

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Norfolk Division

SANDOZ INC.,

Plaintiff,

v.

AMGEN INC., AMGEN MANUFAC-
TURING LIMITED LLC, and IM-
MUNEX CORPORATION,

Defendants.

Civil No. 2:25cv218

ORDER

Pending before the Court are a Motion to Dismiss for Failure to State a Claim (the “Motion”) (ECF No. 33) and a Memorandum in Support thereof (ECF No. 34) filed by Defendants Amgen Inc., Amgen Manufacturing Limited LLC, and Immunex Corporation (collectively, “Defendants” or “Amgen”). The Court has determined that a hearing on the Motion is unnecessary, as the issues for decision are adequately presented in the briefs.¹ *See* E.D. Va. Local Civ. R. 7(J). For the following reasons, the Motion (ECF No. 33) is **GRANTED**.

I. BACKGROUND

A. Factual Background

When ruling on a motion to dismiss for failure to state a claim, courts accept a complaint’s well-pled factual allegations as true and draw any reasonable inferences

¹ The parties’ Joint Request for a Hearing (ECF No. 38) is therefore **DENIED**.

in favor of the non-moving party. *See, e.g., Wag More Dogs, LLC v. Cozart*, 680 F.3d 359, 365 (4th Cir. 2012). The court is “not so bound with respect to a complaint’s legal conclusions.” *Schatz v. Rosenberg*, 943 F.2d 485, 489 (4th Cir. 1991) (quoting *District 28, United Mine Workers, Inc. v. Wellmore Coal Corp.*, 609 F.2d 1083, 1085–86 (4th Cir. 1979)) (cleaned up). Accordingly, the Court accepts as true the factual allegations made by Plaintiff Sandoz Inc. (“Plaintiff” or “Sandoz”) in its Complaint. *See generally* Compl., ECF No. 1. Sandoz brings this case against Amgen, alleging that it unlawfully delayed competition for its blockbuster drug, Enbrel. *Id.* ¶ 1.

1. *Scientific Background of Etanercept*

The immune system is made up of various cells and antibodies that protect the human body from foreign invaders. *Id.* ¶ 57. One component of the immune system is called a cytokine. *Id.* ¶ 59. Cytokines have a wide range of functions, including initiating immune responses, such as regulating inflammation in the body. *Id.* One of the dozens of cytokines made by the human body is tumor necrosis factor (“TNF”). *Id.* TNF is associated with rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, and juvenile idiopathic arthritis. *Id.* TNF activates inflammatory pathways by binding to TNF receptors (“TNFRs”). *Id.* ¶ 60. There are 2 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”). *Id.* Etanercept, the drug at issue in this case, consists of the extracellular region of a p75 TNFR combined with an antibody. *Id.* ¶ 61. Etanercept renders TNF biologically inactive and thereby reduces inflammatory responses in patients. *Id.* Scientists have

also been successful in using the p55 TNFR to inhibit inflammatory immune responses. *Id.* ¶ 64.

2. *Scientific Breakthroughs to Treat Autoimmune Conditions and Associated Patents*^{2,3}

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. *Id.* ¶ 52. These internal attacks can take various forms, including prolonged inflammatory responses that can damage the body's vital organs. *Id.* As many as 50 million Americans—80% of whom are women—have an autoimmune disease. *Id.* In the mid-1980s, advances in understanding inflammatory diseases generated significant interest developing a drug to render TNF biologically inactive. *Id.* ¶¶ 61–62.

F. Hoffman-La Roche AG (“Roche”) is a drug company that competes with Amgen. *Id.* ¶ 10. In the 1980s, a Roche research team made fundamental contributions to the development of TNFRs. *Id.* ¶¶ 62–63. This Roche team was the first to experimentally prove the existence of 2 distinct human TNFRs, the p55 and p75, and set out to isolate, purify, sequence, and clone them. *Id.* ¶ 63. In April 1990, the Roche scientists published the amino acid sequences for the p55 TNFR and its encoding DNA. *Id.* In July 1990, Roche published the same for the p75 TNFR. *Id.*

² Sandoz has provided a helpful “patent tree” which summarizes the evolution of these patent applications and patents. Compl. at 25, ECF No. 1.

³ This Order uses ECF-generated pagination.

Roche filed 3 patent applications in Switzerland in 1989 and 1990 which related to the p55 and p75 TNFRs.⁴ *Id.* ¶ 65. On August 31, 1990, Roche filed European Patent Application No. 90116707.2 (the “EP ’707 Application”), claiming priority to the 3 earlier applications it had filed in Switzerland which related to the p55 and p75 TNFRs.⁵ *Id.* On September 13, 1990, Roche filed U.S. Patent Application No. 07/580,013 (the “’013 Application”), claiming priority to the EP ’707 Application. *Id.* ¶ 66. Roche later abandoned the ’013 Application and, on July 21, 1993, filed U.S. Application No. 08/095,640 (the “’640 Application”) as a continuation.⁶ *Id.* ¶ 67. During Roche’s prosecution of the ’640 Application, the United States Patent and Trademark Office (“PTO”) placed a restriction requirement on the ’640 Application: because the ’640 Application 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. *Id.* 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”). *Id.* In order to pursue the non-elected claims, *i.e.*, those related to the p75 fusion protein,

⁴ This includes Swiss Application No. 3319/89 (filed on September 12, 1989), Swiss Application No. 746/90 (filed on March 8, 1990), and Swiss Application No. 1347/90 (filed on April 20, 1990). Compl. ¶ 65 n.29, ECF No. 1.

⁵ Patent applications can claim “priority” to an earlier-filed patent application, which allows them to use the date of the earlier-filed application. Compl. ¶ 65 n.28, ECF No. 1.

⁶ Filing a patent application as a “continuation” of a previous patent application allows the second patent application to retain the effective filing date of the initial patent application. *In re Owens*, 710 F.3d 1362, 1366 (Fed. Cir. 2013).

