UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

CENTENE CORPORATION,

Plaintiff,

v.

CELGENE CORPORATION, BRISTOL MYERS SQUIBB COMPANY, NATCO PHARMA LTD., ABBVIE, INC., TEVA PHARMACEUTICALS USA, INC., DR. REDDY'S LABORATORIES, INC., and DR. REDDY'S LABORATORIES LTD.,

Defendants.

Civil Action No. 2:26-cv-5125

COMPLAINT

JURY TRIAL DEMANDED

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I. INTRODUCTION

1. This civil action alleges that Defendants Bristol Meyers Squibb Company ("BMS") and Celgene Corporation ("Celgene") are engaging in one of the largest and most disruptive schemes to impair and delay generic drug competition in U.S. pharmaceutical history. BMS and Celgene should have faced robust competition to Revlimid sales by the early 2020s. As Celgene's former CEO stated, when Revlimid has unlimited generic competition, the price will be "**cheaper than aspirin**." That price drop would be devastating for the brand manufacturers. So, they paid off would-be generic competitors to delay entry until January 2026 or later. The consequences of this anticompetitive conduct are enormous.

2. Lenalidomide, sold in the U.S. under the brand name Revlimid, is a prescription medication mostly used to treat life-threatening blood-borne cancers, including multiple myeloma and myelodysplastic syndromes. Lenalidomide belongs to a class of drugs known as immunomodulatory imide drugs ("IMiDs"), drugs known for decades, but which received widespread scientific attention in the 1990s and early 2000s as inhibitors of angiogenesis and TNF. While Celgene's research and development initially lagged behind those of other manufacturers, Celgene eventually displaced other competitive research efforts. In 2005, the U.S. Food and Drug Administration ("FDA") first approved Revlimid, and a year later the product was approved for first-line treatment of multiple myeloma.

3. By 2015, Celgene and the industry generally anticipated robust generic entry by the early 2020s and believed that the long-term projection for Revlimid sales was bleak. In the U.S., several structural industry features—in large part, FDA generic drug approval laws, patent laws, and state generic automatic substitution laws—establish a limited period of legitimate high brand-drug pricing while fostering generic drug entry, and with it a dramatic shift to generic usage at a small fraction of the brand's prices. Celgene expected this well-known monopoly-to-

commodity shift would likely occur for Revlimid by the early 2020s, causing a tremendous loss of Revlimid sales and a long-range revenue shortfall. For their part, multiple would-be generic manufacturers had demonstrated their intent to enter the market, some projecting entry even earlier than Celgene's expectations. Chief among these manufacturers was a collaborative of Natco Pharma Limited ("Natco") and subsidiaries of Allergan plc ("Allergan"). The Natco/Allergan team was winning challenges against Celgene's patents and sat in the coveted position of the likely first-to-file generic for the best-selling dosage forms of Revlimid. Teva Pharmaceuticals USA, Inc. ("Teva"), the global generic giant, was then in the process of buying Allergan's generic interests. When that transaction closed the next year, Celgene would face unfettered competition in the Revlimid market from a Teva/Natco collaboration holding a right to a 180-day exclusivity period, with other generics entrants lining up behind it.

4. Celgene could have sought a lawful resolution with the Natco/Allergan collaborative by negotiating a date for the monopoly-to-commodity generic entry of Revlimid into the U.S. market. Such lawful settlements are often reached. Indeed, negotiated-entry-date-only settlements are encouraged by federal authorities seeking to protect competition and discourage the corruption of generic drug makers. Instead, Celgene chose to pay off its would-be competitors, and in exchange received substantially delayed genericization of the market. However, the payoff would need to be huge, because the Natco/Allergan business venture would expect to make significant revenue as the first-filer on a multi-billion-dollar drug.

5. Early in the negotiations, Allergan proposed the answer. The Natco/Allergan collaborative would agree to a late date for generic entry—they quickly fixed on *ten years* later, *i.e.*, January 2026—but Celgene in the meantime would need to agree to share with Natco/Allergan some of the profits Celgene would be making from the prolonged period of

selling Revlimid in the U.S. The tool to effectuate this scheme was a market-sharing arrangement. The parties agreed that for each of the four years immediately preceding the late-January 2026 date for generic entry, Celgene would share with Allergan the opportunity to sell a small, fixed supply of generic Revlimid into the U.S. market, and then Allergan would discontinue sales for the balance of that year, thereby maintaining significant shortage of generic Revlimid in the market and fostering high prices of both the brand and the generic. The design was to maintain scarcity of available generic supply, forcing purchasers to buy whatever limited generic was on the market at a higher price and, upon the generic's depletion, buy the high-priced brand product.

6. The economic effect of Natco/Allergan's volume-limited sales was the sharing of branded Revlimid profits, not generic competition as contemplated by the Hatch-Waxman Act or the Supreme Court's *FTC v. Actavis* decision. Indeed, the profit share over four years would generate Natco/Allergan likely hundreds of millions, if not billions, more than what it would have made from a lawful launch during its 180-day exclusivity, a pay day worthy of the long wait for unrestrained market entry and the risks of antitrust exposure. In the aftermath of the agreement, Celgene's stock price skyrocketed.

7. Of course, when reaching the final Celgene-Allergan agreement in December 2015, the parties needed to plan how to address potential later would-be generic entrants. The final agreement reflected a plan to wrap later generics into the overall market-allocation plan, protecting the profit-split to Natco/Allergan (and later Teva/Natco) by sharing with the later generics smaller shares of Celgene's monopoly profits (*i.e.*, smaller, incremental capped-volume launches intended to keep the available supply well below demand) in exchange for the later generics' agreement to delay competition until January 2026 or later. Overall scarcity of generic Revlimid supply would be maintained and all participating generic companies would reap greater

profits than they could earn from lawful efforts. Some later generics initially balked at the notion of becoming embroiled in an industry-wide conspiracy to artificially restrict generic availability. But when they raised such concerns, Celgene agreed to indemnify them against any antitrust exposure, and they relented. The end result is astonishing: By the fall of 2021, Celgene had reached similar profit-sharing arrangements (with small, capped-volume generic releases) with *nine* other would-be generic competitors, while still maintaining deep scarcity of available generic lenalidomide and maintaining high prices for both brand Revlimid and generic lenalidomide.

8. With *bona fide* generic competition postponed until 2026, Celgene (and, starting in 2019, with BMS) continued for years to be the only lenalidomide supplier on the market. And in early 2022, when Celgene started its piecemeal sharing of those profits through small, incremental, and capped-volume releases of generic Revlimid product, Celgene maintained high prices for branded Revlimid and U.S. sales.

9. Multiple years of actual results have shown the dramatic anticompetitive harm from this massive plan to restrain generic access. When Teva/Natco released its small, capped quantity generic in early 2022 (and then departed the market), prices were only modestly lower than the brand. Purchasers scrambled to find generic product to purchase, but most were shut out. When later generics released their capped-volume product later that year (and then departed the market), those products launched at prices that were even *higher* than that of Teva/Natco and the planned scarcity disrupted purchasing channels. Prior to Teva/Natco's limited launch, BMS held a special training for its marketing team to handle what it acknowledged would be angry and confused customers. In 2024, the American Society of Health-Systems Pharmacists declared a formal "shortage" of generic lenalidomide due to "volume restrictions as part of the patent settlements between generic companies and Celgene (Bristol Myers Squibb)," and with that

shortage, disruptions to supply, limited access, and inconsistent treatment.

10. Having made a laughingstock out of the distribution of lenalidomide in the United States, Celgene and BMS are simply reaping the rewards from their successful market allocation. BMS reported U.S. revenues from Revlimid of $5.2 billion for 2023 and $2.6 billion for the first half of 2024, then in July 2024 *raised* prices for Revlimid by 7%, ultimately earning $4.999 billion for 2024. In response to concerns over one price increase, Celgene's then-CEO allegedly asked: "Why would you be afraid to take an increase on our products? What could be the worst thing that happens . . . a tweet here or there and bad press for a bit." The CEO did not mention the financial consequences for U.S. purchasers. A Celgene executive later confirmed that Celgene believed cancer patients were willing to pay almost any amount that Celgene charged (in the absence of cheaper generics). Absent the unlawful actions alleged in this Complaint, the expected monopoly-to-commodity entry of generic competition would likely have occurred by at least 2021, and U.S. purchasers would have had adequate, steady, and predictable supplies of generic lenalidomide at a small fraction of the supra-competitive prices forced upon them.

11. As described in a May 2025 *ProPublica* article, "The Price of Remission," written by a multiple myeloma patient:

> Last July [2024], the cost of my monthly Revlimid prescription increased by 7% to **$19,660**.
>
> At the beginning of this year, my insurer switched me to generic Revlimid. I didn't fight it, thinking it would result in a dramatic decrease in what ProPublica's health plan pays for the drug.
>
> It turns out it is not much of a savings: The **generic costs $17,349 a month.**[1]

[1] Armstrong, David, *The Price of Remission*, PROPUBLICA (May 8, 2025), available at https://www.propublica.org/article/revlimid-price-cancer-celgene-drugs-fda-multiple-myeloma (emphasis added) (last visited Dec. 22, 2025).

This is despite a capsule of Revlimid costing just twenty-five cents to produce.[2] Celgene understands that this is the outcome of its plan to restrain generic access, given its former CEO's statement that unlimited generic competition would significantly reduce the price. Instead, due to the small quantities allotted to each of them, the generic manufacturers were able to charge 86% of price of brand Revlimid (before Celgene increased the brand price in July 2024). Celgene manufactured a market that defied the economics of *bona fide* competitive markets.

As anticipated, the price for generic lenalidomide plummeted **after the lenalidomide volume limits expired** on January 31, 2026. For instance, on February 2, **Teva (the marketing partner for the Allergan/Natco lenalidomide) implemented a 98.45% reduction in its WAC list price (from $719.91 to $11.93)**. Two other manufacturers also reduced their prices from $719.91 to between $10.87 and $21.60. And five manufacturers—that received consent to launch after the volume limits expired—set their initial lenalidomide WAC between $6.31 and $33.93, well below the previously consistent $719.91 generic WAC.

II. PARTIES

12. The Plaintiff, Centene Corporation ("Centene" or "Plaintiff"), is a Delaware corporation with its principal place of business at 7700 Forsyth Blvd., St. Louis, Missouri 63105. Centene provides prescription drug benefits through which it has paid for substantial quantities of Revlimid and its AB-rated generic equivalents. Centene seeks recovery for overcharges related to those purchases.

13. Centene is the parent company, or otherwise affiliated/related company, to businesses that operate specialty pharmacies, including AcariaHealth, Inc., a Delaware corporation with its principal place of business at 8517 Southpark Circle, Suite 200, Orlando, FL

[2] *Id.*

32819. During the relevant time period, AcariaHealth purchased substantial quantities of Revlimid and its AB-rated generic equivalents directly from Defendants for the purpose of dispensation as specialty mail order pharmacies. Through AcariaHealth, Centene has purchased Revlimid from Defendants directly. AcariaHealth has assigned its claims based on these direct purchases to Centene. Centene seeks recovery for overcharges related to those purchases on behalf of AcariaHealth.

14. The Defendant, Celgene Corporation, is a drug manufacturer is Delaware corporation with its principal place of business at 86 Morris Avenue, Summit, New Jersey 07901. Celgene manufactures, markets, and sells Revlimid in the United States and its territories.

15. The defendant Bristol Myers Squibb Company ("Bristol Myers") is a pharmaceutical company organized and existing under the laws of the State of Delaware. During most times relevant to the complaint, Bristol Myers maintained its principal executive offices at 430 E. 29th Street, 14FL, New York, NY 10016. Bristol Myers has since changed its principal executive offices to Route 206 & Province Line Road, Princeton, New Jersey 08543. BMS is a publicly traded corporation registered on the New York Stock Exchange.[3]

16. In January 2019, BMS and Celgene executed a merger agreement, and in November of 2019, the companies completed the transaction such that Celgene became a wholly owned subsidiary of BMS. The companies' public statements and filings with the U.S. Securities and Exchange Commission ("SEC") make clear that Revlimid, which had nearly $10 billion in annual worldwide revenue at the time, was a key asset in the transaction. The companies' joint SEC filings for the merger acknowledge that Revlimid's revenue was so critical that any expiration of its patent protection sooner than anticipated "would be harmful to the combined

[3] BMS is publicly traded under the symbol "BMY."

company and could have a material adverse effect on its business, financial condition or results of operations."[4] In the first full year after the acquisition (2020), BMS reported more than $12.1 billion in worldwide Revlimid revenue.[5]

17. The Defendant, Natco Pharma Limited ("Natco"), is an Indian drug manufacturer headquartered at Natco House, Road No. 2, Banjara Hills, Hyderabad-500, 034, India. Natco develops and markets drugs throughout the world, including in the United States. In February 2010, Natco filed the first Abbreviated New Drug Application ("ANDA") for generic Revlimid in four of its six dosage strengths (5 mg, 10 mg, 15 mg, and 25 mg).

18. In November 2009, Natco entered into an agreement providing for the development and marketing of a generic Revlimid product in the United States with Arrow International Limited ("Arrow"), a subsidiary of Watson Pharmaceuticals, Inc. ("Watson"). Generally, the parties agreed that Natco would be responsible for developing and manufacturing the generic Revlimid product, and that Watson/Arrow would be responsible for filing the ANDA, obtaining FDA approval of the generic Revlimid product, and distributing the product in the United States. Subject to adjustments, Natco and Watson/Arrow agreed to share their generic Revlimid profits, with Natco receiving 30%.[6]

19. A series of corporate transactions occurred over the years that followed the original

[4] U.S. House Committee on Oversight and Reform, Staff Report, *Drug Pricing Investigation*: *Celgene and Bristol-Myers Squibb—Revlimid* (Sept. 30, 2020), at p. 2 (footnote omitted), *available at* https://oversightdemocrats.house.gov/sites/evo-subsites/democrats-oversight.house.gov/files/Celgene%20BMS%20Staff%20Report%2009-30-2020.pdf (last visited Sept. 4, 2025) ("Oversight Committee Revlimid Report").

[5] Bristol-Myers Squibb Company, SEC Report on Form 10-K 2020, at p. 46, *available at* https://www.sec.gov/ix?doc=/Archives/edgar/data/14272/000001427221000066/bmy-20201231.htm#i41f64878d2784d5ea6ffaae4477d4823_97 (last visited Sept. 4, 2025).

[6] *Available at* https://images.assettype.com/bloombergquint/2022-06/ef6517c4-0a91-4bd9-821a-e2f291a1a759/Nirmal_Bang_Natco_Pharma_Q4FY22_Result_Update__31_May_2022.pdf (last visited Sept. 4, 2025).

interests of Watson and Arrow in the monetization of the Natco ANDA lenalidomide product. In October 2012, Watson acquired another generic company, the Actavis Group, and on January 23, 2013, Watson changed its corporate name to Actavis, Inc. In October 2013, Actavis plc, an Irish public limited company, was formed to facilitate a business combination between Actavis, Inc. and Warner Chilcott, plc (another drug company), and, following a series of transactions, Actavis Inc. (formerly Watson) became an indirect wholly owned subsidiary of Actavis plc. In June of 2015, Actavis plc changed its name to Allergan plc. On July 26, 2015, Teva agreed to acquire Allergan's generic assets. In August of 2016, Allergan and Teva closed on the generic sale, and as a result Actavis, Inc. (formerly Watson) and Arrow became wholly owned subsidiaries of Teva. Part of the consideration for the agreement was that Allergan would be paid 50% of Teva's total lenalidomide net sales.[7] In May 2020, AbbVie Inc. announced that it had completed its acquisition of Allergan, and Allergan subsequently merged into AbbVie Inc.

20. The Defendant, AbbVie Inc., is a Delaware corporation with a principal place of business at 1 North Waukegan Road, North Chicago, Illinois 60064 ("AbbVie"). AbbVie is a global biopharmaceutical company engaged in the manufacturing, commercialization, and sale of pharmaceuticals. AbbVie is the successor to Allergan.

21. When the Celgene-Allergan agreement that is the subject of allegations herein was negotiated and executed on December 22, 2015, Allergan was the ultimate parent of Actavis (formerly Watson) and Arrow, and Allergan was as directly involved in, and in some ways a party to, the Celgene-Allergan agreement. Even after Teva's acquisition of Actavis (formerly Watson) and Arrow (such that Allergan no longer owned them), Allergan performed on promises it had

[7] https://www.genengnews.com/news/teva-to-acquire-allergans-generics-business-for-40-5b/#:~:text=Teva%20also%20agreed%20to%20acquire,generic%20lenalidomide%20(Revlimid%C2%AE) (last visited Dec. 22, 2025).

made to Celgene as a part of the Celgene-Allergan agreement. Since May of 2020, AbbVie has succeeded to the rights and liabilities of Allergan. In addition, AbbVie has directly received, and continues to receive, 50% of Teva's revenues from generic Revlimid.[8]

22. The Defendant, Teva Pharmaceuticals USA, Inc. ("Teva"), is a Delaware corporation having its principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054. Teva is a wholly owned subsidiary of Teva Pharmaceutical Industries Ltd., an Israeli corporation. At the direction of its parent, Teva performs the rights and duties of Actavis Inc. (formerly Watson) and Arrow under the arrangement with Natco. Teva has performed, and continues to perform, the obligations of Actavis, Inc. (formerly Watson) and Arrow under the Celgene-Allergan agreement.

23. The Defendant, Dr. Reddy's Laboratories, Inc., is a New Jersey corporation having its principal place of business at 107 College Road East, Princeton, NJ 08540. Dr. Reddy's Laboratories, Inc. develops and markets generic drugs in the United States.

24. The defendant, Dr. Reddy's Laboratories Ltd. is an Indian corporation having its principal place of business at 8-2-237, Road No. 3, Banjara Hills, Hyderabad K7 500-034, India. Dr. Reddy's Laboratories Ltd. develops and markets generic drugs throughout the world, including in the United States. Dr. Reddy's Laboratories, Inc. is a wholly owned subsidiary of Dr. Reddy's Laboratories Ltd. Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories Ltd. are collectively referred to as "Dr. Reddy's." Dr. Reddy's entered the Celgene-Dr. Reddy's agreement (alleged to be unlawful in this case), and Dr. Reddy's has performed, and continues to perform, under that unlawful agreement.

[8] *Available at* https://www.genengnews.com/news/teva-to-acquire-allergans-generics-business-for-40-5b/#:~:text=Teva%20also%20agreed%20to%20acquire,generic%20lenalidomide%20(Revlimid%C2%AE) (last visited Sept. 4, 2025).

III. JURISDICTION AND VENUE

25. This Court has jurisdiction over this action pursuant to 15 U.S.C. §§ 15 and 26, and 28 U.S.C. §§ 1331 and 1337. Plaintiff asserts a federal claim for damages, injunctive relief, and costs of suit, including reasonable attorneys' fees, against Defendants under Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, and Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15 and 26.

26. This Court has supplemental jurisdiction over Plaintiff's pendent state law claims pursuant to 28 U.S.C. § 1367, as the state law claims are so related as to form part of the same case or controversy. Such supplemental or pendant jurisdiction will also avoid unnecessary duplication and multiplicity of actions and should be exercised in the interests of judicial economy, convenience, and fairness.

27. This Court has personal jurisdiction over Defendants because Defendants are present in the United States, do business in the United States, have registered agents in the United States, may be found in the United States, and are otherwise subject to the service of process provisions of 15 U.S.C. § 22.

28. Venue is appropriate within this district under Section 12 of the Clayton Act, 15 U.S.C. § 22, 28 U.S.C. §§ 1391(b) and (c). Defendants transact business within this district, have agents and can be found in this district, and the relevant interstate trade and commerce is carried out, in substantial part, in this district.

IV. REGULATORY AND ECONOMIC BACKGROUND

A. The regulatory structure for approval and substitution of generic drugs.

29. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"),[9] manufacturers that

[9] Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended in 21 U.S.C. § 301, *et seq.*).

create a new drug must obtain approval from the FDA to sell the product by filing a New Drug Application ("NDA").[10] An NDA must include specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents.[11]

30. When the FDA approves a brand manufacturer's NDA, the manufacturer submits information to have the FDA list in Approved Drug Products with Therapeutic Equivalence Evaluations (known as the "Orange Book") the patents that claim the drug or a method of using the drug, and that could reasonably be enforced against a generic manufacturer that makes, uses, or sells a generic version of the brand drug before the expiration of the listed patents.[12] The manufacturer may list in the Orange Book within 30 days of issuance any patents issued after the FDA approved the NDA.[13]

31. The FDA relies completely on the brand manufacturer's truthfulness about the nature of the patent, its validity, and the applicability. The FDA does not have the resources or authority to verify the manufacturer's patents for accuracy or trustworthiness. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

1. The Hatch-Waxman Amendments and Abbreviated New Drug Applications.

32. The Hatch-Waxman Amendments, enacted in 1984, simplified regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs.[14] A manufacturer seeking approval to sell a generic version of a brand drug may instead file an ANDA. An ANDA relies on the scientific findings of safety and effectiveness included in

[10] 21 U.S.C. §§ 301–392.

[11] 21 U.S.C. §§ 355(a), (b).

[12] Patents covering processes for making drug products may not be listed in the Orange Book.

[13] 21 U.S.C. § 355(b)(1), (c)(2).

[14] *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355).

the brand manufacturer's original NDA and must further show that the generic contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug and that it is bioequivalent, *i.e.*, absorbed at the same rate and to the same extent as the brand. The FDA assigns generics that meet these criteria relative to their brand counterparts an "AB" rating.

33. The FDCA and Hatch-Waxman Amendments operate on the principle that bioequivalent drug products containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity, and identity are therapeutically equivalent and may be substituted for one another. Bioequivalence demonstrates that the active ingredient of the proposed generic would be present in the blood of a patient to the same extent and for the same amount of time as the brand counterpart.[15]

34. Bioequivalence is generally demonstrated via studies in which the proposed generic is compared to the Reference Listed Drug ("RLD," which is, in this instance, the brand-name drug) in either *in vivo* or *in vitro* studies.[16] These studies require the ANDA applicant to have access to sufficient samples of the RLD to conduct the necessary comparisons. Without RLD samples, it is impossible to complete and file an ANDA application.[17] In the ordinary course, a prospective ANDA sponsor obtains samples by buying them, at market price, from a drug wholesaler or distributor.

35. Through the Hatch-Waxman Amendments, Congress sought to expedite the entry of less expensive generic competitors to brand drugs, thereby reducing healthcare expenses

[15] 21 U.S.C. § 355(j)(8)(B).

[16] *In vivo* studies are studies conducted on live subjects. *In vitro* studies are conducted in a laboratory.

[17] *See* FDA, *Reference Listed Drug (RLD) Access Inquiries*, *available at* https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm607738.htm (last visited Sept. 4, 2025).

nationwide. Congress also sought to protect pharmaceutical manufacturers' incentives to create new and innovative products, including through the 30-month stay discussed below.

36. The Hatch-Waxman Amendments achieved both goals, substantially advancing the rate of generic product launches and ushering in an era of historically high profit margins for brand pharmaceutical manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenues for brands and generics totaled $21.6 billion; by 2013, total prescription drug revenues had climbed to more than $373.9 billion, with generics accounting for 88% of prescriptions.[18] Generics are dispensed about 97% of the time when a generic form is available.[19]

2. Regulatory exclusivities for new drugs.

37. In order to promote a balance between new drug innovation and generic drug competition, the Hatch-Waxman Amendments also provides for exclusivities (or exclusive marketing rights) for new drugs. These exclusivities are granted by the FDA upon approval of a drug if statutory requirements are met. These exclusivities are listed in the Orange Book, along with any applicable patents, and can run concurrently with the listed patents.

38. One such exclusivity, New Chemical Entity ("") exclusivity, applies to products containing chemical entities never previously approved by FDA either alone or in combination. If a product receives NCE exclusivity, the FDA may not accept for review any ANDA for a drug containing the same active moiety for five years from the date of the NDA's approval, unless the

[18] *See* IMS Institute for Healthcare Informatics, *Medicine Use and Shifting Costs of Healthcare: A Review of the Use of Medicines in the United States in 2014*, at 5-6 (2015), *available at* https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/medicines-use-and-spending-shifts-in-the-us-in-2014.pdf (last visited Sept. 4, 2025).

[19] *See* https://web.archive.org/web/20250509150641/https://schaeffer.usc.edu/research/u-s-consumers-overpay-for-generic-drugs/ (last visited Sept. 4, 2025).

ANDA contains a certification of patent invalidity or non-infringement, in which case an application may be submitted after four years.[20]

39. A drug product may also receive a three-year period of exclusivity if a supplemental application is submitted that contains reports of new clinical investigations (other than bioavailability studies) conducted or sponsored by the sponsor that were essential to approval of the supplemental application. If this exclusivity is granted, the FDA may not approve an ANDA for that drug for three years from the date on which the supplemental application is approved.[21]

40. And a drug product may receive a seven-year period of exclusivity for a specific indication if that indication is a "rare disease" under FDA's orphan drug exclusivity program.[22]

41. Regulatory exclusivities are not always absolute bars to generic entry. For example, some can be overcome by carving out information in the label or for other reasons.[23]

3. Paragraph IV certifications and section viii carveouts.

42. To obtain FDA approval of an ANDA, a manufacturer must certify that the generic will not infringe any patents listed in the Orange Book. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications:

- That no patent for the brand has been filed with the FDA (a "paragraph I certification");
- That the patent for the brand has expired (a "paragraph II certification");
- That the patent for the brand will expire on a particular date and the manufacturer does not seek to market its generic before that date (a "paragraph III certification"); or
- That the patent for the brand is invalid or will not be infringed by the generic

[20] 21 U.S.C. § 355(j)(5)(F)(ii); 21 C.F.R. § 314.108(b)(2).

[21] 21 U.S.C. § 355(j)(5)(F)(iv); 21 C.F.R. § 314.108(b)(2)(5).

[22] 21 U.S.C. § 360aa–cc.

[23] *See, e.g.*, 21 C.F.R. §§ 314.94(a)(8)(iv), 314.127(a)(7); 21 U.S.C. § 355a(o).

manufacturer's proposed product (a "paragraph IV certification").[24]

43. In addition, a generic manufacturer's ANDA may "carve out" an indication, and the patents allegedly protecting that indication, by omitting it from its label (a "section viii carveout").[25]

44. If a generic manufacturer files a paragraph IV certification, a brand manufacturer can delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement. Under this counterbalance to Hatch-Waxman's simplified ANDA process, the ANDA filing itself is treated as an artificial act of patent infringement, entitling the patent holder to sue for injunctive relief. If the brand manufacturer initiates a patent infringement action against the generic filer within 45 days of receiving notification of the paragraph IV certification, the FDA will not grant final approval to the ANDA until the earlier of (i) the passage of two-and-a-half years, or (ii) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA.[26] Until one of those conditions occurs, the FDA may grant "tentative approval," but it cannot authorize the generic manufacturer to market its product (*i.e.*, grant final approval). The FDA may grant an ANDA tentative approval when it determines that the ANDA is ready for final approval but for the 30-month stay. The process of obtaining final approval after tentative approval is typically straightforward, merely requiring the applicant to submit an amendment requesting final approval and addressing any changes that may have

[24] 21 U.S.C. § 355(j)(2)(A)(vii).

[25] 21 U.S.C. § 355(j)(2)(A)(viii).

[26] 21 U.S.C. § 355(j)(5)(B)(iii). This period is commonly called a "30-month Hatch-Waxman stay" or "30-month stay." The brand/patent holder can choose to sue the generic after 45 days, including waiting until the generic has launched its product, but, in that event, the brand cannot take advantage of the 30-month stay of FDA approval, and must instead satisfy the showing required to obtain a preliminary injunction to prevent the generic launch.

occurred in the interim.[27] FDA recommends amendments be filed before the exclusivity ends, allowing the final approval to be granted on the earliest possible date.[28]

4. The first-filer's 180-day exclusivity period.

45. Generics may be classified as (i) first-filer generics (the generic company that filed the first ANDA for the relevant product), (ii) later-filer generics (the generic companies that filed ANDAs for the relevant product after the first-filer), or (iii) authorized generics, sometimes abbreviated as "AG" (a generic product sold under the authority of the brand company's NDA, *i.e.*, the brand product labeled as a generic).

46. To encourage manufacturers to seek approval of generic versions of brand drugs, the Hatch-Waxman Amendments grants the first paragraph IV generic manufacturer ANDA filer ("first-filer") a 180-day exclusivity period to market the generic version of the drug, during which the FDA may not grant final approval to any other generic manufacturer's ANDA for the same brand drug.[29] That is, when a first-filer files a substantially complete ANDA with the FDA and certifies that the unexpired patents listed in the Orange Book as covering the brand are either invalid or not infringed by the generic, the FDA cannot approve a later generic manufacturer's ANDA until that first generic has been on the market for 180 days.[30]

47. The 180-day window is often referred to as the first-filer's six-month or 180-day "exclusivity." This is a bit of a misnomer because a brand manufacturer can launch an AG at any

[27] FDA, *ANDA Submissions –Amendments and Requests for Final Approval to Tentatively Approved ANDAs Guidance for Industry*, Sept. 2020, *available at* https://www.fda.gov/media/119718/download (last visited Sept. 4, 2025).

[28] *Id.*

[29] 21 U.S.C. § 355(j)(5)(B)(iv), (D).

[30] Or, until its first-filer exclusivity has been forfeited. A first-filer can forfeit its 180-day exclusivity by, for example, failing to obtain tentative approval from the FDA for its ANDA within 30 months of filing its ANDA. 21 U.S.C. § 355(j)(5)(D)(i)(I)(aa)(BB).

time, manufacturing its AG in accordance with its approved NDA for the branded product but selling through a third party at a lower price point. Brand manufacturers frequently launch AGs in response to generic entry in order to recoup some of the sales they would otherwise lose.

48. The Supreme Court has recognized that "this 180-day period of exclusivity can prove valuable, possibly 'worth several hundred million dollars'" to the first-filer.[31]

49. A first-filer that informs the FDA it intends to wait until all Orange Book-listed patents expire before marketing its generic does not get a 180-day exclusivity period. Congress created this 180-day period to incentivize generic manufacturers to challenge weak or invalid patents or to invent around such patents by creating non-infringing generics.

5. Patents are subject to judicial and administrative scrutiny.

50. A patent may be valid or invalid, infringed or not infringed, and enforceable or unenforceable. Simply owning a patent does not entitle the patent owner to exclude others. Patents are routinely invalidated or held unenforceable, either upon reexamination or *inter partes* proceedings by the Patent and Trademark Office ("PTO"), by court decision, or by jury verdict.

51. A patent holder bears the burden of proving infringement. One way a generic can prevail in patent infringement litigation is to show that its product does not infringe the patent (and/or that the patent holder cannot meet its burden to prove infringement). Demonstrating infringement, or non-infringement, will depend on the scope of a patent's claims. When a patent claims a compound, such as lenalidomide, the infringement analysis will turn on whether the generic's product employs the same compound. When a patent claims a method of use—in which the compound is used in delineated steps or processes to achieve a specific outcome, such as

[31] *F.T.C. v. Actavis, Inc.*, 570 U.S. 136, 144 (2013) (quoting C. Scott Hemphill, Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem, 81 N.Y.U. L. REV. 1553, 1579 (2006)).

treating a certain form of cancer or reducing symptoms associated with leprosy—the infringement analysis will turn on whether the generic's product is to be used in the same manner to achieve the same outcome. While a patent can claim a new unobvious method of use for an old compound, a patent cannot validly claim a compound that is already known.

52. Another way a generic can prevail in a patent-infringement suit is to show that the patent is invalid or unenforceable. A patent is invalid or unenforceable when, among other things: (i) the disclosed invention is not novel or is obvious in light of earlier prior art; (ii) an inventor, an inventor's attorney, or another person involved with the application, with intent to mislead or deceive the PTO, fails to disclose information or submits false information material to patentability to the PTO during prosecution; and/or (iii) two or more related patents claim inventions, which are not patentably distinct from each other and the patents are not subject to a terminal disclaimer linking ownership and terms of the patents (and no exception, such as the safe harbor, applies).

53. In view in part of the *ex parte* nature of patent prosecution, the PTO's decision to issue a patent does not substitute for a fact-specific assessment of: (i) whether the applicant made intentional misrepresentations or omissions on which the PTO relied in issuing the patent; and (ii) whether a reasonable manufacturer in the patent holder's position would have a realistic likelihood of succeeding on the merits of a patent-infringement suit.

54. As a statistical matter, if the parties litigate a pharmaceutical patent-infringement suit to a decision on the merits, it is more likely that a challenged non-drug-substance patent will be found invalid or not infringed than upheld. The Federal Trade Commission ("FTC") reports that generics prevailed in 73% of Hatch-Waxman patent cases resolved on the merits between

1992 and 2002.[32] An empirical study of all substantive decisions rendered in every patent case filed in 2008 and 2009 similarly reports that when a generic challenger stays the course until a decision on the merits, the generic wins 74% of the time.[33] A more recent study found that generics prevailed in 44% of cases since 2002, but in 59% of cases without active-ingredient patents, concluding that this is because cases with weaker patents are settling, while cases with stronger patents are going to trial.[34]

55. Patents can also be challenged through *inter partes* review ("IPR"), in which a third party challenges the validity of the claims of a patent on the basis of prior art comprising patents or printed publications.[35]

6. REMS programs encourage drug manufacturers to work cooperatively to establish single, shared programs.

56. FDA requires drug manufacturers of certain high-risk drugs to implement Risk Evaluation & Mitigation Strategy ("REMS") programs "to help ensure the benefits of the medication outweigh its risks."[36] A REMS distribution program controls the chain of supply so that the drugs are provided only to patients with prescriptions from authorized physicians or pharmacies under specific conditions. REMS programs are intended to give FDA authority to

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[32] FTC, *Generic Drug Entry Prior to Patent Expiration: An FTC Study,* vi-vii (2002), *available at* https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf (last visited Sept. 4, 2025).

[33] John R. Allison, Mark A. Lemley & David L. Schwartz, *Understanding the Realities of Modern Patent Litigation*, 92 TEX. L. REV. 1769, 1787 (2014) ("[P]atentees won only 164 of the 636 definitive merits rulings, or 26%," and "that number is essentially unchanged" from a decade ago.).

[34] Ruben Jacobo-Rubio, et al., *The Distribution of Surplus in the US Pharmaceutical Industry: Evidence from Paragraph iv Patent-Litigation Decisions*, 63 J. Law & Econ. 203, 228-229, 234 (2020), *available at* https://jonwms.web.unc.edu/wp-content/uploads/sites/10989/2021/06/ParIVSettlements_JLE.pdf (last visited Sept. 4, 2025).

[35] 35 U.S.C. § 311.

[36] Food and Drug Administration, *Risk Evaluation and Mitigation Strategies* (May 16, 2023), *available at* www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems (last visited Sept. 4, 2025).

condition drug approval on the implementation of a program designed to address serious risks associated with particular pharmaceutical products. The intention is not to make drugs, or drug samples, less available for appropriate use such as the bioequivalence testing of generic medications. The legislation's focus is on risk assessment, risk management, and pharmacovigilance practices in the post-market setting. In fact, the Food and Drug Administration Amendments Act ("FDAAA") prohibits manufacturers from using their REMS program to "block or delay approval" of generic manufacturers' applications to FDA.[37]

57. More restrictive REMS programs have "Elements to Assure Safe Use" ("ETASU"), which may include prescriber experience requirements, certification systems, patient monitoring or registration, and controlled distribution.[38] Implementation systems provide the operational infrastructure used to monitor and evaluate those in the healthcare system who are responsible for implementing ETASU measures.[39] This typically involves the use of data-collection systems and databases to compile the information required to verify that ETASU commitments are being fulfilled. The system build-out costs are not insignificant, leading many sponsors to engage third parties such as McKesson Corporation to repurpose and redeploy existing infrastructure that is used for other clients.

58. Prior to December 2019, Section 505(i)(1)(B) of the FDCA provided that ANDA filers seeking to develop a generic version of a brand drug must join a "single, shared system" of REMS (often referred to as an SSS REMS) with the brand manufacturer that held the NDA,

[37] 21 U.S.C. § 355-1(f)(8).

[38] Since Congress's enactment of the FDAAA in 2007, REMS have been increasingly common in FDA's approval process. In particular, REMS with ETASU requirements have become an increasingly prevalent part of the FDA approval process. Roughly 40% of new drugs have REMS programs. *See Sharing, Samples, and Generics: an Antitrust Framework,* Cornell Law Review (Vol. 103, Issue 1, Nov. 2017), at 7.

[39] 21 U.S.C. § 355-1(f)(4).

unless the requirement is waived by the FDA.[40] In other words, pharmaceutical companies are required by the FDA to work with competitors to develop, implement, and assess REMS programs under an SSS REMS for both the brand drug and any generic products referencing it. The use of SSS REMS seeks to reduce the burden on the healthcare system by avoiding a differently branded REMS program for each generic drug introduced for a RLD with a REMS.

59. Although the law prohibits a RLD holder from using its REMS program to block or delay approval of a generic drug application, brand manufacturers have used REMS to prevent or delay generic drugs from entering the market.[41] Janet Woodcock, Director of the FDA's Center for Drug Evaluation and Research ("CDER") testified in 2016 that brand companies use REMS programs "as an excuse to not give the drug to the generics so they can compare it to their drug." This behavior, she noted, causes "barriers and delays in getting generics on the market."[42] Through abuse of a regulatory regime intended for a different purpose, brand manufacturers have also refused to participate in good faith in shared REMS programs, in addition to denying samples necessary to establish bioequivalence.

60. To address these concerns of REMS abuse, in December 2019, Congress passed the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act. Under the CREATES Act, a waiver is no longer necessary to bypass the shared REMS requirement. Instead, ANDA filers today have the option either to join a shared REMS or to use "a different,

[40] 21 U.S.C. § 355-1(i)(1)(C) (2012).

[41] *FDA Risk Evaluation and Mitigation Strategies (REMS): Description and Effect on Generic Drug Development* (Mar. 16, 2018), *available at* https://crsreports.congress.gov/product/pdf/R/R44810/5. 16, 2018), at 9 (last visited Sept. 4, 2025).

[42] Hearing Before the S. Comm. on Health, Educ., Labor & Pensions: Generic Drug User Fee Amendments: Accelerating Patient Access to Generic Drugs, 114th Cong. 31 (2016) at 31 (testimony of Janet Woodcock, Director, Center for Drug Evaluation & Research).

comparable aspect" of the REMS ETASU.[43]

B. **The competitive effects of AB-rated generic and authorized generic competition.**

61. Over the forty years that the Hatch-Waxman Act has provided the process for generic approvals in the U.S., the distribution, sales, and pricing of brand and generic drugs has been heavily studied. In large part, for small molecule, retail distribution drugs predictable patterns of distribution, sales, and pricing have emerged.

62. For brand drugs, several structural features of the industry combine to provide a period for high, monopoly pricing for successful brand name prescription drugs. The FDCA affords periods of exclusivity to new drug applicants, and the Hatch-Waxman Act similarly does so through, for example, the 30-month stay discussed earlier. The Patent Act helps create, where lawfully implemented, a period of exclusive exploitation of a patented drug invention. These statutory rights create incentives for drug companies to innovate and launch new drugs by providing a limited period for market power, with high-priced product often at monopoly rent levels.

63. In addition, unlike most other economic markets, healthcare markets in the U.S. have a distinct feature: there is an "agency" issue. With a prescription drug, (i) the physician decides which drug is to be selected, (ii) a health benefit provider pays (all or most) of the cost of the drug, and (iii) the patient consumes the drug. Prescription drugs may only be dispensed pursuant to a doctor's prescription, and a licensed pharmacist may dispense only the brand-name drug named in the prescription or its AB-rated, FDA-approved generic equivalent.[44] These industry features also foster, before the availability of an AB-rated generic, for the brand product

[43] 21 U.S.C. § 355-1(i)(1)(C)(i)(II).

[44] In many states, pharmacists must substitute an AB-rated generic for a brand-name drug without seeking permission from the prescribing doctor.

to be priced at monopoly rent levels during periods of exclusivity.

64. For generic drugs, several structural features of the industry combine to (i) foster the approval of generic drugs, (ii) terminate the period of high, supracompetitive pricing by the brand, and (iii) achieve low, commodity-level pricing of generic prescription drugs. The exclusivities in the FDCA each have strict, limited periods of duration, as do the exclusivities provided under the Hatch-Waxman Amendments to that Act. The Patent Act provides strict expiration periods for patents after which the invention is to be open to the public. Strict generic approval requirements under the FDCA (including, for example, that the generic use the same active pharmaceutical ingredient(s), that the product be bioequivalent to the brand, that the generic comply with the same level of cGMP requirements as the brand, and that the label generally be the same as the brand) mean that, as a matter of federal law, an approved AB-rated generic must be treated the same as the brand (and the same as other AB-rated generics of the same product). Since the passage of the Hatch-Waxman Amendments, every state has adopted drug product selection laws that either require or permit pharmacies to substitute AB-rated generic equivalents for brand prescriptions (unless the prescribing physician specifically directs that substitution is not permitted). Substitution laws and other institutional features of pharmaceutical distribution and use create the economic dynamic such that the launch of AB-rated generics results both in rapid price decline and rapid sales shift from brand to generic purchasing. And extensive health benefit payor designs, largely through formularies, facilitate the substitution of generic products for the brand.

65. These industry features result in a predictable, intended, and dramatic shift in the pricing of small molecule prescription drugs when AB-rated generic versions of the brand enter, or should enter, the U.S. marketplace. A transition from monopoly to commodity is the *quid pro*

quo the brand monopolist must allow for having been provided legal exclusivities that have ended.

66. When there is no generic competition for a brand drug, the brand manufacturer can set and maintain prices without losing sales. The ability to do this is the result of the brand manufacturer's monopoly power over the market for that drug.

1. The first AB-rated generic takes the most market share and is priced below the brand.

67. Experience and economic research show that the first generic manufacturer to market its product prices it below that of its brand counterpart, on average between 82 to 86% of the pre-entry brand price.[45] This price differential is driven by the generic manufacturer's economic incentive to take as much market share from the brand as possible, as quickly as possible. Given that every state either requires or permits that a prescription written for the brand be filled with an AB-rated generic, even with just one generic in the market, about 80%, shifts from the brand to the lower-priced generic in the first six months.[46] Thus, a first, and sole, generic manufacturer almost always captures a large share of sales from the brand. The generic manufacturer usually prices somewhat below the brand, resulting in some reduction in the average price paid for the drug at issue (brand and AB-rated generic combined).

68. During the 180-day exclusivity period, the first-filer generic is the only ANDA-approved generic manufacturer on the market (though the brand's AG can be, and often is, on the market during the 180-day exclusivity period). In the absence of competition from other generics,

[45] FTC 2011 AG Study at ii–iii, vi, 34; FTC Pay-for-Delay Study at 1.

[46] Brand drugs experiencing generic entry in 2017–2019 fell to 23% market share on average after one year; for brand drugs with sales greater than $250 million (like Revlimid), brand market share fell to 18% on average one year after generic entry. Henry Grabowski, et al., *Continuing Trends in U.S. Brand-name and Generic Drug Competition*, Journal of Med. Econ., 24(1), 908, 916 (2021), *available at* https://www.tandfonline.com/doi/full/10.1080/13696998.2021.1952795#d1e258 (last visited Sept. 4, 2025).

the 180-day exclusivity period can be a highly lucrative time for the first-filer generic manufacturer (often amounting to about 80% of all profits that it will ever make on the product).

2. Later generics drive prices down further.

69. Once multiple generic competitors enter the market, the competitive process accelerates, because in an effort to gain market share, generic manufacturers typically compete vigorously with each other over price, driving prices down toward marginal manufacturing costs.[47] The FTC has found that on average, within a year of generic entry, prices drop to 15% of the brand's price.[48] That trend has been corroborated in studies using data from 2010 to 2013, 2015 to 2017, and 2013 to 2022.[49] (Of course, those studies have analyzed full generic competition, rather than a structure in which generic manufacturers were each limited to a percentage allocation of the market). A 2019 FDA study explicitly shows how, as the number of generic producers increases, the price of the drug decreases, following the law of supply and demand:[50]

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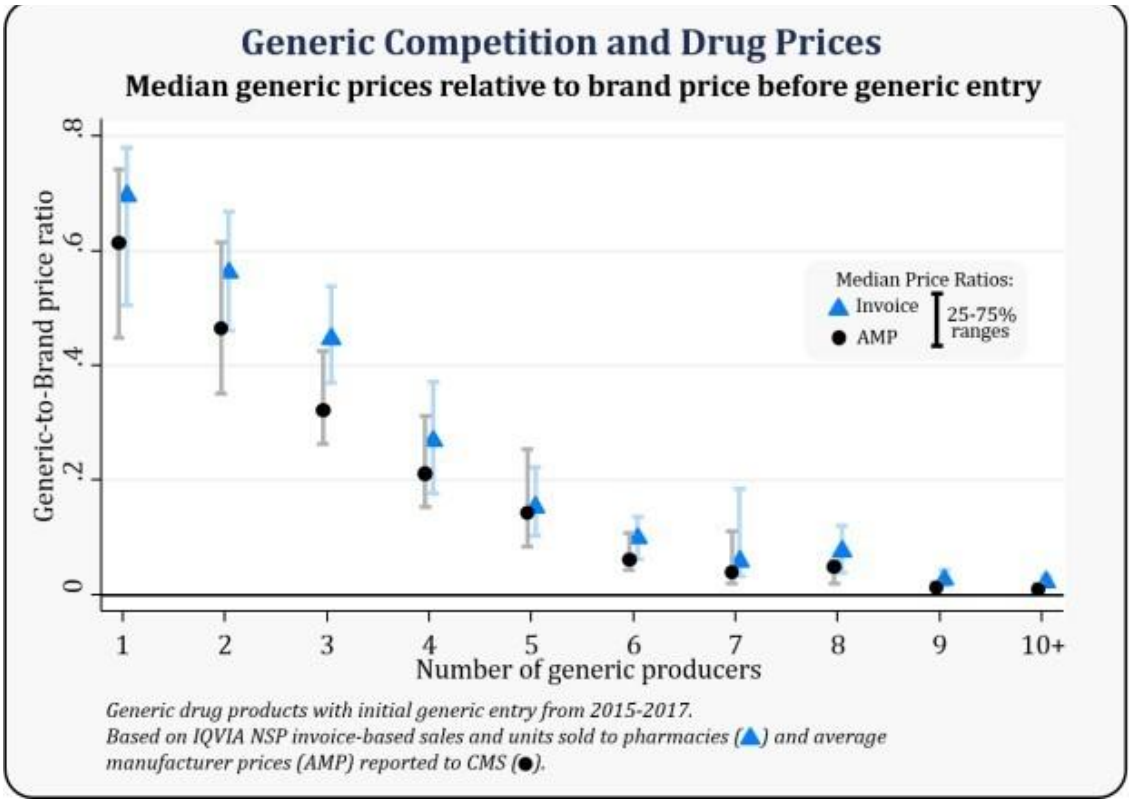
[47] *See, e.g.*, Tracy Regan, *Generic Entry, Price Competition, and Market Segmentation in the Prescription Drug Market*, 26 INT'L J. INDUS. ORG. 930 (2008); Richard G. Frank, The Ongoing Regulation of Generic Drugs, 357 NEW ENG. J. MED. 1993 (2007); Patricia M. Danzon & Li-Wei Chao, Does Regulation Drive Out Competition in Pharmaceutical Markets?, 43 J.L. & ECON. 311 (2000).

[48] FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* 8 (2010), *available at* https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf ("FTC Pay-for-Delay Study") (last visited Sept. 4, 2025).

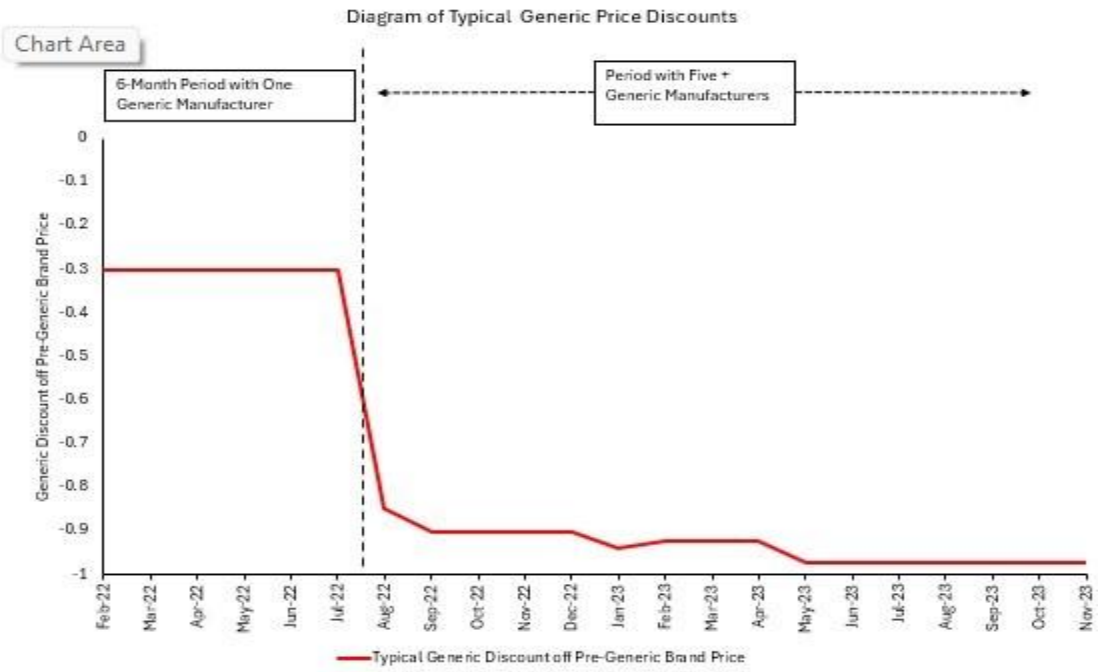
[49] *See, e.g.*, Richard Frank, et al., *The Evolution of Supply and Demand for Generic Drugs*, The Milbank Quarterly, 99(3) 828, 842 (2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8452364/pdf/MILQ-99-828.pdf (for large market oral drugs that lost patent protection between 2010 and 2013, the median index price of generic drugs fell to about 10-20% of brand price after one year) (last visiyed Sept. 4, 2025); FDA, *Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices* (2019), *available at* https://www.fda.gov/media/133509/download?attachment (last visited Sept. 4, 2025); *see also* Mohammed Jamjoom, et al., *Generic Entry and Effect of Market Competition on Outpatient Pharmacy Drug Prices*, Journal of Generic Medicines: The Business Journal of Generic Medicines Sector 20(2) (2024) (study of median generic prices as a percentage of brand name drug from 2013-2018 using prices from the Centers for Medicare and Medicaid Services National Average Drug Acquisition Cost database from January 2013 to February 2022).

[50] FDA, *Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices* 2–3 (2019), *available at* https://www.fda.gov/media/133509/download?attachment (last visited Sept. 4, 2025).



70. The FDA found that, with one generic manufacturer, the average manufacturer price was 39% lower than the brand price before generic competition, and the invoice price was 31% lower. With two competitors, prices drop to 54% and 44% lower, respectively. And with six or more competitors, both measures show a 90% or greater price reduction.[51] The figure below shows these price discounts over time.

[51] *Id.*



Typical Generic Discount based on FDA, Conrad and Lutter (2019).

71. According to the FDA and the FTC, price reductions increase substantially when the number of generic competitors goes from one to two. In that situation, there are two commodities that compete on price. And this effect continues as additional generics enter the market.[52]

72. In the end, the brand manufacturer's sales decline to a small fraction of their level before generic entry. This is so because, "[a]lthough generic drugs are chemically identical to their branded counterparts, they are typically sold at substantial discounts from the branded price. According to the Congressional Budget Office, generic drugs save consumers an estimated $8 to $10 billion a year at retail pharmacies. Even more billions are saved when hospitals use

[52] *See, e.g.*, Conrad, R., and R. Lutter. (2019). *Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices*. FDA, at 3 *available at* https://www.fda.gov/media/133509/download (last visited Sept. 4, 2025); Gupta, R., N. D. Shah and J. S. Ross. (2019). Generic Drugs in the United States: Policies to Address Pricing and Competition. *Clinical Pharmacology & Therapeutics*, 105 (2): 329-37.

generics."[53]

73. In the generic entry scenarios analyzed in the studies cited above, the generics entered the market without any constraints on their ability to use lower prices to capture market share. This ability to capture market share by lowering prices is essential to the regulatory regime created by the Hatch-Waxman Act.

3. Authorized generics, like all generics, compete on price.

74. An "authorized generic"—frequently referred to as an "AG"—is a product sold under the authority of the brand's approved NDA. An AG, then, is chemically identical to the brand drug but is sold as a generic, typically through either the brand manufacturer's subsidiary (if it has one) or through a third-party distributor. If the 180-day exclusivity period applies to a first-filer ANDA, the exclusivity exists only to bar the FDA from approving another ANDA during that time period. The exclusivity does not apply to products sold under the authority of the original NDA. As a result, the 180-day exclusivity does not bar the entry of authorized generics; the statutory scheme does not prevent a brand manufacturer from marketing and selling (directly or indirectly) an AG at any time or from licensing another company to do so.

75. The FDA has found that allowing brand manufacturers to introduce AGs during the 180-day exclusivity period is consistent with the "fundamental objective of the Hatch-Waxman [A]mendments" to encourage competition and, as a result, "lower prices in the pharmaceutical market."[54] The FDA reasoned that if a brand releases an AG at a reduced price during the 180-day exclusivity period, "this might reasonably be expected to diminish the economic benefit" to the

[53] FDA, *What Are Generic Drugs?*, *available at* https://www.fda.gov/drugs/frequently-asked-questions-popular-topics/generic-drugs-questions-answers (last visited Sept. 4, 2025).

[54] FDA Response to Mylan and Teva Citizen Petitions at 11–12, Docket Nos. FDA-2004-P-0400 (formerly 2004P-0075) and FDA-2004-P-0146 (formerly 2004P-0261) (July 2, 2004).

generic first-filer by increasing competition and causing the generic to "reduc[e] the substantial 'mark-up' [generics] can often apply during the [180-day] period."[55] Such competition, and the resulting price decreases, work to benefit drug purchasers.

