UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

LOUISIANA HEALTH SERVICE & INDEMNITY COMPANY D/B/A BLUE CROSS AND BLUE SHIELD OF LOUISIANA and HMO LOUISIANA, INC., individually and on behalf of all others similarly situated,

Plaintiffs,

v.

CELGENE CORPORATION, BRISTOL MYERS SQUIBB COMPANY, AUROBINDO PHARMA LIMITED, AUROBINDO PHARMA USA, INC., AUROLIFE PHARMA LLC, EUGIA PHARMA SPECIALTIES LIMITED, BRECKENRIDGE PHARMACEUTICAL, INC., NATCO PHARMA LIMITED, TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES LIMITED,

Defendants.

Civil Action No. _____

CLASS ACTION

JURY TRIAL DEMANDED

CLASS ACTION COMPLAINT AND DEMAND FOR JURY TRIAL

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The plaintiffs, Louisiana Health Service & Indemnity Company d/b/a/ Blue Cross Blue Shield of Louisiana and HMO Louisiana, Inc., on behalf of themselves and all others similarly situated, for their class action complaint against Celgene Corporation, Bristol Myers Squibb Company, and certain settling generic manufacturers identified herein, allege, based on personal knowledge as to themselves and upon information and belief as to the other allegations, as follows.

I. INTRODUCTION

1. This civil action alleges that pharmaceutical giants Bristol Myers and Celgene unlawfully extended, and continue to extend, a monopoly in the market for pomalidomide, a blockbuster drug used in the treatment of multiple myeloma and sold under the brand name Pomalyst. Celgene accomplished the scheme (i) through a pattern of fraud on the U.S. patent office, (ii) by abuse of the federal judicial system, and (iii) by eventually sharing some of its illicitly acquired, supra-competitive profits with would-be generic competitors to have those generics further delay *bona fide* generic competition. As a result, purchasers of this $2.25 billion a year drug have overpaid, and continue to overpay, for pomalidomide by many hundreds of millions, if not billions, of dollars.

2. *Fraud on the U.S. patent office.* The fraud on the U.S. patent office involved acquiring two series of pomalidomide patents, one for methods-of-using the drug and the other for formulations of it, through misrepresentations and concealment from PTO examiners regarding information that had already been in the public domain about the properties, formulations, and potential uses of pomalidomide. The misrepresentations and concealment by Celgene and its agents were known by them to be false, often because they had been involved in the prior research themselves or because Celgene purchased rights to earlier, prior art research. Had the fraud not occurred, the patents would not have issued, and generic pomalidomide would have been available sooner than it will be.

3. *Abuse of the federal judicial system*. Celgene abused the federal judicial system by filing a series of sham lawsuits, using the pomalidomide method-of-use and formulation patents, along with inapplicable polymorph patents, against the generic companies that sought to enter the U.S. market for pomalidomide. The lawsuits were a sham (i) because, regardless of whether the patents had been procured by fraud, Celgene had no realistic likelihood of prevailing since full factual disclosure during federal litigation would show the patents to be invalid and/or non-infringed, and (ii) because Celgene filed the lawsuits to interfere with the generic companies' attempt to gain market entry. Had the sham lawsuits not been filed or pursued, generic manufacturers would not have been impeded by them, and generic pomalidomide would have been available sooner than it will be.

4. *Reverse payments to, and market allocation with, would-be competitors*. The anticompetitive reverse payment settlements occurred in the wake of Celgene's litigations against the would-be generic competitors. Now acquired by Bristol Myers and knowing that Celgene would not prevail in the patent litigation, Celgene and Bristol Myers paid off at least several of the first-to-file generic companies—including Aurobindo, Eugia, Breckenridge, Natco, and Teva—to have each discontinue its challenge to the pomalidomide patents and delay their entry into the U.S. market. While the form of the payment is cloaked under an effort at absolute secrecy, each of the reverse payment agreements include a payment well into nine figures, and each vastly exceeds the net revenues any one of the generic companies could hope to earn even if it had prevailed in the patent litigation. Each also allocates the pomalidomide market. Had Celgene and Bristol Myers not paid off their would-be competitors, generic pomalidomide would have been available sooner than it will be.

5. Taken severally or together, the wrongdoing violated, and continues to violate, the federal Sherman Act and State law. Monetary relief is sought on behalf of the plaintiffs and classes of health benefit providers. And because the effect of the wrongdoing is ongoing, injunctive relief is sought.

II. PARTIES

6. The plaintiff Louisiana Health Service & Indemnity Company d/b/a/ Blue Cross Blue Shield of Louisiana ("BCBSLA") is a not for profit health insurance company organized and existing under the laws of the state of Louisiana. BCBSLA provides and manage nature of health benefits to more than 1 million participants, members, and beneficiaries primarily in the state of Louisiana, as well as throughout the U.S. BCBSLA also provides third-party administrative services for members of self-funded employee health plans. BCBSLA has paid all or part of the cost of its participants' purchases of pomalidomide.

7. The plaintiff HMO Louisiana, Inc. ("HMOLA") is a domestic health maintenance organization licensed to conduct business in the state of Louisiana and is a wholly owned subsidiary of Louisiana Health Service & Indemnity Company (collectively, "BCBS-LA").

8. The defendant Aurobindo Pharma Limited is a company organized and existing under the laws of India, having a principal place of business office at Maitri Vihar, Plot #2, Ameerpet, Hyderabad - 500038, Telangana, India. Aurobindo has been in the United States since the inception of Aurobindo's formulations business in 1999.

9. The defendant Aurobindo Pharma USA, Inc. is a company organized and existing under the laws of the State of Delaware, having a principal place of business at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520.

10. The defendant Aurolife Pharma LLC is a limited liability company and wholly owned subsidiary of Aurobindo Pharma USA, Inc., having a principal place of business at 2400 Route 130 North, Dayton, New Jersey 08810.

11. The defendant Eugia Pharma Specialties Limited is a company organized and existing under the laws of India, having a principal place of business office at Galaxy, Floor 22-24;

Plot No 1, Sy No 83/1 Hyderabad Knowledge City, Hyderabad, Telangana, 500032. Eugia Pharma Specialties Limited is a subsidiary of Aurobindo Pharma Limited.

12. The defendants Aurobindo Pharma Limited, Aurobindo Pharma USA, Inc., Aurolife Pharma LLC, and Eugia Pharma Specialties Limited, are referred to collectively as "Aurobindo."

13. The defendant Breckenridge Pharmaceutical, Inc. ("Breckenridge") is a corporation organized and existing under the laws of the State of Florida, having a place of business at 15 Massirio Drive, Suite 201 Berlin, CT 06037.

14. 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 to date, 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.

15. The defendant Celgene Corporation is a pharmaceutical company organized and existing under the laws of the State of Delaware with a principal place of business at 86 Morris Avenue, Summit, New Jersey 07901. In 2019, Celgene Corporation was acquired by, and became a wholly owned subsidiary of, Bristol Myers. Celgene Corporation, whether before or after its acquisition by Bristol Myers, is referred to as "Celgene."

16. The defendant Natco Pharma Limited ("Natco") is a corporation organized and existing under the laws of India and has a principal place of business at Natco House, Road No. 2, Banjara Hills, Hyderabad, Andhra Pradesh– 500 034, India.

17. The defendant Teva Pharmaceuticals USA, Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 1090 Horsham Road, North Wales, PA 19454.

18. The defendant Teva Pharmaceutical Industries Limited is a company organized and existing under the laws of Israel, having a princ-pageipal place of business at 5 Basel Street, Petach Tikva 49131 Israel.

19. The defendant Teva Pharmaceuticals USA, Inc. is a wholly owned subsidiary of Teva Pharmaceutical Industries Limited.

20. The defendants Teva Pharmaceutical Industries Limited and Teva Pharmaceuticals USA, Inc. are referred to together as "Teva."

III. JURISDICTION AND VENUE

21. The Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because this is a class action in which the aggregate amount in controversy exceeds $5,000,000 and at least one member of the putative class is a citizen of a state different from that of one of the defendants. The Court further has jurisdiction over this action pursuant to 15 U.S.C. § 26 and 28 U.S.C. §§ 1331 and 1337 as this action also alleges violations of sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 & 2, that are actionable under section 16 of the Clayton Act, 15 U.S.C. § 26. The Court also has jurisdiction over the claims under the various state laws under both 28 U.S.C. § 1332(d) and 28 U.S.C. § 1367(a).

22. This action seeks to recover damages, interest, costs of suit, and reasonable attorneys' fees for the injuries sustained by plaintiffs and members of the Class (defined below) resulting from Celgene's monopolization and from all the defendants' conspiracy to restrain trade in the United States market for Pomalyst and its generic equivalents. The action also seeks permanent injunctive relief against the defendants to undo and prevent the unlawful conduct alleged here.

23. Venue is appropriate within this district as the defendants transact business here, and under 15 U.S.C. § 26 (Clayton Act), 15 U.S.C. § 22 (nationwide venue for antitrust matters), and 28

U.S.C. § 1391(b) (general venue provision). Further, the defendants and/or their agents may be found in this district.

24. The Court has personal jurisdiction over each defendant. Each defendant has transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of the illegal scheme and conspiracy throughout the United States, including in this district. The scheme and conspiracy have been directed at, and have had the intended effect of, causing injury to persons residing in, located in, or doing business throughout the United States, including in this district.

IV. REGULATORY FRAMEWORK

A. The regulatory structure for approval and substitution of generic drugs balances new drug innovation with generic drug competition.

25. Under the federal Food, Drug, and Cosmetic Act (FDCA),[1] manufacturers that create a new drug must obtain approval from the Food and Drug Administration (FDA) to sell the product by filing a New Drug Application (NDA).[2] An NDA must include specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents.[3]

26. When the FDA approves a brand manufacturer's NDA, the manufacturer may list in *Approved Drug Products with Therapeutic Equivalence Evaluations* (known as the "Orange Book") certain kinds of patents that the manufacturer asserts 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.[4] The manufacturer may list in the Orange Book within 30 days of issuance any

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

[2] 21 U.S.C. §§ 301-392.

[3] 21 U.S.C. § 355(a), (b).

[4] For example, patents covering processes for making drug products may not be listed in the Orange Book.

patents issued after the FDA approved the NDA.[5] Valid and infringed patents may lawfully prevent generic competition, at least for a period, but manufacturers can abuse the system to use invalid or non-infringed patents to unlawfully delay generic competition.

27. The FDA relies completely on the brand manufacturer's truthfulness about patent validity and applicability because it 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. Congress designed the Hatch-Waxman Amendments to the FDCA to encourage and hasten generic entry and reduce healthcare costs.

28. The FDCA's 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.[6] A manufacturer seeking approval to sell a generic version of a brand drug may instead file an Abbreviated New Drug Application (ANDA). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's original NDA and must 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.

29. Drug products that the FDA considers therapeutically equivalent to the reference drug product are assigned an "A" code. This includes products for which "there are no known or suspected bioequivalence problems" (AA, AN, AO, AP, or AT, depending on how the drug is

[5] 21 U.S.C. § 355(b)(1), (c)(2).

[6] *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).

administered) and drug products for which "actual or potential bioequivalence problems have been resolved with adequate *in vivo* and/or *in vitro* evidence supporting bioequivalence" (AB).[7]

30. 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.

31. Through the Hatch-Waxman Amendments, Congress sought to expedite the entry of less expensive generic competitors to brand drugs, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical manufacturers' incentives to create new and innovative products.

32. The Hatch-Waxman Amendments achieved both goals, advancing substantially 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, revenues for brand and generic prescription drugs totaled $21.6 billion; by 2013, total prescription drug revenues had climbed to more than $329.2 billion, with generics accounting for 86% of prescriptions.[8] Generics are dispensed about 95% of the time when a generic form is available.[9]

2. The FDA may grant regulatory exclusivities for new drugs, but those exclusivities do not necessarily bar generic entry.

33. To promote a balance between new drug innovation and generic drug competition, the Hatch-Waxman Amendments also provide for exclusivities (or exclusive marketing rights) for

[7] FDA, *Orange Book Preface*, available at https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface (last accessed September 4, 2023).

[8] *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 2013* 30, 51 (2014).

[9] *Id.* at 51.

new drugs. The FDA grants any such exclusivities upon approval of a drug if the sponsor and/or drug meet the relevant statutory requirements. Any such exclusivities for a drug are listed in the Orange Book, along with any applicable patents, and can run concurrently with the listed patents.

34. One such exclusivity, the New Chemical Entity (NCE) exclusivity, applies to products containing chemical entities never previously approved by the 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 ANDA contains a certification of patent invalidity or non-infringement, in which case an application may be submitted after four years.[10] If the patent holder filed a patent infringement suit filed within the one-year period beginning four years after NDA approval, the 30-month stay is extended by amount of time such that a total of 7.5 years will elapse from the date of NDA approval.

35. A drug product may also receive a three-year period of exclusivity if its sponsor submits a supplemental application (sNDA) 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.[11]

36. Regulatory exclusivities may not be absolute bars to generic entry. For example, some can be overcome by carving out information in the label or for other reasons.[12]

[10] 21 U.S.C. § 355(j)(5)(F)(ii); 21 C.F.R. § 314.108(b)(2).

[11] 21 U.S.C. § 355(j)(5)(F)(iv); 21 C.F.R. § 314.108(b)(2)(5).

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

3. Abbreviated New Drug Applications must be accompanied by a certification under paragraphs I, II, III, and/or IV, the last of which can trigger an automatic stay.

37. 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:

a. That no patent for the brand has been filed with the FDA (a paragraph I certification);

b. That any patent(s) for the brand has/have expired (a paragraph II certification);

c. That any patent(s) 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

d. That any patent(s) for the brand is/are invalid or will not be infringed by the generic manufacturer's proposed product (a paragraph IV certification).[13]

38. 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. If the brand manufacturer initiates a patent infringement action against the generic filer within forty-five days of receiving notification of the paragraph IV certification, the FDA will not grant final approval to the ANDA-filer (which would enable the manufacturer to market and sell its product) 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 at issue is invalid or not infringed by the generic manufacturer's ANDA.[14] Until one of those conditions occurs, the FDA may only grant tentative approval, meaning the ANDA meets all regulatory requirements and is approvable but for the 30-month stay. FDA final approval may be delayed beyond the 30-month stay if the brand drug was entitled to the NCE exclusivity period.

[13] 21 U.S.C. § 355(j)(2)(A)(vii).

[14] 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.

39. Once the thirty-month stay ends (and the NCE exclusivity expires, if applicable) the FDA may grant an ANDA that meets all regulatory requirements final approval. Once the ANDA has received final approval, the generic manufacturer may launch its product, even if the patent litigation is still pending. This is known as an "at-risk" generic launch, the "risk" being that the generic manufacturer will have to pay the brand manufacturer its lost profits if the generic manufacturer ultimately loses the patent litigation. However, where the generic manufacturer expects to ultimately prevail in the patent litigation, it is highly incentivized to launch at-risk. In one study, of the 42 generic drugs that had received FDA approval and were not prevented by an injunction from launching, nearly two-thirds launched at risk.[15]

4. The first ANDA filer to issue a paragraph IV certification is entitled, once approved, to 180 days as the only ANDA generic on the market.

40. To encourage manufacturers to seek approval of generic versions of brand drugs, the Hatch-Waxman Amendments grant the first paragraph IV generic manufacturer ANDA filer (first-filer) a 180-day exclusivity period to market the generic version of the drug; the FDA may not grant final approval to any other generic manufacturer's ANDA for the same brand drug during that time.[16] 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-filer generic(s) has been on the market for 180 days.[17]

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[15] Keith M. Drake, Robert He, Thomas McGuire & Alice K. Ndikumana, *No Free Launch: At-Risk Entry By Generic Drug Firms,* National Bureau of Economic Research, Working Paper 29131 (August 2021) at p. 18 ("Of the 42 generic drugs that had received FDA approval before a district court decision and were not prevented from entering by an injunction, 26 were launched at risk before a district court decision and 16 were not.") available at https://www.nber.org/papers/w29131

[16] 21 U.S.C. § 355(j)(5)(B)(iv), (D).

[17] There is an exception: if the first-filer forfeits exclusivity. 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. There is no forfeiture here.

41. 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, though, because a brand manufacturer can launch an authorized generic (AG) at any time, manufacturing its AG in accordance with its approved NDA for the branded product but selling at a lower price point.

42. A first filer who 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.

43. The existence of one or more patents purporting to cover a drug product does not guarantee a monopoly. Patents are routinely invalidated or held unenforceable, either upon reexamination or in *inter partes* proceedings by the U.S. Patent and Trademark Office (PTO), by court decision, or by jury verdict. A patent holder always bears the burden of proving infringement.

44. One way that 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). Another is to show that the patent is invalid or unenforceable.

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

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

47. If the PTO rejects a patent application as obvious, a patent applicant may seek to overcome that rejection by submitting evidence that the claimed invention shows unexpected results, that is, that the claimed invention is at odds with what one would expect based on existing science.

48. As stated in the Manual of Patent Examining Procedure, "Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." 37 CFR 1.56(A). Deceiving the PTO, engaging in inequitable conduct, or violating the duty of disclosure renders the patent invalid.

49. 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.

50. 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 patent will be found invalid or not infringed than upheld. The FTC reports that generics prevailed in 73% of Hatch-Waxman patent

litigation cases resolved on the merits between 1992 and 2002.[18] 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.[19]

51. If a generic manufacturer successfully defends against the brand's infringement lawsuit—either by showing that its ANDA does not infringe any asserted patents and/or that any asserted patents are invalid or unenforceable—the generic may enter the market immediately upon receiving approval from the FDA.

B. AB-rated generics quickly and dramatically drive down prices for purchasers.

52. Generic versions of brand drugs contain the same active ingredient(s) as the brand name drug and are determined by the FDA to be just as safe and effective as their brand counterparts. Because the brand and its A-rated generics are essentially commodities that cannot be therapeutically differentiated, the primary basis for competition between a brand product and its generic version, or between multiple generic versions, is price.

53. Without A-rated generics in the market, the manufacturer of a brand drug has a monopoly—every sale of the product, and the accompanying profit, benefits the brand manufacturer. Without A-rated generic competition, brand manufacturers can, and routinely do, sell their drug for far more than the marginal cost of production, generating profit margins above 70% while making hundreds of millions of dollars in sales. The ability to command these kinds of profit margins is what economists call market power.

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[18] 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 accessed September 4, 2023).

[19] 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).

54. When generic entry occurs, the brand manufacturer loses most of the unit sales; the generic manufacturer sells most of the units, but at reduced prices (which continue to decline).. 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.

55. According to a recent FDA study,[20] "[f]irst-generics often yield substantial cost savings. Generic drugs approved in 2018 yield annual savings of $17.8 billion, with $4.0 billion from first-generic approvals. Savings from 2019 approvals amount to $24.8 billion, with $9.4 billion coming from first-generic approvals. Savings from 2020 approvals are estimated at $10.7 billion, with first-generic approvals contributing $1.8 billion. Over all three years, first-generic approvals account for 29% of the total savings." The FDA also highlighted the price reductions associated with generic drug approvals, reporting that it "observe[d] many instances where, within a year of the first-generic approval, prices fall by more than 75% compared to the brand price."

1. The first AB-rated generic is priced below the brand, driving sales to the generic.

56. Experience and economic research show that the first generic manufacturer to market its product prices it below the prices of its brand counterpart.[21] Every state

[20] Ryan Conrad PhD, *et al.*, *Estimated Cost Savings from New Generic Drug Approvals in 2018, 2019, and 2020* (August 2022), available at https://www.fda.gov/media/161540/download#:~:text=Estimates%20of%20the%20total%2012,estimated%20%2410.7%20billion%20in%20savings (last accessed September 4, 2023).

[21] FTC, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* ii-iii, vi, 34 (2011), available at https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf ("FTC 2011 AG Study") (last accessed September 4, 2023); FTC Pay-for-Delay Study at 1.

requires or permits that a prescription written for the brand be filled with an A-rated generic. Thus, the first generic manufacturer almost always captures a large share of sales from the brand. At the same time, there is a reduction in the average price paid for the drug at issue (brand and A-rated generic combined).

57. During the 180-day exclusivity period, the first filer is the only ANDA-approved generic manufacturer on the market. In the absence of competition from other generics, a first-filer generic manufacturer generally makes about 80% of all the profits that it will ever make on the product during that 180-day exclusivity period, a significant incentive for getting to market as quickly as possible.

58. Once generic competition begins, it quickly captures sales of the corresponding brand drug, often 80% or more of the market within the first six months after entry. (This percentage erosion of brand sales holds regardless of the number of generic entrants.)

2. Later generics drive prices down further.

59. Once additional generic competitors enter the market, the competitive process accelerates, and multiple generic manufacturers typically compete vigorously with each other over price, driving prices down toward marginal manufacturing costs.[22] In a recent study, the Federal Trade Commission (FTC) found that on average, within a year of generic entry, generics had captured 90% of corresponding brand sales[23] and (with multiple generics on the market) prices had dropped 85%.[24]

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[22] *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).

[23] For blockbuster drugs, such as Pomalyst, generic market share after one year is often higher than 90%.

[24] *See* FTC Pay-for-Delay Study.

60. According to the FDA and the FTC, the greatest price reductions occur when the number of generic competitors goes from one to two. The discount from the brand price typically increases to between 50% and 80% (or more) when there are multiple generic competitors on the market for a given brand. Consequently, the launch of a generic usually results in significant cost savings for all drug purchasers: "[a]lthough generic drugs are chemically identical to their branded counterparts, they are typically sold at substantial discounts from the branded price."[25] 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 generics."[26]

61. Generic competition enables all purchasers of a drug to (i) purchase generic versions of the drug at substantially lower prices, and/or (ii) purchase the brand at a reduced price. These competitive effects are known and reliable: brand sales decline to a small fraction of their level before generic entry and, as a result, brand manufacturers view competition from generics as a grave threat to their bottom lines.

62. Until a generic version of a brand drug enters the market, however, there is no FDA-approved bioequivalent drug to substitute for and compete with the brand, leaving the brand manufacturer to continue to profitably charge supra-competitive prices. Recognizing that generic competition will rapidly erode their brand sales, brand manufacturers seek to extend their monopoly for as long as possible, sometimes resorting to illegal means to delay or prevent generic competition.

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

63. An "authorized generic" (sometimes shortened to "AG") is a product sold under the authority of the brand's approved NDA. An AG is chemically identical to the brand

[25] *See* "What Are Generic Drugs?," FDA (Aug. 24, 2017), *available at* https://www.fda.gov/drugs/generic-drugs/what-are-generic-drugs (last accessed September 4, 2023).

[26] *Id.*

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.

64. 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 an AG at any time.

65. 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 Amendments" to encourage competition and, as a result, "lower prices in the pharmaceutical market." 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 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." Such competition, and the resulting price decreases, work to benefit drug purchasers.

66. 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.'"

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

68. 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." The FTC

similarly found that AGs capture a significant portion of sales, reducing the first-filer generic's revenues by about 50% on average. 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.

69. 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 manufacturer's 180-day exclusivity period. All drug industry participants recognize this. PhRMA recognizes it.[27] Generic companies recognize it.[28] Brand companies recognize it.[29]

V. FACTS

A. The development of thalidomide and its analogs, including pomalidomide.

1. Thalidomide and its analogs.

70. Immunomodulatory imide drugs (IMiDs) are a class of immunomodulatory drugs (drugs that adjust immune responses) containing an imide group. The IMiD class includes thalidomide and its analogs (e.g., lenalidomide and pomalidomide). The name "IMiD" alludes to "IMD" for "immunomodulatory drug" and has various imid forms.

71. This case involves wrongdoing regarding pomalidomide, the third of the thalidomide compounds to be marketed in the United States (the first being thalidomide, the second

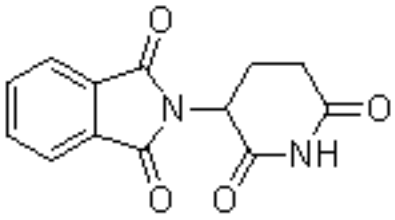
[27] Brand industry group PhRMA sponsored a study that concludes that the presence of an authorized generic causes generic prices to be more than 15% lower as compared to when there is no authorized generic. IMS Consulting, *Assessment of Authorized Generics in the U.S.* (2006).

[28] 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://paragraphfour.com/uploads/educ/2004P0075Apotex.pdf.

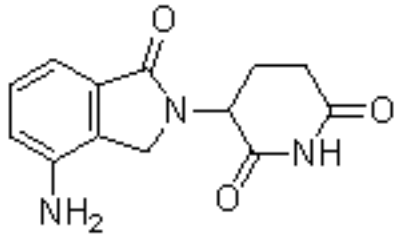
[29] Commenting on an FDA petition by drug manufacturer Teva Pharmaceuticals, Pfizer stated: "Teva's petition [to prevent the launch of an authorized generic] is a flagrant effort to stifle price competition – to Teva's benefit and the public's detriment." Comment of Pfizer at 6- 7, Docket No. 2004P-0261 (June 23, 2004); Comment of Johnson & Johnson at 1, FDA Docket No. 2004P-0075 (May 11, 2004).

lenalidomide). While its marketing is third generation, fundamental research for the use of thalidomide and its analogs, including pomalidomide and lenalidomide, to treat various conditions including multiple myeloma, occurred concurrently.

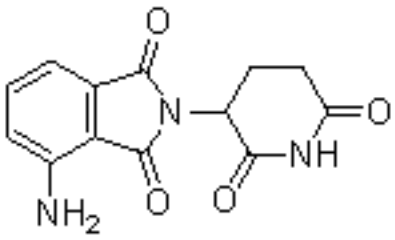
72. The chemical structure of thalidomide is:



73. The chemical structure of lenalidomide is:



74. The chemical structure of pomalidomide is:



75. During research of a chemical compound, the drug is typically referred to by its chemical name. Because chemical names are often complex and cumbersome for general use, a shorthand version of the chemical name or a code name (such as CI 981) is developed for easy reference among researchers, and internally at a company there may be other code names. If the drug is eventually approved by the FDA, the compound is given an official generic name (such as

atorvastatin) and, if applicable, a brand name (such as Lipitor). In the United States, the United States Adopted Names (USAN) Council assigns generic names.

76. The chemical name of pomalidomide is 4-(amino)-2-(2,6-dioxo(3-piperidyl))-isoindoline-1,3-dione. During research of the compound at issue in this case, the drug was at times referred to with the shortened chemical name "3-aminothalidomide" and at later times as "4-aminothalidomide", and it had several code names, including ACTIMID and CC-4047. Eventually, the common generic name for the compound became "pomalidomide."

77. For ease of understanding, these facts use the term "pomalidomide" even for events occurring before the drug was given that official name, although when quoting we of course use the exact reference used. (As later alleged, the potential confusion regarding the compound name was exploited by Celgene during patent prosecution).

2. 1960's to 2002—the study of thalidomide and its analogs.

78. In 1957, thalidomide was originally released in West Germany. Thalidomide gained international attention in the 1960s. Often prescribed to pregnant women to treat morning sickness, thalidomide, when taken during a critical phase of pregnancy, caused severe birth defects, primarily resulting in the malformation or absence of arms and/or legs of the affected children.

79. In 1961, the drug was banned after its teratogenic properties were observed. (Indeed, the thalidomide fiasco is often attributed as leading to major reforms in U.S. drug approval process).

80. Several years after thalidomide was withdrawn from the market for its ability to induce severe birth defects, its anti-inflammatory properties were discovered when patients with erythema nodosum leprosum (ENL), a condition associated with leprosy,[30] used thalidomide as a sedative and it reduced both the clinical signs and symptoms of the disease.

[30] *See* Teo S, Resztak KE, Scheffler MA, Kook KA, Zeldis JB, Stirling DI, Thomas SD., *Thalidomide in the treatment of leprosy.* Microbes Infect. 2002 Sep;4(11):1193-202. doi: 10.1016/s1286-4579(02)01645-3. PMID: 12361920. (stating that

81. The discovery of the anti-angiogenic and anti-inflammatory properties of thalidomide would lead to the development of analogs of thalidomide as a new way of fighting cancer as well as some inflammatory diseases. The notion was that analogs of thalidomide might be more effective and/or safer, and reduce thalidomide's teratogenic side effects, high incidence of other adverse reactions, poor solubility in water, and poor absorption from the intestines.

82. Pomalidomide was one of the analogs showing promising properties. As early as 1965, pomalidomide was known to be an analog of thalidomide that caused dysmelia.[31] By the 1970's and early 1980's, pomalidomide was known to be a teratogenic analog of thalidomide.[32]

83. In the early 1990s, multiple studies reported that thalidomide was discovered to inhibit tumor necrosis factor-alpha (TNF-α).[33] TNF-α is a cytokine produced by macrophages of the immune system, and a mediator of inflammatory response. Elevated levels of TNFα are associated with a few diseases, including cancer.[34]

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thalidomide has been used to treat ENL since the 1960s), available at https://pubmed.ncbi.nlm.nih.gov/12361920/sd (last accessed September 4, 2023).

[31] See R.L. Smith, et al., *Studies on the Relationship Between the Chemical Structure and Embryotoxic Activity of Thalidomide and Related Compounds*, A Symposium on Embryopathic Activity of Drugs, London (1965).

[32] See H. Koch, *The Arene Oxide Hypothesis of Thalidomide Action - Considerations on the Molecular Mechanism of Action of the Classic Teratogen*, sci. phann., p. 49, 67-99 (1981); N.A. Jonsson, *Chemical Structure and teratogenic properties*, acta pharm. Succica, 9:521-542 (1972).

[33] Sampaio, Sarno, Galilly Cohn and Kaplan, JEM 173 (3) 699–703, 1991; Sampaio EP, Kaplan G, Miranda A, Nery J.A., Miguel CP, Viana SM, Sarno EN. *The influence of thalidomide on the clinical and immunologic manifestation of erythema nodosum leprosum*. J Infect Dis. 1993 Aug;168(2):408-14. doi: 10.1093/infdis/168.2.408. PMID: 8335978 ("Patients with systemic ENL demonstrated the highest serum TNF alpha levels, which decreased significantly during thalidomide treatment.")