Roche was required to file separate divisional applications. *Id.* On May 19, 1995, Roche therefore filed two divisional applications: (1) U.S. Patent Application No. 08/444,790 (the “790 Application”), which would later issue as U.S. Patent No. 8,063,182 (the “182 Patent”), and (2) U.S. Patent Application No. 08/444,791 (the “791 Application”), which would later issue as U.S. Patent No. 8,163,522 (the “522 Patent”).⁷ *Id.*

3. *Immunex Obtains License Rights to Roche’s Patents*

Immunex Corporation (“Immunex”) is a pharmaceutical company which was acquired by Amgen, Inc. in 2002. *Id.* ¶¶ 4–5. In the 1980s and 1990s, Immunex was independently researching TNFRs, focusing on the p75 TNFR. *Id.* ¶ 68. In late 1990, Immunex successfully combined the extracellular portion of a p75 receptor with the antibody IgG1—*i.e.* etanercept, which is the active ingredient in Enbrel. *Id.* ¶ 69. Immunex applied for and obtained a series of its own patents directed to etanercept. *Id.* ¶¶ 70–73.⁸ On November 2, 1998, the United States Food and Drug Administration (“FDA”) approved Enbrel for the treatment of moderate to severe rheumatoid

⁷ Paragraph 67 of the Complaint states that the “791 Application issued as U.S. Patent No. 8,163,192 rather than U.S. Patent No. 8,163,522. Compl. ¶ 67. ECF No. 1. The Court considers this a typographical error, as the ’522 Patent is consistently referenced throughout the Complaint.

⁸ 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. Compl. ¶ 71, ECF No. 1. It expired on March 7, 2012. *Id.* 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. *Id.* ¶ 72. It expired on February 25, 2014. *Id.* 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. *Id.* ¶ 73. It expired on March 7, 2012. *Id.*

arthritis. *Id.* ¶ 74. On November 6, 1998, Immunex launched Enbrel in the United States. *Id.* At the time of the launch, Immunex neither owned nor had a license to Roche’s EP ’707 Application which pertained to p75 TNFRs. *Id.* ¶ 76. While Immunex had its own etanercept-related patents, *see supra* p. 5 n.8, Immunex needed such a license from Roche to continue selling Enbrel. *Id.* ¶¶ 76–78. Immunex therefore sought and obtained from Roche a license to Roche’s patent rights, including 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” (the “Roche Patent Rights”). *Id.* ¶ 77 (citing Compl. Ex. 1 § 1.2, ECF No. 1-1).

On September 15, 1999, Roche and Immunex executed a retroactive license agreement (the “1998 License Agreement”), with an effective date of November 6, 1998. *Id.* ¶ 78. Under the 1998 License Agreement, Roche granted Immunex a co-exclusive license (the “1998 License”) under the Roche Patent Rights to make, use, sell, and import etanercept worldwide. *Id.* “Co-exclusive” meant that Immunex and Roche each had the right to commercialize etanercept worldwide. *Id.* In other words, in 1998, Roche maintained the right to manufacture etanercept itself or to allow a third party other than Immunex to do so. *Id.* The 1998 License also expressly provided that Roche would retain ownership of the Roche Patent Rights and was responsible at its own discretion for their prosecution and maintenance. *Id.* ¶ 79 (citing Compl. Ex. 1 §§ 3.1, 3.4, ECF No. 1-1). Therefore, in 1998, Roche maintained all core patent rights—the right to prosecute, maintain, and enforce the Roche Patent Rights.

Id. In exchange for the non-exclusive license grant, Immunex agreed to pay royalties of 4% of its net sales of etanercept products. *Id.* ¶ 80 (citing Compl. Ex. 1 § 5.2, ECF No. 1-1).

4. *Enbrel's Launch*

When Immunex launched Enbrel in November 1998, it was an immediate blockbuster, earning Immunex \$13 million in sales in the United States in its first few weeks on the market. *Id.* ¶ 81. 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." *Id.* By the end of 1999, Enbrel had become an "unprecedented commercial success for Immunex, with \$367 million in U.S. sales." *Id.* ¶ 82. Immunex continued "quarter for quarter" to "set new records for sales of Enbrel." *Id.* ¶ 84. By November 2000, there were more than 1,000 patients on a waiting list for the drug, and total sales by year end exceeded \$650 million. *Id.* Sales in 2001 increased by 17% to \$762 million, cementing Enbrel's launch as the most successful launch in history for a biologic product.⁹ *Id.* As Immunex put it, as a "targeted, potent intervention for inflammation, Enbrel has changed the practice of rheumatology." *Id.*

⁹ Biologics include a wide range of products, including vaccines, gene therapies, blood components, and recombinant proteins. Compl. ¶ 34, ECF No. 1. 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). *Id.* ¶ 37. A biosimilar manufacturer may not submit an abbreviated biologics license application ("aBLA") until 4 years after the reference product is first licensed, and an aBLA may not be approved until 12 years after the reference product is first licensed. *Id.* ¶ 41. Thereafter, biosimilar manufacturers, like Sandoz, are free to compete—subject to lawful patent restraints. *Id.* Here, etanercept is a biologic, Enbrel is Immunex's brand name of that

5. *Amgen, Inc. Acquires Immunex*

In 2001, Amgen Inc. was already the largest biotechnology company in the world. *Id.* ¶ 86. In December 2001, Amgen Inc. announced that it was buying Immunex for \$16 billion in cash and stock—the highest sum ever paid for a biotech acquisition. *Id.* Enbrel was the key driver of the deal for Amgen Inc., which had not launched a significant new drug in a decade. *Id.* ¶ 87. Amgen Inc.’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. *Id.* Amgen Inc.’s executives boasted to investors that Enbrel had the potential to generate more than \$3 billion in annual sales by 2005, and Amgen Inc. was “enthusiastic about the long-term potential of Enbrel.” *Id.* ¶ 88.

Amgen Inc.’s acquisition of Immunex, and the impact it was expected to have on the market of drugs used to treat immunological conditions, drew immediate antitrust concerns from government agencies and industry watchdogs. *Id.* ¶ 89. After reviewing the proposed acquisition, the Federal Trade Commission (“FTC”) issued a complaint against Amgen Inc. 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. *Id.* ¶ 91. Because of the significant difficulty, cost, and time required to develop TNF inhibitors, the FTC

biologic, and competitors to Immunex have produced biosimilars to Enbrel. *Id.* ¶¶ 51, 126–143.

concluded that the consolidation of Amgen Inc.’s and Immunex’s “substantial proprietary rights” in this market could “create large and potentially insurmountable barriers to entry.” *Id.* Amgen Inc. 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”—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. *Id.* ¶ 92. On July 12, 2002, the FTC announced that it would allow Amgen Inc.’s acquisition of Immunex to proceed under the terms of the consent agreement. *Id.* ¶ 93. On July 16, 2002, Amgen Inc.’s acquisition of Immunex was completed, giving Amgen Inc. all rights to Enbrel in the United States and Canada. *Id.*