76. Brand manufacturers recognize the significant economic advantages of releasing their AGs to compete with the first-filer generic during the 180-day exclusivity period. One study noted that "pharmaceutical developers facing competition from generics have large incentives to compete with their own or licensed 'authorized generics.'"[56]

77. Competition from an AG substantially reduces drug prices and the revenues of the first-filer generic (especially during the 180-day exclusivity period).

78. A study analyzing three examples of AGs found that "[f]or all three products, authorized generics competed aggressively against independent generics on price, and both the authorized and independent generics captured substantial market share from the brand."[57]

79. The FTC similarly found that AGs capture a significant portion of sales, reducing the first-filer generic's revenues by about 50% on average.[58] The first-filer generic makes much less money when it faces competition from an AG because: (i) the AG takes a large share of unit sales away from the first-filer; and (ii) the presence of the AG causes prices, particularly generic prices, to decrease.

80. Authorized generics are therefore a significant source of price competition. In fact, they are the only potential source of generic price competition during the first-to-file generic

[55] *Id.* at 12.

[56] Kevin A. Hassett & Robert J. Shapiro, Sonecon, *The Impact of Authorized Generic Pharmaceuticals on the Introduction of Other Generic Pharmaceuticals* 3 (2007), *available at* http://www.sonecon.com/docs/studies/050207_authorizedgenerics.pdf (last visited Sept. 4, 2025).

[57] Ernst R. Berndt, et al., Authorized Generic Drugs, Price Competition, and Consumers' Welfare, 26 Health Affairs 790, 796 (2007).

[58] FTC 2011 AG Study at 139.

manufacturer's 180-day exclusivity period. All drug industry participants recognize this. In 2006, the branded pharmaceuticals industry group known as PhRMA sponsored a study that concludes that the presence of an AG causes generic wholesale prices to be more than 15% lower as compared to when there is no authorized generic.[59] Generic companies recognize it.[60] Brand companies recognize it.[61]

4. Generic drug shortages impact generic drug prices.

81. Whether the result of unintended marketplace changes or by design, scarcity of generic drug products can have significant impacts on the price and accessibility of generic drugs.

82. Over the past decade, reported generic drug shortages have increased and, with that, concerns about availability and increased prices for generic drugs in scarce supply. Drug shortages impact payors and consumers through reduced sales and/or increased prices. The average drug shortage often affects many consumers, (often drug-market wide) with the primary impact on the elderly. Drug shortages impact consumers' ability to fill their prescriptions. And

[59] IMS Consulting, *Assessment of Authorized Generics in the U.S.* (2006), *available at* http://208.106.226.207/downloads/IMSAuthorizedGenericsReport_6-22-06.pdf; archived at Wayback Machine (https://web.archive.org/web/20061009134405/http://www.phrma.org/files/IMS%20Authorized%20Generics%20Report_6-22-06.pdf); (citing a capture dated Oct. 9, 2006) (last visited Sept. 4, 2025).

[60] One generic stated that "[d]ue to market share and pricing erosion at the hands of the authorized [generic], we estimate that the profits for the 'pure' generic during the exclusivity period could be reduced by approximately 60% in a typical scenario." *See* FTC 2011 AG Study at 81. Another generic manufacturer quantified the fiscal consequences of competing with an authorized generic and determined that the authorized generic reduced its first generic's revenues by two-thirds, or by approximately $400 million. Comment of Apotex Corp. in Support of Mylan Citizen Petition at 4, Docket No. 2004P-0075 (Mar. 24, 2004), *available at* https://web.archive.org/web/20041216115511/http://www.fda.gov/ohrms/dockets/dailys/04/apr04/040204/04P-0075-emc00001.pdf (last visited Sept. 4, 2025).

[61] Commenting on an FDA Citizen Petition by drug manufacturer Teva Pharmaceuticals, Pfizer stated: "Teva's petition [to prevent the launch of an authorized generic] is a flagrant effort to stifle price competition – to Teva's benefit and the public's detriment . . ." Comment of Pfizer at 6–7, Docket No. 2004P-0261 (June 23, 2004), *available at* https://web.archive.org/web/20050601041653/http://www.fda.gov/ohrms/dockets/dailys/04/June04/062904/04p-0261-cr00001-01-vol2.pdf (last visited Sept. 4, 2025); Comment of Johnson & Johnson at 1, FDA Docket No. 2004P-0075 (May 11, 2004), *available at* https://web.archive.org/web/20041227172543/http://www.fda.gov/ohrms/dockets/dailys/04/June04/060404/04p-0075-c00002-vol1.pdf (last visited Sept. 4, 2025).

drug shortages lead to higher drug prices. Studies show that in some cases, the increase in the price of the available product supply was at least three times higher than the price increase of the drug in shortage.[62]

83. Fundamental principles of applied microeconomics teaches that a limitation on the amount of generic that may be sold fundamentally changes the pricing dynamics for a generic drug. Experiencing a generic drug shortage (*i.e.*, a reduction in supply) while demand remains constant results in increased price.

84. Drug shortages generally appear to be the result of non-collusive, industry changes. However, an orchestrated effort to impact the availability of generic supply can have a sweeping impact on keeping the price of a generic drug at supracompetitive levels (near brand price).

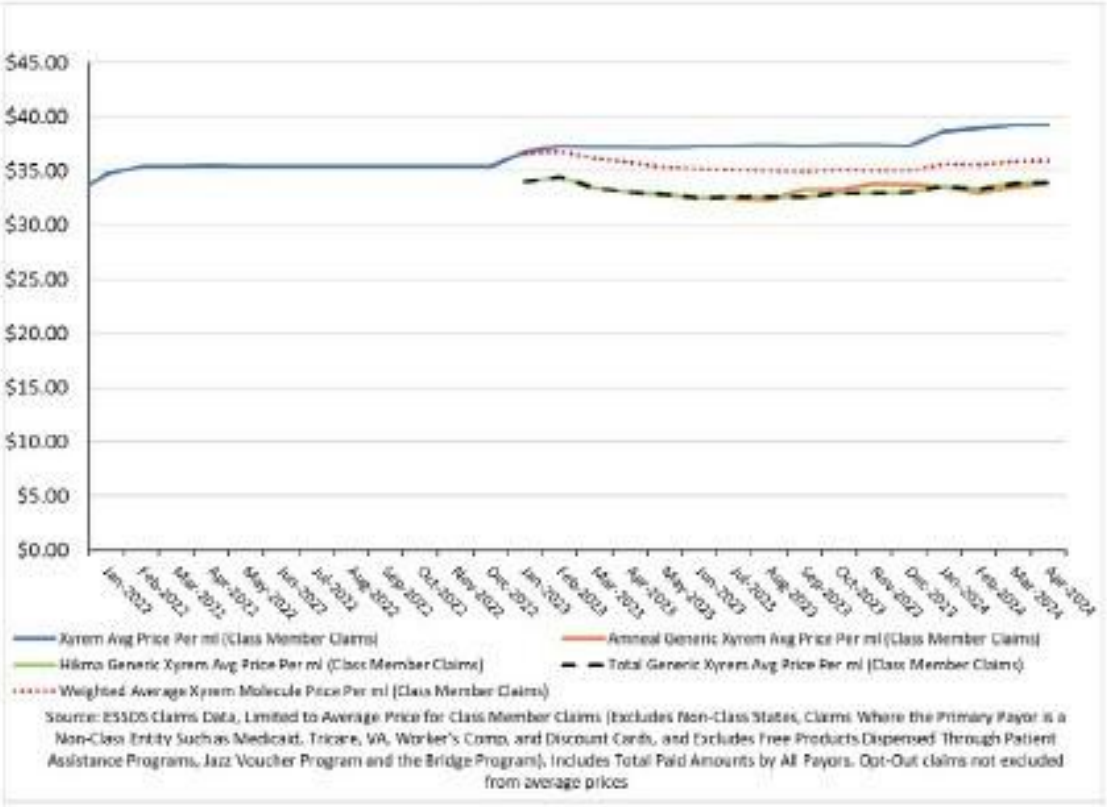
85. For example, the brand and generic companies settled patent litigation involving the drug Xyrem (sodium oxybate) on terms that delayed competition for years (until December 31, 2025) *and* split the resulting unlawful monopoly profits in the earlier period with multiple generics. The brand split its monopoly profits with first-filer Hikma by allowing it to sell an AG but requiring it to pay the brand a sliding-scale royalty that increased as Hikma sold more pills. The brand then further shared its monopoly profits with three other generic companies, allowing each to sell a fixed, small amount of its generic product in later time periods.[63] First-filer Hikma began selling its generic Xyrem in January 2023; it launched at a retail price that was about 93% of brand price. Six months later, a later generic (Amneal) began selling its own small allotment; despite theoretical competition from Hikma's generic product, Amneal launched its allotment at

[62] *See* ASPE Report to Congress: Impact of Drug Shortages on Consumer Costs (2023), *available at* https://aspe.hhs.gov/reports/drug-shortages-impacts-consumer-costs (last visited Sept. 4, 2025).

[63] Each generic is allotted a low single-digit percentage of total sodium oxybate sales annually.

87% of the brand price. And as of April 2024, the last date for which data is available, the generic price for both Hikma and Amneal remained at 87% of the brand price.

Figure 3: U.S. Retail Price of mL of Xyrem and Generic Xyrem for Class Members (January 2022 – April 2024)[16]



Source: ESSDS Claims Data, Limited to Average Price for Class Member Claims (Excludes Non-Class States, Claims Where the Primary Payor is a Non-Class Entity Such as Medicaid, Tricare, VA, Worker's Comp, and Discount Cards, and Excludes Free Products Dispensed Through Patient Assistance Programs, Jazz Voucher Program and the Bridge Program). Includes Total Paid Amounts by All Payors. Opt-Out claims not excluded from average prices

Table 3: Monthly Generic Price Discount off of Brand Xyrem[19]

Month	Generic Price as a Percent of Pre-Generic Brand Price	Generic Price as a Percent of Contemporary Brand Price
Jan-23	96%	93%
Feb-23	97%	92%
Mar-23	94%	90%
Apr-23	93%	89%
May-23	93%	88%
Jun-23	92%	87%
Jul-23	92%	87%
Aug-23	92%	87%
Sep-23	92%	87%
Oct-23	93%	88%
Nov-23	93%	88%
Dec-23	93%	88%
Jan-24	95%	87%
Feb-24	94%	86%
Mar-24	95%	86%
Apr-24	96%	87%

86. This example reflects the economic reality that lower prices are driven not by the number of manufacturers selling the product, but by the efforts of those manufacturers to capture market share by lowering prices.

5. The Federal Trade Commission agrees that settlements for volume-limited generic launches can be reverse payments.

87. On January 15, 2025, the FTC released four reports and an accompanying article authored by the Acting Assistant Director for its Health Care Division, entitled *Reverse Payments: From Cash to Quantity Restrictions and Other Possibilities*.[64] The FTC reports summarize Hatch-Waxman settlement agreements filed with the FTC in 2018-2021 under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"). The reports state FTC's position

[64] *See* Brad Albert, Hannah Lamb, *Reverse Payments: From Cash to Quantity Restrictions and Other Possibilities*, *available at* FTC, Jan. 15, 2025, *available at* https://www.ftc.gov/enforcement/competition-matters/2025/01/reverse-payments-cash-quantity-restrictions-other-possibilities (all four reports can be found linked in this article) (last visited Sept. 4, 2025).

that agreements that restrict the quantity the settling generic can sell for a period of time like those in the Revlimid settlement agreements can be a form of "possible compensation."[65]

88. As the FTC article accompanying the reports explains, quantity restrictions in Hatch-Waxman settlements "have the potential to alter the competitive dynamics of the market, maintain supracompetitive prices, and allow for the sharing of monopoly profits between the patentee and patent challengers."[66] Where, as in the Revlimid settlement agreements, "the quantity permitted to be sold under the restriction is relatively small, the settling company may have little incentive to compete by lowering price, resulting in supracompetitive prices on products sold by both the brand company and its generic or biosimilar competitor. In some cases, such quantity restrictions may be effectively a de facto market allocation between the patent holder and the patent challengers."[67]

89. That is exactly the case here.

C. **Manipulation of the regulatory structure to impair competition.**

90. The brand manufacturer of a pharmaceutical product that has no generic competition in the marketplace gets all the profits on all unit sales. In this circumstance, brand manufacturers can usually sell their drug for far more than the marginal cost of production, generating profit margins in excess of 70% or more, while making hundreds of millions of dollars in sales. The ability to make those kinds of profit margins is what economists call "market power."

91. When a generic equivalent enters the market without volume constraints, however,

[65] *Id.* at, *e.g.*, 2018 Report, at 2 ("[P]ossible compensation include[s] . . . [a]n agreement that restricts the quantity the settling generic can sell for a period of time.").

[66] *Id.*

[67] *Id.*

it quickly captures 80% or more of the unit sales from the brand drug. When true generic entry occurs, the brand manufacturer loses most of the unit sales; the generic manufacturer sells almost all of the units, but at drastically reduced prices—delivering enormous savings to drug purchasers. And when multiple generics compete in the market, that competition drives prices down to near the marginal cost of production. This competition ends the brand manufacturer's market power and delivers enormous savings to drug purchasers. Competition converts what formerly were excess profits into purchaser savings.

92. While brand manufacturers and first-filer generic manufacturers are typically marketplace competitors, they have a collective interest in preventing robust competition from other generic manufacturers, as such competition severely depresses prices. If the brand and first-filer generic work together to prevent or delay such competition, they can keep the profit margins on all of the unit sales at 70% and split the resulting excess profits among themselves. In other words, by stifling competition, the brand manufacturer and first-filer generic manufacturer can maintain high prices, protect their profits, and split between themselves the enormous savings that increased generic competition would have delivered to drug purchasers.

93. For such an anticompetitive pact to work, brand and generic manufacturers need a means by which to divide between them the ill-gotten gains—the increased profit to the detriment of drug purchasers—that delayed competition makes possible. After all, the generic manufacturer will not refrain from competing if it does not share in the profit gains through some means. Such means usually take the form of pay-offs from the brand manufacturer, deals that are often referred to as "pay-for-delay," "exclusion payment," or "reverse payment" agreements.

94. The brand manufacturer may choose —unlawfully—to pay off only the first-filer, even if other generic manufacturers are also lined up to challenge the patents. The first-filer's

agreement to delay marketing its generic drug also prevents other generic manufacturers from marketing their products: none of the later filers can enter until the first-filer's 180-day exclusivity period has run.

95. Later ANDA filers have more modest financial expectations because they may have little or no expectation of any form of market exclusivity. By the time they enter the market, there is at least the brand and one other generic on the market (and often a second generic in the form of an AG) and, thus, the drug has already been, or is on its way to being, commoditized. As a result, later-filing generics can be more readily motivated away from competitively driven modest sales results and toward anticompetitive payoffs by brand companies. Under these unlawful arrangements, the brand shares some of its supracompetitive profits with the later-filing generics, and in exchange the later-filing generics agree to drop their patent challenges and accept a late agreed entry date.

96. Pay-for-delay agreements are fundamentally anticompetitive and contrary to the goals of the Hatch-Waxman statutory scheme. They extend the brand manufacturer's monopoly by blocking access to more affordable generic drugs, forcing purchasers to buy expensive brands instead.

97. In the 1990s, pay-offs from brand manufacturers often took the form of cash payments to would-be generic competitors. Since the 2000s—as a result of regulatory scrutiny, congressional investigations, and class-action lawsuits—brand and generic manufacturers have entered into increasingly more elaborate agreements in an attempt to obscure payoffs.

1. No-authorized-generic provisions are anticompetitive.

98. One form of payoff is a "no-authorized-generic" or "no-AG" agreement. With a no-AG agreement, the brand manufacturer agrees not to market an AG version of the brand drug

for some period of time after the first generic enters the market in exchange for the first generic agreeing to a delayed entry date.

99. No-AG agreements between a brand manufacturer and would-be generic competitors are sometimes explicit. Other times, such agreements may be structured in a way that ostensibly reserves some right for the brand manufacturer to sell a generic version of its branded product, but that still functionally acts as a no-AG agreement by making exercise of that right unprofitable for the brand, resulting in the same impact on competition as an explicit no-AG agreement. The FTC recognizes the existence and impact of such functional no-AG agreements. In a study by the FTC of the settlement agreements, the FTC explained that:

> The most common form of possible compensation—appearing in 9 final settlements—is a commitment from the brand manufacturer not to use a third party to distribute an authorized generic for a period of time, such as during first-filer exclusivity. This type of commitment could have the same effect as an explicit no-AG commitment, for example, if the brand company does not market generics in the United States.[68]

100. Absent a no-AG promise, it often makes economic sense for the brand manufacturer to begin marketing an AG through a third party as soon as (or sometimes weeks or months before) the first-filer generic enters the marketplace. The AG entry affords the brand company a price strategy (competing with a low-priced generic), and this competition takes sales from what would otherwise be sold by the first-filer generic. Competition from an AG typically cuts the first-filer's revenues approximately in half, and by having two generics in the market (the first-filer generic and the AG), the two generics compete on price. This lowers prices, delivering

[68] FTC, *Overview of Agreements Filed in FY 2016: A Report by the Bureau of Competition* (2017), *available at* https://www.ftc.gov/system/files/documents/reports/agreements-filled-federal-trade-commission-under-medicare-prescription-drug-improvement/mma_report_fy2016.pdf (last visited Sept. 4, 2025). *See also* FTC, *MMA Reports: No tricks or treats – just facts*, October 27, 2020, *available at* https://www.ftc.gov/enforcement/competition-matters/2020/10/mma-reports-no-tricks-or-treats-just-facts (last visited Sept. 4, 2025).

savings to drug purchasers.

101. To prevent an AG from causing this substantial loss of revenues and profits, a first-filer generic may be willing to delay its entry into the marketplace in return for the brand manufacturer's agreement to forgo competing with an AG during the exclusivity period. The additional monopoly profits that the brand manufacturer gains from the delayed onset of generic competition more than makes up for the profits it forgoes by temporarily not competing with its AG. The brand manufacturer gains from the delayed onset of generic competition; the first-filer gains from the absence of generic competition for the first 180 days of marketing.

102. In the scenarios described above, drug purchasers lose. The brand and first-filer's reciprocal pledges not to compete harm purchasers thrice over. First, the pact delays the first-filer's generic entry into the marketplace and thereby extends the time during which the more expensive brand is the only product on the market. Second, by delaying the first-filer's entry, the pact also delays the time when other, later, generics enter. Third, the pact prevents the brand from marketing an AG during the 180-day exclusivity period, reducing price competition during that period, particularly price competition that would otherwise occur between the first-filer's generic and the brand's AG.

103. For the first-filer generic, the difference between selling the only generic and competing against an AG for 180 days can amount to tens or even hundreds of millions of dollars, depending on the size of the brand's sales. A no-AG pledge thus has the same economic effect as a pay-off made in cash. As explained by the then-Chairman of the FTC:

> Because the impact of an authorized generic on first-filer revenue is so sizable, the ability to promise not to launch an AG is a huge bargaining chip the brand company can use in settlement negotiations with a first-filer generic. It used to be that a brand might say to a generic, "if you go away for several years, I'll give you $200 million." Now, the brand might say to the generic, "if I

> launch an AG, you will be penalized $200 million, so why don't you go away for a few years and I won't launch an AG."[69]

104. Courts agree that no-AG agreements are a form of payment actionable under *Actavis* and are anticompetitive.[70]

2. Anticompetitive "acceleration" clauses.

105. Another tool by which conspiring brand and generic companies impose restraints on trade that act to delay generic entry is use of a "most-favored-entry" or "acceleration" clause in agreements. Under the terms of such an agreement, the entry date for the settling generic may be advanced to an earlier one, depending on defined events that may happen with respect to later generics.

106. On its face, such a provision might seem to enhance competition because it ostensibly permits, under the prescribed conditions, the ability of the settling generic to enter the market earlier. However, in many circumstances, the intended and real effect is that such a provision acts like a poison pill, creating a situation where later would-be generic competitors are disincentivized from taking the actions that would trigger the clause (as the result is that the challenging generic cannot enjoy the fruits of a challenge, such as a period of *de facto* exclusivity, because the settling generic will be given a free pass to enter as well).

107. In short, the purpose and effect of a most-favored-entry or acceleration clause is to

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[69] FTC, "Statement of Chairman Jon Leibowitz on the Release of the Commission's Interim Report on Authorized Generics," (June 24, 2009), *available at* https://www.ftc.gov/sites/default/files/documents/reports/authorized-generics-interim-report-federal-trade-commission/p062105authgenstatementleibowitz.pdf (last visited Sept. 4, 2025).

[70] *See, e,g., In re Loestrin 24 Fe Antitrust Litig.*, Nos. 14-2071, 15-1250, 2016 U.S. App. LEXIS 3049, at *25–26 (1st Cir. Feb. 22, 2016); *In re Opana ER Antitrust Litig.*, No. 14 C 10150, 2016 U.S. Dist. LEXIS 16700, at *23-25 (N.D. Ill. Feb. 10, 2016); *In re Aggrenox Antitrust Litig.*, 94 F. Supp.3d 224, 242 (D. Conn. 2015); *United Food & Commercial Workers Local 1776 & Participating Emp'rs Health & Welfare Fund v. Teikoku Pharma USA, Inc.*, 74 F. Supp.3d 1052, 1069 (N.D. Cal. 2014); *In re Effexor XR Antitrust Litig.*, No. 11-cv-5479, 2014 U.S. Dist. LEXIS 142206, at *62 (D.N.J. Oct. 6, 2014); *Time Ins. Co. v. AstraZeneca AB*, 52 F. Supp.3d 705, 709–10 (E.D. Pa. 2014); *In re Niaspan Antitrust Litig.*, 42 F. Supp.3d 735, 751 (E.D. Pa. 2014); *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp.2d 367, 392 (D. Mass. 2013).

dramatically reduce any other generic manufacturer's incentive to try to enter the market as quickly as they can. Absent the acceleration clause, other generic manufacturers would have an incentive to enter the market as soon as they were able, thereby enjoying a substantial period as the only ANDA-based generic product on the market. By eliminating this possibility, an acceleration clause results in delayed generic entry by, among other things, disincentivizing generics that would otherwise be willing and able to come to market from doing so because of the knowledge that other generics would immediately flood the market.

108. The Chairman and CEO of Apotex, Inc.—one of the largest generic manufacturers in the world—twice testified to Congress that acceleration clauses represent "the primary anticompetitive aspects of settlements" because they "eliminate any incentive for a subsequent filer to continue to litigate for earlier market entry."[71] Acceleration clauses both induce prospective generic competitors to accept later entry dates and deter others from challenging weak patents:

> [N]o subsequent filer is going to take up the patent fight knowing it will get nothing if it wins. Consumers are the biggest losers under this system. If subsequent filers do not have the incentive to take on the cost of multimillion patent challenges these challenges will not occur. Weak patents that should be knocked out will remain in place, unduly blocking consumer access to generics. The challenges to brand patents by generic companies that Hatch- Waxman was designed to generate will decrease. And settlements that delay consumer access to the generic will, in turn, increase.[72]

[71] Protecting Consumer Access to Generic Drugs Act of 2007: Hearing on H.R. 1902 Before the Subcomm. on Commerce, Trade, and Consumer Protection of the H. Comm. on Energy & Commerce, 110th Cong., at 65, 67 (2007) (statement of Bernard Sherman, CEO, Apotex, Inc.), *available at* http://www.gpo.gov/fdsys/pkg/CHRG-110hhrg38992/pdf/CHRG-110hhrg38992.pdf (last visited Sept. 4, 2025).

[72] Protecting Consumer Access to Generic Drugs Act of 2009: Hearing on H.R. 1706 Before the Subcomm. on Commerce, Trade, and Consumer Protection of the H. Comm. on Energy & Commerce, 111th Cong., at 218 (2009) (statement of Bernard Sherman, CEO, Apotex, Inc.) (hereinafter "Apotex 2009 Statement"), *available at* http://www.gpo.gov/fdsys/pkg/CHRG-111hhrg67822/pdf/CHRG-111hhrg67822.pdf (last visited Sept. 4, 2025). Apotex addressed acceleration clauses in the context in which, as here, the first-filing generic retained the 180-day exclusivity.

109. Scholars agree. A recently published study analyzing empirical pharmaceutical settlement data concluded that "[a]n acceleration clause paired with the 180-day exclusivity period appears to effectively deter other generics . . . ." Indeed, the study found that in cases like this one, where the first-filer retained its 180-day exclusivity, the use of acceleration clauses had not once promoted earlier generic entry. "Among the 54 cases in which the first-filer retained sole rights to the 180-day exclusivity period, there were no cases of early generic entry. In other words, there were no cases in which the first-filer's entry was accelerated, and there were no cases in which a different generic entered before the entry date set in the first-filer's settlement."[73]

110. A poison-pill provision can be particularly anticompetitive when the ostensible earlier entry for the settling generic is triggered by a final court determination that the later generic's ANDA product does not infringe the brand's patent. Generic drug companies compete to better design around brand drug patents; if an innovative generic company can find a unique way to design around the brand drug patent, then that generic will have a leg up on other generics and have the potential for entry for a *de facto* period of exclusivity. When a settling generic bargains for a poison pill that is triggered upon another generic having successfully shown its generic does not infringe, the financial desirability of the *de facto* exclusivity is greatly diminished, thereby disincentivizing efforts by the non-settling generic to compete with early entry of its non-infringing product.

111. A poison-pill provision can also be particularly anticompetitive when it is accomplished through a serial, pile-on effect. A poison pill disincentivizes other generic companies from expending litigation resources to challenge and win brand patent challenges,

[73] Keith M. Drake & Thomas G. McGuire, *Generic Entry Before the Agreed-Upon Date in Pharmaceutical Patent Settlements*, Journal of Competition Law & Economics, 16(2), 188–219 at 194 (2020).

even challenges by non-first-filer generics, because the settling defendant is allowed into the market when the challenging generic wins and enters. The more poison pills the brand company has doled out to settling defendants, the less the incentive for the generics to persist with the challenge.

112. And by reducing the benefits of later generic challengers (*i.e.*, by reducing the benefits of competition intended by the Hatch-Waxman Act by encouraging patent challenges), poison pills increase the likelihood that later generics will settle for a form of payoff from the brand. In other words, it is far better economically for the later-filed patent challengers to settle for a portion of the supracompetitive profits than it is to pay lawyers and experts to litigate the infringement and invalidity claims to completion, only to have real generic competition reduce the market to small fractions of what it was while prompting additional costs of marketing and competing for these slivers of the market with multiple other generic competitors.

V. FACTS

A. The early background of thalidomide and its analogs.

113. Thalidomide was developed by a Swiss pharmaceutical company, CIBA, in the 1950s. Chemi Grunenthal first marketed the drug in 1956 as a sleep aid. Thalidomide then became popular as an anti-nausea treatment for pregnant women.

114. In 1961, thalidomide's use in pregnancy was linked to congenital defects, and it was pulled from most markets. While thalidomide was banned worldwide by the end of the decade, it remained available, primarily in developing countries. Despite the ban, thalidomide and its analogs remained the focus of considerable research in the 1960s and beyond.[74]

[74] Publications on thalidomide and thalidomide analogs include: J. Sheskin and F. Sagher, *Trials With Thalidomide Derivatives in Leprosy Reactions*, Lep. Rev. (1968) 39:203–206 ("Sheskin 1968"); H. J. Schumacher et al, *The Teratogenic Activity of a Thalidomide Analogue, EM12, in Rabbits, Rats, and Monkeys*, Teratologu, 5:233–40

115. By 1990, thalidomide, in the words of the *New York Times*, was "finding new life" as researchers had "discovered that it is a spectacularly effective agent for combatting rejection of foreign tissue and for alleviating the symptoms of several diseases in which the immune system turns against the body."[75]

116. Throughout the 1990s and early 2000s, researchers around the world continued to investigate not just thalidomide but thalidomide analogs such as pomalidomide, EM-12, and lenalidomide for the treatment of a host of conditions.[76]

117. By mid-2002, one such researcher, Dr. Robert D'Amato of Boston Children's Hospital,[77] had amassed a large portfolio of intellectual property claiming methods of using thalidomide, lenalidomide, and pomalidomide. Although many researchers were researching and establishing new uses for these compounds, Dr. D'Amato in particular threatened Celgene's ability to obtain and maintain a monopoly on these drugs. In short, Celgene wasn't first. And when it realized this, it lied, sued, and eventually bought its way out of the problem.

1. In the early 1990s, Dr. D'Amato conducted groundbreaking research on thalidomide analogs, leading to patents that claim methods of using these compounds to treat conditions associated with blood-borne tumors.

(1970); N. Ake Jonsson, *Chemical Structure and Teratogenic Properties: A Review of Available Data on Structure Activity Relationships and Mechanism of Action of Thalidomide Analogues*, Acta Pharm. Suicica, vol. 9, pp. 521–542 (1972).

[75] Sandra Blakeslee, *Scorned Thalidomide Raises New Hopes,* NYT, April 10, 1990, Section C, page 3, *available at* https://www.nytimes.com/1990/04/10/science/scorned-thalidomide-raises-new-hopes.html (last visited Sept. 4, 2025).

[76] For example, in 1991, clinical researchers at Rockefeller University and the Leprosy Unit of Osuatldo Cruz Foundation in Rio de Janeiro published an article on thalidomide's ability to reduce TNFα (a protein involved in the immune response that causes inflammation). *See* Sampaio, Sarno, Galilly, Cohn, and Gilla Kaplan, Thalidomide Selectively Inhibits TumorbNecrosis Factor Alpha Production by Stimulated Human Monocytes, J. Exp. Med. ® The Rockefeller University Press, Volume 173 March 1991 699–703, *available at* http://rupress.org/jem/article-pdf/173/3/699/1671813/699.pdf (last visited Sept. 4, 2025).

[77] Dr. D'Amato joined Boston Children's Hospital in 1994, following a two-year post-doctorate fellowship at Folkman laboratories. *See* https://www.childrenshospital.org/research/researchers/robert-damato#background (last visited Sept. 4, 2025).

118. In 1992, Dr. D'Amato began investigating thalidomide and its analogs to reduce angiogenesis, which is the growth of unwanted blood vessels associated with conditions like cancer. Describing how he came to focus on thalidomide and its analogs, Dr. D'Amato reasoned that drug candidates that stopped *undesired* angiogenesis (e.g., growth of blood vessels that support tumor growth) would be drugs that also stopped *desired* angiogenesis, resulting in unwanted side effects (e.g., hair loss, problems with wound healing, cessation of menstrual cycle, and birth defects). Dr. D'Amato identified roughly fifty drugs that had these side effects and then narrowed the list to approximately ten drugs that had more than one such side effect. That list included thalidomide. Dr. D'Amato then conducted an *in vivo* study using fertilized chicken eggs. Although his initial thalidomide tests did not show results, Dr. D'Amato recalled literature advising that thalidomide must be metabolized by the body to be active. Once he shifted to a thalidomide metabolite, the egg assay reacted, demonstrating thalidomide's effectiveness in inhibiting angiogenesis.

119. By the mid-1990s, Dr. D'Amato had extended his research to treating leukemia models, discovering leukemias and other blood-borne cancers could be treated with angiogenesis inhibitors like thalidomide.

120. On March 1, 1993, D'Amato filed provisional patent application no. 08/025,046, which led to the issuance of several patents, including the 5,712,291 (issued Jan. 27, 1997), the 5,593,990 (issued Jan. 14, 1997) and the 5,629,327 (issued May 13, 1997). These patents claim methods of treating angiogenesis with thalidomide and its analogs, including angiogenesis associated with blood-borne tumors.[78]

[78] The '291 claims, *inter alia*, methods of treating angiogenesis with pomalidomide (claim 1), wherein the undesired angiogenesis occurs in blood borne tumors (claim 65). The '990 claims, *inter alia*, a method of treating chronic inflammation with an angiogenesis-inhibiting compound from the structures disclosed (claim 1), including with thalidomide (claim 3). The '327 claims, *inter alia*, a method of treating angiogenesis with thalidomide (claim 1).

2. In 1997, Celgene obtained a lenalidomide patent; this patent was revoked over earlier research by Boston Children's researcher Dr. D'Amato and only reissued after Celgene defrauded the examiner.

121. In the early 1990s, money was so tight at Celgene that executives engaged in "violent arguments" over whether to charge employees for coffee. On July 24, 1996, Celgene filed a new patent application directed to thalidomide analogs and uses thereof to reduce tumor necrosis factor-α (TNFα). On June 3, 1997, U.S. patent no. 5,635,517 issued.[79] Claims 1–9 of the '517 patent claim methods of using lenalidomide, pomalidomide, and other compounds to reduce TNFα. Claim 10 of the '517 patent claims four compounds, one of which is lenalidomide (Revlimid). The other three compounds claimed in claim 10 were not commercially developed.

122. On April 14, 1998, less than a year after the '517 patent issued, Celgene's patent attorney, Bruce Collins, filed a petition for reexamination of the patent because "of a question raised by a non-adversarial third party, a potential licensee, as to the significance of certain prior art."[80] The petition presented the question of whether the '517 patent was unpatentable over the three D'Amato patents described above (the '291, '990, and '327 patents) in light of two other references, the "Leibovich references," which date to 1987 and disclose the relationship between angiogenesis and TNFα.[81] Celgene essentially sought, in an *ex parte* setting, confirmation that its '517 patent was valid (*i.e.*, not obvious) despite this earlier research.

123. To support its position, Celgene argued that, only by impermissible hindsight, could a worker choose the compounds used in the '517 patent's method of treatment claims (e.g.,

[79] Application no. 08/690,258. Because there was no earlier, provisional patent application, July 24, 1996, marks the priority date for the '517 patent.

[80] File History for U.S. Patent Reexamination Application no. 90/005,157 ("'517 Reexam File History"), Patent Owner's Statement, at 1–2.

[81] US Patent no. 4,808,402 (issued in 1987); Leibovich, et al., *Macrophage-Induced Angiogenesis Is Mediated by Tumor Necrosis Factor-α*, Letters to Nature, Vol 329, 15 October 97, pp. 630–32 (1987).

lenalidomide, pomalidomide) and compound claims (namely, lenalidomide) from the "millions of possibilities" in the disclosure of the three D'Amato patents:

> The Patent Owner's [Celgene's] position is rather that if one of ordinary skill in the art were given the disclosure of the patent under reexamination [the '517 patent], that is, if the Patent Owner provided the blaze marks, a worker could *retrospectively* make choices from literally millions of possibilities in the disclosure of the three D'Amato patents and thereby approximate the compounds used in the method of claims 1-9 and the compounds defined in claim 10.[82]

124. Celgene's plan to confirm its patent's validity over D'Amato's prior research backfired. On February 21, 1999, the patent examiner rejected all ten issued claims as unpatentable over the earlier D'Amato patents in view of the Leibovich references, stating in part:

> Since the properties of the prior art overlap with the Muller et al. (U.S. Patent No. 5,635,517) under reexamination, and the 3 D'Amato patents teach the equivalents of hydrogen, hydroxy, epoxy and amino groups as substituents on each of the four positions on the benzene ring of the isoindoline nucleus, **there is ample information in the prior [art] to motivate one of ordinary skill in the chemical arts to place applicants compounds in possession of the public**.[83]

125. The examiner also rejected Celgene's argument that "the 3 D'Amato Patents teach millions of compounds" such that one would not "arrive at [Celgene's] compounds" (namely lenalidomide and pomalidomide):

> Specifical[l]y, the record has shown and the patentee has admitted in the record that the 3 D'Amato patents contain the same disclosure and said D'Amato patents supra disclose the **very closely analogous compounds**, namely, 1-oxo-2-(2,6-dioxopiperidin-3-yl)-4,5,6 or 7-[hydrogen, hydroxy or epoxy] -iso-indolines and the corresponding 1,3-dioxo-2-(2,6-dioxopiperidin-3-yl)4,5,6 or 7[hydrogen, hydroxy or epoxy]-iso-indolines and methods for their

[82] '517 Reexam File History, Patent Owner's Statement, at 3 (emphasis in original).

[83] '517 Reexam File History, Office Action, at 4.

preparation.[84]

126. In the above quote, the examiner identified two specific formulas from the D'Amato patents that result in "very closely analogous compounds" to those in the '517 patent.

Two sets of compounds disclosed in D'Amato Patents
1-oxo-2-(2,6-dioxopiperidin-3-yl)-**4,5,6 or 7-[hydrogen, hydroxy or epoxy]**-iso-indolines
1,3-dioxo-2-(2,6-dioxopiperidin-3-yl)-**4,5,6 or 7-[hydrogen, hydroxy or epoxy]**-iso-indolines

127. The 4, 5, 6, 7 numbers in the above formulas indicate a particular position on the benzene ring of the molecule. The bracketed portion indicates that a hydrogen, hydroxy, or epoxy group can be substituted at one of those positions.

128. The examiner further stated that the disclosure of the D'Amato patents taught that there is an equivalence between a hydrogen, hydroxy, or epoxy group and an amino group:

> [T]here is a teaching of equivalence between hydrogen, hydroxy, epoxy and amino as possible substituents on the 4,5,6 and 7 positions of the benzene ring . . . .
>
> * * *
>
> [T]he specific columns where the teaching of equivalence for the interchangeable substituents on the phenyl ring of the isoindoline nucleus have been identified, *i.e.*[**amino**, hydrogen, hydroxy and epoxy] respectively.[85]

129. To illustrate, the formulas would then be:

1-oxo-2-(2,6-dioxopiperidin-3-yl)-**4,5,6, or 7-**[**amino**, hydrogen, hydroxy and epoxy]-iso-indolines
1,3-dioxo-2-(2,6-dioxopiperidin-3-yl)-**4,5,6, or 7-**[**amino**, hydrogen, hydroxy and epoxy]-iso-indolines

[84] '517 Reexam File History, Office Action, at 3.

[85] "See sheets 1,2 and 3 of drawings, depicted compounds in columns 6,9-11,17,19 and 21-25 respectively. [F]urther, it is noted that in column 7, lines 25-30 and column 19, lines 40-46, there is a teaching of equivalence between hydrogen,hydroxy,epoxy and amino as possible substituents on the 4,5,6 and 7 positions of the benzene ring of the said 1-oxo- or 1,3-dioxo-isoindoline ring." '517 Reexam File History, Office Action, at 3.

130. If the amino substitution is made at the 4 position of these two formulas, the result is lenalidomide and pomalidomide, respectively:

1-oxo-2-(2,6-dioxopiperidin-3-yl)-**4-amino**-iso-indoline	lenalidomide (Revlimid)
1,3-dioxo-2-(2,6-dioxopiperidin-3-yl)-**4-amino**-iso-indoline	pomalidomide (Pomalyst)

131. As the examiner made clear, the D'Amato disclosures described above result in a "small number of very specific prior art compounds":

> The record above, **clearly shows a small number of very specific prior art compounds**, in addition, the relevant columns where the specific compounds are disclosed in the said D'Amato patents have been identified.

132. Based on this detailed analysis of the D'Amato patents, the examiner concluded that the '517 patent was obvious over the D'Amato patents in view of the Leibovich references and rejected all issued claims.

133. Faced with the revocation of its most important patent, Celgene scrambled to put together testing data. Four days after the PTO rejection of the issued claims, on February 25, 1999, Bruce Collins submitted a request for reconsideration and a declaration from Dr. David Stirling, a co-founder of Celgene.[86] Dr. Stirling wrote that he had supervised tests to evaluate the relative activity of test compounds to inhibit the levels of cytokine TNF-α in human peripheral mononuclear cells that had been stimulated with lipopolysaccharide. He presented results for

[86] *See, e.g.*, BMS, History Timeline, *available at* https://www.bms.com/about-us/our-company/history-timeline.html (last visited Sept. 4, 2025); Dr. Stirling's LinkedIn profile, *available at* https://www.linkedin.com/in/david-stirling-388a0731 (last visited Sept. 4, 2025). That the Dr. Stirling who drafted the declaration is the same as the co-founder of Celgene is not obvious from the declaration itself, where Dr. Stirling describes himself as having started as a manager of research at Celgene in 1986 and progressed to chief scientific officer and executive vice president in 1998. '517 Reexam File History, Declaration of David I. Stirling, PhD, at 2.

"Compound 1" and "Compound 2."[87] Dr. Stirling stated that Compound 2 was the "corresponding amino compound of the present claims." Mr. Collins explained that Compound 1 (the comparator) was "the hydroxythalidomide compound of D'Amato," which he described as "what the Examiner has identified as the closest prior art compound, namely, the hydroxythalidomide compound."

134. On June 29, 1999, the examiner allowed the '517 patent to reissue based on the representations made in the Stirling Declaration:

> 1. The data presented in the Dr. David I. Sterling [sic] Declaration . . . clearly shows unexpected superior results **when the claimed compound**, namely, 7-amino-1-oxo-2(2,6-dioxo-piperidin-3-yl)-isoindoline, [is] compared to the corresponding 7-hydroxy -1-oxo-2(2,6-dioxo-pi_peridin-3-yl)-isoindoline of the prior art in a side-by-side comparison . . .
>
> 2. Looking at the data, **the claimed compound** is clearly superior in the inhibition of TNF-α factor (Tumor Necrosis Factor) at concentration levels IC_{50}. Note that at a concentration a concentration of 0.0183 μM by >10,000 fold more active than compound 1 of the prior art in this primary human cell-based assay. To put in practical terms the greater inhibition of TNF α is less toxic to the immune system.[88]

135. The reissuance of the '517 patent was the result of fraud. Celgene, through its agents Dr. Stirling and Mr. Collins, made materially false and misleading statements upon which the examiner reasonably relied. Absent these misrepresentations, the '517 patent would not have been allowed to reissue.

136. Celgene and its agents presented misleading testing data. Celgene co-founder David Stirling submitted a declaration presenting test results for two compounds—Compound 1 (a comparator from the D'Amato patent disclosures) and Compound 2 (the subject compound).

[87] '517 Reexam File History, Declaration of David I. Stirling, PhD, at 3–4.

[88] '517 Reexam File History, Statement of Reasons for Patentability and/or Confirmation.

Dr. Stirling's tests showed unexpected, superior results of Compound 2 when compared to Compound 1. But Compound 2 is not a compound claimed in the '517 patent. Rather, it is pomalidomide (referred to by Dr. D'Amato as "3-aminothalidomide"). Although the '517 patent claims a *method of using* pomalidomide, it does not *claim the compound* pomalidomide. This is a critical distinction. By pursuing the reissuance of this patent, Celgene was claiming it was entitled to a patent that would enable it to exclude all competition for any use of the compounds of Claim 10, including lenalidomide (Revlimid), for twenty years based on testing data for a different compound—pomalidomide—for which, at best, Celgene could only claim specific methods of use.

137. Based on Celgene's and its agents' misrepresentations, the examiner believed, in error, that Compound 2 was one of the compounds claimed in claim 10 of the '517 patent, as was made clear in his remarks in the subsequent notice of allowance:

> The data presented in the Dr. David I. Sterling [sic] Declaration . . . clearly shows unexpected superior results when the **claimed compound**, **namely, 7-amino-1-oxo-2(2,6-dioxo-piperidin-3-yl)-isoindoline** [is compared to the prior art compound]. . . .[89]

Specifically, the examiner believed that the claimed compound with superior results—Compound 2—was 7-amino-1-oxo-2(2,6-dioxo-piperidin-3-yl)-isoindoline (referred to in Claim 10 of the '517 patent as 1-oxo-2-(2,6-dioxopiperidin-3-yl)-7-aminoisoindoline).[90] This compound is not Compound 2, *i.e.*, pomalidomide. There is no evidence in the record that Celgene, or its agents Mr. Collins or Dr. Stirling, corrected the examiner's misunderstanding, which was material to reissuance of the '517 patent.

[89] '517 Reexam File History, Statement of Reasons for Patentability and/or Confirmation.

[90] "7-amino-1-oxo-2(2,6-dioxo-piperidin-3-yl)-isoindoline" is one of four compounds specified in Claim 10 of the '517 patent, written there as: 1-oxo-2-(2,6-dioxopiperidin-3-yl)-7-aminoisoindoline.

138. Mr. Collins furthered the misdirection by representing that Compound 1, hydroxythalidomide, was the correct comparator. Claim 1 of the '291 D'Amato patent claimed methods of using both hydroxythalidomide *and* pomalidomide (described as 3-aminothalidomide by D'Amato). Celgene thus compared two compounds already expressly claimed by D'Amato as useful for treating angiogenesis in a human—not a prior art compound versus a new compound. Mr. Collins suggested it was the examiner who selected hydroxythalidomide as the appropriate comparator ("what the Examiner has identified as the closest prior art compound, namely, the hydroxythalidomide compound. . . ."[91]), but what the examiner referred not to was not "the closest prior art compound," but "very closely analogous compounds."[92] And while hydroxythalidomide may have been the closest prior art compound from the set of "very closely analogous compounds" to Compound 2, pomalidomide, it was not the closest prior art compound to those that Celgene actually claimed in the '517 patent as compounds.

139. Dr. Stirling's representation of the potency of Compound 2 was misleading. Both the Collins Request for Reconsideration and the supporting Stirling Declaration asserted that "Compound 2 [was] >10,000 fold more active than Compound 1."[86] Yet the data presented in the declaration indicates that at active levels for both compounds, Compound 2 had, depending on concentration, a 2.98-fold to 4.62-fold advantage over Compound 1—a far cry from the 10k fold increase touted by Dr. Stirling and Mr. Collins.

140. The examiner's withdrawal of the rejection of all the issued claims—based on being misled by Celgene's false and misleading claims of unexpected results—did not alter the examiner's findings regarding the disclosures in the D'Amato patents, namely, that the disclosures

[91] '517 Reexam File History, Request for Reconsideration, at 3.

[92] '517 Reexam File History, Office Action, at 3.

in the D'Amato patents (the '291, '990, and '327 patents) provided "ample information" to disclose the compounds at issue.[93]

3. In the early 2000s, D'Amato pursued additional patents claiming methods of using lenalidomide and pomalidomide, including those for the treatment of multiple myeloma and other cancerous conditions.

141. From July 5, 2001, through June 11, 2002, Dr. D'Amato filed eight additional patent applications claiming methods of using lenalidomide (referred to as "6-amino EM-12") and pomalidomide (referred to as "3-amino thalidomide"). Although Dr. D'Amato used different nomenclature, there is no dispute that "6-amino EM-12" and "3-amino thalidomide" refer to lenalidomide and pomalidomide, respectively.

Table 1. 2001–2002 D'Amato Patent Applications

Application No.	Filing Date	Title	Description
09/899,318	July 5, 2001	"Methods for the Inhibition of Angiogenesis with 6-amino EM-12"	Claims methods of using **lenalidomide**, including to treat undesired angiogenesis associated with blood-borne tumors.
10/015,252	Dec. 12, 2001	"Pharmaceutical composition of 6-amino EM-12"	Claims methods of using **lenalidomide** including to treat undesired angiogenesis that occurs in blood borne tumors.
10/026,291 Note there is a similarly numbered D'Amato patent, the 5,712,291.	Dec. 20, 2001	"Enantiomers Of 6-Amino EM-12 and Method of Use"	Claims methods of using **lenalidomide** including to treat angiogenesis and cancer.
10/167,531	June 11, 2002	"Method of Treating Disease Using 6-Amino EM-12"	Claims methods of using **lenalidomide** including to treat a blood or blood vessel disease (claim 106) that is an acute or

[93] '517 Reexam File History, Office Action, at 4.

Application No.	Filing Date	Title	Description
			chronic neoplastic disease of the bone marrow (claim 123) where the neoplastic disease is multiple myeloma (claim 124).
09/899,344	July 5, 2001	"Methods of the Inhibition of Angiogenesis with 3-Amino Thalidomide"	Claims methods of using **pomalidomide** to treat angiogenesis (claim 23, claim 31) including where the undesired angiogenesis is associated with blood-borne tumors (claim 99).
09/966,895	Sept. 28, 2001	"Methods and compositions for inhibition of angiogenesis"	Claims methods of using **pomalidomide** including to treat undesired angiogenesis that occurs in blood borne tumors.
10/166,539	June 10, 2002	"Methods of Treating Diseases Using 3-Amino Thalidomide"	Claims methods of using **pomalidomide** including to treat multiple myeloma.
10/020,391	Dec. 12, 2001	"Pharmaceutical Composition of 4-(amino)-2-(2,6-dioxo(3-piperidyl))-isoindoline 1,3-dione" [chemical name for pomalidomide]	Claims a pharmaceutical composition of **pomalidomide** to reduced undesired angiogenesis (claim 30), including where the angiogenesis is associated with blood borne tumors (claim 97).

142. On October 31, 2001, the examiner issued a notice of allowance for the '318 D'Amato patent application, which claimed methods of using lenalidomide, including to treat undesired angiogenesis associated with blood-borne tumors.

143. On February 12, 2002, the examiner issued a notice of allowance for the '344 D'Amato patent application, which claims methods of using pomalidomide to treat angiogenesis, including angiogenesis associated with blood-borne tumors.

144. On April 16, 2002, the examiner issued a notice of allowance for the '391

D'Amato patent application, which claimed a pharmaceutical composition of pomalidomide to reduce undesired angiogenesis, including where the angiogenesis is associated with blood borne tumors.

145. Previously, Celgene had suffered a near loss of its most important patent, the '517 compound patent, during reexamination because of earlier-in-time D'Amato patents (the '291, '990, and '327 patents). Now, in 2002, the patent examiner had issued notices of allowance for three new D'Amato patent applications (the '318, '344, and '391) while other D'Amato lenalidomide and pomalidomide patent applications were pending (the '252, '291, '531, '895, and '539). D'Amato's acquisition of patents claiming methods of using lenalidomide and pomalidomide for the treatment of multiple myeloma and other blood-borne cancers posed a threat to Celgene's ability to claim for itself a monopoly on these drugs.

4. In mid-2002, Celgene went on the offensive, interfering directly in the D'Amato patent prosecutions; when those efforts failed, Celgene sued the patent office to have the D'Amato patents blocked or revoked.

146. On July 1, 2002, Celgene transmitted a draft petition to the PTO asking the commissioner, John Doll, to withdraw the already-allowed '344 and '318 D'Amato patent applications and to send D'Amato's pending '895 and '252 applications to quality review.[94] Celgene argued that the specific compounds claimed in the '318 and '252 applications ("6-amino-EM-12" or lenalidomide) and the '344 application ("3-amino-thalidomide" or pomalidomide) were not specifically disclosed in the provisional patent application and thus lacked written description support under section 112. Referring to the earlier '517 reexamination, Celgene represented that the PTO had previously found the "D'Amato Patents insufficient to anticipate or

[94] *Children's v. Celgene*, 13-cv-11573 (D. Mass.), ECF 92-5 (the petition was filed in the royalty dispute docket as an exhibit).

render obvious the '517 claims to [lenalidomide] per se or to methods employing [pomalidomide]."[95] In truth, during the reexamination, the examiner found the '517 was unpatentable in light of the earlier D'Amato patents and rejected Celgene's argument that the D'Amato patents did not adequately disclose the compounds at issue. Celgene failed to disclose that the reexamination examiner rejected the issued claims of the '517 for these reasons, and only permitted it to reissue when Celgene submitted its misleading response to the rejection. Celgene is also alleged to have called the Group Director directly to block the D'Amato patent applications.[96]

147. On July 29, 2002, Commissioner John Doll withdrew the allowances for the '318, '344, and '391 D'Amato patent applications.

148. On September 3, 2002, there was an interview with the PTO regarding pending D'Amato patent applications.[97] At least four PTO representatives were involved in this meeting: two Primary Examiners (J. Reamer and J. Goldberg), a Supervisory Patent Examiner (M.A. Seidel), and a Specialist from Quality Control in the Patent Office (R. Hill). Attorney Jeffrey Arnold, attorney Robert Richards,[98] and expert witness Dr. Gary Posner of John Hopkins, participated for Children's (D'Amato's assignee) and EntreMed (Children's commercial

[95] *Children's v. Celgene*, 13-cv-11573 (D. Mass.), ECF 92-5, at p. 4–5.

[96] The '539 (pomalidomide to treat MM) had not yet been allowed when Celgene began to interfere, but the same events played out there.

[97] The interview notes can be found in the '344 and '539 patent application file wrappers. On the face of the interview notes, four patent numbers are handwritten on the upper left corner: the '391, '344, '539, and '895 (all pomalidomide patents).

[98] Jeffrey Arnold appears to have been the main attorney leading the patent prosecutions. The interview was also attended by "R. Richards," likely the "Robert Richards" referenced in one of the Power of Attorney documents in the file wrapper. *See* '391 patent application file wrapper at p. 186.

development partner and licensee of D'Amato patent applications).[99]

149. Shortly after the interview, the PTO began issuing notices of allowance for several D'Amato patent applications.[100]

150. On November 19, 2002, Celgene sued James E. Rogan, in his official capacity as Under Secretary of Commerce for Intellectual Property and Director of the PTO, and EntreMed seeking, *inter alia*, "preliminary and permanent injunctions directing defendant Rogan to withdraw" the '344 and '391 applications from issue and requiring EntreMed to file petitions for withdrawal.[101]

151. On November 21, 2002, EntreMed filed an antitrust lawsuit against Celgene for unlawfully blocking its drug development efforts,[102] prompting Celgene to pivot to a new strategy.

5. In December 2002, Celgene settled the antitrust lawsuit and obtained rights to D'Amato's patent portfolio and to any "Revlimid product"; all key lenalidomide (and pomalidomide) D'Amato patents and applications were abandoned.

152. On December 31, 2002, Celgene entered into an Exclusive Licensing Agreement with Children's and its partner EntreMed, pursuant to which Celgene obtained a license to "any Revlimid product" (where "Revlimid" is defined as the lenalidomide compound) and "any Amino Thalidomide Product" (where "Amino Thalidomide" is defined as the pomalidomide compound), in return for which Celgene was required to pay a royalty on its Revlimid and Pomalyst sales to

[99] *See* '391 patent application file wrapper at p. 334 ("This application is assigned to Children's Medical Center Corporation ('CMCC'). Until December of 2002, this application was licensed to EntreMed Corporation ('EntreMed'), which was responsible for its prosecution.").

[100] On October 21, 2002 (the '344 application), on November 6, 2002 (the '391 application), and on December 13, 2002 (the '539 application). These applications had claims for use of pomalidomide.