[34] De SK, Devadas K, Notkins AL. *Elevated levels of tumor necrosis factor alpha (TNF-alpha) in human immunodeficiency virus type 1-transgenic mice: prevention of death by antibody to TNF-alpha*. J Virol. 2002;76(22):11710-11714. doi:10.1128/jvi.76.22.11710-11714.2002 ("Elevated levels of circulating TNF-α have been linked to a wide variety of diseases, including arthritis, diabetes, Crohn's disease, and cachexia associated with terminal cancer and AIDS."), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC136749/#:~:text=Elevated%20levels%20of%20circulating%20TNF, cancer%20and%20AIDS%20(23) (last accessed September 4, 2023).

84. The renewed interest in thalidomide to treat a host of diseases, including cancer, extended beyond the scientific community, and was reported widely in the media.[35] And so, by the early 1990s, multiple research groups across the country were studying the use of thalidomide and its analogs to treat cancers, AIDs, and other conditions.

85. By this time, researchers at the Children's Hospital in Boston were pursuing the angiogenic theory of tumor growth, a hypothesis that solid tumors require angiogenesis, or the development of blood vessels, for their growth and maintenance. At least as early as 1992, one of the researchers, Dr. Robert D'Amato, began a search for compositions that would inhibit undesired angiogenesis in humans and animals. After careful and laborious testing, D'Amato discovered that thalidomide is an inhibitor of angiogenesis.

86. Over the next decade, D'Amato and other researchers at Children's Hospital developed a large portfolio of intellectual property regarding the properties and uses of thalidomide analogs, including lenalidomide and pomalidomide.

87. For example, a series of patent applications (starting with a priority date of March 1, 1993) disclosed that thalidomide and specific analogs were useful in treating numerous diseases mediated by angiogenesis, such as cancer, both blood-born and solid tumors, chronic inflammation, such as rheumatoid arthritis and osteoarthritis, and other inflammatory diseases, such as ulcerative colitis and Crohn's disease. The patent applications disclosed suitable routes for administration of

[35] *See e.g.,* Lawrence Altman, *Researchers Testing Thalidomide for Use in AIDS,* NYT (July 1, 1993) ("Thalidomide works in laboratory experiments against H.I.V. by selectively suppressing a natural substance produced in the body, the authors reported in the Proceedings of the National Academy of Sciences. The substance, tumor necrosis factor, also called cachectin, defends against infection, and it has been the subject of intense research in cancer and many other diseases."), available at https://www.nytimes.com/1993/07/01/us/researchers-testing-thalidomide-for-use-in-aids.html (last accessed September 4, 2023).

See also Sandra Blakeslee, *Scorned Thalidomide Raises New Hopes,* NYT (April 10, 1990), available at https://www.nytimes.com/1990/04/10/science/scorned-thalidomide-raises-new-hopes.html (last accessed September 4, 2023); *see also* Washington Post (April 11, 1991), *Drug Firms Seek to Make Thalidomide for Research,* available at https://www.washingtonpost.com/archive/politics/1991/04/11/drug-firms-seek-to-make-thalidomide-for-research/bead3a71-7d37-4948-a917-eb8c0aa253b2/ (last accessed September 4, 2023).

the active ingredients. The applications stated that, "angiogenesis inhibition is generally an important mechanism for the operation of teratogenic compounds (particularly compounds that cause dysmelia; i.e., malformation of limbs and extremities). Such anti-angiogenic compounds generally can be used to treat diseases characterized by undesired angiogenesis."

88. In 1994, D'Amato published an article explaining how thalidomide was found to have anti-angiogenic activity. D'Amato RJ, Loughnan MS, Flynn E, Folkman J (April 1994), *Thalidomide is an inhibitor of angiogenesis,* Proc. Natl. Acad. Sci. U.S.A. 91 (9): 4082.

89. In addition to testing thalidomide's effect on angiogenesis, D'Amato tested other compounds, including pomalidomide (then referred to as "3-amino thalidomide"). During the 1990s, D'Amato obtained several patents claiming or teaching the use of 3-amino thalidomide (i.e., pomalidomide) as a method of treating undesired angiogenesis in a human or animal.

90. During the 1990s, Celgene researchers also explored the development of thalidomide and its analogs for their anti-angiogenic and anti-myeloma activities.

91. On July 24, 1996, Celgene[36] filed patent application no. 08/690,258, which led to the 5,635,517 (the "'517 patent"). The '517 patent identified analogs of thalidomide, including lenalidomide and pomalidomide, as compounds decreasing TNFα levels. As the '517 patent explains, "[d]ecreasing TNFα levels . . . constitutes a valuable therapeutic strategy for the treatment of many inflammatory, infectious, immunological or malignant diseases. . . . These include but are not limited to . . . cancer . . . ."

92. In part, the '517 patent claimed a method of using pomalidomide to reduce TNFα. Thus, as early as 1996, Celgene owned a patent that claimed a method of using pomalidomide to

[36] The inventors on the patent are listed as George Muller, David Stirling, and Roger S.C. Chen., all of whom worked for Celgene. The assignee of the patent is Celgene Corporation. Because the inventors were affiliated with Celgene, and Celgene was the assignee of the patent when issued, we refer to the patent applicant as simply "Celgene." For simplicity and clarity, we have adopted this convention when referring to the relevant patent prosecutions.

reduce TNFα, which the '517 discloses is "a valuable therapeutic strategy for the treatment of. . . . cancer. . . ."

93. The '517 patent also claimed the compound lenalidomide, an analog to thalidomide (having one fewer oxygen atom and one more nitrogen atom), and method of using lenalidomide to reduce undesirable levels of TNFα. (The '517 patent would later become the foundation of Celgene's Revlimid franchise, earning it $35 billion in the U.S. in the last five years alone. Revlimid, in combination with the steroid dexamethasone, is used primarily in the treatment of multiple myeloma).

94. In early 1998, Celgene realized that the '517 patent, the cornerstone of its thalidomide analog patents, might be invalid due to earlier patents granted to D'Amato and others. On April 14, 1998, Celgene sought reexamination of the '517 to clear it from the D'Amato patents. Months later, the PTO granted the reexam because the D'Amato patents contained the same disclosure of the '517.

95. The effort to clear the '517 backfired. On February 22, 1999, the PTO rejected all claims of the '517 as unpatentable over the three D'Amato patents (the 5,593,990, 5,629,327, and 5,712,291) and in view of the two other references[37], finding, "there is ample information in the prior [art] to motivate one of ordinary skill in the chemical arts to place [applicant's] compounds in possession of the public."

96. Explaining its determination that the claims were unpatentable as obvious, the PTO stated:

> [T]he record has shown . . . [the] concept of angiogenesis and administering said reference compounds to a patient with toxic concentrations of TNF-α is taught [in the D'Amato patents] . . . . Since the properties of the prior art overlap with the ['517] under reexamination, and the 3-D'Amato patents teach the equivalents . . . there is ample

[37] U.S.Patent No.4,808,402 (Leibovich is a named inventor) and Leibovich et al., *Macrophage-Induced Angiogenesis is Mediated Tumor Necrosis factor-a*, Letters To Nature,Vol.329,Pages 630-32, 15 October 1987.

> information in the prior [art] to motivate one of ordinary skill in the chemical arts to place applicants [sic] compounds in possession of the public.

97. In February 1999 and to resurrect its '517 patent, Celgene filed a declaration with the PTO ostensibly reporting results of the relative activities of test compounds to inhibit the levels of TNF-alpha. Celgene represented that "Compound 2" (which in fact was pomalidomide but was not identified as such) was greater than 10,000-fold more active than another compound (4-hydroxythalidomide) in the primary human cell-based assay. In its submission, Celgene misrepresented that Compound 2 was a compound claimed by the '517. That was false; Compound 2 was neither lenalidomide nor any of the three other compounds claimed in claim 10 of the application. By doing so, Celgene misled the PTO to believe, incorrectly, that Compound 2 was claimed by the '517. (PTO notes refer to "Compound 2" as 7-amino-1-oxo-2(2,6-dioxo-piperidin-3-yl)-isoindoline, which corresponds to the fourth compound claimed in Claim 10, *i.e.* 1-oxo-2-(2,6-dioxopiperidin-3-yl)-7aminoisoindoline.). While the patent issued, Celgene knew that there was broad, public information about thalidomide analogs, that it was now public information that the relative activities of the analogs could vary widely, and that the relative power of pomalidomide had now been publicly disclosed.

98. Meanwhile, Celgene had been pursuing FDA approval of thalidomide to treat erythema nodosum leprosum (ENL).

99. On July 15, 1998, the FDA approved Celgene's new drug application for thalidomide 50 mg for the acute treatment of the cutaneous manifestations of moderate to severe ENL. While the approved indication was for ENL, given increasing scientific research showing the ability of thalidomide (and its analogs) to inhibit TNF-alpha and its effect on multiple myeloma, over time (before the 2006 formal approval for multiple myeloma) thalidomide was used off-label to treat multiple myeloma.

100. Following the approval of thalidomide for ENL, the scientific community continued to report on thalidomide analogs, such as pomalidomide, including regarding their effect on multiple myeloma, relative potency, and the ability of thalidomide analogs (such as lenalidomide and pomalidomide) to treat relapsed or refractory disease.

101. For example, on June 7, 1999, the journal of Bioorganic & Medicinal Chemistry Letters published a study by G.W. Muller and others ("Muller (1999)")[38] disclosing the structure of pomalidomide and teaching that "4-amino substituted analogs were found to be potent inhibitors of TNF-α." On July 1, 1999, the Journal of Immunology published a study by L.G. Corral and others ("Corral (1999)")[39] teaching pomalidomide[40] as a more potent agent with decreased potential for birth defects. In 2000, the journal Blood published a study by Hideshima and others ("Hideshima (2000)") regarding the ability of thalidomide and its analogs to overcome drug resistance of multiple myeloma cells.[41]

102. On April 6, 2000, Celgene filed a patent application (in the '517 family) that led to the 6,281,230 (issued in 2001). The '230 claims methods of treatment involving lenalidomide and discloses pomalidomide in combination with an active agent to treat cancerous conditions and reduce TNFα.

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[38] Muller GW, Chen R, Huang SY, Corral LG, Wong LM, Patterson RT, Chen Y, Kaplan G, Stirling DI. Amino-substituted thalidomide analogs: potent inhibitors of TNF-alpha production. Bioorg Med Chem Lett. 1999 Jun 7;9(11):1625-30. doi: 10.1016/s0960-894x(99)00250-4. PMID: 10386948, available at https://www.sciencedirect.com/science/article/abs/pii/S0960894X99002504?via%3Dihub (last accessed September 4, 2023).

[39] Corral LG, Haslett PA, Muller GW, Chen R, Wong LM, Ocampo CJ, Patterson RT, Stirling DI, Kaplan G. Differential cytokine modulation and T cell activation by two distinct classes of thalidomide analogues that are potent inhibitors of TNF-alpha. J Immunol. 1999 Jul 1;163(1):380-6. PMID: 10384139, available at https://pubmed.ncbi.nlm.nih.gov/10384139/ (last accessed September 4, 2023).

[40] Pomalidomide is referred to in the study as "compound CI-A."

[41] Teru Hideshima, Dharminder Chauhan, Yoshihito Shima, Noopur Raje, Faith E. Davies, Yu-Tzu Tai, Steven P. Treon, Boris Lin, Robert L. Schlossman, Paul Richardson, George Muller, David I. Stirling, Kenneth C. Anderson; *Thalidomide and its analogs overcome drug resistance of human multiple myeloma cells to conventional therapy*. Blood 2000; 96 (9): 2943–2950. doi: https://doi.org/10.1182/blood.V96.9.2943 (last accessed September 4, 2023).

103. On February 12, 2001, Celgene filed a patent application (again in the '517 family) that led to the 6,555,554 (issued in 2003). The '554 claimed methods of treatment involving lenalidomide and disclosed pomalidomide to improve oncogenic or cancerous conditions and reduce TNFα.

104. The scientific community also reported studies on the potency of thalidomide analogs and the use of thalidomide in combination with dexamethasone to treat multiple myeloma.

105. For example, Weber, et al., Abstract #719, *Thalidomide with dexamethasone for resistant multiple myeloma*, Blood, 96(11):167a (2000) ("Weber 2000") disclosed the clinical efficacy of thalidomide with dexamethasone to treat resistant multiple myeloma.

106. On July 1, 2001, the American Society of Hematology journal Blood published a study by Davies and others ("Davies 2001")[42] disclosing that thalidomide analogs can act directly on multiple myeloma cells, and that new thalidomide analogs are 50,000 times more potent in inhibiting TNFα as compared to thalidomide. Davies 2001 further taught that thalidomide produced a response in a portion of patients whose multiple myeloma was refractory and concluded in part, "our results suggest that [thalidomide] and new analogues may . . . be useful in the treatment of refractory/relapsed disease."

107. On December 1, 2001, Robert A. Kyle and others ("Kyle (2001)")[43] published an article disclosing a method of treating multiple myeloma by administering thalidomide in combination with dexamethasone cyclically.

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[42] Davies FE, Raje N, Hideshima T, Lentzsch S, Young G, Tai YT, Lin B, Podar K, Gupta D, Chauhan D, Treon SP, Richardson PG, Schlossman RL, Morgan GJ, Muller GW, Stirling DI, Anderson KC. *Thalidomide and immunomodulatory derivatives augment natural killer cell cytotoxicity in multiple myeloma.* Blood. 2001 Jul 1;98(1):210-6. doi: 10.1182/blood.v98.1.210. PMID: 11418482, available at https://pubmed.ncbi.nlm.nih.gov/11418482/ (last accessed September 4, 2023).

[43] Kyle, Robert A, and S.Vincent Rajkumar. *Therapeutic Application of Thalidomide in Multiple Myeloma.* Seminars in Oncology 28, no. 6 (December 1, 2001): 583–87. doi:10.1016/S0093-7754(01)90028-4, summary available at https://journals.scholarsportal.info/details/00937754/v28i0006/583_taotimm.xml (last accessed September 4, 2023).

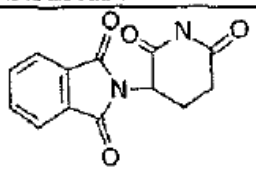
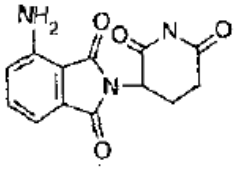
108. Also in December 2001, Dimopoulos, et al., *Thalidomide and dexamethasone combination for refractory multiple myeloma*, Ann. Oncology, 12-991-995 (2001) ("Dimopolous (2001)") disclosed *inter alia* thalidomide plus dexamethasone to treat refractory multiple myeloma.

109. The prior art also disclosed the specific amount of 40mg of dexamethasone plus thalidomide for the treatment of multiple myeloma. *See* Coleman, et al., *BLT-D (Clarithrmycin [Biaxin], Low-Dose Thalidomide, and Dexamethasone) for the Treatment of Myeloma and Waldenstroms Macroglobulinemia*, Leukemia & Lymphona, 43(9):1777-1782 (2002) ("Coleman (2002)").

110. These disclosures regarding the use of thalidomide in combination with 40mg of dexamethasone to treat multiple myeloma were in addition to the much earlier disclosures regarding the cyclical dosing of an anticancer drug (hexamethylamine) for the treatment of multiple myeloma, *i.e.,* 21 days consecutive days of administration of the anticancer drug followed by 7 days of rest, in combination with dexamethasone. *See* Cohen, et al., *Hexamethylamine and prednisone in the treatment of refractory multiple myeloma*, Am. J. Clin. Oncol. (CCT), 5:21-27 (Feb. 1982) ("Cohen (1982)").

111. The prior art also taught the specific thalidomide analog pomalidomide for the treatment of multiple myeloma. In December 2001 Robert J. D'Amato and others published an article entitled *Mechanisms of Action of Thalidomide and 3-Aminothalidomide in Multiple Myeloma* (the "D'Amato (2001)").[44] The title refers to "3-aminothalidomide," and a diagram in the article (among other evidence) makes clear that the compound discussed in the study is pomalidomide:

[44] Robert J D'Amato, Suzanne Lentzsch, Kenneth C Anderson, Michael S Rogers, *Mechanism of action of thalidomide and 3-aminothalidomide in multiple myeloma*, Seminars in Oncology, Volume 28, Issue 6, 2001, Pages 597-601, ISSN 0093-7754, https://doi.org/10.1016/S0093-7754(01)90031-4 (last accessed September 4, 2023).

Compound	Structure	bFGF Inhibition	VEGF Inhibition
Thalidomide		39%	41%
3-Aminothalidomide		30%	42%

112. This reference unquestionably teaches pomalidomide for the treatment of multiple myeloma, stating that pomalidomide "exhibited an unusual capacity to directly inhibit myeloma proliferation." It noted that pomalidomide directly inhibited myeloma cell proliferation and thus inhibited multiple myeloma both on the tumor and vascular compartments. The dual activity of pomalidomide was reported to make it more efficacious than thalidomide both *in vitro* and *in vivo*.[45] This effect was reported to be unrelated to TNF-α inhibition since potent TNF-α inhibitors such as rolipram and pentoxifylline did not inhibit myeloma cell growth nor angiogenesis.[46]

113. Also in December 2001, Lentzsch et al., Abstract #1976, *S-3-Amino-phthalimido-glutarimide Inhibits Growth in Drug Resistant Multiple Myeloma (MM) In Vivo,* Blood, 43rd Annual Amer. Soc. Hematol. (Dec. 7-11, 2001), 98(11): 473a (2001) ("Lentzsch 2001") disclosed that pomalidomide (referred to in the article as S-3-Amino-phthalimido-glutarimide or S-3APG for short) has notable anti-multiple myeloma activity, concluding that "[o]ur results show that S-3APG could be a potent new drug for the treatment of MM. S-3APG exerts its anti-myeloma activity by combination of direct dose-dependent anti-proliferative effect on MM cell lines resistant to

[45] Lentzsch S, Rogers MS, LeBlanc R, et al. (April 2002). *S-3-Amino-phthalimido glutarimide inhibits angiogenesis and growth of B-cell neoplasias in mice*. Cancer Res. 62 (8): 2300–5. PMID 11956087

[46] D'Amato RJ, Lentzsch S, Anderson KC, Rogers MS (December 2001). *Mechanism of action of thalidomide and 3-aminothalidomide in multiple myeloma*. Semin. Oncol. 28 (6): 597–601. doi:10.1016/S0093-7754(01)90031-4. PMID 11740816

conventional therapy and by inhibition of angiogenesis in vivo. Thus, S-3-APG demonstrates superior in vivo anti-MM-activity compared to Thal and induces sustained complete tumor remission in vivo, without evidence of toxicity."

114. In April 2002, Lentzsch and others published *S-3-Amino-phtahlimido-glutarimide Inhibits Angiogenesis and Growth of B-Cell Neoplasias in Mice,* Cancer Research, 62:2300-2305 (2002) ("Lentzsch 2002"), which taught that pomalidomide was able to directly inhibit the proliferation of myeloma and that pomalidomide is "a powerful anti-myeloma and anti-B-cell-lymphoma agent that has both antiproliferative and antiangiogenic effects."

115. Also in April 2002, Schey et al., Abstract #248, *A Phase I Study of an Immunomodulatory Thalidomdie Analogue (CC4047) in Relapse/Refractory Multiple Myeloma,* Experimental Hematology (31st Annual Meeting of the International Society for Experimental Hematology) (July 5-9, 2002) ("Schey (April 2002)") disclosed pomalidomide (referred to in the article as CC4047) for the treatment of multiple myeloma in humans. Schey (April 2002) further disclosed "Phase I dose escalation study in relapsed/refractory multiple myeloma designed to identify the maximum tolerated dose (MTD) and evaluate the safety of CC-4047 when given orally for 4 weeks. Patients were enrolled in cohorts of 3 at each dose level: 1mg/day, 2mg/d, 5mg/d and 10mg/d." Schey (April 2002) established the maximum tolerated dose at 5mg/day.

116. In October 2002, Schey, S.A., *Thalidomide in the management of multiple myeloma,* Hematology 7(5):291-299 (October 2002) ("Schey (October 2002)") disclosed a phase I study of pomalidomide (again referred to in the study as CC-4047) in relapsed and refractory multiple myeloma.

3. 2002—Celgene's acquisition of the D'Amato analog portfolio.

117. By 2002, the D'Amato team at Children's Hospital had developed its thalidomide analog portfolio of intellectual property. And the development partner, EntreMed, had planned

Phase I clinical trials for pomalidomide. D'Amato had also pursued further patents. By mid-2002, some of those issued-patents and patent applications were for compositions and methods of using pomalidomide.[47] Pomalidomide particularly had been shown to induce sustained tumor regression in multiple myeloma, and to do so even in tumors from cell lines resistant to conventional chemotherapy.

118. The competing efforts of the D'Amato team and Celgene led to accusations that Celgene was interfering with D'Amato and his development partner, EntreMed.

119. In November of 2002, litigation ensued between Celgene and EntreMed. Celgene sued EntreMed and the PTO requesting the PTO be enjoined from issuing certain thalidomide analog patents to EntreMed's development partner D'Amato.[48] Entremed sued Celgene for antitrust violations based on Celgene's alleged interference with EntreMed's efforts to develop thalidomide analogs to treat cancer.[49]

120. On December 31, 2002, EntreMed and Celgene settled and entered into a three-way licensing agreement that included Children's Hospital. In exchange for future royalties, "Children's would grant Celgene an exclusive license to patents and patent applications . . . in consideration of Celgene's payment of specified payments, including but not limited to running royalties on Amino Thalidomide and Revlimid products."[50]

121. Under the arrangement, Celgene became the exclusive licensee for a broad portfolio of scores of pending patent applications and published patents—all of which had priority dates

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[47] U.S. patent no. 5,593,990 (issued Jan. 14, 1997); U.S. patent no. 5,712,291 (issued January 27, 1998); patent application no. 09/899,344 (filed July 5, 2001); patent application no. 10/020,391 (filed December 12, 2001).

[48] *Celgene Corp. v. James E. Rogan, et al.,* case no. 02-cv-2277 (D.D.C.) (complaint filed November 19, 2002).

[49] *EntreMed, Inc. v. Celgene,* 02-3787 (D.Md.) (filed November 21, 2002).

[50] The terms of the December 31, 2002 licensing agreement (a three-way agreement between EntreMed, Children's, and Celgene) were disclosed in subsequent litigation filed by Children's against Celgene in 2013 arising out of a royalties dispute. *See Children's Medical Center Corp. v. Celgene,* 13-cv-11573 (D.Mass.), Complaint (ECF 1-1, filed July 2, 2013) at ¶6, describing the December 31, 2002 Exclusive License Agreement (ECF 85-4) at ¶¶4.1 and 4.3.

before November of 2002—that disclosed uses and properties of thalidomide and thalidomide analog compounds, including pomalidomide.

122. Meanwhile, Celgene and other researchers continued publication of pomalidomide findings.

123. For example, on November 13, 2001, the PTO issued U.S. Patent No. 6,316,471 ("the '471 patent") entitled "Isoindolines, Method of Use, and Pharmaceutical Compositions." (Celgene would later list this patent in the Orange Book for Pomalyst). The '471 patent teaches the use of certain compounds including pomalidomide in the treatment of autoimmune diseases and cancers. The '471 patent also discloses that pomalidomide can be administered orally to reduce TNF-α and can be administered in the form of a capsule or tablet containing from 1 to 100 mg of drug per unit dosage. The '471 patent discloses that decreasing TNF-α constitutes a valuable therapeutic strategy to treat cancer. Claim 1 is directed to methods of treatment using pomalidomide and claim 16 is directed to the use of pomalidomide to treat an oncogenic or cancerous condition. The '471 patent also teaches that pomalidomide and lenalidomide can be administered in combination with other active compounds, including antibiotics and steroids, such as dexamethasone.

124. When the '471 patent issued, Celgene announced that the patent claims covered "the use of ACTIMID™ (CDC 394), Celgene's next IMiD™, to treat cancer and inflammatory diseases both as a single agent and in combination with other therapies." *See* Celgene Press Release (Nov. 13, 2001). ACTIMID is pomalidomide.

125. In summary, by mid-2002 scientists from multiple research centers had been studying and publishing findings regarding thalidomide analogs, including pomalidomide, for more than a decade. The specific attributes of pomalidomide were disclosed, including anti-angiogenic properties, the fact and relative power of reducing TNF-alpha levels, that pomalidomide inhibits

angiogenesis and multiple myeloma cell growth (whereas thalidomide only inhibits angiogenesis), its use with dexamethasone, and other features. Celgene's own patents, and the portfolio it bought from Children's Hospital, had already disclosed the administration of pomalidomide to treat multiple myeloma.

126. On December 9, 2002, Celgene obtained approval under an investigational new drug application (IND) to conduct tests using pomalidomide.

B. November 2002—Celgene begins pursuit of thalidomide analog method-of-use patents.

127. On November 6, 2002, Celgene filed provisional patent application no. 60/424,600 generally claiming methods of using immunomodulatory compounds to treat various cancers, and specially claiming lenalidomide (identified by its chemical name, 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione, and by its then-used commercial name, Revimid) and pomalidomide, (identified by its chemical name, 4-(amino)-2-(2,6-dioxo(3-piperidyl))-isoindoline-1,3-dione, and by its then-commercial name, Actimid[51]) for treating refractory or relapsed multiple myeloma. The application also reported the results of Phase I clinical trials for both compounds, trials that had been shaped by and based on the significant, reported scientific research over the prior two decades.

128. Starting from this November 6, 2002, application,[52] Celgene would seek a series of patents for methods of using lenalidomide and pomalidomide for the treatment of multiple myeloma. In doing so, Celgene repeatedly misrepresented known facts, and omitted to provide known material facts, to the U.S. patent office.

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[51] Also referred to as CC-4047.

[52] An earlier provisional application had been filed in May 2002 relating to treatments combining thalidomide analogs with large molecule proteins, and that application is sometimes attributed as being within this patent family. Presumably because that application related to treatments combining the analogs with the proteins, and not the analog alone, the November 6, 2002, application was treated as the relevant priority date by the parties during the subsequent patent litigation. We do the same here.

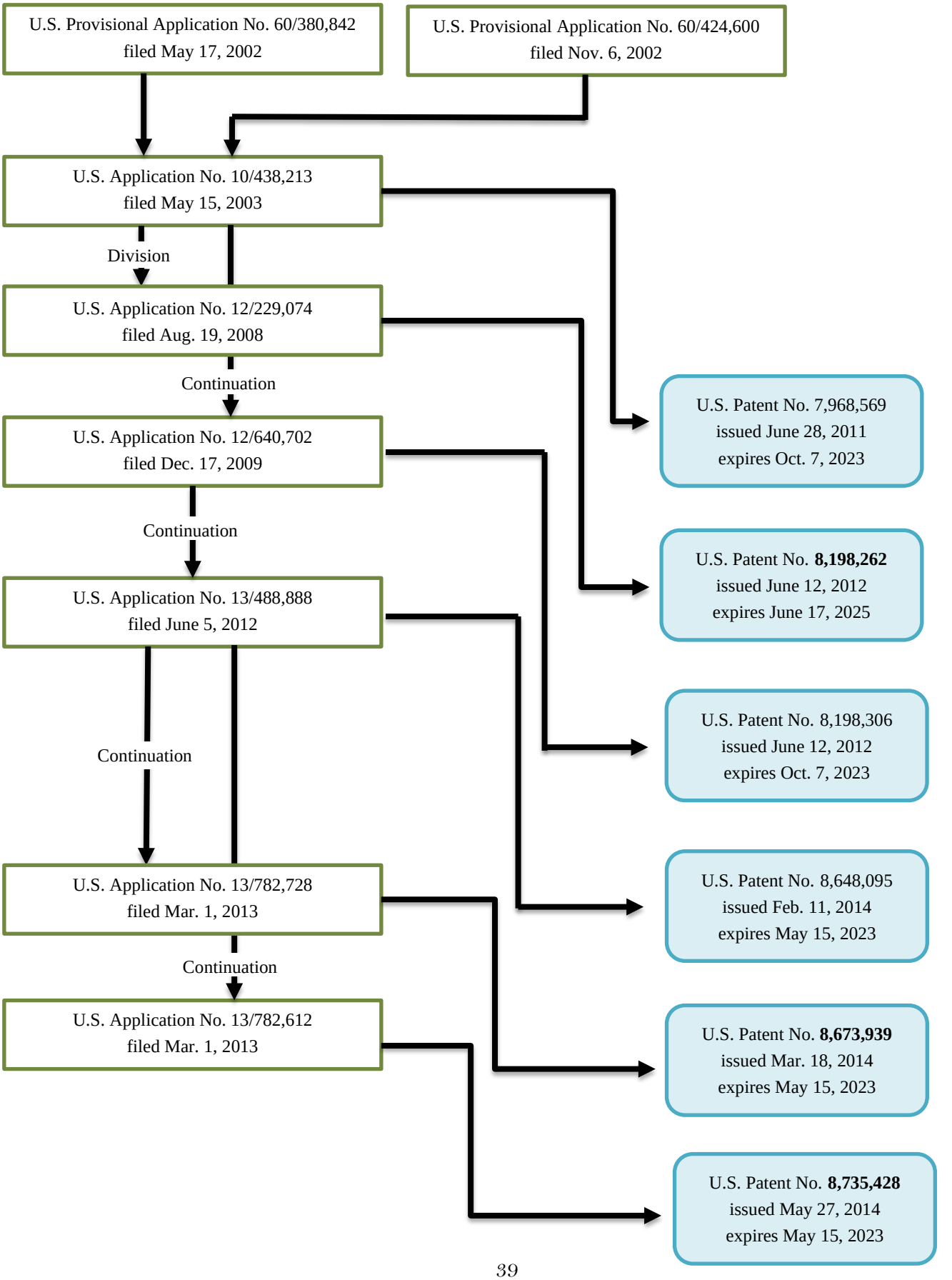
129. All of Celgene's method of treatment patents at issue in this case (the 8,198,262, 8,673,939, and 8,735,428) are derived from the November 2002 provisional application. This means that all information publicly disclosed *before* November 6, 2002, is prior art against which the novelty/inventiveness of these new method of treatment claims would be judged.

130. The family of applications and patents that issued in this family (and that are relevant to this case) is illustrated by the following diagram of patent applications and issued patents.[53] The three relevant, fraudulently acquired pomalidomide method of treatment patents are the '262, the '3939[54], and the '428.

