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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

International Union of Operating Engineers Stationary Engineers Local 39 Health and Welfare Trust Fund, The Detectives' Endowment Association, Inc., and David Mitchell, individually and on behalf of all others similarly situated, **Plaintiffs,** **v.** **Celgene Corporation,** **Defendant.**	**Civil Action No.** **Class Action Complaint** **Jury Trial Demanded**

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Plaintiffs International Union of Operating Engineers Stationary Engineers Local 39 Health and Welfare Trust Fund, The Detectives' Endowment Association, Inc., and David Mitchell (together, "Plaintiffs") bring this class action on behalf of themselves and all other similarly situated end-payors against Celgene Corporation ("Celgene"). Based on personal knowledge as to facts pertaining to them, and upon information and belief as to all other matters, Plaintiffs allege as follows:

I. NATURE OF THE ACTION

1. This is a civil antitrust action seeking damages arising out of Celgene's unlawful exclusion of competition from the market for thalidomide ("Thalomid"), which Celgene sells under the brand-name Thalomid, and lenalidomide ("Revlimid"), which Celgene sells under the brand-name Revlimid.

2. Celgene has sold Thalomid and Revlimid in capsule format, which are administered orally. Both drugs have dangerous side effects; namely, life-threatening birth defects when ingested by pregnant women. As a result, these drugs are highly regulated by the FDA.

3. Since 2006, Celgene has recorded more than $38.9 billion from the sale of Thalomid and Revlimid combined. A twenty-eight day supply of Thalomid could cost from between $8,000 to $10,000, and the same supply of Revlimid could cost approximately $15,000 to $20,000 in 2014. In 2016 alone, Celgene's revenues from Revlimid were $6,973,600,000, and $152,100,000 from Thalomid. And Celgene has taken advantage of its market monopoly: when Thalomid first gained approval to

enter the marketplace, it cost approximately $6 per capsule; in 2014, it cost between $212 and $357 per capsule. In 2014, Celgene charged approximately $500 per capsule of Revlimid.

4. In order to delay the onset of generic competition and squeeze more multi-billion dollar years out of these products, Celgene engaged in a multi-faceted scheme to maintain its monopoly and unlawfully interfere with competitors' efforts to enter the market with generic versions of Thalomid or Revlimid, including:

a. Using FDA safety requirements that were designed to ensure safe access to these dangerous drugs as a pretext to delay and indefinitely postpone the availability of cost-saving generic alternatives to these drugs;

b. Fraudulently obtaining patents on the procedures to ensure safe use of Thalomid and Revlimid in order to block generic entrants from coming to market; and

c. Engaging in sham litigation against any competitor who managed to obtain samples of Thalomid or Revlimid to do its generic bioequivalence testing.

5. Although existing federal law already forbids the use of safety regulations to deny generic drugmakers access to drugs, members of the United States House of Representatives have taken note of Celgene's anticompetitive actions, and introduced H.R. 2051, known as the Fair Access for Safe and Timely

Generics Act, or FAST. FAST would require that brand-name manufacturers, as a condition of product approval, agree not to "adopt, impose or enforce any condition relating to the sale, resale or distribution" of REMS-restricted drugs that would prevent generics makers from obtaining needed samples. FAST would increase the penalties for conduct like Celgene's with Thalomid and Revlimid.

6. Celgene's anticompetitive tactics to block generic entry have caused Plaintiffs and the Classes that they seek to represent (as defined below) to pay higher prices to treat the dangerous conditions (leprosy and multiple myeloma) that Thalomid and Revlimid address.

7. Plaintiffs bring this action as a class action on behalf of all persons and entities that purchased and/or paid for some or all of the purchase price of Thalomid or Revlimid in certain states, the District of Columbia, and Puerto Rico for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries since November 7, 2010.

8. Plaintiffs assert claims for compensatory and treble damages, and for injunctive relief, for violations of the state laws enumerated below.

II. JURISDICTION AND VENUE

9. This 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 Classes is a citizen of a state different from that of one of the Defendant.

10. This Court also has jurisdiction over this matter pursuant to 15 U.S.C. § 26 and 28 U.S.C. §§ 1331 and 1337 in that Plaintiffs bring claims under Section 16 of the Clayton Act, 15 U.S.C. § 26, for injunctive and equitable relief to remedy the Defendant's violations of Sections 1 and 2 of the Sherman Antitrust Act, 15 U.S.C. §§ 1 and 2. The Court has supplemental jurisdiction over Plaintiffs' pendent state law claims pursuant to 28 U.S.C. § 1367.

11. Venue is appropriate within this district under Section 12 of the Clayton Act, 15 U.S.C. § 22 and 28 U.S.C. §1391(b) and (c), because Defendant transact business within this district, and/or has an agent and/or can be found in this district, and the interstate trade and commerce, hereinafter described, is carried out, in substantial part, in this district.

III. THE PARTIES

12. Plaintiff International Union of Operating Engineers Stationary Engineers Local 39 Health and Welfare Trust Fund ("Local 39") maintains its principal place of business in California. Local 39 has purchased and/or provided reimbursement for some or all of the purchase price for Revlimid, other than for re-sale, for its members in California, at supra-competitive prices during the Class Period and has thereby been injured.

13. Plaintiff The Detectives' Endowment Association, Inc. ("DEA") maintains its principal place of business in New York. DEA has purchased and/or

provided reimbursement for some or all of the purchase price for Revlimid, other than for re-sale, for its members in Florida, Michigan, New Jersey, New York, North Carolina, Oregon, Pennsylvania and Tennessee, at supra-competitive prices during the Class Period and has thereby been injured.

14. Plaintiff David Mitchell was diagnosed with multiple myeloma in 2010. His doctor prescribed Revlimid. Under the terms of his insurance, he paid for some of the purchase price of Revlimid for several years during the Class Period, amounting to thousands of dollars a year. The price that Mr. Mitchell paid increased over the years that he was taking Revlimid. Under the terms of his insurance, he would have paid less for Revlimid if a generic version was available. In accordance with Celgene's REMS program, Mr. Mitchell received monthly counseling from a nurse who read a list of cautions to him over the telephone from his office in Washington, D.C. He also answered automated telephonic survey questions in accordance with REMS. He received shipments of Revlimid to his office in Washington, D.C. He was injured by the supra-competitive prices of Revlimid during the Class Period.

15. Defendant Celgene is a corporation organized and existing under the laws of Delaware, having its principal place of business at 86 Morris Avenue, Summit, New Jersey 07901.

16. All of Defendant's wrongful actions described in this complaint are part of, and in furtherance of, the illegal monopolization and restraint of trade alleged

herein, and were authorized, ordered, and/or undertaken by Defendant's various officers, agents, employees, or other representatives while actively engaged in the management of Defendant's affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of Defendant.

IV. INDUSTRY BACKGROUND

A. Characteristics of the Pharmaceutical Marketplace

17. The marketplace for the sale of prescription pharmaceutical products in the United States contains a significant feature that can be exploited by manufacturers in order to extend a monopoly in the sale of a particular pharmaceutical composition. In most industries, the person responsible for paying for a product is also the person who chooses which product to purchase. When the same person has both the payment obligation and the choice of products, the price of the product plays a predominant role in the person's choice of products and, consequently, manufacturers have a strong incentive to lower the price of their products to maintain profitability.

18. The pharmaceutical marketplace, by contrast, is characterized by a "disconnect" between the payment obligation and the product selection. State laws prohibit pharmacists from dispensing many pharmaceutical products, including Thalomid and Revlimid, to patients without a prescription written by the patient's physician. The prohibition on dispensing certain products without a prescription

introduces a "disconnect" in the pharmaceutical marketplace between the payment obligation and the product selection. The patient (and in many cases his or her insurer) has the obligation to pay for the pharmaceutical product, but the patient's physician chooses which product the patient will buy.

19. Many pharmaceutical manufacturers, including Defendant, exploit this feature of the pharmaceutical marketplace. The so-called "brand manufacturers" (i.e., the manufacturers of branded, as opposed to generic, pharmaceuticals) employ large forces of sales representatives, known as "detailers," who visit physicians' offices in an effort to persuade physicians to prescribe the manufacturer's products. Importantly, these detailers do not advise the physicians of the cost of the branded products. Studies show that physicians typically are not aware of the relative costs of branded pharmaceutical products and that, even when physicians are aware of the relative cost, they are insensitive to price differences, because they do not pay for the products themselves. The result is a marketplace in which price plays a comparatively unimportant role in product selection.

20. In situations in which two manufacturers each sell a drug that serves a similar medical function and each manufacturer uses a significant detailer force, those products are often sold at very similar, high prices, thus eliminating any consumer benefit from that "competition." This is in stark contrast to the situation in which the competing seller of an AB-rated, bioequivalent drug is a generic company without a detailer force. In that case, the generic price is significantly lower

than the brand price, and consumers benefit as Congress had intended by enacting the Hatch-Waxman Act, discussed below.

21. When the relative importance of the price between two branded pharmaceuticals, or pharmaceuticals that otherwise are not AB-rated to one another, is low, the price elasticity of demand — the extent to which sales go down when price goes up — is by definition also low, which in turn gives brand manufacturers the ability to raise or maintain price substantially above competitive levels without losing sales. The ability to raise price above competitive levels without losing sales is referred to by economists and antitrust courts as market power or monopoly power. Thus, the net result of the pharmaceutical industry features and marketing practices described above often is to allow brand manufacturers to gain and maintain monopoly power.

22. Congress sought to ameliorate the "disconnect," and to restore some of the normal competitive pressures to the pharmaceutical marketplace, by authorizing the manufacture and sale of generic pharmaceuticals under the Hatch-Waxman Act, discussed below. When a pharmacist receives a prescription for a branded pharmaceutical product, and an AB-rated generic version of that product is available, state laws permit (or in some cases require) the pharmacist to dispense the generic product in lieu of the branded product. In this way, the importance of price is reintroduced to the product selection decision at the pharmacy counter, and the pharmaceutical marketplace "disconnect" is ameliorated between the AB-rated

generic product and the corresponding branded product. When an AB-rated generic product is introduced and is not prevented from competing unfettered, branded pharmaceutical manufacturers are no longer able to exploit the features of the pharmaceutical industry, their monopoly power dissipates, and some of the normal competitive pressures are restored.

23. If Defendant's unlawful conduct had not prevented generic manufacturers from successfully entering the market with generic versions of Thalomid and Revlimid, end-payors like Plaintiffs and members of the Classes would have saved millions of dollars in purchases. Defendant's anticompetitive scheme purposely manipulated generic competition to Thalomid and Revlimid.

B. The Regulatory Structure for Approval of Generic Drugs, Listing Patent Information in the Orange Book, and the Substitution of Generic Drugs for Brand Name Drugs

22. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), branded drug manufacturers must obtain FDA approval to sell a new drug product by filing a New Drug Application ("NDA"). 21 U.S.C. §§ 301–392. An NDA must include specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. § 355(a), (b).

23. When the FDA approves a branded drug manufacturer's NDA, the manufacturer may list in the Orange Book any patents the manufacturer believes could reasonably be asserted against a generic manufacturer that makes, uses, or sells a generic version of the branded drug before the expiration of the listed patents.

The branded drug manufacturer may also list in the Orange Book any patents issued after the FDA approved the NDA within thirty days of their issuance. 21 U.S.C. § 355(b)(1) & (c)(2).

24. The FDA relies completely on a branded drug manufacturer's truthfulness about patent validity and applicability because the FDA does not have the resources or authority to verify a branded drug manufacturer's patents and patent information for accuracy or trustworthiness. In listing patents and patent information in the Orange Book, the FDA merely performs a ministerial act.

1. The Hatch-Waxman Amendments

25. The Hatch-Waxman Act, enacted in 1984, simplified the regulatory hurdles for prospective generic drug manufacturers by eliminating the need to file lengthy and costly NDAs. See Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984). 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 a branded drug manufacturer's original NDA, but must further show that the generic drug (i) contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug, and (ii) is absorbed at the same rate and to the same extent as the brand drug—that is, that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically

equivalent") to the brand drug. The FDA assigns an "AB" rating to generic drugs that are therapeutically equivalent to their brand-name counterparts.

26. The FDCA and Hatch-Waxman Act operate on the presumption that bioequivalent drugs containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity and identity, are therapeutically equivalent and may be substituted for one another. Bioequivalence means that the active ingredient of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as its branded counterpart. 21 U.S.C. § 355(j)(8)(B).

27. Congress enacted the Hatch-Waxman Act to expedite the entry of legitimate (non-infringing) generic competitors, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical manufacturers' incentives to create new and innovative products.

28. The Hatch-Waxman Act achieved both goals, advancing substantially the rate of generic product launches and ushering in an era of historic high profit margins for branded drug manufacturers. In 1983, before the Hatch-Waxman Act, only 35% of the top-selling branded drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, annual prescription drug revenue for branded and generic drugs totaled $21.6 billion; by 2009 total annual prescription drug revenue had soared to $300 billion.