6. *Amgen Buys the Roche Patent Rights*

Amgen’s returns were almost immediate. *Id.* ¶ 95. By December 2002, it had recorded \$362.1 million in Enbrel sales; combined with Immunex’s sales for the first half of the year, the total 2002 sales of Enbrel exceeded \$770 million. *Id.* While Amgen had thus far benefited handsomely from its acquisition of Immunex, and thus Enbrel, Amgen saw a cliff ahead. *Id.* ¶ 101. 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 Roche Patent Rights, as had been reserved by Roche in the 1998 License. *Id.* Therefore, in June 2004, Amgen

bought out all of the Roche Patent Rights that Roche had retained for itself in the 1998 License. *Id.* ¶ 102. The transaction made Amgen the exclusive licensee of the Roche Patent Rights, and gave it the ability to resume prosecution of any pending patent applications within the Roche Patent Rights (the “2004 Exclusive License”). *Id.* The agreement also 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. *Id.* ¶ 107.

Therefore, as of 2004, Amgen obtained all rights to control the prosecution of the ’790 and ’791 Applications. *Id.* ¶ 118. Amgen immediately set out to finish prosecution of those applications. *Id.* For about seven years, Amgen prosecuted the ’790 and ’791 Applications. *Id.* ¶ 120. On November 22, 2011, the PTO approved the ’790 Application and issued the ’182 Patent, with an expiration date of November 22, 2028. *Id.* ¶ 122. On April 24, 2012, the PTO issued the ’522 Patent, with an expiration date of April 24, 2029. *Id.* ¶ 124.

Prior to Amgen’s purchase of the Roche Patent Rights, which eventually resulted in the ’182 and the ’522 Patents, Amgen already enjoyed significant market exclusivity via its own patents that it had acquired over the years¹⁰ and via the license rights that it had acquired from the 1998 License with Roche.¹¹ *Id.* ¶¶ 112–114.

¹⁰ Such patents include 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, and U.S. Patent No. 8,119,604. Compl. ¶ 113 n.64, ECF No. 1.

¹¹ Amgen was enjoying the twelve-year exclusivity period for etanercept under § 351(k)(7) of the Public Health Service Act, which prohibited the FDA from

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. *Id.* ¶ 114.

7. *Amgen Sues Competitors For Infringement of the '182 and '522 Patents*

a. *Sandoz*

Sandoz was the first biosimilar manufacturer to obtain FDA approval to market a biosimilar etanercept product. *Id.* ¶ 127. On September 29, 2015, the FDA accepted Sandoz's aBLA seeking authorization from the FDA to market its biosimilar drug, Erelzi. *Id.* ¶ 128. On February 26, 2016, Amgen, along with Roche, sued Sandoz, asserting infringement of the '182 and '522 Patents as well as 3 of Amgen's 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") (the "*Amgen v. Sandoz Case*"). *Id.* ¶ 129. Amgen sought an injunction to prohibit Sandoz from commercializing Erelzi prior to the expiry of all the patents. *Id.* 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 patents obtained from the Roche Patent Rights to deny Sandoz access to the etanercept market. *Id.* ¶ 130. On August 11, 2016, and subject to the terms of a confidential stipulation, a United States District Court in the District of New Jersey (the "*Sandoz Court*") entered a preliminary injunction prohibiting Sandoz from commercializing Erelzi in the United

approving any § 351(k) application for a proposed Enbrel biosimilar until November 2, 2010. Compl. ¶ 115, ECF No. 1.

States. *Id.* ¶ 131. On August 30, 2016, the FDA approved Erelzi. *Id.* ¶ 132. Given the injunction, however, Sandoz could not launch its biosimilar drug, Erelzi. *Id.* On September 10, 2018, the *Sandoz* Court entered an order which stated that commercialization of Sandoz’s biosimilar etanercept product would infringe upon the ’182 and ’522 Patents. *Id.* ¶ 133. Sandoz and Amgen litigated the infringement claims through trial, and on August 9, 2019, after a bench trial, the *Sandoz* Court issued a decision upholding the validity of the ’182 and ’522 Patents. *Id.* ¶ 134. On July 1, 2020, the Federal Circuit affirmed the *Sandoz* Court’s judgment upholding the validity of the ’182 and ’522 Patents. *Id.* ¶ 136. On May 17, 2021, Sandoz’s petition for *certiorari* to the U.S. Supreme Court was denied. *Id.* ¶ 137. Sandoz therefore has not been able to launch Erelzi to this day. *Id.* ¶ 138.

b. *Samsung Bioepis Co., Ltd. (“Samsung”)*

On April 25, 2019, Samsung received FDA approval for its etanercept biosimilar product, Eticovo. *Id.* ¶ 139. On April 30, 2019, Amgen sued Samsung, alleging, *inter alia*, infringement of the ’182 Patent, and the ’522 Patent (the “*Samsung* Case”). *Id.* ¶ 140. Amgen sought an injunction to prohibit Samsung from commercializing its biosimilar etanercept prior to the expiry of the patents. *Id.* The prior rulings by the *Sandoz* Court had a significant impact on the *Samsung* Case. *Id.* ¶ 142. On November 3, 2021, Samsung was permanently enjoined from commercializing any product containing etanercept in the United States. *Id.* This injunction terminates on April 24, 2029, after both the ’182 Patent and the ’522 Patent expire. *Id.*

8. *Enbrel's Success to Date*

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. *Id.* ¶ 145. 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. *Id.* In 2024, Enbrel delivered nearly \$3.29 billion in total sales. *Id.* ¶ 148. In total, Amgen has amassed more than \$86 billion from cumulative worldwide sales of Enbrel. *Id.* ¶ 5. At all relevant times, Amgen's market share in the etanercept market was and remains 100%. *Id.* ¶ 190.

9. *Harms Suffered by Sandoz*

Sandoz is incorporated under Delaware law and maintains its principal place of business in New Jersey. *Id.* ¶ 20. Sandoz sells generic and biosimilar medicines in the United States across the world, and is committed to increasing patient access by bringing high-quality, more affordable biological products to market. *Id.*

Sandoz alleges that it would have sold Erelzi and made it available for patients across the United States, including for patients who are located within this district, such as those in Norfolk and Virginia Beach. *Id.* ¶ 27. Sandoz further alleges that Amgen has substantially affected and continues to substantially affect commerce throughout the United States, causing injury to Sandoz. *Id.* ¶ 33. Furthermore, Sandoz alleges that 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. *Id.* For example, beginning in 2020 and as recently as 2022, Amgen began to enter into cross-therapeutic rebate bundling arrangements involving Enbrel. *Id.* ¶¶ 164–165. These bundled rebates place Amgen’s products in favorable positions, to the detriment of competing products. *Id.* ¶ 166.