[101] *Celgene v. Rogan and EntreMed*, Case No. 02-cv-02277 (D.D.C.).

[102] Complaint at ¶¶ 10–11, *EntreMed v. Celgene*, No. 02-cv-03787 (D. Md. Nov. 21, 2002), ECF No. 1.

Children's. Under the Exclusive Licensing Agreement, Celgene also acquired rights to over seventy-five D'Amato patents and patent applications (the "Analog Patents").

153. Shortly after acquiring rights to the Analog Patents, Celgene oversaw the selective abandonment of the D'Amato patents and patent applications that claimed methods of using lenalidomide and pomalidomide. Although this did not alter the D'Amato patents' status as invalidating prior art, it removed impediments these earlier-obtained, earlier-expiring D'Amato patents[103] could pose to Celgene, including the risk that the Orange Book-listing requirements would highlight duplicative or overlapping patents. Celgene learned that competition could be neutralized, if it was willing to pay would-be competitors not to compete.

6. Subsequent developments underscore that Celgene's multi-billion-dollar-a-year monopoly is not the result of innovation, but rather manipulation.

154. Celgene's manipulation of the patent process, and its battles with Children's and EntreMed, did not end with the Licensing Agreement. In 2006, Celgene applied to the PTO to have pomalidomide written out of the '291 D'Amato patent (one of the earlier-in-time D'Amato patents that had thwarted Celgene during the '517 reexamination in 1998).[104] And in 2013, Celgene quit paying Children's the royalties it owed under the Licensing Agreement, triggering another lawsuit. Celgene lost that battle, too. After Children's sued Celgene,[105] the court sided with Children's on summary judgment, finding that Celgene obtained a license not just to specific D'Amato patents, but rather to the Revlimid product itself, and therefore owed royalties to

[103] The D'Amato patents and patent applications to which Celgene obtained a license included four applications (U.S. Patent Appl. Nos. 09/899,318; 10/015,252; 10/026,291; 10/167,531) that claimed methods of treatment with lenalidomide. Had these applications issued as patents, they would have had an expiration date of March 1, 2013 (all claimed priority to a March 1, 1993 application).

[104] Reissue Application No. 11/384,188.

[105] *Children's Hospital v. Celgene*, 13-cv-11573 (D. Mass.). *See* ECF 116 (R&R dated Feb. 23, 2016) and ECF 124 (District Court decision dated Sept. 30, 2016).

Children's through October 2019, the date the '517 Revlimid compound patent expired (after adjusting for the patent term extension). The court reasoned:

> Given the parties' disputes, it would have made sense for them to tie royalties to Products, and not to specific patents. If the protections afforded by patents on those Products were extended, so, too, should the royalty payments be extended without the need to resolve the disputed issue as to who had superior rights to any specific applicable patent which may have been extended.
>
> Finally, in this court's view Celgene's own argument compels the conclusion that the [patent term extension] is not limited to [Children's] patents. According to Celgene itself, it was paying royalties on Revlimid® prior to March 1, 2013, despite the fact that CMCC "did not contribute to in any way, or have any rights to," this product.[106]

155. In short, Celgene is not the lone or foremost researcher in developing lenalidomide and other thalidomide compounds to treat cancer that it portrays itself to be. Celgene had all claims of the '517 patent revoked as unpatentable over earlier D'Amato patents, regaining those claims only after defrauding the PTO. Celgene then went on the offensive, attempting to subvert new D'Amato patents claiming methods of using lenalidomide and pomalidomide by petitioning, lying to, and ultimately suing the PTO, leading Children's commercial partner, EntreMed, to sue Celgene for antitrust violations. Confronted with this lawsuit, Celgene entered into an Exclusive Licensing Agreement and oversaw the abandonment of D'Amato's lenalidomide and pomalidomide method of treatment patents. This cleared the way for Celgene's own later-obtained, later-expiring patents, wrongfully extending Celgene's unlawful monopoly for *years* into the future. The upshot is ever-increasing prices on old drugs that have been well-known in the field for decades.

156. Celgene claims it invested hundreds of millions in research and development for

[106] *Children's Hospital v. Celgene*, 13-cv-11573 (D. Mass.), ECF 116 (R&R dated Feb. 23, 2016), at p. 13.

Revlimid, but in fact Celgene relied on substantial pre-existing academic and non-profit research and at least eight research studies funded by taxpayer dollars.[107] Celgene did not make substantial financial investments in developing Revlimid until after government-funded research demonstrated that Revlimid was likely to become a blockbuster drug.[108] Even the amount of money Celgene claims to have spent to have developed Revlimid represents less than 1% of its sales to date.

B. **The 2005 launch of Revlimid.**

157. On April 7, 2005, Celgene submitted NDA 21-880, providing for the use of Revlimid (lenalidomide) to treat patients with transfusion-dependent anemia due to low or intermediate risk myelodysplastic syndromes. The FDA approved Revlimid for this indication on December 27, 2005, and granted Celgene a new chemical entity (NCE) marketing exclusivity until December 27, 2010. The FDA subsequently approved additional indications for Revlimid.

C. **The REMS restrictions for Revlimid.**

158. Both Thalomid and Revlimid are subject to restrictive REMS distribution programs that feature ETASU. The Revlimid REMS is called RevAssist and the Thalomid REMS is called "S.T.E.P.S.". All participants in RevAssist or S.T.E.P.S. must register within a single database maintained by Celgene. That database serves to coordinate the various components of the program and actively seeks to ensure that if some of those requirements and conditions are not

[107] Dr. Bart Barlogie's study of 84 multiple myeloma patients received a $2.3 million grant from NIH in 1997 (CA55819). Seema Singhal, Bart Barlogie, et al., *Antitumor Activity of Thalidomide in Refractory Multiple Myeloma*, New England Journal of Medicine (Nov. 18, 1999) (online at www.nejm.org/doi/full/10.1056/NEJM199911183412102 (last visited Sept. 4, 2025)); National Institutes of Health, *Project Information for Project 2P01CA055819-05A1* (online at https://reporter.nih.gov/project-details/2893415) (last visited Dec. 22, 2025).

[108] National Institutes of Health, *Clinical Trials Sponsored by Celgene Corporation from 1996 to 2000 (www.clinicaltrials.gov)(last visited Dec. 22, 2025)* (showing that Celgene-sponsored multiple myeloma trials began only after Dr. Barlogie's first trial was collecting data from all 84 of its enrolled patients and 8 months after Dr. Barlogie's first trial began treating its patients.).

met, then a block can be imposed on the fulfillment of an individual patient's prescription.

159. The primary difference between S.T.E.P.S. and RevAssist is that Thalomid under S.T.E.P.S. was originally distributed through all pharmacies, whereas Revlimid was distributed through specialty pharmacies. In 2006, however, Celgene began operating S.T.E.P.S. exclusively through specialty pharmacies, because it was of the view that the change in Thalomid distribution from retail to specialty would prevent "generic encroachment." That same year, Alexis Tosti, Celgene's Market Research Analyst, noted in internal company emails that moving to a specialty pharmacy would "be a hurdle for generic companies" and that "[r]estricted distribution is more likely to keep thalidomide out of the hands of generic companies who need product to test against the generic being developed."

160. In 2010, when FDA approved Celgene's proposed REMS for Revlimid, the agency warned Celgene that it is illegal for the company to use its REMS program to "block or delay approval" of generic versions of the drug. Despite this warning, Celgene used its REMS program—which severely limits the distribution of Revlimid—to prevent generic manufacturers from purchasing the samples of Revlimid needed to obtain FDA approval for their generic versions of the drug. Indeed, Celgene's pattern of misusing REMS to pretextually withhold samples was not exclusive to Revlimid; it started with Thalomid. Internal documents from Celgene revealed that the company's primary concern was not drug safety but rather the strategic use of safety claims to prevent or delay generic competition. An internal report of Celgene suggested extending market exclusivity in the U.S. by using bioequivalence as a "generic defense strategy" against generics.

161. Among the manufacturers that Celgene refused to supply samples are Mylan Pharmaceuticals Inc. ("Mylan") between 2004 and 2014 (Thalomid and Revlimid samples);

Lannett Company ("Lannett") between 2007 and 2011 (Thalomid samples); Exela Pharmsci, Inc. ("Exela") between 2006 and 2008 (Thalomid samples); Dr. Reddy's between 2008 and 2009 (Revlimid samples); Watson in 2009 (Revlimid samples); Teva in 2009 (Revlimid samples); and Sandoz Inc. ("Sandoz") in 2012 (Revlimid and Thalomid samples).

162. Celgene's refusal to provide samples was not based on whether the FDA had approved the generic competitor's bioequivalency study protocols. Instead, Celgene persisted in employing delay tactics, such as requiring generic competitors to submit excessive, burdensome, and irrelevant documentation, even after it was notified of the FDA's acceptance of the safety protocols of Mylan, Exela, Lannett, and Roxane/Hikma. Celgene's refusal shows that it indiscriminately withheld samples, regardless of safety concerns. Celgene also entered into an exclusive supply agreement with a French thalidomide supplier to prevent Barr Laboratories ("Barr") from obtaining that company's thalidomide active pharmaceutical ingredient ("API"). Indeed, no generic version of Thalomid has ever reached the market, precisely because Celgene strategically delayed providing samples long enough to shift market demand to Revlimid.

D. **The 2005–2015 U.S. sales of Revlimid.**

163. After its launch in 2005, Celgene repeatedly raised the price of Revlimid at least annually, and sometimes three times in the same year. From an original launch price of about $215 per pill, the price of Revlimid is now ~$891 per pill, and rising still, despite each pill costing Celgene and BMS twenty-five cents to produce.

164. During a 2015 deposition, Celgene's former Senior Vice President of Sales and Marketing testified that the company's executives could raise Revlimid's price "any time they wanted."[109] And they did. For example, in March 2014, Celgene was projecting lower-than-

[109] Oversight Committee Revlimid Report, at 4.

expected Revlimid revenues for the first quarter of 2014, leading then-Executive Vice President (and future CEO) Mark Alles to propose an immediate 4% price increase (instead of the 3% increase that was planned to take place a month later). Celgene's Corporate Market Access Committee approved the price increase, and it took effect the same evening. As a result, the company was able to report a successful first quarter at its next earnings call on April 24, 2014.

E. **Celgene's price increases on Revlimid were unrelated to production costs (cost of goods sold, "COGS"), which remained stable, and the increases far outpaced Celgene's other expenses. Celgene's asserted Revlimid patent portfolio.**

165. Celgene filed for and obtained approximately thirty patents that it asserted would be infringed by various generic manufacturers' ANDAs for generic Revlimid. None of the patents for Revlimid received any exclusivities (e.g., pediatric) that would have extended exclusivity beyond the relevant patent expiration dates listed below.

166. Celgene's patents are grouped into four patent families: the '517 family of patents, REMS patents, Method of Treatment patents, and Polymorph (Crystal Form) patents.

1. The '517 family of patents claims the pharmaceutical compound and methods of using Revlimid.

167. The '517 family of patents claims priority to U.S. Patent Application No. 08/690,258, which Celgene filed on July 24, 1996. The patents in the '517 family include the following patents that Celgene and/or BMS requested be listed in the Orange Book as covering Revlimid:

Table 2. The '517 Patent Family: Patents listed in the Orange Book

US Patent No.	Application Date	Issue Date	Expiry Date
5,635,517	July 24, 1996	June 3, 1997	Oct. 4, 2019
6,281,230	Apr. 6, 2000	Aug. 28, 2001	July 24, 2016
6,555,554	Feb. 12, 2001	Apr. 29, 2003	July 24, 2016

US Patent No.	Application Date	Issue Date	Expiry Date
7,119,106	Jan. 6, 2003	Oct. 10, 2006	July 24, 2016
8,288,415	Dec. 10, 2009	Oct. 16, 2006	July 24, 2016

168. The ’517 family of patents includes Orange Book-listed patents that claim methods of treating cancers with Revlimid (’230, ’554, ’106, and ’415 patents), pharmaceutical compositions (’230, ’554, ’106, ’415), and the pharmaceutical compound for Revlimid (’517, claim 10). The ’517 patent also claimed methods of reducing undesirable levels of TNFα in a mammal.

169. The patents in the ’517 family were set to expire on July 24, 2016, with the exception of the ’517 patent, which received patent term adjustments pursuant to 35 U.S.C. § 154(b).

2. The ’501 REMS and ’720 REMS families of patents claim methods of distributing a drug.

170. The ’501 family of patents all claim priority to U.S. Patent Application No. 09/143,569, which Celgene filed on Aug. 28, 1998. The ’720 family of patents all claim priority to U.S. Patent Application No. 09/694,217, which Celgene filed on October 23, 2000.

171. The ’501 family of patents are all titled, “method for delivering a drug to a patient while preventing the exposure of a foetus or other contraindicated individual to the drug”; the ’720 family of patents are all titled, “methods for delivering a drug to a patient while avoiding the occurrence of an adverse side effect known or suspected of being caused by the drug” (together, here, the “REMS patents”).

172. The patents in the ’501 family include the following patents that Celgene and/or

BMS requested be listed in the Orange Book as covering Revlimid:[110]

Table 3. The '501 Patent Family: Patents listed in the Orange Book

US Patent No.	Application Date	Issue Date	Expiry Date
6,045,501	Aug. 28, 1998	Apr. 4, 2000	Aug. 28, 2018
6,561,976	Sep. 26, 2001	May 13, 2003	Aug. 28, 2018
6,908,432	Jan. 22, 2004	June 21, 2005	Aug. 28, 2018
8,204,763	Dec. 13, 2010	June 19, 2012	Aug. 28, 2018
8,589,188	May 17, 2012	Nov. 19, 2013	Aug. 28, 2018

173. The patents in the '720 family include the following patents that Celgene and/or BMS requested be listed in the Orange Book as covering Revlimid:

Table 4. The '720 Patent Family: Patents listed in the Orange Book

US Patent No.	Application Date	Issue Date	Expiry Date
6,315,720	Oct. 23, 2000	Nov. 13, 2001	Oct. 23, 2020
6,561,977	Sep. 27, 2001	May 13, 2003	Oct. 23, 2020
6,755,784	Mar. 7, 2003	June 29, 2004	Oct. 23, 2020
8,315,886	Dec. 13, 2010	Nov. 20, 2012	Oct. 23, 2020
8,626,531	Aug. 22, 2012	Jan. 7, 2014	Oct. 23, 2020

174. These patents were not eligible for Orange Book listing because they do not claim a drug substance (active ingredient), drug product, or method of use. Celgene nevertheless submitted the '501 and '720 families of patents to the FDA for listing in the Orange Book.

[110] The '501 family also includes United States Patent No. 7,767,326, also claiming priority to Application No. 09/143,569, and which issued on July 27, 2004, and expired on Aug. 28, 2018. The '326 patent claims methods for delivering a drug to a patient while preventing the exposure of a foetus or other contraindicated individual to the drug. Celgene did not list the '326 patent in the Orange Book and has not asserted this patent against any ANDA applicant for generic Revlimid. When Natco asserted a counterclaim for invalidity of the '326 patent, Celgene offered, and the parties executed, a covenant to sue. 2:10-cv-5107, ECF No. 24.

3. The ’740 and ’569 family of patents claim methods of treating myelodysplastic syndrome and multiple myeloma.

175. The ’740 family of patents all claim priority to U.S. Patent Application No. 10/411,649, which Celgene filed on April 11, 2003. The ’740 family of patents are all related to the use of Revlimid to treat myelodysplastic syndromes.

176. The ’569 family of patents all claim priority to U.S. Patent Application No. 10/438,213, which Celgene filed on May 15, 2003. The ’569 family of patents are related to the use of Revlimid to treat (1) multiple myeloma (“MM”) and (2) various lymphomas.

177. The patents in the ’740 family include the following patents that Celgene and/or BMS requested be listed in the Orange Book as covering Revlimid:

Table 5. The ’740 Patent Family: Patents listed in the Orange Book

US Patent No.	Application Date	Issue Date	Expiry Date
7,189,740	Apr. 11, 2003	Mar. 13, 2007	Apr. 11, 2023
8,404,717	Mar. 24, 2011	Mar. 26, 2013	Apr. 11, 2023
9,056,120	Mar. 13, 2013	June 16, 2015	Apr. 11, 2023

178. The patents in the ’569 family include the following MM patents that Celgene and/or BMS requested be listed in the Orange Book as covering Revlimid:

Table 6. The ’569 Patent Family: Patents listed in the Orange Book

US Patent No.	Application Date	Issue Date	Expiry Date
7,968,569	May 15, 2003	June 28, 2011	Oct. 7, 2023
8,530,498	Apr. 8, 2013	Sep. 10, 2013	May 15, 2023
8,648,095	June 5, 2012	Feb. 11, 2014	May 15, 2023
9,101,621	Apr. 17, 2014	Aug. 11, 2015	May 15, 2023
9,101,622	Sep. 10, 2014	Aug. 11, 2015	May 15, 2023

179. The patents in the ’740 family were set to expire on April 11, 2023, and the MM patents in the ’569 family were set to expire on May 15, 2023, with the exception of the ’569 patent, which received patent term adjustments pursuant to 35 U.S.C. § 154(b).

4. The ’800 family claims crystal forms of lenalidomide.

180. The ’800 family of patents all claim priority to U.S. Patent Application No. 10/934,863, which Celgene filed on September 3, 2004. The ’800 family of patents are all entitled, “polymorphic forms of [lenalidomide]” (here, “crystal form patents”). These patents describe eight crystalline forms of lenalidomide, each of which is assigned a letter for identification, *i.e.*, Form A lenalidomide through Form H lenalidomide. The various crystalline forms of lenalidomide are differentiated by the x-ray powder diffraction (“) pattern, infrared (“IR”) spectrum, and thermogravimetric analysis (“TGA”) curve associated with each form.

181. The patents in the ’800 family include the following patents that Celgene and/or BMS maintained would be infringed by generic ANDAs. Celgene asserted that the ’800 and ’217 patents covered Revlimid and asserted these patents in litigations against every ANDA filer. Celgene asserted that eleven generics’ ANDAs would infringe the unlisted polymorph patents:

Table 7. The ’800 Patent Family: Patents asserted in Litigation

US Patent No.	Application Date	Issue Date	Expiry Date
Listed in the Orange Book			
7,465,800	Sep. 3, 2004	Dec. 16, 2008	April 27, 2027
7,855,217	Dec. 15, 2008	Dec. 21, 2010	Nov. 24, 2024
NOT Listed in the Orange Book			

US Patent No.	Application Date	Issue Date	Expiry Date
7,977,357	July 23, 2008	July 12, 2011	Jan. 8, 2025
8,193,219	Oct. 3, 2011	June 05, 2012	Sep. 3, 2024
8,431,598	May 26, 2011	Apr. 30, 2013	Sep. 3, 2024

182. The patents in the ’800 family were set to expire on Sep. 3, 2024, with the exception of the ’800, ’217, and ’357 patents, which received patent term adjustments pursuant to 35 U.S.C. § 154(b).

F. **2010–2015: Natco challenges Celgene’s Revlimid patents.**

183. On February 2, 2010, Natco filed ANDA No. 201452 seeking approval to sell lenalidomide capsules in 5mg, 10mg, 15mg, and 25mg strengths. FDA accepted Natco’s ANDA for filing on July 12, 2010.

184. On August 27, 2010, Natco sent Celgene a paragraph IV certification challenging the claims of certain of the ’517 family patents, REMS patents, and crystal patents as invalid, unenforceable, and/or not infringed by Natco’s generic version of Revlimid.[111]

185. On October 8, 2010, Celgene sued Natco in the United States District Court for the District of New Jersey, Civil Action No. 2:10-05197, alleging infringement of its patents.[112] Celgene later amended its complaint to add Arrow and Watson as defendants (together with Natco, the “Natco Patent Defendants”).[113]

186. Celgene’s suit, filed within 45 days of receiving Natco’s paragraph IV certification,

[111] As described in the chart in Appendix 2, these were the ’517 (claim 10), ’554, ’106, ’501, ’720, ’976, ’977, ’784, ’432, and ’800 patents. Natco also, at that time, provided section viii carveouts stating it did not seek approval for the indication covered by claims 1–9 of the ’517 patent, the ’230 patent, and the ’740 patent, which covered methods of treatment of myelodysplastic syndromes.

[112] On January 20, 2011, Celgene agreed not to sue Natco for infringement of the ’326 and ’432 patents based on its filing of ANDA No. 201452 (ECF No. 24).

[113] On January 7 (ECF No. 16) and March 25, 2011 (ECF No. 53), respectively.

triggered the Hatch-Waxman Act's automatic 30-month stay of FDA approval of Natco's generic product. This stay prevented the FDA from granting final approval of Natco's ANDA until the earlier of: (i) the expiration of the 30-month stay[114] or (ii) entry of a final judgment that the patents at issue were invalid, unenforceable, and/or not infringed.

187. In total, Celgene filed five amended complaints in the 2:10-cv-5197 action, another complaint in Civil Action No. 2:12-cv-4571 (subsequently consolidated with the 2:10-cv-5197 action), and another complaint in Civil Action No. 2:14-cv-3126. The Natco Patent Defendants timely answered and filed counterclaims, alleging that all the asserted patents were invalid, unenforceable, and/or uninfringed.[115] Appendix 2 provides a chart of the patents alleged to be infringed in each complaint and action.

188. At times during its ANDA review, Natco carved out certain indications by certifying to the FDA under Section 505(j)(2)(A)(viii) that the labeling for its proposed lenalidomide capsules (5 mg, 10 mg, 15 mg, and 25 mg) did not include any method of use that was claimed by certain patents (a "section viii carveout"). But by the time the parties began negotiating a settlement in May 2015, Natco was seeking approval of a label that included the RLD-approved indications for treating multiple myeloma and myelodysplastic syndromes and carved out the only then-approved indication for treating mantle cell lymphoma. Celgene never

[114] Celgene's ANDA was the subject of two 30-months stays. The second, based on a later paragraph IV certification, expired on December 12, 2014.

[115] In their January 14, 2011 Answer, the Natco Patent Defendants also asserted counterclaims for invalidity and inequitable conduct as to two related but unasserted REMS patents ('432 and '326 patents) on behalf of themselves as well as Counterclaim Plaintiffs Watson, Actavis, Inc., and Anda, Inc. (related entities that Celgene had initially refused to include in a covenant not to sue which was then being negotiated). 2:10-cv-5197, ECF No. 18. After the parties executed a covenant not to sue on these patents that included Watson, Actavis, and Anda, ECF No. 24, on February 25, 2011, Counterclaim Plaintiffs Watson, Actavis, and Anda voluntarily dismissed their claims without prejudice to Natco Patent Defendants' continued assertion of the counterclaims. ECF No. 41.

On May 15, 2014, Celgene temporarily added Anda, Actavis, and Watson as defendants in a new action before dismissing the entities on June 16, 2014. *See Celgene v. Natco Pharm.,* No. 2:14-cv-3126 (D.N.J.), ECF Nos. 1, 11.

sued Natco for infringement of patents related to the treatment of mantle cell lymphoma (the '363 and '929 patents).[116]

189. Over a period of about five years—from when the first lawsuit was filed in 2010 to an eventual settlement in 2015—Natco took the position that Celgene's patents did not prevent it from coming to market, and Celgene disagreed, claiming that its patents prevented Natco from coming to market until the expiration of the last asserted patent on April 27, 2027.

190. Ultimately, the parties negotiated an agreement that resolved the litigation. The negotiation began around May of 2015 and the agreement (discussed further below in Section V.I.) was finalized on December 22, 2015.

191. By May 2015: (i) Celgene had agreed not to sue Natco for infringement of the '326, '432, '217 and '763 patents;[117] (ii) the parties had stipulated to the dismissal of claims relating to the '230, '554, '106, and '415 patents because Natco had submitted a paragraph III certification that it was no longer seeking approval of its ANDA prior to the latest of the expirations of those patents on July 24, 2016;[118] (iii) the parties had stipulated that Natco's ANDA product would infringe the '501, '720, '976, '977, '784, and '886 (REMS) patents, without limiting Natco's ability to challenge the validity of the asserted claims in those patents,[119] but then the Court granted Celgene's motion to bifurcate and stay discovery related to those patents

[116] On July 20, 2018—after the Celgene-Allergan agreement—Natco submitted newly proposed labeling that added the RLD-approved indication for treatment of MCL and also amended its ANDA to seek approval to market 2.5mg and 20mg strengths of its generic lenalidomide. Natco carved out other later-approved RLD indications for the treatment of multiple myelomas maintenance following autologous hematopoietic stem cell transplantation (auto-HSCT), as well as the RLD-approved indications for the treatment of marginal zone lymphoma and follicular lymphoma. Teva (after transfer from Natco) ultimately obtained FDA approval and launched with a label containing all strengths featuring the MDS, MCL, and the MM indication (but carving out maintenance following auto-HSCT).

[117] *See, e.g.,* 2:10-cv-5197, ECF No. 24 (as to '326 and '432); 2:10-cv-5197, ECF No. 145 and 2:12-cv-4571, ECF No. 14 (as to '763); 2:10-cv-5197, ECF No. 140 and 2:12-cv-4571, ECF No. 8 (as to "217).

[118] 2:10-cv-5197, ECF No. 402.

[119] 2:10-cv-5197, ECF No. 305.

anyway;[120] and (iv) the parties had agreed to temporarily bifurcate and stay discovery related to the ’188 and ’531 (REMS) patents.

192. Thus, Natco was actively asserting invalidity and non-infringement as to the ’517, ’740, ’717, ’569, ’800, ’357, ’219, ’598, ’498, and ’095 patents; Natco also had arguments as to the ’188 and ’531 patents and invalidity arguments as to the ’501, ’720, ’976, ’977, ’784, and ’886 patents, but discovery had been stayed as to those patents. The court issued a Markman opinion adopting Natco’s construction of the ’598 and ’357 patents and adopting Celgene’s construction of the ’800 patent.[121] The construction of the ’800 patent opened up new invalidity arguments for Natco, which it asserted after the Court granted it leave to amend its contentions.[122] The parties had served opening expert reports in April 2015, and would serve responding expert reports in September 2015, but did not serve reply expert reports before settling.

G. **The state of the Revlimid patent litigation in 2015.**

193. By mid-May 2015, the patent picture had been significantly clarified and streamlined such that the parties clearly knew the substantial risks Celgene faced in the litigation. Natco raised numerous meritorious arguments, all of which would have increased the risk to Celgene of litigation loss. The following table and subsections highlight the key reasons why Celgene faced substantial risk of an at-risk launch:

Table 8. Risks to Celgene for at-risk launch

Family	Patent Nos. (Expiration)	Not a Barrier to Entry
’517 patent family	’517 (Aug. 4, 2019)	Invalid: Obvious (thalidomide analogs). Fraudulent: Maintained by fraud.

[120] 2:10-cv-5197, ECF No. 358.

[121] 2:10-cv-5197, ECF No. 312; 2:10-cv-5197, ECF No. 313.

[122] 2:10-cv-5197, ECF No. 366.

Family	Patent Nos. (Expiration)	Not a Barrier to Entry
REMS	’501, ’976, ’188 (Aug. 28, 2018) ’720, ’977, ’784, ’866, ’531 (Oct. 23, 2020)	Invalid: Obvious; invalidated, dropped. Unenforceable: Withheld prior art.
Method of Treatment	MDS: ’740, ’717 (April 11, 2023) MM: ’095 ’498 (May 15, 2023), ’569 (Oct. 7, 2023)	Invalid: Obvious (thalidomide known to treat MM and MDS; testing data showed lenalidomide effective in treating MM; counterpart revoked in Europe).
Crystal form patents: Form A	’219, ’598 (Sept. 3, 2024) ’357 (Jan. 8, 2025)	No infringement: Form A claim construction set forth many characteristics Celgene would need to show were present to prove infringement, which Celgene did not even attempt to show. Invalid: Obvious and inherently anticipated by example 1 of the ’517 patent (counterpart invalided by the EPO); lack of written description.
Crystal form patents: Form B (Revlimid)	’800 (April 27, 2027)	No infringement: Celgene did not test Natco’s operative product, instead offering evidence on an abandoned product and specification. Invalid: Indefinite, lacking written description, and lacking enablement—claiming a water to API ratio of “approximately” 1:2 and claiming all hemihydrates when only disclosing one (Form B).

1. The Compound Patent, expiring Oct. 4, 2019

194. The ’517 patent—the only patent in its family at issue in May 2015—claims the compound lenalidomide (Claim 10) and methods of using lenalidomide and other compounds to reduce TNFα (Claims 1–9). The ’517 patent was maintained by fraud and vulnerable to strong invalidity challenges.

195. During reexamination of the ’517 patent, all ten issued claims were rejected as unpatentable in light of earlier research, including three D’Amato patents. Celgene only succeeded in having the claims of the ’517 patent confirmed after submitting the false and misleading Stirling Declaration and Collins Request for Reconsideration.

196. As the reexamination showed, the ’517 patent was vulnerable to invalidity challenges due to the existence of a robust body of prior art, as expanded upon in expert reports served by Natco in 2015.[123]

197. Even assuming Celgene had meritorious counterarguments to these challenges, the ’517 patent could not justify a 2026 generic competition date because it expired on October 4, 2019.

2. The REMS Patents, expiring August 28, 2018 / October 23, 2020

198. Natco had an extremely strong invalidity counterclaim for the REMS patent portfolio based on the obviousness of the claimed subject matter. Natco also had a strong unenforceability claim based on inequitable conduct in Celgene’s procurement of the REMS patents, as Celgene had withheld key prior art references[124] that were material to patentability during patent prosecution.

199. Celgene had attempted to avoid scrutiny of these patents, first filing a motion to

[123] The ’517 patent also faced additional invalidity challenges, including lack of enablement based on testing data that Celgene’s own expert submitted during proceedings before the European Patent Office (EPO). In those proceedings, Mylan and Teva challenged the patentability of a different patent—Celgene’s crystal form patent claiming Form A lenalidomide—on the basis that, if one followed Example 1 of the ’517 patent (prior art to the Celgene’s crystal form patent), one would obtain Form A lenalidomide. In its rush to defend its crystal form patent during those proceedings, Celgene submitted evidence—the March 6, 2015 Declaration of Ravi Natarajan—that undermined the patentability of Celgene’s ’517 patent. Dr. Natarajan attested that, when following Example 1 of the ’517, he failed to obtain lenalidomide *at all*. If Celgene’s own expert is to be believed, the ’517 patent is invalid for lack of enablement.

[124] Appendix 4 provides a fuller list of prior art references that render the REMS patents invalid and/or unenforceable.

dismiss Natco's inequitable conduct claims, which the Court denied on April 6, 2011.[125] Celgene then attempted to obtain a stay pending Natco's provision of information about its REMS program, prompting Natco to stipulate to infringement of Celgene's REMS patents, while reserving its invalidity defenses, so it could continue its invalidity challenge.[126] Ultimately, the Court ordered that litigation of the REMS claims be stayed, pending reconsideration once Natco submitted its REMS proposal.

200. Both Natco and Celgene knew that these patents had virtually no chance of excluding generic competition. Indeed, on April 23, 2015, a third-party filed a petition for *inter partes* review challenging the validity of the two lead patents in the two REMS patent families, the '501 and '720 patents, based largely on the bases asserted by Natco. In 2015, the Patent Trial and Appeal Board ("PTAB") announced it would be instituting review of the patents, strongly suggesting it would invalidate the patents, which it did on October 26, 2016.[127]

3. The Method of Treatment Patents, expiring April and October 2023

201. By mid-May 2015, Natco had served its opening report detailing the invalidity of the method of treatment patents, including those related to myelodysplastic syndromes ("MDS")[128] and multiple myeloma ("MM").[129]

202. Earlier research disclosed that thalidomide (of which lenalidomide is an analog) is effective in the treatment of MDS. Earlier research also taught that lenalidomide specifically, and

[125] 2:10-cv-5197, ECF Nos. 58 (order), 59 (transcript, providing reasoning for denial of motion to dismiss).

[126] 2:10-cv-5197, ECF No. 305.

[127] *See also Celgene Corp. v. Peter*, 931 F.3d 1342, 1363 (Fed. Cir. 2019) (affirming invalidation of the '501 and '720 patents except for one dependent claim of the '720 patent).

[128] The MDS patents at issue were the '740 and '717 patents.

[129] The MM patents at issue were the '569, '095, and '498 patents. As Natco had not contested infringement of certain claims of both the MDS and MM patents in its earlier-served non-infringement contentions, both parties knew that Celgene's ability to exclude Natco on the bases of these patents would boil down to invalidity rulings.

IMiDs generally, are potent inhibitors of cytokines (proteins, such as TNFα, that control inflammation), which are associated with MDS (and MM). Lenalidomide and other IMiDs are therefore natural candidates to treat MDS.[130] Prior art also taught that lenalidomide was far more potent and effective at suppressing angiogenesis and reducing TNFα,[131] prompting a person of skill in the art to use lenalidomide to treat MDS with a reasonable expectation of success.

203. Similarly, Natco had strong bases for challenging the validity of the MM patents, which claim methods of treating MM using Revlimid and dexamethasone at specified dosages on certain days. By the late 1990s, it was well known that thalidomide was effective in the treatment of multiple myeloma.[132] Prior research also disclosed testing data demonstrating that lenalidomide (Revlimid) specifically was far more effective in inhibiting the proliferation of MM cells than thalidomide alone or thalidomide in combination with dexamethasone.[133]

204. Celgene principally countered with two flawed arguments. *First*, Celgene insisted that the prior art references did not explicitly identify the subject compound(s) as lenalidomide, emphasizing the use in the prior art of code names like "CC-5013" and "IMiD1, IMiD2, and IMiD3." However, Celgene knew this argument would likely fail. Two years prior, the European Patent Office ("EPO") had evaluated Celgene's code name argument as part of its decision

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[130] *See, e.g.*, Thomas and Kantarjian, "The revitalization of thalidomide," Annals of Oncology, vol. 12:885-886 (July 2001); Rajkumar and Kyle, "Thalidomide in the Treatment of Plasma Cell Malignancies," Journal of Clinical Oncology vol. 19(16): 3593-3595 (15 August 2001); *see also* Raza, A., "Anti-TNF Therapies in Rheumatoid Arthritis, Crohn's Disease, Sepsis, and Myelodysplastic Syndromes," Microscopy Research and Technique, vol. 50:229-235 (2000) (reporting successful treatment of MDS with thalidomide, chosen because of properties shared with lenalidomide—suppression of TNFα and inhibition of angiogenesis); Raza, et al., "Thalidomide produces transfusion independence in longstanding refractory anemias of patients with myelodysplastic syndromes," Blood, vol. 98(4):958–65 (15 August 2001).

[131] *Id.*

[132] Singhal, *Antitumor Activity of Thalidomide in Refractory Multiple Myeloma,* New England Journal of Medicine, Vol. 341, Number 21, page 1565 (1999) (reporting results of clinical trials); *see also* Stolberg, *Thalidomide Found to Slow a Bone Cancer*, New York Times, Section A, page 23 (Nov. 18, 1999).

[133] Hideshima, *Thalidomide and its analogues overcome drug resistance of human multiple myeloma cells to conventional therapy*, Blood, vol. 96; 2943–50 (2000) ("Hideshima").

revoking Celgene's European patent for treating MM with Revlimid (EP '973).[134] Although the authors used the code name "CC-5013" in prior research, the EPO found that it "**clearly is lenalidomide**," leading to the revocation of the patent.[135] Celgene ultimately abandoned its appeal of the revocation of the EP '973 patent, implicitly conceding that its code-name gambit had failed, and would fail in future challenges.

205. *Second*, Celgene argued that it was not obvious to treat *humans* with Revlimid and dexamethasone despite prior art demonstrating the efficacy of these drugs in inhibiting the proliferation of MM cells over thalidomide. Celgene argued that these *in vitro* (test tubes, on the effect of MM cells) tests, rather than *in vivo* (in animals, on the effect of the disease in a living human) tests, would not give a person of ordinary skill in the art a reasonable expectation of success in treating MM in humans. This argument was belied by Celgene's very own specification, which relied on the ***very same in vitro tests and data*** to, as is necessary, show that it was in possession of the claimed invention.

206. As Celgene's odds of prevailing on either of these arguments (pertaining to code names or *in vitro* studies) were low, Celgene was left to argue that the claimed dosing regimen (essentially 21 days of treatment followed by 7 days of rest) was sufficiently novel to warrant a patent. However, Celgene faced substantial hurdles both on the law and on the facts; 2014 and 2015 district court decisions (both subsequently affirmed by the Federal Circuit) invalidated patents whose inventiveness depended solely on the claimed dosing regimen.[136] These decisions

[134] European Patent EP-B-1 505 973 ("EP '973").

[135] Although there are slight differences in U.S. and European patent law, and although the full scope of the claims of the U.S. and European MM patents were not identical, this finding of *fact* did not rely on patent law and would have read through on at least this argument. File History for U.S. Patent no. 9,101,622, Feb. 25, 2013 Decision revoking the European Patent (EP-B-1 1 505 973), appended to Mar. 20, 2015 Information Disclosure Statement.

[136] On July 11, 2014, the Federal Circuit affirmed the invalidation of method of treatment patents for the brand drug Boniva, based upon a dosing regimen whose dosage level was obvious to try in light of the combination of

were highlighted in industry reports.

207. Natco argued that the dosing amount also was obvious in light of the disclosures of successful treatment of MDS with Thalomid and knowledge of the comparative potency of Revlimid, with a standard dosing schedule of once or twice a day (like in *Boniva* recently invalidating a dosing patent). For the MM patents, standard compliance issues drove the dosing schedule (like in *Boniva*), which was built around a 28-day (*i.e.*, weekly for approximately a month) schedule, with a one-week break for recovery, which was disclosed in prior art teaching the use of a one-week rest period when using immunomodulatory drugs (including thalidomide) alone or in combination with dexamethasone to treat MM.[137] And the dosage amounts for both would have been obvious in light of prior art, especially as the dosages listed are not claimed to have any special potency or effectiveness, safety-assurance, or optimization. As such, Celgene would have known that it faced a substantial risk that either or both sets of method of treatments patents would have been invalidated had Celgene not induced a settlement of the Natco litigation, paving the way for Natco to launch prior to their mid- to late- 2023 expiration dates.

4. The Crystal Patents – Form A, Expiring September 23, 2024 ('219, '598) & January 4, 2015 ('357)

multiple prior art references, and the rationale for its dosing schedule was built largely to ensure patient compliance. *See Hoffman-La Roche Inc. v. Apotex Inc.*, 748 F.3d 1326, 1332 (Fed. Cir. 2014) ("*Boniva*"). The Federal Circuit reiterated that the prior art need only establish at least a "reasonable expectation of success" that the dosing schedule would succeed for the claim to be rendered obvious. *Id.* at 1331. *See also Cubist Pharms., Inc. v. Hospira, Inc.*, 75 F. Supp.3d 641, 661 (D. Del. Dec. 8, 2014) (invalidating dosing patterns covering the drug Cubicin using similar rationales), *aff'd*, 805 F.3d 1112 (Fed. Cir. 2015).

[137] *See, e.g.*, Aviles, et al. "Dexamethasone, all trans retinoic acid and interferon alpha 2a in patients with refractory multiple myeloma" Cancer Biother Radiopharm vol. 14(1):23-6 (1999 Feb); Tramontana, et al., "Thalidomide Treatment Reduces Tumor Necrosis Factor Alpha Production and Enhances Weight Gain in Patients with Pulmonary Tuberculosis", Molecular Medicine vol. 1(4):384–97 (1995).

Although irrelevant to an evaluation of the patent state of play as of May 2015, Natco's arguments are materially different, and more persuasive, than the failed arguments advanced by Alvogen in Case No. IPR2018-01714. Therein, the PTAB rejected the import of a piece of prior art teaching a similar dosing schedule because it involved a completely unrelated drug (hexamethylmelamine). Here, Natco relied on prior art teaching the use of a one-week rest period to treat MM using an immunomodulatory drug—the exact same class of drug as Revlimid—in combination with dexamethasone.

208. Natco had strong non-infringement and invalidity defenses to Celgene's '219, '598, and '357 patents, which claimed a defined unsolvated crystalline lenalidomide. For example, by 2015, both Celgene and Natco knew that, under the Court's May 27, 2014, Markman Opinion, Celgene would have virtually no chance to prove Natco's ANDA infringed any claim using the term Form A (all claims of the '357 patent and claims 1–4 of the '598 patent). The Markman Opinion construed the term Form A as used in claims 1–17 of the '357 patent and claims 1–4 of the '598 patent to mean "the lenalidomide crystal form described in the specification as Form A, having all of the characteristics assigned to Form A in the specification."

209. During claim construction briefing and oral argument, Celgene had opposed the court's Form A claim construction by arguing how difficult it would be to show that an accused product had all the characteristics described in the specification for Form A lenalidomide. Celgene's representations at oral argument in support of its claim construction—which it lost—underscored that it would be near impossible for Celgene to prove infringement under the claim construction that the court ultimately adopted. Counsel for Celgene listed "all of the characteristics assigned to Form A in the specification" that it would have to show Natco's ANDA infringed:

> This is what they're talking about reading in. So I don't know how you would put the chart in there, but you'd have to put words to it. And they'd have ***another one [1], and another one [2], and another one [3], and another one [4], and another one [5], and another one [6], and another one [7], and another one [8]***, and it's just keeps going. ***This is all the material they are suggesting should be read into this claim, this term, to define Form A***. My finger is getting tired, but I'm almost done. This is what is the claim would look like with—and it's not even all of it I' we couldn't fit it on one slide.[138]

[138] Transcript, *Celgene Corp. v. Natco Pharma Ltd.*, No. 10-5197 (D.N.J. May 20, 2014), ECF No. 310, at 84.

210. Celgene's concerns about its inability to show infringement if the court were to adopt this claim construction (which it did) proved well founded.

211. The court's construction required Celgene to prove for each claim having the term "Form A" that Natco's product had "***all*** of the characteristics assigned to Form A in the specification," which Celgene could not do.

212. In addition to the "Form A" claims, Celgene also asserted claims 1–5, 7–9, 11–13, and 15 of the '219 patent and claims 5–23 of the '598 patent, which purport to cover "unsolvated crystalline [lenalidomide]" having defined characteristics without expressly reciting Form A. While the claims of Celgene's '219 patent do not recite Form A, they all require the presence of the fingerprint X-ray powder diffraction pattern that defines Form A lenalidomide, namely one having XRPD peaks at approximately 8, 14.5, 16, 17.5, 20.5, 24, and 26 degrees 2.

213. Similarly, for example, claims 5–16 of the '598 patent, among other requirements, require the unsolvated crystalline lenalidomide to have XRPD peaks at least at approximately 8, 14.5, and 16 degrees 2.

214. The fact that analytical testing of Natco's ANDA product did not match the characteristics of Celgene's Form A lenalidomide is consistent with Natco's position that its ANDA lenalidomide was a *different* polymorphic form ("Form I") than that claimed by Celgene's patents. Natco had developed its own polymorphic Form I unsolvated crystalline lenalidomide having its own set of characteristics including its own XRPD fingerprint. On November 4, 2014, the PTO issued Natco a patent for Natco's process for producing its anhydrous polymorphic Form I lenalidomide."[139] Thereafter, on August 18, 2015, the PTO issued Natco a separate composition

[139] U.S. Patent No. 8,877,932.

patent for Natco's anhydrous unsolvated Form I lenalidomide.[140] The PTO's issuance of Natco's composition patent confirmed the novelty of Natco's Form-I over all polymorphic forms disclosed in Celgene's polymorph patents, including the crystalline unsolvated polymorphic forms claimed in Celgene's '219, '598, and '357 patents, which include claims to Celgene's Form A lenalidomide.

215. Further, all of the claims of Celgene's '219, '598, and '357 patents had serious invalidity issues. The vulnerability of these patents was made abundantly clear when on May 7, 2015—six days prior to the first settlement outreach between Celgene and Natco—the European Patent Office announced that it was revoking Celgene's counterpart crystalline lenalidomide European Patent 1667682 (EP '682).

216. Similar to the patent application process in the U.S., the European patent application process is an *ex parte* process where the patent applicant argues for patentability of the claimed invention without the presence of any interested third-party presenting reasons why a patent should not be issued. However, the European patent process includes giving notice of the grant of a patent and allowing a limited time for interested third parties to oppose that grant.[141]

217. At the same time Celgene was litigating against Natco in the U.S., Celgene was also facing oppositions filed by Teva and Mylan to the grant of Celgene's counterpart crystalline lenalidomide EP '682, which included claims directed to unsolvated crystalline lenalidomide and hemihydrate crystalline lenalidomide. For example, similar to claims in the U.S. '219, '598, and '357 patents, claim 14 of EP '682 claimed crystalline lenalidomide which has an XRPD pattern comprising peaks at 8, 14.5, and 16 degrees 2. The EPO revoked Celgene's EP '682 patent,

[140] U.S. Patent No. 9,108,945.

[141] The U.S. American Invents Act, effective September 16, 2012, included a similar post-grant review process, but that process was not applicable to the '219, '598, and '357 patents.

including claim 14, in part, based on its acceptance of evidence showing that reproduction of example 1 of the prior art U.S. '517 patent, inevitably lead to production of Form A lenalidomide with all the characteristics of Form A.

218. Th EPO revocation of the EP '682 patent further corroborated the weakness of Celgene's polymorph patents.

5. The Crystal Patents – Form B, Expiring April 27, 2027 ('800)

219. Natco also added strong invalidity contentions following the court's May 27, 2014 Markman Order, heightening the risk of competition to Celgene from not only Natco, but also from the ANDA sponsors Celgene knew would be filing any day.

220. The '800 patent claims crystalline lenalidomide "hemihydrate," meaning a hydrate (substance containing water) in approximately 2:1 (lenalidomide to water) ratio. Since Natco's product comprised an anhydrous (without water) Form I crystalline structure, Celgene could only argue that it had—despite Natco's product specification—found trace amounts of hemihydrate. As with any polymorphs, Form B can be characterized by reference to various analytical methods. Here, Celgene's expert marked a clear delineation via x-ray powder diffraction tests: if the test showed a XRPD peak at 12.05 degrees 2, there might, but not necessarily, be hemihydrate; if there was no peak, there was no hemihydrate (Form B).

221. Natco filed its ANDA in February 2010, becoming the first-filer. However, up until the '800 patent issued on December 16, 2008, Celgene had no hemihydrate patents, nor any polymorph patents at all. After being sued on the '800 patent, Natco submitted a revised specification on April 8, 2014, making clear that its product would only meet specification (and thus be eligible for release and sale) if its XRPD pattern was "concordant with that of Natco's 'Form-I' working/reference standard, **not to contain peak at 2q value of 12.05 degrees ± 0.2º,**

and not to contain Form-B." Under well-settled Federal Circuit law, a drug whose specification directly addresses infringement by precluding the claimed subject matter, as here, does not infringe.[142] Revising a specification is no light matter—introducing a drug that does not comply with its specification poses serious consequences, including debarment from submitting future ANDAs and criminal prosecution.[143]

222. In late 2014, Natco also introduced invalidity arguments that placed the '800 patent at substantial risk of invalidation and ratcheted up the pressure on Celgene that, not only would Natco compete with Celgene during the life of the '800 patent, but also that the patent would be invalidated, removing any doubt that other generics would be competing as well. Under Celgene's adopted claim construction, the claims of the '800 patent are broader than the patent specification describes or teaches. As described above, the EPO's revocation of Celgene's European polymorph patent (with various claims related to, amongst others, Forms A and B) foreshadowed the vulnerability of the '800 patent to similar validity challenges. Claim 1 of the (revoked) EP '682 is *verbatim identical* to claim 1 of the '800 patent, and under Celgene's adopted construction for the meaning of hemihydrate the invalidity problem in the U.S. becomes analogous to that Celgene faced in the EPO—both patents claim a class of hemihydrates, while only demonstrating that Celgene was in possession of a single hemihydrate (Form B), a clear written description problem.

223. During claim construction, the parties disagreed on the meaning of "hemihydrate" used in the claims of the '800 patent. Natco argued the term should be construed as a solid form

[142] *E.g.*, *Bayer AG v. Elan Pharm. Research Corp.,* 212 F.3d 1241, 1249–50 (Fed. Cir. 2000).

[143] *Id. Cf. Exelixis, Inc. v. MSN Labs. Private Ltd., et al*, 1:19-cv-02017, Trial Opinion, ECF 327 at 23–28 (Jan. 19, 2023), (brand's testing was irrelevant to infringement analysis, crediting Dr. Steed, because the brand's "stressed accelerated conditions" were not representative); *Astelllas US LLC, et al. v. Hospira, Inc.*, 1:18-cv-01675, ECF No. 947 at 57-66 (May 19, 2022) (no infringement, crediting Dr. Steed's opinion that trace amounts of infringing polymorph, if any, resulted from airborne water exposure during brand's sampling, storage, transport, and/or testing).

of lenalidomide containing one water molecule for every two molecules of lenalidomide in the crystal form identified for Form B. Celgene argued for a much broader construction where "hemihydrate" means a hydrate containing approximately half of a mole of water to one mole of the compound forming the hydrate. In its May 27, 2014, Markman Order, the district court accepted Celgene's broader construction and found that "hemihydrate means a hydrate containing approximately half of a mole of water to one mole of the compound forming the hydrate."[144] While this "approximately" construction would potentially allow Celgene's "hemihydrate" claims to capture a broader range of lenalidomide/water compounds than just the single Form B hemihydrate, it also further exposed the claims of the '800 patent to invalidity attacks. By accepting Celgene's broadened "approximately" language, one skilled in the art no longer had reasonable certainly as to the meets and bounds of the claim. Additionally, since Celgene had disclosed only *one hemihydrate*, by now expanding the scope of the claims to includes an entire class of hemihydrates, Celgene had expanded the claims to claim inventions not described or enabled by the inventors.

224. One week after the court's Markman Order, the Supreme Court unanimously held that "a patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention."[145] And, two weeks later on June 19, 2014, based on the court's claim construction decision, Natco moved (and was later granted leave) to amend its invalidity contentions to include new indefiniteness, lack of written description, and lack of enablement defenses to the '800 patent based on the court's claim construction of

[144] *Markman* Opinion, *Celgene Corp. v. Natco Pharma Ltd., et al.*, No. 10-5197 (D.N.J. May 20, 2014), ECF No. 312, at 7.

[145] *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014).

"hemihydrate."[146]

225. The strength of Natco's non-infringement and invalidity arguments are further corroborated by the fact that, prior to the Celgene-Allergan agreement, when the parties began settlement negotiations in May 2015, Celgene was separately negotiating an anticompetitive deal to avoid the grave danger these new invalidity arguments posed to its latest-expiring patent.

H. By mid-2015, Celgene expected a multi-billion-dollar revenue decline upon loss of exclusivity of Revlimid.

226. As of May 2015, both Celgene and Allergan (the negotiator of the Celgene-Allergan on behalf of the Allergan Interests – Natco, Teva, and Allergan) expected full genericization of the U.S. Revlimid market in the early 2020s.

1. Celgene was likely to launch an authorized generic for Revlimid to mitigate anticipated losses upon loss of exclusivity.

227. Celgene engaged Greenstone regarding possible authorized generic versions of its products. Greenstone described itself as an "experienced Turn-Key AG Partner" with "Tailored Generic-Market Launch Strategies." Part of Greenstone's pitch was "If You're Going to Compete with Someone, Might as Well be You" and "Get a Little Piece of the Guys Who are Getting a Piece of You."

228. In September 2013, Celgene launched an authorized generic version of its injectable Vidaza product.

229. Celgene's next drug to face loss of exclusivity was Istodax (romidepsin). Pfizer launched AG Istodax in January 2018, a month prior to when it expected the first-filer Fresenius

[146] Letter, *Celgene Corp. v. Natco Pharma Ltd., et al.*, No. 10-5197 (D.N.J. June 19, 2014), ECF No. 321, at 3-6; Opinion, No. 10-5197, ECF No. 366 (granting leave).

to launch.[147]

230. Celgene also planned to launch an Authorized Generic for Abraxane, which was the next drug to face loss of exclusivity, in 2022. BMS—following its acquisition of Celgene—partnered with a generic company to launch an Abraxane authorized generic in March 2022 to "delay or lower [generic] impact."[148]

231. In short, over the years Celgene and BMS have demonstrated that upon generic entry they have and will enter with an authorized generic.

2. Celgene expected that more generics would seek market entry, resulting in full genericization upon loss of exclusivity.

232. By mid-2015, Celgene was closely tracking the status of other potential generic ANDA filers.

233. As discussed above, numerous generic companies sought to acquire Celgene's lenalidomide samples for bioequivalence testing, but Celgene had withheld sales to protect its market position. It was publicly known that up to twelve generic companies aimed to file ANDAs for competing lenalidomide products before Celgene's Revlimid patents expired.[149] These generic companies attempted to purchase lenalidomide samples to support their ANDA filings, designed around Celgene's patents and sought patent protection for their own unique polymorphic form of lenalidomide, or otherwise had taken steps to challenge Celgene's Revlimid patents.

234. Other generics would soon be filing ANDAs and attempting to launch lenalidomide as soon as possible. Dr. Reddy's had filed for a patent for an amorphous form of

[147] *See* https://professionals.optumrx.com/publications/library/newgenerics_istodax_2018-0111.html (last visited Sept. 4, 2025).

[148] *See* https://www.bms.com/assets/bms-ar/documents/bms-2023-10-K.pdf (last vivited Sept. 4, 2025).

[149] Mylan, Synthon, Teva, Roxane/Hikma, Sandoz, Millenium Pharmaceuticals, Alkem, Lannett, Dr. Reddy's, Hetero, ScinoPharm, and Tianjin Hemay.

lenalidomide, which application was noted as prior art by the patent examiner in the course of Natco's prosecution of its patents and noted in Natco's pre-application review of prior art.

235. By May 2015, it was widely known that at least seven generics (other than Natco) had applied for patent protection for their own proprietary and unique polymorphic forms of lenalidomide: Dr. Reddy's, Mylan, Teva, Hetero, Synthon, ScinoPharm, and Tianjin Hemay.[150] All seven had designed around Celgene's latest-expiring Revlimid patents—the polymorph patents—by developing novel crystalline or amorphous forms of lenalidomide. These patent applications telegraphed that all seven generics intended to bring generic version of Revlimid to market, and likely provide paragraph IV certifications to Celgene's polymorph patents and seek to enter the market years before the polymorph patents were to expire in April of 2027.