2. Requirements for Listing Patents in the Orange Book

29. The regulatory structure created by the Hatch-Waxman Act includes a process for identifying and addressing patents that arguably apply to brand and generic drug products. This regulatory structure requires the holder of an NDA to submit information concerning its patents to the FDA, which incorporates the information into the Orange Book. Patent information is listed in the Orange Book for each NDA to which the patent may apply and can be reasonably asserted against potential infringers in patent litigation. Then, when a generic company seeks to file an ANDA, it must submit patent certifications or statements, described more fully below, to each patent listed in the Orange Book for the NDA that is the reference listed drug for the ANDA.

30. Under the Hatch-Waxman Act, the NDA holder must submit certain required information concerning "any patent which claims the drug for which the application was submitted or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1)(G).

31. When Celgene submitted patent information regarding the Thalomid and Revlimid patents, respectively—the relevant statute required the NDA applicant to list "any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which

a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C.A. § 355(b)(1) (1999) & (2002).

32. The then-applicable regulations identified three types of patents that could properly be listed: "drug substance (ingredient) patents, drug product (formulation and composition) patents, and method of use patents." 21 C.F.R. § 314.53(b) (1999) & (2002). The regulations further provided that "[f]or patents that claim a drug substance or drug product, the [NDA] applicant shall submit information only on those patents that *claim a drug product that is the subject of a pending or approved application*, or that claim a drug substance that is a component of such a product." *Id*. (emphasis added). The NDA holder also could properly list a patent for a drug product only "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale *of the drug product*." *Id*. (emphasis added). In short, for patents that claimed a drug product, the NDA applicant could submit information describing the patent as a "drug product patent" only if the patent claimed the drug product that was the subject of the NDA; the patent's drug product claim could claim not just *some* drug product – it had to claim the relevant drug product, *i.e.*, the FDA approved drug product as to which the NDA applicant listed the patent.

33. NDA applicants were on their honor to properly identify the "Type of patent, *i.e.*, drug, drug product, or method of use." 21 C.F.R. § 314.53(c)(2)(ii) (1999) & (2002). The FDA expressly refused to police the proper listing of patents and patent information, noting that it "does not have the resources or the expertise to review patent information for its accuracy and relevance to an NDA," and that it "believes that the declaration requirements under § 314.53(c) [requiring the applicant to declare "that Patent No. ____ covers the formulation, composition, and/or method of use of (name of drug product)"], as well as an applicant's potential liability if it submits an untrue statement of material fact, will help ensure that accurate patent information is submitted." *Abbreviated New Drug Application Regulations: Patent and Exclusivity Provisions*, 59 Fed. Reg. 50338, 50343-45 (Oct. 3, 1994).

34. Important regulatory and competitive consequences flow from the distinction between patents described as containing relevant drug product claims, and patents described as containing only method-of-use claims. If the patentee describes the patent in the patent information as containing a relevant drug product claim, an ANDA applicant desiring to market its generic product before the patent expires must file a Paragraph IV Certification, certifying that the patent is invalid, unenforceable, or would not be infringed by the generic product. 21 U.S.C. § 355(j)(2)(A)(vii)(IV); 21 C.F.R. § 314.94(a)(12)(i)(A)(4). The patentee and/or NDA

holder then has the opportunity to obtain an automatic 30-month stay on generic competition by filing a patent infringement lawsuit against the ANDA applicant. In addition, and of particular importance here, the FDA is prohibited from approving a subsequent applicant's ANDA until 180 days after the first-filer has entered the market. 21 U.S.C. § 355(j)(5)(B)(iv). As discussed in detail below, this "180-day exclusivity" creates an opportunity for the patentee to craft a "bottleneck" to delay *all* generic competition by paying the first-filer to delay its entry into the market.

35. By contrast, if the patentee describes the patent on the basis of method-of-use claims, in certain circumstances an ANDA applicant can submit what is known as a "Section viii Statement." 21 U.S.C. § 355(j)(2)(A)(viii); 21 C.F.R. § 314.94(a)(12)(iii). In a Section viii Statement, the ANDA applicant states it is not seeking approval for the particular use covered by the method-of-use patent. If an ANDA applicant makes only a Section viii Statement, then the patentee or NDA holder cannot obtain an automatic 30-month stay on generic competition even if it sues the ANDA applicant for patent infringement. The FDA can approve an ANDA containing only a Section viii Statement *without regard* to whether any other ANDA applicant is otherwise entitled to a 180-day exclusivity period.

36. Whether a patent actually contains drug product claims that claim the relevant drug product is irrelevant for purposes of Paragraph IV certifications. Rather, FDA regulations and instructions made unmistakably clear that the *patent information* submitted by the NDA applicant determined whether generic

manufacturers would be permitted to make Paragraph IV certifications and thus would be eligible for the 180-day exclusivity period. See, for example, FDA Proposed Rule, *Abbreviated New Drug Application Regulations*, 54 FR 28872, at 28885 (July 10, 1989) ("the patent information submitted to FDA, whether or not published in the list, should be the basis of the [generic company's] certification"); 21 C.F.R. § 314.94(a)(12)(iii) (ability to submit only a Section viii statement is based on "patent information … submitted under … § 319.53").

37. In short, describing a patent as containing a relevant drug product claim gives the patentee two key competitive advantages—an automatic 30-month stay on generic competition, and an ability to create a bottleneck delaying all generic competition by paying the first generic filer to delay entry into the market.

3. Paragraph IV Certifications

38. Where the NDA holder has submitted patent information describing a listed patent as claiming a relevant drug substance or drug product, an ANDA applicant must certify that the generic drug will not infringe those patents. Under the Hatch-Waxman Act, a generic manufacturer's ANDA must contain one of four certifications:

1. that no patent for the branded drug has been filed with the FDA (a "Paragraph I certification");
2. that the patent for the branded drug has expired (a "Paragraph II certification");

3. that the patent for the branded drug will expire on a particular date and the manufacturer does not seek to market its generic product before that date (a "Paragraph III certification"); or

4. that the patent for the branded drug is invalid or will not be infringed by the generic drug manufacturer's proposed product (a "Paragraph IV certification").

39. If a generic drug manufacturer files a Paragraph IV Certification, a branded drug manufacturer can delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement. If the branded drug manufacturer initiates a patent infringement action against the generic drug manufacturer filer within forty-five days of receiving notification of the Paragraph IV certification ("Paragraph IV Litigation"), the FDA will not grant final approval to the ANDA until the earlier of (a) the passage of 30 months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic drug manufacturer's ANDA. Until one of those conditions occurs, the FDA may grant "tentative approval," but cannot authorize the generic drug manufacturer to market its product. FDA may grant an ANDA tentative approval when it determines that the ANDA would otherwise be ready for final approval but for the 30-month stay.

40. As an incentive to generic drug manufacturers to seek approval of generic alternatives to branded drugs, the first generic drug manufacturer to file an ANDA containing a Paragraph IV Certification typically receives a period of protection from competition from other generic versions of the drug. For Paragraph IV Certifications made before December 8, 2003, the first generic drug manufacturer

applicants received 180 days of market exclusivity, which could not be forfeited and was triggered only by commercial marketing of the generic product. For Paragraph IV Certifications made after December 8, 2003, the first generic drug manufacturer applicant receives 180 days of market exclusivity (unless some forfeiture event, like that discussed below, occurs). This means the first approved generic drug is the only available generic drug for at least six months.

41. Branded drug manufacturers can "game the system" by describing patents as containing relevant drug product claims (even if the patents, in fact, do not do so) and suing any generic drug manufacturer competitor filing an ANDA with a Paragraph IV Certification (even if the competitor's product does not actually infringe the listed patents) in order to delay final FDA approval of an ANDA for up to 30 months. That branded drug manufacturers often sue generic drug manufacturers under Hatch-Waxman simply to delay generic drug competition—as opposed to enforcing a valid patent that is actually infringed by the generic drug—is demonstrated by the fact that generic drug manufacturers have prevailed in Paragraph IV Litigation in cases involving 73% of the drug products studied—either by obtaining a judgment of invalidity or non-infringement or by the patent holder's voluntary dismissal of the suit.

42. For Paragraph IV Certifications made before December 8, 2003, the first generic drug manufacturer applicant could help a branded drug manufacturer "game the system" by delaying not only its own market entry, but also the market

entry of all other generic drug manufacturers. The first generic drug manufacturer applicant, by agreeing not to begin marketing its generic drug, thereby could delay the start of the 180-day period of generic market exclusivity, a tactic called exclusivity "parking." This tactic created a "bottleneck" because later generic drug manufacturer applicants could not enter the market until the first generic drug manufacturer applicant's 180-day exclusivity had elapsed.

43. On December 8, 2003, Congress enacted the Medicare Prescription Drug Improvement and Modernization Act of 2003 ("MMA") to make it more difficult for branded drug and generic drug manufacturers to conspire to delay the start of the first-filer's 180-day period of generic market exclusivity. The MMA outlines a number of conditions under which an ANDA applicant forfeits its eligibility for 180-day exclusivity, making way for other ANDA filers to launch their generic drug products. For example, forfeiture occurs if the first ANDA applicant fails to obtain tentative approval within 30 months from filing, unless the failure is caused by a change in, or review of, the approval requirements.

44. Under the "failure to market" provision, a first ANDA applicant forfeits 180-day exclusivity if it fails to market its generic drug by the later of: (a) the earlier of the date that is (i) 75 days after receiving final FDA approval; or (ii) 30 months after the date it submitted its ANDA; or (b) the date that is 75 days after the date as of which, as to each of the patents qualifying the first applicant for exclusivity (i.e., as to each patent for which the first applicant submitted a Paragraph IV

Certification), at least one of the following has occurred: (i) a final decision of invalidity or non-infringement; (ii) a settlement order entering final judgment including a finding the patent is invalid or not infringed; or (iii) the NDA holder delists the patent from the FDA Orange Book.

45. Branded drug manufacturers and first-filing generic drug manufacturers can structure their settlements in order to intentionally skirt the failure-to-market provisions and keep the 180-day exclusivity bottleneck in place by, for example, settling their litigation before a final judgment of invalidity or non-infringement can be entered with respect to each of the patents for which the first applicant submitted a Paragraph IV Certification, or seeking a consent judgment that does not include a finding that all of the patents for which the first applicant submitted a Paragraph IV Certification were invalid or not infringed. When that happens, in order to trigger forfeiture and gain access to the market, subsequent ANDA applicants are forced to obtain a judgment that all patents for which the first filing generic drug manufacturer filed Paragraph IV Certifications are invalid or not infringed. This may require the subsequent ANDA applicant to initiate a declaratory judgment action concerning patents that the branded drug manufacturer did not assert against it in a Paragraph IV Litigation.

C. The Availability of Citizen Petitions to Delay The FDA Approval of Generic Drugs

46. Section 505(j) of the Food, Drug and Cosmetic Act creates a mechanism by which a person may file a petition with the FDA requesting, among other things, that the agency take, or refrain from taking, any form of administrative action. This mechanism is commonly referred to as a citizen petition.

47. Citizen petitions provide a forum for individuals to express and support their genuine concerns about safety, scientific, or legal issues regarding a product any time before, or after, its market entry.

48. Other than the form of such citizen petition, the regulations place no restrictions on the subject matter of a citizen petition.

49. The FDA regulations concerning citizen petitions require the FDA Commissioner to respond to each citizen petition within 180 days of receipt. That response may be to approve the request in whole or in part, or deny the request. The Commissioner also may provide a tentative response with an estimate on a time for a full response.

50. Reviewing and responding to citizen petitions is a resource-intensive and time consuming task because, no matter how baseless a petition may be, the FDA must research the petition's subject, examine scientific, medical, legal and sometimes economic issues, and coordinate internal agency review and clearance of the petition response. These activities strain the FDA's limited resources, and lengthy citizen petitions can delay the FDA approval of generic products even if

those petitions ultimately are found to lack any reasonable evidentiary, regulatory, statutory or scientific basis.

51. Abusive and anticompetitive citizen petitions have become an increasingly common problem in the last several years as brand name companies have sought to compensate for dwindling new product pipelines. In such cases, citizen petitions have been filed with respect to ANDAs that have been pending for a year or more, long after the brand name manufacturer received notice of the ANDA filing, and have had the effect of delaying the approval of the generic product while the FDA evaluates the citizen petition.

52. Delaying generic competition is a lucrative strategy for an incumbent manufacturer. Given the marketplace's preference for generic products over brand names, the cost of filing an improper citizen petition may be trivial compared to the value of securing even a few months delay in a generic rival's entry into the market.

53. The FDA officials have acknowledged abuses of the citizen petition process. Former FDA Chief Counsel Sheldon Bradshaw noted that in his time at the agency he had "seen several examples of citizen petitions that appear designed not to raise timely concerns with respect to the legality or scientific soundness of approving a drug application but rather to try to delay the approval simply by compelling the agency to take the time to consider arguments raised in the petition whatever their merits and regardless of whether or not the petitioner could have made those very arguments months and months before."

