at least $3–4 billion to date.[83]

157. Amgen acted with the intent of keeping prices high—after all, Amgen itself acknowledges the extraordinary benefits of biosimilar entry. As Amgen has observed:

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[79] *See* Amgen, *2020 Biosimilar Trends Report* at 14, 18 (Sept. 2020), https://www.amgenbiosimilars.com/-/media/Themes/Amgen/amgenbiosimilars-com/Amgenbiosimilars-com/pdf/USA-CBU-80723-2020-Amgen-Biosimilar-Trends-Report.pdf ("Amgen 2020 Biosimilar Trends Report") (reporting that "manufacturers are launching biosimilars at a WAC price that is generally 15% to 37% lower than the reference product WAC"); *see also* IQVIA Biosimilars Report at 2 (noting that price discounts for biosimilars "range significantly," but "appear to reflect prior assumptions of roughly 30% discounts").

[80] *See* Amgen 2020 Biosimilar Trends Report ("Within the first year, biosimilar share generally ranged from 20% to 25%."); *see also* IQVIA Biosimilars Report at 10 (indicating that earlier biosimilars achieved 25% share of molecule volume within the first year and 39% after two years, but also noting that two biosimilars launched in 2019 had achieved significantly higher first-year uptake of 38% and 42%).

[81] Based on Amgen's reported Enbrel® sales of $5.05 billion for FY2019.

[82] *See* Amgen, *2022 Biosimilar Trends Report* at 14 (Oct. 2022), https://www.amgenbiosimilars.com/commitment/2022-Biosimilar-Trends-Report ("Amgen 2022 Biosimilar Trends Report") ("For therapeutic areas with biosimilars launched in the last 3 years, the average share was 75%.").

[83] A 30% WAC discount and market share of 25% after the first year and increasing to 60% the fifth year would result in a savings of $2.66B in total sales.

> Since the first biosimilar entered the US marketplace in 2015, 38 biosimilars have been approved, 22 of which have been launched. Biosimilars have gained significant share in the majority of therapeutic areas where they have been introduced. The US marketplace is poised to see further growth in the number of biosimilars approved and welcome many new biosimilars in the years to come. Additional competition may lead to significant savings for the healthcare system, and these savings can be deployed to newer, innovative treatments.[84]

158. Amgen admits that "[c]ompetitive mechanisms are in place to support biosimilar uptake" and that "[b]iosimilars have the potential to reduce healthcare costs by providing significant wholesale acquisition cost (WAC) and average sales price (ASP) savings at launch and through price competition, resulting in the opportunity for additional savings over time."[85] It notes that the "rate of biosimilar uptake is generally increasing over time" and that "first-to-launch biosimilars tend to capture a greater portion of the segment compared to later entrants."[86] It notes that, for "therapeutic areas with biosimilars launched in the last 3 years, the average share was 75%" and "the cumulative savings in drug spend for classes with biosimilar competition is estimated to have been $21 billion over the past 6 years."[87]

159. The fact that Amgen has been able to block biosimilar entry for etanercept this long is egregious given that Sandoz's Erelzi® entry should and likely would have been the first biosimilar drug in the extraordinarily costly autoimmune therapeutic area. In 2021, global sales of autoimmune drugs totaled more than $40 billion. As Amgen has remarked about the autoimmune space, "the planned launches of biosimilars to Humira [another autoimmune drug

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[84] Amgen 2022 Biosimilar Trends Report at 6.

[85] *Id.* at 6, 12.

[86] *Id.* at 14.

[87] *Id*. at 14–15.

used to treat similar conditions as Enbrel®] in 2023 could be a pivotal moment."[88] But that pivotal moment could, and should, have first occurred with Enbrel®. And as Amgen has admitted, "More biosimilars to treat autoimmune conditions will be coming to market this decade, offering an opportunity to inject competition and reduce healthcare costs."[89]

160. Sandoz's inability to launch its biosimilar etanercept in the U.S. is particularly disturbing considering that Sandoz developed and received approval for Erelzi® more than *eight years ago*.

161. But because of the unlawful monopoly conferred by the Brockhaus Patent Rights, Sandoz remains locked out from the etanercept market, causing the healthcare system to incur hundreds of millions of dollars per year in unnecessary overcharges for etanercept purchases. For at least 26 years—from November 1998 (Enbrel®'s launch) through the filing of this complaint—Amgen has enjoyed exclusive sales of Enbrel®, and if not enjoined, will continue to do so until 2029.