236. Given that Dr. Reddy's, Lotus, and Cipla, Ltd. ("Cipla") all filed ANDAs prior to Apotex, these companies likely also had requested samples by this time.

237. By May 2015, three generics had initiated challenges to Celgene's European versions of its U.S. patents—Mylan, Synthon, and Teva—suggesting they were planning to commercialize a generic Revlimid product and, potentially, launch in the U.S.[151]

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[150] Dr. Reddy's (3/11/2009, filed U.S. patent application 12/921,613 related to an amorphous form of lenalidomide and the processes for making it); Hetero (2/16/2012, filed European patent application 2 688 649 B1 related to a novel crystalline Form of lenalidomide (termed "Form HI"), process for its preparation and pharmaceutical compositions comprising it, as well as a novel N-methylpyrrolidone solvate of lenalidomide and process for its preparation); Mylan (7/12/2011, filed U.S. patent application 13/126,538 related to an anhydrous form of lenalidomide and the processes for making it); ScinoPharm (9/17/2009, Filed U.S. Provisional Patent Application No. 61/243,204, which led to U.S. Patent No. 8,420,672. The '672 patent covers a "quarterhydrate" polymorph having four molecules of lenalidomide per one molecule of water, which it refers to as "Form I." The '672 patent also discloses an amorphous form of lenalidomide); Teva (9/26/2011, filed U.S. Patent Application No. 13/128,943 related to stable amorphous or molecularly disperse lenalidomide and pharmaceutical formulations containing stable amorphous or molecularly disperse lenalidomide); Synthon (4/13/2012, filed U.S. Patent Application No. 13/390,204 which led to U.S. Patent No. 8,686,153. The '153 patent covers a specified acid addition salt form of crystalline lenalidomide, having either a 1 to 1 ratio of benzenesulfonate or p-toluenesulfonic acid.); Tianjin Hemay (9/13/2010, filed U.S. Patent Application No. 12/880,983, and later No. 13/675,767. The '983 and '767 applications were directed to a pharmaceutically acceptable strong acid salt of lenalidomide, and polymorphs of those strong acid salts.).

[151] *See* https://register.epo.org/application?number=EP03728969&lng=en&tab=doclist (documents related to revocation of EP '973) (last visited Sept. 4, 2025);

I. The 2015 Celgene-Allergan agreement.

238. By mid-2015, the situation facing Celgene on the future of Revlimid sales was dire. On the patent front, litigation was proceeding apace and, regardless of some slip in the schedule, the case was likely to reach trial readiness by early 2016. The cornerstone compound patent, the '517 patent, would expire in 2019, and that patent itself suffered significant challenges. The REMS patents presented no preclusive ability to generic entry. The method of treatment patents, while less vulnerable than the REMS patents, presented their own challenges and would, in any event, expire in 2023. The Crystal Patents presented no real hurdle to generic entry, having been designed around by multiple likely generic entrants.

239. Celgene could continue its losing patent battles, or settle for a fair, merits-based date for unrestrained generic entry (as is the norm for reasonable, law-abiding companies). Or it could try to pay off its competitors. But doing so would be tricky, because in the summer of 2015, the Third Circuit issued an opinion holding that non-cash consideration—specifically a no-authorized-generic agreement—can be an actionable reverse payment subject to antitrust scrutiny.[152]

1. Negotiations to exchange late agreed entry date for split of brand profits.

240. On July 26, 2015, Teva Pharmaceutical Industries Ltd, entered into a definitive agreement with Allergan to acquire the entirety of Allergan's generic business, under which, once closed, Watson and Arrow would become wholly owned subsidiaries of Teva. As a result, during the 2015 negotiations it was expected that, if the Teva transaction were to close, Teva would succeed to the rights of Allergan's subsidiaries (under terms upon which Allergan and Teva would

https://register.epo.org/application?number=EP04783095&lng=en&tab=event (documents related to the revocation of EP '682) (last visited Sept. 4, 2025).

[152] *King Drug Co. of Florence v. Smithkline Beecham Corp.*, 791 F.3d 388, 403–09 (3d Cir. 2015).

agree).

241. As a result, Celgene would continue selling Revlimid at wildly supra-competitive prices for years to come, and with no fear of a patent loss in the litigation with Natco. Because the Natco ANDA was positioned as the likely first-to-file generic for four of the six dosage forms, the wait by the Allergan interests to enter with full generic competition would also hamper the ability of other, later generics to enter with generic versions of those dosage forms.

242. As explained above, first-filers typically make 80% of their profits during the 180-day exclusivity period. But the Allergan interests proposed to limit their own sales during their exclusivity period, reducing the amount of profit during that period. It would have been economically irrational for the Allergan interests to propose to do so unless they knew that the structure of the agreement would likely result in later-filing generics receiving volume-capped allocations (with the allocations to the Allergan interests and the other manufacturers totaling less than the expected generic share of the market under competitive conditions, *i.e.*, without volume restrictions), ensuring that there would not be generic competition based on price.

2. The Revlimid settlement agreements included output restrictions that kept supply below demand.

243. In December 2015, Celgene began constructing the Generic Revlimid Output Restriction by settling ANDA litigation against a collaborative of Natco and subsidiaries of Allergan plc ("Allergan"), the first-filer on four of six strengths. The Natco/Allergan collaborative agreed to a late date for generic entry—quickly fixed on ten years later, January 2026—with Celgene agreeing in the meantime to share with Natco/Allergan some of the profits Celgene would be making from the prolonged period of selling Revlimid in the U.S. The tool to effectuate the profit share was a market-sharing arrangement that ensured constrained supply and thus constrained competition for four years, while the Natco/Allergan collaborative's share of

monopoly profits increased in each of the four years, starting with a "mid-single-digit percentage."[153]

3. The terms of the Celgene-Allergan agreement.

244. On December 22, 2015, the parties reached the Celgene-Allergan agreement.

245. The terms of Celgene-Allergan agreement are confidential, though some details have been disclosed. This complaint outlines what is publicly known.

246. The participants to the Celgene-Allergan agreement were, on the one hand, Celgene Corporation and Celgene International Sarl II (the Celgene entity holding the applicable patent licenses) and, on the other hand, Natco (the ANDA holder), Arrow, (Natco's exclusive U.S. licensee for the Natco ANDA), Watson (an affiliate of Arrow), and Allergan (the ultimate parent company of Watson and Arrow). For purposes of describing the Celgene-Allergan agreement, Natco, Arrow, Watson, and Allergan are referred to collectively as the "Allergan interests."[154]

247. *Settlement of patent challenge*. Under the Celgene-Allergan agreement, the Allergan interests settled the litigation and dropped the challenges Natco had made to the Celgene Revlimid patents. As a result, Celgene avoided the risk of loss in those cases and avoided the risk of competition that would have ensued from a litigation loss. (Settlement Agreement and Consent Decrees, *et passim*).

248. *Delay of generic entry*. Under the Celgene-Allergan agreement, the Allergan

[153] Paul Kleutghen, *Generic Revlimid in Myeloma: Don't Get Too Excited*, HEALTHTREE FOUNDATION, Apr. 10, 2022, *available at* https://healthtree.org/myeloma/community/articles/generic-revlimid-in-myeloma--dont-get-too-excited (last visited Sept. 4, 2025)

[154] The Celgene-Allergan agreement acknowledged that Teva had entered into a definitive agreement with the corporate parent of Watson and Arrow, Allergan, to acquire the entirety of Allergan's generic business and that, upon closing of the Teva transaction, Teva would succeed to the rights of Allergan's subsidiaries, including Watson and Arrow. (License Agreement, at 15.2).

interests would not launch unrestrained product until January 31, 2026.[155]

249. *Capped-volume sharing*. Under the Celgene-Allergan agreement, the parties accomplished a profit share from Celgene to the Allergan interests through a capped-volume sharing arrangement. The precise volume shares are confidential. Celgene has, however, announced that:

> In settlement of all outstanding claims in the litigation, Celgene will permit entry of generic lenalidomide before the April 2027 expiration of Celgene's last-to-expire patent listed in the Orange Book for REVLIMID®. Celgene has agreed to provide Natco with a license to Celgene's patents required to manufacture and sell an unlimited quantity of generic lenalidomide in the United States beginning on January 31, 2026. In addition, Natco will receive a volume-limited license to sell generic lenalidomide in the United States commencing in March 2022. The volume limit is expected to be a mid-single-digit percentage of the total lenalidomide capsules dispensed in the United States during the first full year of entry. The volume limitation is expected to increase gradually each 12 months until March of 2025, and is not expected to exceed one-third of the total lenalidomide capsules dispensed in the U.S. in the final year of the volume-limited license under this agreement.[156]

250. In exchange for the Allergan interests agreeing to abandon their challenge to Celgene's patents, Celgene transferred a large and unjustified reverse payment via capped-volume profit shares. Under the agreement, Natco/Allergan/Teva collaborative (with Teva joining as the marketer, see ¶ 439 & n. 190) receives an "annual quota" of limited product to sell. [157] This is a tool to effect a large and unjustified transfer of value, as observed in the market for Xyrem, as the FTC has explained, and as is detailed further below.

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[155] Press Release, *Celgene Settles REVLIMID Patent Litigation,* dated December 22, 2015, *available at* https://web.archive.org/web/20230518150907/https://www.businesswire.com/news/home/20151222005986/en/ (last visited Sept. 4, 2025).

[156] *Id.*

[157] Teva Pharmaceuticals, Q1 2025 Aide Memoire, *available at* https://s24.q4cdn.com/720828402/files/doc_financials/2025/q1/Teva-Aide-Memoire-Q1-2025-vF4.pdf (last visited Sept. 4, 2025) (the agreement "provides a new ***annual quota*** in March of each year," until "2026, at which point Teva expects lenalidomide revenues to decrease substantially").

251. The creation of the Generic Revlimid Output Restriction was predictable from the Celgene-Allergan agreement and was in fact predicted in 2018 prior to any other settlement. The intention to create the output restriction and restrain price competition was clear from this first settlement agreement because without assurance from the terms of the settlement agreement that prices would remain restrained under an output restriction, it would have been irrational for the Natco/Allergan collaborative to *voluntarily* sell only a single-digit volume of sales during its 180-day exclusivity period. As described above, a first-filer typically makes 80% of their profits during the 180-day exclusivity period because it can quickly gain 39% market share (with an AG). To completely surrender the ability to maximize the first-filer exclusivity—the cornerstone of the Hatch-Waxman regime—indicates the Natco/Allergan collaborative understood they could make, as publicly available information *confirms they have made*, vastly more money during a longer period of time by agreeing to delay competition and instead receive allocations through the Generic Revlimid Output Restriction.

252. Indeed, in May 2018—*i.e.*, *before any other Revlimid settlement deals had been reached*—a articles spelled out the above-described incentives, noting the classic output restriction features: "The deal gives Natco **no incentive to lower its price** . . . because the company **can't gain additional market share by undercutting Celgene on price** . . . They cut a deal that will **keep the price high**."[158]

253. The agreement also functions as an implicit agreement for Celgene to not launch an authorized generic (AG), because doing so would only capture more lucrative brand sales. As of August 2025, Celgene has not launched an AG despite generic "entry" nearly three-and-a-half

[158] Alison Kodjak, *How a Drugmaker Gamed The System To Keep Generic Competition Away*, NPR, May 17, 2018, *available at* https://www.npr.org/sections/health-shots/2018/05/17/571986468/how-a-drugmaker-gamed-the-system-to-keep-generic-competition-away (last visited Sept. 4, 2025).

years prior. Functionally, promising not to launch an AG ("no-AG promise") is a cognizable form of a reverse payment. The no-AG promise restrains competition and allows generic(s) to sell at supracompetitive prices, resulting in excess profits that the generic would otherwise be unable to make.

254. The capped-volume shares were intended to—and in the end in fact did—share with the Allergan interests Celgene's high-priced Revlimid/lenalidomide profits.

255. Other terms of the Celgene-Allergan agreement are publicly alleged to include a:

- *No-third-party-AG provision*
- *Contractual exclusivity*
- *Final court decision trigger*
- *A no-Celgene-AG provision*
- *A market erosion protection provision*
- *A "most favored licensee" protection clause*
- *At-risk entry provision*
- *License (limited) for the patents*
- *Integrated exchange of promise*s
- *Allergan letter*

256. The Celgene-Allergan agreement also provided for selective and strategic confidentiality to obscure the scheme while still allowing and deputizing Celgene to use the terms of the Celgene-Allergan agreement to recruit other generic challengers to the output restriction and induce them to abandon their patent challenges in exchange for reverse payments on terms that mirrored (but with smaller allocations and reverse payments) those in the Celgene-Allergan agreement.

257. Executives from generic manufacturers acknowledged that they had agreed with Celgene not to disclose lenalidomide-specific revenue figures. An Aurobindo executive stated, "we are not supposed to tell what exactly is the volume settlement"[159] and "I'm not at a liberty to disclose as per our settlement terms with innovator the amount of Lenalidomide sales separately."[160] an Dr. Reddy's executive stated that "I cannot share any numbers about the product, sorry,"[161] and a Natco executive when asked on market pricing, responded, "I can't answer that question, my friend. I'm sorry, I can't answer."[162] Yet, an Aurobindo executive later revealed knowledge of at least some of the terms of the other generics' agreement by stating that "each player is [] restricted by the percentage of [] share."[163]

258. This selective confidentiality indicates the terms of the Celgene-Allergan agreement were forward-thinking and designed to allow recruitment of the remaining generic Revlimid challengers to the output restriction and hence designed (as it has) to keep generic supply below generic demand for the entirety of the output restriction period (through January 31, 2026).

259. At the time the parties negotiated the Celgene-Allergan agreement, the parties and

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[159] Transcript, Aurobindo Pharma Q1 FY24 Earnings Conference Call, Aug. 14, 2023, at 12, *available at* https://www.alphaspread.com/security/nse/aurobindo/investor-relations/earnings-call/q1-2024 (last visited Dec. 22, 2025)

[160] Transcript, Aurobindo Pharma Q3 FY24 Earnings Conference Call, Feb. 12, 2024, at 8, *available at* https://www.aurobindo.com/api/uploads/conferencecalltranscripts/Aurobindo%20Q3%20FY24%20Transcript.pdf (last visited Sept. 4, 2025).

[161] Transcript, Dr. Reddy's Laboratories Lim. Q3 FY23 Earnings Conference Call, Jan. 25, 2023, at 6, *available at* https://www.drreddys.com/cms/cms/sites/default/files/2023-01/DrReddys-Earnings-Jan25-2023.pdf (last visited Sept. 4, 2025).

[162] Transcript, Natco Pharma Lim. Q3 FY '23 Earnings Conference Call, Feb. 10, 2023, at 13, *available at* https://web.archive.org/web/20240701060849/https://www.natcopharma.co.in/wp-content/uploads/2023/02/Nuvama-NatcoPharma-Feb10-2023.pdf (last visited Sept. 4, 2025).

[163] Transcript, Aurobindo Pharma Q4 FY23 Earnings Conference Call, May 29, 2023, at 12, *available at* https://www.aurobindo.com/api/uploads/conferencecalltranscripts/Aurobindo%20Pharma%20Q4%20FY23%20Earnings%20Conference%20Call%20final.pdf (last visited Sept. 4, 2025).

their negotiators were aware of the potential antitrust liability likely to attach to conduct where, in the context of settlement of a Hatch-Waxman patent dispute, a brand company pays off its would-be generic competitor in exchange for a later agreed generic entry date. The Supreme Court had said so two years earlier in *FTC v. Actavis*, and when the Celgene-Allergan negotiations began in the summer of 2015 the Third Circuit in *King Drug* made clear that such a payoff could take forms other than cash payments (there, an agreement by the brand to not launch an authorized generic). The parties knew, therefore, that they had to try to avoid naked provisions by which to pay off the Allergan interests. The trick in negotiating the agreement was to omit or shade the naked restriction while convincing the Allergan interests that they were not buying a pig-in-a-poke. At times this is achieved by provisions that do not explicitly present a restraint on trade, but when taken in context, and with the reality of the economic incentives created by the provisions, amount to a manifest restraint on trade geared toward providing value to a generic company to delay entry.

4. The expected anticompetitive consequences of the Celgene-Allergan agreement.

260. There are a series of reasonably likely, expected anticompetitive consequences from the Celgene-Allergan agreement that were apparent to the parties at the time the agreement was reached. The Celgene-Allergan agreement is not one where Celgene and the Allergan interests simply reached an agreed entry date for bona fide generic entry, it has a series of anticompetitive provisions that, taken together against the realities of pharmaceutical regulation and industry economics, were designed to have, have had, and will continue to have substantial anticompetitive consequences.

261. *First*, the Celgene-Allergan agreement was intended to have—and as will be shown, did have—the effect of maintaining prices at multiple times higher than would have

prevailed under uncapped entry. As explained earlier, in a U.S. drug market such as lenalidomide, when generic competition starts (and even with only one entrant) the generic share of the market quickly takes over the brand and, within a year or so, achieves about 90% of all unit sales. However, under the Celgene-Allergan agreement, the total market share that the Allergan interests could win was capped at a mid-single digit number.

262. Under fundamental principles of applied microeconomics, with supply capped and demand vastly outstripping supply, the Allergan interests could price the quantum-limited supply of generic at near-brand-price levels. And while the capped-volume shares increased for the Allergan interests over the next three periods of profit-splitting, the total quantum-limited supply of generic was always at levels markedly lower than the highly likely demand for all generic lenalidomide, thereby providing the Allergan interests with an arrangement tailored to provide an income stream from Celgene profit-sharing under which, for each of the four periods, the Allergan interests would have an allocated market share in which to charge highly supra-competitive prices for generic lenalidomide. Put differently, the Allergan interests would have no incentive to sell its generic product at a lower price.

263. *Second*, through a combination of provisions, the Celgene-Allergan agreement made it economically irrational for Celgene to launch a lenalidomide authorized generic during the Allergan interests' first six months of the capped-volume profit share and created a reasonable likelihood that it would continue to be irrational during later periods of the profit share.

264. During this initial sales period with a low volume of capped Allergan sales, the capped-volume profit share creates an artificial scarcity of generic supply such that demand needs to be supplied by either brand or (if made available) AG supply. But since Celgene can simply sell the higher-priced brand Revlimid rather than lower priced AG, it makes no economic sense for

Celgene to sell the low-priced product over the high-priced one.[164] As a result, purchasers only have available the specific, low quantum of high-priced Allergan ANDA product and, once that is gone, no choice but to purchase the higher-priced brand product.

265. The no-Celgene AG provision adds to the disincentive by uncapping the Allergan interests' sales volume. By selling an AG, Celgene would (1) replace some of its higher priced brand sales with lower priced AG sales and (2) concede some of its brand sales to the Allergan interests.

266. The same is true for the later sales periods. Considering the Celgene-Allergan agreement in isolation—meaning setting aside Celgene's agreements with later generic filers—the terms of the agreement disincentivize Celgene from launching an AG during the 2022-2026 period of restrained generic competition. Plaintiff's allegations are corroborated by the fact that Celgene has in fact not launched an AG as of filing. So long as the capped allocation to the Allergan interests remained below what they would have sold unconstrained against an AG, Celgene is better off capping them than competing.[165]

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[164] It is only profitable for Celgene to sell its AG if its total profits (from both the brand drug and AG) from doing so are greater than its total profits from withholding its AG. Only if the quantity-limited allocation to Allergan were a very large share of the potential unrestrained generic sales might it be profitable for Celgene to launch an AG. Data from industry averages indicate approximately how large the quantity limitation must be for it to make it rational for Celgene to launch an AG. Unrestrained generic competitors capture about 90% of the total market. *See* Henry Grabowski, et al., Updated Trends in U.S. Brand-name and Generic Drug Competition, *Journal of Med. Econ.*, 19(9), 836, 840, 844 (2016), *available at* https://www.tandfonline.com/doi/epdf/10.1080/13696998.2016.1176578?needAccess=true (last visited Sept. 4, 2025). Studies show that an AG captures about half the generic market. *See* FTC 2011 AG Study at 139. With two generic competitors, the price of the generic and AG will be 60% of the brand price. *See* FDA, *Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices* 2–3 (2019), *available at* https://www.fda.gov/media/133509/download?attachment (last visited Sept. 4, 2025). Based on these averages, until Allergan is allocated 63% of the total market, it would not be profitable for Celgene to launch an AG. Apart from industry averages, so long as the Allergan interests' allocation is less than half of generic demand, Celgene would not be incentivized to launch an AG—it would merely be replacing brand sales with less-profitable AG sales. And the Allergan interests never approached any reasonable estimate of half the share of unrestrained generic sales.

[165] At the time the Celgene-Allergan agreement was inked in December 2015, no other generic companies had filed ANDAs, though Celgene knew more were likely coming. *See supra* Section V.H.4. Without another generic

267. The consequence is that during the periods of capped-volume profit sharing, the only two lenalidomide products on the market would be branded Revlimid and the Natco ANDA product. Each would be able to command high supra-competitive prices for lenalidomide.

268. *Third*, the Celgene-Allergan agreement had the anticompetitive effect of protecting the Allergan interests' profit-share against extraneous market changes through the inclusion of the market decline trigger.

269. *Fourth*, through an elaborate set of provisions, the Celgene-Allergan agreement was intended to have—and as will be shown, did have—a series of anticompetitive effects on later generic would-be competitors.

270. As to the Allergan interests themselves, the agreement assured that the potential impact of later generic activities (by litigation or settlement) would not disrupt the output restriction by containing the provisions to ensure that each generic would be better off settling on terms that mirrored the Allergan interests' agreement with Celgene (which later generics then did) and for licensed amounts small enough to ensure that (as was in both Celgene, the Allergan interests', and the later generics' benefit) supply of generic Revlimid would remain below demand for the entire 2022-2026 period; *i.e.*, that the generic Revlimid output restriction would be preserved. This was done through a series of most-favored entry and a most-favored licensee provision.

271. Most-favored nation clauses like the most-favored licensee provision have been found to (1) be anticompetitive, (2) facilitate horizontal market collusion, and (3) have limiting

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entrant, the economics remain the same throughout the allocated period (March 2022 through January 2026) and Celgene is never incentivized to launch an authorized generic.

effects on subsequent negotiations.[166]

272. As to the later generic companies, the capped-volume market-sharing adjustment provisions also created a template for future similar deals, and for coordinated market sharing with the later generics, setting the stage for a market-wide allocation of the U.S. lenalidomide market (which later in fact occurred).

273. Also, as to the later generic companies, the "acceleration" or "poison pill" clauses (*i.e.*, those provisions that ostensibly provided for the theoretical potential of advancing unrestrained generic entry) created significant disincentives for later generics to see through with litigation (to get earlier generic entry) but rather incentivized later generics to join a market-wide allocation of high-priced, capped-volume profit shares.[167] Among other reasons, the poison-pill provisions eliminated any competitive advantage for a later generic to establish that its ANDA product was non-infringing.

274. *Finally*, the Celgene-Allergan agreement has delayed generic competition, with restrained pricing prevailing in the market for generic Revlimid at more than $500 per pill price that prevails rather than the less than $50 per pill price one would expect with so many generic products.

275. *In sum*, the Celgene-Allergan agreement—both in its design and in its final

[166] *See e.g.*, Jonathan B. Baker, *Vertical Restraints with Horizontal Consequences: Competitive Effects of "Most–Favored–Customer" Clauses,* 64 Antitrust L.J. 517, 520–21 (1996) ("*Competitive Effects*") ("Coordination works better if firms have little incentive to cheat to begin with. Most-favored-customer clauses can create that condition. A firm that has agreed to offer most-favored-customer treatment in its contracts has reduced its incentive to deviate from a coordinated horizontal arrangement because it cannot limit its discounts to a single customer."); *id.* at 520 ("The seller's reduced incentive to negotiate price cuts to individual buyers is complemented by a lessening of buyer efforts to drive a hard bargain.").

[167] While of course any generic manufacturer may independently limit its own sales, it is wholly irrational for it to do so in the absence of a reasonable expectation that its purchasers will not have the option to purchase the product from other suppliers. Creating a situation where all generics have an expectation that purchasers will not have other alternative supply, supra-competitive charges result. So long as total generic demand exceeds total generic supply, price-based competition is precluded.

integrated form—is only one step removed from a naked sharing arrangement in which a generic company agrees to stay off the market for years, and the brand company agrees to share some of the excess profits with the generic by making interval payments to the generic while competition is being stifled. Here, the payment is not interval cash payments, but rather fixed, capped-volume limits carefully shared and managed to ensure that later forces do not impinge on a basic, high level of value to the generic, here the Allergan interests.

5. The reverse-payment nature of the Celgene-Allergan agreement.

276. The Celgene-Allergan agreement may fairly be characterized as both an unlawful market-allocation agreement and as an unlawful reverse-payment agreement.

277. The Celgene-Allergan agreement is unlawful under the Supreme Court's decision in *FTC v. Actavis* because the provisions of the agreement effect a large and unexplained reverse payment from Celgene to the Allergan interests, in exchange for which the Allergan interests agreed to delay *bona fide* generic competition until January 2026, more than ten years after they inked the agreement. The payment takes several forms.

278. The large reverse payment primarily takes the form of Celgene splitting its monopoly profits with the Allergan interests while the latter wait for competitive generic entry in January 2026 (a profit-split achieved through the capped-volume profit shares and related provisions in the agreement). Whether the payment is large (or unexplained) may be viewed from the perspective of the value to the Allergan interests (the generic-side perspective), or from the perspective of the amount provided by Celgene (the brand-side perspective).

279. Using publicly available information, the key pieces of which were only recently disclosed, Plaintiff here alleges the Generic Revlimid Output Restriction transferred hundreds of

millions of dollars in excess profits to the Revlimid generic manufacturers.[168] The payments below reflect the differential between what these companies would have expected to make under competitive conditions given the circumstances, compared to what they are estimated to have made based on publicly available information. The exact size of the reverse payments (likely larger than here estimated) will be determined through transactional data in discovery and expert analysis.

280. Estimates of the reverse payment can be made by applying standard market assumptions with knowledge of the quantities allotted to the Allergan interests. However, as here Plaintiff lacks access to this information as to the Allergan interests' allocated quantities, publicly available revenue estimates and price figures allow another means of valuing the reverse payment from the perspective of the generic.

281. The Natco/Allergan collaboration launched its first-filer generic Revlimid product in March 2022. The Natco/Allergan collaboration, which included Teva after Teva's 2016 acquisition of Allergan[169], received a reverse payment that can be estimated at $2.2 billion, with Natco (30% of profits) receiving ~$660 million and Teva (35% of profits) receiving ~$770 million. These estimates are based on the reports of numerous financial analysts tracking Natco revenue (allowing for calculation of Teva revenue) and attending Natco conference calls. These analysts reported that Natco's lenalidomide sales from 2022-March 2024 totaled ~$406-$413.9

[168] These estimates use standard methods of calculating reverse payments in scenarios where a brand's settlement agreement restrains price competition, transferring a reverse payment based on the excess profits the restraint allowed the generic to make when compared to standard economic assumptions based on the size of the market, price, number of competitors, etc.

[169] Through a series of corporate transactions in 2015-16, Teva acquired Allergan's generics business in a deal in which Allergan (now AbbVie) retained 50% of Teva's future generic Revlimid revenues and Teva obtained the marketing rights. Thus, revenue is split between Teva (marketer/distributor, 35%), Natco (developer/manufacturer, 30%), and AbbVie (35%).

million and its April 2024-March 2026 sales projected to total ~$481.5-$591 million.[170] These reports are reliable and available—despite the prohibition on commentary on price and volume—because the price has been stable for nearly three years and, as an analyst on a Dr. Reddy's earnings call remarked, "this is there in the public domain in terms of the Rx volume."[171]

282. Analyst reports on Natco's lenalidomide revenue are particularly reliable because of Natco's limited portfolio of generics in the US. Although Natco is prohibited from giving lenalidomide-specific revenue data, analysts can accurately glean the impact of Natco's lenalidomide revenue because Natco has few other US generic drugs, all of which were launched prior to 2022, with no other major launches until 2025.[172] Thus it is unsurprising that analysts can deduce the approximate contribution of generic Revlimid when "Between FY21 and FY24, Natco's revenue . . . grew at . . . 25%, 42%, and 46%, respectively, largely driven by the launch of [generic] Revlimid."[173]

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[170] Analysts in late 2024 and early 2025 estimated between 3,000 and 3,500 *crore* for FY22-FY24, *see* Nikitha Devi, FY 206 is Here! Why India Follows an April-March Financial Year?, AngelOne, April 1, 2025, *available at* https://www.angelone.in/news/fy-2026-is-here-why-india-follows-an-april-march-financial-year, which converts to roughly $348.9mm - $407mm. Further, analysts projected 3500-5000 crore in the coming two financial years (April 2024-March 2026), converting to $407mm - $581mm. *See* Natco Pharma Ltd. – Quick Insights, Jan. 21, 2025, *available at* https://www.way2wealth.com/Reports/RR210120255bdd2.pdf (last visited Sept. 4, 2025).; Nishant Kumar, *Stocks to buy for long term: Pankaj Pandey of ICICI Securities recommends these 5 shares to buy, expects 22-54% upside*, MINT, Nov. 21, 2024, *available at* https://www.livemint.com/market/stock-market-news/stocks-to-buy-for-long-term-pankaj-pandey-of-icici-securities-recommends-these-5-shares-to-buy-expects-22-54-upside-11732073816138.html (last visited Sept. 4, 2025).

[171] Transcript, Dr. Reddy's Laboratories Limited's Q1 FY24 Earnings Conference Call, Jul. 26, 2023, at 8, *available at* https://www.drreddys.com/cms/cms/sites/default/files/2023-07/DrReddys-Jul26-2023_v1.pdf (last visited Sept. 4, 2025).

[172] *See e.g.*, Transcript, Natco Pharma Limited Q1 FY23 Earnings Conference Call, Aug. 10, 2022, at 14, *available at* https://web.archive.org/web/20240617195801/https://www.natcopharma.co.in/wp-content/uploads/2022/08/Edelweiss-NatcoPharma-10Aug-2022.pdf (last visited Sept. 4, 2025) ("I think if we remove Lenalidomide which is the elephant in the room, the other portfolio has been steady, it has not, in fact may be declined slightly, but it has been steady, but we have made up with like launches in the other [rest of world] market, I think that is what has happened"); *id.* at 15 ("Lenalidomide doesn't make much of a difference because of the size of Teva's balance sheet. It makes a lot of difference for us because we are a smaller company").

[173] Natco Pharma Ltd. – Quick Insights Update, Feb. 17, 2025, at 2, *available at* https://www.way2wealth.com/reports/RR210120255bdd2.pdf (last visited Sept. 4, 2025).

283. The payment is also large (and unexplained) from the perspective of the amount provided by Celgene (the brand-side perspective). As a practical matter, during each of the four capped-volume periods, Celgene shares with the Allergan interests a specified quantum of sales that Celgene itself will not enjoy (*i.e.*, the market will buy however much of the generic supply that is made available, rather than purchase those needs from the brand, so to the extent that Celgene agree to share market with the generic, Celgene will not sell that share as the brand). And so, Celgene is functionally making a payment to the Allergan interests at a cost of what Celgene otherwise would have recognized from those sales. Since those brand sales would have occurred at higher prices, albeit only slightly higher due to restrained price competition created by the maintenance of a generic Revlimid output restriction, the payment from the brand perspective would be larger than the $2.2 billion payment from the generics' perspective.

284. From the brand perspective, the payment is large (indeed, much greater than the avoided litigation costs of Celgene). A large reverse payment of this magnitude by Celgene to a primary competitor is explained only by the fact that the Allergan interests dropped the patent challenge and agreed to delay entry until January 31, 2026.

285. The large reverse payment also takes forms other than Celgene splitting its monopoly profits through the capped-volume profit shares. These other forms include (i) the no-third-party-AG provision, (ii) the no-Celgene-AG provisions, (iii) the implicit across-the-board likelihood of no authorized generics competition, (iv) the contractual exclusivity provisions and (v) the timed entry, or "acceleration clause" provisions. While these provisions, or payments, work in tandem with the capped-volume profit-sharing, in theory, they also could work independently of it. In most of these situations, the value to the Allergan interests, even when taken independently, would be in the tens of millions of dollars. And these reverse payment

provisions represented an economic sacrifice by Celgene at least equal to the profits it would have earned by launching an AG under normal competitive conditions (approximately equal to what the Allergan interests would have expected to earn under competitive conditions).

J. **The immediate effects of the 2015 Celgene-Allergan agreement.**

1. Celgene's $25.6 billion stock price increase.

286. The anticompetitive consequences of an announced patent settlement for a public company can often be evaluated based on market reactions. Stock prices reflect investors' expectations about a company's future profits. A dramatic upward change in the stock price signals a sudden upward revision in profit expectations. Generally, in the absence of an alternative explanation, a sharp increase in the brand's stock price after a patent litigation settlement indicates that the settlement reduced generic competition compared to investors' expectations.[174]

287. On December 23, 2015, the day on which the Celgene-Allergan agreement was announced, Celgene's stock value leaped upward by 9.8%.[175] Celgene's stock value increase equates to a staggering increase in market capitalization of *$8.6 billion*, by far the largest observed increase in market capitalization after any drug patent infringement litigation settlement.[176] It was also the largest single-day percentage increase in Celgene's stock value in 2015. Because market capitalization represents the net present value of anticipated post-corporate tax earnings, the increase corresponds to approximately *$25.6 billion* in additional pre-tax

[174] *See* Drake, Starr, and McGuire, Do "Reverse Payment" Settlements Constitute an Anticompetitive Pay-for-Delay?" *International Journal of the Economics of Business*, 22(2), 2015, pp. 173–200 and McGuire, et al., "Resolving Reverse-Payment Settlements with the Smoking Gun of Stock Price Movements," *Iowa Law Review*, 101, 2016, pp. 1581-1599.

[175] Stock price and market capitalization data were downloaded from the Capital IQ database (https://www.spglobal.com/en) (last visited Dec. 22, 2025).

[176] AstraZeneca's increase in market capitalization of $2.9 billion is the second largest observed increase after a patent infringement litigation settlement. *See* Drake and McGuire, "Stock Price Evidence for Anticompetitive Effects in the Nexium 'Reverse Payment' Settlement," *Journal of Competition Law and Economics*, 12(4), 2016, pp. 735–47. Celgene's reaction to the Celgene-Allergan agreement was about three times larger.

nominal Revlimid profits for Celgene.[177]

288. There are no plausible explanations for the increase in Celgene's stock price after the Celgene-Allergan agreement other than that it increased U.S. Revlimid profits by reducing generic competition. Trends in the overall market do not explain the spike, as the S&P 500 increased by only 1.2% on the same day. Investors were not surprised by a competitive settlement that was better-than-expected for Celgene, as Natco's stock price went up, too, which would be unlikely if the settlement was worse-than-expected for Natco.

289. It is also not plausible that Celgene's market capitalization increased by $8.6 billion in a single day because the settlement simply resolved uncertainty without changing Celgene's expected profits. Investors can diversify their portfolios to protect against firm-specific risk, particularly in the context of patent litigation in which one of two parties wins and the other loses, so there is no reason in principle that reducing uncertainty should increase the value of a stock. Consistent with theory, settlements with no indication of a reverse payment have not significantly impacted brand firms' stock prices.

K. Celgene plans industry-wide allocation of the U.S. Revlimid market.

290. Having locked down the Celgene-Allergan agreement in December 2015, Celgene intended to induce later generic filers to accept the late January 2026 date for *bona fide* generic entry. To do so, Celgene planned to roll-in other, later generics into similar (but less generous) capped-volume profit shares, while maintaining deep scarcity of available generic lenalidomide in the U.S. After the Celgene-Allergan agreement became public, several other generic manufacturers submitted ANDAs seeking FDA approval of their own generic Revlimid, and they

[177] Celgene's tax rate on US revenue was 38.5% and it used a discount rate of 9%. $25.6 billion * (100.0%-38.5% tax rate) * (100% + 9% discount rate) ^ 7 years between 2016 and 2023 = $8.6 billion. To the extent the Celgene-Allergan agreement reduced generic competition after 2023, this number should be larger. To the extent the Celgene-Allergan agreement delayed the beginning of generic competition, this number should be smaller.

were subsequently sued by Celgene for patent infringement. Those included Dr. Reddy's (who likely had first-to-file exclusivity on two of the six dosages strengths) and Alvogen, Cipla, Apotex, Zydus, Sun, Aurobindo, Mylan, Torrent, Biocon, Hetero, Lupin, Hikma, Oncogen, Alembic, and Qilu (sometimes, the "Later Filers").

291. The Celgene-Allergan agreement showed to each Later Filer (i) that Celgene was willing to include anticompetitive "acceleration" or "poison pill" clauses in generic settlement agreements, (ii) that doing so was in Celgene's interests, (iii) that while Celgene would likely not improve upon the timing and quantity allocations reached with the Allergan interests, in exchange for a late agreed entry date in 2026, Celgene might agree to smaller but still lucrative allocations, (iv) given these deterrents and incentives, it was not in any Later Filer's interest to incur the costs associated with litigating Celgene's patents to conclusion, and (v) the deterrent effects of the restraints in the Celgene-Allergan agreement would increase as Celgene included them in additional settlement agreements.

292. Celgene's unlawful agreement with the Allergan interests set the stage for Celgene to orchestrate a market-wide allocation of the U.S. Revlimid market.

L. The 2019 Celgene-Alvogen profit share agreement.

293. On September 6, 2017, Celgene filed suit against Lotus Pharmaceutical Co., Ltd. and Alvogen Pine Brook, LLC (collectively, "Alvogen") after receiving Alvogen's paragraph IV certification notifying Celgene it had filed ANDA No. 210480, seeking FDA approval to market a generic Revlimid product.[178]

[178] Celgene's first lawsuit against Alvogen alleged infringement of the '517, '720, '977, '784, '740, '800, '217, '569, '886, '717, '498, '531, '095, '120, '621, and '622 patents. *Celgene Corp. v. Lotus Pharmaceutical Co., Ltd., et al.*, No. 2:17-cv-06842 (D.N.J.). On July 10, 2018, Celgene filed a second suit against Alvogen, asserting claims of infringement of the '357, '219, and '598 patents. *Celgene Corp. v. Lotus Pharmaceutical Co., Ltd., et al.*, No. 2:18-

294. On March 29, 2019, Celgene and Alvogen settled the Alvogen litigation by entering into an unlawful reverse-payment agreement that will delay full generic competition until January 2026 (the "Celgene-Alvogen agreement").

295. In exchange for Alvogen agreeing to delay unrestrained entry and full competition in the Revlimid market until January 2026, Celgene gave Alvogen a share of its monopoly profits. By paying Alvogen to abandon its challenge to Celgene's patents, Celgene prevented the risk of competition and eliminated the risk of patent invalidation or a finding of noninfringement. The only conceivable inference is that Celgene used valuable licensing to induce Alvogen to agree to delay generic competition until January 2026.

296. The reverse payment from Celgene to Alvogen is large and unjustified and can be publicly estimated by reference to estimates of the likely smaller reverse payment to Mylan. Publicly available and unintentionally disclosed information confirms that Mylan received a reverse payment of ***at least* $400 million**. This number was able to be publicly confirmed only when Mylan was forced to disclose (per the disclosure requirements of the Security and Exchange Commission) that the Indian plant that manufactures Mylan's lenalidomide received an FDA warning letter and that it would therefore suffer a shortfall of its expected **$200 million in 2025 alone from lenalidomide revenues.**[179] Without volume limits, and given that eleven competitors

cv-11518 (D.N.J.). Celgene's ANDA litigation against Alvogen is collectively referred to herein as the "Alvogen litigation."

[179] Viatris Q4 & Full Year 2024 Earnings Presentation, Feb. 27, 2025, at 2 & 29, *available at* https://investor.viatris.com/static-files/5c33d741-1505-4446-864d-f0ed3cae2525 (last visited Sept. 4, 2025) (specifically, Mylan disclosed that "Lenalidomide represents ~40% of the total estimated 2025 total revenues impact. . .[with] total estimated financial impact in 2025 of ~$500 million to total revenues" or $200 million); Transcript, Viatris Inc.'s Q4 FY24 Earnings Conference Call, Feb. 27, 2025, *available at* https://www.investing.com/news/transcripts/earnings-call-transcript-viatris-inc-q4-2024-misses-eps-estimates-stock-dives-93CH-3896811 (last visited Sept. 4, 2025) ("Lenalidomide, which after discussions with the FDA was not granted an exception, is the largest product impacted and represents approximately 40% of the total revenue impact. . . .").

would have been on the market for two to three years, Mylan would have only expected to be making ~$12 million in 2025.

297. Using Bristol Myers' (public) prices for Revlimid and its publicly disclosed annual revenue from 2021-2025, along with its statement that in 2025 "about 70% of the market will be supplied by generics," plaintiff can estimate the relative brand/generic share across the 2022-2026 period, with generic share gradually increasing over that period to its 70% point in 2025. Assuming Mylan's allocation rose roughly in proportion to generic share and its revenue rose accordingly from 2022-2024 to $200 million in 2025, the plaintiff can estimate total Mylan revenue, comparing against standard competitive assumptions of what Mylan would have made absent the unlawful restraints.

298. That Mylan's share would increase from 2022-2026 in proportion to the overall increase in generic market share is a reasonable assumption because (1) the most-favored licensee provision in the Celgene-Allergan agreement made the quantities allocated to the Allergan interests a reference point for all subsequent negotiations, and (2) the allocations allotted to the Allergan interests also rose roughly in proportion to generic share, starting in 2022 from a small-single digit and gradually increasing to roughly 30% of the market[180], and whereas the *total* generic share similarly has gradually grown from a small amount to roughly 70% of the market, per BMS, and (3) subsequent announcements about later settlements described a similar structure to the quantity of volume allocated across the four years.[181]

[180] Press Release, *Celgene Settles REVLIMID Patent Litigation,* dated December 22, 2015, *available at* https://web.archive.org/web/20230518150907/https://www.businesswire.com/news/home/20151222005986/en/ (last visited Sept. 4, 2025).

[181] *See* https://www.alvogen.com/newsroom/alvogen-settles-u.s.-revlimid-patent-litigation-with ("For each consecutive twelve-month period (or part thereof) following the volume-limited entry date until January 31, 2026, the volume of generic lenalidomide sold by Alvogen cannot exceed certain agreed-upon percentages. Although the agreed-upon percentages are confidential, they increase gradually each period to no more than a single-digit percentage in the final volume-limited period.") (last visited Sept. 4, 2025).

299. The competitive assumptions underpinning the estimate of a $400 million estimate of a Mylan reverse payment would apply to Alvogen, who litigated and launched at the same time (Sept 2022). And, as Mylan was the *last* of the generic Revlimid challengers to settle, it is reasonable to expect that it would have had the *least* leverage and thus that Celgene/Bristol Myers would have needed to offer the smallest reverse payment to induce settlement to Mylan. Thus, the Alvogen reverse payment can be estimated as at least $400 million.

300. Indeed, in its 2025 first quarter sales report, Alvogen (and parent company Lotus) reported new first quarter record for revenues, announcing that "[e]xports grew 14% YoY, fueled by sales of lenalidomide in the U.S."[182]

301. Because Celgene gave Alvogen valuable consideration to agree to the January 2026 entry date, the strong economic inference is that January 2026 is later than the entry date that the parties would have agreed to based solely on their assessment of the strength of Celgene's patents. Except as consideration for Alvogen agreeing to the January 2026 entry date, the payment from Celgene to Alvogen is unexplained.

302. The payment to Alvogen is also large (and unexplained) from the perspective of the amount provided by Celgene (the brand-side perspective). As a practical matter, during each of the four capped-volume periods, Celgene shares with Alvogen a specified quantum of sales that Celgene itself will not enjoy (*i.e.*, the market will buy however much of the generic supply that is made available, rather than purchase those needs from the brand, so to the extent that Celgene agree to share market with the generic, Celgene will not sell that share as the brand). And so, Celgene is functionally making a payment to Alvogen at a cost of what Celgene otherwise would have recognized from those sales. Since those brand sales would have occurred at higher prices,

[182] *See* https://www.lotuspharm.com/newsroom/1q25-earnings-en (last visited Sept. 4, 2025).

albeit only slightly higher due to restrained price competition created by the maintenance of a generic Revlimid output restriction, the payment from the brand perspective would be larger (indeed, much greater than the avoided litigation costs of Celgene) than the $400 million payment to Alvogen from the generics' perspective.

303. A large reverse payment of this magnitude by Celgene to a primary competitor is explained only by the fact that Alvogen dropped the patent challenge and agreed to delay entry until January 31, 2026.

304. When it entered into the Celgene-Alvogen agreement, Alvogen was aware of the material terms of the Celgene-Allergan agreement. The terms of the Celgene-Alvogen agreement made economic sense for Alvogen only because it knew that the Celgene-Allergan agreement operated to restrain competition in the Revlimid market and that Celgene, Teva/Natco, and likely some of the Later Filers would share among them the supra-competitive profits from Revlimid sales.

305. By entering into the Celgene-Alvogen agreement, Alvogen agreed to join the conspiracy to allocate the market for Revlimid and its generic equivalents.

M. **The 2020 Celgene-Dr. Reddy's profit share agreement.**

306. Before addressing the agreement Celgene reached with Dr. Reddy's, further background regarding the weak patent position Celgene faced with Dr. Reddy's is outlined below.

1. The 2016–2019 state of the Dr. Reddy's patent litigation.

307. On October 20, 2016, Celgene filed suit against Dr. Reddy's Laboratories, Ltd., and Dr. Reddy's Laboratories, Inc. (collectively, "Dr. Reddy's") after receiving Dr. Reddy's paragraph IV certification notifying Celgene it had filed ANDA No. 209348, seeking FDA

approval to market a generic Revlimid product.[183]

308. As the first generic manufacturer to file an ANDA for the 2.5 mg and 20 mg dosage strengths of generic Revlimid, the Dr. Reddy's ANDA was likely entitled to the 180-day exclusivity period as to those strengths. If acting competitively, Dr. Reddy's was motivated to enter the market as early as possible and to compete for sales volume by reducing the price of its generic Revlimid product.

309. By early-2019, the patent picture in the Dr. Reddy's litigation had matured, and the parties had clear views of the substantial risks Celgene faced. Expert opening and responsive reports had been served, IPRs had already been decided, and the crystal form patents asserted by Celgene had been whittled down to one; the '800 patent. While Dr. Reddy's raised numerous meritorious arguments, all of which would have increased the risk to Celgene of litigation loss, for brevity's sake the following subsections highlight the key reasons why Celgene faced substantial risk of an at-risk launch by Dr. Reddy's.

a. The REMS patents (expiry August 28, 2018, and October 23, 2020).

310. By early 2019, the PTAB had invalidated the two lead patents from the '501 and '720 patent families due to obviousness. At this point, the parties would have been virtually certain that those patents were not a barrier to entry, and indeed the Federal Circuit affirmed the invalidity of the lead patents (except for one claim which Celgene then dropped) on July 30, 2019. The parties agreed to stay these claims, and the last of the REMS patents expired shortly

[183] Celgene's first lawsuit against Dr. Reddy's alleged infringement of the '800, '217, '569, '498, '095, '621, and '622 patents. *Celgene Corp. v. Dr. Reddy's Labs., Ltd, et al.*, No. 2:16-cv-07704 (D.N.J). On July 20, 2017, Celgene filed a second suit against Dr. Reddy's, asserting claims of infringement of the '740, '717, and '120 patents. *Celgene Corp. v. Dr. Reddy's Labs., Ltd., et al.*, No. 2:17-cv-05314 (D.N.J.). On April 12, 2018, Celgene filed a third suit against Dr. Reddy's, asserting claims of infringement of the '720, '977, '784, '886, and '531 patents. *Celgene Corp. v. Dr. Reddy's Labs., Ltd., et al.*, No. 2:18-cv-06378 (D.N.J.). Celgene's ANDA litigation against Dr. Reddy's is collectively referred to herein as the "Dr. Reddy's litigation."

after the Celgene-Dr. Reddy's Agreement.

b. The Method of Treatment patents (expiry April and October 2023).

311. By early 2019, Dr. Reddy's had served opening and reply expert reports detailing the invalidity of the method of treatment patents, including those related to myelodysplastic syndromes ("MDS")[184] and multiple myeloma ("MM").[185]

312. Dr. Reddy's had developed arguments and evidence beyond what Natco had been able to discover and assert, such as Celgene press releases that disclosed the use of lenalidomide in combination with dexamethasone to treat MM, along with the disclosures that dosage levels, mirroring or in line with those claimed in Celgene's MM and MDS patents, were well tolerated and had been effective.[186]

313. On August 3, 2018, Dr. Reddy's filed IPRs seeking to invalidate the three MDS patents. On February 11, 2019, in three short decisions that mirror each other, the PTAB declined to institute proceedings on a sole criterion, agreeing with Celgene that Dr. Reddy's had not put forward sufficient evidence to establish that Celgene's own press releases had in fact been published (*i.e.*, made publicly available).

314. While Celgene's technical argument allowed it to evade scrutiny at the PTAB, Dr. Reddy's was easily able to overcome this evidentiary hiccup in the district court litigation. Within months of the PTAB decision, Dr. Reddy's obtained a sworn affidavit showing the public availability of the Celgene Press Releases on the Celgene Investors Relations webpage as well as a sworn Certificate of Authenticity showing the public availability of the Celgene Press Releases

[184] The MDS patents at issue were the '740, '717, and '120 patents. *See* 2:17-cv-05314.

[185] The MM patents at issue were the '569, '095, '498, '621, and '622 patents. *See* 2:16-cv-07704.

[186] Press Release, Celgene Corp., Positive Interim Results Presented at the VIIIth International Myeloma Workshop on Celgene Corporation's Lead IMiD(TM) (Revlimid(TM)) (May 8, 2001).

via LexisNexis—both supporting public availability before the priority date. Thus, Celgene faced a material risk of invalidation of its MDS patents, which could have opened the door to a possible skinny label, if not by Dr. Reddy's than certainly by another Later Filer.

315. Dr. Reddy's also honed its strongest arguments against the MM patents, as the press releases described the safe and effective treatment of MM at the relevant dosing amounts. However, unlike the MDS patents, the independent claims of many of the MM patents (and instructions on the Revlimid label) had an additional limitation—they called for a cyclical dosing schedule with lenalidomide administered on days 1-21 of a 28-day cycle, and thereby incorporating a 7-day rest period for patients to recover from the harms of the cancer drug.

316. Thus, Dr. Reddy's presented a material risk of invalidating the MDS and MM patents.

c. The Crystal Form B patent (expiry April 2027).[187]

317. Celgene's '800 patent family describes and claims crystalline forms of lenalidomide. Independent claim 1 of the '800 patent claims "crystalline [lenalidomide] hemihydrate," and each of its dependent claims (2–14) claim that crystalline lenalidomide hemihydrate having additional specified analytical properties. Dr. Reddy's ANDA product was an amorphous form of lenalidomide of its own invention, *i.e.*, a product wherein its compounds did not arrange themselves in crystal form.

318. Dr. Reddy's ANDA specification and quality control testing procedures, which ensure that the active lenalidomide ingredient in its ANDA product consist of only amorphous lenalidomide, should have ended the infringement inquiry.

[187] Celgene did not assert any of the Form A crystal form patents against Dr. Reddy's. These patents (the '357, '219, and '598) therefore posed no barrier to an at-risk launch by Dr. Reddy's.

319. In addition to its rock solid noninfringement defense to the claims of the '800 patent, Dr. Reddy's had strong invalidity defenses that the claims of the '800 patent were invalid as indefinite, lacking adequate written description, and not enabled as construed under Celgene's earlier successful construction for the meaning of "hemihydrate."

320. In short, Celgene's '800 patent did not present any legitimate barrier to entry of Dr. Reddy's amorphous ANDA product. Furthermore, continued litigation would have likely invalidated the '800 patent. And given the '800 patent was the only Crystal Patent at issue, Dr. Reddy's was guaranteed to have been able to launch at unrestrained volumes by October 2023 at the very latest, regardless of how the court ruled on the method of treatment patents.

321. Based on these strong patent positions, Dr. Reddy's expected to launch by the early 2020s under standard competitive conditions.

322. Indeed, Celgene has not contested these noninfringement allegations, nor that, absent their illegal conduct, Celgene's patents could not have prevented at least Dr. Reddy's from launching (in unlimited quantities, without a license) by October 2023. And since Natco and Alvogen settled for acceleration clauses prior to the Dr. Reddy's settlement, at the bare minimum (uncontested), these three generics would have launched and driven down prices starting in October 2023 at the very latest.[188]

323. However, negotiation with Celgene, including likely disclosure of some of the terms of the Celgene-Allergan agreement, revealing the incentives created within for later filers to join the output restriction and abandon their patent challenges, persuaded Dr. Reddy's to accept a

[188] *See Compare* Redacted Opposition to Motion to Dismiss, *In re Revlimid Purchaser Antitrust Litig.*, No. 19-cv-7532 (D.N.J. Mar. 4, 2025), ECF No. 557 at 10-12 & n.8, *with* Redacted Reply in Support of Motion to Dismiss, ECF No. 559 (does not contest patent merit allegations); Redacted Opposition to Motion to Dismiss, No. 19-cv-7532, ECF No. 557 at 37 (settlements had acceleration clauses). Dr. Reddy's settled in 2020, after the 2015 Natco settlement and 2019 Alvogen settlement.

reverse payment, join the conspiracy, and settle for a competitive launch date (with unrestrained quantities) of January 31, 2026.

2. The terms of the Celgene-Dr. Reddy's agreement.

324. On September 16, 2020, Celgene and Dr. Reddy's reached an agreement (the "Celgene-Dr. Reddy's agreement"). The Celgene-Dr. Reddy's agreement was memorialized in three documents—a "Settlement Agreement," a "License Agreement," and a "REMS Services Agreement"—each of which was executed and effective on September 16, 2020. The documents were negotiated simultaneously and are interdependent.

325. The participants to the Celgene-Dr. Reddy's agreement were, on the one hand, Celgene Corporation and Celgene International Sarl II (the Celgene entity holding the applicable patent licenses) and, on the other hand, Dr. Reddy's Laboratories, Limited, and Dr. Reddy's Laboratories, Inc.