54. In July 2006, Gary Buehler, R.Ph., former Director of the Office of Generic Drugs Center for Drug Evaluation and Research at the FDA, noted that of 42 citizen petitions raising issues about the approvability of generic products, "very few... have presented data or analysis that significantly altered the FDA's policies." Of these 42, only three petitions led to a change in the FDA policy on the basis of data or information submitted in the petition.

55. It is the practice of the FDA, well known in the pharmaceutical industry, to withhold ANDA approval until after its consideration of and response to a citizen petition was complete. On this subject, Director Buehler acknowledged that "[i]t is very rare that petitions present new issues that CDER has not fully considered, but the Agency must nevertheless assure itself of that fact by reviewing the citizen petitions."

D. The Benefits of Generic Drugs

56. Generic versions of branded drugs contain the same active ingredient, and are determined by the FDA to be just as safe and effective, as their branded counterparts. In particular, generic drugs that are pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to their brand-name counterparts are given an "AB" rating by the FDA. Pharmacists substitute an AB-rated generic product for the corresponding brand-name product unless the doctor has indicated that the prescription for the brand-name product must be dispensed as written.

57. As more generic manufacturers enter the market, prices for generic versions of a drug predictably decrease even further because of competition among the generic manufacturers, and the loss of sales volume by the brand-name drug to the corresponding generics accelerates. The only material difference between generic drugs and branded drugs is their price: generic drugs are usually at least 25% less expensive than their branded drug counterparts when there is a single generic drug competitor. The discount typically increases to 50% to 80% (or more) when there are multiple generic drug manufacturer competitors in the market for a given branded drug. The launch of a generic drug thus usually brings huge cost savings for all drug purchasers. The Federal Trade Commission ("FTC") estimates that about one year after market entry, a generic drug takes over 90% of the branded drug's unit sales at 15% of the price of the branded drug. As a result, competition from generic drugs is viewed by branded drug manufacturers, such as Celgene, as a grave threat to their bottom lines.

58. Due to the price differentials between branded and generic drugs, and other institutional features of the pharmaceutical industry, pharmacists liberally and substantially substitute the generic drug when presented with a prescription for the branded drug. Since passage of the Hatch-Waxman Act, every state has adopted substitution laws requiring or permitting pharmacies to substitute generic drug equivalents for branded drug prescriptions (unless the prescribing physician

specifically orders otherwise by writing "dispense as written" or similar language on the prescription).

59. There is an incentive to choose the less expensive generic drug equivalent in every link in the prescription drug chain. As a result of federal reimbursement rules and the industry pricing structure, pharmacies typically earn a higher markup on generic drugs than on branded drugs. Private health insurers similarly offer direct incentives to pharmacies to substitute cheaper generic drugs for more expensive branded drugs. Health insurers are contractually obligated to pay for the bulk of their insureds' prescriptions, whether filled with branded drugs or generic drugs, so they offer lower copays for generic drugs in order to encourage their use.

60. Generic drug competition enables all putative class members to (i) purchase generic versions of a drug at substantially lower prices; and/or (ii) purchase a branded drug at a reduced price.

61. Until the generic version of a branded drug enters the market, however, there is no bioequivalent generic drug to substitute for, and compete with, the branded drug, and, therefore, the branded drug manufacturer can continue to profitably charge supracompetitive prices. As a result, brand drug manufacturers, such as Celgene, which are well aware of the rapid erosion of branded drug sales by generic drugs, have a strong incentive to delay the introduction of generic drug

competition into the market, including through tactics such as the improper patent listing and Exclusion Payment Agreements.

E. The Impact of Authorized Generics

62. The 180-day marketing exclusivity to which first-filer generic drug manufacturers may be entitled does not prevent a branded drug manufacturer from marketing its own generic drug alternative to the branded drug during the 180-day period. Such an "authorized generic" is chemically identical to the branded drug, but is sold as a generic drug through either the branded manufacturer's subsidiary (if it has one) or through a third-party generic drug manufacturer. Competition from an authorized generic drug during the 180-day exclusivity period substantially reduces the first-filer's revenue, and substantially reduces drug prices for consumers.

63. In its recent study, Authorized Generic Drugs: Short-term Effects and Long-Term Impact (August 2011) (the "FTC Study"), the FTC found that authorized generic drugs capture a significant portion of sales, reducing the first-filer generic drug manufacturer's revenues by approximately half on average during the 180-day exclusivity period. The first-filing generic drug manufacturer makes significantly less money when it faces competition from an authorized generic because (i) the authorized generic drug takes a large share of unit sales away from the first filer; and (ii) the presence of an additional generic drug in the market causes prices to decrease.

64. Although first-filing generic drug manufacturers make significantly less money when they must compete with an authorized generic drug during the first 180 days, consumers and other drug purchasers, such as Plaintiffs and members of the putative Classes, benefit from the lower prices caused by competition between the authorized generic drug manufacturer and the first-filing generic drug manufacturer.

65. Given the significant negative impact of an authorized generic drug manufacturer on the first-filing generic drug manufacturer's revenues, a branded drug manufacturer's agreement not to launch an authorized generic drug has tremendous monetary value to the generic drug manufacturer. Branded drug manufacturers have used such agreements as a way to pay the first-filer to delay entering the market. Such non-competition agreements deprive consumers and other drug purchasers, such as Plaintiffs and members of the putative Classes, of the lower prices resulting from two forms of competition: (i) between the branded drug and the generic drug; and (ii) between the generic drugs.

V. DEFENDANT'S ANTICOMPETITIVE CONDUCT

66. The drug thalidomide was originally marketed and used in the 1950s and 1960s by pregnant women as a sleeping pill, and to treat morning sickness. However, when used by pregnant women, thalidomide resulted in life-threatening fetal deformities and birth defects. Ingesting thalidomide resulted in other dangerous

adverse side effects, such as peripheral neuropathy, which can lead to permanent nerve damage.

67. As a result of thalidomide's disastrous effects, the drug was banned worldwide, including in the United States. It was not approved for usage again until 1998, when the FDA approved Celgene's Thalomid as a treatment for erythema nodosum leprosum, a form of leprosy. However, to prevent dangerous fetal exposure to the drug, the FDA conditioned its approval upon Celgene's implementation of the REMS restricted distribution program (formerly known as the System for Thalidomide Education and Prescribing Safety, or "S.T.E.P.S"). Celgene's distributors, pharmacists, and all recipient patients are required to enroll in this program.

68. Because of Thalomid's restricted distribution program, sample quantities of the drug needed by generic manufacturers for bioequivalence testing are only available directly from Celgene. As described in detail below, Celgene has repeatedly refused to provide Thalomid samples to generic manufacturers for bioequivalence testing, stating that to do so would violate its REMS program (even after being instructed by the Food and Drug Administration that providing samples to the requesting manufacturer would pose *no* safety risk).

69. Revlimid (also called lenalidomide) is a drug commonly used for the treatment of multiple myeloma, often in combination with the drug dexamethasone. Revlimid is a thalidomide analogue, and presents many of the same dangerous side

effects as Thalomid, particularly in pregnant women. Therefore, it is also subject to a REMS distribution program, and is only available to prescribers and pharmacies enrolled in the Revlimid REMS program.

A. Celgene's Monopolization through Anticompetitive Interference by Refusing to Sell to Generic Manufacturers

70. Celgene has engaged in an extensive anticompetitive scheme to prevent any generic alternatives to Thalomid and Revlimid from entering the marketplace and disrupting Celgene's supraprofitable monopoly. Celgene has consistently refused to sell samples to generic manufacturers for bioequivalence testing, claiming that to do so would violate its REMS programs.

71. Celgene has refused to provide the necessary samples to its would-be generic competitors, including but not limited to Mylan Pharmaceuticals ("Mylan") between 2004 and the present, Lannett Company ("Lannett") in 2006, and Dr. Reddy's Laboratories ("Dr. Reddy's") in 2008 and 2009, using the REMS process as a pretextual justification for its refusal.

72. In direct contravention of the 2007 Food and Drug Administration Amendments Act ("FDAAA"), Celgene has utilized the REMS programs' distribution restrictions as a pretextual justification for its refusal to provide samples to generic competitors.

73. Recognizing that certain REMS programs could be used to impede generic competition, Congress included language in FDAAA clarifying that REMS provisions may not be used for such purposes. FDAAA subsection f(8) states that no holder of a REMS-covered drug shall use any aspect of the REMS to "block or delay approval" of an ANDA. 21 U.S.C. § 355-1(f)(8).

74. The FDA has also publicly remarked that REMS programs should not be used to block or delay generic competition. (See Center for Drug Evaluation and Research, FDA, Risk Evaluation and Mitigation Strategy (REMS) Public Meeting (July 28, 2010), at 270-71 (statement by Jane Axelrad, Associate Director of Policy, Center for Drug Evaluation and Research), *available* at http://www.fda.gov/downloads/Drugs/NewsEvents/UCM224950.pdf.

75. And the FDA has specifically issued letters to Celgene confirming that it may sell REMS drugs, such as Thalomid and Revlimid, subject to restricted distribution programs to particular generic firms, including Lannett and Mylan, for bioequivalence testing without violating the REMS.

76. Celgene's refusal to provide samples to generic competitors based on safety concerns is a mere anticompetitive pretext, as demonstrated by the fact that on numerous occasions, Celgene has frequently allowed access to Thalomid and Revlimid samples – directly or indirectly – to non-competitor research organizations for the purpose of conducting clinical studies using the drugs.

77. For example, Celgene provided Thalomid to the Johns Hopkins University School of Medicine in order to conduct clinical trials and provided Revlimid to international researchers like at Intergroupe Francophone du Myelome, University Hospital of Toulouse, and Groupe Francophone Des Myelodysplasies, as well as the National Cancer Institute, Eastern Cooperative Oncology Group, Mayo Clinic, and MD Anderson Cancer Center in Houston, TX.

78. Not only has Celgene itself refused to provide necessary samples to generic manufacturers, but has engaged in anticompetitive practices with other suppliers in order to retain its market monopoly.

1. Celgene Prevents Barr from Obtaining Samples from Seratec by Entering into an Exclusive Supply Contract with Seratec

79. Barr Laboratories ("Barr") was a pharmaceutical manufacturer known for developing, manufacturing, and marketing lower-priced generic versions of brand-name drugs. After Celgene gained FDA approval for Thalomid, Barr sought to develop its own generic version of thalidomide, in order to file an ANDA with the FDA and market its generic thalidomide pharmaceutical as an AB-rated Thalomid equivalent.

80. Developing a generic version of a brand-name drug requires a sample supply of the original brand-name drug. This sample supply includes the active pharmaceutical ingredient ("API"). The API is necessary in order to engage in bio-

studies and validation testing before the generics manufacturer can submit an ANDA for FDA approval. The FDA requires the submitting generic drug company to identify its API supplier in the ANDA. The API supplier must submit a Drug Master File ("DMF") to the FDA, which is considered along with the ANDA in determining whether the ANDA will be approved.

81. Few companies are capable of supplying drug companies with thalidomide API. In or about 2004, Barr managed to procure a French supplier of thalidomide API, Seratec S.A.R.L. ("Seratec") for use in its generic Thalomid ANDA application.

82. Barr used its Seratec thalidomide API supply in conducting bio-studies and developing a generic version of Thalomid, which was formulated by September, 2005. Barr was prepared to file its thalidomide ANDA with the FDA, and needed only a DMF reference letter from Seratec.

83. Barr never obtained a DMF letter from Seratec; while the two companies were finalizing negotiations for a thalidomide supply, Celgene and Seratec entered into an exclusive thalidomide supply arrangement. On information and belief, Celgene required exclusivity from Seratec in order to interfere with potential generic competitors' ability to market a generic version of Thalomid, and not because it was in need of additional thalidomide supply.

84. As a result of the exclusive contract between Celgene and Seratec, Barr was forced to find a different supplier and repeat its bio-studies and validation testing once more, causing it great expense and delay.

85. But for Celgene's interference, a lower-priced competing thalidomide generic product would have been introduced years earlier. Barr submitted a thalidomide ANDA on September 22, 2006, after performing new bio-studies and validation testing on samples from its new supplier. The ANDA showed that Barr's generic thalidomide pharmaceutical product was bioequivalent to Celgene's brand-name Thalomid. The FDA accepted Barr's thalidomide ANDA for filing on December 4, 2006.

86. Celgene has maintained its exclusivity in the market by manipulating the REMS provisions, which were intended by Congress to raise awareness of and safeguard the public from improper usage of pharmaceuticals, in order to delay and indefinitely postpone the availability of generic alternatives to Thalomid and Revlimid. This manipulation of the law was expressly disavowed by Congress. See Food Drug and Cosmetic Act § 505-1(f)(8) (21 U.S.C. § 355-1).

87. Due to Celgene's REMS programs, generic manufacturers are unable to purchase Thalomid and Revlimid samples through normal wholesale distribution channels. As a result, generic manufacturers have attempted to purchase Thalomid and Revlimid capsules, with the FDA's endorsement, from Celgene itself in order to conduct the necessary bioequivalence studies to develop generic versions of

Celgene's branded drugs. Celgene has consistently refused to provide requested samples in order to block generic entry.