Sandoz asserts that the aforementioned 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. *Id.* ¶ 33. Additionally, Sandoz alleges that, had both Sandoz and Samsung been able to launch their biosimilar products by August 13, 2019, the healthcare system would have collectively saved at least \$3 to \$4 billion to date. *Id.* ¶ 156. Furthermore, Sandoz alleges that 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 biosimilars entered the market. *Id.* ¶ 216. Instead, due to Amgen’s purchase of the Roche Patent Rights, Amgen’s alleged monopoly power over etanercept will extend until April 24, 2029, when the ’182 and ’522 Patents expire. *Id.*

B. Procedural History

On April 11, 2025, Sandoz filed its Complaint in this Court. *See generally* Compl., ECF No. 1. Therein, Sandoz brings one federal and two state claims for relief. *Id.* ¶¶ 211–248. Count 1 alleges monopolization in violation of Section 2 of the Sherman Act¹² and seeks declaratory and injunctive relief. *Id.* ¶¶ 211–226. Count 2 alleges

¹² The Sherman Act is codified in 15 U.S.C. § 2.

monopolization in violation of New Jersey state law, and seeks damages and injunctive relief. ¹³ *Id.* ¶¶ 227–239. Count 3 alleges tortious interference with prospective economic advantage in violation of New Jersey state law, and seeks damages and injunctive relief. ¹⁴ *Id.* ¶¶ 240–248.

On June 20, 2025, Amgen filed the instant Motion pursuant to Federal Rule of Civil Procedure 12(b)(1) and (6) (ECF No. 33) and a Memorandum in Support thereof (ECF No. 34). On July 21, 2025, Sandoz filed its Response in Opposition to the Motion. Resp. Opp’n, ECF No. 36. On August 21, 2025, Amgen filed its reply. Reply, ECF No. 37. The Motion is ripe for adjudication.

II. LEGAL STANDARD

Federal Rule of Civil Procedure 12(b)(6) permits a defendant to seek dismissal based on a plaintiff’s “failure to state a claim upon which relief can be granted.” Fed. R. Civ. P. 12(b)(6). A motion to dismiss for failure to state a claim should be granted if the complaint does not allege “enough facts to state a claim to relief that is plausible on its face.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). An adequate claim requires more than a “sheer possibility that a defendant has acted unlawfully.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). “A claim has facial plausibility when the

¹³ Specifically, Count 2 alleges a violation of N.J. Stat. Ann. § 56:9-4.

¹⁴ The Complaint does not specify a statute under which Count 3 is brought. Compl. ¶¶ 240–248, ECF No. 1. However, in Sandoz’s response in opposition to the instant Motion, Sandoz clarifies that Count 3 pertains to alleged “tortious interference with prospective economic advantage *under New Jersey law*[.]” Resp. Opp’n at 13, ECF No. 36 (emphasis added).

plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.*

A threadbare recitation of the “elements of a cause of action, and bare assertions devoid of further factual enhancement fail to constitute well-pled facts for Rule 12(b)(6) purposes.” *Nemet Chevrolet, Ltd. v. Consumeraffairs.com, Inc.*, 591 F.3d 250, 255 (4th Cir. 2009). Although the truth of the facts alleged is assumed, and the facts are taken in the light most favorable to the plaintiff, courts are not bound by “legal conclusions drawn from the facts” and “need not accept as true unwarranted inferences, unreasonable conclusions, or arguments.” *E. Shore Mkts., Inc. v. J.D. Assocs. Ltd. P’ship*, 213 F.3d 175, 180 (4th Cir. 2000).

A motion to dismiss pursuant to Rule 12(b)(6) must be read in conjunction with Federal Rule of Civil Procedure 8(a)(2). Rule 8(a)(2) requires only “a short and plain statement of the claim showing that the pleader is entitled to relief,” so as to “give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.” *Twombly*, 550 U.S. at 555 (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)). Fair notice is provided by setting forth enough facts for the complaint to be “plausible on its face” and to “raise a right to relief above the speculative level on the assumption that all the allegations in the complaint are true (even if doubtful in fact).” *Id.* at 555, 570 (internal citations and footnote omitted). A complaint may survive a motion to dismiss “even if it appears that a recovery is very remote and unlikely.” *Id.* at 556 (quoting *Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974)) (internal quotation marks omitted).

III. ANALYSIS

A. Federal Antitrust Claim: Monopolization in Violation of 15 U.S.C. § 2 (Count 1)

Amgen asserts that Count 1 should be dismissed on numerous grounds. *See generally* Mem. Supp., ECF No. 34. However, the Court need only consider one: whether Sandoz was required to bring the instant federal antitrust claim (Count 1) as a compulsory counterclaim during the 2016 *Amgen v. Sandoz* Case. *Id.* at 30–35. Pursuant to Fourth Circuit precedent, the Court finds that Sandoz was required to do so, and therefore Count 1 must be dismissed with prejudice.

The below analysis proceeds in 5 parts. First, the Court sets forth the compulsory counterclaim rule under Federal Rule of Civil Procedure 13(a). Next, the Court briefly summarizes some of the relevant arguments and evidence raised in the *Amgen v. Sandoz* Case. Third, the Court considers the appropriate scope of the antitrust issues alleged in the instant case. Fourth, the Court conducts the compulsory counterclaim analysis, comparing the *Amgen v. Sandoz* Case to the instant case. Finally, having found that the instant antitrust claim was a compulsory counterclaim in the *Amgen v. Sandoz* Case, the Court considers whether any exceptions apply.

1. Federal Rule of Civil Procedure 13(a)

Federal Rule of Civil Procedure 13(a) provides in pertinent part:

(a) Compulsory Counterclaim.

(1) *In General.* A pleading must state as a counterclaim any claim that—at the time of its service—the pleader has against an opposing party if the claim:

(A) arises out of the transaction or occurrence that is the subject matter of the opposing party's claim; and

(B) does not require adding another party over whom the court cannot acquire jurisdiction.