[53] "Expires" represents the patent expiration date exclusive of pediatric exclusivity ("PED").

[54] We refer to this patent as the '3939 as there is another Celgene (formulation patent 10,555,939) that ends in the same three digits. We refer to the formulation patent (discussed *infra*) as the '5939.

THALIDOMIDE ANALOG METHOD-OF-USE PATENT TREE



131. On May 15, 2003, Celgene filed patent application no. 10/438,213, which addressed lenalidomide and its use for treating cancer, including multiple myeloma. This application would eventually result in the 7,968,569, which claimed a method of treating multiple myeloma through cyclical dosing of lenalidomide, *i.e.,* 21 consecutive days of administration followed by 7 days of rest, in combination with dexamethasone.

132. On December 27, 2005, the FDA approved lenalidomide, under the brand name Revlimid, for use in the treatment of patients with myelodysplastic syndromes,[55] a group of disorders that occur when blood-forming cells in bone marrow become abnormal (a condition considered a type of cancer).

133. On May 25, 2006, the FDA approved Celgene's new drug application for the use of thalidomide capsules, 50 mg, 100 mg, and 200 mg, under the brand name Thalomid, for the treatment of patients with newly diagnosed multiple myeloma. For treatment of multiple myeloma, the approved label stated that thalidomide is administered in combination with dexamethasone 40 mg.

134. On June 29, 2006, the FDA approved Celgene's NDA for lenalidomide 5 mg, 10 mg, 15 mg, and 25 mg capsules, under the brand name Revlimid, in combination with dexamethasone for the treatment of multiple myeloma patients who had received one prior therapy. The recommended starting dosage was 25 mg daily on days 1-21 of a 28-day repeated cycle with dexamethasone 40 mg. (Lenalidomide 5 mg and 10 mg capsules had been approved approximately six months earlier for treatment of certain patient with transfusion-dependent anemia due to myelodysplastic syndromes).

[55] It was approved "for the treatment of patients with transfusion dependent anemia due to low or intermediate-1 risk myelodysplastic syndromes associated with a deletion 5 q cytogenetic abnormality with or without additional cytogenetic abnormalities." *See* December 27, 2005 Final Approval Letter, available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2005/021880rev2.pdf (last accessed September 4, 2023).

C. August 2008—Celgene files the application for the first of its pomalidomide method-of-use patents, which it obtains by fraud.

135. On August 19, 2008, Celgene filed patent application 12/229,074 claiming treating multiple myeloma with pomalidomide (1 mg to 4 mg), with and without using dexamethasone and a cyclic dosing regimen. (This application would eventually lead to the incorrect issuance of the 8,198,262 method of treatment patent.)

136. On June 24, 2010, the PTO issued an office action rejecting the claims based on obviousness and double patenting. For the obviousness rejection, the office relied on three references (the '517, Davies (2001), and either the 6,555,554 or 6,281,230) to conclude that it would have been obvious to use the thalidomide analog pomalidomide (referred in the action as ACTIMID) in the cyclical treatment of multiple myeloma as it was a known effective agent in decreasing TNFα and that a skilled artisan would adjust dose depending on the level of disease and the potency of the drug. The double patenting objections also relied on the '517 and Davies to show that there would be double patenting over a series of five patents that already issued in Celgene's favor.

137. While the office action rejected the claims, it did so on a basis that required the *combined* teaching of the three specific references. The office was under the impression that neither the '517 nor Davies (2001) expressly taught pomalidomide, and that the '554/'230 did not expressly teach multiple myeloma. Nor did the office cite other earlier scientific literature or patents showing the treatment of multiple myeloma with pomalidomide itself. Rather, the office concluded—based only on the three references it was able to appreciate—that the references taken together showed the use of thalidomide and its analogs act directly on multiple myeloma cells, and that one of ordinary skill in the art would have been motivated by the reasonable expectation that the thalidomide analog pomalidomide (which is also effective in decreasing TNFα) would also be effective in the treatment

of multiple myeloma since the decrease in TNFα provided the rationale for treating the disease with thalidomide.

138. On December 23, 2010, Celgene filed an amendment and response. The response was materially false and misleading.

139. First, Celgene's response to the examiner's citation to the '517 was false and misleading. In the office action, the examiner had mistakenly attributed to the '517 specific statements of the treatment of multiple myeloma with thalidomide and dexamethasone. (As he would make clear later, the reference should have been to Kyle (2001)). And in describing the '517, the examiner twice mentioned that the '517 "did not expressly teach ACTIMID [pomalidomide]." But this was incorrect. In fact, the '517 claims a method of reducing undesirable levels of TNFα where the compound is pomalidomide, which the '517 discloses is "a valuable therapeutic strategy for the treatment of. . . . cancer. . . ." The '517 specifically disclosed pomalidomide and its use to reduce TNFα.

140. But in its response, Celgene simply notes that the '517 did not have the material in it that the examiner reported; it concealed the true import of the '517. Celgene is the owner of the '517 patent, the compound patent for Celgene's multi-billion dollar a year drug Revlimid. The '262 patent applicant, Jerome Zeldis, and his attorneys who prosecuted the '262 patent, Anthony Insogna and Yeah-Sil Moon, knew the '517 patent specifically disclosed pomalidomide, and they knew that the '517 claimed a method of using pomalidomide to reduce TNFα and taught that reduction of TNFα was a means of treating cancer. Yet they fraudulently withheld and omitted this material information from the PTO to obtain the '262 patent.

141. Not only did Celgene fail to disclose the truth of the '517 in the December 2010 response, Celgene exploited the mistake (about the absence of mention of pomalidomide in the '517) by repeating it and failing to correct it. "The PTO admits that the primary reference [the '517]

does not teach ACTIMID (page 5 of the Action). Thus, the primary reference does not direct the skilled person to use the recited compound in the treatment of multiple myeloma." This is wrong. Celgene, the applicants, and its counsel knew that.

142. But Celgene and its agents, Zeldis, Insogna, and Moon fraudulently omitted to disclose the truth about the '517 because it undermined the patentability of the '262.

143. Second, Celgene repeated and perpetuated the examiner's mistaken belief that Davies did not teach pomalidomide. Davies (2001) disclosed that thalidomide and the 3 immunomodulatory drugs studied, referred to as ImiD1, ImiD2, and ImiD3, can act directly on multiple myeloma cells and are useful in relapsed/refractory disease. Celgene coined the term "immunomodulatory drugs" or "IMiDs" to refer to its thalidomide analogue drugs, most prominently pomalidomide and lenalidomide. Davies (2001) did not identify the three IMiDs by chemical structure or by chemical name, a fact that Celgene capitalized on to mislead the examiner into believing that pomalidomide was not one of the drugs studied in Davies (2001). This was false. Pomalidomide has been one of Celgene's two most important IMiDs since its research into thalidomide analogues began (the other being lenalidomide). Davies' teachings are about pomalidomide. Celgene does not affirmatively assert otherwise, instead parroting the examiner's mistaken belief ("the Office admits that [Davies] does not teach ACTIMID."). Celgene knew this was false, as two of its senior scientists, George Muller and David Stirling, were involved in the Davies study and are named authors on it.

144. Third, Celgene concealed that D'Amato (2001) taught pomalidomide in the treatment of multiple myeloma. The PTO makes no mention of D'Amato (2001) during the patent prosecution. But Celgene knew better. In response to the PTO's initial rejection, Celgene[56] argued that, while the '230 and '554 taught the use of pomalidomide to treat cancer, those two patents do

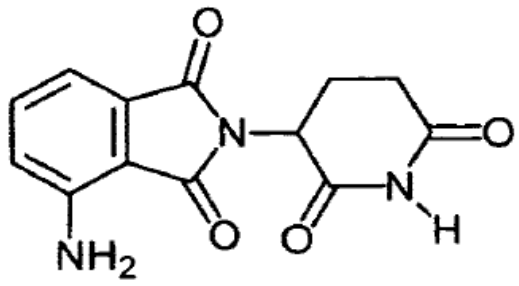
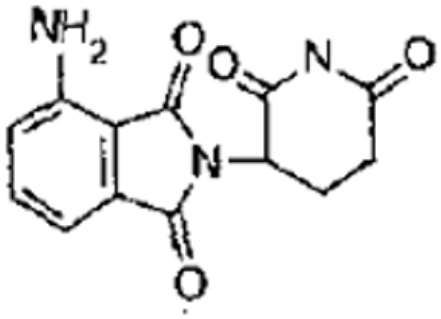
[56] The named inventor is Jerome Zeldis, a Celgene executive. Celgene Corporation is the assignee of the method of treatment patents. For simplicity, the applicant is referred to as "Celgene."

not teach the treatment of multiple myeloma specifically. In making these arguments, Celgene concealed that D'Amato 2001 *did* teach the use of pomalidomide to treat multiple myeloma specifically. Patent applicant Dr. Zeldis, a researcher in the field and Celgene executive, was well aware that D'Amato (2001) referred to pomalidomide yet omitted to disclose that information while making closely related representations about other prior art references.

145. During the prosecution of the '262 patent, the PTO focused on whether the prior art taught pomalidomide or taught treating multiple myeloma. D'Amato (2001) teaches not just one, but both, of these critical points, *i.e.,* the use of pomalidomide to treat multiple myeloma. This fact appears to have been lost on the PTO, likely due to confusion regarding nomenclature (the study refers to pomalidomide as 3-aminothalidomide instead of 4-aminothalidomide).[57]

146. Dr. Zeldis, Mr. Insogna, and Ms. Moon knew this material information, but fraudulently omitted to disclose the truth about D'Amato (2001) to the PTO because it undermined the patentability of the claimed invention. Dr. Zeldis, Mr. Insogna, and Ms. Moon submitted to the PTO a "List of Referenced Cited by the Applicant," which included D'Amato (2001) (reference C04). The '262 patent application and D'Amato (2001) included diagrams that made clear the application and D'Amato (2001) were referring to the same compound (the diagrams are oriented differently but represent the same information):

[57] Compounds like thalidomide, pomalidomide, and lenalidomide are named based on where the amino group (denoted "NH_2") attaches to the phthalimide ring. In the past, there was some discrepancy about where on the phthalimide ring one begins counting for the purposes of identification. This led to pomalidomide sometimes being referred to as "3-aminothalidomide." The accepted view is that pomalidomide is referred to as "4-aminothalidomide."

'262 Patent Application	D'Amato (2001)
	

147. Dr. Zeldis, Mr. Insogna, and Ms. Moon were knowledgeable about Dr. D'Amato's research involving thalidomide compounds, including pomalidomide, and knew D'Amato (2001) taught pomalidomide to treat multiple myeloma.

148. In short, in its December 23, 2010, response, Celgene intended to deceive the examiner into withdrawing prior rejections by misleading the examiner about the full prior public disclosures regarding pomalidomide's potential to treat multiple myeloma. Celgene's ruse worked.

149. On August 9, 2011, the PTO (same examiner) issued an office action. Based on the deceptive representations and omissions made by Celgene in its December 23, 2010, response, the examiner withdrew the prior rejections, including its objections based on the '517. In the office action, the examiner made no further mention of the '517 as an objection to obviousness, nor as a basis to reject the claims for double patenting with the five patents in the '517 patent tree.

150. Instead, in the August 2011 office action, the examiner again rejected all claims, this time relying on Kyle (2001) (the correct reference for the material regarding cyclical dosing thalidomide analogs with dexamethasone previously attributed to the '517) and several other references (Davies (2001), Corral (1999), Muller (1999), and the '554/'230). The examiner wrote it "would have been obvious to one having ordinary skill in the art at the time the invention was made

to treat [multiple myeloma] with pomalidomide as suggested by Kyle[,] Davies, Corral and Muller by administering pomalidomide in a tablet or capsule . . . ."

151. On December 20, 2011, Celgene filed an amendment and response. The response was in material ways false and misleading.

152. First, Celgene misrepresented that the treatment of multiple myeloma with pomalidomide had not been publicly disclosed previously. That was knowingly false. Second, Celgene misrepresented that the use of one thalidomide compound over another had not been publicly disclosed previously. That was knowingly false. Third, Celgene misrepresented that pomalidomide combined with dexamethasone produced unexpected results for treating relapsed or refractory multiple myeloma patients. That was knowingly false, as there was nothing surprising about these results.

153. The combination of thalidomide analogs, including pomalidomide, with dexamethasone had already been publicly disclosed, and the relative power of pomalidomide to reduce TNFα levels was publicly disclosed by 2002 (the date of the purported invention). For example, as part of the 1998-1999 reexamination of the '517 Revlimid patent, Celgene submitted data to the patent office showing that pomalidomide was purportedly 10,000 fold more active than the comparator compound selected by Celgene. Other prior art references, including D'Amato (2001), Lentzsch (2001), Lentzsch (2002), Schey (April 2002), and Schey (October 2002), specifically taught pomalidomide for the treatment of multiple myeloma and/or relapsed/refractory multiple myeloma. There is nothing surprising about the fact that the more potent thalidomide analog pomalidomide would be used where the multiple myeloma patient had become relapsed or refractory to less potent analogs such as thalidomide and lenalidomide.

154. In short, Celgene's December 2011 response was intended to deceive the examiner into withdrawing prior rejections, having the examiner not appreciate the full prior public

disclosures regarding the potential to treat multiple myeloma using pomalidomide, and to believe the ostensible unexpected results were a lawful basis to allow the claims.

155. On March 1, 2012, Celgene initiated a call with the PTO to discuss the application. Celgene's ruse worked once again. As the PTO summarized the interview:

> "Discussed potential allowability of claims if independent claims are amended to incorporate the limitations of claim 1 of U.S. Pat 7,968,569. Particularly the cyclical administration of the current amounts of the compound for 21 consecutive days followed by 7 consecutive days of rest from administration of the compound in a 28 day cycle in combination with 40 mg of dexamethasone."[58]

156. The concept of cyclical administration of pomalidomide in combination with dexamethasone was not novel. For example, Kyle (2001) discloses methods of treating multiple myeloma by cyclically administering thalidomide and dexamethasone. Coleman (2002) taught the specific amount of 40 mg of dexamethasone combined with thalidomide to treat multiple myeloma. And Cohen (1982) taught the specific 28-day dosing regimen, *i.e.,* 21 days administration of an anticancer drug followed by 7 days of rest, in combination with dexamethasone.

157. On March 15, 2012, Celgene amended the claims as contemplated at the March 1, 2012, meeting and reiterated that the PTO should withdraw all obviousness objections based on the representations it had made in its December 2011 response.

158. On April 9, 2012, the PTO issued a notice of allowance of the '262 application. Celgene had obtained the '262 patent by fraud.

159. The PTO would not have allowed the '262 patent to issue absent the fraud committed by Celgene, Dr. Jerome Zeldis (the patent applicant and long-term Celgene senior executive), Mr. Anthony Insogna (attorney prosecuting the patent and counsel to Celgene since

[58] Typographical errors and misspellings corrected.

1996), and Ms. Yeah-Sil Moon (attorney prosecuting the patent who had assisted Celgene in building its Thalomid, Revlimid, and Pomalyst patent portfolio).

160. Together and separately, the fraudulent representations and omissions by Celgene, Zeldis, Insogna and Moon about (i) the '517 patent, (ii) Davies (2001), (iii) D'Amato (2001), and/or (iv) the purported "unexpected results" deceived the PTO into issuing the '262. Celgene, Zeldis, Insogna, and Moon also omitted to disclose (or omitted to disclose the import of) key prior art references. This included Lentzsch (2001), Lentzsch (2002), Schey (April 2002), and Schey (October 2002), all of which teach pomalidomide for treating multiple myeloma, but refer to pomalidomide by names other than Actimid (the examiner's term for pomalidomide). In granting the patent, the PTO justifiably relied on the information submitted by Celgene, Zeldis, Insogna, and Moon. Absent the fraudulent, material omissions, the '262 would not have been granted.

161. The '262 is also invalid as obvious over the prior art. To highlight just a few references: Celgene's own patent, the '517, claimed a method of using pomalidomide to reduce TFNα and taught reduction of TNFα as a cancer treatment; Davies (2001) taught IMiDs, including pomalidomide, to treat multiple myeloma and relapsed/refractory disease; D'Amato (2001) taught the use of pomalidomide specifically to treat multiple myeloma; Kyle (2001) taught the multiple myeloma by administering thalidomide in combination with dexamethasone[59]; Hideshima (2000) taught thalidomide and its analogues ability to overcome drug resistance of multiple myeloma cells; Lentzsch (2001), Lentzsch (2002), Schey (April 2002), and Schey (October 2002) taught pomalidomide to treat multiple myeloma and/or relapsed/refractory multiple myeloma; Coleman (2002) taught 40 mg of dexamethasone combined with thalidomide to treat multiple myeloma; and Cohen (1982) taught the 21 day administration of an anticancer drug, followed by 7 days of rest, in

[59] Kyle, Robert A., and S.Vincent Rajkumar. *Therapeutic Application of Thalidomide in Multiple Myeloma*. Seminars in Oncology 28, no. 6 (December 1, 2001): 583–87. doi:10.1016/S0093-7754(01)90028-4, summary available at https://journals.scholarsportal.info/details/00937754/v28i0006/583_taotimm.xml (last accessed September 4, 2023).

combination with dexamethasone. The '262 did not claim anything beyond what was already known in the prior art.

162. The unexpected results Celgene relied upon did not overcome a finding of obviousness or otherwise support a finding of patentability. For one, and as noted by the PTO, certain studies did not say what Celgene claimed. More fundamentally, the information at issue (*e.g.,* use of pomalidomide to treat relapsed or refractory multiple myeloma, combining thalidomide analogs with dexamethasone to treat multiple myeloma) was already known. *See e.g.,* Davies (2001), Lentzsch (2001), Lentzsch (2002), Schey (April 2002), Schey (October 2002), Kyle (2001), Coleman (2002).

163. In short, the '262 (and Celgene's other Pomalyst method of treatment patents) were invalid from their inception, as well as unenforceable due to Celgene's fraud on the PTO.

164. On April 10, 2012, Celgene submitted a new drug application (NDA) to the FDA for approval to market Pomalyst (pomalidomide) capsules.

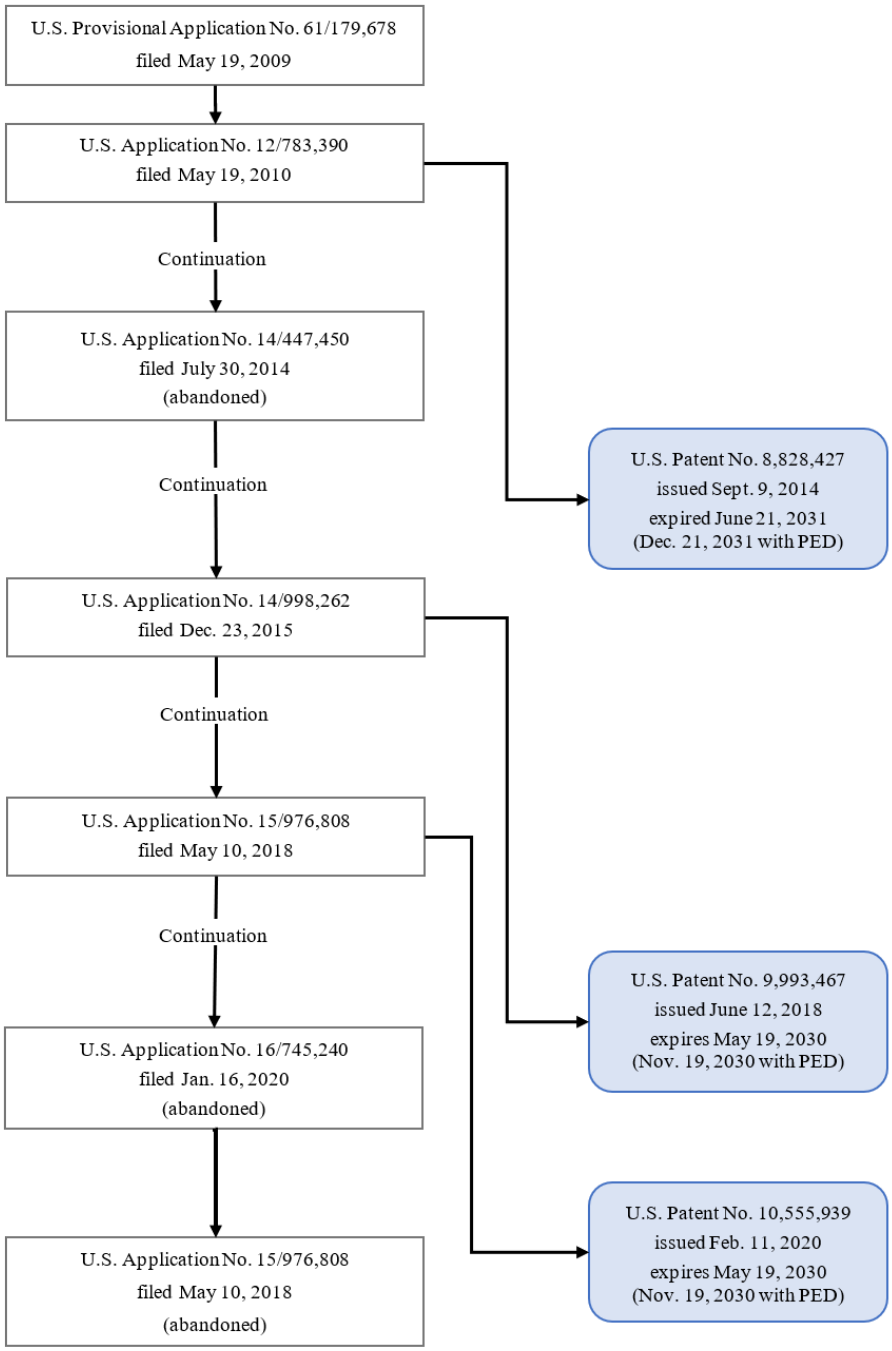
165. On February 8, 2013, the FDA approved Celgene's NDA for pomalidomide 1 mg, 2 mg, 3 mg and 4 mg capsules, under the brand name Pomalyst, in the treatment of patients with multiple myeloma who had received prior lenalidomide therapies and demonstrated disease progression. The recommended dosage was 4 mg daily on days 1-21 of a repeated 28-day cycle and could be taken with dexamethasone.

166. Following FDA approval, Celgene was granted a period of regulatory exclusivity. For new chemical entities, such as Pomalyst, the brand is granted a five-year exclusivity period. However, by filing the paragraph IV patent infringement litigation, Celgene effectively extended the period of exclusivity from five years to seven and a half years, *i.e.* to approximately August 8, 2020. *See* 21 CFR 314.107(b)(3)(i) (where brand manufacturer files patent infringement litigation within the

specified time period, 30-month stay will be extended until 7.5 years after the NDA approval date). During this time, the FDA was barred from granting final approval to any Pomalyst ANDA.

D. In 2009, Celgene also began seeking a series of formulation patents for Pomalyst by falsely claiming "unexpected results."

167. Beginning in 2009 (and continuing for over a decade), Celgene also sought a series of formulation patents for pomalidomide, falsely claiming its formulation showed "unexpected results" that were "surprising." Below is the Pomalyst formulation patent family:



1. The prior art had already disclosed pomalidomide formulations as well as the need to address pomalidomide's instability issues.

168. Prior to Celgene's formulation patent applications, it was well known and well documented in the scientific community that thalidomide compounds are notoriously unstable due to hydrolysis (*i.e.,* degradation of the compound in the presence of water). *See e.g.* H. Schumacher, R.

L. Smith, and R.T. Williams, *The Metabolism of Thalidomide: The Spontaneous Hydrolysis of Thalidomide in Solutions,* Brit. J. Pharmacol. (1965), 25, 324-337 ("in this paper we describe the conditions for the spontaneous hydrolysis of thalidomide in aqueous solution at various *p*H values.")[60]

169. There are also numerous sources, including Remington's Pharmaceutical Sciences, a pharmaceutical textbook first published more than 100 years ago, that teach methods of preparing oral dosage forms. As relevant here, the 17th edition of Remington's (published in 1985) teaches: the range of capsule sizes that can be swallowed and the capacity of each capsule size to hold a specified amount of powdered drug material; the use of excipients, such as mannitol; the advantages of spray drying mannitol; and the amount of filler or binder typically used.[61] In addition, sodium stearyl fumarate has been known since at least the 1990s to be an acceptable lubricant. *See e.g.,* the 5,593,696 patent ("McNally").

170. Additionally, Schey (April 2002) taught pomalidomide at specific dosing amounts, up to a maximum tolerated dosing amount of 5 mg per day.

171. On December 21, 2006, Celgene[62] filed patent application no. 11/645,319 claiming pomalidomide in combination with an acceptable carrier or excipient. The '319 patent application disclosed that pregelatinized starch and mannitol are acceptable excipients for use in combination with pomalidomide. The '319 patent application was rejected four times, including for obviousness and double patenting, and subsequently abandoned.

172. On May 19, 2009, Celgene filed provisional patent application no. 61/179,678. All of the formulation patents here at issue (the 8,828,427, 9,993,467, and 10,555,939) are related to this

[60] Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1510736/pdf/bripharmchem00017-0044.pdf (last accessed September 4, 2023).

[61] The specific edition cited by the PTO is the 17th edition of Remington's Pharmaceutical Sciences (published in 1985) ("Remington's").

[62] Jerome Zeldis, a Celgene executive, is the first named inventor and Celgene is the assignee.

provisional patent and therefore have a priority date of May 19, 2009. As of this date, the '319 patent application, Remington's, and McNally had been disclosed in the prior art, and it was well known that thalidomide and its analogs faced stability issues due to hydrolysis.

2. Celgene defrauded the patent office to obtain the '427 formulation patent.

173. On May 19, 2010, Celgene filed patent application no. 12/783,390, which would lead to the '427 patent, the first of the Pomalyst formulation patents here at issue. The proposed patent claimed an oral dosage form of a given weight (*e.g.*, weighing "about 62.5mg") comprised of pomalidomide and a pharmaceutically acceptable carrier or excipient, such as mannitol, pregelatinized starch, and sodium stearyl fumarate.

174. On April 24, 2012, the PTO rejected the patent application as obvious in light of the prior art, stating: "It would have been *prima facie* obvious to a person of ordinary skill in the art at the time of the invention to have made oral dosage forms comprising pomalidomide and excipients such as mannitol and pre-gelatinized starch, with a reasonable expectation of success because Zeldis et al. taught such oral dosage forms." The PTO also pointed to Remington's as teaching capsule sizes and the benefits of spray drying common diluents like mannitol and to McNally as showing sodium stearyl fumarate is a known lubricant in the art.

175. The PTO also noted that, as Celgene defined and used the term "about," the claimed amounts of pomalidomide and excipients would be ranges: "The claims contain the term 'about' in front of quantities of active agents and excipients. Based on the specification the term 'about' is defined as a dose, amount, or weight percent within 30%, 25%, 20%, 15%, 10%, or 5% of the specified dose, amount, or weight percent. . . . Therefore, the claimed amounts of active and excipients are viewed as ranges." In other words, Celgene sought to define the scope of the claims very broadly.

176. On August 16, 2012, Celgene submitted a response arguing, "although Zeldis may generally disclose a laundry list of compositions [sic] containing pomalidomide in combination with a broad range of possible excipients that may be used in such compositions, there is no disclosure in Zeldis that would have prompted one skilled in the art to prepare a composition having pomalidomide at the specified amounts, along with the particular binders and fillers" as claimed. Celgene omitted to disclose that the prior art, including Schey (April 2002), disclosed pomalidomide dosage amounts up to a maximum tolerated dosage of 5 mg per day. Celgene dismissed Remington and McNally on the basis that they did not teach the advantages of the specific oral dosage forms claimed.

177. On November 15, 2012, (and despite Celgene's misrepresentations and omissions), the PTO again rejected the patent application on the basis that the claimed invention was obvious over Zeldis in view of Remington's and McNally's. The PTO also rejected the claims for failure to comply with the written description requirement, stating that Celgene failed to "convey to one skilled in the relevant art that the inventor . . . at the time the application was filed, had possession of the claimed invention," and for indefiniteness.

178. The PTO was also not persuaded by Celgene's claims regarding "unexpected results" in part because the submission "lack[s] data that shows alleged unexpected results." The PTO continued, "In the instant case the applicant did not show that the results were unexpected, unobvious, and of both statistical and practical significance. Applicant instead provided a conclusion that advantageous and unexpected properties were observed without showing any evidence that supports those conclusions . . . this is not sufficient to overcome obviousness."

179. On June 17, 2013, to overcome the examiner's repeated rejections of the patent application, Celgene submitted a declaration signed by Celgene's Executive Director, Global Pharmaceutical Technology & Development, Anthony Tutino (the "Tutino Declaration") presenting

data in support of Celgene's assertion of patentability based on "unexpected results." The Tutino Declaration does not specify when the reported testing was conducted, vaguely stating that "tests have been conducted between pomalidomide and various candidate excipients." Based on these undated tests, which appear to be a post-hoc exercise to support a claim of patentability, Mr. Tutino asserts that the claimed invention is patentable because it was "unexpected" that many of the other pomalidomide/excipient combinations he tested posed stability issues over time. The assertion is unfounded.

180. Thalidomide is notoriously unstable due to hydrolysis (*i.e.,* degradation of the compound in the presence of water), a fact that has been well known and well documented in the scientific community for decades. Mr. Tutino feigns ignorance of these known stability issues and, when he encounters hydrolysis (which he addresses through standard, routine optimization), proclaims this was "unexpected." There would have been nothing surprising or "unexpected" about these stability issues given the known tendency of thalidomide compounds to degrade in the presence of water. Dr. Tutino misled and deceived the PTO when he suggested otherwise.

181. The Tutino Declaration also failed to address (or even acknowledge) any of the prior art references cited in the PTO's rejection of the patent application, except Zeldis. Instead, Dr. Tutino approached the selection of excipients as though Zeldis is the only prior art reference, and in that very constrained (and erroneous) framework, claimed that he encountered unexpected results. This ignores not only the specific prior art references that were the subject of the patent prosecution (and the PTO's statements that one would have been motivated to combine the relevant prior art references), but also the broader context of these compounds: thalidomide and its analogues have been the subject of intense study in the scientific community for more than 50 years. Dr. Tutino's claim of unexpected results omitted this important context.

182. Following Celgene's submission of the misleading Tutino Declaration, the PTO allowed the '427 formulation patent to issue.