2. Celgene Refuses to Sell Samples to Lannett Despite FDA Approval to Do So

88. Lannett identified the thalidomide market as an area in which a generic product would greatly benefit consumers by providing them with a lower-priced pharmaceutical alternative.

89. In order to obtain FDA approval of an ANDA for a generic thalidomide product, bioequivalence testing is a necessary requirement. Accordingly, Lannett wrote to the FDA in a letter dated September 6, 2006, requesting bioequivalence recommendations regarding thalidomide capsules.

90. The FDA Office of Generic Drugs ("OGD") responded to Lannett's request in a letter dated February 12, 2007. The OGD stated that "it is not agency's [sic] intention to permit the restrictions of the S.T.E.P.S. program to prevent manufacturers of generic drugs from obtaining Thalomid for use in the bioequivalence testing necessary to obtain approval of an abbreviated new drug application for a thalidomide product."

91. The OGD letter further stated:

> To ensure that the intention of Congress in enacting the Generic Drug Approval Provisions in Section 505(i) is not frustrated by the terms of the S.T.E.P.S. program, FDA has notified Celgene that the agency intends to exercise its enforcement discretion to permit Celgene to provide to another drug manufacturer (or its

> agent) 500 units of Thalomid. . . for the purpose of conducting bioequivalence testing.

92. Arthur P. Bedrosian, President and CEO of Lannett, wrote by letter dated July 26, 2007, to Celgene:

> In order to complete our bio-study, the FDA has instructed us to purchase 250 Thalomid 200 MG Capsules from you. We kindly request information as to how to best carry out this transaction. We will be happy to supply a purchase order once you provide us with the total product cost. Submitted with this document, you will find the appropriate licenses necessary for us to purchase product from you. We kindly ask that you inform us of any additional information you will need to complete this transaction.

93. On or about September 27, 2007, Lannett faxed to Celgene, at its request, a copy of the FDA letter that Lannett received, which authorized Lannett to acquire Thalomid samples from Celgene.

94. Despite being in receipt of Lannett's purchase order and the FDA authorization letter, Celgene refused to fill Lannett's purchase order.

95. Lannett filed a complaint against Celgene on January 14, 2008, seeking, inter alia, mandatory injunctive relief requiring Celgene to provide samples of Thalomid in order for Lannett to conduct bioequivalence testing as contemplated by the FDA's letter dated February 12, 2007. The case was dismissed without prejudice and re-filed in August 2008.

96. Celgene and Lannett reached a confidential settlement in 2011. As discussed below, Lannett eventually filed a thalidomide ANDA in late 2014. Celgene brought suit, alleging patent infringement and further delaying the

availability of generic thalidomide. That lawsuit is pending and, as of this date, no generic thalidomide product has come to market.

3. Celgene Refuses to Sell Samples to Mylan, Despite FDA Approval to Do So

97. In addition, Celgene has refused to provide samples to the generic manufacturer Mylan.

98. Mylan Inc., based in Cecil Township, Pennsylvania, is the second largest generic and specialty pharmaceuticals company in the world.

99. Mylan's efforts to develop a generic thalidomide pharmaceutical began in September, 2003. On October 5, 2004, Mylan sent a letter to Celgene through a third party requesting to purchase Thalomid capsules for the purpose of conducting bioequivalence studies. Celgene did not respond. On May 3, 2005, Mylan repeated its request.

100. On June 21, 2005, Celgene finally responded, by confirming the unavailability of Thalomid through normal wholesale distribution channels, explaining that its S.T.E.P.S. program required the tracking of all Thalomid dispenses, and further stating that it was against policy to deal with third parties in the provision of Thalomid.

101. Mylan directly contacted Celgene on September 2, 2005, and requested to purchase Thalomid capsules for the purposes of developing a generic product. Mylan stated that the "FDA had recommended that we contact you directly to request

a sample" of Thalomid samples for bioequivalence testing, and explained that "obtaining samples through other traditional channels is nearly impossible."

102. Celgene responded on October 20, 2005, stating that it required additional time to thoroughly consider the request. Celgene claimed that this extra time was necessary in order to consider granting Mylan's bioequivalency testing request, in order to comply with its S.T.EP.S. program and "to avoid fetal exposure."

103. On December 19, 2005, Celgene provided a "complete" response, stating that Celgene would need the FDA's agreement in order for Mylan to purchase samples outside of the S.T.E.P.S. program, "[W]e recommend that you contact the FDA's [Division of Special Pathogen and Transplant Products] to discuss the importance of the *S.T.E.P.S.* program to them." Furthermore, Celgene stated that if the FDA subsequently "contacts us in writing and recommends that we violate our S.T.E.P.S. program by providing you with the quantity of THALOMID you request, we will further evaluate your request at that time."

104. Mylan's next step, in accordance with Celgene's instructions, was to submit a letter, dated January 11, 2006, to the FDA, asking for the FDA's assistance in obtaining the necessary Thalomid samples required for bioequivalence testing. Included with the letter was Mylan's proposed restricted distribution protocols for the samples in order to avoid fetal exposure. Mylan received a response dated February 12, 2007, in which the FDA requested an investigational new drug application (IND) so that the FDA could "ensure that all appropriate safeguards for

a clinical investigation with thalidomide are in place," as a substitute for the S.T.E.P.S. program.

105. Further, the FDA's response echoed the OGD letter of February 12, 2007, stating:

> It is the FDA's view that certain restrictions are needed to ensure safe use of the drug; however, it is not the agency's intention to permit the restrictions of the S.T.E.P.S. program to prevent manufacturers of generic drugs from obtaining Thalomid for use in the bioequivalence testing necessary to obtain approval of an abbreviated new drug application for a thalidomide product. The agency believes that such bioequivalence studies can be conducted safely under either an IND or in circumstances that provide alternative assurance of patient safety. To ensure that the intention of Congress in enacting the generic drug approval provisions in section 505(j) is not frustrated by the terms of the S.T.E.P.S. program, FDA has notified Celgene that the agency intends to exercise its enforcement discretion to permit Celgene to provide to another drug manufacturer (or its agent) 500 units of Thalomid (including 200 units for the purpose of conducting bioequivalence (including dissolution) testing and 300 units for a limited number of retained samples) when Celgene has received confirmation in writing from the sponsor, its agent, or FDA that the sponsor of the study either has an IND in effect for the study or has otherwise provided the agency with sufficient assurance that the bioequivalence study will be conducted in such a manner as to ensure the safety of the subjects.

106. Mylan provided the FDA with its proposed thalidomide bioequivalence testing safety protocols on May 1, 2007.

107. On September 11, 2007, the FDA notified Mylan that its proposed safety protocols had been reviewed by the Division of Bioequivalence, which had found the proposed protocols "acceptable."

108. On November 16, 2007, Mylan informed Celgene that the FDA had approved its proposed safety protocols, thus addressing Celgene's given reason for not providing samples.

109. Celgene's purported concerns over safety soon proved pretextual; although their alleged safety concerns should have been alleviated by receipt of the FDA's approval of Mylan's proposed safety protocol, Celgene has not provided Mylan with any Thalomid samples, and, in fact, no generic manufacturer has been able to bring a generic thalidomide product to market.

110. Following Mylan's November 16, 2007, submission to Celgene of FDA approval, Celgene continued its extensive efforts to indefinitely delay the possibility of bioequivalence studies conducted by generic manufacturers. Mylan made many further requests over the next three years, only to be met with repeated delay tactics such as numerous requests for overly burdensome, irrelevant, and duplicative information from Celgene.

111. In fact, beginning in 2009, after Mylan attempted to purchase lenalidomide samples with the intent of developing a generic form of Revlimid, Celgene once again engaged in the same forestalling tactics, and has continued to refuse to provide samples, even when informed of FDA approval for the proposed bioequivalency testing and safety protocols.

112. On April 3, 2014, Mylan brought a lawsuit against Celgene under federal and state antitrust laws for its anticompetitive tactics to maintain monopoly

power in the market for Thalomid and Revlimid (D. New Jersey, Case No. 14-cv-2094).

113. Mylan alleges that Celgene cited safety concerns as a sham pretext for its refusal to provide the samples of Thalomid and Revlimid that are necessary for Mylan to conduct bioequivalence testing.

114. Mylan alleges that Celgene uses a "playbook of obstructing its generic competitors by gaming the regulatory system."

115. The Federal Trade Commission (FTC) filed an amicus brief in support of Mylan's lawsuit against Celgene. The FTC noted that the FDAAA was written to explicitly prevent drug manufacturers from using REMS programs to impede generic competition, as Celgene was doing with Thalomid and Revlimid.

116. On December 22, 2014, Celgene's motion to dismiss Mylan's complaint was denied. On February 5, 2015, Celgene filed a Petition for Permission to Appeal with the United States Court of Appeals for the Third Circuit. That Petition was denied on March 5, 2015.

4. Celgene Refuses to Sell Samples to Dr. Reddy's Laboratories, Despite FDA Approval to Do So

117. Dr. Reddy's is a global pharmaceutical company based in Telengana, India. Dr. Reddy's has been in the business of developing generic U.S. pharmaceuticals since 1994.

118. In August 2008, Dr. Reddy's requested samples of Revlimid from Celgene so that it could perform bioequivalence testing. Celgene ignored Dr. Reddy's request.

119. In January 2009, Dr. Reddy's wrote to Celgene again, requesting samples of Revlimid from Celgene so that it could perform bioequivalence testing. Celgene responded with one sentence: "Celgene has no obligation to supply Dr. Reddy's with Revlimid and declines to do so."

120. In June 2009, Dr. Reddy's filed a Citizen Petition with the FDA, alleging that Celgene was yet again refusing to provide samples to a generic drug manufacturer for the purpose of bioequivalence testing. *Id.*

121. Celgene's purported justification for its refusal to permit Dr. Reddy's to conduct bioequivalence testing with its monopolized products was once again premised on Celgene's REMS program, although the FDA has unequivocally stated that the REMS program is not a sufficient basis for categorically refusing to provide samples for testing to generic drug manufacturers with similar FDA-approved drug restriction program steps in place.

122. Celgene's pattern of conduct and course of dealings with Barr, Lannett, Mylan, and Dr. Reddy's exhibits the same characteristics of delay and purported safety concerns that have been complied with time and time again, motivated by anticompetitive animus that has no basis in either fact or law.

B. Celgene Fraudulently Obtained Patents on Thalidomide and Lenalidomide to Obstruct Generic Competition and Maintain its Monopoly on Thalomid and Revlimid

123. In a further attempt to secure and maintain its monopoly on Thalomid (and later, Revlimid), Celgene obtained numerous patents related to its plan for safe distribution of the drug. These patents are directed to methods of delivering a drug to a patient while preventing exposure of a fetus or other contraindicated individual to that drug. The patents generally claim the use of registries to register patients, prescribers and pharmacies when the patient is using a particular drug that should not be exposed to a fetus or other contraindicated individual; testing and regularly retesting the patient for risks associated with the drug (including pregnancy testing to prevent exposure to a fetus); counseling patients about the risk of the drug; limiting the amount of drug dispensed; and/or prescribing and dispensing the drug only after determining the risk is acceptable.

124. Celgene's patents on the procedures for safe distribution are the 6,045,501 patent, the 6,315,720 patent, the 6,561,976 patent, the 6,561,977 patent and the 6,755,784 patent (the "Distribution Method Patents"), and the 8,315,886 patent. The chronological history of these patents is as follows:

Patent Number	Patent No. Abbreviation Herein	Date Filed with USPTO	Date Patent Obtained
6,045,501	'501 patent	August 28, 1998	April 4, 2000
6,315,720	'720 patent	October 23, 2000	November 13, 2001
6,561,976	'976 patent	September 26, 2001	May 13, 2003
6,561,977	'977 patent	September 27, 2001	May 13, 2003
6,755,784	'784 patent	March 7, 2003	June 29, 2004
8,315,886	'886 patent	December 13, 2010	November 20, 2012

125. The '501 and '720 patents were invalidated by the Patent Trial and Appeal Board on October 26, 2016. (*See* IPR2015-01092, Paper No. 73; IPR2015-01096, Paper No. 73; IPR2015-01102, Paper No. 75; IPR2015-01103, Paper No. 76.)

126. Thalomid was approved by the FDA for use in 1998; Revlimid was approved by the FDA in December 2005.

127. When Thalomid was first approved by the FDA, the only patent that Celgene had listed in connection with it was the '501 patent. However, as these other patents were obtained, Celgene listed them in the Orange Book in connection with Thalomid. And when Revlimid was approved by the FDA in December 2005, Celgene listed these patents in the Orange Book in relation to Revlimid as well (adding the '886 patent when it was obtained in 2012).

128. Celgene listed these patents in the Orange Book with the intent and purpose of discouraging thalidomide or lenalidomide ANDA filings and delaying FDA approval of any thalidomide or lenalidomide ANDA for at least thirty months under the statutory stay of 21 U.S.C. § 355(j)(5)(B)(iii).