162. And despite the fact that 2029 will mark more than three decades of Amgen operating with an unimpeded monopoly in the U.S. etanercept market, upon information and belief, Amgen has already begun to take actions to further entrench its monopoly position through anticompetitive cross-therapeutic rebate bundling arrangements with payors and PBMs to ensure that once its patent protection from the Brockhaus Patent Rights finally expires, it will still be able to thwart competition from Sandoz and other biosimilar manufacturers.

163. In sum, Amgen knowingly and willfully acquired the exclusive license to the Brockhaus Patent Rights to delay competition from would-be etanercept biosimilar competitors

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[88] *Id.* at 24.

[89] *Id.*

and to further entrench its etanercept monopoly. Amgen's acquisition of the Brockhaus Patent Rights was for the purpose, and has had the consequence of, unlawfully extending and maintaining Amgen's monopoly in the market for etanercept in the United States.

J. Amgen continues to further buttress and entrench its monopoly through additional overt acts: anticompetitive cross-therapeutic rebate bundling arrangements with payors and PBMs and through securing approval for new indications.

164. Upon information and belief, beginning in 2020, Amgen began to enter into anticompetitive cross-therapeutic rebate bundling arrangements with third-party payors, including prominent PBMs, involving Enbrel®.

165. Upon information and belief, Amgen has entered into anticompetitive cross-therapeutic rebate bundling arrangements involving Enbrel® at least as recently as September 1, 2021, and January 1, 2022.

166. Upon information and belief, Amgen's bundled-rebate scheme requires third-party payors to place Amgen's products in favorable formulary positions, to the detriment of competing products.

167. Upon information and belief, Amgen has included Enbrel® in bundled rebates along with another blockbuster medication, Otezla, an oral treatment for moderate-to-severe psoriasis that Amgen acquired through an FTC-required divestiture sale, paying an FTC-record $13.4 billion for Otezla.

168. This is a routine practice for Amgen and demonstrates that Amgen has not stopped engaging in its anticompetitive scheme to ensure that Sandoz, or other biosimilar manufacturers, are never able to compete on a level playing field with Amgen for etanercept sales.

169. Indeed, Amgen's practice of leveraging rebates across its broad product portfolio using cross-therapeutic rebate bundles has been confirmed—and the anticompetitive impact of

this practice corroborated—by the Federal Trade Commission's allegations against Amgen in challenging its proposed merger with Horizon Therapeutics. *See* Complaint ¶ 4, *Federal Trade commission v. Amgen Inc. and Horizon Therapeutics PLC*, 2023 WL 3584650 (N.D. Ill. May 18, 2023) ("Amgen provides greater rebates on one or more of its blockbuster products to secure favorable formulary placement for other medications in different product markets.").

170. According to the FTC, "Amgen has a history of leveraging its broad portfolio of blockbuster drugs to gain advantages over potential rivals. In particular, the company has engaged in cross-market bundling, which involves conditioning rebates (or offering incremental rebates) on products such as Enbrel® in exchange for giving Amgen drugs preferred placement on the insurers' and PBMs' list of covered medications in different product markets."[90]

171. While Enbrel® currently faces no competing biosimilars on the market, upon information and belief, Amgen has already taken steps to include Enbrel® as part of its cross-therapeutic rebate bundling arrangements with PBMs and other third-party payors to ensure that Enbrel® is well positioned to be unlawfully protected against forthcoming biosimilar competition.

172. Following its well-worn playbook, upon information and belief, Amgen has positioned Enbrel® as a part of these rebate bundles so that when etanercept biosimilars are finally permitted to launch—after the expiration of Amgen's unlawfully extended patent-protected monopoly period—Amgen will condition rebates for other, unrelated products on favorable formulary placement for Enbrel®, to the detriment of Sandoz, and other manufacturers', competing biosimilar etanercept products.

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[90] https://www.ftc.gov/news-events/news/press-releases/2023/05/ftc-sues-block-biopharmaceutical-giant-amgen-acquisition-would-entrench-monopoly-drugs-used-treat

173. In addition to entrenching its monopoly power for etanercept through unlawful bundled rebate agreements, Amgen continues to seek approval for new indications, broadening and further buttressing its monopoly in the etanercept market.