183. The '427 would not have issued but for Dr. Tutino's false representations and deliberate omissions regarding the prior art and the purportedly unexpected results. This was material information on which the PTO justifiably relied; although the PTO had repeatedly rejected the patent as obvious, following the submission of the Tutino Declaration, the patent was allowed to issue.

184. Although the PTO allowed the '427 patent to issue, it allowed only a narrow set of claims, which were easy to design around to avoid infringement. The claims are to a capsule comprising pomalidomide, pregelatinized starch, sodium stearyl fumarate, and spray-dried mannitol, where the capsule is one of six specific weights, *i.e.,* "[a]n oral dosage form in the form of a capsule which weighs [x] mg. . . ." where "[x]" is either 62.5, 125, 250, 180, 240, or 300. A generic manufacturer would readily be able to design around this patent by, *inter alia*, developing a capsule with a weight other than one of the six weights claimed by the patent.

E. Celgene defrauds the patent office to obtain two more method of treatment patents (the '428 and '3939).

185. On March 1, 2013, Celgene filed two patent applications seeking to extend or broaden method-of-use patent protection for pomalidomide. The applications (nos. 13/782,612 and 13/782,728) continued in the '262 family and claimed priority back to the November 2002 provisional application. The applications would lead to the '428 and the '3939 method of treatment patents, respectively.

186. Patent application no. 13/782,612 (leading to the '428) claimed *inter alia* a method of treating multiple myeloma with pomalidomide for 21 days followed by 7 consecutive days of rest, where the multiple myeloma is relapsed and/or refractory and there is demonstrated disease progression after certain specified treatments. Although the proposed claims included a dependent

claim for the administration of pomalidomide in combination with dexamethasone, the independent claim did not specify treatment in combination with dexamethasone.

187. The independent claims of the '3939 patent are the same as the '428, except the '3939 states that the compound is to be administered in "one or more cycles, each of which comprises administering the compound for a period of time followed by a period of rest," rather than specifying the exact cyclical schedule (*i.e.,* 21 days followed by 7 consecutive days of rest). The two patents were prosecuted in parallel, with essentially the same submissions, meetings, and evidence; the following discussion summarizes the prosecution history for the '428, which is substantially similar for the '3939.

188. On June 11, 2013, the PTO conducted an interview with Celgene regarding its method of treatment patent application. On July 9, 2013, the PTO rejected the claims on the basis of double patenting over the '262.[63] The PTO also rejected the claims because "the claimed invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made." The prior art references cited by the PTO included Kyle (2001), Davies (2001), Corral (1999), Muller (1999), and the '554. Regarding the claims "wherein the previous therapy is, *inter alia,* thalidomide, lenalidomide or a proteasome inhibitor," the PTO stated in part, "one of ordinary skill in the art would have understood that [pomalidomide] would provide benefits in treating [multiple myeloma ("MM")] whether the patient had previous therapy with thalidomide, lenalidomide, proteasome inhibitor, etc. The skilled artisan would have at least found it obvious to try in these patients as well as others with MM."

189. On October 4, 2013, the PTO conducted an interview with Celgene. According to the interview summary,[64] in order to overcome the examiner's rejection of the patent, the "Applicant

[63] The '262 patent is erroneously referred to here as 8,198,232. The error is subsequently noted and corrected.

[64] The interview summary is dated October 13, 2013.

submitted that its claims, as is, are patentable because pomalidomide (POM) alone was shown to unexpectedly treat multiple myeloma that is or has become resistant to lenalidomide (LEN). . . . Applicant submitted that one of ordinary skill in the art would not have recognized this because, inter alia, the compoinds [sic] are so close in structure." The PTO suggested that Celgene submit the argument and supporting data as a declaration.

190. On October 8 and 9, 2013, to address the PTO's double patenting objection, Celgene filed the following terminal disclaimers:

Patent application	**Resulting patent**	**Terminal disclaimer as to:**
13/782,612	'428	(a) the '262
13/782,728	'3939	(a) the '262 and (b) any patent resulting from patent application no. 13/782,612

191. On October 9, 2013, to address the PTO's request for a sworn statement of Celgene's assertions made during the examiner interview, Celgene submitted the declaration of Dr. Anjan Thakurta, Senior Director in Translational Development at Celgene (the "Thakurta Declaration") along with an Amendment and Request for Reconsideration. Dr. Thakurta is not a clinician and, at the time he produced this opinion, had no experience working on clinical trials. Nor was Dr. Thakurta a registered physician involved in treating patients. Dr. Thakurta does not appear to be a person qualified to offer an opinion (a "person of ordinary skill in the art" or "POSA") on the matters set forth in his declaration. In addition, the Thakurta Declaration makes fraudulent misrepresentations and omissions of material facts regarding "unexpected results," and does not support a finding of patentability.

192. Dr. Thakurta's claims regarding unexpected results proceed from two premises. First, he states that three studies, Jagannath (2013)[65], Siegel (2013)[66], and Richardson (2011)[67], show that patients with relapsed or refractory multiple myeloma previously treated with lenalidomide had a clinically significant response rate when treated with pomalidomide. Second, Dr. Thakurta states (without citation or reference to any timeframe) that it "has been surprisingly found that resistance of multiple myeloma cells to pomalidomide and lenalidomide is not reciprocal," *i.e.,* if a patient is first treated with pomalidomide and develops a resistance to it, lenalidomide will not work. From these two premises, Dr. Thakurta concludes: "It is therefore my opinion that the results of the studies for treating relapsed and/or refractory multiple myeloma with single-agent pomalidomide would have been unexpected and surprising at the time the claimed invention was made." The Thakurta Declaration suffers from misrepresentations of fact and defects of logic.

193. Dr. Thakurta deceptively omits that, at the time of the claimed invention, the use of thalidomide analogues for the treatment of relapsed/refractory disease and the ability of thalidomide analogues, including pomalidomide, to overcome drug resistance of multiple myeloma cells was well known in the prior art. *See e.g.,* Hideshima (2000),Webber (2000), Dimopoulous (2001), (Davies (2001), Schey (April 2002), and Schey (October 2002). It was also known that pomalidomide was many times more potent than other thalidomide analogs, including lenalidomide. Celgene had already, as part of the 1998-1999 reexamination of the '517, touted the ostensible 10,000 fold

[65] Sundar Jagannath, Craig C. Hofmeister, Rachid C. Baz, David Samuel DiCapua Siegel, Ravi Vij, Christine Chen, Sagar Lonial, Kenneth Carl Anderson, Min Chen, Mohamed H. Zaki, and Paul Gerard Guy Richardson, *Pomalidomide (POM) with or without low-dose dexamethasone (LoDEX) in patients (Pts) with relapsed and refractory multiple myeloma (RRMM): MM-002 phase II age subgroup analysis,* Journal of Clinical Oncology 2013 31:15 (suppl. Abstr. 8532), available at https://ascopubs.org/doi/abs/10.1200/jco.2013.31.15_suppl.8532 (last accessed September 4, 2023).

[66] Siegel, D. et al, *Long-term safety and efficacy of pomalidomide (POM) with or without low-dose dexamethasone (LoDEX) in relapsed and refractory multiple myeloma (RRMM) patients enrolled in the MM-002 phase II trial*, J Clin Oncol 31, 2013 (suppl; abstr 8588), available at https://ascopubs.org/doi/abs/10.1200/jco.2013.31.15_suppl.8588 (last accessed September 4, 2023).

[67] Richardson et al. (Haematologica 2011; 96 (Suppl. 1):O-12), available at https://haematologica.org/article/download/5980/29772 (last accessed September 4, 2023).

increase in activity represented by pomalidomide. It was false to assert that pomalidomide's efficacy was surprising. There would have been nothing surprising about the fact that, once a patient's myeloma had become resistant to one thalidomide analog, the patient would be moved to a more potent thalidomide analog. Nor would it have been surprising that, if a patient's myeloma became resistant to the analog with greater potency, a less potent analog would not be effective. Dr. Thakurta's assertions to the contrary were false and intended to defraud the examiner into allowing the patent.

194. Dr. Thakurta made these deceptive representations and omissions with the intent to deceive the PTO. The PTO justifiably relied on the information provided by Dr. Thakurta, as evidenced by the PTO's reversal of its prior decisions rejecting the patents, allowing the patents to issue after Dr. Thakurta submitted his declaration.

195. In addition to Dr. Thakurta's fraudulent declaration, during the '428 and '3939 patent prosecutions, Celgene reiterated many of the same fraudulent misrepresentations and omissions it made to obtain the earlier method of treatment patent, the '262. For example, Celgene (again) repeated and perpetuated the examiner's mistaken belief that Davies (2001) did not teach pomalidomide, when in fact it taught pomalidomide to treat multiple myeloma and relapsed/refractory disease. Celgene also failed to disclose the truth about the '517 and D'Amato (2001).

196. Through its deception, Celgene achieved its goal. On March 18, 2014, and May 27, 2014, respectively, the PTO issued the '3939 and '428 patents, further extending Celgene's unlawful Pomalyst monopoly. Absent its deceptive representations and deliberate omissions, neither the '428 nor the '3939 would have issued. Both patents are unenforceable due to Celgene's fraudulent conduct and invalid as obvious over the prior art.

F. Celgene procures a second Pomalyst formulation patent (the '467) by fraud.

197. On December 23, 2015, Celgene filed patent application 14/998,262, which would lead to the '467 formulation patent.

198. As originally styled, the application sought to expand the scope of the previous formulation claims (which required formulations in absolute weight terms) by now claiming formulations in terms of the relative weight of pomalidomide to the combined binders and fillers.

199. Over the next two and a half years, the PTO repeatedly, and correctly, rejected the claims in the application as obvious.

200. On February 7, 2017, the PTO rejected the claims for a third time, stating in part:

> Applicant's arguments directed to picking and choosing and impermissible hindsight are not persuasive because **Zeldis teaches a limited list of fillers** [] (talc, calcium carbonate, microcrystalline cellulose, cellulose, dextrates, kaolin, mannitol, silicic acid, sorbitol, starch, pregelatinzed starch, and mixtures thereof), **a limited list of disintegrants** [] (agar-agar, alginic acid, calcium carbonate, microcrystalline cellulose, croscarmellose sodium, crospovidone, polacrilin potassium, sodium starch glycolate, potato starch, tapioca starch, starches, pre-gelatinized starch, clays, algins, celluloses, gums, and mixtures thereof), and **a limited list of lubricants** []. It would have been obvious to have formed a solid dosage form comprising pamolidomide [sic] in any combination of filler(s), binder(s), and lubricant(s) as described by Zeldis. Zeldis teaches ranges of concentrations of the components and it would have been obvious to have varied the amounts of components within the taught ranges. A person of ordinary skill in the art would have arrived at the claimed invention through **routine experimentation** and it would have been **obvious** to have formed a solid dosage form from any possible combination of excipients disclosed by Zeldis.

201. Meanwhile, would be generic makers had been developing their products. On February 8, 2017—the first date on which ANDA applicants could file an application for generic pomalidomide—at least seven generic manufacturers (Teva, Natco/Breckenridge, Apotex, Hetero, Par, Aurobindo, and Mylan) filed ANDAs to market generic Pomalyst.

202. In the following months, some ANDA applicants provided information to Celgene about their ANDA products, including how some ANDA applicants had formulated their versions of generic pomalidomide.

203. By September of 2017, Celgene had a plan as to how to modify the pending formulation claims to increase the scope of the previously approved formulation claims (and thereby increase the potential for infringement by would-be competitors) while at the same time potentially persuade the PTO to issue a patent.

204. On September 21, 2017, an interview was conducted between the PTO and Celgene's representatives, during which Celgene represented that it could supply a declaration showing unexpected stability results.

205. On October 20, 2017, Celgene amended the claims to add a requirement that the starch to mannitol ratio be from 1:1 to 1:1.5. And on February 22, 2018, Celgene submitted yet another response and a new declaration by Dr. Tutino.

206. The February 2018 Tutino declaration was false and misleading. First, the declaration presents undated stability test results of six formulations of pomalidomide (0.5 mg, 1.0 mg, 2.0 mg, 3.0 mg, 4.0 mg and 5.0 mg) and falsely states the stability results are surprising and unexpected. It was well known and well documented in the prior art that thalidomide and its analogs such as pomalidomide posed stability issues, which a person skilled in the art would have been aware of in conducting the type of routine experimentation that led to the claimed invention. And the techniques to achieve stable formulations of such compounds were also well known. Second, the formulations presented used only two close ratios of starch to mannitol (i.e., 1:1.30402385 and 1:1.33069307) and did not support the range claimed by Celgene (i.e., 1:1.0 to 1:1.5).

207. On March 15, 2018, the PTO allowed the '467 formulation patent to issue, subject to a terminal disclaimed as to the '427 patent.

208. The '467 patent would not have issued absent the deceptive declarations submitted by Dr. Tutino during the patent prosecution. The second Tutino Declaration repeats the same fraudulent representations as the first Tutino Declaration regarding "unexpectedly" encountering

and addressing stability issues, which Dr. Tutino supplements in his second declaration with undated testing data. There would have been nothing surprising about the well-known fact that thalidomide analogs are unstable due to hydrolysis, an issue that would be addressed through standard, routine optimization. Dr. Tutino misled and deceived the PTO when he suggested otherwise. The PTO justifiably relied on the deceptive Tutino declarations, allowing the patents to issue based on the submission of the Tutino declarations after repeated prior rejections of the claims.

209. In addition to being unenforceable, the '467 is invalid for obviousness and, in any event, is very limited in scope. During the patent prosecution (during which Celgene saw its claims rejected four separate times), Celgene was forced to narrow the claims substantially. As issued, the '467 has one independent claim, which claims:

> An oral dosage form in the form of a capsule which comprises: 1) pomalidomide at an amount of 0.1 to 3 weight percent of the total weight of the composition; 2) a binder or filler at an amount of 90 to 99 weight percent of total weight of the composition, wherein the binder or filler is a mixture of starch and mannitol; and wherein the ratio of mannitol: starch in the dosage form is from about 1:1 to about 1:1.5 . . . ."

210. Thus, even if the patent were valid, it is highly unlikely Celgene would be able to prove infringement. The '467 does not claim any kind of complexity, such as bioequivalence metrics, that would require a generic manufacturer to do extensive testing to ascertain whether its formulation would infringe. Instead, the patents are more akin to a recipe, identifying a finite list of ingredients (primarily pomalidomide, starch, mannitol, and sodium stearyl fumarate) combined in certain specified amounts or ratios. A generic manufacturer would be able to design around these patents to produce a non-infringing product, for example, by adjusting the ratios or by using different binders/fillers, while still maintaining the desirable features, such as stability and bioavailability.

G. In February 2017, numerous generic manufacturers filed generic Pomalyst ANDAs, leading to the first wave of patent infringement lawsuits by Celgene.

211. On February 8, 2017, at least seven generic manufacturers (Teva, Natco/Breckenridge, Apotex, Hetero, Par, Aurobindo, and Mylan) filed ANDAs to market generic Pomalyst.[68] At least nine ANDAs have been filed to date[69], listed here.

Generic	ANDA No.
Teva	209956
Natco/Breckenridge	210111
Apotex	210164
Synthon/Alvogen	210232
Hetero	210236
Par	210245
Aurobindo/Eugia	210249
Mylan	210275
Dr. Reddy's	213234

212. In late March/early April 2017, Celgene received seven paragraph IV letters from the ANDA filers certifying that Celgene's Pomalyst patents were either invalid and/or would not be infringed by the manufacturer's ANDA product.

213. On May 4, 2017, Celgene filed its first Pomalyst patent infringement lawsuit. The suit, against Par and Teva, alleged infringement of four patents. On May 11, 2017, Celgene sued Hetero, Aurobindo/Eugia, Apotex, Mylan, and Natco/Breckenridge, for infringement of the same four patents:

8,198,262	Method of treatment[70]
8,673,939	Method of treatment
8,735,428	Method of treatment

[68] The final approval letters for Natco/Breckenridge and Aurobindo state that the filing dates for these ANDA is February 8, 2017. The final approval letter for Mylan is not publicly available. The plaintiffs have inferred that the Mylan ANDA, as well as the Teva, Apotex, Hetero, and Par ANDAs were also filed on February 8, 2017, based in part of the dates the paragraph IV letters were sent (as disclosed in Celgene's complaints against these entities).

[69] In 2018 and 2019, Synthon/Alvogen and DRL, respectively, filed ANDAs.

[70] Method of treatment patents typically take the form of "a method of treating condition A, comprising administering a therapeutically effective amount of drug B."

8,828,427	Formulation[71]

214. All four of the asserted patents were unenforceable due to Celgene's fraud on the patent office, invalid as obvious over the prior art, and, in the case of at least the '427, subject to strong non-infringement arguments. However, by simply filing these patent lawsuits, Celgene triggered an automatic 30-month stay, which was extended to August 8, 2020 (*i.e.,* 7.5 years after NDA approval) due to the NCE exclusivity. During this time, the FDA was barred from granting final approval to any ANDA.

1. Celgene's lawsuits alleging infringement of the Pomalyst method of treatment patents (the '262, '428, '3939) and the only then-existing formulation patent (the '427) were a sham.

215. Celgene's infringement lawsuit was objectively and subjectively baseless. A reasonable pharmaceutical company in Celgene's position could not realistically expect to succeed on the merits of its lawsuits alleging infringement of the method of treatment patents and the '427 formulation patent.

216. All four patents were obtained through fraud on the patent office and were therefore unenforceable. Because Celgene's fraudulent and deceptive conduct would have been revealed during the patent litigation, Celgene could not have expected that it would prevail in the patent infringement litigation.

217. There was no objective basis for asserting that the method of treatment patents were valid and infringed for the additional reason that the patents were clearly obvious over the prior art, which taught: a method of using pomalidomide to reduce TFNα and that reduction of TNFα is an effective cancer treatment (the '517); the use of pomalidomide specifically to treat multiple myeloma

[71] Formulation patents seek to cover the unique combination of the active pharmaceutical ingredient (here, pomalidomide) with the excipients that comprise the particular dosage form to be given to the patient.

and/or relapsed/refractory multiple myeloma (D'Amato (2001), Davies (2001), Lentzsch (2001), Lentzsch (2002), Schey (April 2002), and Schey (October 2002)); the maximum tolerated daily dosage of pomalidomide (Schey (April 2002)); the clinical efficacy of dexamethasone with thalidomide to treat resistant multiple myeloma (Weber (2000)); the specific amount of dexamethasone claimed (40 mg) combined with thalidomide to treat multiple myeloma (Coleman (2002)); the cyclical treatment of multiple myeloma (Kyle (2001)); the specific 28-day dosing cycle, *i.e.,* 21 days administration of an anticancer drug followed by 7 days of rest, in combination with dexamethasone (Cohen (1982)); thalidomide and its analogues ability to overcome drug resistance of multiple myeloma cells (Hideshima (2000)); and pomalidomide is a more potent agent with decreased potential for birth defects (Corral (1999)).

218. The '427 formulation patent was similarly invalid as obvious over the prior disclosures, claiming an invention that was not, in fact, novel, but the result of routine optimization.

219. Even if the formulation patents were somehow valid, a brand company in Celgene's position could not reasonably expect to prove that the '427 was infringed. The '427 is a simple patent claiming a finite combination of ingredients and weights. Generic companies routinely design around formulation patents like the '427 to avoid infringement. Celgene had so little confidence in the '427 patent, it would end up withdrawing its infringement claims as to this patent before most, if not all, of the settlements occurred.[72]

220. If litigated to a decision on the merits, these patents (the ''262, '428, '3939, and '427) would be adjudged unenforceable, invalid, and/or not infringed for the reasons given above. Celgene pursued the litigation, not because it had an expectation of achieving a favorable outcome, but rather to use the litigation process itself to impede generic entry. By simply filing the lawsuit,

[72] *See Celgene v. Hetero,* 17-3387 (D.N.J.), Special Discovery Master Order No. 14 dated Dec. 31, 2020 (ECF 821) at fn. 1 ("Celgene is not asserting the '427 patent against defendants.")

Celgene obtained a 30 month delay during which the FDA could not grant final approval to any generic Pomalyst product.

H. Throughout 2017, the generic manufacturers aggressively defended against Celgene's claims of infringement, with some generics filing counterclaims against Celgene.

221. After Celgene instituted the patent infringement litigation, the generic manufacturers filed answers stating that the asserted patents either would not be infringed by the generic's ANDA product or were invalid. Several of the generic manufacturer defendants also asserted counterclaims against Celgene. Celgene filed answers as to these counterclaims and in some instances filed counter-counterclaims, which precipitated another round of answers. The filing of these pleadings occupied much of 2017 and early 2018. One generic manufacturer, Mylan, took a different tact. On August 8, 2017, Mylan filed a motion to dismiss for, *inter alia,* improper venue. The court did not initially grant the motion and instead allowed the parties to engage in venue related discovery.

222. During this time, Celgene was continuing to work on all fronts to extend its monopoly. On July 17, 2017, the PTO granted a final determination of a patent extension for the '262 patent, moving the original expiry date from October 19, 2024 to June 17, 2025.

223. As of the end of 2017, Celgene was litigating infringement claims as to four patents (the three method of treatment patents and one formulation patent) and it was in the process of prosecuting the patent application that would eventually lead to the '467 formulation patent.

224. On December 17, 2017, the world-be generic companies filed a nearly two-hundred-page statement of invalidity contentions regarding the '262, '3939, '428, and '427 patents. Aware of the weaknesses of these patents, Celgene sought to bolster its generic blockade by acquiring even more patents.

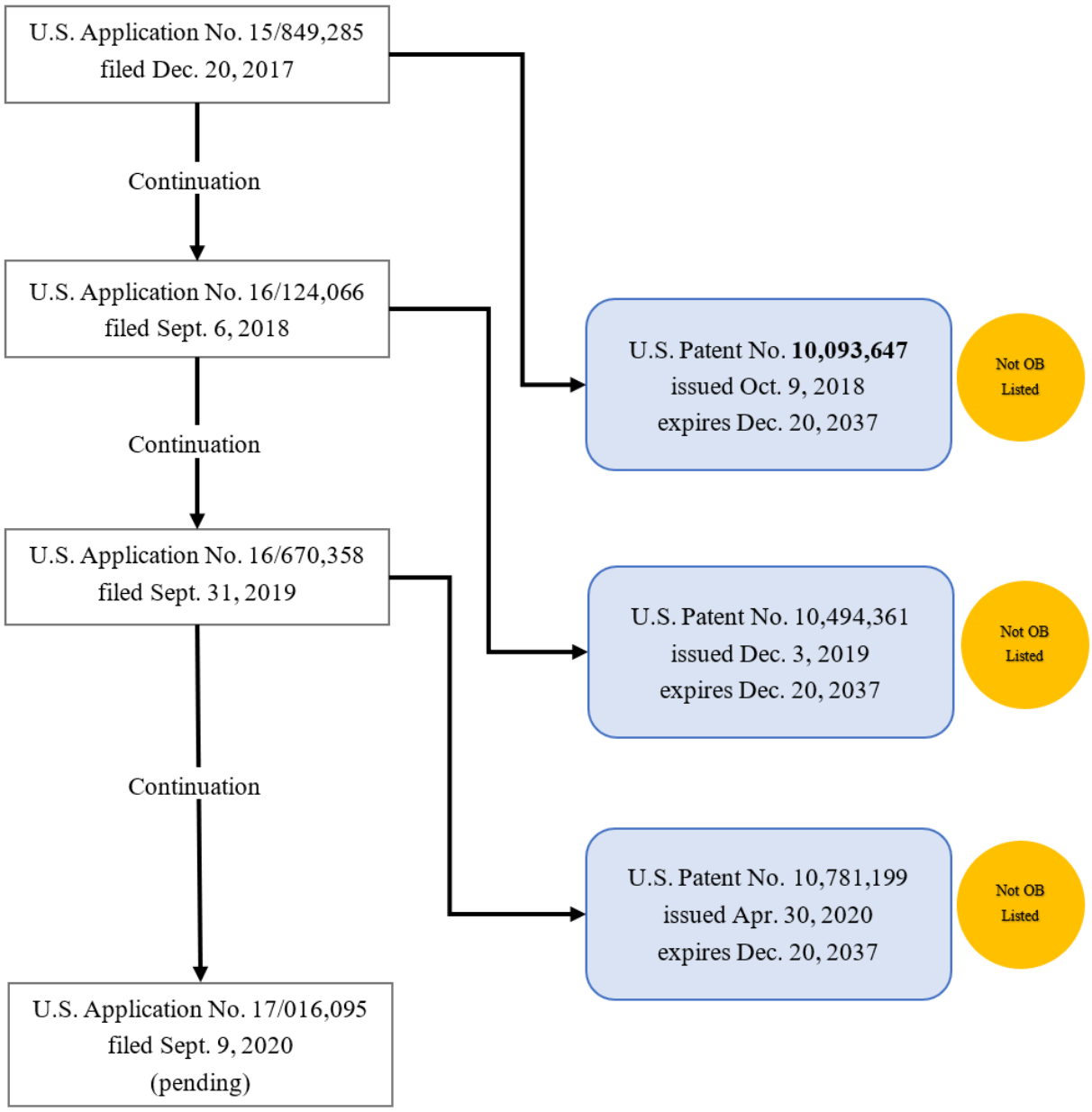
I. In late 2017, approximately nine months after receiving the paragraph IV letters, Celgene sought three new patents claiming polymorphic forms (the '647, '648, and '649).

225. On December 20, 2017, Celgene[73] filed three new patent applications claiming polymorphs[74], which would ultimately lead to the '647, '648, and '649. Each of these patents derives from a separate patent application:

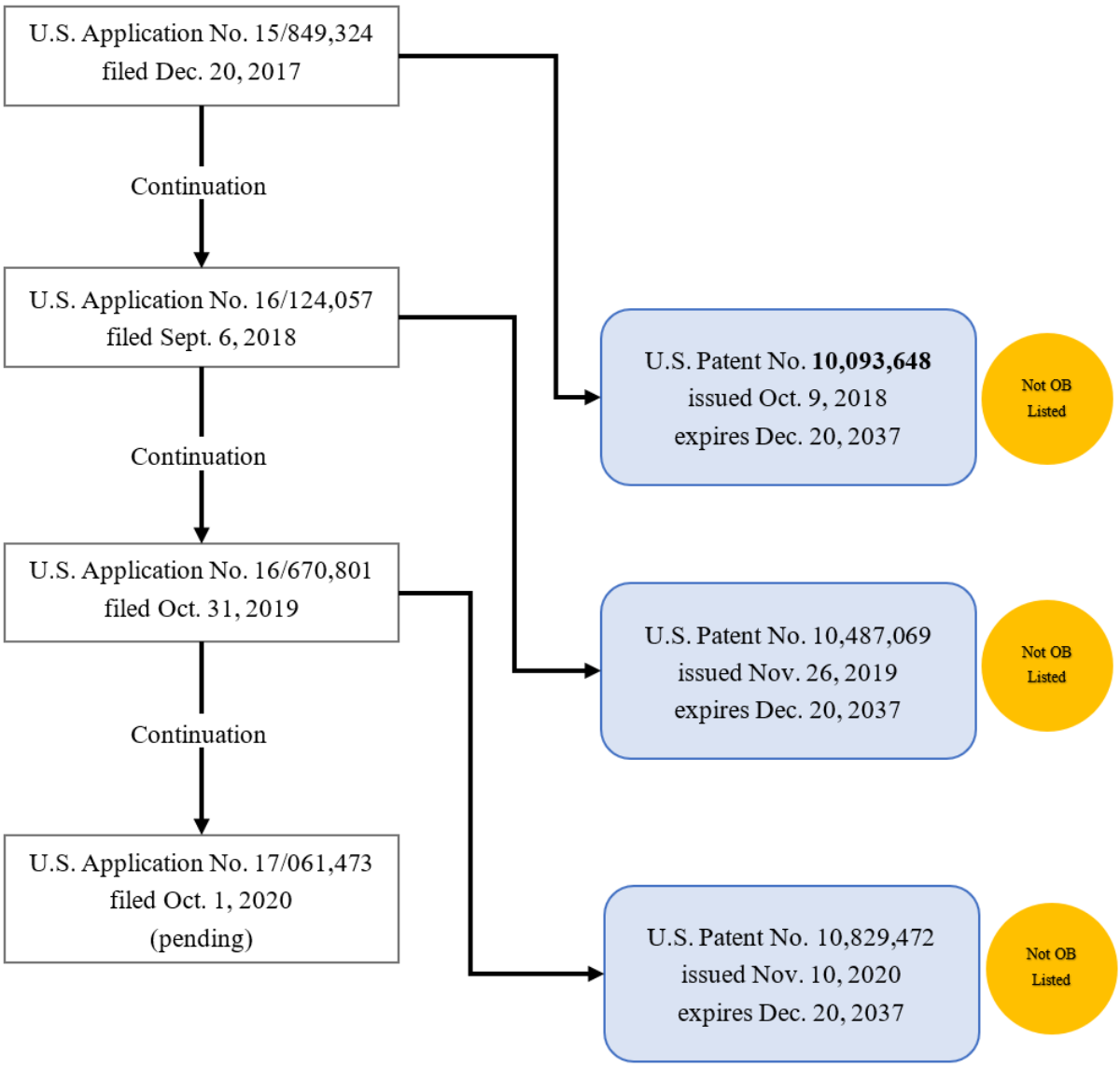
[73] The named inventor is Jerry Atwood, who subsequently assigned the patents to Celgene. To avoid confusion, the applicant for the polymorph patents is referred to here simply as "Celgene."

[74] Polymorphism refers to the ability of a chemical compound to crystallize into different three-dimensional crystal structures.