129. Prosecuting a patent application is an ex parte process, and therefore, the law imposes a duty of good faith, candor, and disclosure on everyone associated with filing and prosecuting the application. See 37 C.F.R. § 1.56; Manual of Patent Examining Procedure § 2000. The duty of candor/disclosure requires, inter alia, the applicant, his or her agents and/or attorneys, and anyone else substantively involved in prosecuting the application to disclose all information that is material to the patentability of the claims.

130. An applicant's intentional withholding of information known to be material to patentability with intent to deceive the USPTO constitutes inequitable conduct and renders a patent unenforceable.

131. The existence of prior art is material to patentability. See 35 U.S.C. § 102.

132. Procedures for safe distribution and use of dangerous drugs like Thalomid and Revlimid had been discussed, written about, and utilized for years prior to Celgene's separate patent applications, including:

a. The "Clozaril Patient Monitoring Service" ("CPMS") (a/k/a "Clozaril National Registry"), a program for the distribution of

CLOZARIL™, which uses a national registry of prescribers, patients and pharmacies;

b. Honigfeld, "Effects of the Clozapine National Registry System on Incidence of Deaths Related to Agranulocytosis," *Psychiatric Services* 47(1): 52-56 (1996) ("*Honigfeld I*"), which describes the CPMS;

c. Honigfeld, *et al.*, "Reducing Clozapine-Related Morbidity and Mortality: 5 Years of Experience With the Clozaril National Registry," J. *Clin*. *Psychiatry* 59(suppl 3): 3-7 (1998) ("Honigfeld II"), which also describes the CPMS;

d. The "Guide to the Clozaril Patient Monitoring Service," Novartis Pharmaceuticals UK Ltd. (Nov. 1997) ("the Guide"), which describes details of the CPMS;

e. The ACCUTANE® Pregnancy Prevention Program ("PPP") is a program for the distribution of Accutane, also known to be a human teratogen;

f. The Accutane PPP Package ("PPP Package"), a 1994 patient and prescriber information package for Accutane, distributed by Roche Pharmaceuticals, that describes details of the PPP;

g. A Centers for Disease Control ("CDC") public meeting entitled "Preventing Birth Defects Due to Thalidomide Exposure" and

transcript from March 26, 1997, at which the risks associated with thalidomide use and procedures for safe distribution and use were discussed;

h. Zeldis, *et al.*, "S.T.E.P.S™: A Comprehensive Program for Controlling and Monitoring Access to Thalidomide," *Clinical Therapeutics* 21(2): 319-30 (1999) ("*Zeldis*"), which describes the "System for Thalidomide Education and Prescribing Safety" or "S.T.E.P.S." developed by Celgene;

i. The September 4 and 5, 1997 Center for Drug Evaluation and Research of the Food and Drug Administration public meeting ("CDER Meeting") at which Celgene employee Bruce Williams explained that Clozaril and Accutane procedures were a "starting point" in developing distribution procedures for thalidomide; and

j. The September 9 and 10, 1997 public workshop held by the National Institutes of Health, FDA, and CDC, entitled "Thalidomide: Potential Benefits and Risks, Open Public Scientific Workshop" (the "NIH Meeting"), at which Celgene employee Bruce Williams gave a presentation about a Celgene proposal "for a distribution and education system" for thalidomide.

133. Each of the above constitutes prior art that Celgene was required to, but did not, disclose to the USPTO, for each of the Distribution Method Patents.

134. In its 2010 application for the '886 patent, Celgene disclosed much of the above prior art; however, as with the Distribution Method Patents, it did not disclose the existence of the PPP Package or CDC Transcript.

135. The Distribution Method Patents and the '886 patent were obtained from the USPTO through knowing and willful fraud and are unenforceable.

136. Celgene caused the Distribution Method Patents and the '886 patent to be listed in the Orange Book with knowledge that they were fraudulently obtained from the USPTO and are unenforceable.

137. Celgene's intentional withholding of information known to be material to patentability with intent to deceive the USPTO was done for the anticompetitive purpose of excluding generic competitors.

The CPMS.

138. The CPMS is a program for the distribution of CLOZARIL™, known generically as clozapine. Clozaril is used to treat persons with schizophrenia. Its use is associated with an increased risk of agranulocytosis, a potentially fatal blood disorder.

139. Clozaril is distributed through the CPMS, which employs a national registry for prescribers, patients and pharmacies in order to identify and reduce the risk of agranulocytosis associated with the use of Clozaril.

140. The CPMS employs the following steps, among others: registering prescribers, pharmacies and patients in a computerized registry; including information in the registry about the patient, such as baseline white blood cell ("WBC") counts, to determine the potential risk of agranulocytosis to the patient; performing blood testing for WBC counts before providing Clozaril to the patient; performing weekly blood testing for WBC counts after therapy has started; prescribing and dispensing a limited supply of Clozaril only after the prescriber determines that the risk is acceptable and provides the pharmacy with a report containing the patient's WBC count and the prescriber's assessment that the patient is eligible to receive Clozaril; denying or discontinuing treatment with Clozaril if the prescriber determines that the risk of agranulocytosis is unacceptable based on the testing; and providing weekly refills of Clozaril only after the same criteria for the initial prescription have been met again each week.

141. The CPMS qualifies as prior art to the claims of the Distribution Method Patents and the '886 patent under 35 U.S.C. § 102(b) because it was commercially used in the United States more than one year before the earliest priority date of the Distribution Method Patents and the '886 patent.

142. The applicants of those patents, their agents and/or their attorneys did not disclose the CPMS to the USPTO during pendency of the applications from which the Distribution Method Patents issued.

Honigfeld I.

143. Details of the CPMS are described in *Honigfeld I* (Honigfeld, "Effects of the Clozapine National Registry System on Incidence of Deaths Related to Agranulocytosis," Psychiatric Services 47(1): 52-56 (1996)).

144. *Honigfeld I* qualifies as prior art to the Distribution Method Patents and the '886 patents under 35 U.S.C. § 102(b) because it was publicly available and accessible more than one year before the earliest priority date of the Distribution Method Patents and the '886 patents.

145. The applicants, their agents and/or their attorneys did not disclose *Honigfeld I* to the USPTO during pendency of the applications from which the Distribution Method Patents issued.

Honigfeld II.

146. Details of the CPMS are described in *Honigfeld II* (Honigfeld, et al., "Reducing Clozapine-Related Morbidity and Mortality: 5 Years of Experience With the Clozaril National Registry," *J. Clin. Psychiatry* 59(suppl 3): 3-7 (1998)).

147. *Honigfeld II* qualifies as prior art to the '501 and '976 patents under 35 U.S.C. § 102(a) because it was publicly available and accessible before the earliest priority date of the '501 and '976 patents. *Honigfeld II* qualifies as prior art to the '720, '977, '784 and '886 patents under 35 U.S.C. § 102(b) because it was publicly available and accessible more than one year before the earliest priority date of the '720, '977, '784 and '886 patents.

148. The applicants, their agents and/or their attorneys did not disclose *Honigfeld II* to the USPTO during pendency of the applications from which the Distribution Method Patents issued.

The Guide.

149. Details of the CPMS are described in the Guide ("Guide to the Clozaril Patient Monitoring Service," Novartis Pharmaceuticals UK Ltd. (Nov. 1997)).

150. The Guide qualifies as prior art to the '501 and '976 patents under 35 U.S.C. § 102(a) because it was publicly available and accessible before the earliest priority date of the '501 and '976 patents. The Guide qualifies as prior art to the '720, '977, '784 and '886 patents under 35 U.S.C. § 102(b) because it was publicly available and accessible more than one year before the earliest priority date of the '720, '977, '784 and '886 patents.

151. The applicants, their agents and/or their attorneys did not disclose the Guide to the USPTO during pendency of the applications from which the Distribution Method Patents issued.

The PPP (Accutane Pregnancy Prevention Program).

152. The PPP is a program for the distribution of ACCUTANE®, known generically as isotretinoin. Accutane is used to treat certain kinds of acne. Accutane is known to be a human teratogen, meaning it is known to cause congenital malformations in the fetus of a pregnant woman.

153. The PPP was developed and established to limit or prevent fetal exposure to isotretinoin. The PPP employed, among other things: an information package for physicians warning of the dangers of administering isotretinoin to pregnant women; a patient informed consent form containing warnings detailing the risks associated with Accutane and the requirements to receive Accutane; required pregnancy testing and birth control counseling before the patient started treatment with Accutane; and a patient survey on compliance.

154. The PPP qualifies as prior art to the claims of the Distribution Method Patents and the '886 patent under 35 U.S.C. § 102(b) because it was commercially used in the United States more than one year before the earliest priority date of the Distribution Method Patents and the '886 patent.

155. The applicants, their agents and/or their attorneys did not disclose the PPP to the USPTO during pendency of the applications from which the Distribution Method Patents issued.

The Accutane PPP Package.

156. Details of the PPP are described in the PPP Package (a 1994 patient and prescriber information package) distributed by Roche Pharmaceuticals.

157. The PPP Package qualifies as prior art to the Distribution Method Patents and the '886 patent under 35 U.S.C. § 102(b) because it was publicly available and accessible more than one year before the earliest priority date of the Distribution Method Patents and the '886 patent.

158. The applicants, their agents and/or their attorneys did not disclose the PPP Package to the USPTO during pendency of the applications from which the Distribution Method Patents and the '886 patent issued.

The CDC Meeting And Transcript.

159. On March 26, 1997, the CDC held a public meeting to discuss thalidomide and the risks associated with its use, entitled "Preventing Birth Defects Due to Thalidomide Exposure" (the "CDC Meeting").

160. The CDC Meeting was attended by at least two Celgene employees, Dr. Jerome Zeldis, then the Vice President of Medical Affairs at Celgene, and Mr. Bruce A. Williams, one of the named inventors on the Distribution Method Patents and the '886 patent.

161. The transcript of the CDC Meeting ("CDC Transcript") records the discussions that took place at the meeting. The CDC Transcript shows that the PPP and the CPMS were discussed, as was the use of the elements of those two systems in designing a similar program for thalidomide.

162. During the CDC Meeting, the attendees discussed use of the following elements, among others, as part of a thalidomide distribution program: registration of male and female patients, pharmacies and prescribers; counseling patients about the risks of thalidomide and the need for contraception; required pregnancy testing before thalidomide is prescribed; monthly testing thereafter before refilling the prescription; providing proof to the pharmacy before the drug can be dispensed that

the patient is not pregnant; providing contraceptives with the drug; limiting the length of the prescription to a monthly supply; and requiring revisits to the prescriber before refilling the prescription.

163. The CDC Transcript was publicly available and accessible under the Freedom of Information Act more than one year before the earliest priority date of the Distribution Method Patents and the ’886 patent. Accordingly, the CDC Transcript qualifies as prior art to the Distribution Method Patents and the ’886 patent under 35 U.S.C. § 102(b).

164. The applicants, their agents and/or their attorneys did not disclose the CDC Meeting or the CDC Transcript to the USPTO during pendency of the applications from which the Distribution Method Patents and the ’886 patent issued.

Zeldis.

165. *Zeldis* (Zeldis, et al., “S.T.E.P.S™: A Comprehensive Program for Controlling and Monitoring Access to Thalidomide,” *Clinical Therapeutics* 21(2): 319-30 (1999)), qualifies as prior art to the ‘720, ’977 and ’784 patents under 35 U.S.C. § 102(b) because it was publicly available and accessible more than one year before the earliest priority date of the ’720, ’977, ’784 and ’886 patents.

166. *Zeldis* is co-authored by Celgene employees, including Zeldis and named inventor Williams.

167. *Zeldis* describes the “System for Thalidomide Education and Prescribing Safety” or “S.T.E.P.S.” developed by Celgene, in conjunction with

FDA, to monitor and control access to thalidomide. *Zeldis* states that S.T.E.P.S. "is based in part on experience gained with other drugs – specifically isotretinoin and clozapine – that offer important clinical benefits but carry the potential for serious harm."

168. *Zeldis* discusses the systems established and used for Accutane (the PPP) and Clozaril (the CPMS), and states:

> Celgene has incorporated elements of both these successful programs into the S.T.E.P.S.™ program for controlling the distribution of thalidomide. Educational materials for patients and physicians and label warnings similar to those used in the isotretinoin program are coupled with clinician and patient registration and testing similar to those used in the clozapine program.

169. *Zeldis* cites *Honigfeld I* and *Honigfeld II* in its discussion of Clozaril.

170. The applicants, their agents and/or their attorneys did not disclose *Zeldis* to the USPTO during pendency of the applications from which the Distribution Method Patents issued.

The CDER Meeting And Transcript.

171. The CDER Meeting (a Center for Drug Evaluation and Research of the Food and Drug Administration public meeting on September 4 and 5, 1997 on the safety and efficacy of thalidomide) was recorded in a publicly available transcript ("CDER Transcript").