174. Most recently, in October 2023, Amgen secured approval from the FDA for Enbrel® to be used for the treatment of active juvenile psoriatic arthritis in pediatric patients two years of age or younger.

VI. MARKET POWER AND MARKET DEFINITION

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

176. The relevant product market is etanercept.

177. At all times relevant to this civil action, Amgen had monopoly power in the market for etanercept in the United States.

A. Direct evidence demonstrates Amgen's market power.

178. *Supracompetitive prices*. At all times relevant to this civil action, Amgen charged supracompetitive prices for Enbrel®—i.e., prices that were and are markedly higher than those Amgen could have charged had there been biosimilar competition for etanercept. Amgen also steadily *increased* the price of Enbrel® over the years.

179. From 1998 to the present, Amgen *never* lowered Enbrel® prices or lost sales volume in response to the pricing of other drugs, even though other biologic products were available in the U.S. to treat rheumatoid arthritis, psoriasis, PsA, ankylosing spondylitis, and JIA, indicating that its sales are not constrained by any other products.

180. *Supracompetitive profit margins.* At all times relevant to this action, Amgen enjoyed extraordinarily high profit margins from the sale of Enbrel®.

181. *Combination patent protection and other barriers*. From Enbrel®'s 1998 launch through the filing of this complaint, Amgen has enjoyed and continues to enjoy patent protection

for etanercept. As a result, Amgen has the power to exclude competition from etanercept biosimilars.

182. *Lack of interchangeability*. Etanercept is not readily interchangeable with other treatments for rheumatoid arthritis, psoriasis, PsA, ankylosing spondylitis, or JIA. Etanercept is a unique treatment for these diseases, ostensibly offering advantages over other available treatments for these conditions.

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

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

185. 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.

186. Amgen, in its 2022 Biosimilar Trends report, admitted that biosimilar entrants are typically 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."[91] Amgen further remarked: "For therapeutic areas with biosimilars

[91] Amgen 2022 Biosimilar Trends Report at 14.

launched in the last 3 years, the average share was 75%," and "[f]or therapeutic areas with biosimilars launched prior to 2019, the average share after 3 years was 39%."[92]

187. A 2022 study published in the *Journal of the American Medical Association* 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). . . ."[93]

188. The effects of biosimilar competition in the U.S. market for etanercept would also have substantial downward pressure on the price of etanercept.

189. Direct evidence shows that Amgen has monopoly power over the sale of etanercept in the United States and that entry of a biosimilar etanercept would cause significant downward pressure on price, resulting in more affordable and accessible etanercept products.

B. Indirect evidence demonstrates Amgen's market power.

190. Indirect evidence also confirms Amgen's market power. The relevant product market is the sale of etanercept in the United States and has, thus far, consisted solely of Enbrel®. Biosimilar versions of etanercept will also be in the relevant market once they are available. At all relevant times, Amgen's share in the market was and remains 100%.

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

192. Enbrel® does not exhibit significant, positive cross-elasticity of demand with any other medication. The existence of non-etanercept products that may be used to treat similar indications as etanercept has not constrained Amgen's ability to raise or maintain Enbrel® prices

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[92] *Id.*

[93] David L. Carl, Yannic Laube & Miguel Serra-Burriel, *Comparison of Uptake and Prices of Biosimilars in the US, Germany, and Switzerland*, 5 JAMA Netw. Open 1, 6 (2022).

without losing substantial sales. As a result, those other drug products do not occupy the same relevant antitrust market as Enbrel®.

193. Amgen needed to control only etanercept, and no other products, to maintain a supracompetitive price for Enbrel® while preserving all or virtually all its sales. Only market entry of a competing, biosimilar etanercept, such as Sandoz's Erelzi®, would undermine Amgen's ability to keep Enbrel® prices high without losing substantial sales.

194. Indirect evidence shows that Amgen had monopoly power in an antitrust market of the sale of etanercept in the United States.

VII. MARKET EFFECTS AND DAMAGES

195. In the absence of the anticompetitive conduct alleged above, Sandoz would have entered the market with Erelzi® at least by August 2019, and potentially as early as August 2016.