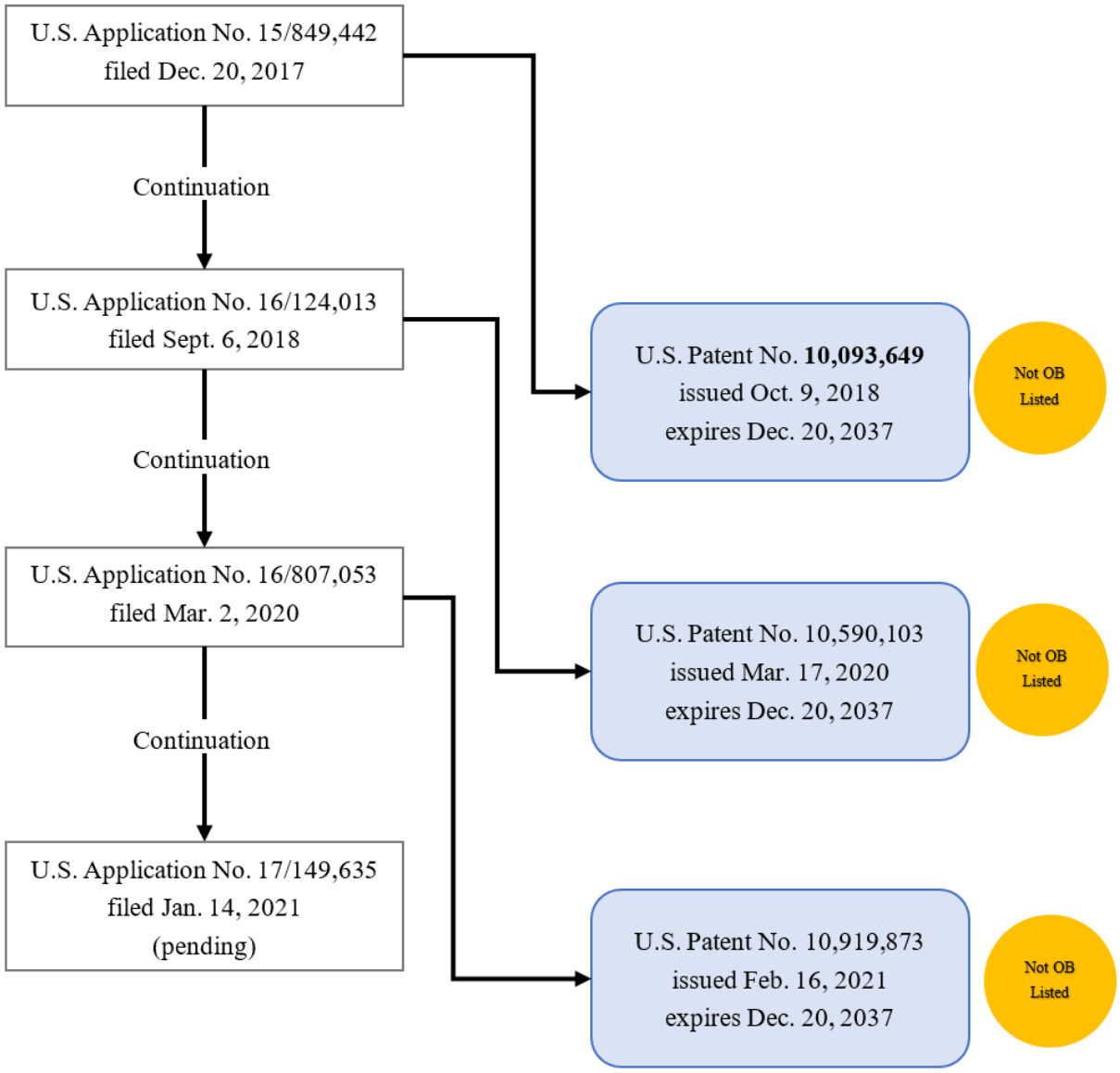
'285 PATENT APPLICATION TREE



'324 PATENT APPLICATION TREE



'442 PATENT APPLICATION TREE



226. The priority date for each of these patents post-dates the majority of the first filers' Paragraph IV letters, which were transmitted in March and April 2017:

Patent	Application Date	Priority Date
'647	12/20/2017	5/26/2017
'648	12/20/2017	9/22/2017
'649	12/20/2017	9/22/2017

227. Each of Celgene's polymorph patents has a single independent claim, claiming a crystalline form identified by an x-ray powder diffraction pattern ("XRPD") with specific peaks. An XRPD is like a thumbprint for crystalline forms. For example, the '647 claims "Crystalline 4-amino-2-(2,6-dioxopiperidine-3-yl)isoindoline-1,3-dione dihydrate, having an X-ray powder diffraction pattern comprising peaks at 13.9, 16.6, and 25.5 degrees 2θ±0.2 degrees 2θ." The identification of those peaks helps to identify the specific polymorphic form at issue. The Pomalyst polymorph patents are further limited to three specific hydrate forms of pomalidomide: dihydrate ('647); hemihydrate ('648); and monohydrate ('649).

228. Celgene applied for these three patents approximately nine months *after* receiving seven paragraph IV letters, which described the generic Pomalyst ANDA products in detail. It defies logic that these patents could be both infringed by an earlier-in-time ANDA product and simultaneously novel over the prior art. Celgene applied for these patents to create additional hurdles for generics, rather than for any legitimate purpose.

J. In the Spring of 2018, Celgene pursued a third formulation patent (the '5939) through fraud.

229. Celgene's quest to acquire additional Pomalyst patents to block generic competition continued unabated. On May 10, 2018, Celgene filed application no. 15/976,808. Celgene filed this patent application more than a year after receiving seven paragraph IV letters describing in detail the ANDA products those generic manufacturers sought to bring to market:

Generic manufacturer	Date of paragraph IV letter
Teva	March 30, 2017
Natco/Breckenridge	April 11, 2017
Apotex	March 30, 2017
Hetero	March 29, 2017
Par	April 12, 2017
Aurobindo	April 5, 2017
Mylan	April 6, 2017

Synthon/Alvogen	May 4, 2018
DRL	May 31, 2019

230. Patent application no. 15/976,808 would eventually lead to the 10,555,939. The '5939 is identical to the '467, except that the '5939 claims slightly broader ranges as compared to the '467 in two claims:

Claim no. (type)	**'467**	**'5939**
1 (independent)	1. An oral dosage form in the form of a capsule which comprises: 1) pomalidomide at an amount of 0.1 to 3 weight percent of the total weight of the composition; 2) a binder or filler at an amount of **90** to 99 weight percent of total weight of the composition, wherein the binder or filler is a mixture of starch and mannitol; and wherein the ratio of mannitol: starch in the dosage form is from about 1:1 to about 1:1.5.	1. An oral dosage form in the form of a capsule which comprises: 1) pomolidomide at an amount of 0.1 to 3 weight percent of the total weight of the composition; 2) a binder or filler at an amount of **70** to 99 weight percent of total weight of the composition, wherein the binder or filler is a mixture of mannitol and starch; and wherein the ratio of mannitol:starch in the dosage form is from about 1:1 to about 1:1.5.
3 (dependent)	3. The oral dosage form of claim 1, wherein the binder or filler is present at an amount of **95** to 99 weight percent of total weight of the composition.	3. The oral dosage form of claim 1, wherein the binder or filler is present at an amount of **85** to 99 weight percent of total weight of the composition.

231. During the prosecution of this formulation patent, Celgene again tried to define the scope of the claims broadly, as it did with the prior formulation patent applications. The PTO rejected the patent application four separate times as obvious over the prior art (*i.e.,* Zeldis, Remington's, and McNally) and for double patenting.

232. Celgene again sought to overcome the PTO's obviousness rejections by resubmitting the June 17, 2013 Tutino Declaration and claiming "unexpected results." During the prosecution of the '5939, the PTO specifically stated that the argument regarding "unexpected results" was not

persuasive: "Applicant's arguments related to unexpected results were fully considered but are not persuasive for reasons of record."

233. The PTO ultimately allowed the patent to issue after Celgene filed a terminal disclaimer as to the '427 and '467.

234. The '5939, which was nearly identical to the '467 (differing only as to the ranges in two discrete respects), is invalid as obvious over the prior art and (as with the other formulation patents) was exceedingly easy to design around.

K. In June 2018, the '467 patent (Celgene's second formulation patent) issued, prompting a wave of new of sham litigation by Celgene.

235. On June 12, 2018, the '467 formulation patent issued. Although this patent did not issue until more than a year after the ANDA filings, Celgene nevertheless promptly filed new lawsuits against the generic manufacturers alleging infringement of this newly-issued patent:

Generic Manufacturer	Date sued for infringement of the '467
Teva	September 27, 2018
Breckenridge and Natco	October 5, 2018
Hetero	October 9, 2018
Mylan	November 11, 2018
Apotex	November 21, 2018
Aurobindo	January 4, 2019

236. Although the generics would be forced to defend against Celgene's '467 infringement claims, the filing of those lawsuits could not trigger an automatic 30-month stay as to eight of the ANDAs, as the '467 did not exist at the time those ANDAs were filed. Thus, the filing of these lawsuits could not prevent the FDA from granting final approval. The filing of the '467 infringement litigation therefore could not have prevented an at-risk launch. Nor would the '467 have deterred an at-risk launch under competitive conditions, as the patent was invalid and easily designed around.

237. A reasonable litigant in Celgene's position could not realistically expect to prevail on the merits of its lawsuits alleging infringement of the '467. The patent was obtained through the fraudulent Tutino declarations, which would have been revealed during the patent litigation, as well as invalid over the prior art. Even without these hurdles, Celgene had no hope of proving that any generic's ANDA product, let alone all of the ANDA products, would infringe this very narrow, easy to design around patent. Celgene did not pursue the litigation with any expectation of achieving a favorable outcome. Instead, Celgene's lawsuit was motivated by the intent to use the litigation process itself to create hurdles for the generics to delay generic competition.

L. In mid-2018, Celgene also filed patent infringement litigation against the later ANDA filer Synthon/Alvogen.

238. In May 2018, Synthon and Alvogen, which had partnered on a Pomalyst ANDA, sent their Paragraph IV letter to Celgene. Because Synthon/Alvogen were not first-filers (most generics sent their Paragraph IV letters in February 2017, approximately fifteen months earlier), Synthon/Alvogen would be precluded from entering the market until expiration of any 180 day exclusivity period awarded to (and shared by) the first-filers.

239. On June 19, 2018, Celgene filed suit against Synthon/Alvogen for infringement of four of the Pomalyst patents: the '267, '3939, '428, and '427. In November 2018, Celgene filed an amended complaint adding infringement claims as to the '467 patent.

240. For the same reasons as discussion above, a brand company in Celgene's position could not realistically expect to prevail on the merits in this infringement lawsuit, but nonetheless filed the lawsuits with the intent to use the judicial process itself to impede generic entry by Synthon/Alvogen.

M. In November 2018, the parties filed their opening claim construction briefs, previewing arguments on which Celgene's infringement claims would rise and fall.

241. On November 15, 2018, the parties filed their Opening Claim Construction briefs regarding the four patents Celgene initial sued on (the '262, '428, '3939, and '427).

242. As relevant to the three method of treatment patents, Celgene conceded that "*Patentability of the claimed methods depends upon efficacy*." Celgene was clear in this position, reiterating the point multiple times in its briefing:

- "[T]he examiner allowed the claims to issue over the prior art because the claimed methods were shown to be efficacious against MM when another therapy failed. In requiring evidence of efficacy to allow the claims to issue, the Examiner confirmed that efficacy is a required part of the claimed inventions."
- "Defendants seek to read efficacy – the very crux of the invention – out of the claims."
- "Here, '[a] method of treating multiple myeloma' requires efficacy against MM. If not, then the invention would lose its entire purpose. That is neither what the inventors intended, or what the intrinsic evidence shows."
- "Adopting Defendants' position that the preamble is not limiting, and therefore does not require efficacy, would negate the purpose of the claimed inventions."
- "[H]ere, efficacy against MM is a fundamental feature of the claimed invention."
- "Without a limiting preamble [claiming efficacy], the 'invention would have no purpose.'"
- "[H]ere, the preamble – 'a method of treating multiple myeloma' – is limiting because it is the basis upon which the Patent Office allowed the claims. The

Examiner allowed each of the MM patents to issue specifically because the inventions claimed therein demonstrated efficacy against MM."

- "[T]he claims issued only because the inventors demonstrated to the Examiner that their invention was efficacious against MM."
- "Because the prosecution history makes clear that the claims would not have issued absent evidence that the claimed methods resulted in efficacy against MM, which is conveyed through the preamble, the Court should construe "a method of treating multiple myeloma" as a claim limitation."

243. As the generic manufacturers explained in their Opening Claim Construction Brief, "Celgene seeks such a limiting construction so that it may argue during the merits phase of this case, incorrectly, that [the generic manufacturer defendants'] prior art does not anticipate or render obvious the asserted [method of treatment] patent claims because the prior art allegedly did not disclose that administration of pomalidomide would be efficacious in treating multiple myeloma."

N. In late 2018 to early 2019, the Celgene obtained the polymorph patents and promptly filed new sham litigation as to those three patents.

244. On October 9, 2018, the three polymorph patents (the '647, '648, and '649) issued. Celgene had not even applied for the polymorph patents until months after receiving the ANDA filers' paragraph IV letters. Celgene nevertheless promptly filed new lawsuits against the generic manufacturers alleging infringement of the newly issued polymorph patents ('647, 648, and '649):

Generic Manufacturer	Date sued for infringement of the polymorph patents
Mylan	February 14, 2019
Hetero	February 14, 2019
Natco/Breckenridge	February 14, 2019
Apotex	February 14, 2019
Teva	March 19, 2019
Synthon/Alvogen	April 12, 2019

245. Celgene's claims of infringement were doomed from the start by a catch-22 of Celgene's own making: if an earlier-in-time ANDA product would infringe one of Celgene's later-in-time polymorph patents, then the patent is invalid as anticipated and/or obvious in light of the prior art. *See* 35 U.S.C. §§102, 103.

246. Even if the polymorph patents were somehow valid, it is impossible that Celgene could prove all nine of the differing ANDA products infringed these three patents. To block generic entry based on the polymorph patents, Celgene would be required to establish that all nine ANDA products were a dihydrate, hemihydrate, or monohydrate exhibiting the same x-ray pattern diffraction pattern with the same peaks as those claimed in the patents. Even if Celgene could overcome the serious invalidity issues described above, Celgene could not succeed in proving that all (or even most) of the generic ANDA products possessed the very specific x-ray pattern diffraction claimed by the polymorph patents.

247. A brand company in Celgene's position could not realistically expect to prevail on its claims that the polymorph patents were valid and infringed. Celgene filed the litigation with the purpose and the intent to create yet another hurdle to impede generic entry.

O. In the Spring of 2019, a new generic manufacturer, Dr. Reddy's, sought to enter the market with generic pomalidomide, and Celgene sued it for infringement to block its entry.

248. On March 29, 2019, Dr. Reddy's filed an ANDA for generic Pomalyst. Like Synthon/Alvogen, Dr. Reddy's was not one of the first filers and therefore would not be able to enter the market with generic Pomalyst until after expiration of any 180 day exclusivity period awarded to the first filers.

249. On May 31, 2019, Dr. Reddy's sent written notice of its paragraph IV certification to Celgene.

250. On July 12, 2019, Celgene sued Dr. Reddy's for infringement of the '262, '3939, '428, '427, and '467.

251. For the same reasons as discussion above, a brand company in Celgene's position could not realistically expect to prevail on the merits in this infringement lawsuit. Celgene nonetheless filed the lawsuits with the intent to use the judicial process itself to impede generic entry by Dr. Reddy's.

P. In February 2020, the third formulation patent (the '5939) issued, leading Celgene to file a new wave of sham litigation, brought by Celgene in a last-ditch effort to block generic entry by tying the generics up in more meritless litigation.

252. On February 11, 2020, the '5939 formulation patent issued. Although this patent did not exist until *three years after* the ANDAs were filed, Celgene nevertheless initiated a new wave of patent litigation, filing substantially identical complaints alleging infringement of the '5939 against the following generic manufacturers on March 10, 2020: Apotex; Natco/Breckenridge; Hetero; Aurobindo; Mylan; Teva.

253. The '5939, a continuation of the '427 and '467 formulation patents, is invalid as obvious considering the prior art, including Zeldis, Remington's, and McNally. The PTO expressly stated it was not persuaded by the Tutino Declaration's assertion of "unexpected results." The '5939 only issued after Celgene filed a terminal disclaimer as to the '427 and '467. As with the other Pomalyst formulation patents, the '5939 was also exceedingly easy to design around.

254. The '5939 litigation was subjectively and objectively baseless. Celgene could not hope to prevail on its infringement claims regarding this patent. As with the '427 and '467, the '5939 was a simple patent that generics would readily design around to avoid infringement. With nine different generics seeking to bring generic Pomalyst to market, Celgene could not expect to prove that any one, let alone all nine, ANDA products infringed this simple patent.

255. Even if Celgene could prove infringement, it knew that its family of formulation patents were obtained based on the fraudulent Tutino declarations and unenforceable. Celgene pursued the litigation, not because it had a reasonable expectation of prevailing on the merits, but with the intent to impede and prevent generic competition.

Q. In 2020, Celgene's campaign to block generic competition suffered a series of setbacks, as the generic manufacturers scored key wins in the patent litigation.

256. By Spring 2020, the original Pomalyst patent litigation had been pending for approximately three years. During this time, the parties filed a number of briefs related to claims construction, *i.e.,* determining the definitions of disputed patent terms. In addition, Mylan and Celgene had engaged in venue related discovery and, on April 13, 2020, Mylan renewed its motion to dismiss for, *inter alia,* improper venue.

257. On June 16, 2020, the court issued its Claim Construction Order. *Celgene v. Hetero,* case no. 17-3387, 2020 WL 3249117, *2 (D.N.J.)(ES)(MAH). The order addressed four disputed terms in the three method of treatment patents (the '262, '428, and '3939) and the three formulation patents (the '427, '467, and '5939).

258. With respect to the method of treatment patents, the parties disputed *inter alia* whether the preamble of the method of treatment claims, specifically the phrase "A method of treating multiple myeloma," should be construed as limiting the claims.[75] Celgene argued that "the phrase 'treating multiple myeloma' in the preamble limits the claim by requiring efficacy in patients who received pomalidomide."[76] The generic manufacturers argued that the claims were not limited to the efficacious treatment of multiple myeloma, claiming only the administration of the compound as described in the claims.

[75] *Celgene v. Hetero,* case no. 17-3387, 2020 WL 3249117, *4 (D.N.J.)(ES)(MAH).

[76] *Id.*

259. The dispute is of central importance to the validity of the method of treatment patents, as Celgene would argue at the merits phase of the case that the claimed invention was not anticipated or obvious over the prior art because the prior art did not disclose that pomalidomide would be efficacious in the treatment of multiple myeloma. In its effort to persuade the court that the method of treatment patents were limited to the *efficacious* treatment of multiple myeloma, Celgene argued that the "[p]atentability of the claimed methods depends upon efficacy." *Celgene v. Hetero,* case no. 17-3387 (D.N.J.), Celgene Opening Markman Brief, p. 11; *see also* ¶242, *supra.*

260. The court rejected Celgene's interpretation, agreeing with the generic manufacturers that the method of treatment claims were not limited to the *efficacious* treatment of multiple myeloma: "While the Court agrees that the dispute term, 'treating multiple myeloma,' must be construed in its entirety, **nothing in the claim language, the specification, or the prosecution history warrants reading into the claim an efficacy limitation based on the preamble**."[77]

261. The ruling eliminated any question that the method of treatment patents are invalid, as Celgene itself had conceded that patentability depended upon the claims being limited to the efficacious treatment of multiple myeloma.

262. Shortly after the court's Markman Decision, the court granted Mylan's motion to dismiss for improper venue. *Celgene v. Mylan,* case no. 19-cv-5802, 2020 WL 12570814 (D.N.J. Sept. 25, 2020).

263. As 2020 continued, Celgene suffered additional setbacks in its generic exclusion scheme.

[77] *Id.* at *5.

R. Fall of 2020—Generic entry for pomalidomide is imminent.

264. By the fall of 2020, generic entry for pomalidomide was growing imminent, for a few reasons.

265. First, as to those generic companies who shared first-to-file ANDA status (having all filed on the first available date of February 8, 2017), the 30-month stay of ANDA approval had long since passed.

266. Second, in August 2020, the NCE exclusivity period for Pomalyst expired. Expiry of the 30-month stays and NCE exclusivity meant that no further regulatory exclusivities stood in the way of the FDA granting final ANDA approval for generic pomalidomide.

267. Third, in October 2020 five of Celgene's Orange Book listed patents (the REMS patents) expired, eliminating any arguable issue those ever presented to generic competition.

268. Fourth, on October 30, 2020, FDA granted final approval to the Aurobindo and Natco/Breckenridge ANDAs.

269. Fifth, market dynamics presented a significant likelihood of imminent generic entry. Pomalyst was selling over $2 billion a year, making it a highly desirable market for generic entry. While both Natco/Breckenridge and Aurobindo shared first-to-file status with other generics, those other generics had not yet received final FDA approval, opening an opportunity of *de facto* generic exclusivity for the first entrant or entrants. And while entry before conclusion of the patent litigation would require at-risk entry, those risks here were minimal (if not non-existent), and at-risk entrants, in any event, typically pay less in damages than what they earn during at-risk launch.[78]

270. In short, in the fall of 2020 Celgene faced imminent pomalidomide generic competition and, with that, the loss of its $2 billion Pomalyst franchise.

[78] Keith M. Drake, Robert He, Thomas McGuire, and Alice K. Ndikumana, No Free Launch: At-Risk Entry by Generic Drug Firms, NBER Working Paper No. 29131, August 2021, JEL No. D22,I11,I18,O32, available at https://www.nber.org/system/files/working_papers/w29131/w29131.pdf (last accessed September 4, 2023).

S. November 2020—the Celgene-Natco reverse payment agreement.

271. Rather than allow lawful competition in the U.S. market for pomalidomide, starting in November 2020, Celgene began a serial scheme to pay off its would-be pomalidomide competitors to have them delay generic entry for about six years, until early 2026.

272. In about late October or early November 2020, Celgene and BMS, on the one hand, and Natco and Breckenridge, on the other, settled the pending pomalidomide litigation between them under terms that provide for a large, unjustified payment from Celgene/BMS to Natco/Breckenridge. In return, Natco/Breckenridge agreed to delay entry into the U.S. pomalidomide market until six years later, *i.e.*, the first quarter of 2026.

273. The terms of the arrangement were in part reflected in documentation, but also by the combined effect of incentives created by the agreement and industry economics. This complaint refers to the arrangements between Celgene/BMS and Natco/Breckenridge as the "Celgene-Natco agreement."

274. Under the Celgene-Natco agreement, the value of the payment from BMS/Celgene to Natco/Breckenridge is substantial, certainly magnitudes larger than Celgene's avoided litigation expenses, and likely well into the nine figures (*i.e.*, of about $150 to $300 million).

275. The size of the *de facto* payment to Natco/Breckenridge may be estimated as follows. Under normal market conditions, after several months of *bona fide* generic entry, the generic penetration rate is typically 90%. If the only ANDA generic to enter the market was Natco/Breckenridge, a single first filer with 180 days of exclusivity would expect to take roughly half of these generic sales (with the other half of generic sales going to the brand company's authorized generic product, which for conservative purposes we assume would enter). Facing competition from the brand product and the authorized generic, the generic product is typically priced at approximately 60% of the brand price. Applying those figures to the pomalidomide market, during

the first six months, a generic company with exclusivity would expect sales of about $300 million. ($2.25 billion in 2021 U.S. sales x 0.5 years x 90% of the market is generic x 50% of generic market x 60% price of the brand).

276. Even if both Natco/Breckenridge and Aurobindo (the two companies with final ANDA approvals as of November 2020) were to enter the market (thereby sharing the 180-day exclusivity period), the revenues from the generic products would be divided a third each (the two ANDA generic products and the authorized generic product). In addition, the presence of an additional generic would likely have caused some degree of additional price erosion. However, each of the ANDA filers would still expect to earn about $167 million. ($2.25 billion in 2021 U.S. sales x 0.5 years x 90% of the market is generic x 33% of generic market x 50% price of the brand).

277. As a result, a reasonable company in the position of Natco/Breckenridge in November 2020, having first-to-file status and being one of only two finally approved ANDA applicants, would expect to achieve about $167 to $300 million in revenues over six months were it to launch generic pomalidomide and exploit a period of oligopolistic pricing.

278. On the other hand, because of the reverse payment in the Celgene-Natco agreement settlement with Celgene, Natco/Breckenridge is required to wait six years and not launch its approved ANDA product until early 2026. And at that time, the market expectation is that all or most of the *other* first-to-file generics would by then have obtained their final ANDA approvals. And as this was a classic, post-NCE pile-on (where multiple generics file ANDAs on the first allowed date, and at least seven generics filed on the same date with first-to-file status), the expectation would be that, after waiting six years to enter in early 2026, the entry by Natco/Breckenridge would occur into an immediately, fully genericized market.

279. In a fully genericized market, generic penetration is about 90%, the price discount is often about the same (or larger), and most generics estimate similar shares of the market. Even

assuming the pomalidomide market would grow at 5% a year, by waiting for six years to enter in the first quarter of 2026, a reasonable company in the position of Natco/Breckenridge would expect to achieve about $19.4 million over six months. (Projected $3.02 billion in 2026 U.S. sales x 0.5 years x 90% of the market is generic x 0.143 (i.e., 1/7th of the generic market[79]) x 10% of the brand).

280. The enormous difference between the reasonably estimated returns under these circumstances ($167-$300 million over the first six months from imminent launch, versus about $19.4 million under the settlement and six years later) requires significant compensation to Natco/Breckenridge for the settlement.

281. Other facts also show the existence of a large, unjustified payment.

282. First, the facts of the existing patents and litigation show that the Celgene-Natco agreement is not based on the merits of the patent dispute; Natco/Breckenridge had little reason to settle, and certainly not on terms where market entry is delayed until early 2026.

283. At the time, Celgene had nine unexpired pomalidomide patents: the three method of treatment patents (’262, ’3939, ’428), the three polymorph patents (’647, ’648, ’649), and the three formulation patents (’427, ’467, ’5939).

284. As to the three method of treatment patents, Celgene had no colorable basis to prosecute to conclusion infringement litigation based on them (as previously alleged), and all three were to expire *before* the agreed entry date (of the first quarter of 2026). As a result, the method-of-use patents cannot explain a delay into 2026.

Patent	**Expiration Date**	**Delay Between Patent Expiration and Generic Entry**
’262	June 17, 2025[80]	At least 6.5 months

[79] The 1/7 figure is based on there being seven generic products, *i.e.,* six ANDA products, plus an AG, which Celgene would launch under competitive conditions. To clarify, there were seven first filers, but Par withdrew its paragraph IV certification early on, leaving 6.

[80] Celgene received a 241-day patent term extension for the ’262, extending the expiration date to June 17, 2025. Celgene subsequently received pediatric exclusivity (PED), which expires December 17, 2025.

'3939	May 15, 2023	At least 31.5 months
'428	May 15, 2023	At least 31.5 months

285. As to the three polymorph patents, Celgene had no colorable basis to prosecute to conclusion infringement litigation based on them. (As previously alleged, these patents were applied for *after* the generic companies had developed their ANDA products and served paragraph IV notices; it could not be the case that both the generics' products infringed the polymorph patents and that the polymorph patents were not obvious over the prior art, *i.e.*, the ANDAs). Celgene had no ability to protect its pomalidomide franchise against the filed ANDA applicants with these patents.

286. As to the three formulation patents, one of those patents (the '427 formulation patent) was withdrawn from litigation by Celgene (at least by December 2020). Because Celgene could not prosecute patent infringement litigation based on it, that patent cannot explain the 2026 agreed entry date.

287. The remaining two formulation patents—the '467 and the '5939—were both set to expire on May 19, 2030. That date, extending as it does into the future, is quite telling. Celgene did not even bother to apply for these patents until well after all or nearly all the Pomalyst ANDAs were filed (in the case of the '5939, approximately *three years* later.) The notion that these patents are somehow essential to Pomalyst (and thus capable of blocking generic entry) is not credible. In any event, both patents were obtained based on the fraudulent Tutino declarations and are therefore unenforceable, as well as invalid as obvious over the prior art. The claims of the formulation patents are also quite narrow and would be easy for a generic manufacturer to design around.

288. Second, the facts of Natco's earlier dealings with Celgene in settling lenalidomide litigation show that the pomalidomide Celgene-Natco settlement agreement also contains an anticompetitive reverse payment.

289. Several years earlier in 2015, Celgene and Natco had settled patent litigation over Natco's (and Teva's) proposed generic for Revlimid through an anticompetitive reverse payment agreement. That agreement explicitly contained market allocation arrangements. There, Celgene and Natco carved up the lenalidomide market by agreeing to have Natco delay all generic entry until 2022. Beginning in March 2022, Natco can sell a "mid-single-digit percentage of the total lenalidomide capsules dispensed in the United States during the first full year of entry." That "volume limitation is expected to increase gradually each 12 months until March of 2025" but 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." In that arrangement, the volume caps were to end in January 2026. Natco has disclosed that the volume-limited license is royalty free, meaning Natco has no obligation to pay Celgene a portion of its profits, as is the norm. The agreement also contained a most-favored entry clause to coordinate entry dates amongst would-be generics. Both by design and effect, Celgene and Natco worked an arrangement for lenalidomide to delay generic entry until 2022, and even then, maintain supra-competitive pricing of lenalidomide until 2026.

290. Individually and collectively, these payment terms are anticompetitive. As Teva (Natco's Revlimid marketing partner) described it: with its Revlimid settlements, Celgene set up a "profit share." The royalty-free generic license prior to true generic competition constitutes a large reverse payment from Celgene to the generic that equates to hundreds of millions of dollars in the first year of generic sales alone. And the most-favored entry clause deters other generics from continuing to challenge Celgene's patents and provides assurance to Natco that it will receive the most favorable entry date and retain its lucrative exclusivity period.

291. Celgene would continue this pattern with other generics, engaging in a series of payoffs to would-be lenalidomide competitors. In the lenalidomide settlements, Celgene's payoffs

took the form of market allocation agreements in which Celgene sequentially granted small, volume-limited licenses to each generic company to sell lenalidomide starting in 2022 and going to early 2026 (at which time there would be unconstrained competition). The volume-limited license agreements, which also contain no royalties to Celgene, significantly reduce the extent of price reduction and effectively allocate the market amongst competitors. In design and effect, the lenalidomide volume-limited licenses function to have Celgene pay off would-be generic competitors by having them share, over a four-year period (early 2022 to early 2026), supra-competitive profits for lenalidomide. And Celgene entered these lenalidomide arrangements both several months before and several months after cutting the November 2020 pomalidomide Celgene-Natco agreement.