172. At least seven Celgene employees, including named inventor Williams, attended the CDER Meeting.

173. Williams made a presentation on preventing fetal exposure to thalidomide at the CDER Meeting.

174. During this presentation at the CDER Meeting, Williams stated:

> [w]e recognize that there may be some models in the marketplace today which could serve as at least a starting point in our thinking as we develop this program. Two of them came to mind that I would like to just speak very briefly to, to indicate why we feel that they are relevant models, but also where we feel they may not go far enough for this particular circumstance. The first is one that this committee, particularly, is very familiar with. And that is Roche's Accutane, used to treat severe acne, and known to be a human teratogen.

175. Williams then described the Accutane system, the PPP, and its purported drawbacks, which he described as a lack of a mandatory registry and an inability to determine at the pharmacy whether the patient has participated in Roche's programs.

176. Williams stated that the purported drawbacks with the PPP caused Celgene to look at other programs, specifically, the CPMS. He stated:

> In looking at how Sandoz structured this [Clozaril] system, we began to see that by taking elements from the Roche program [Accutane], elements from the Clozaril program and other unique elements, we would create a system that really would be state of the art, represent a significant step, we believe, forward in the ability to make drugs like thalidomide available to patients who need it, while at the same time providing a very high margin for protection.

177. The CDER Transcript qualifies as prior art to the Distribution Method Patents and the '886 patent under 35 U.S.C. § 102(a) because it was publicly available and accessible under the Freedom of Information Act before the earliest priority date of the Distribution Method Patents and the '886 patent. The CDER Transcript also qualifies as prior art to the '720, '977 and '784 patents under 35 U.S.C. § 102(b) because it was publicly available and accessible under the Freedom of Information Act more than one year before the earliest priority date of the '720, '977 and '784 patents.

178. The applicants, their agents and/or their attorneys did not disclose the CDER Meeting or Williams' presentation at the CDER Meeting to the USPTO during pendency of the applications from which the Distribution Method Patents issued.

The NIH Meeting And Transcript.

179. The NIH Meeting (a National Institutes of Health, FDA, and CDC public workshop entitled "Thalidomide: Potential Benefits and Risks, Open Public Scientific Workshop" September 9 and 10, 1997) was recorded in a publicly available transcript ("NIH Transcript").

180. On September 10, 1997, Williams gave a presentation at the NIH Meeting about a Celgene proposal "for a distribution and education system" for thalidomide.

181. During his presentation at the NIH Meeting, Williams stated that:

> when we started in this endeavor we looked to see what else was in the marketplace that might serve as a model. We accepted that we were unlikely to find any single model that carried all of the elements that would likely be necessary for this drug, but we did find two that in part covered many of the elements that might be required. Accutane, we heard about yesterday. Comprehensive educational program, counseling, and good contraception, informed consent, a package with integrated product warnings, and a surveillance system, albeit voluntary. Many elements that clearly with either change or updating or enhancement would likely be relevant to what needed to be done for thalidomide. We also heard about the Novartis program for Clozaril, a drug used to treat schizophrenia and introduced in an era where existing antischizophrenia drugs were not particularly effective for many patients. In addition they carried their own baggage of side effects. However, in a small proportion of patients who take this drug, a granular cytosis [sic] can develop in a very short period of time.

182. The NIH Transcript qualifies as prior art to the Distribution Method Patents and the ’886 patent under 35 U.S.C. § 102(a) because it was publicly available and accessible under the Freedom of Information Act before the earliest priority date of the Distribution Method Patents and the ’886 patent. The NIH Transcript also qualifies as prior art to the ’720, ’977 and ’784 patents under 35 U.S.C. § 102(b) because it was publicly available and accessible under the Freedom of Information Act more than one year before the earliest priority date of the ’720, ’977 and ’784 patents.

183. The applicants, their agents and/or their attorneys did not disclose the NIH Meeting or Williams’ presentation at the NIH Meeting to the USPTO during pendency of the applications from which the Distribution Method Patents issued.

Unenforceability of the Distribution Method Patents.

184. Any or all of the CPMS, *Honigfeld I*, *Honigfeld II*, the Guide, the PPP, the PPP Package, *Zeldis*, the CDC Meeting and Transcript, the CDER Meeting and Transcript, the NIH Meeting and Transcript, as well as Williams' presentations at any of these meetings, is material to the patentability of the Distribution Method Patents because, individually and/or in combination with one another, they establish a prima facie case of unpatentability under 35 U.S.C. §§ 102 and/or 103.

185. Any or all of the CPMS, *Honigfeld I*, *Honigfeld II*, the Guide, the PPP, the PPP Package, *Zeldis*, the CDC Meeting and Transcript, the CDER Meeting and Transcript, the NIH Meeting and Transcript, as well as Williams' presentations at any of these meetings, is material to the patentability of the Distribution Method Patents because, had the USPTO been aware of those undisclosed prior art references, the USPTO would not have allowed any or all of the claims of the Distribution Method Patents to issue.

186. Any or all of the CPMS, *Honigfeld I*, *Honigfeld II*, the Guide, the PPP, the PPP Package, *Zeldis*, the CDC Transcript, the CDC Meeting, and the CDER and NIH Meetings and Transcripts, and Williams' presentations at those meetings is material to the patentability of the Distribution Method Patents because, individually and/or in combination with one another, they refute or are inconsistent with positions

the applicants took in opposing arguments of unpatentability relied on by the USPTO or asserting arguments of patentability.

187. Any or all of the CPMS, Honigfeld I, Honigfeld II, the Guide, the PPP, the PPP Package, Zeldis, the CDC Transcript, the CDC Meeting, and the CDER and NIH Meetings and Transcripts, and Williams' presentations at those meetings is material to the patentability of the Distribution Method Patents because individually and/or taken together they constitute information that a reasonable Examiner reviewing the applications would consider important in determining whether to allow the proposed claims to issue.

188. The applicants of the Distribution Method Patents, including Bruce Williams, their agents, their attorneys and/or others substantively involved in the prosecution, owed a duty of candor to the USPTO during pendency of the applications from which the Distribution Method Patents issued. As part of that duty of candor, they were required to disclose information material to the applications from which the Distribution Method Patents issued.

189. During pendency of the applications from which the Distribution Method Patents issued, the applicants, including Williams, their agents, their attorneys and/or others substantively involved in the prosecution, were aware of the CPMS, *Honigfeld I*, *Honigfeld II*, the Guide, the PPP, the PPP Package, the CDC Meeting, the CDC Transcript, *Zeldis*, the CDER Meeting (including Williams'

presentation) and Transcript and/or the NIH Meeting (including Williams' presentation) and Transcript.

190. While the applications from which the Distribution Method Patents issued were pending, the applicants, including Williams, as well as their agents, their attorneys and/or others substantively involved in the prosecution knew that the CPMS, *Honigfeld I*, *Honigfeld II*, the Guide, the PPP, the PPP Package, the CDC Meeting, the CDC Transcript, *Zeldis*, the CDER Meeting (including Williams' presentation) and Transcript and/or the NIH Meeting (including Williams' presentation) and Transcript was material to those applications.

191. The applicants of the Distribution Method Patents, including Williams, as well as their agents, their attorneys and/or others substantively involved in the prosecution withheld the CPMS, *Honigfeld I*, *Honigfeld II*, the Guide, the PPP, the PPP Package, the CDC Meeting, the CDC Transcript, *Zeldis*, the CDER Meeting (including Williams' presentation) and Transcript and/or the NIH Meeting (including Williams' presentation) and Transcript with intent to deceive the Patent Examiner.

192. The applicants of the Distribution Method Patents, including Williams, as well as their agents, their attorneys and/or others substantively involved in the prosecution, knowingly and willfully misrepresented and omitted material information during pendency of the applications from which the Distribution

Method Patents issued. But for these misrepresentations and omissions, the Distribution Method Patents would not have issued.

193. The Distribution Method Patents were obtained from the USPTO through knowing and willful fraud and are unenforceable. In fact, two of the Distribution Method Patents – the '501 patent and the '720 patent – were found to be unenforceable by the Patent Trial and Appeal Board in 2016.

194. Celgene caused the Distribution Method Patents to be listed in the Orange Book with knowledge that they were fraudulently obtained from the USPTO and are unenforceable.

195. Celgene listed the Distribution Method Patents in the Orange Book with the intent and purpose of discouraging thalidomide and lenalidomide ANDA filings and delaying FDA approval of any thalidomide or lenalidomide ANDAs for at least thirty months under the statutory stay of 21 U.S.C. § 355(j)(5)(B)(iii).

196. Celgene's lawsuits to enforce these patents constitutes sham litigation, brought for the purpose of delaying generic entry of thalidomide and lenalidomide to the market.

Unenforceability of the '886 Patent

197. On December 13, 2010, after both Barr and Natco Pharma Limited ("Natco") had filed ANDAs for thalidomide, Celgene applied for yet another patent on its Distribution Procedure (the '886 patent).

198. Celgene's application for the '886 patent did not disclose the PPP Package and CDC Transcript as prior art.

199. The PPP Package and CDC Transcript are material to the patentability of the '886 patent because, had the USPTO been aware of those undisclosed prior art references, the USPTO would not have allowed any or all of the claims of the '886 patent to issue.

200. The PPP Package and the CDC Transcript are material to the patentability of the '886 patent because, individually and/or in combination with one another, they refute or are inconsistent with positions the applicants took in opposing arguments of unpatentability relied on by the USPTO or asserting arguments of patentability. Non-limiting examples of materiality of each of these references to one or more claims of these patents are shown in the attached claim chart (Exhibit A).

201. The PPP Package and the CDC Transcript are material to the patentability of the '886 patent because, individually and/or taken together, they constitute information that a reasonable Examiner reviewing the application would consider important in determining whether to allow the proposed claims of the '886 patent to issue.

202. On November 20, 2012, Celgene obtained the '886 patent from the USPTO.

203. The ’886 patent was also obtained from the USPTO through knowing and willful fraud and is unenforceable.

204. Celgene caused the ’886 patent to be listed in the Orange Book with knowledge that it was fraudulently obtained from the USPTO and is unenforceable.

205. Celgene listed the ’886 patent in the Orange Book with the intent and purpose of discouraging thalidomide or lenalidomide ANDA filings and delaying FDA approval of any thalidomide or lenalidomide ANDA for at least thirty months under the statutory stay of 21 U.S.C. § 355(j)(5)(B)(iii).

206. The applicants of the ’886 patent, their agents, their attorneys and/or others substantively involved in the prosecution owed a duty of candor to the USPTO during pendency of the applications from which the ’886 patent issued. As part of that duty of candor, they were required to disclose information material to the application from which the ’886 patent issued.

207. During pendency of the application from which the ’886 patent issued, the applicants, including Williams, as well as their agents, their attorneys and/or others substantively involved in the prosecution, were aware of the PPP Package and the CDC Transcript.

208. While the application from which the ’886 patent issued was pending, the applicants, including Williams, as well as their agents, their attorneys and/or others substantively involved in the prosecution, knew that the PPP Package and CDC Transcript were material to that application.

209. The applicants of the ’886 patent, including Williams, as well as their agents, their attorneys and/or others substantively involved in the prosecution, withheld the actual PPP Package and CDC Transcript themselves with intent to deceive the Patent Examiner.

210. The applicants of the ’886 patent, including Williams, as well as their agents, their attorneys and/or others substantively involved in the prosecution, knowingly and willfully misrepresented and omitted material information during pendency of the application from which the ’886 patent issued. But for these misrepresentations and omissions, the ’886 patent would not have issued.

211. Despite Celgene’s knowing misrepresentations to the USPTO, Celgene sued lenalidomide ANDA applicants Natco, Arrow International Limited (“Arrow”), and Watson Laboratories, Inc. (“Watson”) for a statutory violation of these unenforceable patents. (Natco partnered with Arrow and Watson to market and distribute Natco’s generic lenalidomide.) In response to Celgene’s lawsuit, Natco alleged counterclaims of fraud on the patent office. (D.N.J., 10-cv-5197). As discussed below, this case settled in 2015.

C. Celgene Files Litigation against Barr, Natco, Arrow, Watson, and Lannett to Prevent or Delay Them from Marketing their Proposed ANDA Product in Competition with Celgene

212. In the rare circumstance when one of its potential generic competitors has managed to obtain samples of Thalomid or Revlimid from a source other than Celgene, and has filed ANDA applications and Paragraph IV certifications, Celgene

has blocked the generic drugs from coming to market by filing sham patent lawsuits and baseless Citizen Petitions with the FDA.

213. Celgene filed sham lawsuits against Barr in 2008 and Lannett in 2015 for thalidomide, and against Natco in 2010 for lenalidomide, claiming that the generic versions of Thalomid and Revlimid proposed by Barr, Lannett and Natco infringe Celgene's patents. Celgene's patents on Thalomid and Revlimid are related to the Risk Evaluation and Mitigation Strategies (REMS) procedures of ensuring safe use of the drug (the Distribution Method Patents, among others). As described in Barr, Lannett and Natco's answers and subsequent briefing in the cases Celgene brought against them, Celgene's patents related to this process are invalid as prior art or for obviousness, under 35 U.S.C. §§ 102 and/or 103. Because these patents are invalid, Celgene knew its litigation to enforce these patents would be unsuccessful, but brought these patent infringement cases for the sole purpose of delaying generic entry into the Thalomid and Revlimid markets.