196. Instead, Amgen (i) willfully and unlawfully maintained and extended its monopoly power in the U.S. market for etanercept through the unlawful acquisition of the Brockhaus Patent Rights, and then by reason of that acquisition, (ii) prosecuted the '790 and '791 Applications to obtain the '182 and '552 Patents, and (iii) used those patents to buttress and entrench its monopoly and delay competition from Sandoz. The unlawful acquisition was the violation of the antitrust laws, and the subsequent prosecution of the '790 and '791 Applications and enforcement of the '182 and '552 Patents issued therefrom caused anticompetitive harm. Amgen continues to buttress and entrench its monopoly and delay true competition in the U.S. market for etanercept by entering into anticompetitive and unlawful cross-therapeutic rebate bundling arrangements with payors and PBMs to ensure that even once its patent-protected monopoly expires, it will maintain market power and the ability to exclude Sandoz and other biosimilar manufacturers from gaining share in the U.S. market for etanercept. Amgen also

continues to expand its monopolistic reach by securing FDA approval for new indications for Enbrel®.

197. Amgen's conduct had, and continues to have, the purpose and effect of preventing biosimilar competition, permitting Amgen to maintain supracompetitive monopoly prices for Enbrel® and enabling Amgen to sell Enbrel® without competition. Absent Amgen's illegal conduct, Sandoz's Erelzi® would have already launched.

198. Because Sandoz was blocked from launching Erelzi® in 2019, or as early as 2016, Sandoz has lost out on billions of dollars in sales to date.

199. As a result, Amgen's conduct has (i) blocked Sandoz from launching its biosimilar etanercept and (ii) cost Sandoz more than $1 billion in lost profits from sales of Erelzi® over the last four years.

VIII. ANTITRUST IMPACT

200. The effect of Amgen's conduct is to net Amgen billions of dollars in revenue, a portion of which would have been earned by Sandoz through sales of its cheaper biosimilar etanercept product, Erelzi®.

201. Amgen's conduct further harmed competition by precluding all other biosimilar etanercept manufacturers from being able to launch competing etanercept products.

202. Amgen's monopoly rents come at the expense of purchasers, payors, and patients, who have paid, and will continue to pay hundreds of millions, if not billions, of dollars in unlawful overcharges.

203. During the relevant period—from April 11, 2021 through the filing of this complaint—and absent Amgen's anticompetitive conduct, Sandoz would have earned close to a billion dollars in profit from sales of Erelzi®, had Sandoz been able to launch unimpeded.

204. As a direct and proximate result of Amgen's anticompetitive conduct, Sandoz lost out on more than a billion dollars in profits from sales of Erelzi®.

205. As a result, Sandoz has sustained substantial losses and damage to its business and property in the form of lost profits. The full amount, forms, and components of such damages will be calculated after discovery and upon proof at trial.

206. Sandoz's lost profits are directly traceable to Amgen's anticompetitive conduct, because but-for Amgen's unlawful scheme to acquire, prosecute, and enforce the Brockhaus Patent Rights, Sandoz would have launched Erelzi® at least as early as 2019.

IX. IMPACT ON INTERSTATE COMMERCE

207. Amgen's efforts to monopolize and restrain competition in the market for etanercept have substantially affected interstate and foreign commerce.

208. At all material times, Amgen manufactured, sold, and shipped substantial amounts of Enbrel® across state lines in an uninterrupted flow of commerce across state and national lines throughout the United States.

209. At all material times, Amgen 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 Enbrel®.

210. To further its monopolization and restraint on competition in the market for etanercept, Amgen 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. Amgen engaged in illegal activities, as charged herein, within the flow of—and substantially affecting—interstate commerce, including in this district.

X. 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

211. Sandoz repeats and incorporates the above paragraphs as though fully set forth herein.

212. At all relevant times, Amgen possessed and continues to possess substantial market power (i.e., monopoly power) in the market for etanercept in the United States. Amgen 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 etanercept.

213. Amgen's market power is coupled with strong regulatory and contractual barriers to entry.

214. At all relevant times, Amgen knowingly, willfully, and improperly maintained its monopoly power in the U.S. market for etanercept from as early as 2016 until the present through restrictive and exclusionary conduct, rather than through growth or development resulting from a superior product, business acumen, or historic accident, and thereby injured Sandoz. Amgen's conscious objective was to further its dominance and monopoly power in the market for etanercept in the United States.

215. Amgen knowingly, willfully, and improperly maintained its monopoly power and substantially reduced and harmed competition in the market for etanercept in the United States by wrongfully acquiring an exclusive license to the Brockhaus Patent Rights and using those rights to delay and/or prevent would-be competitors, including Sandoz and Bioepis, from entering the market.