292. In short, Celgene and Natco worked anticompetitive arrangements in the past by settling patent litigation and did so with respect to a product used in a complementary way to treat the same conditions. The date for bona fide agreed entry in the lenalidomide settlement is the first quarter of 2026, the same quarter to which the pomalidomide Celgene-Natco agreement delays pomalidomide entry. And Celgene is a repeat offender in reaching anticompetitive, market allocation agreements in the same period it reached the Celgene-Natco agreement.

293. Third, the facts surrounding the disclosure of the settlement also show that the Celgene-Natco agreement contains an anticompetitive reverse payment.

294. Under the settlement, the parties apparently agreed to keep secret *all* the specific terms of the settlement, even the agreed entry date, for some period. For example, during an earnings call on November 13, 2020, analysts repeatedly pressed Natco's CEO Rajeev Nannapaneni for the most basic information about the terms of the settlement. The CEO declined to provide any information, stating at one point, "I already answered the question, but I will just repeat it one more time. . . . we will not disclose the [generic launch] date because the settlement agreement was very particular that we do not talk about the date."

295. The parties kept the entry date secret for about a year and a half. Eventually in February 2022 —and only after settling with all the other would-be pomalidomide generic entrants—BMS disclosed the entry date to the public. There would be no generic entry into the pomalidomide market until the first quarter of 2026:

> As it relates to U.S. IP for Pomalyst, we are pleased that there is now no outstanding litigation. At this point, we don't expect generic entry in the U.S. market prior to the first quarter of 2026.

296. The publicly disclosed terms of the Celgene-Natco agreement are the facts that (i) the parties settled all pomalidomide litigation between them, (ii) the agreed entry date is the first quarter of 2026, and (iii) that there are other terms of the agreement, but the parties refuse to disclose them to the public.

297. To settle Hatch-Waxman patent litigation, it is sufficient for the parties to settle based on an agreed entry date, and nothing more. In fact, the Federal Trade Commission (FTC) published a study finding that from 2004 through 2009, seventy percent of final settlements agreements (152 out of 218) "did not involve compensation from the brand to the generic combined with a delay in generic entry." As the FTC explained, "[t]his large number of settlements not involving compensation from the brand to the generic undermines brand and generic firms' arguments that compensation is the only way to settle patent litigation. In fact, there are a variety of ways to settle litigation that do not involve these payments."[81] In settling based on an agreed entry date and only an entry date, the settlement is likely assured to be based on the relative merits of the parties' positions in the underlying patent litigation. But when the parties add additional consideration going to the settling generic in the agreement, the likelihood is that non-patent-merits considerations are influencing the agreed entry date.

[81] FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* (2010), at 4, available at https://www.ftc.gov/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study (last accessed September 4, 2023).

298. Here, the Celgene-Natco agreement contains provisions other than the agreed entry date, and the parties seek to conceal those other terms. Taken in the context of all other facts, this further shows that the Celgene-Natco agreement provides a large, unjustified payment to the Natco parties. While the settling parties to the Celgene-Natco agreement have had some success keeping the specific *form* of the reverse payment secret, they have not been able to conceal the *existence and size* of the reverse payment in the November 2020 agreement.

299. Finally, the likelihood of anticompetitive provisions in the Celgene-Natco agreement is shown by the fact that similar agreements between Celgene and Natco have failed review by competition authorities outside the U.S., authorities that apply competition principles similar to those in the U.S.

300. On December 3, 2021, Celgene and Natco submitted settlement/licensing agreements for Pomalyst and Revlimid to the Australian Competition and Consumer Commission (ACCC) for approval. On March 23, 2022, the ACCC issued a Draft Determination recommending rejection of the application, stating the "ACCC considers the settlement and licence agreement is likely to result in public detriment by reducing competitive tension in relation to generic entry in the supply of lenalidomide and pomalidomide. The ACCC considers the settlement and licence agreement provides Celgene with greater control and certainty over the timing of generic entry by Juno/Natco, seeks to confer on Juno/Natco a 'first mover advantage', may deter other generic entry, [REDACTED]." On July 29, 2022 (the eve of the deadline for the ACCC's final determination), Celgene and Natco withdrew their application. One report about the incident wrote "the ACCC's draft determination marks one of the first opportunities the regulator has had to consider a reverse payment settlement in the Australian context — and is likely to have a chilling effect on similar applications for the foreseeable future."

301. In sum, the Celgene-Natco agreement contains an anticompetitive, reverse payment arrangement which functions to delay and/or impair generic entry of pomalidomide into the U.S. market for pomalidomide.

T. March 2021—the Celgene-Teva reverse payment agreement.

302. In or about March 2021, Celgene and BMS, on the one hand, and the Teva defendants, on the other, settled the pending pomalidomide litigation between them under terms that provide for a large, unjustified payment from Celgene/BMS to Teva. In return, Teva agreed to delay entry into the U.S. pomalidomide market until six years later, *i.e.*, the first quarter of 2026. The terms of the arrangement were in part reflected in documentation, but also by the combined *de facto* economics of the industry and incentives created by the agreement. This complaint refers to the arrangements between Celgene/BMS and Teva as the "Celgene-Teva agreement."

303. Under the Celgene-Teva agreement, the value of the payment from BMS/Celgene to Teva is substantial, certainly magnitudes larger than Celgene's avoided litigation expenses, and likely well into the nine figures.

304. Several facts, when viewed together, reveal the existence of a large, unjustified payment from Celgene/BMS to Teva. First, Celgene's patents (several of which expire before the agreed-to entry date or were withdrawn prior to settlement) are weak and cannot explain the extended delay in generic entry.

305. Second, Teva (through its affiliate Arrow, which partnered with Natco on Revlimid) and Celgene entered into an agreement to settle the Revlimid litigation in 2015. That settlement agreement, involving the same parties and a complementary drug, provided for a volume-limited, royalty free license and most favored entry clauses. The Revlimid settlement agreement between Celgene and Teva functions as an unlawful market allocation agreement that will restrict competition and keep prices at supracompetitive levels until sometime after the first quarter of 2026. The

agreement also effectuates a substantial, unjustified payment to Teva by cutting Teva in on Celgene's and BMS's monopoly profits.

306. Third, although Teva and Celgene had settled their Pomalyst dispute by early March 2021, all information, including even the fact of settlement, was concealed for nearly a year. When the Pomalyst settlements were finally announced by BMS in February 2022, it was revealed that all generics, including Teva, have agreed to delay their entry date until the first quarter of 2026.

307. Finally, Teva has adhered to the secret agreement, refraining from launching generic Pomalyst, despite receiving FDA final approval on May 4, 2022.

308. The Celgene-Teva agreement contains provisions other than the agreed entry date, and the parties seek to conceal those other terms. Taken in the context of all other facts, this further shows that the Celgene-Teva agreement provides of a large, unjustified payment to the Teva parties. While the settling parties to the Celgene-Teva agreement have had some success keeping the specific form of the reverse payment secret, they have not been able to conceal the existence of a substantial reverse payment.

U. Spring 2021—the Celgene-Aurobindo reverse payment agreement.

309. By April 2021, Aurobindo (which had also received final approval on October 30, 2020) had discontinued its ANDA. A short while later, on July 16, 2021, Aurobindo and Celgene notified the court that they had resolved their dispute as to the Pomalyst patents.

310. Celgene and BMS, on the one hand, and the Aurobindo defendants, on the other, settled the pending pomalidomide litigation between them under terms that provide for a large, unjustified payment from Celgene/BMS to Aurobindo. In return, Aurobindo agreed to delay entry into the U.S. pomalidomide market until six years later, *i.e.*, the first quarter of 2026. The terms of the arrangement were in part reflected in documentation, but also by the combined *de facto*

economics of the industry and incentives created by the agreement. This complaint refers to the arrangements between Celgene/BMS and Aurobindo as the "Celgene-Aurobindo agreement." Under the Celgene-Aurobindo agreement, the value of the payment from BMS/Celgene to Aurobindo is substantial, certainly magnitudes larger than Celgene's avoided litigation expenses, and likely well into the nine figures.

311. The publicly disclosed facts, particularly when viewed together, show the existence of a large, unjustified payment from Celgene to Aurobindo. First, Celgene's patents (several of which expire before the agreed-to entry date or were withdrawn prior to settlement) are weak and cannot explain the extended delay in generic entry.

312. Second, Aurobindo received final approval for generic Pomalyst on October 30, 2020. Had it launched immediately, it would have earned between $167 to $300 million in the first six months alone. Instead, Aurobindo agreed to delay market entry for six years. This means that, absent some other terms to compensate Aurobindo, Aurobindo would earn approximately $19.4 million over the first six months of entry if launching into a fully genericized market in 2026.

313. Third, not only did Aurobindo not launch its generic pomalidomide after receiving FDA approval, foregoing hundreds of millions of dollars in near term profits, it withdrew its ANDA.

314. Fourth, Aurobindo and Celgene ended their disputes regarding Revlimid and Pomalyst *on the same day,* filing consent decrees in both matters on July 16, 2021.

315. Fifth, Aurobindo and Celgene have concealed the terms of both agreements. However, to the extent the terms of other Revlimid settlements have been disclosed, all provide for volume-limited license agreements, capping the generic's lenalidomide sales until the first quarter of 2026 (when generic Pomalyst entry begins).

316. Here, the Celgene-Aurobindo agreement contains provisions other than the agreed entry date, and the parties seek to conceal those other terms. Taken in the context of all other facts, this further shows that the Celgene-Aurobindo agreement provides a large, unjustified payment to the Aurobindo parties. While the settling parties to the Celgene-Aurobindo agreement have had some success keeping the specific form of the reverse payment secret, they have not been able to conceal the existence of a substantial reverse payment.

V. February 2022—Celgene reveals that all generic pomalidomide entry is delayed until early 2026.

317. To this point in time, Celgene, Bristol Myers, and the settling generics had withheld all information about the Pomalyst settlements and concealed their terms.

318. It was not until a February 4, 2022, earnings call that Bristol Myers disclosed for the first time that there would be no generic entry for Pomalyst until the first quarter of 2026.

319. This means that, in addition to Celgene's illegal reverse payment agreements with Natco/Breckenridge, Aurobindo, and Teva, Celgene also reached settlement agreements with Hetero, Apotex, Mylan (another generic that discontinued its ANDA after receiving final approval), Par, Dr. Reddy's, and Synthon/Alvogen (the "Additional Settling Generics"). Celgene and the Additional Settling Generics have concealed all information about their Pomalyst settlements, other than to disclose that no generic will enter the market prior to the first quarter of 2026.

320. However, nearly all the generics that had a Pomalyst ANDA also had a Revlimid ANDA. After being sued by Celgene for infringement of Celgene's Pomalyst and Revlimid patents, a generic often settled the two matters concurrently.

ANDA filer(s)	Date Pomalyst consent judgment filed with the court	Date Revlimid settlement disclosed to the public
Alvogen	May 9, 2019	March 29, 2019
Apotex	April 19, 2021	March 9, 2021
Hetero	August 18, 2021	September 24, 2021

Mylan	N/A – November 2021 is estimated settlement date.	July 21, 2021
Dr. Reddy's	January 28, 2022	September 17, 2020

321. In July 2022, Bristol Meyers confirmed – for the first time – that it had obtained "a longer than previously expected market exclusivity period for Pomalyst."

322. At a minimum, Celgene's settlement agreements with the Additional Settling Generics ensure that the illegal reverse payment agreements will function as intended, delaying generic Pomalyst entry and ensuring supracompetitive pricing for at least six years beyond what would have occurred absent the unlawful reverse payment agreements.

W. *Bona fide* generic competition will not begin until early 2026, causing the plaintiffs and the class to suffer substantial overcharges on their purchases of Pomalyst.

323. The Pomalyst anticompetitive reverse payment settlements and complementary agreements will prevent true generic competition for Pomalyst until 2026. As a result, the plaintiffs will be and have been forced to purchase brand Pomalyst at supra-competitive prices through at least that time, even with the earlier, volume-limited introduction of generic Pomalyst.

324. Shortly after announcing the settlements, Bristol Myers acknowledged that it was able to achieve a longer delay in generic entry than previously expected. In its quarterly report for the first quarter of 2022, Bristol Myer reported: "Amortization of acquired intangible assets decreased by $96 million in the first quarter of 2022, due to a longer than previously expected market exclusivity period for Pomalyst." In other words, Bristol Myers reported that during the quarter that it announced all Pomalyst patent litigation had been settled, Bristol Myer's expectations regarding its exclusivity period for Pomalyst had changed, because it now expected its exclusivity period to last longer than previously expected, further indicating that the settlement agreements provide for generic delay period that exceeds what one would have expected based on the patents alone.

325. Absent Celgene's anticompetitive conduct, generic Pomalyst would have been available years ago, on a date to be determined during discovery and potentially on October 30, 2020 (when Natco/Breckenridge received final approval).

326. Absent the Pomalyst agreements, under competitive conditions, a reasonable generic company in the position of Natco/Breckenridge would have (i) launched generic Pomalyst after prevailing at trial, (ii) launched at risk at some point after obtaining final approval, or (iii) entered into a payment-free agreement that provides for unrestricted sales and/or an earlier, risk-adjusted, agreed entry date. Absent the Pomalyst agreements, Natco/Breckenridge would have been able to launch on October 30 2020, after receiving final approval from the FDA or – in the absence of entering into an anticompetitive payment-ladened agreement with competitor Celgene – at some point between then and early 2026.

327. A 2010 study by the FTC found that on average, within a year of generic entry, generics had captured 90% of corresponding brand sales and (with multiple generics on the market) prices had dropped 85%, findings confirmed by later studies. Given that there were multiple generic filers, it is likely that additional generics would have entered subsequent to Natco/Breckenridge, driving down prices in accord with industry experience.[82] Thus, the plaintiffs will suffer substantial damages in overcharges on their Pomalyst purchases through at least early 2026.

VI. CLASS ALLEGATIONS

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

> All entities in the United States and its territories that, other than for resale, purchased, paid for, and/or provided reimbursement for some or all of the purchase price for Pomalyst and/or pomalidomide from October 30, 2020 until the

[82] *See* R. Conrad and R. Lutter, *Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices*, FDA: Generic Competition and Drug Prices (December 2019), available at https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices (last accessed September 4, 2023).

anticompetitive effects of the defendants' conduct cease for consumption by their members, employees, insured, participants, or beneficiaries.

329. Excluded from the Class are the defendants and any of their officers, directors, management, employees, subsidiaries, and affiliates.

330. Also excluded from the Class are fully insured health plans, *i.e.,* health plans that purchased insurance from another third-party payor covering 100 percent of the plan's reimbursement obligations to its members, and pharmacy benefit managers.

331. Also excluded from the Class are: (1) the government of the United States and all agencies thereof; and (2) all state agencies thereof.

332. As used in the preceding paragraph, the government of the United States and agencies thereof does not include Federal Employees Health Benefits Act ("FEHBA") plans or carriers offering FEHBA plans. For avoidance of doubt, FEHBA plans and carriers of FEHBA plans are included in the Class definition.

333. Members of the Class are so numerous and geographically dispersed that joinder of all members is impracticable. Given the costs of complex antitrust litigation, it would be uneconomic for many plaintiffs to bring individual claims and join them together. The Class is readily identifiable.

334. The plaintiffs' claims are typical of those of the Class members. The plaintiffs and all Class members were damaged by the same wrongful conduct of the defendants—*i.e.*, as a result of the defendants' conduct, Class members were forced, and will continue to be forced, to purchase Pomalyst and pomalidomide at supra-competitive prices.

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

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

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

338. Questions of law and fact common to the Class include:

a. Whether Celgene unlawfully maintained monopoly power through all or part of its overall generic suppression scheme;

b. Whether direct proof of Celgene's monopoly power is available and, if so, whether it is sufficient to prove Celgene's monopoly power without need to define the relevant market;

c. Whether Celgene possessed the ability to suppress generic competition for Pomalyst;

d. Whether the defendants' scheme, in whole or in part, has substantially affected interstate commerce;

e. Whether the defendants conspired to delay generic competition for Pomalyst;

f. Whether the defendants' conduct harmed competition;

g. To the extent procompetitive justifications exist, whether there were less restrictive means for achieving them;

h. Whether the terms of the settlement agreements effectuated a large reverse payment from Celgene to one or more of the defendant generic manufacturers;

i. Whether Celgene's unlawful monopolistic conduct was a substantial contributing factor in causing some amount of delay in the entry of AB-rated generic Pomalyst;

j. Determination of a reasonable estimate of the amount of delay caused by the defendants' anticompetitive conduct; and

k. The quantum of overcharges paid by the Class in the aggregate.

339. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would require. The benefits of proceeding through the class mechanism—including providing injured persons or entities with a method for obtaining redress on claims that they could not practicably pursue on an individual basis—substantially outweigh potential difficulties in management of this class action.

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

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

VII. MARKET POWER AND RELEVANT MARKET

342. The relevant product market is brand Pomalyst and its AB-rated generic equivalents. Since 2013, Celgene has possessed monopoly power in the United States with respect to this market by virtue of its 100% market share.

343. In the pharmaceutical marketplace, there is a disconnect between product selection and payment. State laws prohibit pharmacists from dispensing many pharmaceutical products, including Pomalyst, to patients without a prescription. Patients must obtain prescriptions from their physicians. However, a patient's physician has no role in the purchase of the prescription

medication. The patient's doctor chooses which product the patient will buy, while the patient (and in most cases his or her insurer) must pay for it.

344. Brand manufacturers, including Celgene, exploit this disconnect by employing large sales forces that visit doctors' offices and persuade them to prescribe the brand manufacturers' products. These sales representatives do not advise doctors on the cost of their branded products. Studies show that doctors are typically unaware of the relative costs of brand pharmaceuticals and, even when they are aware, are largely insensitive to price differences because they do not pay for the products. The result is a marketplace where price plays a comparatively unimportant role in product selection.

345. The relative unimportance of price in the pharmaceutical marketplace reduces what economists call the own-price elasticity of demand—the extent to which unit sales go down when price goes up. This reduced-price elasticity enables brand manufacturers to raise prices substantially above marginal cost without losing enough sales to make the price increase unprofitable. The ability to profitably raise prices substantially above marginal costs is what economists and antitrust courts refer to as market power. Economists refer to monopoly power when market power rises to a level as would be held by a dominant firm. The result of these pharmaceutical market imperfections and marketing practices is that brand manufacturers gain and maintain monopoly power with respect to many brand prescription pharmaceuticals, including Pomalyst.

346. Celgene has monopoly power in the market for Pomalyst because it has the power to exclude competition and raise or maintain the price of Pomalyst to supra-competitive levels without losing enough sales to make these prices unprofitable.

347. Celgene needs to control only brand Pomalyst, and its AB-rated generic equivalents, and no other products, in order to maintain the price of Pomalyst profitably at supra-competitive

levels. Only the market entry of competing, AB-rated generic versions of Pomalyst would render Celgene unable to profitably maintain its prices for Pomalyst without losing substantial sales.

348. For years, Celgene has sold Pomalyst at prices well in excess of marginal costs and in excess of the competitive price and, therefore, Celgene had high profit margins.

349. Celgene had, and exercised, the power to exclude generic competition to brand Pomalyst.

350. At all relevant times, Celgene was protected by high barriers to entry 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. The products in these markets require significant investments of time and money to design, develop, and distribute. In addition, the markets require government approvals to enter and/or the drugs at issue may be covered by patents or other forms of intellectual property. Celgene's unlawful conduct further restricted entry. Thus, during the relevant time, existing and potential market entrants could not enter and/or expand output quickly in response to Celgene's higher prices or reduced output.

351. There is direct evidence of market power and anticompetitive effects available in this case sufficient to show Celgene's ability to control the price of Pomalyst, and to exclude relevant competitors, without the need to define the relevant antitrust markets. The direct evidence consists of, *inter alia*, the following facts: (1) generic Pomalyst would have entered the market at a much earlier date, at a substantial discount to brand Pomalyst, but for Celgene's anticompetitive conduct; (2) Celgene's gross margin on Pomalyst at all relevant times was very high; (3) Celgene never lowered the price of Pomalyst to the competitive level in response to the pricing of other brand or generic drugs; and (4) from 2013 through 2021, Celgene profitably raised the price of Pomalyst by nearly 200%. The plaintiffs also allege that Celgene made a large reverse payment to the settling

generics that exceeded its anticipated litigation costs. One can infer, based on the size of the payment itself, that Celgene possessed market power.

352. To the extent proof of monopoly power by defining a relevant product market is required, the plaintiffs allege that the relevant antitrust market is the market for Pomalyst and its AB-rated generic equivalents.

353. The United States, the District of Columbia, and the U.S. territories constitute the relevant geographic market.

354. Celgene will have a 100% market share in the relevant market until the 2026 agreed-to entry date, after which the defendants, collectively, will have a 100% market share in the relevant market and possess monopoly power. The presence of volume caps would result in no downward pressure on price during the duration of the caps.

VIII. EFFECT ON INTERSTATE COMMERCE

355. During the relevant time period, Celgene manufactured, sold, and shipped Pomalyst across state lines in an uninterrupted flow of interstate commerce.

356. During the relevant time period, the plaintiffs and Class members purchased substantial amounts of Pomalyst directly from Celgene. As a result of Celgene's illegal conduct, the plaintiffs and Class members were compelled to purchase brand Pomalyst at supra-competitive prices.

357. During the relevant time period, the 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. The defendants engaged in illegal activities, as charged in herein, within the flow of—and substantially affecting—interstate commerce, including in this district.

IX. CLAIMS FOR RELIEF

COUNT ONE

VIOLATION OF 15 U.S.C. § 2
UNLAWFUL MONOPOLIZATION:
DECLARATORY AND INJUNCTIVE RELIEF

(Against Defendants Celgene and Bristol Myers)

358. The plaintiffs hereby repeat and incorporate by reference each preceding paragraph as though fully set forth herein.

359. At all relevant times, Celgene (and subsequently Celgene and its new parent Bristol Myers) possessed substantial market power (*i.e.*, monopoly power) in the relevant market. Celgene, and later Celgene and Bristol Myers, possessed the power to control prices in, prevent prices from falling in, and exclude competitors from, the relevant market.

360. Through the overarching anticompetitive scheme, as alleged above, Celgene and Bristol Myers willfully maintained monopoly power in the relevant market using restrictive or exclusionary conduct, rather than by means of greater business acumen or a historic accident, and thereby injured the plaintiffs and the Class. Celgene's and Bristol Myers' anticompetitive conduct was done with the specific intent to maintain a monopoly in the market for brand and generic Pomalyst in the United States.

361. Celgene and Bristol Myers accomplished their scheme by entering into unlawful agreements for delay in generic entry. They did so in order to lengthen the period in which Celgene's brand Pomalyst could monopolize the market, enabling Celgene and Bristol Myers to make supra-competitive profits.

362. Had Celgene and Bristol Myers competed on the merits instead of unlawfully maintaining a monopoly in the market for Pomalyst, one or more generic equivalents would have been available by no later than October 30, 2020. The plaintiffs and Class members would have

substituted lower-priced generic Pomalyst for the higher-priced brand-name Pomalyst for some or all of their Pomalyst requirements and would have paid substantially lower prices for brand-name Pomalyst and generic Pomalyst.

363. The goal, purpose, and effect of Celgene's and Bristol Myers' overarching anticompetitive scheme was to block generic drugs from entering the market for Pomalyst, extend their dominance in that market, and maintain Pomalyst's prices at supra-competitive levels. The scheme has had the further effect of depriving the market of competition.

364. Celgene's and Bristol Myers' scheme substantially harmed competition in the relevant market and was an unreasonable restraint of trade.

365. There is and was no non-pretextual, procompetitive justification for Celgene's or Bristol Myers' actions that outweighs the scheme's harmful effects. Even if there were some conceivable justification that Celgene or Bristol Myers could assert, the scheme is and was broader than necessary to achieve such a purpose.

366. But for Celgene's and Bristol Myers' illegal conduct, competitors would have begun marketing generic versions of Pomalyst beginning no later than October 30, 2020. The plaintiffs' allegations comprise a violation of Section 2 of the Sherman Act, as well as violation of state laws as alleged below.

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

368. Pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, the plaintiffs and the Class further seek equitable and injunctive relief to correct for the anticompetitive market effects caused by Celgene's and Bristol Myers' unlawful conduct and to assure that similar anticompetitive conduct does not occur in the future.

COUNT TWO

VIOLATION OF 15 U.S.C. § 1
CONTRACT, COMBINATION, OR CONSPIRACY IN RESTRAINT OF TRADE: DECLARATORY AND INJUNCTIVE RELIEF

(Against All Defendants)

369. The plaintiffs hereby repeat and incorporate by reference each preceding paragraph as though fully set forth herein.

370. The defendants violated 15 U.S.C. § 1 by entering into unlawful settlement agreements that restrained competition in the market for Pomalyst.

371. The defendants' violations of 15 U.S.C. § 1 injured the plaintiffs in their business or property. The injuries of the plaintiffs and members of the Class consist of having paid and having to continue to pay higher prices for Pomalyst than they 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 the defendants' conduct unlawful.

372. From the launch of brand Pomalyst in 2013 through the present, Celgene (and subsequently Celgene and its new parent Bristol Myers) possessed monopoly power in the relevant market – *i.e.*, the market for brand Pomalyst and its AB-rated generic equivalents in the United States. But for Celgene's and Bristol Myers' wrongful conduct, as alleged herein, Celgene and its parent Bristol Myers should have lost their monopoly power in the relevant market by not later than October 30, 2020.

373. Celgene and Bristol Myer entered into these agreements in order to, and with the likely effect of, unreasonably restraining trade in market for brand and generic Pomalyst, the purpose and effect of which was to: (a) delay entry of generic Pomalyst in order to length the period in which Celgene and Bristol Myer could monopolize the market and make supra-competitive

projects, and (b) maintain and raise the prices that the plaintiffs and other members of the Class would pay for Pomalyst.

374. There is and was no legitimate, non-pretextual, pro-competitive business justification for Celgene's or Bristol Myers' conduct that outweighs its harmful effect on purchasers and competition. Celgene's and Bristol Myers' conduct can only be explained by anticompetitive motives and a desire to foreclose competition in the market for brand and generic Pomalyst. Even if there were some conceivable and cognizable justification for the settlement agreements, an agreement to forestall all generic competition until 2026 was not necessary to achieve such a purpose.

375. As a direct and proximate result of the defendants' anticompetitive conduct, including the settlement agreements described herein, the plaintiffs and Class members were harmed.

376. The defendants' unlawful conduct continues and, unless restrained, will continue. Unless and until the activities complained of are enjoined, the plaintiffs and members of the Class will suffer immediate and irreparable injury for which they are without an adequate remedy at law.

COUNT THREE
MONOPOLIZATION UNDER STATE LAW

(Against Defendants Celgene and Bristol Myers)

377. The plaintiffs repeat and incorporate by reference all preceding averments.

378. Count three is pled on behalf of the plaintiffs and the Class under the antitrust laws of each jurisdiction identified below. Count three arises from Celgene's and Bristol Myers' exclusionary, anticompetitive scheme designed to create and maintain a monopoly for brand Pomalyst and exclude or substantially exclude its generic equivalents from the market.

379. The essential elements of each antitrust claim in this count are the same. The above-alleged conduct that violates the federal Sherman Antitrust Act will, if proven, establish a claim under each of the laws cited below.

380. At all relevant times, Celgene and Bristol Myers possessed substantial market power (*i.e.*, monopoly power) in the relevant market: the market for brand Pomalyst and its FDA approved AB-rated generic equivalents ("brand and generic Pomalyst"). Celgene and Bristol Myers possessed the power to control prices in, prevent prices from falling in, and exclude competitors from, the relevant market.

381. Through its anticompetitive overarching scheme and conduct described more fully above, Celgene and Bristol Myers willfully maintained monopoly power in the market for brand and generic Pomalyst through restrictive or exclusionary conduct, rather than by means of greater business acumen or a historic accident, and thereby injured the plaintiffs and the Class. This anticompetitive conduct was undertaken with the specific intent to maintain a monopoly in the market for generic and brand Pomalyst in the United States.

382. Celgene and Bristol Myers accomplished their goals by entering into unlawful agreements to delay or prevent entry of generic Pomalyst into the market in order to lengthen the period in which Celgene's and Bristol Myers' brand Pomalyst could monopolize the market and Celgene and Bristol Myers could make supra-competitive profits.

383. The defendants' anticompetitive conduct directly impacts and disrupts commerce within each jurisdiction below.

384. Celgene's and Bristol Myers' anticompetitive activities have directly, foreseeably, and proximately caused injury to the plaintiffs and members of the Class throughout the United States. The plaintiffs' and Class members' injuries consist of: (a) being denied the opportunity to purchase lower-priced Pomalyst from Celgene and Bristol Myers, (b) paying higher prices for brand and/or generic Pomalyst than they would have paid in the absence of Celgene's and Bristol Myers' unfair, illegal, and deceptive conduct, and (c) being denied the opportunity to purchase generic versions of Pomalyst at a price substantially lower than what they were forced to pay for Pomalyst. These

injuries are of the type that the laws of the jurisdictions below were designed to prevent, and they flow from that which makes Celgene's and Bristol Myers' conduct unlawful.