326. *Settlement of patent challenge.* Under the Celgene-Dr. Reddy's agreement, Dr. Reddy's settled the litigation and dropped its challenges to the Celgene Revlimid patents. As a result, Celgene avoided the risk of loss in those cases and avoided the risk of competition that would have ensued from a litigation loss. (Settlement Agreement and Consent Decrees, *et passim*).

327. *Delay of generic entry*. Under the Celgene-Dr. Reddy's agreement, Dr. Reddy's would delay competitive entry until January 31, 2026, the same as the Allergan interests.

328. *Capped-volume sharing*. Under the Celgene-Dr. Reddy's agreement, the parties accomplished a profit share from Celgene to Dr. Reddy's through a capped-volume sharing arrangement. The exact volumes are subject (as above) to strict confidentiality. However, the parties have announced that:

> Celgene has agreed to provide DRL with a license to Celgene's patents required to manufacture and sell certain volume-limited amounts of generic lenalidomide in the U.S. beginning sometime after the March 2022 volume-limited license date that Celgene previously provided to Natco. The specific volume-limited license date and percentages agreed-upon with DRL were not disclosed and are confidential. In addition, Celgene has agreed to provide DRL with a license to Celgene's patents required to manufacture and sell an unlimited quantity of generic lenalidomide in the U.S. beginning no earlier than January 31, 2026.[189]

329. In exchange for Dr. Reddy's agreeing to abandon its challenge to Celgene's patents, Celgene gave Dr. Reddy's a large and unjustified reverse payment. The capped-volume shares were intended to—and in the end, in fact did—share with Dr. Reddy's Celgene's high-priced Revlimid/lenalidomide profits.

330. The agreement also provided Dr. Reddy's with most-favored-entry and most-favored-quantity protections, the details of which are confidential.

331. Similar to the agreement with the Allergan interests, Celgene's agreement with Dr. Reddy's also contained:

- *A de facto no-AG provision*
- *Final court decision trigger*.
- *At-risk entry provision*
- *"License" to the patents*.
- *Integrated exchange of promise*s.
- *Confidentiality*.

3. The expected anticompetitive consequences of the Celgene-Dr. Reddy's agreement.

[189] Bristol Myers Squibb Announces Settlement of U.S. Patent Litigation for Revlimid (lenalidomide) with Dr. Reddy's, *available at* https://www.businesswire.com/news/home/20200917005211/en/Bristol-Myers-Squibb-Announces-Settlement-of-U.S.-Patent-Litigation-for-REVLIMID%C2%AE-lenalidomide-With-Dr.-Reddy%E2%80%99s (last visited Sept. 4, 2025).

332. There are a series of reasonably likely, and expected, anticompetitive consequences from the Celgene-Dr. Reddy's agreement that were apparent to the parties at the time the agreement was reached. The Celgene-Dr. Reddy's agreement has a series of anticompetitive provisions that, taken together against the realities of pharmaceutical regulation and industry economics, were designed to have, have had, and will continue to have substantial anticompetitive consequences.

333. *First*, the Celgene-Dr. Reddy's agreement was intended to have—and as will be shown, did have—the effect of enabling Dr. Reddy's to enter the U.S. lenalidomide market with allocated and capped-volume shares of generic product enabling it to charge prices magnitudes higher than would be possible in an unrestrained market, thereby providing a payoff for Dr. Reddy's to drop its patent challenge and delay entry until 2026.

334. *Second*, through a combination of provisions, the Celgene-Dr. Reddy's agreement eliminates the likelihood that Celgene will launch a lenalidomide AG during any period (thereby maintaining value to Dr. Reddy's to delay its generic entry).

335. *Finally*, Dr. Reddy's agreed to delay unrestrained market entry until January 31, 2026 in exchange for a reverse payment. The delay not only impacts entry of Dr. Reddy's ANDA product, but also has the effect of bottlenecking other generics for the two of six dosages forms for which Dr. Reddy's could have the 180-day exclusivity. The magnitude of the anticompetitive effect from this delay is unprecedented, amounting in nominal dollar losses well in excess of $20 billion.

336. *In sum*, the Celgene-Dr. Reddy's agreement—both in its design and in its final integrated form ensure that later forces do not impinge on a basic, high level of value to the generic, here Dr. Reddy's.

4. The reverse-payment nature of the Celgene-Dr. Reddy's agreement.

337. The Celgene-Dr. Reddy's agreement may fairly be characterized as both an unlawful market-allocation agreement and as an unlawful reverse-payment agreement.

338. The Celgene-Dr. Reddy's agreement is unlawful under the Supreme Court's decision in *FTC v. Actavis* because the provisions of the agreement effect a large and unexplained reverse payment from Celgene to Dr. Reddy's, in exchange for which Dr. Reddy's agreed to delay bona fide generic competition until January 2026. The payment takes several forms.

339. The large reverse payment primarily takes the form of Celgene splitting its monopoly profits with Dr. Reddy's while the latter waits for competitive generic entry in January 2026 (a profit-split achieved through the capped-volume profit shares and related provisions in the agreement). Whether the payment is large (or unjustified) may be viewed from the perspective of the value to Dr. Reddy's (the generic-side perspective), or from the perspective of the amount provided by Celgene (the brand-side perspective).

340. In exchange for Dr. Reddy's agreeing to delay unrestrained entry and full competition in the Revlimid market until January 2026, Celgene gave Dr. Reddy's a share of its monopoly profits. By paying Dr. Reddy's to abandon its challenge to Celgene's patents, Celgene prevented the risk of competition and eliminated the risk of patent invalidation or a finding of noninfringement. The only conceivable inference is that Celgene used valuable licensing to induce Dr. Reddy's to agree to delay generic competition until January 2026.

341. Estimating the precise size of the Dr. Reddy's reverse payment from publicly available information is difficult. Nonetheless, precision is not needed because publicly available information confirms that the size of the payment is extremely large, and *at least* $400 million.

342. Similar to Alvogen, this estimate of the floor of the payment can be estimated from

greater competitive posture and leverage Dr. Reddy's possessed at settlement vis a vis Alvogen, given that it had invented an amorphous crystalline form that did not infringe Celgene's polymorph patents and was virtually certain to be able to launch at unrestrained quantities by October 2023 *at the latest* (uncontested by either Celgene or Dr. Reddy's).[190]

343. Since Mylan (the eighth generic to settle) received a reverse payment of *at least* $400 million, Dr. Reddy's likely received a reverse payment of at least $400 million as well.

344. Dr. Reddy's, however, almost certainly received more than a $400 million reverse payment. In addition to its rock solid non-infringement argument on all relevant patents that expired after October 2023, Dr. Reddy's was a first-filer on two of six Revlimid strengths, and was just the third to settle, meaning it had significantly greater leverage than Mylan to extract a large reverse payment.

345. Given its strong leverage, and Celgene's motivation to build the Generic Revlimid Output Restriction (and reap the financial gains of four more years of greater brand sales), Dr. Reddy's likely obtained a reverse payment at least roughly twice the size of Mylan ($800 million), which would still be less than half of the other First-Filer's reverse payment (Natco/Teva/Allergan's approximately $2.2 billion reverse payment). This coheres with analyst estimates in mid-2023 that Dr. Reddy's had been "achieving 6% kind of volume share," in 2023.[191]

346. Regardless of the ultimate details, the payment was large and unexplained and was paid to eliminate the risk that Dr. Reddy's would have launched earlier, triggering acceleration

[190] *Compare* Redacted Opposition to Motion to Dismiss, *In re Revlimid Purchaser Antitrust Litig.*, No. 19-cv-7532 (D.N.J. Mar. 4, 2025), ECF No. 557 at 10-12 & n.8, *with* Redacted Reply in Support of Motion to Dismiss, ECF No. 559 (does not contest patent merit allegations).

[191] Transcript, Dr. Reddy's Laboratories, Ltd. Q1 FY24 Earnings Conference Call, Jul. 26, 2023, at 8, *available at* https://www.drreddys.com/cms/cms/sites/default/files/2023-07/DrReddys-Jul26-2023_v1.pdf (last visited Sept. 4, 2025).

clauses in other generics' (Natco/Allergan/Teva and Alvogen) settlement agreements and leading to more and earlier competition.

347. The payment is also large from the perspective of Celgene.

348. As above, during each of the four capped-volume periods, Celgene shares with the Dr. Reddy's a specified quantum of sales that Celgene itself will not enjoy (*i.e.*, the market will buy however much of the generic supply that is made available, rather than purchase those needs from the brand, so to the extent that Celgene agree to share market with the generic, Celgene will not sell that share as the brand). And so, Celgene is functionally making a payment to Dr. Reddy's at a cost of what Celgene otherwise would have recognized from those sales. Since those brand sales would have occurred at higher prices, albeit only slightly higher due to restrained price competition created by the maintenance of a generic Revlimid output restriction, the payment from the brand perspective would be larger (indeed, much greater than the avoided litigation costs of Celgene) than the at least $800 million payment to Dr. Reddy's from the generics' perspective.

349. A large reverse payment of this magnitude by Celgene to a primary competitor is explained only by the fact that Dr. Reddy's dropped the patent challenge and agreed to delay entry until January 31, 2026.

N. The 2020–2021 Celgene agreements with Later Filers.

1. Over two years, Celgene bought out the remaining would-be generic entrants with similar reverse payments primarily in the form of profit shares valued, based on publicly available information, at least hundreds of millions of dollars.

350. After reaching the agreements with the Allergan interests, Alvogen, and Dr. Reddy's, Celgene had now established a method by which to buy off would-be generic competition to Revlimid. Over the next two years, Celgene offered the remaining Later Filers their own shares of the monopoly profits in exchange for keeping the late, 2026 entry for *bona*

fide generic competition. With respect to Alvogen, Dr. Reddy's, Cipla, Apotex, Zydus, Sun, Aurobindo, Mylan, Biocon, and Hetero, Celgene gave each the valuable opportunity to sell a limited quantity of generic Revlimid capsules in a price-protected market at near-brand-level prices during one or more specified periods prior to January 2026.

351. Similar to Alvogen, the value of the reverse payments to Cipla, Apotex, and Zydus can be estimated by reference to Mylan's. Like Alvogen and Mylan, Cipla, Apotex, and Zydus also launched in September 2022 and litigated at the same time. Cipla, Apotex, and Zydus therefore faced similar competitive conditions, all extracted the same launch date, and—as the fourth, fifth, and sixth to settle—would have exerted greater leverage than Mylan (ninth to settle) and hence extracted larger reverse payments to induce settlement. Thus, the reverse payments are estimated to be *at least* $400 million, and likely much more, based on publicly confirmable information.

352. The assumptions underpinning the Mylan estimates would apply to Alvogen, Cipla, Apotex, and Zydus as well, because they were four generic manufacturers who litigated and launched at the same time as Mylan. As Mylan was the last of these generics to settle, it is reasonable to expect—given the pile-on effect of acceleration clauses in all of the Later Filer settlements[192] to reduce the expected amount of profit of later settlers—that Mylan would have the least leverage and would thus that Celgene/Bristol Myers would offer the smallest reverse payment to induce settlement. As Mylan had at least a $400 million reverse payment, it is likely that the reverse payments for these four other generic manufacturers would have far larger reverse payments.

[192] Redacted Opposition to Motion to Dismiss, No. 19-cv-7532, ECF No. 557 at 37 (settlements had acceleration clauses).

353. As to Sun, Hetero, and Aurobindo, publicly available and unintentionally disclosed information confirms that each were granted generic Revlimid allocations and launched beginning in Spring and October 2023. Each received reverse payments of at least $160 million.

354. As the eighth, ninth, and tenth generics on the market, and launching throughout 2023 instead of in September 2022, it is reasonable to expect that Sun, Hetero, and Aurobindo had smaller allocations than Mylan (the seventh generic). Indeed, an Aurobindo executive confirmed that "we are in the third wave. We are expected to be much lower . . .."[193]

355. The minimum amount of the Sun, Hetero, and Aurobindo reverse payments is confirmable from publicly available information, including Aurobindo's statements about its expected revenue in comparison to the competitive dynamics it would have faced as the likely *eleventh* generic (10 generics + an AG) product to launch (and admission that "the pricing remains constant", see below).

356. Specifically, an Aurobindo executive implicitly disclosed that it was forecasting Revlimid would provide annual revenue reaching $50-150 million in revenue over the limited competition period. "So, first thing is, we will treat these as two different things. One is, how do we grow the base business. That is the 500, how we can go to 550 and all, plus Revlimid. Put together, it might be 600-650."[194] Conservatively estimating $100 million in 2025 (period with the greatest generic market share per Bristol Myers's statements), the reverse payment is at least ~$160 million. Given that Hetero's and Sun's competitive postures were similar to Aurobindo's, Sun and Hetero likely received a similarly sized, if not bigger (both launching in Spring as the

[193] *See* Transcript, Aurobindo Pharma Q1 FY24 Earnings Conference Call, Aug. 14, 2023, at 12, *available at* https://www.aurobindo.com/api/uploads/conferencecalltranscripts/Aurobindo%20Q1%20FY24%20con%20call%20Transcript.pdf (last visited Sept. 4, 2025).

[194] *Id.* at 10.

eighth and ninth generics), reverse payment.

357. Hetero and Sun litigated at the same time as Aurobindo and would have expected to launch with similar numbers of competitors, to gain similar market share at similar prices, and earn roughly similar revenue. As Sun and Hetero launched before Aurobindo, its payment would have likely been more.

358. Furthermore, publicly available price and volume snapshots from IQVIA show that all the generic Revlimid manufacturers are selling at prices multiple times higher than would be observed in a competitive market, and at limited volumes.[195] *See infra* V.O (generics are selling at over $500 per pill rather than the expected less than $50 per pill).

359. Indeed, the generic manufacturers have over the past several years regularly exhausted their quotas within a certain financial quarter, resulting in unpredictable quarter to quarter growth and decline, which are regularly attributed to the sporadic nature of the sales under the annual volume quotas.[196]

360. The agreements above (Allergan interests, Dr. Reddy's, Alvogen, Mylan, Cipla, Zydus, Apotex, Sun, Hetero, and Aurobindo) are all individually unlawful reverse payment agreements.

361. The agreements are also collectively part of a single overarching agreement to delay lenalidomide competition and instead maintain lenalidomide prices at supracompetitive levels.

[195] Since IQVIA does not cover all sales, it is impossible to know what the exact volume numbers are, but it is clear that the amounts are relatively small, and for most manufacturers stop for months at a time.

[196] *See e.g.*, Transcript, Dr. Reddy's Laboratories Lim. Q1 FY24 Earnings Conference Call, Jan. 25, 2023, *available at* https://www.insidermonkey.com/blog/dr-reddys-laboratories-limited-nyserdy-q1-2024-earnings-call-transcript-1172238/3/ (last visited Sept. 4, 2025) ("I have the full knowledge of the quantities obviously and I cannot share that as per our agreement. But what I can say is that these kind of levels of sales of Lenalidomide likely to continue and fluctuate from a quarter-to-quarter based on the supplier, based on the orders and based on the preference of customers").

362. As above, the Revlimid agreements for profit shares contained for selective confidentiality. This selective confidentiality not only allowed Celgene to coordinate with each of the above generic manufacturers, but also allowed each generic manufacturer to know that each party had the same material terms and would abide by the agreement to limit lenalidomide supply and maintain high prices through January 31, 2026.

363. The overarching nature of the conspiracy is also buttressed by the acceleration clauses in each (as to both launch date and triggering of the lifting of volume restrictions) agreement.

364. Finally, the overarching nature is also buttressed by the use of the most-favored licensee clause in at least the Celgene-Allergan agreement. As above, such most-favored nation clauses can oftentimes be used as tools to coordinate horizontal market collusion, such as the output restriction here alleged.

2. Publicly available information suggests that the reverse payments are much larger than the hundreds of millions of dollars that is publicly confirmable, regardless of how the pie of Revlimid profits was specifically divided.

365. Although the above alleged reverse payments are all large, the publicly available information on the total generic revenue and hence total generic reverse payments, are far larger than what is here alleged based on publicly disclosed information. The total generic revenue and reverse payments, based on the inferable *total generic volume* and the publicly observed prices at which generic manufacturers are selling lenalidomide, indicates that the reverse payments to Alvogen, Dr. Reddy's, Cipla, Apotex, and Zydus received far more than the $400 million payments publicly *confirmable* above[197], and that Sun, Hetero, and Aurobindo received far more

[197] As above, the key data points for valuing the reverse payments are (1) publicly observed (steady) prices for Revlimid and generic Revlimid, (2) publicly disclosed BMS revenue from 2021-2025 (allowing for an estimate of both the total lenalidomide market size and the generic/brand market share split across those years), and (3) the February 2025 disclosure of Mylan's anticipated 2025 revenue.

than the $165 million payments confirmable above as well.[198]

366. This is because the above alleged reverse payments, if totaled, would only account for roughly $2.874 billion of the conservatively estimated $3.652 billion the Revlimid Generics are estimated to be making *in 2025 alone*.[199] Thus, while $160 million to Hetero and Aurobindo is publicly confirmable, the likely reverse payments for Hetero, Aurobindo, and Sun total $219-$256 million.

367. These generic manufacturers would only be expected to be making ~$12 million in 2025 absent the volume limits, and it is not publicly knowable how Celgene/Bristol Myers doled out the remaining allocations that would account for the $778 million in estimated 2025 generic Revlimid revenue between the eight generics *other* than Mylan.[200] To illustrate, if the allocations were divided evenly, Aurobindo and Hetero's reverse payment would be at least $256 million. And if the generics that launched in September 2022 had allocations twice the size of those that launched in 2023, Aurobindo and Hetero's reverse payment would be $219 million.

368. In sum, given the observed prices in comparison to the generic market share inferable from BMS's price and reported Revlimid revenues, there is significant sums of generic profits unaccounted for in Plaintiff's conservative estimates of the reverse payments. However, since each of the alleged and observed reverse payments are large, it does not legally matter the

[198] Since the valuation of the reverse payment to the Allergan interests is based on a comparison of the multiple publicly reported investor analyses of Natco's revenue (itself reliable based on the few numbers of drugs Natco marketed in the US) and standard market assumptions regarding competitive markets, the estimated reverse payment to the Allergan interests is likely roughly accurate.

[199] This is publicly knowable because the volume of the market is growing while the price is constant (~$574 or 84% of the brand price from 2021, when Bristol Myers made $8.695 billion), and Bristol Myers itself said that generics will supply 70% of the market in 2025. Thus, even if the price fell from the observed 2024 price of ~$574 to ~$410.40 (60% of brand price from 2021), 70% of the market would still account for $3.652 billion.

[200] The same would be true for the proportionally smaller payments doled out between 2022-2024 to these Later Filers – the amount actually being transferred is likely greater than here alleged because we know from prices and inferable generic market share that the Later Filers are making more generic lenalidomide profit than here alleged.

exact value of each reverse payments. *I.e.*, regardless of whether Apotex has received a $400 million payment and Cipla a $600 million payment, or *vice versa*, all have received large and unjustified reverse payments.

369. The payments to the Later Filers are also large from the perspective of Celgene.

370. As above, during each of the four capped-volume periods (and three for Sun, Hetero, and Aurobindo), Celgene shares with the Later Filers a specified quantum of sales that Celgene itself will not enjoy (*i.e.*, the market will buy however much of the generic supply that is made available, rather than purchase those needs from the brand, so to the extent that Celgene agree to share market with the generic, Celgene will not sell that share as the brand). And so, Celgene is functionally making a payment to the Later Filers at a cost of what Celgene otherwise would have recognized from those sales. Since those brand sales would have occurred at higher prices, albeit only slightly higher due to restrained price competition created by the maintenance of a generic Revlimid output restriction, the payment from the brand perspective would be larger (indeed, much greater than the avoided litigation costs of Celgene) than the at least $400 million payments (to Cipla, Apotex, and Zydus), or the at least $160 million payments (to Sun, Hetero, and Aurobindo) from the generics' perspective.

371. A large reverse payment of this magnitude by Celgene to a primary competitor is explained only by the fact that Later Filers dropped their patent challenges and agreed to delay entry until January 31, 2026.

372. The restraints in the Later Filer agreements, together with the restraints in the Celgene-Allergan agreement, ensured that the price of generic Revlimid would stay substantially above the competitive level during the payment periods. Because Later Filers can sell only a limited quantity of generic Revlimid capsules during the periods prior to January 2026, they have

no incentive or ability to price-compete for market share—*i.e.*, reduce their price to increase their sales volume.

373. In exchange for Later Filers agreeing to delay unrestrained entry and full competition in the Revlimid market until January 2026, Celgene gave Later Filers shares of its monopoly profits. By paying Later Filers to abandon their challenges to Celgene's patents, Celgene prevented the risk of competition and eliminated the risk of patent invalidation or a finding of noninfringement. The only conceivable inference is that Celgene used valuable licensing to induce Later Filers to agree to delay generic competition until January 2026.

374. Because Celgene gave Later Filers valuable consideration to agree to the January 2026 entry date, the strong economic inference is that January 2026 is later than the entry date that the parties would have agreed to based solely on their assessment of the strength of Celgene's patents. Except as consideration for Later Filers agreeing to the January 2026 entry date, the payments from Celgene to Later Filers are unexplained.

375. When it entered into the Celgene-Later Filer agreements, Later Filers were aware of the material terms of the Celgene-Allergan agreement. The terms of the Celgene-Later Filer agreements made economic sense for Later Filers only because they knew that the Celgene-Allergan Agreement operated to restrain competition in the Revlimid market and that Celgene, Teva/Natco, and the other Later Filers would share among them the supra-competitive profits from Revlimid sales.

376. By entering into the Celgene-Later Filers agreements, Later Filers agreed to join the conspiracy to allocate the market for Revlimid and its generic equivalents. Like the prior agreements, the Celgene-Later Filer agreements included a de facto no-AG agreement, which

Celgene has abided by for nearly three and a half years. It also contained acceleration clauses.[201]

377. As with the payment from Celgene to the Allergan interests, Celgene's reverse payments to the Later Filers do not increase overall output, significantly reduce price, or increase consumer choice. The payments merely substitute the generic manufacturers as the sellers of Revlimid units at near-brand-level prices, while preserving Celgene's massive monopoly profits over the remaining units and sharing them with the Later Filers who received allocations.

378. Celgene also knew it would be able to bring other generics into the scheme because the acceleration clauses reduced the incentive for generic challengers to litigate *through final court judgment and launch* and/or launch at risk.

379. As above, acceleration clauses can have a serial, pile-on effect for each subsequent generic. To illustrate, a generic like Apotex (fifth to settle) would know that launching (at risk or after prevailing at trial) would trigger the launch of *five* competing generics (those that had already settled – the Allergan interests, Alvogen, Dr. Reddy's, Cipla, and likely an authorized generic by Celgene). Under such competitive circumstances, it would only expect to gain ~10% market share or less and sell at a severely decreased price (e.g., 15% of pre-2022 brand price). It would thus take a smaller allocation and promise of future revenue streams from Celgene to induce Apotex to settle as compared to the previous four settlers. This pile-on effect becomes more pronounced as generics settled – e.g., Mylan would trigger nine competitors, Hetero would trigger eleven competitors, etc. Thus, it is unsurprising that the thirteenth through seventeenth generic manufacturers to settle may not (the information is confidential and these entities have not launched as of the date of this complaint) have received volume-limited allocations for the output

[201] Redacted Opposition to Motion to Dismiss, No. 19-cv-7532, ECF No. 557 at 37 (settlements had acceleration clauses).

restriction period – they would not have expected to make significant revenues by launching at risk or after a final court judgment, so would have less leverage to extract a reverse payment.

380. That some of the Later Filers litigated through expert reports and filed *inter partes* reviews against *only* the method of treatment patents does not diminish the pile-on effect of the acceleration clauses,but rather illustrates that Celgene's negotiations with the generics occurred on multiple dimensions. Because of the structure of the output restriction, generics were disincentivized from launching at full quantities (limiting potential generic entry) and triggering unlimited competition and less revenue. Yet litigating also allowed generics to gain leverage over Celgene and extract larger reverse payments (while still keeping generic supply below generic demand).

3. The Later Filers had strong patent defenses.

381. The Later Filers had strong patent defenses. Armed with the arguments and discovery from the Natco litigation, as well as the arguments and facts confirmed in the EPO revocations of Celgene's MM and polymorph patents, the Later Filers built upon the already strong invalidity challenges.

382. Indeed, ten other ANDA filers—eight of whom were induced to settle with profit shares—filed ANDAs for anhydrous products.[202] Thus, at least these ten Later Filers would have been able to (1) avoid infringement of the '800 patent altogether, as Natco had done, and (2) invent around the anhydrous patents as Natco had done, particularly given the narrow claim construction issued by the district court for the term "Form A."

383. For instance, Hetero developed its own unique anhydrous lenalidomide polymorph. In 2019, the EPO issued Hetero EP 2,688,649 covering a polymorphic form Hetero

[202] Zydus, Cipla, Lotus, Sun, Apotex, Mylan, Lupin, Hetero, Aurobindo, and Hikma.

called "Form HI", finding it novel and distinguishable from both Celgene's Form A and Natco's Form I.[203] Thus, Hetero had a meritorious non-infringement defense to any valid claim of Celgene's polymorph patents.

384. Additionally, five of the latest Later Filers (Torrent, Hikma, Oncogen, Alembic, and Qilu, together the "Last Wave Filers") filed ANDAs and were sued on the '800 patent, but not (at least at the point of settlement) on the three "Form A" family of Crystal patents. The "Last Wave Filers" were sued between April 9, 2021 and June 13, 2022, and each had pending Revlimid litigations for less than a year. Plaintiff lacks sufficient information to evaluate the infringement cases of these ANDA filers, but each at least had strong invalidity arguments (building off the earlier generics' arguments) against the '800 patent. Each settled for an entry date of January 31, 2026, and cash payments purporting to cover "avoided litigation costs.". Plaintiff does not allege that these settlements—which do not confer profit shares—are anticompetitive.

385. In sum, the merits of the Later Filers' cases would have ratcheted up the pressure on Celgene and BMS, heightening the risk to its monopoly and explaining why it would pay billions in dollars of its monopoly profits to eliminate the risk of competition.

386. The Later Filers' profit shares conferred significantly more value than their expectations of revenue in a competitive market.

387. The Later Filers agreed to late dates for unrestrained generic entry because Celgene paid them off, *i.e.*, Celgene transferred significantly more value to the Later Filers than those would-be generic competitors expected to make by selling into a legal, competitive market.

388. The litigation and settlement details of these Later Filers are laid out below.

[203] Other generics, such as Mylan, had been granted patents related to lenalidomide forms as well. *See, e.g.*, U.S. Patent No. 8,946,265 (Mylan).

389. On August 15, 2017, Celgene filed suit against Cipla, Ltd. ("Cipla") after receiving Cipla's paragraph IV certification notifying Celgene it had filed ANDA No. 210435, seeking FDA approval to market a generic Revlimid product.[204] On December 10, 2020, Celgene and Cipla settled the Cipla litigation by entering into an unlawful reverse-payment agreement that will delay full generic competition until January 2026 (the "Celgene-Cipla agreement").

390. On January 11, 2018, Celgene filed suit against Apotex Inc. ("Apotex") after receiving Apotex's paragraph IV certification notifying Celgene it had filed ANDA No. 211022, seeking FDA approval to market a generic Revlimid product.[205] On March 8, 2021, Celgene and Apotex settled the Apotex litigation.

391. On April 12, 2017, Celgene filed suit against Zydus Pharmaceuticals (USA) Inc., Zydus International Pvt. Ltd, and Cadila Healthcare Ltd. (collectively, "Zydus") after receiving Zydus's paragraph IV certification notifying Celgene it had filed ANDA No. 210154, seeking FDA approval to market a generic Revlimid product.[206] On March 23, 2021, Celgene and Zydus

[204] Celgene's first lawsuit against Cipla alleged infringement of the '800, '217, '569, '498, '095, '621, and '622 patents. *Celgene Corp. v. Cipla, Ltd.*, No. 2:17-cv-06163 (D.N.J.). On May 8, 2018, Celgene filed a second suit against Cipla, asserting claims of infringement of the '357, '219, and '598 patents. *Celgene Corp. v. Cipla, Ltd., et al.*, No. 2:18-cv-08964 (D.N.J.). After Cipla filed a second ANDA, Celgene filed a third suit against Cipla on July 3, 2019, asserting claims of infringement of the '800, '217, '569, '498, '095, '621, '622, '740, '717, and '120 patents. *Celgene Corp. v. Cipla, Ltd., et al.*, No. 2:19-cv-14731 (D.N.J.). After Cipla filed a third ANDA, Celgene filed a fourth suit against Cipla on June 24, 2020, asserting claims of infringement of the '800, '217, '569, '498, '095, '621, '622, '740, '717, and '120 patents, and '217 patents. *Celgene Corp. v. Cipla, Ltd., et al.*, No. 2:20-cv-07759 (D.N.J.). Celgene's ANDA litigation against Cipla is collectively referred to herein as the "Cipla litigation."

[205] Celgene's first lawsuit against Apotex alleged infringement of the '720, '977, '784, '886, '531, '800, '217, '363, and '929 patents. *Celgene Corp. v. Apotex Inc.*, No. 2:18-cv-00461 (D.N.J.). On February 26, 2019, Celgene filed a second suit against Apotex, asserting claims of infringement of the '740, '717, and '120 patents. *Celgene Corp. v. Apotex Inc.*, No. 2:19-cv-06999 (D.N.J.). On June 19, 2019, Celgene filed a third suit against Apotex, asserting claims of infringement of the '357, '219, and '598 patents. *Celgene Corp. v. Apotex Inc.*, No. 2:19-cv-13994 (D.N.J.). Celgene's ANDA litigation against Apotex is collectively referred to herein as the "Apotex litigation."

[206] Celgene's first lawsuit against Zydus alleged infringement of the '800, '217, '569, '498, '095, '621, and '622 patents. *Celgene Corp. v. Zydus Pharm. (USA) Inc., et al.*, No. 2:17-cv-02528 (D.N.J.). On April 27, 2018, Celgene filed a second suit against Zydus, asserting claims of infringement of the '357, '219, and '598 patents. *Celgene Corp. v. Zydus Pharm. (USA) Inc., et al.*, No. 2:18-cv-08519 (D.N.J.). Celgene's ANDA litigation against Zydus is collectively referred to herein as the "Zydus litigation."

settled the Zydus litigation.

392. On July 13, 2018, Celgene filed suit against Sun Pharma Global FZE, Sun Pharma Global Inc., Sun Pharmaceutical Industries, Inc. and Sun Pharmaceuticals Industries Limited (collectively, "Sun") after receiving Sun's paragraph IV certification notifying Celgene it had filed ANDA No. 211846, seeking FDA approval to market a generic Revlimid product.[207] On June 21, 2021, Celgene and Sun settled the Sun litigation.

393. On January 8, 2020, Celgene filed suit against Aurobindo Pharma Limited, Eugia Pharma Specialties Limited, Aurobindo Pharma USA, Inc., and Aurolife Pharma LLC (collectively, "Aurobindo") after receiving Aurobindo's paragraph IV certification notifying Celgene it had filed ANDA No. 213885, seeking FDA approval to market a generic Revlimid product.[208] On July 15, 2021, Celgene and Aurobindo settled the Aurobindo litigation.

394. On December 31, 2019, Celgene filed suit against Mylan Laboratories Ltd. after receiving Mylan's paragraph IV certification notifying Celgene it had filed ANDA No. 213912, seeking FDA approval to market a generic Revlimid product.[209] On July 21, 2021, Celgene and Mylan settled the Mylan litigation.

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[207] Celgene's first lawsuit against Sun alleged infringement of the '800, '217, and '569 patents. *Celgene Corp. v. Sun Pharm. Indus., Inc., et al.*, No. 2:18-cv-11630 (D.N.J). On April 16, 2019, Celgene filed a second suit against Sun, asserting claims of infringement of the '357, '219, and '598 patents. *Celgene Corp. v. Sun Pharm. Indus., Inc., et al.*, No. 2:19-cv-10099 (D.N.J.). On February 2, 2021, Celgene filed a third suit against Sun, asserting claims of infringement of the '498, '095, '621, and '622 patents. *Celgene Corp. v. Sun Pharm. Indus., Inc., et al.*, No. 2:21-cv-01734 (D.N.J.). Celgene's ANDA litigation against Sun is collectively referred to herein as the "Sun litigation."

[208] Celgene's first lawsuit against Aurobindo alleged infringement of the '800, '217, '569, '498, '095, '621, and '622 patents. *Celgene Corp. v. Aurobindo Pharma Ltd., et al.*, No. 2:20-cv-00315 (D.N.J). On January 12, 2021, Celgene filed a second suit against Aurobindo, asserting claims of infringement of the '357, '219, and '598 patents. *Celgene Corp. v. Aurobindo Pharma Ltd., et al.*, No. 2:21-cv-00624 (D.N.J.). Celgene's ANDA litigation against Aurobindo is collectively referred to herein as the "Aurobindo litigation."

[209] Celgene's first lawsuit against Mylan alleged infringement of the '740, '800, '217, '569, '717, '498, '095, '120, '621, and '622 patents. *Celgene Corp. v. Mylan Labs. Ltd.*, No. 2:19-cv-22231 (D.N.J). On January 3, 2020, Celgene filed a second suit against Mylan Pharmaceuticals Inc., Mylan Inc., and Mylan N.V. (collectively and together with Mylan Laboratories Ltd., "Mylan") in the Northern District of West Virginia, asserting claims of infringement of the same patents. *Celgene Corp. v. Mylan Pharms., Inc., et al.*, No. 1:20-cv-00003 (N.D.W. Va.). Celgene's ANDA litigation against Mylan is collectively referred to herein as the "Mylan litigation."

395. On December 20, 2018, Celgene filed suit against Hetero Labs Limited, Hetero Labs Limited Unit-V, Hetero Drugs Limited, and Hetero USA, Inc. (collectively, "Hetero") after receiving Hetero's paragraph IV certification notifying Celgene it had filed ANDA No. 212414, seeking FDA approval to market a generic Revlimid product.[210] On September 22, 2021, Celgene and Hetero settled the Hetero litigation.

4. The expected anticompetitive consequences of serial capped-volume profit sharing.

396. *Capped-volume sharing is irrational as a patent settlement method*. A second observation is that the presence of capped volume sharing in a settlement of Hatch-Waxman patent litigation is an irrational way to allocate the settlement benefits between the parties. Generally, parties to a negotiation have an incentive to maximize joint profits. One implication of this is that a given transfer of value from one party should yield as much benefit to the other party as possible. In the commonplace *agreed-entry-date-only* Hatch-Waxman settlement there is a highly efficient ability to transfer value, *viz.*, a change in the agreed entry date. A change in the agreed entry date later benefits the brand greatly but only harms the generic by the time value of its market entry. Thus, the sensible, efficient way to transfer value to the brand in Hatch-Waxman settlements is by adjusting the agreed entry date.

397. As economic research shows, using generic-to-brand royalties in a Hatch-Waxman patent settlement to transfer value to the brand violates this principle. Generic-to-brand royalties transfer funds from the generic to the brand one-for-one. In the presence of an obviously more

[210] Celgene's first lawsuit against Hetero alleged infringement of the '800, '217, '363, and '929 patents. *Celgene Corp. v. Hetero Labs Ltd., et al.*, No. 2:18-cv-17463 (D.N.J). On July 16, 2019, Celgene filed a second suit against Hetero, asserting claims of infringement of the '740, '569, '717, '498, '095, '120, '621, and '622 patents. *Celgene Corp. v. Hetero Labs Ltd., et al.*, No. 2:19-cv-15449 (D.N.J.). On October 13, 2020, Celgene filed a third suit against Hetero, asserting claims of infringement of the '357 and '219 patents. *Celgene Corp. v. Hetero Labs Ltd., et al.*, No. 2:20-cv-14389 (D.N.J.). Celgene's ANDA litigation against Hetero is collectively referred to herein as the "Hetero litigation."

efficient form of exchanging value (the agreed entry date), the appearance of the inefficient form of exchange (generic-to-brand royalties) raises the question: why are the royalties included by rational negotiators? Economic scholarship has shown that the likely purpose of the royalty provision is to disincentivize the brand from launching an AG as part of an anticompetitive reverse-payment agreement.[211]

398. A similar observation follows for capped-volume profit sharing. In a circumstance such as this, a capped-volume provision transfers the funds from the generic to the brand is about 8.5:10.0. Given the presence to the obviously more efficient form of exchanging value (the generic can give up much less to get the brand the same value), the appearance of a capped-sharing arrangement is far less efficient, raising the question as to why the parties chose to use this device to allocate settlement benefits rather than the more efficient, *agreed-entry-date-only* approach.

399. *Capped-volume profit sharing means anticompetitive results*. Finally, as a matter of theoretical and applied microeconomics and healthcare economics, the only rational explanation for a capped-volume profit share arrangement of the type alleged in this complaint is that the brand is giving a large payment in exchange for an agreement by the generic to delay entry. This can be shown by comparing the gainshares when there are competitive *entry-date-only* negotiations to when there are *capped-volume-profit-share* negotiations.

400. We can contrast two ways to move value between the brand and the generic.

401. One way to move value between the brand and the generic with first-filer exclusivity—the *agreed-entry-date-only* approach—is simply by moving the agreed entry date.

[211] Keith Drake and Thomas McGuire, "The Simple Math of Royalties and Drug Competition During the 180-Day Generic Exclusivity Period," *Journal of Competition Law and Economics*, online ahead of print, 2024, pp. 1-10, at 5. (https://doi.org/10.1093/joclec/nhae001 (last visited Sept. 4, 2025)).

The *later* the date, the more value to the brand (a longer period of monopoly sales) and the less to the generic (lost time value of launching into the market). On the other hand, the *earlier* the date, the less time the brand is on the market with its high prices, and the earlier the generic can begin recognizing revenue. Note, however, that a move of the date impacts *all* the brand's revenues for each day moved (it loses or gains the full day of revenue), whereas the move only impacts *the time value* of the generic's revenues (it will make the generic revenue, but the issue is when it will). And note, the brand daily revenues are much larger than generic daily revenues. As a result, the impact of moving the date earlier (or later) impacts the brand far more than the generic.

402. This dynamic is shown through real world competitive settlements. It is common for there to be an overlap in the range of settlements dates that might be acceptable to settling brand and generic companies. In those situations, the issue is where *within* the range to agree on a specific date, and it is quite common for the agreed entry date to lean well in favor of the brand (but still be in the competitive range acceptable to the generic). This is because of the dynamic above. For example, the relative gainshare between a brand and a generic is often about 10:1, meaning that the brand gets about 95% of the settlement benefits and the generic gets about 5%. (Under these circumstances the settlement, while favoring the brand within the range of overlapping settlement dates, is still pro-competitive, because the agreed entry date is within the overlapping range of dates was established by what the brand and generic expected would occur in a competitive market).

403. In theory, another way to move value between the brand and the generic—the *capped-volume profit share* approach—is through a capped-volume profit share of the type witnessed here. In this arrangement, the brand and generic agree to split the market (e.g., where the generic will sell a defined percentage of units through its approved ANDA product, which

percentage is upon some definition of historic brand unit sales) at a level where the generic share will be far less than generic demand, but the generic gets to charge supra-competitive prices for the profit share period. And note, because for some period the generic is making supra-competitive profits, the range of acceptable dates for the generic moves out (*i.e.*, later) in time relative to what it would need in a competitive market (it is making more money, and so it can wait longer than it could under competitive conditions).

404. As we have seen with data from generic drug markets, this supra-competitive generic level pricing (where the set percentage of agreed generic launch is well below overall demand) is about 85% of the brand price. Thus, during the period of capped-volume profit split, for each $1.00 of market share the brand company agrees to allocate to the generic, the generic gains $.85. And so, here the ratio of transferred value from the settlement during the period of capped-share volume profit split is brand to generic of 10:8.5.

405. The contrast of the two methods is striking. Under a competitively negotiated settlement, the *entry-date-only* approach results in a gainshare favorable to the brand of 10:1, whereas the under the *capped-volume profit share* approach, during the period of capped-sharing the brand-to-generic transfer of value ratio is 10:8.5.

406. Since under competitive conditions the brand can insist on, and get, about 10:1 of the settlement benefits, but under the time of the capped-volume profit split arrangement it is "only" getting 10:8.5, what explanation is available for it to do so? The ratios are telling. In a competitive negotiation about a date only, moving the date earlier by one day costs the brand a great deal but benefits the generic relatively little. Any given transfer of value to the generic sufficient to induce it to drop the patent challenge thus yields great benefit to purchasers. The capped-volume agreement subverts this process. By allocating one pill to the generic the brand

sacrifices brand price and the generic benefits by almost as much. The generic can be induced to drop the patent challenge by a certain allocation of pills (and the profits) without yielding the intended benefits of a patent settlement to purchasers.

407. It would be irrational for a brand company to cede so much of the value of the settlement to the generic unless there were some off-setting benefits. And the only remaining explanation is that *the date for generic entry* has been moved later in time to increase the value of the settlement to the brand back to the equilibrium state of 10:1. The supra-competitive profits moved the acceptable range for the generic later. As a result, where there is a capped-volume profit share that achieves supra-competitive prices for the generics, the settlement must be anticompetitive not only because there are supra-competitive prices being paid for the generic, but also because the arrangement implies a significant later agreed entry date for the generic.

5. The Later Filers did not expect competition in the Revlimid market to commence until January 2026.

408. In 2022, after these other Revlimid Generics also settled for small volume-limited entry similar to the agreement with the Natco/Allergan collaborative, observers noted the "'unique' patent settlement where US major Bristol Myers Squibb is 'sharing the pie' of drug Revlimid with Indian generics, including Natco and Dr Reddy's."[212] In April 2022, after an additional nine generics had been induced to join the Generic Revlimid Output Restriction, but after *only* the Natco/Allergan collaboration had actually launched at limited quantities (on March 7, 2022), the intention and effects of the output restriction were clear. As a former pharmaceutical executive who had retired after being diagnosed with multiple myeloma explained:

> Teva/Natco will have little incentive to lower the price of Revlimid to us patients as they will not have to face competition from other

[212] Rupali Mukherjee, *Unique deal gives desi pharma cos slice of cancer drug's $8bn US pie*, THE TIMES OF INDIA, Mar. 14, 2022, *available at* https://timesofindia.indiatimes.com/business/india-business/unique-deal-gives-desi-pharma-cos-slice-of-cancer-drugs-8bn-us-pie/articleshow/90189785.cms (last visited Sept. 4, 2025).

> generic manufacturers/marketers for some months. That is just pure economics where companies will do their best to maximize their profits. Please be aware that while we (in the US) are used to Revlimid pricing of about $908 per capsule (e.g., as is currently paid by Medicare), its manufacturing cost is about $1.00 for that same capsule . . . the **price differential between the brand and the generic is a mere 9%.**
>
> Even if there will be 6 generic manufacturers/marketers present on the US market by year-end, they will only be allowed a combined total of about 30% market share. **This is simply not competition** that will meaningfully lower the cost/copay of this badly needed medication, not today and not in the next two years. **True competition and meaningful price/copay reductions in the Revlimid /lenalidomide market will not happen until the total supply that can be made available by generic companies will exceed the total demand of the market** (estimated around 2025)**.**[213]

409. Although forbidden from commenting on revenue, volume, and actual prices by the settlement agreements, an Aurobindo executive accidentally explained in May 2023 that the scheme eliminated price competition regardless of the number of competitors:

> "this is going to be limited share for multiple players, so we expect the price pricing[] to be stable and **it doesn't matter before Jan 2026 whoever or a number of launches might happen . . . because each player is [] restricted by the percentage of [] share . . . we expect the pricing to be stable up to Jan 2026**. . ."[214]

410. Predictions that the Generic Revlimid Output Restriction would restrain competition and maintain pricing have been confirmed, both directly by executives of the generic companies and by publicly available pricing data. In August 2023, the Aurobindo executive again stated: "**we expect the pricing to be stable** because you know it very well, **it is a limited volume**

[213] Paul Kleutghen, *Generic Revlimid in Myeloma: Don't Get Too Excited*, HEALTHTREE FOUNDATION, Apr. 10, 2022, *available at* https://healthtree.org/myeloma/community/articles/generic-revlimid-in-myeloma--dont-get-too-excited#:~:text=Teva%2FNatco%20will%20have%20little,best%20to%20 maximize%20their%20profits (last visited Sept. 4, 2025) (emphasis added).

[214] Transcript, Aurobindo Pharma Q4 FY23 Earnings Conference Call, May 29, 2023, at 12, *available at* https://www.aurobindo.com/api/uploads/conferencecalltranscripts/Aurobindo%20Pharma%20Q4%20FY23%20Earnings%20Conference%20Call%20final.pdf (last visited Sept. 4, 2025) (emphasis added).

. . . So we expect the pricing to be stable till the end of 2025."[215] The accuracy of those expectations were then confirmed again when a year later in August 2024, he said, "Qualitatively **at this point of time, yes, the pricing remains constant. We don't see any decline** . . . ."[216]

411. During a Teva's earnings calls, analysts regularly referred (uncorrected by Teva executives) to lenalidomide's "**limited competition dynamics**," during the 2022-2026 period, which Teva's executives admitted "there is going to come to a point where this is going to end."[217] The reason for the limited competition was unambiguous, as Teva executives described the market: "**Revlimid is allocated**."[218] As a Dr. Reddy's executive explained, "The volume is impacted primarily by the **type of agreement and less about capturing market share** or anything like that. And so far so good. We are selling the product exactly in accordance to the contract."[219] As Mylan's CEO explained, generic Revlimid had outsized revenue due to its unique "**profit profile**."[220]

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[215] Transcript, Aurobindo Pharma Q1 FY24 Earnings Conference Call, Aug. 14, 2023, at 12, *available at* https://www.aurobindo.com/api/uploads/conferencecalltranscripts/Aurobindo%20Q1%20FY24%20con%20call%20Transcript.pdf (last visited Sept. 4, 2025)

[216] Transcript, Aurobindo Pharma Q1 FY2025 Earnings Conference Call, Aug. 12, 2024, at 8, *available at* https://www.aurobindo.com/api/uploads/conferencecalltranscripts/Aurobindo%20Q1%20FY25%20Transcript_Final.pdf (last visited Sept. 4, 2025) (emphasis added).

[217] Transcript, Teva Pharmaceuticals Industries, Ltd. Q2 FY24 Earnings Conference Call, Jul. 31, 2024, at 13-14, *available at* https://s24.q4cdn.com/720828402/files/doc_financials/2024/q2/CORRECTED-TRANSCRIPT-Teva-Pharmaceutical-Industries-Ltd-TEVA-IL-Q2-2024-Earnings-Call-31-July-2024-8-00-AM-ET.pdf (last visited Sept. 4, 2025) (emphasis added).

[218] Transcript, Teva Pharmaceuticals Industries, Ltd. Q2 FY24 Earnings Conference Call, Jan. 29, 2025, *available at* https://www.fool.com/earnings/call-transcripts/2025/01/29/teva-pharmaceutical-industries-teva-q4-2024-earnin (last visited Sept. 4, 2025) (emphasis added). A Natco executive explained their thoughts in the earnings call following Natco/Teva's 2022 launch, "unless you have something interesting and special or limited competition, it is very difficult to make money." Transcript, Natco Pharma Limited Q1 FY23 Earnings Conference Call, Aug. 10, 2022, at 14, *available at* https://web.archive.org/web/20240617195801/https://www.natcopharma.co.in/wp-content/uploads/2022/08/Edelweiss-NatcoPharma-10Aug-2022.pdf (last visited Sept. 4, 2025).

[219] Transcript, Dr. Reddy's Laboratories Limited's Q1 FY25 Earnings Conference Call, Jul. 27, 2024, at 12, *available at* https://www.drreddys.com/cms/cms/sites/default/files/2024-08/DRL_Q1FY25%20Earnings%20Call%20Transcript_27July2024.pdf (last visited Sept. 4, 2025).

[220] Transcript, Viatris Inc.'s Q4 FY24 Earnings Conference Call, Feb. 27, 2025, *available at* https://seekingalpha.com/article/4762846-viatris-inc-vtrs-q4-2024-earnings-call-transcript (last visited Sept. 4, 2025) (emphasis added).

412. Industry observers agree. "Looking ahead, the competitive dynamics for Revlimid will dramatically shift after the expiration of volume-limited agreements in January 2026. Without these constraints, a flood of generic versions will likely saturate the market and lead to aggressive price competition. Market forecasts indicate that owing to the sheer number of companies capable of producing bioequivalent lenalidomide, Revlimid's market share is expected to decline rapidly—a trend compounded by potential regulatory pressures to cut prices and ensure broader patient access."[221]

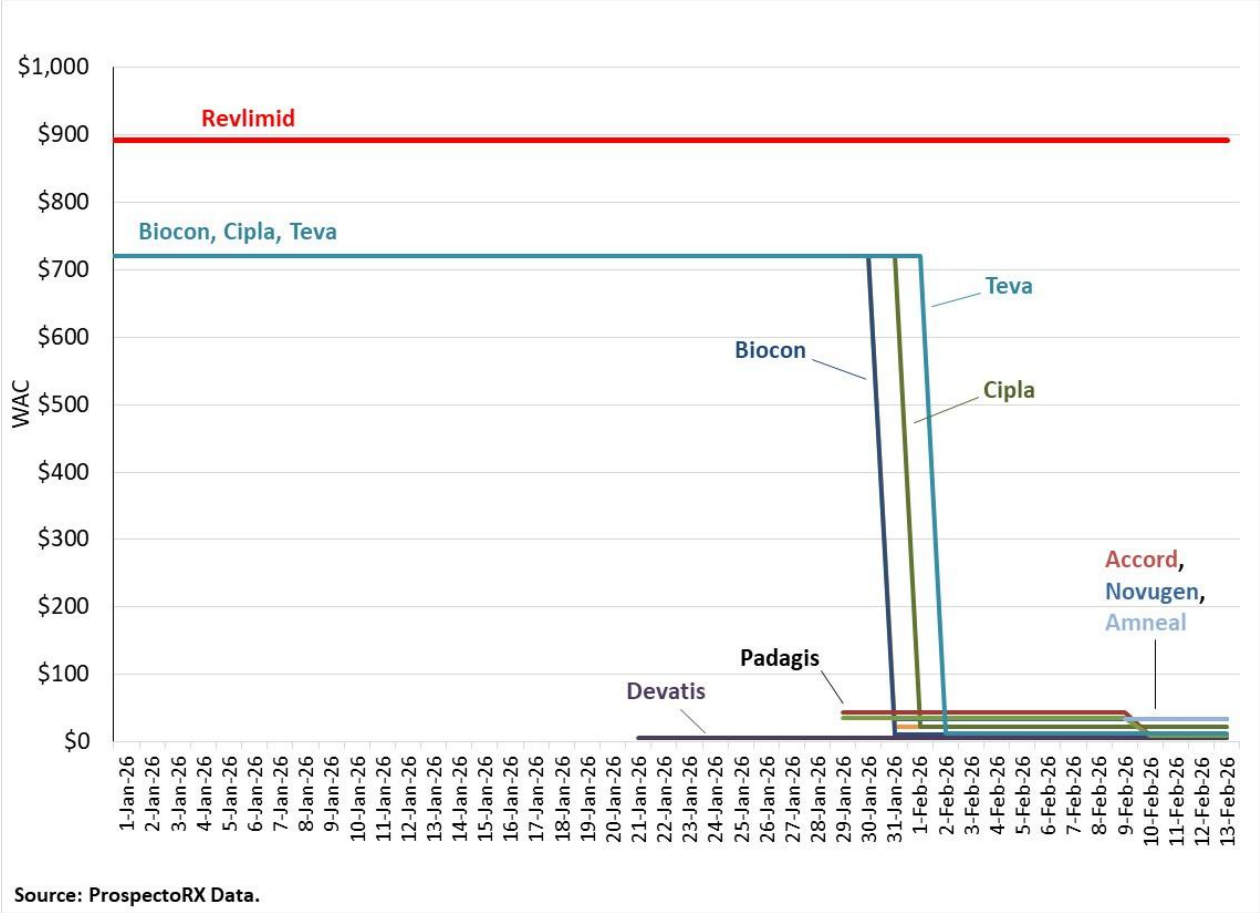
413. Mylan and Aurobindo have confirmed that they expect lenalidomide prices to plummet when generic competition commences in January 2026.[222]

414. As detailed, list price changes observed since the expiration of the January 31, 2026 of the volume limits in fact show that the price for generic Revlimid quickly plummeted. These newly-announced, post-volume-limits prices are detailed below:

Revlimid and Generic Lenalidomide Wholesale Acquisition Cost (WAC), 2026
Limited to generics that saw changes in WAC in 2026 or that launched in 2026

[221] *See* https://synapse.patsnap.com/article/what-are-the-market-competitors-for-revlimid (last visited Sept. 4, 2025).

[222] Transcript, Viatris Inc.'s Q4 FY24 Earnings Conference Call, Feb. 27, 2025, *available at* https://www.investing.com/news/transcripts/earnings-call-transcript-viatris-inc-q4-2024-misses-eps-estimates-stock-dives-93CH-3896811 ("However, lenalidomide is scheduled to hit a secondary patent cliff, I'll say, or expected to the economics of it are expected to significantly diminish as we get into January of 'twenty six.") (last visited Sept. 4, 2025); Transcript, Aurobindo Pharma Q4 FY25 Earnings Call, May 27, 2025, at 18, *available at* https://www.aurobindo.com/api/uploads/conferencecalltranscripts/LtrToSEsEarningCallTranscript020622025.pdf (for lenalidomide, "FY26 will be less than FY25") (last visited Sept. 4, 2025).



Source: ProspectoRX Data.

O. **The 2022 to 2024[223] effects of planned lenalidomide scarcity.**

415. Since the capped-volume product dumps have begun in March of 2022 (first by Teva/Natco, and then followed by the other scheme participants), the real-world, on-the-ground-evidence shows that the planned U.S. scarcity of available generic lenalidomide has had the intended, and carefully crafted, anticompetitive effects.