216. Amgen's monopoly power over etanercept should have expired no later than 2019—and as early as 2016—when Amgen's patents had expired and Sandoz obtained FDA approval of its etanercept biosimilar. Instead, due to its unlawful acquisition and enforcement of the Brockhaus Patent Rights, Amgen's monopoly power will have extended *at least* five years too long, until Amgen is enjoined by this Court, or the Brockhaus Patents expire on April 24, 2029. As a result of Amgen's unlawful anticompetitive conduct, no other entity currently sells biosimilar etanercept in the United States. This is true even though the FDA has already approved two etanercept biosimilars.

217. The goal, purpose, and effect of Amgen's acquisition of the Brockhaus Patent Rights was to delay and/or block etanercept biosimilars, like Sandoz's, from entering the market, maintain its monopoly in that market, and maintain its supracompetitive prices for Enbrel®.

218. Amgen's anticompetitive conduct substantially reduced and harmed competition in the relevant market and was an unreasonable restraint on trade.

219. Had Amgen competed on the merits, instead of unlawfully maintaining its monopoly in the market for etanercept, Sandoz's etanercept biosimilar would have been available by no later than 2019, and as early as 2016.

220. To the extent that Amgen 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 Amgen were permitted to assert, Amgen's conduct is and was broader than necessary to achieve such a purpose.

221. Amgen's conduct has no legitimate business purpose or pro-competitive effect.

222. Amgen's anticompetitive activities have directly, foreseeably, and proximately caused injury to Sandoz throughout the United States. Sandoz was injured in its business or property as a result of Amgen's anticompetitive conduct and it has suffered and will continue to suffer injury of the type that the antitrust laws were intended to prevent, and they flow from that which makes Amgen's conduct unlawful.

223. Sandoz is a proper plaintiff to bring a case concerning Amgen's unlawful anticompetitive conduct.

224. Sandoz has been injured, and unless Amgen's unlawful conduct is enjoined, Sandoz will continue to be injured, in its businesses and property, as a direct and proximate result of Amgen's continuing monopolization in violation of Section 2 of the Sherman Act.

225. Pursuant to Fed. R. Civ. P. 57 and 28 U.S.C. § 2201(a), Sandoz seeks a declaratory judgment that Amgen's conduct seeks to prevent competition as described in the preceding paragraphs and violates § 2 of the Sherman Act.

226. Pursuant to Sections 7 and 16 of the Clayton Act, 15 U.S.C. §§ 18, 26, and other applicable law, Sandoz further seeks equitable and injunctive relief to correct for the anticompetitive market effects Amgen's unlawful conduct caused and to ensure that similar anticompetitive conduct does not occur in the future.

XI. STATE CLAIMS FOR RELIEF

COUNT TWO

MONOPOLIZATION (N.J. Stat. Ann. § 56:9-4)

227. Sandoz repeats and incorporates the above paragraphs as though fully set forth herein.

228. Amgen is a "person" within the meaning of N.J. Stat. § 56:9-2(a).

229. Etanercept is a "commodity" within the meaning of N.J. Stat. § 56:9-2(c), and therefore Amgen's business marketing, selling, and/or distributing etanercept is "trade or commerce" within the meaning of N.J. Stat. § 56:9-2(b).

230. At all relevant times, Amgen possessed and continues to possess substantial market power (i.e., monopoly power) in the market for etanercept in the United States. Amgen 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 etanercept.

231. Amgen's market power is coupled with strong regulatory and contractual barriers to entry.

232. As set forth above, at all relevant times, Amgen knowingly, willfully, and improperly maintained its monopoly power in the U.S. market for etanercept from as early as 2016 until the present through restrictive and exclusionary conduct, rather than through growth or development resulting from a superior product, business acumen, or historic accident, and thereby injured Sandoz. Amgen's conscious objective was to further its dominance and monopoly power in the market for etanercept in the United States.

233. Amgen engaged in its anticompetitive conduct with the specific intent to maintain its monopoly in the market for etanercept in the United States.

234. Amgen accomplished its anticompetitive acts by: (i) wrongfully acquiring the rights to the Brockhaus Patents; and (ii) using the wrongfully acquired Brockhaus Patents to unlawfully delay competition from would-be etanercept biosimilar competitors.