Fed. R. Civ. P. 13(a). The Fourth Circuit has developed a four-inquiry test to determine if a counterclaim “arises out of the [same] transaction or occurrence”:

(1) Are the issues of fact and law raised in the claim and counterclaim largely the same? (2) Would *res judicata* bar a subsequent suit on the party's counterclaim, absent the compulsory counterclaim rule? (3) Will substantially the same evidence support or refute the claim as well as the counterclaim? and (4) Is there any logical relationship between the claim and counterclaim?

Painter v. Harvey, 863 F.2d 329, 331 (4th Cir. 1988) (citing *Sue & Sam Mfg. Co. v. B-L-S Const. Co.*, 538 F.2d 1048 (4th Cir. 1976)). “A court need not answer all these questions in the affirmative for the counterclaim to be compulsory. Rather, the tests are less a litmus, more a guideline.” *Id.* (internal citations omitted).

2. *The Amgen v. Sandoz Case*

On February 26, 2016, Amgen, along with Roche, sued Sandoz, asserting, *inter alia*, infringement of the '182 and '522 Patents. Compl. ¶ 129, ECF No. 1. Amgen sought an injunction to prohibit Sandoz from commercializing its biosimilar drug to Enbrel, Erelzi, prior to the expiry of all the patents. *Id.* Sandoz put forth numerous defenses in that patent suit, including obvious-type double patenting. *See Immunex Corp. v. Sandoz Inc.*, 395 F. Supp. 3d 366, 380–423 (D.N.J. 2019). The *Sandoz* Court explained:

The judicially-created doctrine of obviousness-type double patenting prevents a party from extending their right to exclude by obtaining a later patent with claims that are not patentably distinct from claims in a commonly-owned previous patent. The purpose of the rule against double patenting is to prevent an inventor from effectively extending the

term of exclusivity by the subsequent patenting of variations that are not patentably distinct from the first-patented invention.

Id. at 408–09 (internal citations and quotation marks omitted). Sandoz, as a defendant in that case, argued that the ’182 and ’522 Patents “should be invalidated because Immunex has used the [’182 and ’522 Patents] to obtain an unjustified timewise extension of its etanercept monopoly in violation of 35 U.S.C. § 121.” *Id.* at 409 (citation modified). In support of that argument, Sandoz relied on two witnesses—one of whom “was Roche’s former Senior Counsel and Managing Attorney involved in drafting and negotiating the [2004 Exclusive License] on behalf of Roche.” *Id.* at 410. Amgen also relied on two witnesses, one of whom was the “former Vice President of Law and Intellectual Property Officer at Amgen, who was involved in the prosecution of the [’182 and ’522 Patents] and the negotiation and drafting of licensing agreements for the company.” *Id.* In putting forth their obviousness-type double patenting defense, Sandoz argued “common ownership,” based upon the 2004 Exclusive License which, Sandoz argued, “transferred all substantial rights from Roche to Amgen and Immunex and any rights that Roche did retain were illusory.” *Id.* at 414 (internal quotation marks omitted).

3. *The Instant Case: Sandoz v. Amgen*

Before determining whether the antitrust claim in the instant case was a compulsory counterclaim in the *Amgen v. Sandoz* Case, the Court must briefly consider the appropriate scope of the antitrust claim in the instant case, and whether it “arises out of the [same] transaction or occurrence” as the issues litigated in the *Amgen v. Sandoz* Case. Fed. R. Civ. P. 13(a). In the instant case, Sandoz alleges that Amgen

engaged in 4 phases of anticompetitive activity: (1) the acquisition of the Roche Patent Rights (“Phase 1”), Compl. ¶¶ 101–117, ECF No. 1; (2) the prosecution of the ’182 and ’522 Patents (“Phase 2”), *id.* ¶¶ 118–125; (3) the patent infringement lawsuits against Sandoz and Samsung (“Phase 3”), *id.* ¶¶ 126–143; and (4) price increases and therapeutic-rebate bundling arrangements (“Phase 4”), *id.* ¶¶ 144–48; 164–174.

Sandoz argues that the Court should consider all 4 phases—what it refers to as a “scheme”—of alleged antitrust violations in the instant case when conducting the compulsory counterclaim analysis, stating:

Amgen cannot state at this stage that the factual record supporting Sandoz’s claims here is substantially similar to the record developed in the [*Amgen v. Sandoz Case*]. The record there was developed through discovery and a two-week trial. Here, discovery has not yet commenced, and arguments regarding the factual record in a suit that has yet to be developed cannot be resolved in a motion to dismiss. And even if the factual record were developed, Amgen mischaracterizes the nature of Sandoz’s claims . . . [h]ere, Sandoz seeks to hold Amgen liable for its scheme to extend its monopoly in the etanercept market using a variety of anticompetitive tactics—many not yet employed at the time of the [*Amgen v. Sandoz Case*]. For example, since the conclusion of the [*Amgen v. Sandoz Case*], Amgen has sought to expand the scope of uses for Enbrel and packaged rebates for Enbrel as part of its coercive rebate bundling scheme to further entrench and extend its monopoly.

Resp. Opp’n at 37, ECF No. 36 (internal citations omitted). However, in the same pleading, Sandoz also states:

But the Complaint does not hinge upon a multi-part scheme in which Amgen’s patent prosecution and litigation are essential components of the violation: the Complaint states explicitly that ‘[t]he 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 ’5[2]2 Patents issued therefrom caused anticompetitive harm.’

Id. at 18 (quoting Compl. ¶ 196, ECF No. 1). Sandoz appears to be trying to shapeshift Amgen’s allegedly anticompetitive activity into a scheme when it suits one legal argument, and into a single event—the allegedly unlawful acquisition of the Roche Patent Rights—when it suits a different argument. This Court recently considered such legal maneuvering in a related case concerning nearly identical facts. *See* Second Am. Compl., *Carefirst of Maryland, Inc. v. Amgen, Inc.*, No. 2:24cv484 (E.D. Va. Nov. 25, 2024), ECF No. 52. In ruling on a motion to dismiss brought by Amgen in that case, the Court noted:

[W]hether Amgen’s actions—purchasing the Roche Patent Rights, prosecuting the ’790 Application and the ’791 Application, and enforcing the ’182 Patent and the ’522 Patents in courts—are treated as a scheme or as individual acts, is really of no import, because the *Noerr-Pennington*¹⁵ immunity that Amgen receives for the latter two actions, the prosecution and enforcement, does not immunize Amgen from the allegedly anticompetitive conduct of purchasing the Roche Patent Rights.