385. By engaging in the foregoing conduct, Celgene and Bristol Myers intentionally and flagrantly violated the following antitrust laws:

a. Ariz. Rev. Stat. §§ 44-1401, *et seq.*, including Ariz. Rev. Stat. § 44-1403, with respect to purchases of brand and generic Pomalyst in Arizona;

b. Cal. Bus. & Prof. Code §§ 16700, *et seq.* with respect to purchases of brand and generic Pomalyst in California;

c. Conn. Gen. Stat. §§ 35-24, *et seq.*, including Conn. Gen. Stat. § 35-27, with respect to purchases of brand and generic Pomalyst in Connecticut;

d. D.C. Code §§ 28-4501, *et seq.*, including D.C. Code § 28-4503, with respect to purchases of brand and generic Pomalyst in the District of Columbia;

e. 740 Ill. Comp. Stat. 10/1, *et seq.*, including 740 Ill. Comp. Stat. 10/3, with respect to purchases of brand and generic Pomalyst in Illinois;

f. Iowa Code §§ 553.1, *et seq.*, including Iowa Code § 553.5, with respect to purchases of brand and generic Pomalyst in Iowa;

g. Kan. Stat. Ann. §§ 50-101, *et seq.*, including Kan. Stat. Ann. § 50-132, with respect to purchases of brand and generic Pomalyst in Kansas;

h. Me. Rev. Stat. Ann. tit. 10, §§ 1101, *et seq.*, including Me. Rev. Stat. Ann. tit. 10, §1102, with respect to purchases of brand and generic Pomalyst in Maine;

i. Md. Code Comm'l Law §§ 11-201, *et seq.*, including Md. Code Comm'l Law § 11-204, with respect to purchases of brand and generic Pomalyst in Maryland;

j. Mich. Comp. Laws Ann. §§ 445.771, *et seq.*, including Mich. Comp. Laws Ann. § 455.773, with respect to purchases of brand and generic Pomalyst in Michigan;

k. Minn. Stat. Ann. §§ 325D.49, *et seq.*, including Minn. Stat. Ann. § 325D.52, with respect to purchases of brand and generic Pomalyst in Minnesota;

l. Miss. Code. Ann. §§ 75-21-1, *et seq.*, including Miss. Code. Ann. § 75-21-3, with respect to purchases of brand and generic Pomalyst in Mississippi;

m. Neb. Rev. Stat. Ann. §§ 59-801, *et seq.*, including Neb. Rev. Stat. Ann. § 59-802, respect to purchases of brand and generic Pomalyst in Nebraska;

n. Nev. Rev. Stat. Ann. §§ 598A.030, *et seq.*, including Nev. Rev. Stat. Ann. § 598A.060, with respect to purchases of brand and generic Pomalyst in Nevada;

o. N.H. Rev. Stat. Ann. §§ 356:1, *et seq*., including N.H. Rev. Stat. Ann. § 356:3, with respect to purchases of brand and generic Pomalyst in New Hampshire;

p. N.M. Stat. Ann. §§ 57-1-1, *et seq*., including N.M. Stat. Ann. § 57-1-2, with respect to purchases of brand and generic Pomalyst in New Mexico;

q. N.Y. Gen. Bus. Law § 340, with respect to purchases of brand and generic Pomalyst in New York;

r. N.C. Gen. Stat. Ann. §§ 75-1, *et seq*., including N.C. Gen. Stat. Ann. § 75-2.1, with respect to purchases of brand and generic Pomalyst in North Carolina;

s. N.D. Cent. Code §§ 51-08.1, *et seq*., including N.D. Cent. Code § 51-08.1-03 with respect to purchases of brand and generic Pomalyst in North Dakota;

t. Or. Rev. Stat. §§ 646.705, *et seq*., including Or. Rev. Stat. § 646.730, with respect to purchases of brand and generic Pomalyst in Oregon;

u. R.I. Gen. Laws §§ 6-36-1, *et seq*., including R.I. Gen. Law § 6-36-5, with respect to purchases of brand and generic Pomalyst in Rhode Island;

v. S.D. Codified Laws §§ 37-1-3.1, *et seq*., including S.D. Codified Laws § 37-1-3.2, with respect to purchases of brand and generic Pomalyst in South Dakota;

w. Tenn. Code Ann. §§ 47-25-101 *et seq*., with respect to purchases of brand and generic Pomalyst in Tennessee;

x. Utah Code Ann. §§ 76-10-3101, *et seq*., including Utah Code Ann. § 76-10-3104, with respect to purchases of brand and generic Pomalyst in Utah by Utah residents or citizens;

y. Vt. Stat. Ann. tit. 9, §§ 2451, *et seq*., including Vt. Stat. Ann. tit. 9, § 2453(a), with respect to purchases of brand and generic Pomalyst in Vermont;

z. W. Va. Code §§ 47-18-1 *et seq*., including W. Va. Code § 47-18-4, with respect to purchases of brand and generic Pomalyst; and

aa. Wis. Stat. §§ 133.01, *et seq*., including Wis. Stat. § 133.04, with respect to purchases of brand and generic Pomalyst in Wisconsin.

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

COUNT FOUR
CONTRACT, COMBINATION, OR CONSPIRACY TO RESTRAIN TRADE UNDER STATE LAW

(Against All Defendants)

387. The plaintiffs repeat and incorporate by reference all preceding averments.

388. Count Four is pled on behalf of the plaintiffs and the Class under the antitrust laws of each jurisdiction identified below.

389. During the Class Period, the defendants engaged in a continuing contract, combination, conspiracy, and/or trust intended to prevent or impede the entry into the market of generic Pomalyst in order to fix, raise, inflate, stabilize, and/or maintain the price of brand and generic Pomalyst at supra-competitive levels. The defendants' conduct constitutes an unreasonable restraint of trade and commerce and violates the antitrust and other statutes set forth below.

390. In formulating and effectuating this conspiracy, the defendants performed acts in furtherance of the trust, combination, and conspiracy, including, on information and belief, participating in meetings and conversations among themselves in the United States and elsewhere during which they agreed to enter into the exclusionary contracts described above.

391. The defendants' trust, combination, and conspiracy had, or will have, the following effects: (1) delay of market entry for more affordable generic Pomalyst; (2) suppression of free and open competition; (3) restraint of price competition for brand and generic Pomalyst throughout each jurisdiction below; (4) raising, fixing, maintaining, and/or stabilizing prices for brand and generic Pomalyst at artificially high levels throughout each jurisdiction below; and (4) the plaintiffs and Class members have paid, and will continue to pay, supra-competitive, artificially inflated prices for Pomalyst.

392. During the class period, the defendants' illegal conduct substantially affected commerce in each jurisdiction below.

393. As a direct and proximate result of the defendants' unlawful conduct, theplaintiffs and Class members have been injured in their business and property and are threatened with further injury.

394. The plaintiffs and members of the Class seek all forms of relief available under each of the statutes listed below, including injunctive relief, damages, treble damages, and costs of suit, including a reasonable attorney's fee.

395. The defendants' anticompetitive acts described above were knowing and willful and constitute violations or flagrant violations of the following statutes:

a. Ariz. Rev. Stat. §§ 44-1401, *et seq.*, including Ariz. Rev. Stat. § 44-1402, with respect to purchases of brand and generic Pomalyst in Arizona;

b. Cal. Bus. & Prof. Code §§ 16700, *et seq.*, including Cal. Bus. & Prof. Code §§ 16720 and 16726, with respect to purchases of brand and generic Pomalyst in California;

c. Conn. Gen. Stat. §§ 35-24, *et seq.*, including Conn. Gen. Stat. § 35-26, with respect to purchases of brand and generic Pomalyst in Connecticut;

d. D.C. Code §§ 28-4501, *et seq.*, including D.C. Code § 28-4502, with respect to purchases of brand and generic Pomalyst in the District of Columbia;

e. 740 Ill. Comp. Stat. 10/1, *et seq.*, including 740 Ill. Comp. Stat. 10/3, with respect to purchases of brand and generic Pomalyst in Illinois;

f. Iowa Code §§ 553.1, *et seq.*, including Iowa Code § 553.4, with respect to purchases of brand and generic Pomalyst in Iowa;

g. Kan. Stat. Ann. §§ 50-101, *et seq.*, including Kan. Stat. Ann. § 50-112, with respect to purchases of brand and generic Pomalyst in Kansas;

h. Me. Rev. Stat. Ann. tit. 10, §§ 1101, *et seq.*, including Me. Rev. Stat. Ann. tit. 10, §1102, with respect to purchases of brand and generic Pomalyst in Maine;

i. Md. Code Comm'l Law §§ 11-201, *et seq.*, including Md. Code Comm'l Law § 11-204, with respect to purchases of brand and generic Pomalyst in Maryland;

j. Mich. Comp. Laws Ann. §§ 445.771, *et seq.*, including Mich. Comp. Laws Ann. § 455.772, with respect to purchases of brand and generic Pomalyst in Michigan;

k. Minn. Stat. §§ 325D.49, *et seq.*, including Minn. Stat. § 325D.51, with respect to purchases of brand and generic Pomalyst in Minnesota;

l. Miss. Code. Ann. §§ 75-21-1, *et seq*., including Miss. Code. Ann. § 75-21-3, with respect to purchases of brand and generic Pomalyst in Mississippi;

m. Neb. Rev. Stat. Ann. §§ 59-801, *et seq*. with respect to purchases of brand and generic Pomalyst in Nebraska;

n. Nev. Rev. Stat. Ann. §§ 598A.030, *et seq*., including Nev. Rev. Stat. Ann. § 598A.060, with respect to purchases of brand and generic Pomalyst in Nevada;

o. N.H. Rev. Stat. Ann. §§ 356:1, *et seq*., including N.H. Rev. Stat. Ann. § 356:2, with respect to purchases of brand and generic Pomalyst in New Hampshire;

p. N.M. Stat. Ann. §§ 57-1-1, *et seq*. with respect to purchases of brand and generic Pomalyst in New Mexico;

q. N.Y. Gen. Bus. Law § 340 with respect to purchases of brand and generic Pomalyst in New York;

r. N.C. Gen. Stat. Ann. §§ 75-1, *et seq*. with respect to purchases of brand and generic Pomalyst in North Carolina;

s. N.D. Cent. Code §§ 51-08.1, *et seq*., including N.D. Cent. Code § 51-08.1-02 with respect to purchases of brand and generic Pomalyst in North Dakota;

t. Or. Rev. Stat. §§ 646.705, *et seq*., including Or. Rev. Stat. § 646.725, with respect to purchases of brand and generic Pomalyst in Oregon;

u. R.I. Gen. Laws §§ 6-36-1, *et seq*., including R.I. Gen. Laws § 6-36-4, with respect to purchases of brand and generic Pomalyst in Rhode Island;

v. S.D. Codified Laws §§ 37-1-3.1, *et seq*. with respect to purchases of brand and generic Pomalyst in South Dakota;

w. Tenn. Code Ann. §§ 47-25-101 *et seq*. with respect to purchases of brand and generic Pomalyst in Tennessee;

x. Utah Code Ann. §§ 76-10-3101, *et seq*., including Utah Code Ann. § 76-10-3104, with respect to purchases of brand and generic Pomalyst in Utah by Utah residents or citizens;

y. Vt. Stat. Ann. tit. 9, §§ 2451, *et seq*., including Vt. Stat. Ann. tit. 9, § 2453(a), with respect to purchases of brand and generic Pomalyst in Vermont;

z. W. Va. Code §§ 47-18-1 *et seq*., including W. Va. Code § 47-18-3, with respect to purchases of brand and generic Pomalyst; and

aa. Wis. Stat. §§ 133.01, *et seq*., including Wis. Stat. § 133.03, with respect to purchases of brand and generic Pomalyst in Wisconsin.

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

COUNT FIVE
VIOLATIONS OF STATE CONSUMER PROTECTION LAWS

(Against All Defendants)

397. The plaintiffs repeat and incorporate by reference all preceding averments.

398. The defendants' above-described scheme and conduct constitute unfair competition or unfair, unconscionable conduct or deceptive or fraudulent acts or practices in violation of the consumer protection statutes set forth below.

399. Celgene and Bristol Myers established, maintained, or used a monopoly, or attempted to establish a monopoly, of trade or commerce in the market for brand and generic Pomalyst, a substantial part of which occurred within each jurisdiction identified below. Celgene and Bristol Myers intended to injure competitors and exclude or substantially lessen competition. Celgene and Bristol Myers intended to injure consumers by unlawfully reaping supra-competitive profits.

400. All the defendants engaged in a continuing contract, combination, conspiracy, and/or trust intended to prevent or impede the entry into the market of generic Pomalyst in order to fix, raise, inflate, stabilize, and/or maintain the price of brand and generic Pomalyst at supra-competitive levels. The defendants' conduct constitutes an unreasonable restraint of trade and commerce and violates the antitrust and other statutes set forth below.

401. By unlawfully delaying the entry of generic Pomalyst and the initiation of fulsome generic competition in the market for brand and generic Pomalyst, the defendants created a

fraudulent or deceptive act or practice committed by a supplier in connection with a consumer transaction.

402. The defendants' conduct constitutes consumer-oriented deceptive acts or practices that resulted in consumer injury and broad adverse impact on the public at large and harmed the public interest of consumers in an honest marketplace in which economic activity is conducted in a competitive manner.

403. The defendants withheld material facts and information from the plaintiffs and Class members, including that Celgene and Bristol Myers were unlawfully conspiring to exclude manufacturers of generic Pomalyst from the market and monopolizing the market for Pomalyst, thereby profiting from the resulting supra-competitive prices paid by the plaintiffs and Class members who made purchases of or reimbursements for Pomalyst. The plaintiffs and Class members paid higher prices for brand and generic Pomalyst than they would have paid but for the defendants' actions.

404. The defendants' conduct was willful and knowing.

405. The defendants intended to deceive the plaintiffs and Class members regarding the nature of its actions within the stream of commerce in each jurisdiction below.

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

407. The defendants' conduct had a direct or indirect impact upon the ability of the plaintiffs and members of the Class to protect themselves.

408. The plaintiffs and members of the Class purchased (or reimbursed their members for their purchases of) goods, namely Pomalyst, primarily for personal, family, or household purposes.

409. The plaintiffs and members of the Class include non-profit labor unions and non-profit health and welfare plans whose core mission includes providing health benefits, including prescription drug benefits, to their members and members' spouses and dependents. In carrying out that core mission, those labor unions and health and welfare plans purchase or provide reimbursement for brand and generic Pomalyst.

410. The plaintiffs and Class members who do not profit from purchasing brand or generic Pomalyst or from reimbursing their members for purchases of brand or generic Pomalyst are "consumers" under the consumer protection laws of the jurisdictions below.

411. There was and is a gross disparity between the price that the plaintiffs and Class members paid for Pomalyst and the value they received, given that a less expensive generic equivalent should have been available.

412. As a direct and proximate result of the defendants' unlawful conduct, the plaintiffs and members of the Class have been injured and are threatened with continued injury.

413. As a direct and proximate result of the defendants' anticompetitive, deceptive, unfair, fraudulent, and/or unconscionable acts or practices, the plaintiffs and the Class were denied the opportunity to purchase lower-priced FDA-approved AB-rated generic versions of Pomalyst and paid higher prices for branded and generic Pomalyst than they should have paid.

414. The gravity of harm from the defendants' wrongful conduct significantly outweighs any conceivable utility from that conduct. The plaintiffs and Class members could not reasonably have avoided injury from the defendants' wrongful conduct.

415. The defendants' unlawful conduct substantially affected the trade and commerce of each jurisdiction in which brand or generic Pomalyst was sold.

416. The defendants' unfair and deceptive acts described above were knowing and willful, and constitute violations or flagrant violations of the following unfair trade practices and consumer protection statutes:

a. Ariz. Rev. Stat. §§ 44-1521, *et seq.*, with respect to purchases in Arizona;

b. Cal. Bus. & Prof. Code §§ 17200, *et seq.*, including §§ 17203 and 17204, with respect to purchases in California;

c. D.C. Code §§ 28-3901, *et seq.*, with respect to purchases in the District of Columbia;

d. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases in Florida;

e. 815 ILCS §§ 505/1, *et seq.*, with respect to purchases in Illinois;

f. Mich. Comp. Laws Ann. §§ 445.901, *et seq.*, on behalf of persons residing or injured in Michigan;

g. Minn. Stat. §§ 325F.68, *et seq.*, with respect to purchases in Minnesota;

h. Mo. Rev. Stat. §§ 407.010, *et seq.*, with respect to purchases in Missouri;

i. Mont. Code, §§ 30-14-101, *et seq.*, with respect to purchases in Montana;

j. Neb. Rev. Stat. §§ 59-1601, *et seq.*, with respect to purchases in Nebraska;

k. Nev. Rev. Stat. §§ 598.0903, *et seq.*, with respect to purchases in Nevada;

l. N.H. Rev. Stat. §§ 358-A:1, *et seq.*, with respect to purchases in New Hampshire and purchases by New Hampshire residents;

m. N.M. Stat. Ann. §§ 57-12-1, *et seq.*, with respect to purchases in New Mexico;

n. New York Gen. Bus. Law § 349 with respect to purchases in New York;

o. N.C. Gen. Stat. §§ 75-1.1, *et seq.*, with respect to purchases in North Carolina;

p. Or. Rev. Stat. §§ 646.605, *et seq.*, with respect to purchases in Oregon;

q. R.I. Gen. Laws §§ 6-13.1-1, *et seq.*, with respect to purchases in Rhode Island;

r. S.C. Code §§ 39-5-10, *et seq.*, with respect to purchases in South Carolina;

s. S.D. Codified Laws §§ 37-24-1, *et seq.*, with respect to purchases in South Dakota;

t. Tenn. Code. §§ 47-18-101, *et seq.* with respect to purchases in Tennessee;

u. Utah Code. §§ 13-11-1, *et seq.* with respect to purchases in Utah;

v. Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases in Vermont; and

w. West Va. Code §§ 46A-6-101, *et seq.*, with respect to purchases in West Virginia.

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

COUNT SIX
UNJUST ENRICHMENT UNDER STATE LAW

(Against Defendants Celgene and Bristol Myers)

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

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

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

421. It would be futile for the plaintiffs and Class members to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which they indirectly purchased Pomalyst, as those intermediaries are not liable for, and would not compensate the plaintiffs and Class members for, Celgene's and Bristol Myers' unlawful conduct.

422. The economic benefit Celgene and Bristol Myers derived from purchases of Pomalyst by the plaintiffs and Class members is a direct and proximate result of Celgene's and Bristol Myers' unlawful and anticompetitive practices.

423. The financial benefits Celgene and Bristol Myers derived are ill-gotten gains that rightfully belong to the plaintiffs and Class members who paid and continue to pay artificially inflated prices that inured to Celgene's and Bristol Myers' benefit.

424. It would be inequitable under unjust enrichment principles under the laws of the jurisdictions identified below for Celgene and Bristol Myers to retain any of the benefits they derived from their unfair, anticompetitive, and unlawful methods, acts, and trade practices.

425. Celgene and Bristol Myers are aware of and appreciate the benefits that the plaintiffs and Class members have bestowed upon them.

426. Celgene and Bristol Myers should be ordered to disgorge all unlawful or inequitable proceeds they received to a common fund for the benefit of the plaintiffs and Class members who collectively have no adequate remedy at law.

427. A constructive trust should be imposed upon all unlawful or inequitable sums Celgene and Bristol Myers received that are traceable to the plaintiffs and members of the Class.

428. By engaging in the unlawful or inequitable conduct described above, which deprived the plaintiffs and Class members of the opportunity to purchase lower-priced generic versions of Pomalyst and forced them to pay higher prices for branded and generic versions of Pomalyst,

Celgene and Bristol Myers have been unjustly enriched in violation of the common law of the following jurisdictions:

Alabama

429. Celgene and Bristol Myers unlawfully profited from overcharges paid by the plaintiffs and Class members who made purchases of or reimbursements for Pomalyst or its AB-rated generic equivalents in Alabama. The plaintiffs and Class members paid higher prices for brand and generic Pomalyst than they would have paid but for Celgene's actions.

430. Celgene and Bristol Myers received money from the plaintiffs and the Class as a direct result of the unlawful overcharges and have retained this money.

431. Celgene and Bristol Myers have benefitted at the expense of the plaintiffs and the Class from revenue resulting from unlawful overcharges for Pomalyst and/or its AB-rated generic equivalents.

432. It is inequitable for Celgene and Bristol Myers to accept and retain the benefits received without compensating the plaintiffs and the Class.

Alaska

433. Celgene and Bristol Myers unlawfully profited from overcharges paid by the plaintiffs and Class members who made purchases of or reimbursements for Pomalyst and/or its AB-rated generic equivalents in Alaska. The plaintiffs and Class members paid higher prices for brand and generic Pomalyst than they would have paid but for Celgene's actions.

434. Celgene and Bristol Myers have received a benefit from the Class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Celgene and Bristol Myers, to the economic detriment of the plaintiffs and the Class.

435. Celgene and Bristol Myers appreciated the benefits bestowed upon them by the plaintiffs and the Class.

436. Celgene and Bristol Myers accepted and retained the benefits bestowed upon them under inequitable and unjust circumstances arising from unlawful overcharges to the plaintiffs and the Class.

437. Under the circumstances, it would be inequitable for Celgene and Bristol Myers to retain such benefits without compensating the plaintiffs and the Class.

Arizona

438. Celgene and Bristol Myers unlawfully profited from overcharges paid by the plaintiffs and Class members who made purchases of or reimbursements for Pomalyst and/or its AB-rated generic equivalents in Arizona. The plaintiffs and Class members paid higher prices for brand and generic Pomalyst than they would have paid but for Celgene's and Bristol Myers' actions.

439. Celgene and Bristol Myers have been enriched by revenue resulting from unlawful overcharges for branded and generic Pomalyst.

440. The plaintiffs and the Class have been impoverished by the overcharges for branded and generic Pomalyst resulting from Celgene's and Bristol Myers' unlawful conduct.

441. Celgene's and Bristol Myers' enrichment and the impoverishment of the plaintiffs and the Class are connected. Celgene and Bristol Myers have paid no consideration to any other person for any benefits they received from the plaintiffs and Class members.

442. There is no justification for Celgene's and Bristol Myers' receipt of the benefits causing their enrichment and the impoverishment of the plaintiffs and the Class because the plaintiffs and the Class paid supra-competitive prices that inured to Celgene's and Bristol Myers' benefit, and it would be inequitable for Celgene and Bristol Myers to retain any revenue gained from their unlawful overcharges.

443. The plaintiffs and the Class have no adequate remedy at law.

Arkansas

444. Celgene and Bristol Myers unlawfully profited from overcharges paid by the plaintiffs and Class members who made purchases of or reimbursements for Pomalyst and/or its AB-rated generic equivalents in Arkansas. The plaintiffs and Class members paid higher prices for brand and generic Pomalyst than they would have paid but for Celgene's actions.

445. Celgene and Bristol Myers received money from the plaintiffs and the Class as a direct result of the unlawful overcharges and have retained this money.

446. Celgene and Bristol Myers has paid no consideration to any other person in exchange for this money.

447. Under the circumstances, it would be inequitable for Celgene and Bristol Myers to retain such benefits without compensating the plaintiffs and the Class.

California

448. Celgene and Bristol Myers unlawfully profited from overcharges paid by the plaintiffs and Class members who made purchases of or reimbursements for Pomalyst and/or its AB-rated generic equivalents in California. The plaintiffs and Class members paid higher prices for brand and generic Pomalyst than they would have paid but for Celgene's and Bristol Myers' actions.

449. Celgene and Bristol Myers have received a benefit from the plaintiffs and the Class as a direct result of Celgene's and Bristol Myers' fraudulent and misleading conduct and the resulting unlawful overcharges to the Class.

450. Celgene and Bristol Myers retained the benefits bestowed upon it under inequitable and unjust circumstances at the expense of the plaintiffs and the Class.

451. The plaintiffs and members of the Class are entitled to restitution from Celgene and Bristol Myers.

Colorado

452. Celgene and Bristol Myers unlawfully profited from overcharges paid by the plaintiffs and Class members who made purchases of or reimbursements for Pomalyst and/or its AB-rated generic equivalents in Colorado. The plaintiffs and Class members paid higher prices for brand and generic Pomalyst than they would have paid but for Celgene's and Bristol Myers' actions.

453. Celgene and Bristol Myers have received a benefit from the Class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Celgene and Bristol Myers, to the economic detriment of the plaintiffs and the Class.

454. Celgene and Bristol Myers retained the benefit bestowed upon them under inequitable and unjust circumstances arising from unlawful overcharges to the plaintiffs and the Class.

455. Under the circumstances, it would be inequitable and unjust for Celgene and Bristol Myers to retain such benefits without compensating the plaintiffs and Class members.

Connecticut

456. Celgene and Bristol Myers unlawfully profited from overcharges paid by the plaintiffs and Class members who made purchases of or reimbursements for Pomalyst and/or its AB-rated generic equivalents in Connecticut. The plaintiffs and Class members paid higher prices for brand and generic Pomalyst than they would have paid but for Celgene's and Bristol Myers' actions.

457. Celgene and Bristol Myers have received a benefit from the Class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Celgene and Bristol Myers, to the economic detriment of the plaintiffs and the Class.

458. Celgene and Bristol Myers have paid no consideration to any other person in exchange for this benefit.

459. Celgene and Bristol Myers retained the benefits bestowed upon them under inequitable and unjust circumstances at the expense of the plaintiffs and Class members.

460. Under the circumstances, it would be inequitable and unjust for Celgene and Bristol Myers to retain such benefits.

Delaware

461. Celgene and Bristol Myers unlawfully profited from overcharges paid by the plaintiffs and Class members who made purchases of or reimbursements for Pomalyst and/or its AB-rated generic equivalents in Delaware. The plaintiffs and Class members paid higher prices for brand and generic Pomalyst than they would have paid but for Celgene's and Bristol Myers' actions.

462. Celgene and Bristol Myers have been enriched by revenue resulting from unlawful overcharges for branded and generic Pomalyst.

463. The plaintiffs and the Class have been impoverished by the overcharges for branded and generic Pomalyst resulting from Celgene's and Bristol Myers' unlawful conduct.

464. Celgene's and Bristol Myers' enrichment and the impoverishment of the plaintiffs and the Class are connected. Celgene and Bristol Myers have paid no consideration to any other person for any benefits they received from the plaintiffs and Class members.

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

466. The plaintiffs and the Class have no remedy at law.

District of Columbia

467. Celgene and Bristol Myers unlawfully profited from overcharges paid by the plaintiffs and Class members who made purchases of or reimbursements for Pomalyst and/or its AB-rated generic equivalents in the District of Columba. The plaintiffs and Class members paid higher prices for brand and generic Pomalyst than they would have paid but for Celgene's and Bristol Myers actions.

468. Celgene and Bristol Myers have received a benefit from the Class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Celgene and Bristol Myers, to the economic detriment of plaintiffs and the Class.

469. Celgene and Bristol Myers accepted and retained the benefit bestowed upon them under inequitable and unjust circumstances arising from unlawful overcharges to the Class.

470. Under the circumstances, it would be inequitable and unjust for Celgene and Bristol Myers to retain such benefits.

Florida

471. Celgene and Bristol Myers unlawfully profited from overcharges paid by the plaintiffs and Class members who made purchases of or reimbursements for Pomalyst and/or its AB-rated generic equivalents in Florida. The plaintiffs and Class members paid higher prices for brand and generic Pomalyst than they would have paid but for Celgene's and Bristol Myers' actions.

472. Celgene and Bristol Myers have received a benefit from the Class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Celgene and Bristol Myers, to the economic detriment of plaintiffs and the Class.

473. Celgene and Bristol Myers appreciated and retained the benefit bestowed upon it by the plaintiffs and Class members.

474. It is inequitable and unjust for Celgene and Bristol Myers to accept and retain such benefits without compensating the plaintiffs and Class members.

Georgia

475. Celgene and Bristol Myers unlawfully profited from overcharges paid by the plaintiffs and Class members who made purchases of or reimbursements for Pomalyst and/or its AB-rated generic equivalents in Georgia. The plaintiffs and Class members paid higher prices for brand and generic Pomalyst than they would have paid but for Celgene's and Bristol Myers' actions.

476. Celgene and Bristol Myers have received a benefit from the Class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Celgene and Bristol Myers, to the economic detriment of the plaintiffs and the Class.

477. Under the circumstances, it would be inequitable for Celgene and Bristol Myers to retain such benefits without compensating the plaintiffs and the Class.

Hawaii

478. Celgene and Bristol Myers unlawfully profited from overcharges paid by the plaintiffs and Class members who made purchases of or reimbursements for Pomalyst and/or its AB-rated generic equivalents in Hawaii. The plaintiffs and Class members paid higher prices for brand and generic Pomalyst than they would have paid but for Celgene's and Bristol Myers' actions.

479. Celgene and Bristol Myers have received a benefit from the Class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Celgene and Bristol Myers, to the economic detriment of the plaintiffs and the Class.

480. It is unjust for Celgene and Bristol Myers to retain such benefits without compensating the plaintiffs and the Class.

Idaho

481. Celgene and Bristol Myers unlawfully profited from overcharges paid by the plaintiffs and Class members who made purchases of or reimbursements for Pomalyst and/or its AB-rated generic equivalents in Idaho. The plaintiffs and Class members paid higher prices for brand and generic Pomalyst than they would have paid but for Celgene's and Bristol Myers' actions.

482. Celgene and Bristol Myers have received a benefit from the plaintiffs and the Class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Celgene, to the economic detriment of the plaintiffs and the Class.

483. Celgene and Bristol Myers appreciated the benefit conferred upon them by the Class.

484. Under the circumstances, it would be inequitable for Celgene and Bristol Myers to retain such benefits without compensating the Class.

Illinois

485. Celgene and Bristol Myers unlawfully profited from overcharges paid by the plaintiffs and Class members who made purchases of or reimbursements for Pomalyst and/or its AB-rated generic equivalents in Illinois. The plaintiffs and Class members paid higher prices for brand and generic Pomalyst than they would have paid but for Celgene's and Bristol Myers' actions.

486. Celgene and Bristol Myers have received a benefit from the Class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Celgene and Bristol Myers, to the economic detriment of the plaintiffs and the Class.

487. Celgene and Bristol Myers retained the benefits bestowed upon them under unjust circumstances arising from unlawful overcharges to the Class.

488. It is against equity, justice, and good conscience for Celgene and Bristol Myers to be permitted to retain the revenue resulting from their unlawful overcharges without compensating the plaintiffs and Class members.

Iowa

489. Celgene and Bristol Myers unlawfully profited from overcharges paid by the plaintiffs and Class members who made purchases of or reimbursements for Pomalyst and/or its AB-rated generic equivalents in Iowa. The plaintiffs and Class members paid higher prices for brand and generic Pomalyst than they would have paid but for Celgene's and Bristol Myers' actions.

490. Celgene and Bristol Myers have been enriched by revenue resulting from unlawful overcharges for Pomalyst and/or its AB-rated generic equivalents, which revenue resulted from anticompetitive prices paid by the Class, which inured to Celgene's and Bristol Myers' benefit.

491. Celgene's and Bristol Myers' enrichment has occurred at the expense of the Class.

492. It is against equity and good conscience for Celgene and Bristol Myers to retain such benefits without compensating the Class.