1. National benchmark prices show supra-competitive generic prices.

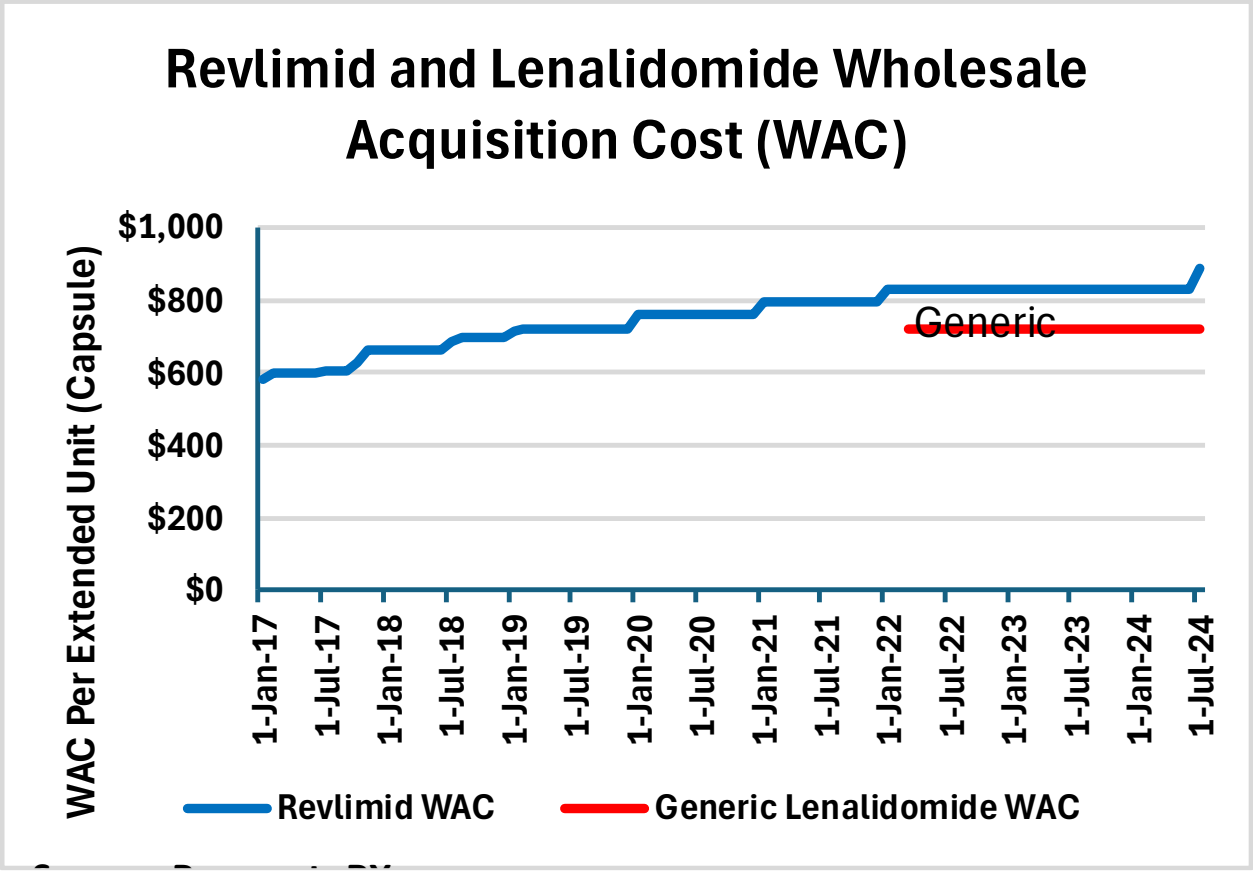
416. In December 2021, the WAC of brand Revlimid was $797.34. In January 2022, the WAC increased to $833.22, where it would remain until July 2024.[224]

[223] Plaintiff provides publicly available sales data through 2024 but expect similar prices prevailed until January 31, 2026 as witnessed in the dramatic decline in pricing at that time.

[224] Celgene increased the WAC of brand Revlimid to $891.55 in July 2024.

417. When Teva/Natco began to sell its generic lenalidomide, limited to its volume-capped portion of the market, in March 2022, it set a WAC of $719.91, 86% of the brand WAC.

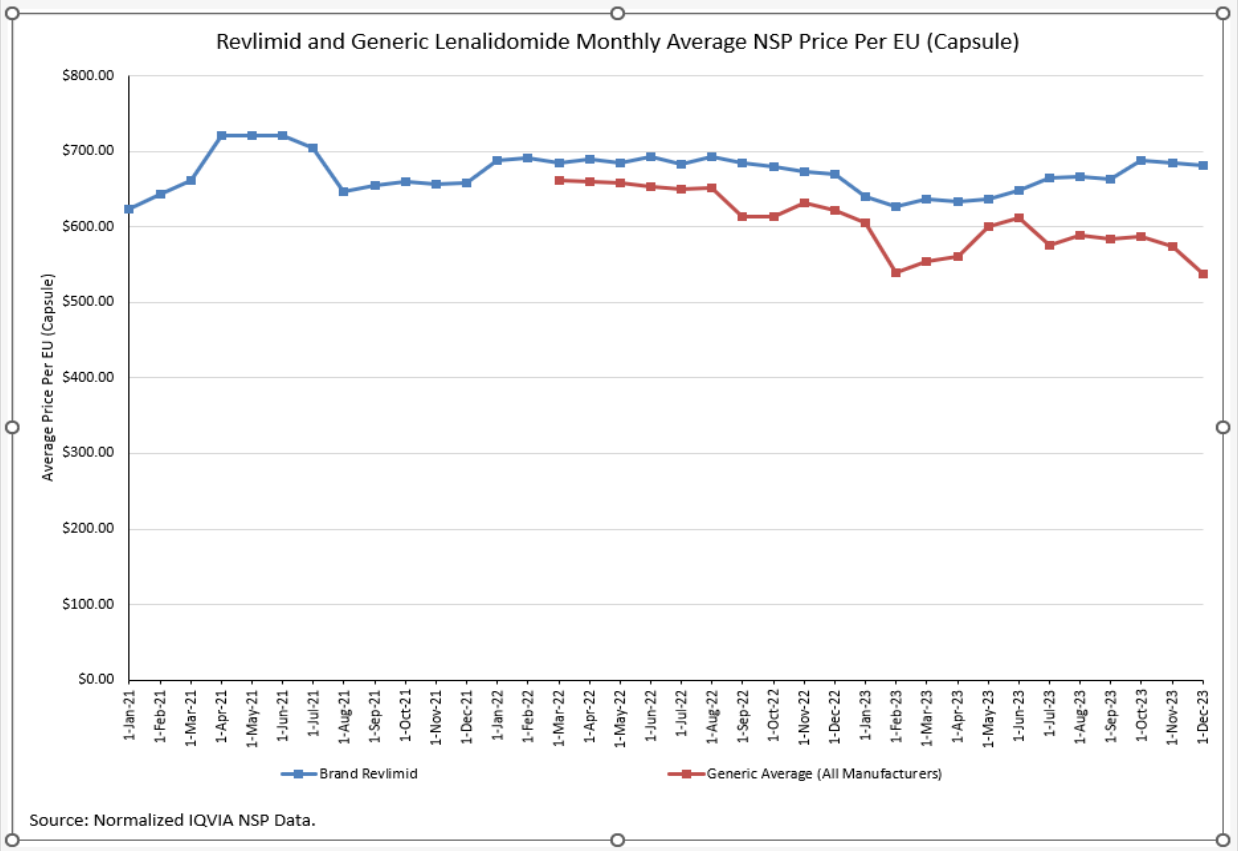
418. As additional generic manufacturers have begun selling their allocated portion of the market, the WAC of generic lenalidomide has remained $719.91, 86% of the brand WAC.

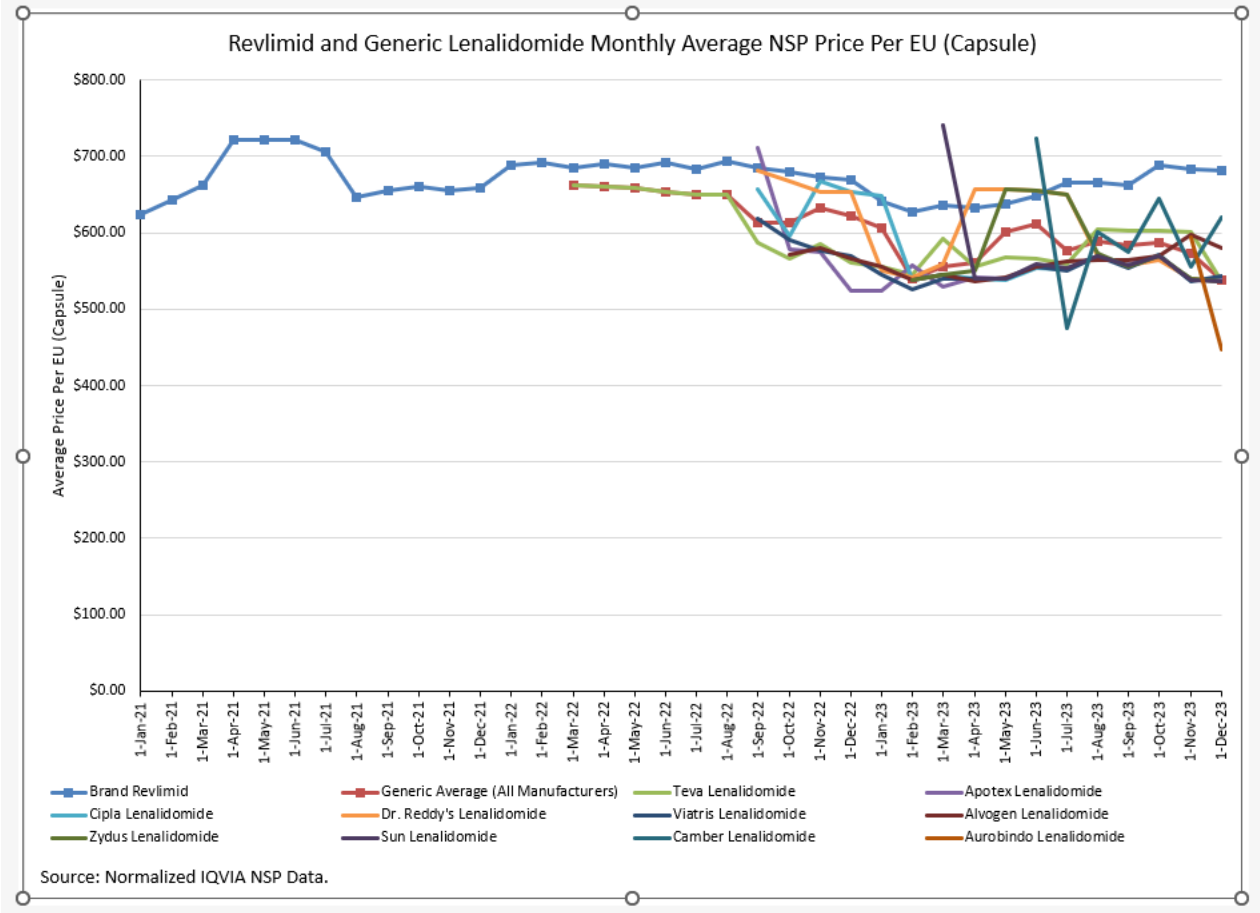


2. Publicly available IQVIA data shows supra-competitive generic prices.

419. Sales data from IQVIA of Celgene and BMS and the generic manufacturers' prices confirms that, contrary to what would be expected under competitive conditions, generic manufacturers have been able to set a higher price for their products relative to the brand price, and that prices have remained high even after multiple generic manufacturers began selling their allocations. Rather than the (at least) **less than $50 per pill** price one would expect to see in a market with *eleven* generic products (10 generic products + an AG), the price for lenalidomide is

consistently **greater than $500 per pill.**





420. The prices set by the generic manufacturers during these periods of capped-volume sales are dramatically higher than all reasonable expectations. In a fully genericized market (e.g., 3 or more entrants), the price of a generic is expected to quickly drop to 15% or less than the price of the brand. Studies (and the expectations of many of these conspirators) show that generic prices are 15% or less the brand prices within a year of generic entry, and that equilibrium is reached when there are six or more competitors, resulting in a 10% or less price of the brand. But, here, even with seven generics selling their capped-volume shares into the marketplace, the price effects are the opposite, with some of the generics selling at about 90% to 95% of the price of the brand.

3. Hospital distribution disturbance show generic drug "shortages" and higher price.

421. An effect of the limited allocations to each generic manufacturer has been periods of shortages. When a manufacturer is able to sell its entire yearly allocation before the end of the year, purchasers are unable to purchase additional quantities from that manufacturer—or potentially any manufacturer if generic demand exceeds the supply allotted to all generic manufacturers and all manufacturers have sold their allotments.

422. The American Society of Health-Systems Pharmacists ("ASHP") maintains a database of drug shortages reported by healthcare providers around the country. ASHP defines shortages as "a supply issue that affects how the pharmacy prepares or dispenses a drug product or influences patient care when prescribers must use an alternative agent."[225] For each generic drug entity in shortage, the ASHP database tracks which specific products are available or unavailable and lists any reasons that drug manufacturers have provided for the shortage.

423. Pharmaceutical shortages have severe economic and clinical impacts on those purchasing and relying on the affected medication. Most alarmingly, shortages risk patient safety by increasing the risk of medication errors or delaying effective treatment. Hospital pharmacies prefer to purchase a single version of a medication from a single manufacturer.[226] This consistency and familiarity reduces the risk that an incorrect medication or dosage will be administered. By contrast, medication-error risk is at its highest when a shortage forces hospital pharmacies to purchase other brands or concentrations of a drug.[227] In some cases, shortages have been found to increase medication errors by 127%.[228] According to one survey, 38% of medical

[225] ASHP Guidelines on Managing Drug Product Shortages, ASHP 100, *available at* https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/managing-drug-product-shortages.pdf (last visited Sept. 4, 2025).

[226] Erin R. Fox et al., Drug Shortages: A Complex Health Care Crisis, 89 MAYO CLINIC PROC. 361, 365 (2014).

[227] *Id.*

[228] Minje Park, et al., Linking Medication Errors to Supply Chain Disruptions: Evidence from Heparin Shortages Caused by Hurricane Maria 17 (2023).

facility-respondents stated that at least one medication error occurred as a direct result of a drug shortage between July and December 2018.[229] Additionally, shortages may cause delays in treatment, negatively affecting patient outcomes. In the previously mentioned study, 68% of respondent stated that shortages have resulted in delays for inpatient treatment.[230]

424. Pharmaceutical shortages also have severe economic consequences on their purchasers by increasing both commodity and personnel costs. In 2023, researchers observed that the price of generic drugs in shortage increased by a median of 14.6%.[231] In addition to increased commodity costs, shortages force hospitals to dramatically increase labor costs to manage shortages. In 2019, shortages cost hospitals nearly $360 million per year in labor alone.[232] This reflects approximately 8.6 million additional hours per year to obtain alternative supplies of needed medication and implement mitigation strategies to address increased risks to patient safety.[233] This number, while staggering, is likely an underestimate. It does not include more difficult-to-quantify costs such as purchases through non-traditional channels, delayed patient treatment, or worsened patient outcomes.

425. This shortage was directly and explicitly caused by Celgene's anticompetitive conduct. As ASHP reports, the reason for this shortage is that "[g]eneric lenalidomide have volume restrictions as part of the patent settlements between generic companies and Celgene (Bristol Myers Squibb). The volume restrictions are expected to be in effect until January 31,

[229] Vizient, Drug Shortages and labor costs: Measuring the hidden costs of drug shortages on U.S. hospitals 10 (2019).

[230] *Id.* at 22.

[231] Office of the Assistant Secretary for Planning and Evaluation, Report to Congress: Impact of Drug Shortages on Consumer Costs 10 (2023).

[232] Vizient at 5.

[233] *Id.* at 6.

2026."[234]

426. So long as even a single generic lenalidomide manufacturer is in shortage, purchasers will be forced to bear the economic burden of increased commodity and shortage mitigation costs. Likewise, patients will continue to suffer increased risk and worsened outcomes that arise under shortage conditions.

P. Absent the anticompetitive acts, *bona fide* generic entry would have occurred by 2021.

427. Absent the wrongful conduct by Celgene, the named co-conspirator defendants, and the unnamed co-conspirators (the "Unnamed Co-Conspirators;" *see* ¶ 493), *bona fide* generic competition in the U.S. market for Revlimid would have occurred by at least 2021.

428. Under competitive conditions, as to the Teva/Natco first-to-file dosage forms (the 5mg, 10mg, 15mg, and 25mg strengths), (i) a reasonable generic in the position of Teva/Natco would have entered the market in late May 2021, (ii) a reasonable company in the position of Celgene/BMS would have entered at that time for those dosages with an authorized generic, and (iii) six months later, multiple other generics would have entered with their approved ANDA products. Over 2021, the U.S. market for 5mg, 10mg, 15mg, and 25mg strengths of lenalidomide would have moved from monopoly to commodity, and all purchasers would have witnessed prices at 15% or less the price of the brand.

429. Under competitive conditions, as to the Dr. Reddy's first-to-file dosage forms (the 2.5mg and 20mg strengths), (i) a reasonable generic in the position of Dr. Reddy's would have entered the market in mid-October 2021, (ii) a reasonable company in the position of Celgene/BMS would have entered at that time for those dosages with an authorized generic, and

[234] Lenalidomide Capsules, ASHP (May 12, 2024), *available at* https://www.ashp.org/drug-shortages/current-shortages/drug-shortage-detail.aspx?id=1023&loginreturnUrl=SSOCheckOnly (last visited Sept. 4, 2025).

(iii) six months later, multiple other generics would have entered with their approved ANDA products. Over 2021 and early 2022, the U.S. market for 2.5mg and 20mg strengths of lenalidomide would have moved from monopoly to commodity, and all purchasers would have witnessed prices at 15% or less the price of the brand.

430. By March 2022, the entire U.S. market for lenalidomide should have been fully genericized.

431. There were no realistic regulatory impediments to FDA approvals of generic ANDAs to meet the earlier dates for bona fide entry identified above.

432. Based on the FDA's website, numerous Revlimid generics were ready for earlier generic regulatory approval. Indeed, the following companies received tentative approvals for at least one strength:

- Alvogen: September 24, 2020
- Natco: May 21, 2021
- Zydus: August 16, 2021
- Apotex: October 1, 2021

433. Given the early-entry advantages, reasonable generic companies in the position of Alvogen, Zydus, Apotex, and Dr. Reddy's would have launched without volume restraints on or around November 17, 2021.[235]

434. On October 14, 2021, the FDA granted final approval for Dr. Reddy's ANDA for the two dosages forms for which it was the first-filer (the 2.5mg and 20mg dosage strengths).

[235] Alternatively, even in the unlikely event that tentative approvals were not converted, as they should, to final approvals, the FDA had granted final approval to Alvogen on August 31, 2022, Zydus on September 12, 2022, Apotex on August 30, 2022, Dr, Reddy's on August 30, 2022, Aurobindo on March 6, 2023, and Mylan on August 30, 2022. At the very latest, reasonable generic companies in the position of Alvogen, Zydus, Apotex, Dr. Reddy's, Aurobindo, and Mylan would have launched without volume restraints on or around the dates they received final approval.

435. In addition to these competitive ANDA launches, absent the unlawful conduct a reasonable company in the position of Celgene/BMS would have entered the market with an authorized generic at the time of the first-filer entries by Teva/Natco and Dr. Reddy's.

436. Generic companies have strong incentives to begin selling their products as soon as possible. There are widely recognized price and market share advantages that accrue to the earliest generic entrants in a prescription drug market. For example, generic prices tend to be higher when fewer generic options are on the market, but prices significantly decline as more generic options enter and compete for sales by offering lower prices. Generic companies also capture a higher portion of the market when fewer generic options are available. Generic companies therefore pursue market entry as early as possible in order to benefit from the high-priced environment and market-share opportunities that prevail when fewer generic options are available. Put simply, generic companies sell more product at higher prices (and, therefore, make more money) when they beat their competitors to market.

437. Moreover, seven companies were able to launch in 2022, including all on or soon after September 2022, which is 180-days after Teva launched the Allergan interests' generic Revlimid product and thus likely the first date these companies were licensed to launch (*i.e.*, upon expiration of the Allergan interests' period of statutory exclusivity). That these companies were able to all launch without issue, together with the huge financial interests implicated by generic Revlimid and its ease of manufacture as a small molecule tablet, suggests that these companies could have launched earlier and at unrestrained volumes.

438. Absent the unlawful conduct, reasonable generics in the positions of the generic companies above, by the times identified above, would have either (i) won their patent litigation, allowing immediate entry, (ii) entered the market prior to a patent victory (*i.e.*, technically at risk

but with little real litigation risk, or (iii) entered into an agreement with a reasonable company in the position of Celgene that did not contain a reverse payment or market share allocation, but instead provided for a reasonable, arm's length agreed date for bona fide generic entry well before January 2026.

439. As to entry following a win in patent litigation, the Allergan interests and each of the Later Filers had the strong upper hand in litigation and were likely to prevail on any remaining patent charges that Celgene might present. The litigation regarding the Natco ANDA product would have been near trial ready by early 2016, and any result from that case would likely have occurred within a year or so.

440. As to entry prior to a win in patent litigation (*i.e.*, "at risk"), the benefits of entry strongly outweighed the small risks presented by Celgene's patent position. The *de jure* and *de facto* potentials of generic product exclusivity presented strong economic incentive to launch at risk.

441. As to entry following a payment-free settlement, reasonable brand and generic drug companies reach such settlements frequently. FTC reports show that most Hatch-Waxman patent litigations settlement based on an agreed date for entry, and with no further provisions shifting value from the brand to the generic. There are no facts that would have prevented a reasonable company in the position of Celgene from settling without a reverse payment to would-be competitors, in exchange for a fair entry date well before 2026.

VI. ANTITRUST INJURY

442. A specific scientific literature for oral anti-cancer medications exists that may provide more nuanced inputs for the rate of generic incursion and the rate of price decline. That literature suggests that in the short-term, effects are somewhat less dramatic than for other drugs, but that in the longer run the effects catch up and are as dramatic. For current purposes, the

nuanced differences do not impact the allegations of market dynamics and estimations of payments and overcharges alleged in this Complaint.

443. The effect of Defendants' conduct is to net Defendants billions of dollars in revenue at the expense of Plaintiff, which will pay hundreds of millions of dollars in unlawful overcharges.

444. During the relevant period, Plaintiff purchased substantial amounts of Revlimid and generic Revlimid from Defendants. Since 2020, Plaintiff has purchased substantial amounts of Revlimid and generic Revlimid for its members in the District of Columbia and in at least the following 46 states:

> **Alabama, Arkansas, Arizona, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Iowa, Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana, Massachusetts, Maryland, Maine, Michigan, Minnesota, Missouri, Mississippi, North Carolina, North Dakota, Nebraska, New Hampshire, New Jersey, New Mexico, Nevada, New York, Ohio, Oklahoma, Oregon, Pennsylvania, , South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Washington, and Wisconsin.**

445. As a direct and proximate result of Defendants' anticompetitive conduct, Plaintiff has paid and will continue to pay supra-competitive prices for lenalidomide because (1) the price of Revlimid was and is artificially inflated by Defendants' anticompetitive conduct, and (2) Plaintiff was and is deprived of the opportunity to purchase lower-priced generic versions of lenalidomide.

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

447. Defendants' anticompetitive conduct has prevented price competition for Revlimid.

448. Prices for Revlimid have been and will continue to be inflated as a direct and

foreseeable result of Defendants' anticompetitive conduct. The inflated prices that Plaintiff has paid and will continue to pay are traceable to, and are the proximate foreseeable result of, the overcharges by Defendants.

VII. IMPACT ON INTERSTATE COMMERCE

449. Defendants' efforts to monopolize and restrain competition in the market for lenalidomide have substantially affected interstate and foreign commerce.

450. At all material times, Defendants manufactured, sold, and shipped substantial amounts of brand and/or generic lenalidomide across state lines in an uninterrupted flow of commerce across state and national lines throughout the United States.

451. At all material times, Defendants 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 brand and/or generic lenalidomide.

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

VIII. MARKET POWER AND MARKET DEFINITION

453. At all relevant times, Celgene and later, BMS, had monopoly power over the market for Revlimid in all its forms and dosages, even after the limited volume launch of generic Revlimid in March 2022. Celgene and BMS had and continue to have the power to profitably maintain and increase the price of Revlimid at supra-competitive levels (*i.e.*, without losing sufficient sales to other products to make the supra-competitive prices unprofitable).

454. There is direct evidence of Celgene's market power, including (a) Celgene's gross margin on Revlimid (including the costs of ongoing research/development, marketing, selling, and administrative expenses) steadily rose from around 100% in 2009 to almost 350% by 2018; (b) Celgene never lost Revlimid sales or lowered the price of Revlimid to the competitive level in response to the pricing of other brand or generic drugs; and (d) from 2005 to 2022, Celgene profitably raised the price of Revlimid by more than $500.

455. If required, circumstantial evidence of Celgene's market power can be demonstrated by the fact that (a) the relevant product market consists of Revlimid of all dosages of lenalidomide, *i.e.*, Revlimid and its AB-rated generic equivalents; (b) at the time of the unlawful agreements and at all times before March 2022, Celgene possessed a 100% share of the relevant market; and (c) thereafter and through January 2026, Celgene eliminated cross-price dynamics between brand and generic Revlimid products by permitting only capped and limited quantities of generic Revlimid to become available, all at a level that maintained overall generic lenalidomide at a scarcity level, such that Celgene maintained monopoly pricing power over the segment it had retained.

456. There are no interchangeable drug products available for purchasers of Revlimid. Although, there are two other immunomodulatory agents on the market—Thalomid and Pomalyst—which are both also owned by Celgene—Revlimid (including its AB-rated generic) is therapeutically differentiated from these other available immunomodulatory agents.

457. Neither the existence of these other immunomodulatory agents, nor other products designed to treat the conditions treated by Revlimid, has constrained the price of Revlimid to the competitive level. Celgene needed to control only Revlimid and its AB-rated generic equivalents, and no other products, to maintain the price of Revlimid above the competitive level. As stated,

Celgene's executives understood that it had the power to maintain supracompetitive prices for Revlimid. They believed that they could raise the price of Revlimid "any time they wanted."[236] Only the unrestricted market entry of a competing AB-rated generic version of Revlimid would render Celgene unable to maintain its market monopoly.

458. A small but significant, non-transitory increase in the price of Revlimid and its generic equivalents did not, and would not, cause a significant loss of sales to any other product. At competitive prices, Revlimid and its generic equivalents do not exhibit significant, positive cross-elasticity of demand, with respect only, as to any other product.

459. Celgene needed to control the output of Revlimid and its AB-rated generic equivalents only, and no other products, to maintain the price of Revlimid profitably at supracompetitive prices. Only the market entry of a competing AB-rated generic version of Revlimid would render Celgene unable to profitably maintain its current prices of those drugs without losing substantial sales.

460. At all relevant times, the Defendants were protected by high barriers to entry with respect to competition in the above-defined market due to patent protection, the high cost of entry and expansion, expenditures in marketing and physician detailing, and state statutes that require prescriptions for the purchase of the products at issue and restrict substitution of those products at the pharmacy counter. Defendants' unlawful conduct further restricted entry. Thus, during the relevant time, existing and potential market entrants lacked the ability to enter the market and/or expand output quickly in the short run in response to Defendants' higher prices or reduced output.

461. Without the power to exclude and restrict competition for Revlimid, and the ability to sell its own branded version of those drugs at supracompetitive prices—well over marginal

[236] Oversight Committee Revlimid Report, at 4.

costs, it would not have been economically rational for Celgene to make exorbitant payments to settle with the Allergan interests, Dr. Reddy's, and the Later Filers to delay the launch of generic Revlimid.

462. Celgene's reverse payment to the Allergan interests, Dr. Reddy's, and the Later Filers demonstrates that Celgene enjoyed monopoly power in the relevant market.

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

IX. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF
For Violations of Section 1 of the Sherman Act
(Celgene, BMS, Natco, Teva, and AbbVie)

464. Plaintiff incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

465. Celgene, BMS, Natco, Teva, and AbbVie (as successor in interest to Allergan) violated 15 U.S.C. § 1 by entering into, furthering, and/or enforcing an unreasonable restraint of trade. More specifically, Celgene and BMS agreed with Natco, Teva, and AbbVie to make a reverse payment in exchange for an agreement to delay competition from Natco's AB-rated generic Revlimid until January 31, 2026, and to allocate the market for branded and AB-rated generic Revlimid. Celgene and BMS individually had market power with respect to sales of Revlimid and its AB-rated generic equivalents in the United States.

466. On or about December 22, 2015, Celgene entered into an anticompetitive reverse-payment agreement, which was later entered into, furthered, and/or enforced by BMS, wherein Celgene and BMS agreed to pay, and did pay, Natco, Teva, and AbbVie a large and unexplained payment in exchange for an agreement to delay unrestricted market entry of Natco's generic version of Revlimid until January 31, 2026.

467. As a result of Celgene, BMS, Natco, Teva, and AbbVie's unlawful conduct, Plaintiff has been harmed by being forced to pay artificially inflated, supracompetitive prices for Revlimid and its AB-rated generic equivalents.

468. In formulating and carrying out the alleged agreement, understanding, contract, combination, and conspiracy, Celgene, BMS, Natco, Teva, and AbbVie did those things that they combined and conspired to do, including but not limited to the acts, practices, and course of conduct set forth herein.

469. Celgene, BMS, Natco, Teva, and AbbVie's conspiracy had the following effects, among others: the reverse payment agreement between Celgene/BMS and Teva/Natco/AbbVie delayed generic competition (with its attendant lower prices), and the market-allocation output-restriction agreement and reverse payment effectively fixed prices at an artificially high level.

470. Celgene, BMS, Natco, Teva, and AbbVie engaged in the actions described above for the purpose of carrying out their unlawful agreements to fix, raise, maintain, or stabilize prices of Revlimid and its AB-rated generic equivalents.

471. There was no legitimate, non-pretextual, pro-competitive business justification for this reverse payment agreement that outweighs its harmful effect on Plaintiff and competition. Even if there were some conceivable and cognizable justification, the payment was not necessary to achieve the purpose. Accordingly, these acts constitute violations of the antitrust laws in accordance with *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013).

472. The agreement caused lingering and persistent inflation in the prices for brand and AB-rated generic Revlimid that continue to this day and, if the terms of the agreement are abided by, will continue through at least January 31, 2026.

473. There is no procompetitive justification for the anticompetitive agreement challenged here. The harm to Plaintiff and other purchasers in the form of paying inflated prices for brand and AB-rated generic Revlimid outweighs any conceivable procompetitive justification for the agreement.

474. As a direct result of Celgene, BMS, Natco, Teva, and AbbVie's violation of 15 U.S.C. § 1, Plaintiff has been injured. Unless Plaintiff obtains equitable relief, Celgene, BMS, Natco, Teva, and AbbVie's violation will continue to injure Plaintiff in its business or property. Plaintiff's injury consists of its past and continued payment of higher prices for Revlimid and its AB-rated generic equivalents than it would have paid in the absence of the violation. Such injury, known as "overcharges," is the type of injury the antitrust laws were designed to prevent. This overcharge flows from the unlawful conduct of Celgene, BMS, Natco, Teva, and AbbVie.

SECOND CLAIM FOR RELIEF
For Violations of Section 1 of the Sherman Act
(Celgene, BMS, and Dr. Reddy's)

475. Plaintiff incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

476. Celgene, BMS, and Dr. Reddy's violated 15 U.S.C. § 1 by entering into, furthering, and/or enforcing an unreasonable restraint of trade. More specifically Celgene and BMS agreed with Dr. Reddy's to make a reverse payment in exchange for an agreement to delay competition from Dr. Reddy's AB-rated generic Revlimid until January 31, 2026, and to allocate the market for branded and AB-rated generic Revlimid. Celgene and BMS individually had market power with respect to sales of Revlimid and its AB-rated generic equivalents in the United States.

477. On or about September 16, 2020, Celgene entered into an anticompetitive reverse payment agreement, which was later entered into, furthered, and/or enforced by BMS, wherein Celgene and BMS agreed to pay, and did pay, Dr. Reddy's a large and unexplained payment in

exchange for an agreement to delay unrestricted market entry of Dr. Reddy's generic version of Revlimid until January 31, 2026.

478. As a result of Celgene, BMS, and Dr. Reddy's unlawful conduct, Plaintiff has been harmed by being forced to pay artificially inflated, supracompetitive prices for Revlimid and its AB-rated generic equivalents.

479. In formulating and carrying out the alleged agreement, understanding, contract, combination, and conspiracy, Celgene, BMS, and Dr. Reddy's did those things that they combined and conspired to do, including but not limited to the acts, practices, and course of conduct set forth herein.

480. Celgene, BMS, and Dr. Reddy's conspiracy had the following effects, among others: the reverse payment agreement between Celgene/BMS and Dr. Reddy's delayed generic competition (with its attendant lower prices), and the market allocation output restriction agreement and reverse payment effectively fixed prices at an artificially high level.

481. Celgene, BMS, and Dr. Reddy's engaged in the actions described above for the purpose of carrying out their unlawful agreements to fix, raise, maintain, or stabilize prices of Revlimid and its AB-rated generic equivalents.

482. There was no legitimate, non-pretextual, pro-competitive business justification for this reverse payment agreement that outweighs its harmful effect on Plaintiff and competition. Even if there were some conceivable and cognizable justification, the payment was not necessary to achieve the purpose. Accordingly, these acts constitute violations of the antitrust laws in accordance with *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013).

483. The agreement caused lingering and persistent inflation in the prices for brand and AB-rated generic Revlimid that continue to this day and, if the terms of the agreement are abided by, will continue through at least January 31, 2026.

484. There is no procompetitive justification for the anticompetitive agreements challenged here. The harm to Plaintiff and other purchasers in the form of paying inflated prices for brand and AB-rated generic Revlimid outweighs any conceivable procompetitive justification for the agreement.

485. As a direct result of Celgene, BMS, and Dr. Reddy's violation of 15 U.S.C. § 1, Plaintiff has been injured. Unless Plaintiff obtains equitable relief, Celgene, BMS, and Dr. Reddy's violation will continue to injure Plaintiff in its business or property. Plaintiff's injury consists of its past and continued payment of higher prices for Revlimid and its AB-rated generic equivalents than it would have paid in the absence of the violation. Such injury, known as "overcharges," is the type of injury the antitrust laws were designed to prevent. This overcharge flows from the unlawful conduct of Celgene, BMS, and Dr. Reddy's.

THIRD CLAIM FOR RELIEF
FOR VIOLATIONS OF SECTION 1 OF THE SHERMAN ACT
(All Defendants)

486. Plaintiff incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

487. Defendants and Alvogen, Cipla, Apotex, Zydus, Sun, Aurobindo, Mylan, and Hetero (together, the "Unnamed Co-Conspirators") violated 15 U.S.C. § 1 by entering into, furthering, and/or enforcing unreasonable restraints of trade in the market for Revlimid and/or its AB-rated generic equivalents as detailed Sections V.I., V.L., V.M., and V.N.

488. More specifically, Celgene and BMS agreed with Natco/Teva/Allergan, Dr. Reddy's, and each of the Unnamed Co-Conspirators to make a reverse payment in exchange for

agreements to delay competition from each's AB-rated generic Revlimid until January 31, 2026, and to allocate the market for branded and AB-rated generic Revlimid.

489. Plaintiff has been injured in its business or property as a direct result of 15 U.S.C. § 1. Its injury consists of having paid higher prices for its lenalidomide requirements than it would have paid in the absence of those violations. Such injury, called "overcharges," is of the type that the antitrust laws were designed to prevent, and it flows from that which makes Defendants and Unnamed Co-Conspirators' conduct unlawful.

490. In formulating and carrying out the alleged agreement, understanding, contract, combination, and conspiracy, Defendants and Unnamed Co-conspirators did those things that they combined and conspired to do, including but not limited to the acts, practices, and course of conduct set forth herein.

491. Defendants' and Unnamed Co-Conspirators' conspiracy had the following effects, among others: the reverse payment agreements between Celgene/BMS and Natco/Teva/Allergan, Dr. Reddy's, and the Unnamed Co-Conspirators delayed generic competition (with its attendant lower prices), and the market allocation output restriction agreement and reverse payment effectively fixed prices at an artificially high level.

492. Celgene/BMS, Natco/Teva/Allergan, Dr. Reddy's, and the Unnamed Co-Conspirators engaged in the actions described above for the purpose of carrying out their unlawful agreements to fix, raise, maintain, or stabilize prices of Revlimid and its AB-rated generic equivalents.

493. From the launch of Revlimid in 2005 through the present, Celgene (later, BMS) possessed, continues to possess, monopoly power in the relevant market—i.e., the market for sales of lenalidomide in the United States. But for Defendants' and Unnamed Co-Conspirators'

wrongful conduct, as alleged herein, Celgene (later, BMS) would have lost its monopoly power in the relevant market as early as May 2021 and in any event well before 2026.

494. Starting in March 2022, Celgene and BMS began sharing its monopoly power. First with Teva/Natco/AbbVie, and then, six months later, with Dr. Reddy's and the Unnamed Co-Conspirators, as a result of its anticompetitive reverse-payment and market-allocation agreements with each. These agreements individually and collectively will cover a sufficiently substantial percentage of the relevant market to harm competition.

495. There is and was no legitimate, non-pretextual, pro-competitive business justification for these reverse payment agreements that outweighs their harmful effect on purchasers and competition. Even if there were some conceivable and cognizable justification, the payments were not necessary to achieve such a purpose.

496. As a direct and proximate result of Defendants' and Unnamed Co-Conspirators' anticompetitive conduct, Plaintiff was harmed and continues to be harmed in the form of overcharges.

497. The agreement caused lingering and persistent inflation in the prices for brand and AB-rated generic Revlimid that continue to this day and, if the terms of the agreement are abided by, will continue through at least January 31, 2026.

498. Defendants' acts and combinations in furtherance of the conspiracy have caused unreasonable restraints in the market for Revlimid and/or its AB-rated generic equivalents.

499. As a direct result of Defendants and the Unnamed Co-Conspirators' violation of 15 U.S.C. § 1, Plaintiff has been injured. Unless Plaintiff obtains equitable relief, Defendants and the Unnamed Co-Conspirators' violation will continue to injure Plaintiff in its business or property. Plaintiff's injury consists of its past and continued payment of higher prices for Revlimid and its

AB-rated generic equivalents than it would have paid in the absence of the violation. Such injury, known as "overcharges," is the type of injury the antitrust laws were designed to prevent. This overcharge flows from the unlawful conduct of Defendants and the Unnamed Co-Conspirators.

FOURTH CLAIM FOR RELIEF
FOR VIOLATIONS OF SECTION 2 OF THE SHERMAN ACT
(Celgene, BMS)

500. Plaintiff incorporates by reference the preceding allegations.

501. Celgene and BMS knowingly and willfully engaged in a course of conduct designed to prevent generic manufacturers from entering the lenalidomide market and unlawfully extend its monopoly power. This course of conduct included settling patent litigation with ANDA filers for generic lenalidomide with reverse payments and allocating the market for brand and AB-rated generic lenalidomide. Celgene's conduct was designed to delay indefinitely the introduction of generic formulations of Revlimid into the market and was in violation of Section 2 of the Sherman Act.

502. Celgene and BMS intentionally and improperly maintained monopoly power with respect to Revlimid in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. Celgene and BMS's monopoly power was maintained through exclusionary tactics, and not from growth or development resulting from a superior product, business acumen, or historic accident. Because of this unlawful maintenance of monopoly power, Plaintiff paid artificially inflated prices for Revlimid.

503. Plaintiff has been injured in its business or property by reason of Celgene and BMS's antitrust violations. Its injury consists of having paid and continuing to pay higher prices for Revlimid from at least May 2021 to the present, including by assignment from its subsidiaries that purchased, and continue to purchase, Revlimid or its AB-rated generic alternatives directly from Defendants, than it would have paid in the absence of Celgene and BMS's violations. Such

overcharges are the type of injury the antitrust laws were designed to prevent and flows from that which makes Celgene and BMS's acts unlawful.

504. Even after generic competition begins, Plaintiff will continue to pay supracompetitive prices for brand and AB-rated generic versions of Revlimid until the market achieves equilibrium.

FIFTH CLAIM FOR RELIEF
DECLARATORY AND INJUNCTIVE RELIEF UNDER SECTION 16 OF THE CLAYTON ACT FOR DEFENDANTS' VIOLATIONS OF SECTION 1 AND 2 OF THE SHERMAN ACT
(CELGENE, BMS)

505. Plaintiff incorporates by reference the preceding allegations.

506. Defendants knowingly, intentionally, and cooperatively engaged in an anticompetitive scheme designed to delay and block entry of AB-rated generic equivalents of Revlimid. Defendants injured Plaintiff through this conduct.

507. Had manufacturers of generic Revlimid entered the market and lawfully competed with Celgene, Plaintiff would have substituted lower-priced generic Revlimid for the higher-priced brand-name drugs for most of its purchases.

508. Plaintiff has suffered harm and will continue to suffer harm in the future as a result of paying higher prices for Revlimid than it would have absent Defendants' continuing anticompetitive conduct.

509. Plaintiff's allegations described herein comprise violations of Sections 1 and 2 of the Sherman Act, as well as state laws.

510. Plaintiff has overpaid for substantial amounts of Revlimid between at least 2021 and the present.

511. Plaintiff seeks a declaratory judgment under Federal Rule of Civil Procedure 57 and 28 U.S.C. § 2201(a) ruling that Defendants' conduct violates Sections 1 and 2 of the Sherman Act.

512. Plaintiff also seeks equitable and injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, to correct for the anticompetitive market effects caused by Defendants' unlawful conduct and other relief to assure that similar anticompetitive conduct does not recur.

513. Plaintiff has no adequate alternative form of relief in the United States for its overpayment for Revlimid purchased indirectly in the states that do not provide damages remedies to indirect purchasers injured by Defendants' anticompetitive agreement.

SIXTH CLAIM FOR RELIEF
CONSPIRACY AND COMBINATION IN RESTRAINT OF TRADE UNDER STATE LAW
(CELGENE, BMS, NATCO, TEVA, and ABBVIE)

514. Plaintiff incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

515. Celgene, BMS, Natco, Teva, and AbbVie violated the various below state antirust laws by entering into, furthering, and/or enforcing an unreasonable restraint of trade. More specifically, Celgene and BMS agreed with Natco, Teva, and AbbVie to make a reverse payment in exchange for an agreement to delay competition from Natco's AB-rated generic Revlimid until January 31, 2026, and to allocate the market for branded and AB-rated generic Revlimid. Celgene and BMS individually had market power with respect to sales of Revlimid and its AB-rated generic equivalents in the United States.

516. On or about December 22, 2015, Celgene entered into an anticompetitive reverse-payment agreement, which was later entered into, furthered, and/or enforced by BMS, wherein

Celgene and BMS agreed to pay, and did pay, Natco, Teva, and AbbVie a large and unexplained payment in exchange for an agreement to delay unrestricted market entry of Natco's generic version of Revlimid until January 31, 2026.

517. As a result of Celgene, BMS, Natco, Teva, and AbbVie's unlawful conduct, Plaintiff has been harmed by being forced to pay artificially inflated, supracompetitive prices for Revlimid and its AB-rated generic equivalents.

518. In formulating and carrying out the alleged agreement, understanding, contract, combination, and conspiracy, Celgene, BMS, Natco, Teva, and AbbVie did those things that they combined and conspired to do, including but not limited to the acts, practices and course of conduct set forth herein.

519. Celgene, BMS, Natco, Teva, and AbbVie's conspiracy had the following effects, among others: the reverse payment agreement between Celgene/BMS and Teva/Natco/AbbVie delayed generic entry and its attendant lower prices for Plaintiff, and the market allocation output restriction agreement and reverse payment effectively fixed prices at an artificially high level.

520. Celgene, BMS, Natco, Teva, and AbbVie engaged in the actions described above for the purpose of carrying out their unlawful agreements to fix, raise, maintain, or stabilize prices of Revlimid.

521. There was no legitimate, non-pretextual, pro-competitive business justification for this reverse payment agreement that outweighs its harmful effect on Plaintiff and competition. Even if there were some conceivable and cognizable justification, the payment was not necessary to achieve the purpose. Accordingly, these acts constitute violations of the antitrust laws of various states in accordance with *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013).

522. The agreement caused lingering and persistent inflation in the prices for brand and

AB-rated generic Revlimid that continue to this day and, if the terms of the agreement are abided by, will continue through at least January 31, 2026.

523. There is no procompetitive justification for the anticompetitive agreement challenged here. The harm to Plaintiff and other purchasers in the form of paying inflated prices for brand and AB-rated generic Revlimid outweighs any conceivable procompetitive justification for the agreement.

524. As a direct result of Celgene, BMS, Natco, Teva, and AbbVie's violation of 15 U.S.C. § 1, Plaintiff has been injured. Unless Plaintiff obtains equitable relief, Celgene, BMS, Natco, Teva, and AbbVie's violation will continue to injure Plaintiff in its business or property. Plaintiff's injury consists of its past and continued payment of higher prices for Revlimid and its AB-rated generic equivalents than it would have paid in the absence of the violation. Such injury, known as "overcharges," is the type of injury the antitrust laws were designed to prevent. This overcharge flows from the unlawful conduct of Celgene, BMS, Natco, Teva, and AbbVie.

525. By engaging the foregoing conduct, Celgene, BMS, Natco, Teva, and AbbVie intentionally and wrongfully engaged in a contract, combination, or conspiracy in restraint of trade in violation of the following state antitrust laws:

A. Ala. Code § 8-10-3, *et seq*., with respect to purchases in Alabama.

B. Arizona Rev. Stat. §§ 44-1401, *et seq*., with respect to purchases in Arizona.

C. Cal. Bus. & Prof. Code §§ 16700, *et seq*., with respect to purchases in California.

D. C.G.S.A. §§ 35-26 and 28, *et seq*., with respect to purchases in Connecticut.

E. D.C. Code §§ 28-4501, *et seq*., with respect to purchases in the District of Columbia.

F. Fla. Stat. §§ 501.201, *et seq*., with respect to purchases in Florida.

G. Haw. Rev. Stat. §§ 480-1, *et seq*., with respect to purchases in Hawaii.

H. 740 Ill. Comp. Stat. 10/1, *et seq*., with respect to purchases in Illinois.

I. Iowa Code § 553.1, *et seq*., with respect to purchases in Iowa.

J. Kan. Stat. Ann. § 50-101, *et seq*., with respect to purchases in Kansas.

K. Me. Rev. Stat. Ann. 10, §§ 1101, *et seq*., with respect to purchases in Maine.

L. Md. Code Ann., Com. Law, §§ 11-204, *et seq*., with respect to purchases in Maryland.

M. Mich. Comp. Laws Ann. §§ 445.771, *et seq*., with respect to purchases in Michigan.

N. Minn. Stat. §§ 325D.49, *et seq*., and Minn. Stat. §§ 8.31, *et seq*., with respect to purchases in Minnesota.

O. Miss. Code Ann. §§ 75-21-1, *et seq*., with respect to purchases in Mississippi.

P. Neb. Rev. Stat. Ann. §§ 59-801, *et seq*., with respect to purchases in Nebraska.

Q. Nev. Rev. Stat. Ann. §§ 598A.010, *et seq*., with respect to purchases in Nevada.

R. N.H. Rev. Stat. Ann. §§ 356:1, *et seq*., with respect to purchases in New Hampshire.

S. N.M. Stat. Ann. §§ 57-1-1, *et seq*., with respect to purchases in New Mexico.

T. N.Y. Gen. Bus. Law § 340, *et seq*., with respect to purchases in New York.

U. N.C. Gen. Stat. §§ 75-1, *et seq*., with respect to purchases in North Carolina.

V. N.D. Cent. Code §§ 51-08.1-01, *et seq*., with respect to purchases in North Dakota.

W. Or. Rev. Stat. §§ 646.705, *et seq*., with respect to purchases in Oregon.

X. S.D. Codified Laws §§ 37-1-3.1, *et seq*., with respect to purchases in South Dakota.

Y. Tenn. Code Ann §§ 47-25-101, *et seq*., with respect to purchases in Tennessee.

Z. Utah Code Ann. §§ 76-10-3101, *et seq*., with respect to purchases in Utah.

AA. Wis. Stat. §§ 133.01, *et seq*., with respect to purchases in Wisconsin.

526. Plaintiff has been injured in its business or property by reason of Celgene, BMS, Natco, Teva, and AbbVie's violations of the laws set forth above, in that it was, and continues to

be: (i) denied the opportunity to purchase lower-priced generic Revlimid; and (ii) paid higher prices for Revlimid than it would have paid but for Defendants' unlawful conduct. These injuries are of the type that the above laws were designed to prevent and flow from that which makes Defendants' conduct unlawful.

527. Plaintiff seeks damages and multiple damages as permitted by law.

SEVENTH CLAIM FOR RELIEF
CONSPIRACY AND COMBINATION IN RESTRAINT OF TRADE UNDER STATE LAW
(CELGENE, BMS, and DR. REDDY'S)

528. Plaintiff incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

529. Celgene, BMS, and Dr. Reddy's violated the various below state antitrust laws by entering into, furthering, and/or enforcing an unreasonable restraint of trade. More specifically, Celgene and BMS agreed with Dr. Reddy's to make a reverse payment in exchange for an agreement to delay competition from Dr. Reddy's AB-rated generic Revlimid until January 31, 2026, and to allocate the market for branded and AB-rated generic Revlimid. Celgene and BMS individually had market power with respect to sales of Revlimid and its AB-rated generic equivalents in the United States.

530. On or about September 16, 2020, Celgene entered into an anticompetitive reverse payment agreement, which was later entered into, furthered, and/or enforced by BMS, wherein Celgene and BMS agreed to pay, and did pay, Dr. Reddy's a large and unexplained payment in exchange for an agreement to delay unrestricted market entry of Dr. Reddy's generic version of Revlimid until January 31, 2026.

531. As a result of Celgene, BMS, and Dr. Reddy's unlawful conduct, Plaintiff has been harmed by being forced to pay artificially inflated, supracompetitive prices for Revlimid and its

AB-rated generic equivalents.

532. In formulating and carrying out the alleged agreement, understanding, contract, combination, and conspiracy, Celgene, BMS, and Dr. Reddy's did those things that they combined and conspired to do, including but not limited to the acts, practices, and course of conduct set forth herein.

533. Celgene, BMS, and Dr. Reddy's conspiracy had the following effects, among others: the reverse payment agreement between Celgene/BMS and Dr. Reddy's delayed generic competition (with its attendant lower prices), and the market allocation output restriction agreement and reverse payment effectively fixed prices at an artificially high level.

534. Celgene, BMS, and Dr. Reddy's entered into an unlawful reverse payment agreement that restrained, and continues to restrain, competition in the market for Revlimid and/or its AB-rated generic equivalents.

535. Defendants' acts and combinations in furtherance of the conspiracy have caused unreasonable restraints in the market for Revlimid and/or its AB-rated generic equivalents.

536. Celgene, BMS, and Dr. Reddy's engaged in the actions described above for the purpose of carrying out their unlawful agreements to fix, raise, maintain, or stabilize prices of Revlimid and its AB-rated generic equivalents.

537. There was no legitimate, non-pretextual, pro-competitive business justification for this reverse payment agreement that outweighs its harmful effect on Plaintiff and competition. Even if there were some conceivable and cognizable justification, the payment was not necessary to achieve the purpose. Accordingly, these acts constitute violations of the antitrust laws of various states in accordance with *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013).

538. The agreement caused lingering and persistent inflation in the prices for brand and

AB-rated generic Revlimid that continue to this day and, if the terms of the agreement are abided by, will continue through at least January 31, 2026.

539. There is no procompetitive justification for the anticompetitive agreements challenged here. The harm to Plaintiff and other purchasers in the form of paying inflated prices for brand and AB-rated generic Revlimid outweighs any conceivable procompetitive justification for the agreement.

540. By engaging the foregoing conduct, Defendants intentionally and wrongfully engaged in a contract, combination, or conspiracy in restraint of trade in violation of the following state antitrust laws:

A. Ala. Code § 8-10-3, *et seq*., with respect to purchases in Alabama.

B. Arizona Rev. Stat. §§ 44-1401, *et seq*., with respect to purchases in Arizona.

C. Cal. Bus. & Prof. Code §§ 16700, *et seq*., with respect to purchases in California.

D. C.G.S.A. §§ 35-26 and 28, *et seq*., with respect to purchases in Connecticut.

E. D.C. Code §§ 28-4501, *et seq*., with respect to purchases in the District of Columbia.

F. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases in Florida.

G. Haw. Rev. Stat. §§ 480-1, *et seq*., with respect to purchases in Hawaii.

H. 740 Ill. Comp. Stat. 10/1, *et seq*., with respect to purchases in Illinois.

I. Iowa Code § 553.1, *et seq*., with respect to purchases in Iowa.

J. Kan. Stat. Ann. § 50-101, *et seq*., with respect to purchases in Kansas.

K. Me. Rev. Stat. Ann. 10, §§ 1101, *et seq*., with respect to purchases in Maine.

L. Md. Code Ann., Com. Law, §§ 11-204, *et seq*., with respect to purchases in Maryland.

M. Mich. Comp. Laws Ann. §§ 445.771, *et seq*., with respect to purchases in Michigan.

N. Minn. Stat. §§ 325D.49, *et seq*., and Minn. Stat. §§ 8.31, *et seq*., with respect to

purchases in Minnesota.

O. Miss. Code Ann. §§ 75-21-1, *et seq*., with respect to purchases in Mississippi.

P. Neb. Rev. Stat. Ann. §§ 59-801, *et seq*., with respect to purchases in Nebraska.

Q. Nev. Rev. Stat. Ann. §§ 598A.010, *et seq*., with respect to purchases in Nevada.

R. N.H. Rev. Stat. Ann. §§ 356:1, *et seq*., with respect to purchases in New Hampshire.

S. N.M. Stat. Ann. §§ 57-1-1, *et seq*., with respect to purchases in New Mexico.

T. N.Y. Gen. Bus. Law § 340, *et seq*., with respect to purchases in New York.

U. N.C. Gen. Stat. §§ 75-1, *et seq*., with respect to purchases in North Carolina.

V. N.D. Cent. Code §§ 51-08.1-01, *et seq*., with respect to purchases in North Dakota.

W. Or. Rev. Stat. §§ 646.705, *et seq*., with respect to purchases in Oregon.

X. S.D. Codified Laws §§ 37-1-3.1, *et seq*., with respect to purchases in South Dakota.

Y. Tenn. Code Ann §§ 47-25-101, *et seq*., with respect to purchases in Tennessee.

Z. Utah Code Ann. §§ 76-10-3101, *et seq*., with respect to purchases in Utah.

AA. Wis. Stat. §§ 133.01, *et seq*., with respect to purchases in Wisconsin.