¹⁵ “The *Noerr-Pennington* doctrine is an outgrowth of two anti-trust cases in the 1960s, *Eastern Railroad Conference v. Noerr Freight Co.*, 365 U.S. 127, 81 S.Ct. 523, 5 L.Ed.2d 464 (1961) and *United Mine Workers v. Pennington*, 381 U.S. 657, 85 S.Ct. 1585, 14 L.Ed.2d 626 (1965).” *N. C. Elec. Membership Corp. v. Carolina Power & Light Co.*, 666 F.2d 50, 52 (4th Cir. 1981). The doctrine is “an affirmative defense which exempts from anti-trust liability any petitioning activity designed to influence legislative bodies or governmental agencies.” *Id.* In other words, conduct which might otherwise be deemed anticompetitive is immune from liability pursuant to *Noerr-Pennington* when such conduct involves petitioning the government. Courts have held that patent prosecutions before the PTO and *inter partes* review proceedings before the Patent Trial and Appeal Board (“PTAB”) is “petitioning” conduct which is protected by the *Noerr-Pennington* doctrine. *See, e.g., In re Humira (Adalimumab) Antitrust Litig.*, 465 F. Supp. 3d 811, 831 (N.D. Ill. 2020) (“[Defendant’s] petitioning before the USPTO and the PTAB is protected by *Noerr-Pennington*.”). Courts have also held that filing lawsuits in courts is protected activity. *See, e.g., Baltimore Scrap Corp. v. David J. Joseph Co.*, 237 F.3d 394, 399 (4th Cir. 2001) (“*Noerr-Pennington* immunity from antitrust laws extends to petitioning the courts as well.”); *Organon Inc. v. Mylan Pharms., Inc.*, 293 F. Supp. 2d 453, 457 (D.N.J. 2003) (“[*Noerr-Pennington*] has been expanded to include litigation to protect rights such as patents.”).

Order at 26, *Carefirst of Maryland, Inc. v. Amgen, Inc.*, No. 2:24cv484 (E.D. Va. Sept. 30, 2025), ECF No. 66. The Court went on to find that the plaintiffs in that case had “plausibly alleged anticompetitive conduct pursuant to Federal Rule of Civil Procedure 12(b)(6)” based upon the acquisition of the Roche Patent Rights, *id.* at 30–35, but found that Amgen’s subsequent patent prosecution and enforcement efforts constituted protected activity pursuant to the *Noerr-Pennington* doctrine, *id.* at 26. The same analysis applies here. Therefore, with respect to Phases 1, 2, and 3 alleged here, only Phase 1—the acquisition of the Roche Patent Rights—can be properly considered allegedly anticompetitive conduct. Accordingly, only that conduct will be examined in assessing whether Sandoz’s antitrust claim in the instant case was a compulsory counterclaim in the *Amgen v. Sandoz* Case.

With respect to Phase 4, Sandoz additionally alleges that, following the *Amgen v. Sandoz* Case and the *Samsung* Case, Amgen has continued to engage in allegedly anticompetitive behavior by increasing prices and entering into “cross-therapeutic rebate bundling arrangements with third-party payors[.]” Compl. ¶ 164, ECF No. 1. While such conduct may indeed be profit-driven, the Court agrees with Amgen that “[n]o explanation is given in the Complaint for how any of that could have been anti-competitive,” Mem. Supp. at 16, ECF No. 34, other than that it placed Amgen’s products in “favorable formulary positions,” Compl. ¶ 166, ECF No 1. The effects of the price increases and rebate bundles could be considered anticompetitive *harm* which flowed from prior anticompetitive activity, such as the acquisition of the Roche Patent

Rights.¹⁶ Indeed, even Sandoz refers to such rebates as having “anticompetitive impact.” *Id.* ¶ 169.

4. *Compulsory Counterclaim Analysis*

Having laid out the arguments raised during the *Amgen v. Sandoz* Case and the appropriate scope of the antitrust claim in the instant case, the Court now considers the Fourth Circuit’s four-inquiry test to determine whether Count 1 was a compulsory counterclaim in the *Amgen v. Sandoz* Case.

- a. *Are the issues of fact and law raised in the claim and counterclaim largely the same?*

First, the Court finds that the facts raised in the *Amgen v. Sandoz* Case and the instant case are largely the same. The *Sandoz* Court laid out the facts of that case in detail, and they are strikingly similar to those alleged in the Complaint and summarized *infra* pp. 2–14. See *Immunex*, 395 F. Supp. 3d at 375–380 (explaining cytokines, TNFs, the role of TNF in auto-immune disorders, the composition of etanercept, Roche and Immunex’s research breakthroughs in the 1990s, Roche’s European

¹⁶ Even if the Court did find that Sandoz had plausibly alleged that the price increases and rebate bundling arrangements constituted anticompetitive conduct, that would still not bar the Court’s finding that the instant antitrust claim was a compulsory counterclaim in the *Amgen v. Sandoz* Case. In *Painter*, the Court noted that “[s]ome counterclaims may thus be compulsory even though they do not involve a substantial identity of evidence with the claim. A counterclaim may still arise from the same ‘transaction or occurrence’, as a logically related claim even though the evidence needed to prove the opposing claims may be quite different.” 863 F.2d at 332 (internal citations omitted). Therefore, even if Sandoz *may* be able to present *some* new evidence that price increases and rebate bundling were anticompetitive, this would not bar a finding that the instant antitrust claim arises out of the same transaction or occurrence as the issues litigated in the *Amgen v. Sandoz* Case.

patent applications, Amgen’s acquisition of the Roche Patent Rights via the 2004 Exclusive License, and the issuance of the ’182 and ’522 Patents). In that case, as here, Sandoz argued, *inter alia*, that the ’182 and ’522 Patents should be invalidated because Amgen had used the patents to obtain an “unjustified timewise extension of its etanercept monopoly.” *Id.* at 409. Here, Sandoz argues that Amgen “sought to prolong [its] market exclusivity—and entrench its monopoly—by acquiring patent rights for the entire U.S. market for etanercept[.]” Compl. ¶ 112, ECF No. 1. Of course, the issues of law in the *Amgen v. Sandoz* Case involved patent law, whereas here, the issues of law involve antitrust law. Therefore, given that the facts are largely the same but the legal issues are somewhat different, this Court gives this factor neutral weight in deciding whether the instant antitrust claim was a compulsory counterclaim in the *Amgen v. Sandoz* Case.

b. Would res judicata bar a subsequent suit on the party's counterclaim, absent the compulsory counterclaim rule?