1. Celgene's Sham Litigation and Citizen Petition Against Barr

214. As described in section V.A above, Celgene successfully blocked generic entry by competitor Barr Pharmaceuticals by entering into an exclusive dealing arrangement with Barr's would-be supplier, Seratec (*see* ¶¶ 79-87, above). Nonetheless, Barr obtained enough Thalomid from an alternative supplier to support an ANDA application filed with the FDA in September 2006, seeking approval for

manufacturing a generic version of Thalomid. In paragraph IV of Barr's application, Barr alleged that Celgene's patents were invalid.

215. In response to Barr's ANDA application, Celgene filed a patent lawsuit against Barr in this Court in 2007, as well as a Citizen Petition with the FDA on September 20, 2007, which asked that the FDA not approve a generic version of Thalomid, purportedly due to safety concerns regarding the drug. Barr filed counterclaims against Celgene, alleging monopolization, conspiracy to monopolize, and anticompetitive acts, including sham litigation.

216. Celgene's patent lawsuit was filed solely to take advantage of the 30-month stay of FDA approval for Barr's generic thalidomide pharmaceutical. See 21 U.S.C. § 355(j)(5)(B)(iii). Celgene's delay strategy paid off. During the pendency of the lawsuit-induced stay, Celgene brought Revlimid to market and Barr to withdrew its ANDA for generic thalidomide.

217. On May 26, 2010, Barr and Celgene announced that they had resolved both the patent litigation and the antitrust counterclaims.

218. As discussed further below, the Celgene patents at issue concerned method-of-use for Thalomid and Revlimid, rather than the underlying pharmaceutical process itself. Furthermore, Celgene's patents were, in essence, the result of academic studies and conferences, and thus prone to invalidity on the grounds of obviousness. Therefore, Celgene's patent litigation was not undertaken

in good faith, but rather as a means to collusively and illegally ensure its continued market monopoly, and not to protect their patents from illegal infringement.

219. On information and belief, Celgene's conduct had the anticompetitive effect of delaying and indefinitely postponing the testing and introduction of generic alternatives. This anticompetitive effect has resulted in great expense to customers and a market monopoly for Celgene. Indeed, a generic thalidomide product has never been brought to market.

220. Along with filing a sham patent complaint against Barr, Celgene responded to Barr's 2008 thalidomide ANDA by filing a Citizen Petition with the FDA, urging it not to approve Barr's application.

221. Celgene's positions set forth in the petition were wholly devoid of merit; the FDA did not respond to the baseless allegations therein. Due to Celgene's confidential settlement with Barr, Barr's new purchaser, Teva, suddenly decided that the lucrative Thalomid market did not make rational economic sense, and the petition became moot, as against Barr.

222. Celgene's petition asked the FDA to withhold approval of any generic thalidomide product, specifically mentioning Barr's ANDA by name and number, or, in the alternative: (1) require the application for generic thalidomide to be subject to the same conditions of approval applied to Thalomid under Subpart H of 21 C.F.R., Part 314; and (2) prohibit the restricted distribution program for the generic thalidomide product from actively authorizing prescriptions for multiple myeloma

and registering patients with multiple myeloma and oncologists in violation of Celgene's orphan drug exclusivity, an exclusivity which, by Celgene's own admission, expired in 2013.

223. Celgene's petition was filed for the sole purpose of preventing competition by delaying and foreclosing the FDA approval of generic Thalomid capsule ANDAs when its strategy of sabotaging competitors' development process through contractual interference was no longer guaranteed to work. In the months preceding Celgene's petition, at no time did Celgene share with Barr, the generic Thalomid ANDA filer, any of the information contained in Celgene's petition. Instead, Celgene kept its petition and its contents a tactical surprise. Given the purported safety-related bases of Celgene's petition, Celgene's secrecy — as well as its failure to take the very actions to protect patients that it sought to require of the generic tablet sellers — exposes the tactical, anticompetitive nature of the petition. Companies with genuine public safety concerns do not keep them a secret. Companies with genuine public safety concerns seek to adjust their own existing products, not just the products of competitors.

224. Celgene's petition was also objectively baseless. No reasonable petitioner could realistically expect to succeed on the merits of the petition Celgene filed. Celgene's petition lacked any reasonable regulatory, scientific, medical, or other reasonable basis. The FDA lacked the statutory authority to withhold approval of generic Thalomid capsule ANDAs on the bases cited by Celgene, or to require

the actions Celgene sought to impose on the ANDA filer. Celgene's petition lacked clinically meaningful evidence that lent support to its assertions or that bore on the approvability of generic Thalomid ANDAs. Celgene's petition stood no chance of affecting the FDA policy or procedure. In short, it was a sham.

2. Celgene's Sham Litigation Against Lannett

225. In December 2014, Lannett filed an ANDA application with the FDA in order to gain approval for manufacturing a generic version of Thalomid. In paragraph IV of Lannett's application, it alleged that Celgene's patents were invalid.

226. In response to Lannett's ANDA application, Celgene filed a patent lawsuit against Lannett in this Court in early 2015. (*See Celgene Corp. v. Lannett Holdings, Inc.*, 2:15-cv-00697 (D.N.J.) (Wigenton, J.). Lannett filed counterclaims against Celgene, alleging monopolization, conspiracy to monopolize, and anticompetitive acts, including sham litigation.

227. Celgene's patent lawsuit against Lannett triggered a 30-month stay of FDA approval for Lannett's generic thalidomide pharmaceutical. See 21 U.S.C. § 355(j)(5)(B)(iii).

228. As of the date of the filing of this complaint, the case is pending.

3. Celgene's Sham Litigation against Natco, Arrow, and Watson

229. Before August 30, 2010, Celgene had listed the Distribution Method Patents, the '886 patent, and several patents it had obtained related to the chemical

composition of Revlimid (including patent numbers 5,635,517 (the "'517 patent"), 6,281,230 (the "'230 patent"), 6,555,554 (the "'554 patent"), 7,119,106 (the "'106 patent"), 7,465,800 (the "'800 patent"), and 8,288,415 (the "'415 patent")), in the Orange Book in connection with NDA No. 21-880.

230. On August 30, 2010, Natco sent to Celgene a statutorily-required notice letter of its paragraph IV certifications, which contains a detailed factual and legal statement as to why the Distribution Method Patents and the '517, '230, '554, '106, and '800 patents, among others, are invalid, unenforceable, and/or not infringed by Natco's ANDA products.

231. On or around September 24, 2010, Natco filed ANDA No. 201-452 seeking generic approval for lenalidomide capsules 5 mg, 10 mg, 15 mg and 25 mg ("Natco's ANDA products").

232. The ANDA shows that Natco's ANDA products are bioequivalent to the product that is the subject of NDA No. 21-880, the holder of which FDA lists as Celgene.

233. On October 8, 2010, Celgene filed a patent infringement suit against Natco.

234. More than two years after Natco's ANDA filing, Celgene caused additional patents to be listed in the Orange Book in connection with the chemical composition of Revlimid (the '415 patent was added on or about November 16, 2012, and the '886 patent was added on or about December 20, 2012).

235. In response, on March 14, 2013, Natco sent to Celgene an additional statutorily-require notice letter of its Paragraph IV certifications, which contains a detailed factual and legal statement as to why the ’415 and ’886 patents are invalid, unenforceable, and/or not infringed by Natco’s ANDA products.

236. On or about April 10, 2013, nearly three years after Natco’s ANDA filing, Celgene caused the 8,404,717 (the “’717 patent”) to be listed in the Orange Book in connection with Revlimid®.

237. On April 30, 2013, the USPTO issued the 8,431,598 patent (‘598 patent) to Celgene.

238. On May 6, 2013, Celgene filed its Fifth Amended Complaint against Natco, Arrow and Watson, alleging that Natco’s ANDA products would infringe the Distribution Method Patents, the ‘886 patent, and the ’517, ’230, ’554, ’106, ’800, ’415, ’717 and ’598 patents, which Defendants denied.

239. The invalidity of the Distribution Method Patents is discussed at paragraphs 123-195.

240. As Natco has responded in the patent infringement case, the ‘517, ‘230, ‘554, ‘106, ‘800, ‘415, ‘717, and ‘589 patents are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, 112, and/or doctrines of double-patenting. Furthermore, Natco’s lenalidomide does not infringe Celgene’s ‘800 patent, because Natco’s lenalidomide does not contain lenalidomide hemihydrate.

241. Natco filed counterclaims against Celgene, alleging fraud on the U.S. Patent and Trademark Office, and invalid or unenforceable patents.

242. Celgene's sole purpose in litigating this patent infringement case against Natco was to delay generic entry into the Revlimid market.

D. Celgene's Settlements with Natco and Lannett Had Anticompetitive Effects

243. On December 22, 2015, Celgene and Natco announced that they had agreed to settle the case and dismiss all claims and counterclaims. The terms of the settlement provide that Natco cannot bring a generic lenalidomide product to market until March 2022 and can only sell a limited quantity of its generic product at that time. As Celgene has stated, "[t]he volume limit is expected to be a mid-single-digit percentage of the total lenalidomide capsules dispensed in the United States during the first full year of entry." While the volume Natco will be permitted to sell will increase slightly over time, Natco will not be able to sell unlimited quantities of generic lenalidomide until January 31, 2026. Thus, as a result of the settlement, a generic lenalidomide product continues to be unavailable to consumers and they are forced to continue to purchase brand-name Revlimid at Celgene's supracompetitive prices until at least 2022.

244. As described above, Celgene also reached a confidential settlement with Lannett, which may have had additional anticompetitive repercussions.

245. On information and belief, Celgene agreed to sell Thalomid to Lannett under the terms of the settlement. Lannett announced in late 2013 that its bioequivalence studies were going well, and it expected to submit an ANDA application to the FDA in January 2014. Lannett filed its ANDA in late 2014 and provided noticed of its Paragraph IV Certifications to Celgene on December 22, 2014. As discussed above, Celgene sued Lannett, alleging patent infringement, on January 23, 2015. That case is currently pending (D.N.J. 2015-cv-00697).

246. The anticompetitive effect of Celgene's conduct was to delay Lannett's ANDA. More specifically, though Lannett began requesting samples of Thalomid in 2006, it was unable to obtain such samples until after the 2011 settlement and did not file its ANDA until 2014, at which time Celgene filed sham patent litigation to further delay Lannett's generic thalidomide product. As of this date, no generic thalidomide product is available for consumers to purchase.

E. Celgene's Scheme Was Intended To, And Did, Harm Competition and Delay Generic Entry

247. Celgene's scheme, as a whole and in its individual parts, was intended to, and has, blocked and delayed generic Thalomid and Revlimid competition, disrupted the normal channels, and the statutory and regulatory mechanisms, by which generic competition takes place and was prescribed by Congress to take place,

and excluded would-be generic competitors from the most efficient means of distributing their products.

248. But for Celgene's anticompetitive conduct, generic Thalomid would have been brought to market before the class period alleged here, which begins in 2010. Multiple competitors (Mylan beginning in 2004, and both Lannett and Barr in or before 2006) attempted to obtain Thalomid for bioequivalence testing, but were thwarted by Celgene. And when Barr filed its ANDA in September 2006 after managing to circumvent Celgene's conduct, Celgene filed a sham lawsuit to enforce its invalid patents. In 2015, Celgene similarly filed a sham lawsuit against Lannett for the same purpose. These lawsuits have resulted in a continued exclusion of generic Thalomid from the market.

249. Multiple competitors (at least Mylan, Natco, and Dr. Reddy's) attempted to obtain Revlimid for bioequivalence testing beginning at least in 2009; Celgene refused to supply samples to Mylan and Mylan has been unable, to this day, to complete bioequivalence testing or file an ANDA. Natco filed its ANDA in September 2010, after which Celgene filed its sham patent litigation. Nacto and Celgene subsequently settled that lawsuit, agreeing that Natco would not sell a generic lenalidomide product until 2022 (and then, only in limited quantities). All of Celgene's patents on Revlimid are invalid under 35 U.S.C. §§ 101, 102, 103, 112, and/or doctrines of double-patenting. Thus, but for Celgene's conduct, including its

sham lawsuit against Natco, a generic manufacturer would have already brought to market a generic version of Revlimid.

250. But for Celgene's anticompetitive refusals to sell samples of Thalomid and Revlimid to generic competitor and/or sham litigation against generic manufacturers that were able to obtain samples, generic versions of these drugs would have entered the market even earlier.

251. Celgene's unjustifiable delay and refusal to cooperate with the generic ANDA filers directly prevented the generic ANDA filers from obtaining FDA approval. But for Celgene's unlawful conduct, the FDA would have given final approval to the pending generic tablet manufacturers and allowed them to enter the market.