Kansas

493. Celgene and Bristol Myers unlawfully profited from overcharges paid by the plaintiffs and Class members who made purchases of or reimbursements for Pomalyst and/or its AB-rated generic equivalents in Kansas. The plaintiffs and Class members paid higher prices for brand and generic Pomalyst than they would have paid but for Celgene's and Bristol Myers' actions.

494. Celgene and Bristol Myers have received a benefit from the Class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive

prices that inured to the benefit of Celgene and Bristol Myers, to the economic detriment of the plaintiffs and the Class.

495. Celgene and Bristol Myers retained the benefits bestowed upon them under unjust circumstances arising from unlawful overcharges to the Class.

496. Celgene and Bristol Myers were unjustly enriched at the expense of the plaintiffs and the Class members.

Kentucky

497. Celgene and Bristol Myers unlawfully profited from overcharges paid by the plaintiffs and Class members who made purchases of or reimbursements for Pomalyst and/or its AB-rated generic equivalents in Kentucky. The plaintiffs and Class members paid higher prices for brand and generic Pomalyst than they would have paid but for Celgene's and Bristol Myers' actions.

498. Celgene and Bristol Myers have received a benefit from the Class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Celgene and Bristol Myers, to the economic detriment of the plaintiffs and the Class.

499. Celgene and Bristol Myers appreciated the benefit bestowed upon them by the Class.

500. Under the circumstances, it would be inequitable for Celgene and Bristol Myers to retain such benefits without compensating the Class.

Louisiana

501. Celgene and Bristol Myers unlawfully profited from overcharges paid by the plaintiffs and Class members who made purchases of or reimbursements for Pomalyst and/or its AB-rated generic equivalents in Louisiana. The plaintiffs and Class members paid higher prices for brand and generic Pomalyst than they would have paid but for Celgene's and Bristol Myers' actions.

502. Celgene and Bristol Myers have been enriched by revenue resulting from unlawful overcharges for brand and Pomalyst.

503. The plaintiffs and Class members have been impoverished by the overcharges for brand and generic Pomalyst resulting from Celgene's and Bristol Myers' unlawful conduct.

504. Celgene's and Bristol Myers' enrichment and the impoverishment of the plaintiffs and the Class are connected.

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

506. The plaintiffs and the Class have no other remedy at law.

Maine

507. Celgene and Bristol Myers unlawfully profited from overcharges paid by the plaintiffs and Class members who made purchases of or reimbursements for Pomalyst and/or its AB-rated generic equivalents in Maine. The plaintiffs and Class members paid higher prices for brand and generic Pomalyst than they would have paid but for Celgene's and Bristol Myers' actions.

508. Celgene and Bristol Myers have received a benefit from the Class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Celgene and Bristol Myers, to the economic detriment of the plaintiffs and the Class.

509. Celgene and Bristol Myers wer aware of or appreciated the benefit bestowed upon them by the plaintiffs and the Class.

510. Under the circumstances, it would be inequitable for Celgene and Bristol Myers to retain such benefits without compensating the Class.

Maryland

511. Celgene and Bristol Myers unlawfully profited from overcharges paid by the plaintiffs and Class members who made purchases of or reimbursements for Pomalyst and/or its AB-rated generic equivalents in Maryland. The plaintiffs and Class members paid higher prices for brand and generic Pomalyst than they would have paid but for Celgene's and Bristol Myers' actions.

512. Celgene and Bristol Myers have received a benefit from the Class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Celgene and Bristol Myers, to the economic detriment of the plaintiffs and the Class.

513. Celgene and Bristol Myers were aware of or appreciated the benefit bestowed upon them by the Class.

514. Under the circumstances, it would be inequitable for Celgene and Bristol Myers to retain such benefits without compensating the Class.

Massachusetts

515. Celgene and Bristol Myers unlawfully profited from overcharges paid by the plaintiffs and Class members who made purchases of or reimbursements for Pomalyst and/or its AB-rated generic equivalents in Massachusetts. The plaintiffs and Class members paid higher prices for brand and generic Pomalyst than they would have paid but for Celgene's and Bristol Myers' actions.

516. Celgene and Bristol Myers have received a benefit from the Class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive

prices that inured to the benefit of Celgene and Bristol Myers, to the economic detriment of the plaintiffs and the Class.

517. Celgene and Bristol Myers were aware of or appreciated the benefit conferred upon them by the Class.

518. Under the circumstances, it would be inequitable for Celgene and Bristol Myers to retain such benefits without compensating the Class. Fairness and good conscience require Celgene and Bristol Myers not be permitted to retain the revenue resulting from its unlawful overcharges at the expense of the plaintiffs and Class members.

Michigan

519. Celgene and Bristol Myers unlawfully profited from overcharges paid by the plaintiffs and Class members who made purchases of or reimbursements for Pomalyst and/or its AB-rated generic equivalents in Michigan. The plaintiffs and Class members paid higher prices for brand and generic Pomalyst than they would have paid but for Celgene's and Bristol Myers' actions.

520. Celgene and Bristol Myers have received a benefit from the Class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Celgene and Bristol Myers.

521. Celgene and Bristol Myers retained the benefits bestowed upon them under unjust circumstances arising from unlawful overcharges to the Class.

522. Celgene and Bristol Myers were unjustly enriched at the expense of the plaintiffs and the Class members.

Minnesota

523. Celgene and Bristol Myers unlawfully profited from overcharges paid by the plaintiffs and Class members who made purchases of or reimbursements for Pomalyst and/or its

AB-rated generic equivalents in Minnesota. The plaintiffs and Class members paid higher prices for brand and generic Pomalyst than they would have paid but for Celgene's and Bristol Myers' actions.

524. Celgene and Bristol Myers appreciated and knowingly accepted the benefits bestowed upon them by the plaintiffs and Class members. Celgene and Bristol Myers have paid no consideration to any other person for any of the benefits they have received from the plaintiffs and Class members.

525. It would be inequitable for Celgene and Bristol Myers to accept and retain such benefits without compensating the Class.

Mississippi

526. Celgene and Bristol Myers unlawfully profited from overcharges paid by the plaintiffs and Class members who made purchases of or reimbursements for Pomalyst and/or its AB-rated generic equivalents in Mississippi. The plaintiffs and Class members paid higher prices for brand and generic Pomalyst than they would have paid but for Celgene's and Bristol Myers' actions.

527. Celgene and Bristol Myers received money from the Class as a direct result of the unlawful overcharges. Celgene and Bristol Myers retained the benefit of overcharges received on the sales of brand Pomalyst, which in equity and good conscience belong to the Class on account of Celgene's and Bristol Myers' anticompetitive conduct.

528. Under the circumstances, it would be inequitable for Celgene and Bristol Myers to retain such benefits without compensating the Class.

Missouri

529. Celgene and Bristol Myers unlawfully profited from overcharges paid by the plaintiffs and Class members who made purchases of or reimbursements for Pomalyst and/or its AB-rated generic equivalents in Missouri. The plaintiffs and Class members paid higher prices for brand and generic Pomalyst than they would have paid but for Celgene's and Bristol Myers' actions.

530. Celgene and Bristol Myers have received a benefit from the Class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Celgene and Bristol Myers, to the economic detriment of the plaintiffs and the Class.

531. Celgene and Bristol Myers appreciated the benefit bestowed upon them by the Class.

532. Celgene and Bristol Myers accepted and retained the benefit bestowed upon them under inequitable and unjust circumstances arising from unlawful overcharges to the Class.

Montana

533. Celgene and Bristol Myers unlawfully profited from overcharges paid by the plaintiffs and Class members who made purchases of or reimbursements for Pomalyst and/or its AB-rated generic equivalents in Montana. The plaintiffs and Class members paid higher prices for brand and generic Pomalyst than they would have paid but for Celgene's and Bristol Myers' actions.

534. The plaintiffs and the Class have conferred an economic benefit upon Celgene and Bristol Myers in the form of revenue resulting from unlawful overcharges, to the economic detriment of the plaintiffs and the Class.

535. Under the circumstances, it would be inequitable for Celgene and Bristol Myers to retain such benefits without compensating the Class.

Nebraska

536. Celgene and Bristol Myers unlawfully profited from overcharges paid by the plaintiffs and Class members who made purchases of or reimbursements for Pomalyst and/or its AB-rated generic equivalents in Nebraska. The plaintiffs and Class members paid higher prices for brand and generic Pomalyst than they would have paid but for Celgene's and Bristol Myers' actions.

537. Celgene and Bristol Myers received money from the Class as a direct result of the unlawful overcharges and have retained this money. Celgene and Bristol Myers have paid no consideration to any other person in exchange for this money.

538. In justice and fairness, Celgene and Bristol Myers should disgorge such money and remit the overcharged payments back to the Class.

Nevada

539. Celgene and Bristol Myers unlawfully profited from overcharges paid by the plaintiffs and Class members who made purchases of or reimbursements for Pomalyst and/or its AB-rated generic equivalents in Nevada. The plaintiffs and Class members paid higher prices for brand and generic Pomalyst than they would have paid but for Celgene's and Bristol Myers' actions.

540. The plaintiffs and the Class have conferred an economic benefit upon Celgene and Bristol Myers in the form of revenue resulting from unlawful overcharges.

541. Celgene and Bristol Myers appreciated the benefits bestowed upon them by the Class, for which they has paid no consideration to any other person.

542. Celgene and Bristol Myers have knowingly accepted and retained the benefits bestowed upon them by the plaintiffs and Class members.

543. The circumstance under which Celgene and Bristol Myers have accepted and retained the benefits bestowed on them by the plaintiffs and the Class are inequitable in that they result from Celgene's and Bristol Myers' unlawful overcharges.

New Hampshire

544. Celgene and Bristol Myers unlawfully profited from overcharges paid by the plaintiffs and Class members who made purchases of or reimbursements for Pomalyst and/or its AB-rated generic equivalents in New Hampshire. The plaintiffs and Class members paid higher

prices for brand and generic Pomalyst than they would have paid but for Celgene's and Bristol Myers' actions.

545. Celgene and Bristol Myers have received a benefit from the Class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Celgene and Bristol Myers, to the economic detriment of the plaintiffs and the Class.

546. Under the circumstances, it would be unconscionable for Celgene and Bristol Myers to retain such benefits.

New Jersey

547. Celgene and Bristol Myers unlawfully profited from overcharges paid by the plaintiffs and Class members who made purchases of or reimbursements for Pomalyst and/or its AB-rated generic equivalents in New Jersey. The plaintiffs and Class members paid higher prices for brand and generic Pomalyst than they would have paid but for Celgene's and Bristol Myers' actions.

548. Celgene and Bristol Myers have received a benefit from the Class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Celgene and Bristol Myers, to the economic detriment of the plaintiffs and the Class.

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

550. Celgene and Bristol Myers have paid no consideration to any other person for any of the unlawful benefits they received from the plaintiffs and Class members with respect to Celgene's and Bristol Myers' sales of brand Pomalyst.

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

New Mexico

552. Celgene and Bristol Myers unlawfully profited from overcharges paid by the plaintiffs and Class members who made purchases of or reimbursements for Pomalyst and/or its AB-rated generic equivalents in New Mexico. The plaintiffs and Class members paid higher prices for brand and generic Pomalyst than they would have paid but for Celgene's and Bristol Myers' actions.

553. Celgene and Bristol Myers have knowingly benefitted at the expense of the Class from revenue resulting from unlawful overcharges for Pomalyst.

554. To allow Celgene and Bristol Myers to retain the benefits would be unjust because the benefits resulted from anticompetitive pricing that inured to Celgene's and Bristol Myers' benefit and because Celgene and Bristol Myers have paid no consideration to any other person for any of the benefits they received.

New York

555. Celgene and Bristol Myers unlawfully profited from overcharges paid by the plaintiffs and Class members who made purchases of or reimbursements for Pomalyst and/or its AB-rated generic equivalents in New York. The plaintiffs and Class members paid higher prices for brand and generic Pomalyst than they would have paid but for Celgene's and Bristol Myers' actions.

556. Celgene and Bristol Myers have been enriched by revenue resulting from unlawful overcharges for brand Pomalyst, which revenue resulted from anticompetitive prices paid by the Class, which inured to Celgene's and Bristol Myers' benefit.

557. Celgene's and Bristol Myers' enrichment has occurred at the expense of the Class.

558. It is against equity and good conscience for Celgene and Bristol Myers to be permitted to retain the revenue resulting from their unlawful overcharges.

North Carolina

559. Celgene and Bristol Myers unlawfully profited from overcharges paid by the plaintiffs and Class members who made purchases of or reimbursements for Pomalyst and/or its AB-rated generic equivalents in North Carolina. The plaintiffs and Class members paid higher prices for brand and generic Pomalyst than they would have paid but for Celgene's and Bristol Myers' actions.

560. Celgene and Bristol Myers have received a benefit from the Class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Celgene and Bristol Myers, to the economic detriment of the plaintiffs and the Class.

561. The Class did not interfere with Celgene's and Bristol Myers' affairs in any manner that conferred these benefits upon Celgene and Bristol Myers.

562. The benefits conferred upon Celgene and Bristol Myers were not gratuitous, in that they comprised revenue created by unlawful overcharges arising from Celgene's and Bristol Myers' actions in delaying entry of generic versions of Pomalyst to the market and preventing fulsome generic competition in the market for brand and generic Pomalyst.

563. The benefits conferred Celgene and Bristol Myers are measurable, in that the revenue Celgene and Bristol Myers have earned due to unlawful overcharges is ascertainable by review of sales records.

564. Celgene and Bristol Myers consciously accepted the benefits conferred upon them and continue to do so as of the date of this filing.

North Dakota

565. Celgene and Bristol Myers unlawfully profited from overcharges paid by the plaintiffs and Class members who made purchases of or reimbursements for Pomalyst and/or its AB-rated generic equivalents in North Dakota. The plaintiffs and Class members paid higher prices for brand and generic Pomalyst than they would have paid but for Celgene's and Bristol Myers' actions.

566. Celgene and Bristol Myers have been enriched by revenue resulting from unlawful overcharges paid by the plaintiffs and members of the Class.

567. The Class has been impoverished by the overcharges for Pomalyst or its AB-rated generic equivalents resulting from Celgene's and Bristol Myers' unlawful conduct.

568. Celgene's and Bristol Myers' enrichment and the Class's impoverishment are connected. Celgene and Bristol Myers have paid no consideration to any other person for any benefits they received directly or indirectly from the plaintiffs and Class members.

569. There is no justification for Celgene's and Bristol Myers' receipt of the benefits causing its enrichment, because the Class paid supra-competitive prices that inured to Celgene's and Bristol Myers' benefit, and it would be inequitable for Celgene and Bristol Myers to retain any revenue gained from their unlawful overcharges.

570. The Class has no remedy at law.

Oklahoma

571. Celgene and Bristol Myers unlawfully profited from overcharges paid by the plaintiffs and Class members who made purchases of or reimbursements for Pomalyst and/or its AB-rated generic equivalents in Oklahoma. The plaintiffs and Class members paid higher prices for brand and generic Pomalyst than they would have paid but for Celgene's and Bristol Myers' actions.

572. Celgene and Bristol Myers received money from the plaintiffs and Class members as a direct result of the unlawful overcharges and have retained this money.

573. Celgene and Bristol Myers have paid no consideration to any other person in exchange for this money.

574. The plaintiffs and Class members have no remedy at law.

575. It is against equity and good conscience for Celgene and Bristol Myers to be permitted to retain the revenue resulting from their unlawful overcharges.

Oregon

576. Celgene and Bristol Myers unlawfully profited from overcharges paid by the plaintiffs and Class members who made purchases of or reimbursements for Pomalyst and/or its AB-rated generic equivalents in Oregon. The plaintiffs and Class members paid higher prices for brand and generic Pomalyst than they would have paid but for Celgene's and Bristol Myers' actions.

577. Celgene and Bristol Myers have received a benefit from the Class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Celgene and Bristol Myers, to the economic detriment of the plaintiffs and the Class.

578. Celgene and Bristol Myers were aware of the benefit bestowed upon them by the Class.

579. Under the circumstances, it would be unjust for Celgene and Bristol Myers to retain any of the overcharges derived from their unfair conduct without compensating the plaintiffs and the Class.

Pennsylvania

580. Celgene and Bristol Myers unlawfully profited from overcharges paid by the plaintiffs and Class members who made purchases of or reimbursements for Pomalyst and/or its AB-rated generic equivalents in Pennsylvania. The plaintiffs and Class members paid higher prices

for brand and generic Pomalyst than they would have paid but for Celgene's and Bristol Myers' actions.

581. Celgene and Bristol Myers have received a benefit from the Class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Celgene and Bristol Myers, to the economic detriment of the plaintiffs and the Class.

582. Under the circumstances, it would be inequitable for Celgene and Bristol Myers to retain such benefits without compensating the Class.

Puerto Rico

583. Celgene and Bristol Myers unlawfully profited from overcharges paid by the plaintiffs and Class members who made purchases of or reimbursements for Pomalyst and/or its AB-rated generic equivalents in Puerto Rico. The plaintiffs and Class members paid higher prices for brand and generic Pomalyst than they would have paid but for Celgene's and Bristol Myers' actions.

584. Celgene and Bristol Myers have been enriched by revenue resulting from unlawful overcharges.

585. The Class has been impoverished by the overcharges for Pomalyst or its AB-rated generic equivalents resulting from Celgene's and Bristol Myers' unlawful conduct.

586. Celgene's and Bristol Myers' enrichment and the Class's impoverishment are connected.

587. There is no justification for Celgene's and Bristol Myers' receipt of the benefits causing their enrichment and the Class's impoverishment because the Class paid supra-competitive prices that inured to Celgene's and Bristol Myers' benefit, and it would be inequitable for Celgene and Bristol Myers to retain any revenue gained from their unlawful overcharges.

588. The Class has no remedy at law.

Rhode Island

589. Celgene and Bristol Myers unlawfully profited from overcharges paid by the plaintiffs and Class members who made purchases of or reimbursements for Pomalyst and/or its AB-rated generic equivalents in Rhode Island. The plaintiffs and Class members paid higher prices for brand and generic Pomalyst than they would have paid but for Celgene's and Bristol Myers' actions.

590. Celgene and Bristol Myers have received a benefit from the Class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Celgene and Bristol Myers, to the economic detriment of the plaintiffs and the Class.

591. Celgene and Bristol Myers were aware of and/or recognized the benefit bestowed upon them by the Class.

592. Under the circumstances, it would be inequitable for Celgene and Bristol Myers to retain such benefits without compensating the Class.

South Carolina

593. Celgene and Bristol Myers unlawfully profited from overcharges paid by the plaintiffs and Class members who made purchases of or reimbursements for Pomalyst and/or its AB-rated generic equivalents in South Carolina. The plaintiffs and Class members paid higher prices for brand and generic Pomalyst than they would have paid but for Celgene's and Bristol Myers' actions.

594. The benefits conferred upon Celgene and Bristol Myers were not gratuitous, in that they comprised revenue created by unlawful overcharges arising from unlawful overcharges to the Class.

595. Celgene and Bristol Myers realized value from the benefit bestowed upon them by the Class.

596. Under the circumstances, it would be inequitable for Celgene and Bristol Myers to retain such benefits without compensating the Class.

South Dakota

597. Celgene and Bristol Myers unlawfully profited from overcharges paid by the plaintiffs and Class members who made purchases of or reimbursements for Pomalyst and/or its AB-rated generic equivalents in South Dakota. The plaintiffs and Class members paid higher prices for brand and generic Pomalyst than they would have paid but for Celgene's and Bristol Myers' actions.

598. Celgene and Bristol Myers have received a benefit from the Class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Celgene and Bristol Myers, to the economic detriment of the plaintiffs and the Class.

599. Celgene and Bristol Myers were aware of the benefit bestowed upon them by the Class.

600. Under the circumstances, it would be inequitable and unjust for Celgene and Bristol Myers to retain such benefits without reimbursing the Class.

Tennessee

601. Celgene and Bristol Myers unlawfully profited from overcharges paid by the plaintiffs and Class members who made purchases of or reimbursements for Pomalyst and/or its AB-rated generic equivalents in Tennessee. The plaintiffs and Class members paid higher prices for brand and generic Pomalyst than they would have paid but for Celgene's and Bristol Myers' actions.

602. Celgene and Bristol Myers have received a benefit from the Class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Celgene and Bristol Myers, to the economic detriment of the plaintiffs and the Class.

603. Celgene and Bristol Myers were aware of or appreciated the benefit bestowed upon them by the Class.

604. Under the circumstances, it would be inequitable for Celgene and Bristol Myers to retain such benefits without compensating the Class.

605. It would be futile for the Class to seek a remedy from any party with whom they have privity of contract. Celgene and Bristol Myers have paid no consideration to any other person for any of the unlawful benefits they received indirectly from the Class with respect to Celgene's and Bristol Myers' sale of Pomalyst. It would be futile for the Class to exhaust all remedies against the entities with which the Class has privity of contract because the Class did not purchase Pomalyst or its AB-rated generic equivalents directly from any defendant.

Texas

606. Celgene and Bristol Myers unlawfully profited from overcharges paid by the plaintiffs and Class members who made purchases of or reimbursements for Pomalyst and/or its AB-rated generic equivalents in Texas. The plaintiffs and Class members paid higher prices for brand and generic Pomalyst than they would have paid but for Celgene's and Bristol Myers' actions.

607. Celgene and Bristol Myers have received a benefit from the Class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Celgene and Bristol Myers, to the economic detriment of the plaintiffs and the Class.

608. Celgene and Bristol Myers were aware of or appreciated the benefit bestowed upon them by the plaintiffs and Class members.

609. The circumstances under which Celgene and Bristol Myers have retained the benefits bestowed upon them by the plaintiffs and Class members are inequitable in that they result from Celgene's and Bristol Myers' unlawful conduct.

610. The plaintiffs and Class members have no remedy at law.

Utah

611. Celgene and Bristol Myers unlawfully profited from overcharges paid by the plaintiffs and Class members who made purchases of or reimbursements for Pomalyst and/or its AB-rated generic equivalents in Utah. The plaintiffs and Class members paid higher prices for brand and generic Pomalyst than they would have paid but for Celgene's and Bristol Myers' actions.

612. Celgene and Bristol Myers have received a benefit from the Class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Celgene and Bristol Myers, to the economic detriment of the plaintiffs and the Class.

613. Celgene and Bristol Myers were aware of or appreciated the benefit bestowed upon them by the Class.

614. Under the circumstances, it would be inequitable for Celgene and Bristol Myers to retain such benefits without compensating the Class.

Vermont

615. Celgene and Bristol Myers unlawfully profited from overcharges paid by the plaintiffs and Class members who made purchases of or reimbursements for Pomalyst and/or its AB-rated generic equivalents in Vermont. The plaintiffs and Class members paid higher prices for brand and generic Pomalyst than they would have paid but for Celgene's and Bristol Myers' actions.

616. Celgene and Bristol Myers have received a benefit from the Class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Celgene and Bristol Myers, to the economic detriment of the plaintiffs and the Class.

617. Celgene and Bristol Myers accepted the benefit bestowed upon them by the Class.

618. Under the circumstances, it would be inequitable for Celgene and Bristol Myers to retain such benefits without compensating the Class.

Virginia

619. Celgene and Bristol Myers unlawfully profited from overcharges paid by the plaintiffs and Class members who made purchases of or reimbursements for Pomalyst and/or its AB-rated generic equivalents in Virginia. The plaintiffs and Class members paid higher prices for brand and generic Pomalyst than they would have paid but for Celgene's and Bristol Myers' actions.

620. Celgene and Bristol Myers have received a benefit from the Class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Celgene and Bristol Myers, to the economic detriment of the plaintiffs and the Class.

621. Celgene and Bristol Myers were aware of the benefit bestowed upon it.

622. Celgene and Bristol Myers should reasonably have expected to repay the Class.

623. The benefits conferred upon Celgene and Bristol Myers were not gratuitous, in that they constituted revenue created by unlawful overcharges arising from the Celgene's and Bristol Myers' illegal and unfair actions to inflate the prices of Pomalyst and/or its AB-rated generic equivalents.

624. Celgene and Bristol Myers have paid no consideration to any other person for any of the benefits they have received from the Class.

Washington

625. Celgene and Bristol Myers unlawfully profited from overcharges paid by the plaintiffs and Class members who made purchases of or reimbursements for Pomalyst and/or its AB-rated generic equivalents in Washington. The plaintiffs and Class members paid higher prices for brand and generic Pomalyst than they would have paid but for Celgene's and Bristol Myers' actions.

626. Celgene and Bristol Myers have received a benefit from the Class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Celgene and Bristol Myers, to the economic detriment of the plaintiffs and the Class.

627. Celgene and Bristol Myers were aware of or appreciated the benefit bestowed upon them by the Class.

628. Under the circumstances, it would be inequitable for Celgene and Bristol Myers to retain such benefits without compensating the Class.

West Virginia

629. Celgene and Bristol Myers unlawfully profited from overcharges paid by the plaintiffs and Class members who made purchases of or reimbursements for Pomalyst and/or its AB-rated generic equivalents in West Virginia. The plaintiffs and Class members paid higher prices for brand and generic Pomalyst than they would have paid but for Celgene's and Bristol Myers' actions.

630. Celgene and Bristol Myers have received a benefit from the Class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Celgene and Bristol Myers, to the economic detriment of the plaintiffs and the Class.

631. Celgene and Bristol Myers were aware of or appreciated the benefit bestowed upon them by the Class.

632. Under the circumstances, it would be inequitable for Celgene and Bristol Myers to retain such benefits without compensating the Class.

Wisconsin

633. Celgene and Bristol Myers unlawfully profited from overcharges paid by the plaintiffs and Class members who made purchases of or reimbursements for Pomalyst and/or its AB-rated generic equivalents in Wisconsin. The plaintiffs and Class members paid higher prices for brand and generic Pomalyst than they would have paid but for Celgene's and Bristol Myers' actions.

634. Celgene and Bristol Myers have received a benefit from the Class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Celgene and Bristol Myers, to the economic detriment of the plaintiffs and the Class.

635. Celgene and Bristol Myers appreciated the benefit bestowed upon them by the Class.

636. Under the circumstances, it would be inequitable for Celgene and Bristol Myers to retain such benefits without compensating the Class.

Wyoming

637. Celgene and Bristol Myers unlawfully profited from overcharges paid by the plaintiffs and Class members who made purchases of or reimbursements for Pomalyst and/or its AB-rated generic equivalents in Wyoming. The plaintiffs and Class members paid higher prices for brand and generic Pomalyst than they would have paid but for Celgene's and Bristol Myers' actions.

638. Celgene and Bristol Myers have received a benefit from the Class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive

prices that inured to the benefit of Celgene and Bristol Myers, to the economic detriment of the plaintiffs and the Class.

639. Celgene and Bristol Myers accepted, used, and enjoyed the benefits bestowed upon them by the Class under inequitable and unjust circumstances arising from unlawful overcharges to the plaintiffs and Class members.

640. Under the circumstances, it would be inequitable for Celgene and Bristol Myers to retain such benefits.

X. COMPLIANCE WITH NOTICE REQUIREMENTS

641. As directed by Arizona Rev. Stat. § 44-1415, Conn. Gen. Stat. § 624:35-37, 815 Ill. Comp. Stat. Ann. 505/10a, 5 Me. Rev. Stat. § 213(3), Minn. Stat. § 325D.63, Mo. Rev. Stat. § 407.025.7, Mont. Code § 30-14-133, Nev. Rev. Stat. § 598A.210(3), N.Y. Gen. Bus. Law § 340(5), Or. Rev. Stat. § 646.780(5)(b), Or. Rev. Stat. § 646.638(2), R.I. Gen. Laws § 6-36-21, S.C. Code § 39-5-140, and Utah Code § 76-10-2109(9) and/or Utah Code § 13-11-21, upon filing of this consolidated complaint, counsel will send, or will cause the appropriate authority to send, the complaint and any additional required materials to:

a. Kris Mayes, Attorney General of Arizona;

b. William Tong, Attorney General of Connecticut;

c. Aaron Frey, Attorney General of Maine;

d. Keith Ellison, Attorney General of Minnesota;

e. Andrew Bailey, Attorney General of Missouri;

f. Austin Knudsen, Attorney General of Montana;

g. Aaron Ford, Attorney General of Nevada;

h. Letitia James, Attorney General of New York;

i. Ellen Rosenblum, Attorney General of Oregon;

j. Peter Neronha, Attorney General of Rhode Island;

k. Alan Wilson, Attorney General of South Carolina; and

l. Sean Reyes, Attorney General of Utah, and Daniel O'Bannon, Director, Utah Division of Consumer Protection.

XI. DEMAND FOR JUDGMENT

WHEREFORE, the plaintiffs, on behalf of themselves and the proposed Class, respectfully demand that this Court:

[A] Determine that this action may be maintained as a class action pursuant to Rules 23(a), (b)(2), and (b)(3) of the Federal Rules of Civil Procedure; direct that reasonable notice of this action, as provided by Rule 23(c)(2), be provided to the Class; and declare the plaintiffs as the representative of the Class;

[B] Enter joint and several judgments against the defendants and in favor of the plaintiffs and the Class;

[C] Award the Class treble damages (*i.e.*, three times overcharges) in an amount to be determined at trial;

[D] Grant permanent injunctive relief pursuant to § 16 of the Clayton Act to remedy the ongoing anticompetitive effects of Celgene's and Bristol Myers' unlawful conduct;

[E] Award the plaintiffs and the Class their costs of suit, including reasonable attorneys' fees as provided by law; and

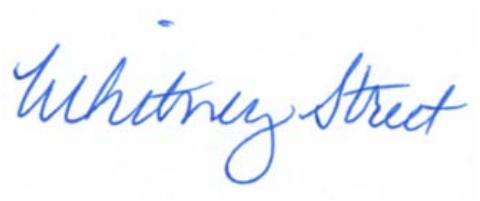
[F] Award such further and additional relief as the case may require and the Court may deem just and proper under the circumstances.

XII. JURY DEMAND

642. Pursuant to Rule 38 of the Federal Rules of Civil Procedure, the plaintiffs, on behalf of themselves and the proposed Class, demand a trial by jury on all issues so triable.

Dated: September 5, 2023

Respectfully submitted,



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