541. Plaintiff has been injured in its business or property by reason of Celgene, BMS, and Dr. Reddy's violations of the laws set forth above, in that it was, and continues to be: (i) denied the opportunity to purchase lower-priced generic Revlimid; and (ii) paid higher prices for Revlimid than it would have paid but for Celgene, BMS, and Dr. Reddy's unlawful conduct. These injuries are of the type that the above laws were designed to prevent and flow from that which makes Celgene, BMS, and Dr. Reddy's conduct unlawful.

542. Plaintiff seeks damages and multiple damages as permitted by law.

EIGHTH CLAIM FOR RELIEF
CONSPIRACY AND COMBINATION IN RESTRAINT OF TRADE UNDER STATE LAW
(ALL DEFENDANTS)

543. Plaintiff incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

544. Defendants and Alvogen, Cipla, Apotex, Zydus, Sun, Aurobindo, Mylan, and Hetero (together, the "Unnamed Co-Conspirators") violated the various below state antitrust laws by entering into, furthering, and/or enforcing an unreasonable restraints of trade in the market for Revlimid and/or its AB-rated generic equivalents as detailed Sections V.I., V.L., V.M., and V.N.

545. More specifically, Celgene and BMS agreed with Teva/Natco/AbbVie, Dr. Reddy's, and each of the Unnamed Co-Conspirators to make a reverse payment in exchange for agreements to delay competition from each's AB-rated generic Revlimid until January 31, 2026, and to allocate the market for branded and AB-rated generic Revlimid.

546. Plaintiff has been injured in its business or property as a direct result of violations of the various state antitrust laws below. Its injury consists of having paid higher prices for its lenalidomide requirements than its would have paid in the absence of those violations. Such injury, called "overcharges," is of the type that the antitrust laws were designed to prevent, and it flows from that which makes Defendants' and Unnamed Co-Conspirators' conduct unlawful.

547. In formulating and carrying out the alleged agreement, understanding, contract, combination, and conspiracy, Defendants and Unnamed Co-Conspirators did those things that they combined and conspired to do, including but not limited to the acts, practices, and course of conduct set forth herein.

548. Defendants' and Unnamed Co-Conspirators' conspiracy had the following effects, among others: the reverse payment agreements between Celgene/BMS and Teva/Natco/AbbVie, Dr. Reddy's, and the Unnamed Co-Conspirators delayed generic competition (with its attendant lower prices), and the market allocation output restriction agreement and reverse payment

effectively fixed prices at an artificially high level.

549. Celgene/BMS, Teva/Natco/AbbVie, Dr. Reddy's, and the Unnamed Co-Conspirators engaged in the actions described above for the purpose of carrying out their unlawful agreements to fix, raise, maintain, or stabilize prices of Revlimid and its AB-rated generic equivalents.

550. From the launch of Revlimid in 2005 through the present, Celgene (later, BMS) possessed, continues to possess, monopoly power in the relevant market—*i.e.*, the market for sales of lenalidomide in the United States. But for Defendants' and Unnamed Co-Conspirators' wrongful conduct, as alleged herein, Celgene (later, BMS) would have lost its monopoly power in the relevant market as early as May 2021 and in any event well before 2022.

551. Starting in March 2022, Celgene and BMS began sharing its monopoly power. First with Teva/Natco/AbbVie, and then, six months later, with Dr. Reddy's and the Unnamed Co-Conspirators, as a result of its anticompetitive reverse-payment and market-allocation agreements with each. These agreements individually and collectively will cover a sufficiently substantial percentage of the relevant market to harm competition.

552. There is and was no legitimate, non-pretextual, pro-competitive business justification for these reverse payment agreements that outweighs their harmful effect on purchasers and competition. Even if there were some conceivable and cognizable justification, the payment was not necessary to achieve such a purpose.

553. Defendants' acts and combinations in furtherance of the conspiracy have caused unreasonable restraints in the market for Revlimid and/or its AB-rated generic equivalents.

554. There was no legitimate, non-pretextual, pro-competitive business justification for these reverse payment agreements that outweighs its harmful effect on Plaintiff and competition.

Even if there were some conceivable and cognizable justification, the payments were not necessary to achieve the purpose. Accordingly, these acts constitute violations of the antitrust laws of various states in accordance with *FTC v. Actavis, Inc*., 570 U.S. 136 (2013).

555. The agreement caused lingering and persistent inflation in the prices for brand and AB-rated generic Revlimid that continue to this day and, if the terms of the agreement are abided by, will continue through at least January 31, 2026.

556. There is no procompetitive justification for the anticompetitive agreements challenged here. The harm to Plaintiff and other purchasers in the form of paying inflated prices for brand and AB-rated generic Revlimid outweighs any conceivable procompetitive justification for the agreement.

557. By engaging the foregoing conduct, Defendants intentionally and wrongfully engaged in a contract, combination, or conspiracy in restraint of trade in violation of the following state antitrust laws:

A. Ala. Code § 8-10-3, *et seq*., with respect to purchases in Alabama.

B. Arizona Rev. Stat. §§ 44-1401, *et seq*., with respect to purchases in Arizona.

C. Cal. Bus. & Prof. Code §§ 16700, *et seq*., with respect to purchases in California.

D. C.G.S.A. §§ 35-26 and 28, *et seq*., with respect to purchases in Connecticut.

E. D.C. Code §§ 28-4501, *et seq*., with respect to purchases in the District of Columbia.

F. Fla. Stat. §§ 501.201, *et seq*., with respect to purchases in Florida.

G. Haw. Rev. Stat. §§ 480-1, *et seq*., with respect to purchases in Hawaii.

H. 740 Ill. Comp. Stat. 10/1, *et seq*., with respect to purchases in Illinois.

I. Iowa Code § 553.1, *et seq*., with respect to purchases in Iowa.

J. Kan. Stat. Ann. § 50-101, *et seq*., with respect to purchases in Kansas.

K. Me. Rev. Stat. Ann. 10, §§ 1101, *et seq*., with respect to purchases in Maine.

L. Md. Code Ann., Com. Law, §§ 11-204, *et seq*., with respect to purchases in Maryland.

M. Mich. Comp. Laws Ann. §§ 445.771, *et seq*., with respect to purchases in Michigan.

N. Minn. Stat. §§ 325D.49, *et seq*., and Minn. Stat. §§ 8.31, *et seq*., with respect to purchases in Minnesota.

O. Miss. Code Ann. §§ 75-21-1, *et seq*., with respect to purchases in Mississippi.

P. Neb. Rev. Stat. Ann. §§ 59-801, *et seq*., with respect to purchases in Nebraska.

Q. Nev. Rev. Stat. Ann. §§ 598A.010, *et seq*., with respect to purchases in Nevada.

R. N.H. Rev. Stat. Ann. §§ 356:1, *et seq*., with respect to purchases in New Hampshire.

S. N.M. Stat. Ann. §§ 57-1-1, *et seq*., with respect to purchases in New Mexico.

T. N.Y. Gen. Bus. Law § 340, *et seq*., with respect to purchases in New York.

U. N.C. Gen. Stat. §§ 75-1, *et seq*., with respect to purchases in North Carolina.

V. N.D. Cent. Code §§ 51-08.1-01, *et seq*., with respect to purchases in North Dakota.

W. Or. Rev. Stat. §§ 646.705, *et seq*., with respect to purchases in Oregon.

X. S.D. Codified Laws §§ 37-1-3.1, *et seq*., with respect to purchases in South Dakota.

Y. Tenn. Code Ann §§ 47-25-101, *et seq*., with respect to purchases in Tennessee.

Z. Utah Code Ann. §§ 76-10-3101, *et seq*., with respect to purchases in Utah.

AA. Wis. Stat. §§ 133.01, *et seq*., with respect to purchases in Wisconsin.

558. Plaintiff has been injured in its business or property by reason of Defendants' violations of the laws set forth above, in that it was, and continues to be: (i) denied the opportunity to purchase lower-priced generic Revlimid; and (ii) paid higher prices for Revlimid than it would have paid but for Defendants' unlawful conduct. These injuries are of the type that the above laws were designed to prevent and flow from that which makes Defendants' conduct unlawful.

559. Plaintiff seeks damages and multiple damages as permitted by law.

NINTH CLAIM FOR RELIEF
MONOPOLIZATION AND MONOPOLISTIC SCHEME UNDER STATE LAW
(CELGENE & BMS)

560. Plaintiff incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

561. Celgene and BMS possessed monopoly power in the defined relevant market at all times since its NDAs for Revlimid were respectively approved. Celgene and BMS knowingly and willfully engaged in a course of exclusionary conduct designed to prevent generic manufacturers from entering the market and unlawfully extended its monopoly power.

562. Celgene intentionally extended its monopoly power in the relevant market through its anticompetitive and illegal scheme. Thus, Plaintiff paid artificially inflated prices for its indirect purchases Revlimid, including by assignment from its subsidiaries. There is and was no non-pretextual justification for Celgene and 's anticompetitive actions.

563. As a direct and proximate result of Celgene's conduct, as alleged herein, Plaintiff was injured.

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

A. Ala. Code § 8-10-3, *et seq*., with respect to purchases in Alabama.

B. Arizona Rev. Stat. §§ 44-1403, *et seq*., with respect to purchases of Revlimid in Arizona.

C. Cal. Bus. & Prof. Code §§ 17200, *et seq*., and California common law, with respect to purchases of Revlimid in California.

D. Conn. Gen. Stat. §§ 35-27 and 29, *et seq*., with respect to purchases of Revlimid in Connecticut.

E. D.C. Code §§ 28-4503, *et seq*., with respect to purchases of Revlimid in the District of Columbia.

F. Fla. Stat. §§ 501.201, *et seq*., with respect to purchases of Revlimid in Florida.

G. Hawaii Code §§ 480, *et seq*., with respect to purchases of Revlimid in Hawaii.

H. 740 Ill. Comp. Stat. 10/3, *et seq*., with respect to purchases of Revlimid in Illinois.

I. Iowa Code §§ 553.5 *et seq*., with respect to purchases of Revlimid in Iowa.

J. Mass. Gen. L. Ch. 93A, *et seq*., with respect to purchases of Revlimid in Massachusetts by Plaintiff, which paid substantially higher prices for Revlimid in actions and transactions occurring substantially within Massachusetts.

K. Me. Rev. Stat. Ann. 10, §§ 1102, *et seq*., with respect to purchases of Revlimid in Maine.

L. Md. Code, Com. Law §§ 11-204, *et seq*., with respect to purchases of Revlimid in Maryland.

M. Mich. Comp. Laws Ann. §§ 445.773, *et seq*., with respect to purchases of Revlimid in Michigan.

N. Minn. Stat. §§ 325D.52, *et seq*., and Minn. Stat. § 8.31, *et seq*., with respect to purchases of Revlimid in Minnesota.

O. Miss. Code Ann. §§ 75-21-3, *et seq*., with respect to purchases of Revlimid in Mississippi.

P. Neb. Code Ann. §§ 59-802, *et seq*., with respect to purchases of Revlimid in Nebraska.

Q. Nev. Rev. Stat. Ann. §§ 598A.060, *et seq*., with respect to purchases of Revlimid in Nevada by Plaintiff, which paid substantially higher prices for Revlimid in actions and transactions occurring substantially within Nevada.

R. N.H. Rev. Stat. Ann. §§ 356.1, *et seq*., with respect to purchases of Revlimid in New Hampshire.

S. N.M. Stat. Ann. §§ 57-1-2, *et seq*., with respect to purchases of Revlimid in New Mexico.

T. N.C. Gen. Stat. §§ 75-2.1, *et seq*., with respect to purchases of Revlimid in North Carolina.

U. N.D. Cent. Code §§ 51-08.1-03, *et seq*., with respect to purchases of Revlimid in North Dakota.

V. Or. Rev. Stat. §§ 646.705, *et seq*., with respect to purchases of Revlimid in Oregon.

W.

X. S.D. Codified Laws §§ 37-1-3.2, *et seq*., with respect to purchases of Revlimid in South Dakota.

Y. Utah Code Ann. §§ 76-10-911, *et seq*., with respect to purchases of Revlimid in Utah.

Z. Wis. Stat. §§ 133.03, *et seq*., with respect to purchases of Revlimid in Wisconsin by Plaintiff, in that the actions and transactions alleged herein substantially affected and continue to affect the people of Wisconsin, whereby Plaintiff paid substantially higher prices for Revlimid at Wisconsin pharmacies.

565. Plaintiff has been injured in its business or property by reason of Defendants' violations of the laws set forth above, in that they were, and continue to be: (i) denied the opportunity to purchase lower-priced generic Revlimid; and (ii) paid higher prices for Revlimid than it would have paid but for Defendants' unlawful conduct. These injuries are of the type that the above laws were designed to prevent and flow from that which makes Defendants' conduct unlawful.

566. Plaintiff seeks damages and multiple damages as permitted by law.

TENTH CLAIM FOR RELIEF
ATTEMPTED MONOPOLIZATION UNDER STATE LAW
(CELGENE & BMS)

567. Plaintiff incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

568. Celgene and BMS, through their anticompetitive scheme, specifically intended to maintain monopoly power in the relevant market. It was Celgene and BMS's conscious objective to control prices and exclude competition in the relevant market.

569. The natural, intended, and foreseeable consequences of Celgene and BMS's anticompetitive scheme was to control prices and exclude competition in the relevant market, to

the extent it did not succeed.

570. There is a substantial and real chance, a reasonable likelihood, and/or a dangerous probability that Celgene and BMS will succeed in and achieve their goal of maintaining monopoly power in the relevant market.

571. As a direct and proximate result of Celgene and BMS's conduct, Plaintiff was harmed with respect to its indirect purchases of Revlimid as aforesaid.

572. By engaging in the foregoing conduct, Celgene and BMS have intentionally and wrongfully attempted to monopolize the relevant market in violation of the following state laws:

A. Ala. Code § 8-10-3, *et seq*., with respect to purchases in Alabama.

B. Arizona Rev. Stat. §§ 44-1403, *et seq*., with respect to purchases of Revlimid in Arizona.

C. Cal. Bus. & Prof. Code §§ 17200, *et seq*., and California common law, with respect to purchases of Revlimid in California.

D. Conn. Gen. Stat. §§ 35-27 and 29, *et seq*., with respect to purchases of Revlimid in Connecticut.

E. D.C. Code §§ 28-4503, *et seq*., with respect to purchases of Revlimid in the District of Columbia.

F. Fla. Stat. §§ 501.201, *et seq*., with respect to purchases of Revlimid in Florida.

G. Hawaii Code §§ 480, *et seq*., with respect to purchases of Revlimid in Hawaii.

H. 740 Ill. Comp. Stat. 10/3, *et seq*., with respect to purchases of Revlimid in Illinois.

I. Iowa Code §§ 553.5 *et seq*., with respect to purchases of Revlimid in Iowa.

J. Me. Rev. Stat. Ann. 10, §§ 1102, *et seq*., with respect to purchases of Revlimid in Maine.

K. Md. Code, Com. Law §§ 11-204, *et seq*., with respect to purchases of Revlimid in Maryland.

L. Mass. Gen. L. Ch. 93A, *et seq*., with respect to purchases of Revlimid in Massachusetts by Plaintiff, which paid substantially higher prices for Revlimid in actions and transactions occurring substantially within Massachusetts.

M. Mich. Comp. Laws Ann. §§ 445.773, *et seq*., with respect to purchases of Revlimid in Michigan.

N. Minn. Stat. §§ 325D.52, *et seq*., and Minn. Stat. § 8.31, *et seq*., with respect to purchases of Revlimid in Minnesota.

O. Miss. Code Ann. §§ 75-21-3, *et seq*., with respect to purchases of Revlimid in Mississippi.

P. Neb. Code Ann. §§ 59-802, *et seq*., with respect to purchases of Revlimid in Nebraska.

Q. Nev. Rev. Stat. Ann. §§ 598A.060, *et seq*., with respect to purchases of Revlimid in Nevada by Plaintiff, which paid substantially higher prices for Revlimid in actions and transactions occurring substantially within Nevada.

R. N.H. Rev. Stat. Ann. §§ 356.1, *et seq*., with respect to purchases of Revlimid in New Hampshire.

S. N.M. Stat. Ann. §§ 57-1-2, *et seq*., with respect to purchases of Revlimid in New Mexico.

T. N.Y. Gen. Bus. Law §§ 340, *et seq*., with respect to purchases of Revlimid in New York.

U. N.C. Gen. Stat. §§ 75-2.1, *et seq*., with respect to purchases of Revlimid in North Carolina.

V. N.D. Cent. Code §§ 51-08.1-03, *et seq*., with respect to purchases of Revlimid in North Dakota.

W. Or. Rev. Stat. §§ 646.705, *et seq*., with respect to purchases of Revlimid in Oregon.

X. S.D. Codified Laws §§ 37-1-3.2, *et seq*., with respect to purchases of Revlimid in South Dakota.

Y. Utah Code Ann. §§ 76-10-911, *et seq*., with respect to purchases of Revlimid in Utah.

Z. Wis. Stat. §§ 133.03, *et seq*., with respect to purchases of Revlimid in Wisconsin by Plaintiff, in that the actions and transactions alleged herein substantially affected and continue to affect the people of Wisconsin, whereby Plaintiff paid substantially higher prices for Revlimid at Wisconsin pharmacies.

573. Plaintiff has been injured in its business or property by reason of Defendants' violations of the laws set forth above, in that it was, and continues to be: (i) denied the

opportunity to purchase lower-priced generic Revlimid; and (ii) paid higher prices for Revlimid than it would have paid but for Defendants' unlawful conduct. These injuries are of the type that the above laws were designed to prevent and flow from that which makes Defendants' conduct unlawful.

574. Plaintiff seeks damages and multiple damages as permitted by law.

ELEVENTH CLAIM FOR RELIEF
UNFAIR AND DECEPTIVE TRADE PRACTICES UNDER STATE LAW
(ALL DEFENDANTS)

575. Plaintiff incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

576. Defendants engaged in unfair competition or unfair, unconscionable, deceptive and/or fraudulent acts or practices in violation of the state consumer protection statutes listed below. As a direct and proximate result of Defendants' anticompetitive, deceptive, unfair, unconscionable, and/or fraudulent conduct, Plaintiff was deprived of the opportunity to purchase generic versions of Revlimid at lower prices and was forced to pay artificially inflated prices for brand and generic versions of the drug.

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

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

579. Defendants withheld materials facts and information from Plaintiff, including that Defendants were unlawfully monopolizing the market for lenalidomide and thereby profiting from the resulting supra-competitive prices that Plaintiff paid for brand and generic Revlimid.

580. Defendants intended to deceive Plaintiff regarding the nature of their actions within the stream of commerce in each jurisdiction below.

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

582. Plaintiff purchased brand and generic Revlimid primarily for personal, family, or household purposes of its members and insureds.

583. There was and is a gross disparity between the price that Plaintiff paid and continues to pay for its purchases of Revlimid, and the value received, given that a much cheaper substitute generic product should have been available earlier and without limitations, and prices for Revlimid should be much lower, but for Defendants' unlawful scheme.

584. As a direct and proximate result of Defendants' unlawful conduct, Plaintiff has been injured and is threatened with continued injury.

585. By engaging in the foregoing conduct, Defendants have engaged in unfair, unconscionable, or deceptive acts and practices in violation of the consumer protection statutes listed below, which conduct denied Plaintiff the opportunity to purchase lower-priced lenalidomide generics and made it pay higher prices for brand and generic Revlimid than it otherwise would have paid.

586. Defendants' unfair and deceptive acts described above were knowing, willful, unconscionable, and constitute violations or flagrant violations of the following unfair trade

practices and consumer protection statutes:

A. Ariz. Rev. Stat. §§ 44-1521, *et seq.*, with respect to purchases of brand and generic Revlimid in Arizona.

587. Section 44-1522 of the Arizona Revised Statutes provides:

> A. The act, use or employment by any person of any deception, deceptive or unfair act or practice, fraud, false pretense, false promise, misrepresentation, or concealment, suppression or omission of any material fact with intent that others rely on such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise whether or not any person has in fact been misled, deceived or damaged thereby, is declared to be an unlawful practice.

588. As set forth in detail above in Sections V.D. through V.P. and Sections VI through VIII of this Complaint, Defendants violated § 44-1522 of the Arizona Revised Statutes by entering into unlawful reverse-payment agreements that constituted unfair and deceptive acts and that will delay full generic competition in the Revlimid market until January 2026.

589. As a direct and proximate result of Defendants' conduct, Plaintiff suffered injury and actual damages in the form of paying higher prices for Revlimid than it would have paid but for Defendants' unlawful conduct.

590. Plaintiff's injury is of the type that § 44-1522 of the Arizona Revised Statutes was intended to prevent.

591. Plaintiff is entitled to bring this action for damages pursuant to § 44-1533 of the Arizona Revised Statutes.

592. Plaintiff is entitled to recover actual damages and punitive damages because Defendants' conduct is wanton, reckless, shows spite or ill will, and demonstrates a reckless indifference to the interests of others.

B. Ark. Code §§ 4-88-101, *et seq.*, with respect to purchases of brand and generic Revlimid in Arkansas.

593. Section 4-88-107 of the Arkansas Code provides as follows:

> (a) Deceptive and unconscionable trade practices made unlawful and prohibited by this chapter include, but are not limited to, the following:
>
> . . .
>
> (10) Engaging in any . . . unconscionable, false, or deceptive act or practice in business, commerce, or trade;
>
> . . .
>
> (b) The deceptive and unconscionable trade practices listed in this section are in addition to and do not limit the types of unfair trade practices actionable at common law or under other statutes of this state.

594. As set forth in detail above in Sections V.D. through V.P. and Sections VI through VIII of this Complaint, Defendants violated § 4-88-107 of the Arkansas Code by entering into unlawful reverse-payment agreements that will delay full generic competition in the Revlimid market until January 2026.

595. As a direct and proximate result of Defendants' unlawful conduct, and Plaintiff's reliance thereon, Plaintiff suffered injury and actual financial damages in the form of paying higher prices for Revlimid than it would have paid but for Defendants' unlawful conduct.

596. Plaintiff's injury is of the type that § 4-88-107 of the Arkansas Code was intended to prevent.

597. Plaintiff is entitled to bring this action for damages pursuant to § 4-88-113 of the Arkansas Code.

598. Plaintiff is entitled to recover its actual damages, along with reasonable attorney fees. Ark. Code § 4-88-113(f).

C. Cal. Bus. & Prof. Code §§ 17200, *et seq.*, with respect to purchases of brand and generic Revlimid in California.

599. The purpose of chapter 4 of the California Business & Professional Code is "to safeguard the public against the creation or perpetuation of monopolies and to foster and

encourage competition, by prohibiting unfair, dishonest, deceptive, destructive, fraudulent and discriminatory practices by which fair and honest competition is destroyed or prevented." The chapter is to be construed liberally so "that its beneficial purposes may be subserved." Cal. Bus. & Prof. Code §§ 17001, 17002 (2023).

600. California's Unfair Competition Law, Cal. Bus. & Prof. Code § 17200 *et seq.*, which is part of chapter 4 of that Code, prohibits "any unlawful, unfair or fraudulent business act or practice."

601. As set forth in detail above in Sections V.D. through V.P. and Sections VI through VIII of this Complaint, Defendants violated the California Unfair Competition Law, Cal. Bus. & Prof. Code § 17200 by entering into unlawful reverse-payment agreements that constituted unfair and deceptive acts and that will delay full generic competition in the Revlimid market until January 2026.

602. As a direct and proximate result of Defendants' conduct, Plaintiff suffered injury and actual damages in the form of paying higher prices for Revlimid than it would have paid but for Defendants' unlawful conduct.

603. Plaintiff's injury is of the type the California Unfair Competition Law was intended to prevent.

604. Plaintiff is entitled to restoration of all monies that Defendants acquired by means of the unfair competition described in this Complaint, along with declaratory and injunctive relief. Cal. Bus. & Prof. Code § 17203.

D. Colo. Rev. Stat § 6-1-105, *et seq.*, with respect to purchases of brand and generic Revlimid in Colorado.

605. Colorado Rev. Stat. § 6-1-113 provides, in relevant part, that the provisions of the Colorado Consumer Protection Act (C.R.S. § 6-1-101, *et seq.*) "shall be available in a civil action

for any claim against any person who has engaged in or caused another to engage in any deceptive trade practice listed in this article." Section 6-1-113(c) provides that an action under this section shall be available to any person who, "in the course of the person's business or occupation, is injured as a result of such deceptive trade practice."

606. The Colorado Consumer Protection Act, Colo. Rev. Stat. § 6-1-105(1) prohibits "deceptive trade practices." Subsection 6-1-105(1)(e) prohibits "knowingly mak[ing] a false representation as to the characteristics, ingredients, uses, [or] benefits . . . of goods."

607. As set forth in detail above in Sections V.D. through V.P. and Sections VI through VIII of this Complaint, Defendants violated the Colorado Consumer Protection Act by entering into unlawful reverse-payment agreements that constituted deceptive acts and that will delay full generic competition in the Revlimid market until January 2026.

608. As a direct and proximate result of Defendants' conduct, Plaintiff suffered injury and actual damages in the form of paying higher prices for Revlimid than it would have paid but for Defendants' unlawful conduct.

609. Plaintiff's injury is of the type that the Colorado Consumer Protection Act was intended to prevent.

610. Plaintiff is entitled to bring this action for damages pursuant to § 6-1-113 of the Colorado Code.

611. Plaintiff is entitled to recover three times the amount of actual damages sustained because of the Defendants' willful, knowing, and intentional conduct that caused injury, along with reasonable attorney fees and litigation costs. Colo. Rev. Stat. § 6-1-113(2).

E. Conn. Gen. Stat. §§ 42-110, *et seq.*, with respect to purchases of brand and generic Revlimid in Connecticut.

612. Connecticut General Statutes § 42-110b(a) provides, "No person shall engage in

unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce."

613. Connecticut General Statutes § 42-110g(a) provides that any person "who suffers any ascertainable loss of money or property, real or personal, as a result of the use or employment of a method, act or practice prohibited by section 42-110b may bring an action in the judicial district in the judicial district in which the plaintiff or defendant resides or has his principal place of business or is doing business . . . " to recover actual damages, and permits the court in its discretion to award punitive damages and equitable relief.

614. As set forth in detail above in Sections V.D. through V.P. and Sections VI through VIII of this Complaint, Defendants violated § 42-110b of the Connecticut General Statutes by entering into unlawful reverse-payment agreements, which were contracts that monopolized the U.S. market for lenalidomide and that will delay full generic competition in the Revlimid market until January 2026.

615. As a direct and proximate result of Defendants' conduct, Plaintiff suffered injury and actual damages in the form of paying higher prices for Revlimid than it would have paid but for Defendants' unlawful conduct.

616. Plaintiff's injury is of the type that § 42-110b of the Connecticut General Statutes was intended to prevent.

617. Plaintiff is entitled to bring this action for damages and equitable relief pursuant to Connecticut General Statutes § 42-110g.

618. Plaintiff is entitled to recover actual damages and punitive damages, along with costs and reasonable attorney fees. Conn. Gen. Stat. § 42-110g.

F. D.C. Code §§ 28-3901, *et seq.*, with respect to purchases of brand and generic Revlimid in the District of Columbia.

619. District of Columbia Code § 28-3904 provides that "[i]t shall be a violation of this chapter for any person to engage in an unfair or deceptive trade practice. . . ."

620. District of Columbia Code § 28-4502 provides that every contract or conspiracy "in restraint of trade or commerce all or any part of which is within the District of Columbia is declared to be illegal."

621. District of Columbia Code § 28-4503 provides that it shall be unlawful for any person "to monopolize, attempt to monopolize, or combine or conspire with any other person or persons to monopolize any part of trade or commerce, all or any part of which is within the District of Columbia."

622. As set forth in detail above in Sections V.D. through V.P. and Sections VI through VIII of this Complaint, Defendants violated §§ 28-3901, *et seq.* by entering into unlawful reverse-payment agreements, which were contracts that monopolized the U.S. market for lenalidomide and that will delay full generic competition in the Revlimid market until January 2026.

623. As a direct and proximate result of Defendants' conduct, Plaintiff suffered injury and actual damages in the form of paying higher prices for Revlimid than it would have paid but for Defendants' unlawful conduct.

624. Plaintiff's injury is of the type that §§ 28-3901, *et seq.* of the District of Columbia Code was intended to prevent.

625. Plaintiff is entitled to bring this action for damages pursuant to District of Columbia Code § 28-3905.

626. Plaintiff is entitled to recover actual damages, treble damages and punitive damages, along with reasonable attorney fees and expenses. D.C. Code §§ 28-3905(k).

G. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases of brand and generic Revlimid in Florida.

627. The Florida Deceptive and Unfair Trade Practices Act, Florida Statutes § 501.204(1), provides, "Unfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful."

628. As set forth in detail above in Sections V.D. through V.P. and Sections VI through VIII of this Complaint, Defendants violated Florida Statutes § 501.204(1) by entering into unlawful reverse-payment agreements, which will delay full generic competition in the Revlimid market until January 2026.

629. As a direct and proximate result of Defendants' conduct, Plaintiff suffered injury and actual damages in the form of paying higher prices for Revlimid than it would have paid but for Defendants' unlawful conduct.

630. Plaintiff's injury is of the type that Florida Statutes § 501.201 *et seq.* was intended to prevent.

631. Plaintiff is entitled to bring this action for damages pursuant to Florida Statutes § 501.211.

632. Plaintiff is entitled to recover actual damages along with reasonable attorney fees and court costs. Fla. Stat.§ § 501.211, 501.2015.

H. Idaho Code §§ 48-601, *et seq.*, with respect to purchases of brand and generic Revlimid in Idaho.

633. The Idaho Consumer Protection Act, Idaho Code § 48-601, *et seq.*, makes unlawful "unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce where a person knows, or in the exercise of due care should know" that he has "engag[ed] in any act or practice that is … misleading, false, or deceptive to the consumer" (§ 48-603(17)), or "engag[ed] in any unconscionable method, act or practice in the conduct of

trade or commerce" (§ 48-603(18)).

634. As set forth in detail above in Sections V.D. through V.P. and Sections VI through VIII of this Complaint, Defendants violated Idaho Code §§ 48-601, *et seq.*, by entering into unlawful reverse-payment agreements, which will delay full generic competition in the Revlimid market until January 2026.

635. As a direct and proximate result of Defendants' conduct, Plaintiff suffered injury, ascertainable loss, and actual damages in the form of paying higher prices for Revlimid than it would have paid but for Defendants' unlawful conduct.

636. Plaintiff's injury is of the type that Idaho Code § 48-601, *et seq.* was intended to prevent.

637. Plaintiff is entitled to bring this action for damages and equitable relief pursuant to Idaho Code § 48-608.

638. Plaintiff is entitled to recover actual damages and punitive damages, along with reasonable costs and attorney fees. Idaho Code § 48-608(5).

I. 815 ILCS §§ 505/1, *et seq.*, with respect to purchases of brand and generic Revlimid in Illinois.

639. The Illinois Consumer Fraud and Deceptive Business Practices Act, 815 Illinois Compiled Statutes § 505/2, makes unlawful "[u]nfair methods of competition and unfair or deceptive acts or practices, including but not limited to the use or employment of any deception, fraud, false pretense, false promise, misrepresentation or the concealment, suppression or omission of any material fact, with intent that others rely upon the concealment, suppression or omission of such material fact . . . in the conduct of any trade or commerce."

640. As set forth in detail above in Sections V.D. through V.P. and Sections VI through VIII of this Complaint, Defendants violated § 815 ILCS §§ 505/1, *et seq.* by entering into

unlawful reverse-payment agreements, which will delay full generic competition in the Revlimid market until January 2026.

641. As a direct and proximate result of Defendants' conduct, Plaintiff suffered injury and actual damages in the form of paying higher prices for Revlimid than it would have paid but for Defendants' unlawful conduct.

642. Plaintiff's injury is of the type that 815 ILCS §§ 505/1, *et seq.* was intended to prevent.

643. Plaintiff is entitled to bring this action for damages and injunctive relief pursuant to 815 Illinois Statutes § 505/10a.

644. Plaintiff is entitled to recover actual damages and punitive damages, along with reasonable attorney fees and costs. 815 ILCS §§ 505/10a(a) and 505/10a(c).

J. Ind. Code §§ 24-5-0.5-1, *et seq.*, with respect to purchases of brand and generic Revlimid in Indiana.

645. Indiana Code §§ 24-5-0.5-3 provides that "[a] supplier may not commit an unfair, abusive, or deceptive act, omission, or practice in connection with a consumer transaction. . . . An Act, omission, or practice prohibited by this section includes both implicit and explicit misrepresentations."

646. As set forth in detail above in Sections V.D. through V.P. and Sections VI through VIII of this Complaint, Defendants violated Indiana Code § 24-5-0.5-3 by entering into unlawful reverse-payment agreements, which will delay full generic competition in the Revlimid market until January 2026.

647. As a direct and proximate result of Defendants' conduct, Plaintiff suffered injury and actual damages in the form of paying higher prices for Revlimid than it would have paid but for Defendants' unlawful conduct.

648. Plaintiff's injury is of the type that Indiana Code §§ 24-5-0.5-1, *et seq.* was intended to prevent.

649. Plaintiff is entitled to bring this action for damages pursuant to Indiana Code § 24-5-0.5-4.

650. Plaintiff is entitled to recover three times its actual damages, along with reasonable attorney fees. Indiana Code § 24-5-0.5-4(a), (b).

K. Kan. Stat. §§ 50-623, *et seq.*, with respect to purchases of brand and generic Revlimid in Kansas.

651. The Kansas Consumer Protection Act, Kansas Statutes § 50-623 provides that "no supplier shall engage in any deceptive act or practice in connection with a consumer transaction."

652. Additionally, Kansas Statutes § 50-624 provides that no supplier shall engage in any unconscionable act or practice in connection with a consumer transaction. An unconscionable act or practice violates this act whether it occurs before, during or after the transaction."

653. As set forth in detail above in Sections V.D. through V.P. and Sections VI through VIII of this Complaint, Defendants violated §§ 50-623 and 50-624 of the Kansas Consumer Protection Act by entering into unlawful reverse-payment agreements that will delay full generic competition in the Revlimid market until January 2026.

654. As a direct and proximate result of Defendants' conduct, Plaintiff suffered injury in the form of paying higher prices for Revlimid than it would have paid but for Defendants' unlawful conduct.

655. Plaintiff's injury is of the type that §§ 50-623 and 50-624 of the Kansas Consumer Protection Act were intended to prevent.

656. Plaintiff is entitled to bring this action for damages and equitable relief pursuant to § 50-634 of the Kansas Statutes.

L. La. Rev. Stat. Ann. § 51:1401, *et seq.*, with respect to purchases of brand and generic Revlimid in Louisiana.

657. The Louisiana Unfair Trade Practices and Consumer Protection Law provides that "unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful." *See* La. Stat. Ann. § 51:1405.

658. As set forth in detail above in Sections V.D. through V.P. and Sections VI through VIII of this Complaint. Defendants violated § 51:1405 of the Louisiana Revised Statutes by entering into unlawful reverse-payment agreements that will delay full generic competition in the Revlimid market until January 2026. Specifically, such unlawful reverse-payment agreements are an unfair method of competition.

659. As a direct and proximate result of Defendants' conduct, Plaintiff suffered injury in the form of paying higher prices for Revlimid than it would have paid but for Defendants' unlawful conduct.

660. Plaintiff's injury is of the type that § 51:1405 of the Louisiana Revised Statutes was intended to prevent.

661. Plaintiff is entitled to bring this action for damages and equitable relief pursuant to § 51:1409 of the Louisiana Revised Statutes.

M. 5 Me. Rev. Stat. §§ 207, *et seq.*, with respect to the purchases of Revlimid in Maine.

662. Section 207 of the Maine Revised Statutes provides that "unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are declared unlawful."

663. As set forth in detail above in Sections V.D. through V.P. and Sections VI through VIII of this Complaint, Defendants violated § 207 of the Maine Revised Statutes by entering into unlawful reverse-payment agreements that will delay full generic competition in the Revlimid

market until January 2026. Specifically, Defendants engaged in unfair methods of competition and unfair or deceptive acts in connection with the sale of Revlimid. *See* Me. Rev. Stat. tit. 5, § 207

664. As a direct and proximate result of Defendants' conduct, Plaintiff suffered injury in the form of paying higher prices for Revlimid than it would have paid but for Defendants' unlawful conduct.

665. Plaintiff's injury is of the type that § 207 of the Maine Revised Statutes was intended to prevent.

666. Plaintiff is entitled to bring this action for damages pursuant to § 213 of the Maine Revised Statutes.

N. Md. Code, Com. Law §§ 13-301, *et seq.*, with respect to purchases of brand and generic Revlimid in Maryland.

667. Section 13-303 of the Maryland Code provides as follows:

> (a) A person may not engage in any unfair, abusive, or deceptive trade practice, as defined in this subtitle or as further defined by the Division, in:
>
> > (1) The sale, lease, rental, loan, or bailment of any consumer goods, consumer realty, or consumer services[.]

668. As set forth in detail above in Sections V.D. through V.P. and Sections VI through VIII of this Complaint, Defendants violated § 13-303 of the Maryland Code by entering into unlawful reverse-payment agreements that will delay full generic competition in the Revlimid market until January 2026.

669. As a direct and proximate result of Defendants' conduct, Plaintiff suffered injury in the form of paying higher prices for Revlimid than it would have paid but for Defendants' unlawful conduct.

670. Plaintiff's injury is of the type that § 13-303 of the Maryland Code was intended to

prevent.

671. Plaintiff is entitled to bring this action for damages pursuant to § 13-408 of the Maryland Code.

O. Mass. Ann. Laws ch. 93A, *et seq.*, with respect to purchases of brand and generic Revlimid in Massachusetts.

672. Massachusetts General Laws, chapter 93A, § 2 provides as follows:

> (a) Unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful.

673. As set forth in detail above in Sections V.D. through V.P. and Sections VI through VIII of this Complaint, Defendants violated Massachusetts General Laws, chapter 93A, § 2 by entering into unlawful reverse-payment agreements that will delay full generic competition in the Revlimid market until January 2026.

674. As a direct and proximate result of Defendants' conduct, Plaintiff suffered injury in the form of paying higher prices for Revlimid than it would have paid but for Defendants' unlawful conduct.

675. Plaintiff's injury is of the type that Massachusetts General Laws, chapter 93A, § 2 was intended to prevent.

676. Plaintiff is entitled to bring this action for damages pursuant to Massachusetts General Laws, chapter 93A, § 9.

677. Plaintiff is entitled to a damages award up to three times the amount of its actual damages. Mass. Gen. Laws Ann. ch. 93A, § 9. Plaintiff is also entitled to recover costs and reasonable attorney fees. *Id.*

P. Mich. Stat. §§ 445.901, *et seq.*, with respect to purchases of brand and generic Revlimid in Michigan.

678. Section 445.903 of the Michigan Compiled Laws provides as follows:

> Sec. 3. (1) Unfair, unconscionable, or deceptive methods, acts, or practices in the conduct of trade or commerce are unlawful and are defined as follows:
> …
>
> (s) Failing to reveal a material fact, the omission of which tends to mislead or deceive the consumer, and which fact could not reasonably be known by the consumer.

679. As set forth in detail above in Sections V.D. through V.P. and Sections VI through VIII of this Complaint, Defendants violated § 445.903 of the Michigan Compiled Laws by entering into unlawful reverse-payment agreements that will delay full generic competition in the Revlimid market until January 2026.

680. As a direct and proximate result of Defendants' conduct, Plaintiff suffered injury in the form of paying higher prices for Revlimid than it would have paid but for Defendants' unlawful conduct.

681. Plaintiff's injury is of the type that § 445.903 of the Michigan Compiled Laws was intended to prevent.

682. Plaintiff is entitled to bring this action for damages pursuant to § 445.911 of the Michigan Compiled Laws.

683. Plaintiff is entitled to recover actual damages and punitive damages, along with reasonable attorney fees. Mich. Comp. Laws Ann. § 445.911.

Q. Minn. Stat. § 325D.43, *et seq.*, with respect to purchases of brand and generic Revlimid in Minnesota.

684. Section 325D.44 of the Minnesota Statutes provides as follows:

> A person engages in a deceptive trade practice when, in the course of business, vocation, or occupation, the person:
> …
>
> (13) engages in (i) unfair methods of competition, or (ii) unfair or unconscionable acts or practices.

685. Section 325F.69 of the Minnesota Statutes provides as follows:

> The act, use, or employment by any person of any fraud, unfair or unconscionable practice, false pretense, false promise, misrepresentation, misleading statement or deceptive practice, with the intent that others rely thereon in connection with the sale of any merchandise, whether or not any person has in fact been misled, deceived, or damaged thereby, is enjoinable . . . .

686. As set forth in detail above in Sections V.D. through V.P. and Sections VI through VIII of this Complaint, Defendants violated § 325D.43, et seq. of the Minnesota Statutes by entering into unlawful reverse-payment agreements that will delay full generic competition in the Revlimid market until January 2026.

687. As a direct and proximate result of Defendants' conduct, Plaintiff suffered injury in the form of paying higher prices for Revlimid than it would have paid but for Defendants' unlawful conduct.

688. Plaintiff's injury is of the type that § 325D.43, *et seq.* of the Minnesota Statutes was intended to prevent.

689. Plaintiff is entitled to bring this action for damages pursuant to § 8.31 of the Minnesota Statutes.

690. Plaintiff is entitled to recover actual damages, along with reasonable attorney fees and costs. Minn. Stat. Ann. § 8.31.

R. Miss. Code. Ann. §§ 75-24-5, *et seq.*, with respect to purchases of brand and generic Revlimid in Mississippi.

691. Section 75-24-5 of the Mississippi Code provides that "unfair methods of competition affecting commerce and unfair or deceptive trade practices in or affecting commerce are prohibited."

692. As set forth in detail above in Sections V.D. through V.P. and Sections VI through VIII of this Complaint, Defendants violated § 75-24-5 of the Mississippi Code by entering into unlawful reverse-payment agreements that will delay full generic competition in the Revlimid

market until January 2026. Specifically, Defendants engaged in unfair methods of competition or deceptive trade practices in connection with the sale of Revlimid. *See* Miss. Code Ann. § 75-24-5.

693. As a direct and proximate result of Defendants' conduct, Plaintiff suffered injury in the form of paying higher prices for Revlimid than it would have paid but for Defendants' unlawful conduct.

694. Plaintiff's injury is of the type that § 75-24-5 of the Mississippi Code was intended to prevent.

695. Plaintiff is entitled to bring this action for damages pursuant to § 75-24-15 of the Mississippi Code.

S. Missouri Stat. §§ 407.010, *et seq.*, with respect to purchases of brand and generic Revlimid in Missouri.

696. Section 407.020 of the Missouri Statutes provides:

> 1. the act, use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, unfair practice or the concealment, suppression, or omission of any material fact in connection with the sale or advertisement of any merchandise in trade or commerce or the solicitation of any funds for any charitable purpose, as defined in section 407.453, in or from the state of Missouri, is declared to be an unlawful practice.

697. As set forth in detail above in Sections V.D. through V.P. and Sections VI through VIII of this Complaint, Defendants violated § 407.020 of the Missouri Statutes by entering into unlawful reverse-payment agreements that will delay full generic competition in the Revlimid market until January 2026. Specifically, Defendants engaged in unfair practice in connection with the sale of Revlimid. See Mo. Ann. Stat. § 407.020.

698. As a direct and proximate result of Defendants' conduct, Plaintiff suffered injury in the form of paying higher prices for Revlimid than it would have paid but for Defendants' unlawful conduct.

699. Plaintiff's injury is of the type that § 407.020 of the Missouri Statutes was intended to prevent.

700. Plaintiff is entitled to bring this action for damages pursuant to § 407.025 of the Missouri Statutes.

T. Neb. Rev. Stat. §§ 59-1601, *et seq.*, with respect to purchases of brand and generic Revlimid in Nebraska.

701. Section 59-1602 of the Nebraska Consumer Protection Act provides that "unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce shall be unlawful.

702. Additionally, § 59-1603 of the Nebraska Consumer Protection Act provides that "any contract, combination, in the form of trust or otherwise, or conspiracy in restraint of trade or commerce shall be unlawful.

703. Additionally, § 59-1604 of the Nebraska Consumer Protection Act provides that "it shall be unlawful for any person to monopolize or attempt to monopolize or combine or conspire with any other person or persons to monopolize any part of trade or commerce."

704. As set forth in detail above in Sections V.D. through V.P. and Sections VI through VIII of this Complaint, Defendants violated §§ 59-1602, 59-1603, and 59-1604 by entering into unlawful reverse-payment agreements that will delay full generic competition in the Revlimid market until January 2026. Specifically, Defendants engaged in unfair methods of competition and unfair or deceptive acts or practices in connection with the sale of Revlimid.

705. Plaintiff's injury is of the type that §§ 59-1602, 59-1603, and 59-1604 of the Nebraska Statutes was intended to prevent.

706. Plaintiff is entitled to bring this action for damages pursuant to § 59-1609 of the Nebraska Statutes.

U. Nev. Rev. Stat. §§ 598.0903, *et seq.*, with respect to purchases of brand and generic Revlimid in Nevada.

707. Section 41.600 of the Nevada Revised Statues provides as follows:

> 1. An action may be brought by any person who is a victim of consumer fraud.
> 2. As used in this section, "consumer fraud" means:
> . . .
> (e) A deceptive trade practice as defined in NRS 598.0915 to 598.0925, inclusive.

708. Section 598.015 of the Nevada Revised Statutes states:

> A person engages in a "deceptive trade practice" if, in the course of his or her business or occupation, he or she:
> . . .
> 13. Makes false or misleading statements of fact concerning the price of goods or services for sale or lease, or the reasons for, existence of or amounts of price reductions.

709. Section 598.0923 of the Nevada Revised Statutes provides as follows:

> 1. A person engages in a "deceptive trade practice" when in the course of his or her business or occupation he or she knowingly:
> . . .
> (e) Uses an unconscionable practice in a transaction.

710. As set forth in detail above in Sections V.D. through V.P. and Sections VI through VIII of this Complaint, Defendants violated § 41.600 of the Nevada Revised Statues by entering into unlawful reverse-payment agreements that will delay full generic competition in the Revlimid market until January 2026.

711. As a direct and proximate result of Defendants' conduct, Plaintiff suffered injury in the form of paying higher prices for Revlimid than it would have paid but for Defendants' unlawful conduct.

712. Plaintiff's injury is of the type that § 41.600 of the Nevada Revised Statues was intended to prevent.

713. Plaintiff is entitled to bring this action for damages pursuant to § 41.600 of the

Nevada Revised Statues.

714. Plaintiff is entitled to recover actual damages, along with costs and reasonable attorney fees. Nev. Rev. Stat. Ann. § 41.600.

V. N.H. Rev. Stat. §§ 358-A:1, *et seq.*, with respect to purchases of brand and generic Revlimid in New Hampshire.

715. Section 358-A:2 of the New Hampshire Revised Statues provides as follows:

> It shall be unlawful for any person to use any unfair method of competition or any unfair or deceptive act or practice in the conduct of any trade or commerce within this state. Such unfair method of competition or unfair or deceptive act or practice shall include, but is not limited to, the following:
>
> . . .
>
> XIV. Pricing of goods or services in a manner that tends to create or maintain a monopoly, or otherwise harm competition, including the pricing of generic prescription drugs.

716. As set forth in detail above in Sections V.D. through V.P. and Sections VI through VIII of this Complaint, Defendants violated § 358-A:2 of the New Hampshire Revised Statues by entering into unlawful reverse-payment agreements that will delay full generic competition in the Revlimid market until January 2026. Specifically, Defendants engaged in the pricing of goods in a manner that created or maintained a monopoly or otherwise harmed competition, including with respect to the pricing of generic prescription drugs (*i.e.*, generic Revlimid). *See* N.H. Rev. Stat. § 358-A:2.

717. As a direct and proximate result of Defendants' conduct, Plaintiff suffered injury in the form of paying higher prices for Revlimid than it would have paid but for Defendants' unlawful conduct.

718. Plaintiff's injury is of the type that § 358-A:2 of the New Hampshire Revised Statues was intended to prevent.

719. Plaintiff is entitled to bring this action for damages and equitable relief pursuant to § 358-A:10 of the New Hampshire Revised Statues.

720. Because Defendants' conduct constitutes a willful or knowing violation of § 358-A:2 of the New Hampshire Revised Statues, Plaintiff is entitled to a damages award up to three times the amount of its actual damages, together with its costs of suit and reasonable attorneys' fees. *See* N.H. Rev. Stat. § 358-A:10.

W. N.M. Stat. §§ 57-12-1, *et seq.*, with respect to purchases of brand and generic Revlimid in New Mexico.

721. Section 57-12-3 of the New Mexico Statutes provides as follows:

> Unfair or deceptive trade practices and unconscionable trade practices in the conduct of any trade or commerce are unlawful.

722. As set forth in detail above in Sections V.D. through V.P. and Sections VI through VIII of this Complaint, Defendants violated § 57-12-3 of the New Mexico Statutes by entering into unlawful reverse-payment agreements that will delay full generic competition in the Revlimid market until January 2026. Specifically, Defendants engaged in unfair or deceptive trade practices and/or unconscionable trade practices in connection with the sale of Revlimid. *See* N.H. Rev. Stat. § 358-A:2.

723. As a direct and proximate result of Defendants' conduct, Plaintiff suffered injury in the form of paying higher prices for Revlimid than it would have paid but for Defendants' unlawful conduct.

724. Plaintiff's injury is of the type that § 57-12-3 of the New Mexico Statutes was intended to prevent.

725. Plaintiff is entitled to bring this action for damages and equitable relief pursuant to § 57-12-10 of the New Mexico Statutes.

726. Because Defendants' conduct constitutes a willful violation of § 57-12-10 of the

New Mexico Statutes, Plaintiff is entitled to a damages award up to three times the amount of its actual damages, together with its costs of suit and reasonable attorneys' fees. *See* N.M. Stat. § 57-12-10.

X. N.Y. Gen. Bus. Law §§ 349, *et seq.*, with respect to purchases of brand and generic Revlimid in New York.

727. Section 349(a) of New York General Business Law provides as follows:

> Deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state are hereby declared unlawful.

728. As set forth in detail above in Sections V.D. through V.P. and Sections VI through VIII of this Complaint, Defendants violated § 349(a) of New York General Business Law by entering into unlawful reverse-payment agreements that will delay full generic competition in the Revlimid market until January 2026. Specifically, Defendants engaged in deceptive acts or practices in connection with the sale of Revlimid. *See* N.Y. Gen. Bus. Law § 349(a).

729. As a direct and proximate result of Defendants' conduct, Plaintiff suffered injury in the form of paying higher prices for Revlimid than it would have paid but for Defendants' unlawful conduct.

730. Plaintiff's injury is of the type that § 349(a) of New York General Business Law was intended to prevent.

731. Plaintiff is entitled to bring this action for damages pursuant to § 349(h) of New York General Business Law.

732. Plaintiff is entitled to recover its actual damages, together with reasonable attorneys' fees. *See* N.Y. Gen. Bus. Law § 349(h).

Y. N.C. Gen. Stat. §§ 75-1.1, *et seq.*, with respect to purchases of brand and generic Revlimid in North Carolina.

733. Section 75-1.1(a) of North Carolina General Statues provides as follows:

> Unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are declared unlawful.

734. As set forth in detail above in Sections V.D. through V.P. and Sections VI through VIII of this Complaint, Defendants violated § 75-1.1(a) of North Carolina General Statues by entering into unlawful reverse-payment agreements that will delay full generic competition in the Revlimid market until January 2026. Specifically, Defendants engaged in unfair methods of competition or unfair or deceptive acts or practices in connection with the sale of Revlimid. See N.C. Gen. Stat. §§ 75-1.1(a).

735. As a direct and proximate result of Defendants' conduct, Plaintiff suffered injury in the form of paying higher prices for Revlimid than it would have paid but for Defendants' unlawful conduct.

736. Plaintiff's injury is of the type that § 75-1.1(a) of North Carolina General Statues was intended to prevent.

737. Plaintiff is entitled to bring this action for damages pursuant to § 75-16 of North Carolina General Statues.

738. Plaintiff is entitled to a damages award three times the amount of its actual damages. See N.C. Gen. Stat. §§ 75-16. Because Defendants' conduct constitutes a willful violation of § 75-1.1(a) of North Carolina General Statues, Plaintiff is also entitled to recover its costs of suit and reasonable attorneys' fees. See N.C. Gen. Stat. §§ 75-16.1.

Z. N.D. Cent. Code §§ 51-15-01, *et seq.*, with respect to purchases of brand and generic Revlimid in North Dakota.

739. Section 51-15-02 of North Dakota Century Code provides, in relevant part, as follows:

> The act, use, or employment by any person of any act or practice, in connection with the sale or advertisement of any merchandise, which

> is unconscionable or which causes or is likely to cause substantial injury to a person which is not reasonably avoidable by the injured person and not outweighed by countervailing benefits to consumers or to competition, is declared to be an unlawful practice.

740. As set forth in detail above in Sections V.D. through V.P. and Sections VI through VIII of this Complaint, Defendants violated § 51-15-02 of North Dakota Century Code by entering into unlawful reverse-payment agreements that will delay full generic competition in the Revlimid market until January 2026. Specifically, Defendants engaged in acts or practices in connection with the sale of Revlimid that were unconscionable and/or that caused substantial injury that was and is not reasonably avoidable by Plaintiff and that was and is not outweighed by countervailing benefits to consumers or to competition. See N.D. Cent. Code § 51-15-09.

741. As a direct and proximate result of Defendants' conduct, Plaintiff suffered injury in the form of paying higher prices for Revlimid than it would have paid but for Defendants' unlawful conduct.