With respect to the second factor, the res judicata inquiry requires three elements: “(1) a final judgment on the merits in an earlier suit, (2) an identity of the cause of action in both the earlier and the later suit, and (3) an identity of parties or their privies in the two suits.” *Nash Cnty. Bd. of Ed. v. Biltmore Co.*, 640 F.2d 484, 486 (1981). Regarding the first element, the judgment in the *Amgen v. Sandoz* Case is certainly final. Sandoz and Amgen litigated the infringement claims through trial, and on August 9, 2019, and after a bench trial, the *Sandoz* Court issued a decision upholding the validity of the ’182 and ’522 Patents. Compl. ¶ 134, ECF No. 1. On July

1, 2020, the Federal Circuit affirmed the *Sandoz* Court’s judgment upholding the validity of the ’182 and ’522 Patents. *Id.* ¶ 136. On May 17, 2021, Sandoz’s petition for certiorari to the U.S. Supreme Court was denied. *Id.* ¶ 137. Regarding the second element, both suits at issue here “deal with the same subject-matter . . . [t]he two suits allege the same wrongful act, the same illegal [monopoly], the same operative facts in support of such [monopoly] . . . the identity of two actions, as intimately tied together as these two, will not be destroyed in the res judicata context simply because the two suits are based on different statutes.” *Nash*, 640 F.2d at 488. Finally, regarding the third element, the identity of the parties here is the same—Amgen sued Sandoz in 2016 for patent infringement, and Sandoz sues Amgen today for alleged antitrust violations. All elements of res judicata are met, and this factor weighs in favor of finding that the present antitrust claim was a compulsory counterclaim in the *Amgen v. Sandoz* Case.

c. *Will substantially the same evidence support or refute the claim as well as the counterclaim?*

Turning to the related third factor, the Court finds that substantially the same evidence presented in the *Amgen v. Sandoz* Case—to demonstrate that the patents were obtained in violation of patent law—would be presented in this case to show that the patents were obtained in violation of antitrust law. Sandoz alleges that the original sin of Amgen’s antitrust violations stems from the 2004 Exclusive License, through which Amgen bought the Roche Patent Rights to extend its monopoly, despite already enjoying \$770 million in Enbrel sales in 2002. Compl. ¶ 95, ECF No. 1.

The purchase of the Roche Patent Rights in 2004 is really at the heart of this case. The lawyers who were involved in drafting and negotiating the related agreements, and then prosecuting those patent applications before the PTO, would presumably be called to testify in this case to offer any procompetitive defense to Sandoz’s antitrust claims—likely the same lawyer-witnesses who testified before the *Sandoz* Court. Furthermore, as evidenced by the Background section in the *Sandoz* Court’s lengthy opinion following the two-week patent trial, the evidence presented at that trial and summarized by that Court is nearly identical to the facts alleged here. *See Immunex*, 395 F. Supp. 3d at 375 –380 (summarizing the evidence regarding the patents and patent prosecutions based upon the *Sandoz* Court’s findings of fact following a two-week bench trial). Therefore, this factor weighs in favor of finding that Count 1 was a compulsory counterclaim in the *Amgen v. Sandoz* Case.

d. Is there any logical relationship between the claim and counterclaim?

The fourth inquiry, oft referred to as the logical relationship test, “allows the court to apply Rule 13(a) to any counterclaim that from an economy or efficiency perspective could be profitably tried with the main claim.” *Banner Indus. of New York, Inc. v. Sansom*, 830 F. Supp. 325, 328 n.3 (S.D. W.Va. 1993) (quoting Wright, Miller, & Kane, *Federal Practice & Procedure* § 1410 (1990)). Given the duplicative facts and evidence stated above, “[a]llowing both of these actions to proceed in parallel fashion would result in not only the duplication of evidence and effort but also wasted judicial resources.” *Id.* at 328. The *Amgen v. Sandoz* Case “was litigated for years and culminated in a two-week trial and a Federal Circuit appeal[.]” Mem. Supp. at 30, ECF No.

34. The Court agrees that proceeding to discovery in the instant case would “merely indulge Sandoz’s effort to have another bite at the apple and defeat the entire point of the compulsory counterclaim rule.” Reply at 26, ECF No. 37. Accordingly, the fourth factor weighs in favor of finding that Count 1 was a compulsory counterclaim in the *Amgen v. Sandoz* Case.

* * *

In sum, 3 out of 4 of the above inquiries weigh in favor of finding that Sandoz’s present antitrust claim was a compulsory counterclaim, and the first factor was given neutral weight. On balance, the Court finds that Sandoz was required to bring the instant federal antitrust claim (Count 1) as a counterclaim in the *Amgen v. Sandoz* Case in 2016.

5. *The Mercoïd Exception*

While the antitrust counterclaim in this case would typically be treated as compulsory given the above analysis, the parties dispute whether *Mercoïd Corp. v. Mid-Continent Inv. Co.*, 320 U.S. 661 (1944) or *Burlington Indus., Inc. v. Milliken & Co.*, 690 F.2d 380 (4th Cir. 1982) controls. The Supreme Court created an exception in *Mercoïd* whereby antitrust counterclaims are not compulsory but rather permissive, however, the Supreme Court “fail[ed] . . . to discuss the principles upon which the decision rest[ed].” *United States v. Eastport S.S. Corp.*, 255 F.2d 795, 805 (2d Cir. 1958). Indeed, various appellate courts, including the Fourth Circuit, have interpreted *Mercoïd* narrowly, such that antitrust counterclaims are permissive counterclaims only in certain circumstances. See *Critical-Vac Filtration Corp. v. Minuteman*

Int'l, Inc., 233 F.3d 697, 702 n.6 (2d Cir. 2000) (recognizing that the Second and Fourth Circuits, as well as numerous district courts, have seriously criticized and narrowed *Mercoïd*, whereas the Fifth and Ninth Circuits “have recognized its continuing vitality.”).