235. The goal, purpose, and effect of Amgen's anticompetitive conduct was to delay and/or block etanercept biosimilars from entering the market, extend Amgen's monopoly in that market, and maintain its supracompetitive prices for Enbrel®.

236. Amgen's anticompetitive conduct substantially reduced and harmed competition in the relevant market and was an unreasonable restraint on trade.

237. Amgen's unlawful conduct has and will continue to directly and proximately cause injury or loss to New Jersey commerce.

238. Amgen's unlawful conduct further harms competition and thereby causes and threatens injury or loss to Sandoz's business, property, and competitive position, which will continue unless Amgen's anticompetitive conduct is enjoined. Specifically, Sandoz has and will continue to lose billions of dollars in sales and profits from within the market for etanercept that would take place but for Amgen's unlawful behavior. Sandoz's injuries are of the type that antitrust laws are intended to prohibit, and flow directly from Amgen's anticompetitive conduct in violation of Section 56:9-4 of the New Jersey Antitrust Act.

239. Amgen's conduct violates Section 56:9-4 of the New Jersey Antitrust Act. Thus, Sandoz is entitled to damages for its lost profits in the last four years and injunctive relief pursuant to Sections 56:9-10 and 56:9-12 of the New Jersey Antitrust Act, N.J. Stat. §§ 56:9-10 and 56:9-12.

COUNT THREE

TORTIOUS INTERFERANCE WITH PROSPECTIVE ECONOMIC ADVANTAGE

240. Sandoz repeats and incorporates the above paragraphs as though fully set forth herein.

241. Sandoz had a reasonable expectation of marketing and selling biosimilar etanercept to the market once Sandoz's Erelzi® was approved. In addition, Sandoz had a reasonable expectation of capturing a material share of the market for etanercept given its lower price.

242. Amgen knew that Sandoz had a reasonable expectation of economic advantage. Amgen intentionally and wrongfully interfered with Sandoz's expected business dealings with respect to biosimilar etanercept by wrongfully acquiring the rights to the Brockhaus Patents and using them to unlawfully delay and/or block competition—unfair, deceptive acts, and unconscionable acts that had the goal, purpose, and effect of delaying and/or blocking the launch of etanercept biosimilars, extending Amgen's monopoly in the etanercept market, and maintaining supracompetitive prices for Enbrel®.

243. As a direct result of Amgen's intentional and wrongful interference, Sandoz has and will continue to lose billions of dollars in sales and profits from within the market for etanercept that would take place but for Amgen's unlawful behavior.

244. But for Amgen's interference, there was a reasonable probability that Sandoz would receive the economic benefits resulting from its marketing and sale of biosimilar etanercept through Sandoz's capture of a material share of the market for etanercept.

245. Amgen had no adequate justification to interfere with Sandoz's business relations with respect to its market and sale of biosimilar etanercept. Amgen's conduct is outrageous and against the public interest because Amgen acted with malice and/or reckless indifference to the rights of others.

246. Amgen's interference with Sandoz's business relations with respect to its market and sale of biosimilar etanercept will continue to cause Sandoz to suffer damages, including lost profits and other damages.

247. Upon information and belief, Amgen's acts of tortious interference will continue unless restrained by this Court.

248. Sandoz is entitled to money damages, injunctive relief, and such other relief as this cause of action allows.

DEMAND FOR RELIEF

WHEREFORE, Sandoz respectfully demands that this Court:

A. Grant permanent injunctive relief pursuant to Sections 7 and 16 of the Clayton Act to remedy the ongoing anticompetitive effects of Amgen's unlawful monopolization in the market for etanercept in the United States and permit Sandoz to launch its biosimilar etanercept immediately;

B. Grant permanent injunctive relief pursuant to Sections 7 and 16 of the Clayton Act to remedy Amgen's attempted monopolization in the market for etanercept in the United States;

C. Conduct expedited discovery proceedings leading to a prompt trial on the merits before a jury on all claims and defenses;

D. Enter judgment against Amgen and in favor of Sandoz;

E. Award Sandoz damages (including treble damages) in an amount to be determined at trial, plus interest in accordance with law;

F. Award Sandoz its costs of suit, including reasonable attorneys' fees as provided by law; and

G. Award such further and additional relief as is necessary to correct for the anticompetitive market effects Amgen'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, Sandoz demands a trial by jury on all issues so triable.

Dated: April 11, 2025

Respectfully submitted,

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