742. Plaintiff's injury is of the type that § 51-15-02 of North Dakota Century Code was intended to prevent.

743. Plaintiff is entitled to bring this action for damages pursuant to § 51-15-09 of North Dakota Century Code.

744. Because Defendants' conduct constitutes a knowing violation of § 51-15-02 of North Dakota Century Code, Plaintiff is entitled to a damages award up to three times the amount of its actual damages, together with its costs of suit and reasonable attorneys' fees. See N.D. Cent. Code § 51-15-09.

AA. Or. Rev. Stat. §§ 646.605, *et seq.*, with respect to purchases of brand and generic Revlimid in Oregon.

745. Section 646.608 of the Oregon Revised Statutes provides as follows:

> (1) A person engages in an unlawful practice if in the course of the person's

business, vocation or occupation the person does any of the following:

. . .

(u) Engages in any other unfair or deceptive conduct in trade or commerce.

746. As set forth in detail above in Sections V.D. through V.P. and Sections VI through VIII of this Complaint, Defendants violated § 646.608 of the Oregon Revised Statues by entering into unlawful reverse-payment agreements that will delay full generic competition in the Revlimid market until January 2026.

747. As a direct and proximate result of Defendants' conduct, Plaintiff suffered injury in the form of paying higher prices for Revlimid than it would have paid but for Defendants' unlawful conduct.

748. Plaintiff's injury is of the type that § 646.608 of the Oregon Revised Statues was intended to prevent.

749. Plaintiff is entitled to bring this action for damages pursuant to § 646.638 of the Oregon Revised Statues.

750. Plaintiff is entitled to recover actual damages, along with punitive damages, and reasonable attorney fees and costs at trial. Or. Rev. Stat. Ann. § 646.638.

BB. 73 Pa. Stat. Ann. §§ 201-1, *et seq.*, with respect to purchases of brand and generic Revlimid in Pennsylvania.

751. Section 201-3 of the Pennsylvania Statutes provides as follows:

> (a) Unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce as defined . . . this act are hereby declared unlawful.

752. As set forth in detail above in Sections V.D. through V.P. and Sections VI through VIII of this Complaint, Defendants violated § 201-3 of the Pennsylvania Statues by entering into unlawful reverse-payment agreements that will delay full generic competition in the Revlimid market until January 2026.

753. As a direct and proximate result of Defendants' conduct, Plaintiff suffered injury in the form of paying higher prices for Revlimid than it would have paid but for Defendants' unlawful conduct.

754. Plaintiff's injury is of the type that § 201-3 of the Pennsylvania Statues was intended to prevent.

755. Plaintiff is entitled to bring this action for damages pursuant to § 201-9.2 of the Pennsylvania Statues.

756. Plaintiff is entitled to a damages award up to three times the amount of its actual damages. 73 Pa. Stat. § 201-9.2. Plaintiff is also entitled to recover costs and reasonable attorney fees. *Id*.

CC. S.C. Stat. Ann. §§ 39-5-10, *et seq.*, with respect to purchases of brand and generic Revlimid in South Carolina.

757. Section 39-50-20 of the Code of Laws of South Carolina provides that "unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful."

758. As set forth in detail above in Sections V.D. through V.P. and Sections VI through VIII of this Complaint, Defendants violated § 39-50-20 of the Code of Laws of South Carolina by entering into unlawful reverse-payment agreements that will delay full generic competition in the Revlimid market until January 2026. Specifically, Defendants engaged in unfair methods of competition and unfair or deceptive acts or practices in connection with the sale of Revlimid. *See* S.C. Code § 39-5-20.

759. As a direct and proximate result of Defendants' conduct, Plaintiff suffered injury in the form of paying higher prices for Revlimid than it would have paid but for Defendants' unlawful conduct.

760. Plaintiff's injury is of the type that § 39-5-20 of the Code of Laws of South Carolina was intended to prevent.

761. Plaintiff is entitled to bring this action for damages pursuant to § 39-5-140 of the Code of Laws of South Carolina.

762. Because Defendants' conduct constitutes a willful or knowing violation of § 39-5-20, Plaintiff is entitled to a damages award up to three times the amount of its actual damages, together with reasonable attorneys' fees. See S.C. Code § 39-5-140.

DD. S.D. Code Laws §§ 37-24-1, *et seq.*, with respect to purchases of brand and generic Revlimid in South Dakota.

763. Section 37-24-6 of the South Dakota Codified Laws provides:

> It is a deceptive act or practice for any person to:
>
> > Knowingly act, use, or employ any deceptive act or practice, fraud, false pretense, false promises, or misrepresentation or to conceal, suppress, or omit any material fact in connection with the sale or advertisement of any merchandise or the solicitation of contributions for charitable purposes, regardless of whether any person has in fact been misled, deceived, or damaged thereby[.]

764. As set forth in detail above in Sections V.D. through V.P. and Sections VI through VIII of this Complaint, Defendants violated § 37-24-6 of the South Dakota Codified Laws by entering into unlawful reverse-payment agreements that will delay full generic competition in the Revlimid market until January 2026. Specifically, Defendants engaged in deceptive acts or practices in connection with the sale of Revlimid. See S.D. Codified Laws § 37-24-6.

765. As a direct and proximate result of Defendants' conduct, Plaintiff suffered injury in the form of paying higher prices for Revlimid than it would have paid but for Defendants' unlawful conduct.

766. Plaintiff's injury is of the type that § 37-24-6 of the South Dakota Codified Laws

was intended to prevent.

767. Plaintiff is entitled to bring this action for damages pursuant to § 37-24-31 of the South Dakota Codified Laws.

EE. Utah Code §§ 13-11-1, *et seq.*, with respect to purchases of brand and generic Revlimid in Utah.

768. Section 13-11-5 of the Utah Code provides as follows:

> (1) An unconscionable act or practice by a supplier in connection with a consumer transaction violates this act whether it occurs before, during, or after the transaction.

769. As set forth in detail above in Sections V.D. through V.P. and Sections VI through VIII of this Complaint, Defendants violated §13-11-5 of the Utah Code by entering into unlawful reverse-payment agreements that will delay full generic competition in the Revlimid market until January 2026.

770. As a direct and proximate result of Defendants' conduct, Plaintiff suffered injury in the form of paying higher prices for Revlimid than it would have paid but for Defendants' unlawful conduct.

771. Plaintiff's injury is of the type that § 13-11-5 of the Utah Code was intended to prevent.

772. Plaintiff is entitled to bring this action for damages pursuant to § 13-1119 of the Utah Code.

773. Plaintiff is entitled to recover actual damages plus court costs and reasonable attorney fees. Utah Code Ann. § 13-11-19.

FF.Va. Code Ann. §§ 59.1-196, *et seq.*, with respect to purchases of brand and generic Revlimid in Virginia.

774. Section 59.1-200 of the Virginia Code provides as follows:

> A. The following fraudulent acts or practices committed by a supplier

> in connection with a consumer transaction are hereby declared unlawful:
> . . .
> 14. Using any other deception, fraud, false pretense, false promise, or misrepresentation in connection with a consumer transaction.

775. As set forth in detail above in Sections V.D. through V.P. and Sections VI through VIII of this Complaint, Defendants violated § 59.1-200 of the Virginia Code by entering into unlawful reverse-payment agreements that will delay full generic competition in the Revlimid market until January 2026.

776. As a direct and proximate result of Defendants' conduct, Plaintiff suffered injury in the form of paying higher prices for Revlimid than it would have paid but for Defendants' unlawful conduct.

777. Plaintiff's injury is of the type that § 59.1-200 of the Virginia Code was intended to prevent.

778. Plaintiff is entitled to bring this action for damages pursuant to § 59.1-204 of the Virginia Code.

779. Because Defendants' conduct was willful, Plaintiff is entitled to a damages award up to three times the amount of its actual damages, along with reasonable attorney fees and court costs. Va. Code § 59.1-204.

GG. Wis. Stat. § 100.18; Wis. Stat. § 100.20, *et seq.*, with respect to purchases of brand and generic Revlimid in Wisconsin.

780. Section 100.20 of the Wisconsin Statutes provides as follows:

> (1) Methods of competition in business and trade practices in business shall be fair. Unfair methods of competition in business and unfair trade practices in business are hereby prohibited.

781. As set forth in detail above in Sections V.D. through V.P. and Sections VI through VIII of this Complaint, Defendants violated § 100.20 of the Wisconsin Statutes by entering into unlawful reverse-payment agreements that will delay full generic competition in the Revlimid

market until January 2026.

782. As a direct and proximate result of Defendants' conduct, Plaintiff suffered injury in the form of paying higher prices for Revlimid than it would have paid but for Defendants' unlawful conduct.

783. Plaintiff's injury is of the type that §100.20 of the Wisconsin Statutes was intended to prevent.

784. Plaintiff is entitled to bring this action for damages pursuant to § 100.20 of the Wisconsin Statutes.

785. Plaintiff is entitled to a damages award of twice the amount of its actual pecuniary loss, along with costs and reasonable attorney fees. Wis. Stat. § 100.20(5).

TWELFTH CLAIM FOR RELIEF
UNJUST ENRICHMENT UNDER STATE LAW
(ALL DEFENDANTS)

786. Plaintiff incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

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

788. As a result of its unlawful conduct described above, Defendants have and will continue to be unjustly enriched by the receipt of unlawfully inflated prices and unlawful profits from sales of Revlimid. Defendants' financial benefits are traceable to the overpayments for Revlimid by Plaintiff. Defendants have received a benefit from Plaintiff in the form of revenue resulting from unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants, to the economic detriment of Plaintiff. Defendants have benefited from their unlawful acts, and it would be inequitable for Defendants to retain any of the ill-gotten gains resulting from the overpayments made by Plaintiff for Revlimid during the relevant

period.

789. It would be futile for Plaintiff to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which they indirectly purchased Revlimid, as those intermediaries are not liable for, and would not compensate Plaintiff for, Defendants' unlawful conduct.

790. The economic benefit Defendants derived from purchases of Revlimid by Plaintiff is a direct and proximate result of Defendants' unlawful and anticompetitive practices.

791. The financial benefits Defendants derived are ill-gotten gains that rightfully belong to Plaintiff, which paid and continue to pay artificially inflated prices that inured to Defendants' benefit.

792. It would be inequitable under unjust enrichment principles under the laws of the jurisdictions identified below for Defendants to retain any of the benefits they derived from their unfair, anticompetitive, and unlawful methods, acts, and trade practices.

793. Defendants are aware of and appreciate the benefits that Plaintiff has bestowed upon them.

794. Defendants should be ordered to disgorge all unlawful or inequitable proceeds they received to a common fund for the benefit of Plaintiff, which has no adequate remedy at law.

795. A constructive trust should be imposed upon all unlawful or inequitable sums Defendants received that are traceable to Plaintiff.

796. By engaging in the unlawful or inequitable conduct described above, which deprived Plaintiff of the opportunity to purchase lower-priced generic versions of Revlimid and forced them to pay higher prices for branded and generic versions of Revlimid, Defendants have been unjustly enriched in violation of the common law of the following jurisdictions:

1. Alabama

797. Defendants unlawfully profited from overcharges paid by Plaintiff, which made purchases of or reimbursements for Revlimid or its AB-rated generic equivalents in Alabama. Plaintiff paid higher prices for brand and generic Revlimid than it would have paid but for Defendants' actions.

798. Defendants received money from Plaintiff as a direct result of the unlawful overcharges and have retained this money.

799. Defendants have benefitted at the expense of Plaintiff from revenue resulting from unlawful overcharges for Revlimid and/or its AB-rated generic equivalents.

800. It is inequitable for Defendants to accept and retain the benefits received without compensating Plaintiff.

2. Arizona

801. Defendants unlawfully profited from overcharges paid by Plaintiff, which made purchases of or reimbursements for Revlimid and/or its AB-rated generic equivalents in Arizona. Plaintiff paid higher prices for brand and generic Revlimid than it would have paid but for Defendants' actions.

802. Defendants have been enriched by revenue resulting from unlawful overcharges for branded and generic Revlimid.

803. Plaintiff has been impoverished by the overcharges for branded and generic Revlimid resulting from Defendants' unlawful conduct.

804. Defendants' enrichment and the impoverishment of Plaintiff are connected. Defendants have paid no consideration to any other person for any benefits they received from Plaintiff.

805. There is no justification for Defendants' receipt of the benefits causing their

enrichment and the impoverishment of Plaintiff because Plaintiff paid supra-competitive prices that inured to Defendants' benefit, and it would be inequitable for Defendants to retain any revenue gained from their unlawful overcharges.

806. Plaintiff has no adequate remedy at law.

3. Arkansas

807. Defendants unlawfully profited from overcharges paid by Plaintiff, which made purchases of or reimbursements for Revlimid and/or its AB-rated generic equivalents in Arkansas. Plaintiff paid higher prices for brand and generic Revlimid than it would have paid but for Defendants' actions.

808. Defendants received money from Plaintiff as a direct result of the unlawful overcharges and have retained this money.

809. Defendants have paid no consideration to any other person in exchange for this money.

810. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiff.

4. California

811. Defendants unlawfully profited from overcharges paid by Plaintiff, which made purchases of or reimbursements for Revlimid and/or its AB-rated generic equivalents in California. Plaintiff paid higher prices for brand and generic Revlimid than it would have paid but for Defendants' actions.

812. Defendants have received a benefit from Plaintiff as a direct result of Defendants' fraudulent and misleading conduct and the resulting unlawful overcharges to Plaintiff.

813. Defendants retained the benefits bestowed upon them under inequitable and unjust circumstances at the expense of Plaintiff.

814. Plaintiff is entitled to restitution from Defendants.

5. Colorado

815. Defendants unlawfully profited from overcharges paid by Plaintiff, which made purchases of or reimbursements for Revlimid and/or its AB-rated generic equivalents in Colorado. Plaintiff paid higher prices for brand and generic Revlimid than it would have paid but for Defendants' actions.

816. Defendants have received a benefit from Plaintiff in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants, to the economic detriment of Plaintiff.

817. Defendants retained the benefit bestowed upon them under inequitable and unjust circumstances arising from unlawful overcharges to Plaintiff.

818. Under the circumstances, it would be inequitable and unjust for Defendants to retain such benefits without compensating Plaintiff.

6. Connecticut

819. Defendants unlawfully profited from overcharges paid by Plaintiff, which made purchases of or reimbursements for Revlimid and/or its AB-rated generic equivalents in Connecticut. Plaintiff paid higher prices for brand and generic Revlimid than it would have paid but for Defendants' actions.

820. Defendants have received a benefit from Plaintiff in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants, to the economic detriment of Plaintiff.

821. Defendants have paid no consideration to any other person in exchange for this benefit.

822. Defendants retained the benefits bestowed upon them under inequitable and unjust

circumstances at the expense of Plaintiff.

823. Under the circumstances, it would be inequitable and unjust for Defendants to retain such benefits.

7. Delaware

824. Defendants unlawfully profited from overcharges paid by Plaintiff, which made purchases of or reimbursements for Revlimid and/or its AB-rated generic equivalents in Delaware. Plaintiff paid higher prices for brand and generic Revlimid than it would have paid but for Defendants' actions.

825. Defendants have been enriched by revenue resulting from unlawful overcharges for branded and generic Revlimid.

826. Plaintiff has been impoverished by the overcharges for branded and generic Revlimid resulting from Defendants' unlawful conduct.

827. Defendants' enrichment and the impoverishment of Plaintiff are connected. Defendants have paid no consideration to any other person for any benefits they received from Plaintiff.

828. There is no justification for Defendants' receipt of the benefits causing its enrichment and the impoverishment of Plaintiff because Plaintiff paid supra-competitive prices that inured to Defendants' benefit, and it would be inequitable for Defendants to retain any revenue gained from their unlawful overcharges.

829. Plaintiff has no remedy at law.

8. District of Columbia

830. Defendants unlawfully profited from overcharges paid by Plaintiff, which made purchases of or reimbursements for Revlimid and/or its AB-rated generic equivalents in the District of Columbia. Plaintiff paid higher prices for brand and generic Revlimid than it would

have paid but for Defendants' actions.

831. Defendants have received a benefit from Plaintiff in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants, to the economic detriment of Plaintiff.

832. Defendants accepted and retained the benefit bestowed upon them under inequitable and unjust circumstances arising from unlawful overcharges to Plaintiff.

833. Under the circumstances, it would be inequitable and unjust for Defendants to retain such benefits.

9. Florida

834. Defendants unlawfully profited from overcharges paid by Plaintiff, which made purchases of or reimbursements for Revlimid and/or its AB-rated generic equivalents in Florida. Plaintiff paid higher prices for brand and generic Revlimid than it would have paid but for Defendants' actions.

835. Defendants have received a benefit from Plaintiff in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants, to the economic detriment of Plaintiff.

836. Defendants appreciated and retained the benefit bestowed upon them by Plaintiff.

837. It is inequitable and unjust for Defendants to accept and retain such benefits without compensating Plaintiff.

10. Georgia

838. Defendants unlawfully profited from overcharges paid by Plaintiff, which made purchases of or reimbursements for Revlimid and/or its AB-rated generic equivalents in Georgia. Plaintiff paid higher prices for brand and generic Revlimid than it would have paid but for Defendants' actions.

839. Defendants have received a benefit from Plaintiff in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants, to the economic detriment of Plaintiff.

840. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiff.

11. Hawaii

841. Defendants unlawfully profited from overcharges paid by Plaintiff, which made purchases of or reimbursements for Revlimid and/or its AB-rated generic equivalents in Hawaii. Plaintiff paid higher prices for brand and generic Revlimid than it would have paid but for Defendants' actions.

842. Defendants have received a benefit from Plaintiff in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants, to the economic detriment of Plaintiff.

843. It is unjust for Defendants to retain such benefits without compensating Plaintiff.

12. Idaho

844. Defendants unlawfully profited from overcharges paid by Plaintiff, which made purchases of or reimbursements for Revlimid and/or its AB-rated generic equivalents in Idaho. Plaintiff paid higher prices for brand and generic Revlimid than it would have paid but for Defendants' actions.

845. Defendants have received a benefit from Plaintiff in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants, to the economic detriment of Plaintiff. Defendants appreciated the benefit conferred upon them by Plaintiff.

846. Under the circumstances, it would be inequitable for Defendants to retain such

benefits without compensating Plaintiff.

13. Illinois

847. Defendants unlawfully profited from overcharges paid by Plaintiff, which made purchases of or reimbursements for Revlimid and/or its AB-rated generic equivalents in Illinois. Plaintiff paid higher prices for brand and generic Revlimid than it would have paid but for Defendants' actions.

848. Defendants have received a benefit from Plaintiff in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants, to the economic detriment of Plaintiff.

849. Defendants retained the benefits bestowed upon them under unjust circumstances arising from unlawful overcharges to Plaintiff.

850. It is against equity, justice, and good conscience for Defendants to be permitted to retain the revenue resulting from their unlawful overcharges without compensating Plaintiff.

14. Iowa

851. Defendants unlawfully profited from overcharges paid by Plaintiff, which made purchases of or reimbursements for Revlimid and/or its AB-rated generic equivalents in Iowa. Plaintiff paid higher prices for brand and generic Revlimid than it would have paid but for Defendants' actions.

852. Defendants have been enriched by revenue resulting from unlawful overcharges for Revlimid and/or its AB-rated generic equivalents, which revenue resulted from anticompetitive prices paid by Plaintiff, which inured to Defendants' benefit.

853. Defendants' enrichment has occurred at the expense of Plaintiff.

854. It is against equity and good conscience for Defendants to retain such benefits without compensating Plaintiff.

15. Kansas

855. Defendants unlawfully profited from overcharges paid by Plaintiff, which made purchases of or reimbursements for Revlimid and/or its AB-rated generic equivalents in Kansas. Plaintiff paid higher prices for brand and generic Revlimid than it would have paid but for Defendants' actions.

856. Defendants have received a benefit from Plaintiff in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants, to the economic detriment of Plaintiff.

857. Defendants retained the benefits bestowed upon them under unjust circumstances arising from unlawful overcharges to Plaintiff.

858. Defendants were unjustly enriched at the expense of Plaintiff.

16. Kentucky

859. Defendants unlawfully profited from overcharges paid by Plaintiff, which made purchases of or reimbursements for Revlimid and/or its AB-rated generic equivalents in Kentucky. Plaintiff paid higher prices for brand and generic Revlimid than it would have paid but for Defendants' actions.

860. Defendants have received a benefit from Plaintiff in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants, to the economic detriment of Plaintiff.

861. Defendants appreciated the benefit bestowed upon them by Plaintiff.

862. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiff.

17. Louisiana

863. Defendants unlawfully profited from overcharges paid by Plaintiff, which made

purchases of or reimbursements for Revlimid and/or its AB-rated generic equivalents in Louisiana. Plaintiff paid higher prices for brand and generic Revlimid than it would have paid but for Defendants' actions.

864. Defendants have been enriched by revenue resulting from unlawful overcharges for brand and Revlimid.

865. Plaintiff has been impoverished by the overcharges for brand and generic Revlimid resulting from Defendants' unlawful conduct.

866. Defendants' enrichment and the impoverishment of Plaintiff are connected.

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

868. Plaintiff has no other remedy at law.

18. Maine

869. Defendants unlawfully profited from overcharges paid by Plaintiff, which made purchases of or reimbursements for Revlimid and/or its AB-rated generic equivalents in Maine. Plaintiff paid higher prices for brand and generic Revlimid than it would have paid but for Defendants' actions.

870. Defendants have received a benefit from Plaintiff in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants, to the economic detriment of Plaintiff.

871. Defendants were aware of or appreciated the benefit bestowed upon them by Plaintiff.

872. Under the circumstances, it would be inequitable for Defendants to retain such

benefits without compensating Plaintiff.

19. Maryland

873. Defendants unlawfully profited from overcharges paid by Plaintiff, which made purchases of or reimbursements for Revlimid and/or its AB-rated generic equivalents in Maryland. Plaintiff paid higher prices for brand and generic Revlimid than it would have paid but for Defendants' actions.

874. Defendants have received a benefit from Plaintiff in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants, to the economic detriment of Plaintiff.

875. Defendants were aware of or appreciated the benefit bestowed upon them by Plaintiff.

876. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiff.

20. Massachusetts

877. Defendants unlawfully profited from overcharges paid by Plaintiff, which made purchases of or reimbursements for Revlimid and/or its AB-rated generic equivalents in Massachusetts. Plaintiff paid higher prices for brand and generic Revlimid than it would have paid but for Defendants' actions.

878. Defendants have received a benefit from Plaintiff in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants, to the economic detriment of Plaintiff.

879. Defendants were aware of or appreciated the benefit conferred upon them by Plaintiff.

880. Under the circumstances, it would be inequitable for Defendants to retain such

benefits without compensating Plaintiff. Fairness and good conscience require Defendants not be permitted to retain the revenue resulting from its unlawful overcharges at the expense of Plaintiff.

21. Michigan

881. Defendants unlawfully profited from overcharges paid by Plaintiff, which made purchases of or reimbursements for Revlimid and/or its AB-rated generic equivalents in Michigan. Plaintiff paid higher prices for brand and generic Revlimid than it would have paid but for Defendants' actions.

882. Defendants have received a benefit from Plaintiff in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants.

883. Defendants retained the benefits bestowed upon them under unjust circumstances arising from unlawful overcharges to Plaintiff.

884. Defendants were unjustly enriched at the expense of Plaintiff.

22. Minnesota

885. Defendants unlawfully profited from overcharges paid by Plaintiff, which made purchases of or reimbursements for Revlimid and/or its AB-rated generic equivalents in Minnesota. Plaintiff paid higher prices for brand and generic Revlimid than it would have paid but for Defendants' actions.

886. Defendants appreciated and knowingly accepted the benefits bestowed upon them by Plaintiff. Defendants have paid no consideration to any other person for any of the benefits they have received from Plaintiff.

887. It would be inequitable for Defendants to accept and retain such benefits without compensating Plaintiff.

23. Mississippi

888. Defendants unlawfully profited from overcharges paid by Plaintiff, which made purchases of or reimbursements for Revlimid and/or its AB-rated generic equivalents in Mississippi. Plaintiff paid higher prices for brand and generic Revlimid than it would have paid but for Defendants' actions.

889. Defendants received money from Plaintiff as a direct result of the unlawful overcharges. Defendants retained the benefit of overcharges received on the sales of brand and generic Revlimid, which in equity and good conscience belong to Plaintiff on account of Defendants' anticompetitive conduct.

890. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiff.

24. Missouri

891. Defendants unlawfully profited from overcharges paid by Plaintiff, which made purchases of or reimbursements for Revlimid and/or its AB-rated generic equivalents in Missouri. Plaintiff paid higher prices for brand and generic Revlimid than it would have paid but for Defendants' actions.

892. Defendants have received a benefit from Plaintiff in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants, to the economic detriment of Plaintiff.

893. Defendants appreciated the benefit bestowed upon them by Plaintiff.

894. Defendants accepted and retained the benefit bestowed upon them under inequitable and unjust circumstances arising from unlawful overcharges to Plaintiff.

25. Nebraska

895. Defendants unlawfully profited from overcharges paid by Plaintiff, which made purchases of or reimbursements for Revlimid and/or its AB-rated generic equivalents in Nebraska.

Plaintiff paid higher prices for brand and generic Revlimid than it would have paid but for Defendants' actions.

896. Defendants received money from Plaintiff as a direct result of the unlawful overcharges and have retained this money. Defendants have paid no consideration to any other person in exchange for this money.

897. In justice and fairness, Defendants should disgorge such money and remit the overcharged payments back to Plaintiff.

26. Nevada

898. Defendants unlawfully profited from overcharges paid by Plaintiff, which made purchases of or reimbursements for Revlimid and/or its AB-rated generic equivalents in Nevada. Plaintiff paid higher prices for brand and generic Revlimid than it would have paid but for Defendants' actions.

899. Plaintiff has conferred an economic benefit upon Defendants in the form of revenue resulting from unlawful overcharges.

900. Defendants appreciated the benefits bestowed upon them by Plaintiff, for which they have paid no consideration to any other person.

901. Defendants have knowingly accepted and retained the benefits bestowed upon them by Plaintiff.

902. The circumstances under which Defendants have accepted and retained the benefits bestowed on them by Plaintiff are inequitable in that they result from Defendants' unlawful overcharges.

27. New Hampshire

903. Defendants unlawfully profited from overcharges paid by Plaintiff, which made purchases of or reimbursements for Revlimid and/or its AB-rated generic equivalents in New

Hampshire. Plaintiff paid higher prices for brand and generic Revlimid than it would have paid but for Defendants' actions.

904. Defendants have received a benefit from Plaintiff in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants, to the economic detriment of Plaintiff.

905. Under the circumstances, it would be unconscionable for Defendants to retain such benefits.

28. New Jersey

906. Defendants unlawfully profited from overcharges paid by Plaintiff, which made purchases of or reimbursements for Revlimid and/or its AB-rated generic equivalents in New Jersey. Plaintiff paid higher prices for brand and generic Revlimid than it would have paid but for Defendants' actions.

907. Defendants have received a benefit from Plaintiff in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants, to the economic detriment of Plaintiff.

908. The benefits conferred upon Defendants were not gratuitous, in that they comprised revenue created by unlawful overcharges to Plaintiff.

909. Defendants have paid no consideration to any other person for any of the unlawful benefits they received from Plaintiff with respect to Defendants' sales of brand and generic Revlimid.

910. Under the circumstances, it would be unjust for the defendants to retain such benefits without compensating Plaintiff.

29. New Mexico

911. Defendants unlawfully profited from overcharges paid by Plaintiff, which made

purchases of or reimbursements for Revlimid and/or its AB-rated generic equivalents in New Mexico. Plaintiff paid higher prices for brand and generic Revlimid than it would have paid but for Defendants' actions.

912. Defendants have knowingly benefitted at the expense of Plaintiff from revenue resulting from unlawful overcharges for Revlimid.

913. To allow Defendants to retain the benefits would be unjust because the benefits resulted from anticompetitive pricing that inured Plaintiff to Defendants' benefit and because Defendants have paid no consideration to any other person for any of the benefits they received.

30. New York

914. Defendants unlawfully profited from overcharges paid by Plaintiff, which made purchases of or reimbursements for Revlimid and/or its AB-rated generic equivalents in New York. Plaintiff paid higher prices for brand and generic Revlimid than it would have paid but for Defendants' actions.

915. Defendants have been enriched by revenue resulting from unlawful overcharges for brand and generic Revlimid, which revenue resulted from anticompetitive prices paid by Plaintiff, which inured to Defendants' benefit.

916. Defendants' enrichment has occurred at the expense of Plaintiff.

917. It is against equity and good conscience for Defendants to be permitted to retain the revenue resulting from their unlawful overcharges.

31. North Carolina

918. Defendants unlawfully profited from overcharges paid by Plaintiff, which made purchases of or reimbursements for Revlimid and/or its AB-rated generic equivalents in North Carolina. Plaintiff paid higher prices for brand and generic Revlimid than it would have paid but for Defendants' actions.

919. Defendants have received a benefit from Plaintiff in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants, to the economic detriment of Plaintiff.

920. Plaintiff did not interfere with Defendants' affairs in any manner that conferred these benefits upon Defendants.

921. The benefits conferred upon Defendants were not gratuitous, in that they comprised revenue created by unlawful overcharges arising from Defendants' actions in delaying entry of generic versions of Revlimid to the market and preventing fulsome generic competition in the market for brand and generic Revlimid.

922. The benefits conferred upon Defendants are measurable, in that the revenue Defendants have earned due to unlawful overcharges is ascertainable by review of sales records.

923. Defendants consciously accepted the benefits conferred upon them and continue to do so as of the date of this filing.

32. North Dakota

924. Defendants unlawfully profited from overcharges paid by Plaintiff, which made purchases of or reimbursements for Revlimid and/or its AB-rated generic equivalents in North Dakota. Plaintiff paid higher prices for brand and generic Revlimid than it would have paid but for Defendants' actions.

925. Defendants have been enriched by revenue resulting from unlawful overcharges paid by Plaintiff.

926. Plaintiff has been impoverished by the overcharges for Revlimid or its AB- rated generic equivalents resulting from Defendants' unlawful conduct.

927. Defendants' enrichment and Plaintiff's impoverishment are connected. Defendants have paid no consideration to any other person for any benefits they received directly or indirectly

from Plaintiff.

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

929. Plaintiff has no remedy at law.

33. Oklahoma

930. Defendants unlawfully profited from overcharges paid by Plaintiff, which made purchases of or reimbursements for Revlimid and/or its AB-rated generic equivalents in Oklahoma. Plaintiff paid higher prices for brand and generic Revlimid than it would have paid but for Defendants' actions.

931. Defendants received money from Plaintiff as a direct result of the unlawful overcharges and have retained this money.

932. Defendants have paid no consideration to any other person in exchange for this money.

933. Plaintiff have no remedy at law.

934. It is against equity and good conscience for Defendants to be permitted to retain the revenue resulting from their unlawful overcharges.

34. Oregon

935. Defendants unlawfully profited from overcharges paid by Plaintiff, which made purchases of or reimbursements for Revlimid and/or its AB-rated generic equivalents in Oregon. Plaintiff paid higher prices for brand and generic Revlimid than it would have paid but for Defendants' actions.

936. Defendants have received a benefit from Plaintiff in the form of revenue resulting

from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants, to the economic detriment of Plaintiff.

937. Defendants were aware of the benefit bestowed upon them by Plaintiff.

938. Under the circumstances, it would be unjust for Defendants to retain any of the overcharges derived from their unfair conduct without compensating Plaintiff.

35. Pennsylvania

939. Defendants unlawfully profited from overcharges paid by Plaintiff, which made purchases of or reimbursements for Revlimid and/or its AB-rated generic equivalents in Pennsylvania. Plaintiff paid higher prices for brand and generic Revlimid than it would have paid but for Defendants' actions.

940. Defendants have received a benefit from Plaintiff in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants, to the economic detriment of Plaintiff.

941. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiff.

36. South Carolina

942. Defendants unlawfully profited from overcharges paid by Plaintiff, which made purchases of or reimbursements for Revlimid and/or its AB-rated generic equivalents in South Carolina. Plaintiff paid higher prices for brand and generic Revlimid than it would have paid but for Defendants' actions.

943. The benefits conferred upon Defendants were not gratuitous, in that they comprised revenue created by unlawful overcharges arising from unlawful overcharges to Plaintiff.

944. Defendants realized value from the benefit bestowed upon them by Plaintiff.

945. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiff.

37. South Dakota

946. Defendants unlawfully profited from overcharges paid by Plaintiff, which made purchases of or reimbursements for Revlimid and/or its AB-rated generic equivalents in South Dakota. Plaintiff paid higher prices for brand and generic Revlimid than it would have paid but for Defendants' actions.

947. Defendants have received a benefit from Plaintiff in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants, to the economic detriment of Plaintiff.

948. Defendants were aware of the benefit bestowed upon them by Plaintiff.

949. Under the circumstances, it would be inequitable and unjust for Defendants to retain such benefits without reimbursing Plaintiff.

38. Tennessee

950. Defendants unlawfully profited from overcharges paid by Plaintiff, which made purchases of or reimbursements for Revlimid and/or its AB-rated generic equivalents in Tennessee. Plaintiff paid higher prices for brand and generic Revlimid than it would have paid but for Defendants' actions.

951. Defendants have received a benefit from Plaintiff in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants, to the economic detriment of Plaintiff.

952. Defendants were aware of or appreciated the benefit bestowed upon them by Plaintiff.

953. Under the circumstances, it would be inequitable for Defendants to retain such

benefits without compensating Plaintiff.

954. It would be futile for Plaintiff to seek a remedy from any party with which they have privity of contract. Defendants have paid no consideration to any other person for any of the unlawful benefits they received indirectly from Plaintiff with respect to Defendants' sale of Revlimid. It would be futile for Plaintiff to exhaust all remedies against the entities with which Plaintiff has privity of contract because Plaintiff did not purchase Revlimid or its AB-rated generic equivalents directly from any defendant.

39. Texas

955. Defendants unlawfully profited from overcharges paid by Plaintiff, which made purchases of or reimbursements for Revlimid and/or its AB-rated generic equivalents in Texas. Plaintiff paid higher prices for brand and generic Revlimid than it would have paid but for Defendants' actions.

956. Defendants have received a benefit from Plaintiff in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants, to the economic detriment of Plaintiff.

957. Defendants were aware of or appreciated the benefit bestowed upon them by Plaintiff.

958. The circumstances under which Defendants have retained the benefits bestowed upon them by Plaintiff are inequitable in that they result from Defendants' unlawful conduct.

959. Plaintiff has no remedy at law.

40. Utah

960. Defendants unlawfully profited from overcharges paid by Plaintiff, which made purchases of or reimbursements for Revlimid and/or its AB-rated generic equivalents in Utah. Plaintiff paid higher prices for brand and generic Revlimid than it would have paid but for

Defendants' actions.

961. Defendants have received a benefit from Plaintiff in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants, to the economic detriment of Plaintiff.

962. Defendants were aware of or appreciated the benefit bestowed upon them by Plaintiff.

963. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiff.

41. Virginia

964. Defendants unlawfully profited from overcharges paid by Plaintiff, which made purchases of or reimbursements for Revlimid and/or its AB-rated generic equivalents in Virginia. Plaintiff paid higher prices for brand and generic Revlimid than it would have paid but for Defendants' actions.

965. Defendants have received a benefit from Plaintiff in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants, to the economic detriment of Plaintiff.

966. Defendants were aware of the benefit bestowed upon it.

967. Defendants should reasonably have expected to repay Plaintiff.

968. The benefits conferred upon Defendants were not gratuitous, in that they constituted revenue created by unlawful overcharges arising from the Defendants' illegal and unfair actions to inflate the prices of Revlimid and/or its AB-rated generic equivalents.

969. Defendants have paid no consideration to any other person for any of the benefits they have received from Plaintiff.

42. Washington

970. Defendants unlawfully profited from overcharges paid by Plaintiff, which made purchases of or reimbursements for Revlimid and/or its AB-rated generic equivalents in Washington. Plaintiff paid higher prices for brand and generic Revlimid than it would have paid but for Defendants' actions.

971. Defendants have received a benefit from Plaintiff in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants, to the economic detriment of Plaintiff.

972. Defendants were aware of or appreciated the benefit bestowed upon them by Plaintiff.

973. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiff.

43. Wisconsin

974. Defendants unlawfully profited from overcharges paid by Plaintiff, which made purchases of or reimbursements for Revlimid and/or its AB-rated generic equivalents in Wisconsin. Plaintiff paid higher prices for brand and generic Revlimid than it would have paid but for Defendants' actions.

975. Defendants have received a benefit from Plaintiff in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants, to the economic detriment of Plaintiff.

976. Defendants appreciated the benefit bestowed upon them by Plaintiff.

977. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating Plaintiff.

DEMAND FOR JUDGMENT

WHEREFORE, Centene demands judgment against Defendants, as follows:

978. Awarding Centene actual, consequential, compensatory, treble, punitive, and/or other damages, in an amount to be proven at trial, including pre- and post- judgment interest at the statutory rates;

979. Awarding Centene equitable relief in the nature of disgorgement, restitution, and the creation of a constructive trust to remedy Defendants' unjust enrichment;

980. Permanently enjoining Defendants pursuant to Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15 (a) and 26, from continuing their unlawful conduct;

981. Declaring the acts alleged herein to be unlawful under the federal and state statutes set forth above, and the common law of unjust enrichment of the states and territories set forth above;

982. Awarding Centene its reasonable costs and expenses, including attorneys' fees; and

983. Awarding all other legal or equitable relief as the Court deems just and proper.

JURY DEMAND

Centene demands a jury trial on all claims so triable under Federal Rule of Civil Procedure Rule 38(b).

Dated: May 7, 2026 Respectfully submitted,

By s/ *Peter D. St. Phillip, Jr.*
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APPENDIX 1

Additional, Carved-out Method of Treatment Patents

Method of Treatment Lymphoma Patents: carved out indications.

The ’569 family of patents all claim priority to U.S. Patent Application No. 10/438,213, which Celgene filed on May 15, 2003, and in addition to the MOT-MM patents, include patents related to the use of Revlimid to treat various lymphomas, including mantle cell lymphoma (“MCL”) (’363 patent), follicular lymphoma (’406, ’730 and ’238 patents), and marginal zone lymphoma (also the ’363 patent). The ’929 patent claims priority to U.S. Patent Application No. 11/888,881, which Celgene filed on August 1, 2007, and relates to treating MCL with Revlimid.

Celgene and BMS only asserted that one of the eighteen generics’ ANDAs infringed any of these patents (Apotex, for the ’363 and ’929 patents).[237] They are thus irrelevant for all ANDA filers except Apotex.

The Lymphoma Patents: Listed in the Orange Book

US Patent No.	Application Date	Issue Date	Expiry Date
The ’569 Family Lymphoma Patents			
7,468,363	Apr. 8, 2005	Dec. 23, 2008	Oct. 7, 2023
8,492,406	Apr. 7, 2010	July 23, 2013	Oct. 7, 2023
9,155,730	Mar. 26, 2014	Oct. 13, 2015	May 15, 2023
9,393,238	Dec. 8, 2014	July 19, 2016	May 15, 2023
The ’929 Family Lymphoma Patents			
8,741,929	Nov. 19, 2009	June 3, 2014	Mar. 8, 2028

[237] Celgene dismissed claims alleging infringement of the ’363 and ’929 patents against Hetero a year before settling after Hetero submitted a section viii carveout of MCL. Stipulation of Dismissal, *Celgene Corp. v. Hetero Labs Ltd., et al.*, 2:18-cv-17463, ECF No. 54 (D.N.J. Jan. 21, 2020).

APPENDIX 2

Celgene's Complaints Against Natco and Asserted Patents		
Complaint Date	**Docket No. (D.N.J.)**	**Patent(s) in suit**
Oct. 8, 2010	10-5917	Composition family: '517 (claim 10), '554, '106, '230 REMS: '501, '720, '976, '977, '784 Crystal: '800
Jan. 7, 2011	10-5917	Composition family: '517 (claim 10), '554, '106, '230 REMS: '501, '720, '976, '977, '784 Crystal: '800
Mar. 25, 2011	10-5917	Composition family: '517 (claim 10), '554, '106, '230 REMS: '501, '720, '976, '977, '784 Crystal: '800
July 20, 2012	12-4571[238]	Composition family: '517 **(all claims)**, '554, '106, '230 REMS: '501, '720, '976, '977, '784 MDS: **'740** MM: **'569** Crystal: '800, **'357, '219**
March 22, 2013	10-5917	Composition family: '517 (all claims), '554, '106, '230, **'415** REMS: '501, '720, '976, '977, '784, **'886** MDS: '740 MM: '569 Crystal: '800, '357, '219
April 16, 2013	10-5917	Composition family: '517 (all claims), '554, '106, '230, '415 REMS: '501, '720, '976, '977, '784, '886 MDS: '740, **'717** MM: '569, Crystal: '800, '357, '219

[238] On November 9, 2012, the 12-4571 action was consolidated with the 10-5197 action, with all papers maintained and captioned in 10-5197. *See* 2:12-cv-4571, ECF No. 25.

May 16, 2013	10-5917	Composition family: ’517 (all claims), ’554, ’106, ’230, ’415 REMS: ’501, ’720, ’976, ’977, ’784, ’886 MDS: ’740, ’717 MM: ’569 Crystal: ’800, ’357, ’219, **’598**
May 15, 2014	14-3126	REMS: **’188, ’531** MM: **’498, ’095**

APPENDIX 3

Patents NOT at Issue in *Natco* as of Mid-May 2015			
Patent Family	**Patent Nos.**	**Latest Expiration**	**Reason NOT at Issue**
REMS	’326, ’432, ’763	Aug. 28, 2018	Covenants not to sue[239]
Compound	’230, ’554, ’106, ’415	July 24, 2016	By stipulation,[240] after Natco submitted a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III) (“paragraph III certification”) that it was no longer seeking approval of its ANDA prior to the expiration of those patents
Crystal – Form B	’217	Nov. 24, 2024	Covenant not to sue[241]
Method of Treatment – Mantle Cell Lymphoma	’363, ’929	Mar. 8, 2028	Natco carved out the indication, Celgene **did not assert** ’363 nor ’929 patents

[239] 2:10-cv-5197, ECF No. 24 (as to ’326 and ’432); 2:10-cv-5197, ECF No. 145 and 2:12-cv-4571, ECF No. 14 (as to ’763).

[240] 2:10-cv-5197, ECF No. 402.

[241] 2:10-cv-5197, ECF No. 140 and 2:12-cv-4571, ECF No. 8.

APPENDIX 4

1) The Clorazil Patient Monitoring Service ("the CPMS")

The CPMS is a program for the distribution of Clorazil™. Clorazil treats schizophrenia. A major side effect of Clorazil is agranulocytosis, a potentially fatal blood disorder.

Clorazil is distributed through the CPMS, which uses a national registry for patients, prescribers, and pharmacies. This registry identifies and reduces the risk of Clorazil-related complications.

The CPMS uses a computerized registry that includes patient information such as white blood cell counts to determine risk factors. The CPMS also tests white blood cell counts prior to starting Clorazil therapy. The CPMS mandates prescribing and dispensing only a limited supply of Clorazil after the prescriber determines that the risk is acceptable and provides the dispensing pharmacy with a report containing white blood cell counts and the doctor's opinion that the patient is eligible to receive required Clorazil. Additionally, the CPMS contains protocols for discontinuing treatment if the doctor determines, based on weekly blood tests, that the risk becomes unacceptable. Weekly refills are only provided after the same criteria for the initial dispensation are met again at the start of each week.

The CPMS qualifies as prior art to the claims of the Distribution Method Patents and the '886 Patent under 35 U.S.C. § 102(b), because it was commercially used in the United States more than one year before the earliest priority date of the Distribution Method Patents and the '886 Patent.

The applicants of those patents, their agents, and/or their attorneys did not disclose the CPMS to the USPTO during pendency of the applications from which the Distribution Method Patents issued.

2) Honigfeld, "Effects of the Clozapine National Registry System on Incidence of Deaths Related to Agranulocytosis," *Psychiatric Services*, 47(1):52-56 (1996)

("Honigfeld I")

Honigfeld I describes details of the CPMS and qualifies as prior art to the Distribution Method Patents and the '886 Patent because it was publicly available and accessible more than one year prior to the earliest priority date of the Distribution Method Patents and the '886 Patent.

The applicants, their agents, and/or their attorneys did not disclose Honigfeld I to the USPTO during the pendency of the applications from which the Distribution Method Patents issued.

3) Honigfeld, et al., "Reducing Clozapine-Related Morbidity and Mortality: 5 Years of Experience With the Clozaril National Registry," J. *Clin. Psychiatry* 59 (suppl 3): 3-7 (1998) ("Honigfeld II")

Honigfeld II also details the protocols of the CPMS and qualifies as prior art to the '501 and '976 patents under 35 U.S.C. § 102(a) because it was publicly available information prior to the earliest priority date of the '501 and '976 patents. Honigfeld II qualifies as prior art to the '720, '977, '784, and '886 patents under 35 U.S.C. § 102(b), because it was publicly available information more than one (1) year prior to the earliest priority date of the '720, '977, '784, and '886 patents.

The applicants, their agents, and/or their attorneys did not disclose Honigfeld II to the USPTO during the pendency of the applications from which the Distribution Method Patents issued.

4) The "Guide to the Clozaril Patient Monitoring Service," Novartis Pharmaceuticals UK Ltd. (Nov. 1997) ("The Guide")

Details of the CPMS are described in the Guide, which qualifies as prior art to the '501 and '976 patents under 35 U.S.C. § 102(a) because it was publicly available prior to the earliest priority date of the '501 and '976 patents. The Guide qualifies as prior art to the '720, '977, '784, and '886 patents under 35 U.S.C. §102(b), because it was publicly available more than one (1)

year prior to the earliest priority date of the '720, '977, '784, and '886 patents.

The applicants, their agents, and/or their attorneys did not disclose the Guide to the USPTO during the pendency of the applications from which the Distribution Method Patents issued.

5) The ACCUTANE® Pregnancy Prevention Program ("PPP")

The PPP is a program for the distribution of Accutane, known generically as isotretinoin. The PPP was developed and implemented to prevent fetal exposure to isotretinoin. The PPP included an information package for physicians warning of the risks of dispensing the drug to pregnant women, a patient informed consent form containing warnings detailing the risks associated with Accutane and the requirements to receive Accutane and required pregnancy testing and birth control counseling before the patient started a course of Accutane therapy. It also required a patient survey on compliance.

The PPP qualifies as prior art to the claims of the Distribution Method Patents and the '886 patent under 35 U.S.C. § 102(b), because it was commercially used in the United States more than one (1) year prior to the earliest priority date of the Distribution Method Patents and the '886 patent.

The applicants, their agents, and/or their attorneys did not disclose the PPP to the USPTO during the pendency of the applications from which the Distribution Method Patents and the '886 patent issued.

6) The Accutane PPP Package, a 1994 patent and prescriber information package for Accutane, distributed by Roche Pharmaceuticals ("PPP Package")

The PPP Package described details of the PPP. It qualifies as prior art to the Distribution Method Patents and the '886 patent under 35 U.S.C. § 102(b), because it was publicly available more than one (1) year prior to the earliest priority date of the Distribution Method Parents and

the ’886 patent.

The applicants, their agents, and/or their attorneys did not disclose the PPP Package to the USPTO during the pendency of the applications from which the Distribution Method Patents and the ’886 patent issued.

7) A Centers for Disease Control public meeting entitled “Preventing Birth Defects Due to Thalidomide Exposure” and transcript from March 26, 1997 “The CDC Meeting and Transcript”

On March 26, 1997, the CDC held a public meeting to discuss thalidomide and its associated risks. The meeting was attended by at least two Celgene employees: Dr. Jerome Zeldis, the then Vice President of Medical Affairs at Celgene, and Mr. Bruce A. Williams, a named inventor for the Distribution Method Patents and the ’886 patent.

The transcript of the CDC Meeting shows that the PPP and the CPMS were discussed, as was the use of the protocols in those two systems in designing a similar protocol for thalidomide.

The CDC Meeting attendees discussed potential elements to be part of a thalidomide distribution program, including: (1) patient, pharmacy, and prescriber registration; (2) counseling patients about the risks of thalidomide and the need for contraception; (3) required pregnancy testing before thalidomide is prescribed; (4) monthly testing thereafter; (5) providing proof that the patient is not pregnant before the drug can be dispensed and providing contraceptives with the drug; (6) limiting the length of the prescription to a monthly supply; and (7) requiring return to the prescriber before refilling the prescription.

The CDC Transcript was publicly available under the Freedom of Information Act more than one (1) year prior to the earliest priority date of the Distribution Method Patents and the ’886 patent. It therefore qualifies as prior art to the Distribution Method Patents and the ’886 patent under 35 U.S.C § 102(b).

The applicants, their agents, and/or their attorneys did not disclose the CDC Meeting or

the CDC Transcript to the USPTO during the pendency of the applications from which the Distribution Method Patents and the ’886 patent issued.

8) Zeldis, et al., “S.T.E.P.S.™: A Comprehensive Program for Controlling and Monitoring Access to Thalidomide,” *Clinical Therapeutics* 21(2): 319-30 (1999) (“Zeldis”)

Zeldis qualifies as prior art to the ’720, ’977, and ’784 patents under 35 U.S.C. § 102(b), because it was publicly available more than one (1) year prior to the earliest priority date of the ’720, ’977, and ’784 patents.

Zeldis is co-authored by Celgene employees, including Zeldis and named inventor Williams. It described the S.T.E.P.S. program developed by Celgene, with the guidance of the FDA, to monitor and control access to thalidomide. Zeldis states that the S.T.E.P.S. protocol is “based in part on experience gained with other drugs—specifically isotretinoin and clozapine—that offer important clinical benefits but carry the potential for serious harm.”

Zeldis states:

> Celgene has incorporated elements of both these successful programs into the S.T.E.P.S.™ program for controlling the distribution of thalidomide. Educational materials for patients and physicians and label warnings similar to those used in the isotretinoin program are coupled with clinician and patient registration and testing similar to those used in the clozapine program.

Zeldis cites Honigfeld I and Honigfeld II in its discussion of Clorazil.

The applicants, their agents, and/or their attorneys did not disclose Zeldis to the USPTO during the pendency of the applications from which the Distribution Method Patents issued.

9) The September 4 and 5, 1997 Center for Drug Evaluation and Research of the Food and Drug Administration public meeting (“The CDER Meeting and Transcript”)

The CDER Meeting was recorded in a publicly-available transcript and at least seven (7) Celgene employees, including named inventor Bruce Williams who made a presentation on

preventing fetal exposure to thalidomide, attended the meeting.

Williams stated:

> [w]e recognize that there may be some models in the marketplace today which could serve as at least a starting point in our thinking as we develop this program. Two of them came to mind that I would like to just speak very briefly to, to indicate why we feel that they are relevant models, but also where we feel they may not go far enough for this particular circumstance. The first is one that this committee, particularly, is very familiar with. And that is Roche's Accutane, used to treat severe acne, and known to be a human teratogen.

Williams described the Accutane system, the PPP, and its purported drawbacks, which he described as a lack of a mandatory registry and an inability for a pharmacist to determine at dispensing whether the patient has participated in Roche's program.

He noted that the PPP's purported drawbacks drove Celgene to analyze the CPMS protocol, to which he stated:

> In looking at how Sandoz structured this [Clozaril] system, we began to see that by taking elements from the Roche program [Accutane], elements from the Clozaril program and other unique elements, we would create a system that really would be state of the art, represent a significant step, we believe, forward in the ability to make drugs like thalidomide available to patients who need it, while at the same time providing a very high margin for protection.

The CDER Transcript qualifies as prior art to the Distribution Method Patents and the '886 patent under 35 U.S.C. § 102(a), because it was publicly available under the Freedom of Information Act prior to the earliest priority date of the Distribution Method Patents and the '886 patent. The CDER Transcript also qualifies as prior art to the '720, '977, and '784 patents under 35 U.S.C. § 102(b), because it was publicly available information under the Freedom of Information Act more than one (1) year prior to the earliest priority date of the '720, '977, and '784 patents.

The applicants, their agents, and/or their attorneys did not disclose the CDER Transcript to

the USPTO during the pendency of the applications from which the Distribution Method Patents issued.

10) The September 9 and 10, 1997 public workshop held by the National Institutes of Health, FDA, and CDC, entitled "Thalidomide: Potential Benefits and Risks, Open Public Scientific Workshop" ("The NIH Meeting and Transcript")

The NIH Meeting on` September 10, 1997, was recorded in a publicly available transcript. There, named inventor Williams gave a presentation regarding a Celgene proposal "for a distribution and education system" for thalidomide.

Williams stated:

> when we started in this endeavor we looked to see what else was in the marketplace that might serve as a model. We accepted that we were unlikely to find any single model that carried all of the elements that would likely be necessary for this drug, but we did find two that in part covered many of the elements that might be required. Accutane, we heard about yesterday. Comprehensive educational program, counseling, and good contraception, informed consent, a package with integrated product warnings, and a surveillance system, albeit voluntary. Many elements that clearly with either change or updating or enhancement would likely be relevant to what needed to be done for thalidomide. We also heard about the Novartis program for Clozaril, a drug used to treat schizophrenia and introduced in an era where existing antischizophrenia drugs were not particularly effective for many patients. In addition, they carried their own baggage of side effects. However, in a small proportion of patients who take this drug, a granular cytosis [sic] can develop in a very short period of time.

The NIH Transcript qualifies as prior art to the Distribution Method Patents and the '886 patent under 35 U.S.C. § 102(a), because it was publicly available under the Freedom of Information Act before the earliest priority date of the Distribution Method Patents and the '886 patent. The NIH Transcript also qualifies as prior art to the '720, '977, and '784 patents under 35 U.S.C. § 102(b), because it was publicly available and accessible under the Freedom of Information Act more than one (1) year prior to the earliest priority date of the '720, '977, and

’784 patents.

CERTIFICATE OF SERVICE

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

Dated: May 7, 2026

/s/ Peter D. St. Phillip, Jr.
Peter D. St. Phillip, Jr.