In *Mercoïd*, Mid-Continent Investment Corporation (“Mid-Continent”) was “the holder of a patent for a domestic heating system composed of a furnace and a separate thermostatic control device.” *Critical-Vac*, 233 F.3d at 701. Mercoïd manufactured thermostatic control devices. *Id.* In the first case, Mid-Continent “sued a Mercoïd customer . . . for patent infringement as a result of his installation of a heating system in his home that used a thermostatic control device manufactured by Mercoïd. Mercoïd was not made a party to the lawsuit, but directed and paid for its customer’s unsuccessful defense.” *Id.* (internal citation omitted). After Mid-Continent won the first case against the Mercoïd customer,

Mid-Continent sought to initiate settlement negotiations with Mercoïd for having installed thermostatic control devices in *other homes*, and sent Mercoïd a license agreement that would have required payment of a license fee for the sale of each such device. When Mercoïd refused to cooperate, Mid-Continent filed a second patent infringement suit—this time against Mercoïd [rather than against a Mercoïd customer] . . . Mercoïd responded with an antitrust counterclaim challenging Mid-Continent’s licensing practices and seeking damages under the Sherman Act.

Id. (emphasis added and internal citation omitted). Mercoïd prevailed in the district court, but lost on appeal. *Id.* The Seventh Circuit held that, *inter alia*, “Mercoïd was barred by principles of res judicata from raising its antitrust counterclaim because it had failed to raise the claim when it defended [Mercoïd’s customer] in the earlier proceeding.” *Id.* The Supreme Court reversed. *Id.* In so reversing, the Supreme Court

reasoned “that Mid-Continent’s patent covered only the heating system, not its individual components . . . [and] that Mid-Continent’s *misuse* of its patent ‘for the purpose of monopolizing unpatented material’ barred relief against *Mercoïd*.” *Id.* (quoting *Mercoïd*, 320 U.S. at 668) (emphasis added).

In *Burlington*, the Fourth Circuit treated an antitrust claim as a compulsory counterclaim, finding that it should have been raised in a prior patent infringement case between the parties. 690 F.2d at 389. In so holding, the Fourth Circuit stated that in its view, *Mercoïd* “does not require a different conclusion. Justice Douglas’s opinion in that case treated antitrust and patent *misuse* claims as merely permissive counterclaims in response to a complaint for patent infringement. The opinion has been read narrowly in this respect, and its continuing validity is open to serious question.” *Id.* (emphasis added) (citations omitted). The Second Circuit also reads *Mercoïd* narrowly, recognizing a “distinction between claims of patent *misuse* and patent *invalidity*.” *Critical-Vac*, 233 F.3d at 703. The Second Circuit further reasoned that “the patent misuse/patent validity distinction provides a sensible rationale for the *Mercoïd* exception to Rule 13(a). Antitrust claims based on patent *misuse*, such as the counterclaims in *Mercoïd*, are likely to involve factual issues distinct from those involved in patent infringement litigation between the same parties.” *Id.*

Here, Sandoz’s antitrust claim is not based upon patent *misuse* after a patent has been lawfully obtained. It is based upon alleged patent *invalidity*. Specifically, Sandoz alleges that pursuant to antitrust law, Amgen engaged in anticompetitive conduct by acquiring the Roche Patent Rights in 2004. After Amgen acquired those

rights, it lawfully prosecuted those patent applications before the PTO and enforced its patent rights in the *Amgen v. Sandoz* Case and the *Samsung* Case. Sandoz’s anti-trust claim in the instant case therefore involves nearly identical “‘matters in issue or points controverted’ from those involved in the earlier patent infringement litigation.” *Critical-Vac*, 233 F.3d at 703 (quoting *Mercoïd*, 320 U.S. at 671). Therefore, *Mercoïd* does not control in the instant case—instead, *Burlington* does, and the *Mercoïd* exception does not apply.

* * *

Sandoz’s claim against Amgen for monopolization in violation of 15 U.S.C. § 2 (Count 1) is properly treated as a compulsory antitrust counterclaim which must have been raised during the *Amgen v. Sandoz* Case. “[T]he effect of a defendant’s failure to assert a counterclaim made compulsory by [Federal Rule of Civil Procedure 13(a)] is to preclude its assertion in a later action against the former plaintiff.” *Mesker Bros. Iron Co. v. Donato Corp.*, 401 F.2d 275, 279 (4th Cir. 1968). Accordingly, Count 1 is **DISMISSED**.

B. State Law Claims: Monopolization (Count 2) and Tortious Interference with Prospective Economic Advantage (Count 3)

As the Court has found that Sandoz has not established a viable federal anti-trust claim, the Court declines to exercise jurisdiction over Sandoz’s state claims alleging monopolization (Count 2) and tortious interference with prospective economic advantage (Count 3) under New Jersey state law. “Having found in favor of the defendant on the plaintiff’s federal claim[], and considering the factors of convenience and fairness to the parties, existence of underlying issues of federal policy and comity,

and judicial economy, the court declines to exercise jurisdiction over [the] remaining state claims.” *Coffey v. Morris*, 401 F. Supp. 2d 542, 548–49 (W.D. Va. 2005) (citing 28 U.S.C. § 1367(c)(3); *Shanaghan v. Cahill*, 58 F.3d 106, 110 (4th Cir. 1995)); *see also Royal Canin U.S.A., Inc. v. Wullschleger*, 604 U.S. 22, 31–2 (2025) (“[A] district court may decline to exercise supplemental jurisdiction . . . if the district court has dismissed all claims over which it has original jurisdiction. In [this] context[], federal law is not where the real action is. So although supplemental jurisdiction persists, the district court need not exercise it: Instead, the court may (and indeed, ordinarily should) kick the case to state court.”) (internal quotation marks and citation omitted). Sandoz’s state law claims for monopolization (Count 2) and tortious interference with prospective economic advantage (Count 3) under New Jersey law are therefore **DISMISSED without prejudice**.

IV. CONCLUSION

For the foregoing reasons, the Motion (ECF No. 33) is **GRANTED**. Count 1 of the Complaint (ECF No. 1) is **DISMISSED with prejudice**, as the Court finds that it would be futile to grant leave to amend. Counts 2 and 3 of the Complaint (ECF No. 1) are **DISMISSED without prejudice**, with leave to file in state court. The Clerk is **DIRECTED** to close the case. The Clerk is further **REQUESTED** to forward a copy of this Order to counsel of record for all parties.

IT IS SO ORDERED.

/s/
Arenda L. Wright Allen
United States District Judge

February 17, 2026
Norfolk, Virginia