252. To the extent it is even permitted to do so, Celgene cannot justify its scheme by pointing to any offsetting consumer benefit. The enormous cost savings offered by generic drugs (and, correspondingly, the anticompetitive harm caused by suppressing generic competition to Thalomid and Revlimid) outweigh any cognizable, nonpretextual procompetitive justifications Celgene could possibly offer.

253. Any cognizable justifications Celgene could offer for its scheme are, in fact, pretexts. Celgene's monopoly power, as alleged more fully below, was maintained through willfully exclusionary conduct, as distinguished from growth or development as a consequence of a superior product, business acumen or historic

accident. Neither Celgene's scheme as a whole, nor any of its constituent parts, constituted competition on the merits.

254. As a result of Celgene's anticompetitive conduct, Plaintiffs and class members still do not have access to generic versions of either Thalomid or Revlimid.

255. As alleged in more detail below, Celgene violated the state statutes and common law through its overarching scheme to improperly maintain and extend its monopoly power by foreclosing and delaying competition from lower-priced generic versions of Thalomid and Revlimid.

VI. CLASS ACTION ALLEGATIONS

256. Plaintiffs bring this action on their own behalves and as representatives of two Rule 23(b)(3) classes defined as follows:

The "Antitrust/Consumer Protection Damages Class":

> All persons or entities who purchased and/or paid for some or all of the purchase price for thalidomide or lenalidomide in any form, in Arizona, Arkansas, California, the District of Columbia, Florida, Hawaii, Idaho, Illinois, Iowa, Kansas, Maine, Michigan, Minnesota, Mississippi, Missouri, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, Pennsylvania, Puerto Rico, Rhode Island, South Dakota, Tennessee, Utah, Vermont, Virginia, West Virginia, or Wisconsin, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries at any time during the period November 7, 2010 through and until the anticompetitive effects of Defendant's unlawful conduct cease;

The "Unjust Enrichment Damages Class":

> All persons or entities who purchased and/or paid for some or all of the purchase price for thalidomide or lenalidomide in any form, in every state and territory in the United States except for Ohio and Indiana, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries at any time during the period November 7, 2010 through and until the anticompetitive effects of Defendant's unlawful conduct cease (the "Unjust Enrichment Damages Class").

The Antitrust/Consumer Protection Damages Class and the Unjust Enrichment Damages Class shall be collectively termed "the Damages Classes."

257. Plaintiffs bring this action on their own behalves and as representatives of a Rule 23(b)(2) class defined as follows:

> All persons or entities who purchased and/or paid for some or all of the purchase price for thalidomide or lenalidomide in any form, in the United States or its territories for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries at any time during the period November 7, 2010 through and until the anticompetitive effects of Defendant's unlawful conduct cease (the "Injunction Class").

258. The following persons or entities are excluded from the Damages Classes and the Injunction Class (collectively, the "Classes"):

a. Defendant and their officers, directors, management, employees, subsidiaries, or affiliates;

b. Government entities, except for government-funded employee benefit plans;

c. All persons or entities who purchased Revlimid or Thalomid for purposes of resale or directly from Defendant or their affiliates;

d. Fully insured health plans (i.e., Plans that purchased insurance from another third party payor covering 100% of the Plan's reimbursement obligations to its members);

e. "Single flat co-pay" consumers who purchased Revlimid or Thalomid only via a fixed dollar co-payment that does not vary on the basis of the purchased drug's status as branded or generic (e.g., $20 for both branded and generic drugs);

f. The judges in this case and any members of their immediate families.

259. Members of the Classes are so numerous that joinder is impracticable. Plaintiffs believe the Class includes hundreds of thousands, if not millions, of consumers, and thousands of third-party payors.

260. Plaintiffs' claims are typical of the claims of the members of the Classes. Plaintiffs and all members of the Classes were damaged by the same wrongful conduct by Celgene, i.e., they paid artificially inflated prices for Revlimid or Thalomid products and were deprived of the benefits of competition from less-expensive generic versions of Revlimid or Thalomid as a result of Celgene's wrongful conduct.

261. Plaintiffs will fairly and adequately protect and represent the interests of the Classes. Plaintiffs' interests are coincident with, and not antagonistic to, those of the Classes.

262. Plaintiffs are represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation, and have particular experience with class action antitrust litigation in the pharmaceutical industry.

263. Questions of law and fact common to the members of the Classes predominate over questions, if any, that may affect only individual class members because Celgene has acted on grounds generally applicable to the entire class. Such generally applicable conduct is inherent in Celgene's wrongful conduct.

264. Questions of law and fact common to the Damages Classes include:

a. whether Celgene unlawfully maintained monopoly power through all or part of its overarching scheme;

b. whether Celgene's anticompetitive scheme suppressed generic competition to Revlimid and/or Thalomid;

c. whether a reasonable petitioner would have expected the arguments made in Celgene's "citizen petition" against Barr to succeed;

d. whether Celgene's "citizen petition" was submitted to interfere with competition;

e. as to those parts of Celgene's challenged conduct for which such justifications may be offered, whether there exist cognizable, non-pretextual procompetitive justifications, which Celgene's challenged conduct was the least restrictive means of achieving, that offset the harm to competition in the market(s) in which Thalomid and Revlimid is sold;

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

g. to the extent a relevant market or markets must be defined, what that definition is or those definitions are;

h. whether Celgene's scheme, in whole or in part, has substantially affected interstate commerce;

i. whether Celgene's scheme, in whole or in part, caused antitrust injury to the business or property of Plaintiffs and the members of the Damages Classes in the nature of overcharges; and

j. the quantum of overcharges paid by the Damages Classes in the aggregate.

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

k. whether Celgene unlawfully maintained monopoly power through all or part of its overarching scheme;

l. whether Celgene's anticompetitive scheme suppressed generic competition to Revlimid and/or Thalomid;

m. whether a reasonable petitioner would have expected the arguments made in Celgene's "citizen petition" against Barr to succeed;

n. whether Celgene's "citizen petition" was submitted to interfere with competition;

o. as to those parts of Celgene's challenged conduct for which such justifications may be offered, whether there exist cognizable, non-pretextual procompetitive justifications, which Celgene's challenged conduct was the least restrictive means of achieving, that offset the harm to competition in the market(s) in which Thalomid and Revlimid is sold;

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

q. to the extent a relevant market or markets must be defined, what that definition is or those definitions are;

r. whether Celgene's scheme, in whole or in part, has substantially affected interstate commerce; and

s. whether Celgene's scheme, in whole or in part, caused antitrust injury to the business or property of Plaintiffs and the members of the Injunction Class.

266. Class action treatment is a superior method for the fair and efficient adjudication of the controversy in that, among other things, 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, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress on claims that might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

267. Plaintiffs know of no difficulty to be encountered in this action that would preclude its maintenance as a class action.

VII. OTHER FACTUAL ALLEGATIONS

A. Effects on Competition and Damages to Plaintiffs and the Classes

268. Celgene's overarching anticompetitive scheme to suppress generic competition to Thalomid and Revlimid tablets has, both as a whole and in its individual parts, delayed and prevented the sale of generic Thalomid and Revlimid

by suppressing the ability of generic Thalomid and Revlimid alternatives to compete through the most efficient means of competition under the governing statutory and regulatory regime.

269. General economic theory recognizes that any overcharge at a higher level of distribution generally results in higher prices at every level below. Moreover, the institutional structure of pricing and regulation in the pharmaceutical drug industry assures that overcharges at the higher level of distribution are passed on to end-payors. Retailers passed on the inflated prices of Thalomid and Revlimid to Plaintiffs and members of the Classes. The complete foreclosure of generic competition injured end-payors who would have paid less for Thalomid or Revlimid, or their generic equivalents by (a) substituting purchases of less-expensive AB-rated generic Thalomid or Revlimid for their purchases of more-expensive branded Thalomid or Revlimid, (b) receiving discounts on their remaining branded Thalomid or Revlimid purchases, and (c) purchasing generic Thalomid or Revlimid at lower prices sooner.

270. During the relevant period, Plaintiffs and other members of the Classes purchased substantial amounts of Thalomid and/or Revlimid. As a result of Defendant's illegal conduct as alleged herein, Plaintiffs and other members of the Classes were compelled to pay, and did pay, artificially inflated prices for Thalomid and/or Revlimid requirements. Plaintiffs and the other Class members paid prices

for Thalomid and/or Revlimid that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein.

271. As a consequence, Plaintiffs and other members of the Damages Classes have sustained substantial losses and damage to their business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial.

B. Effect on Interstate and Intrastate Commerce

272. At all material times, Thalomid and Revlimid, manufactured and sold by Celgene, was shipped across state lines and sold to customers located outside its state of manufacture.

273. During the relevant time period, in connection with the purchase and sale of Thalomid and Revlimid, monies as well as contracts, bills and other forms of business communication and transactions were transmitted in a continuous and uninterrupted flow across state lines.

274. During the relevant time period, various devices were used to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign telephone commerce. The activities of Celgene, as alleged in this Complaint, were within the flow of, and have substantially affected, interstate commerce.

275. Celgene's anticompetitive conduct also has substantial intrastate effects in that, *inter alia*, retailers within each state are foreclosed from offering cheaper

generic Thalomid and Revlimid to end-payors inside each respective state. The foreclosure of generic Thalomid and Revlimid directly impacts and disrupts commerce for end-payors within each state.

C. Monopoly Power

276. At all relevant times, Celgene had monopoly power over Thalomid and Revlimid, because it had the power to raise and/or maintain the price of Thalomid and Revlimid at supracompetitive levels without losing substantial sales.

277. To the extent that Plaintiffs are required to prove monopoly power circumstantially by first defining a relevant product market, Plaintiffs allege that the relevant product markets are Thalomid in all its forms and dosage strengths and the respective AB-rated generic bioequivalents, and Revlimid in all its forms and dosage strengths and the respective AB-rated generic bioequivalents.

278. A small but significant, non-transitory price increase by Celgene to Thalomid would not have caused a significant loss of sales to other drugs or products used for the same purposes, with the exception of AB-rated generic versions of Thalomid.

279. A small but significant, non-transitory price increase by Celgene to Revlimid would not have caused a significant loss of sales to other drugs or products used for the same purposes, with the exception of AB-rated generic versions of Revlimid.

280. Thalomid does not exhibit significant, positive cross-elasticity of demand with respect to price, with any leprosy or multiple myeloma treatment or other product other than AB-rated generic versions of Thalomid.

281. Revlimid does not exhibit significant, positive cross-elasticity of demand with respect to price, with any multiple myeloma treatment or other product other than AB-rated generic versions of Revlimid.

282. Celgene needed to control only Thalomid and its AB-rated generic equivalents, and no other products, in order to maintain the price of Thalomid profitably at supra-competitive prices. Only the market entry of a competing, AB-rated generic version of Thalomid would render Celgene unable to profitably maintain its prices for Thalomid without losing substantial sales.

283. Celgene needed to control only Revlimid and its AB-rated generic equivalents, and no other products, in order to maintain the price of Revlimid profitably at supra-competitive prices. Only the market entry of a competing, AB-rated generic version of Revlimid would render Celgene unable to profitably maintain its prices for Revlimid without losing substantial sales.

284. Celgene also sold branded Thalomid and Revlimid well in excess of marginal costs, and in excess of the competitive price, and enjoyed unusually high profit margins.

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

286. At all relevant times, Celgene enjoyed high barriers to entry with respect to the above-defined relevant market due to patent and other regulatory protections, and high costs of entry and expansion.

287. Celgene's market share in the relevant market is and was 100% at all times.

VIII. CLAIMS FOR RELIEF

CLAIM I

MONOPOLIZATION AND MONOPOLISTIC SCHEME UNDER STATE LAW

288. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

289. At all relevant times, Celgene possessed substantial market power (i.e., monopoly power) in the relevant market. Celgene possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

290. Through the overarching anticompetitive scheme, as alleged extensively above, Celgene willfully maintained its monopoly power in the relevant market using restrictive or exclusionary conduct, rather than by means of greater business acumen, and injured Plaintiffs and the Classes thereby.

291. It was Celgene's conscious objective to further its dominance in the relevant market by and through the overarching anticompetitive scheme.

292. Celgene's scheme harmed competition as aforesaid.

293. To the extent Celgene is permitted to assert one, there is and was no cognizable, non-pretextual procompetitive justification for Celgene's actions comprising the anticompetitive scheme that outweighs the scheme's harmful effects. Even if there were some conceivable such justification that Celgene were permitted to assert, the scheme is and was broader than necessary to achieve such a purpose.

294. As a direct and proximate result of Celgene's illegal and monopolistic conduct, as alleged herein, Plaintiffs and the Classes were injured.

295. By engaging in the foregoing conduct, Celgene has intentionally and wrongfully maintained monopoly power in the relevant market in violation of the following state laws:

a. Arizona Rev. Stat. §§ 44-1401, et seq., with respect to purchases of Thalomid and Revlimid in Arizona by members of the Class.

b. Cal. Bus. & Prof Code §§ 17200, et seq., and California common law with respect to purchases of Thalomid and Revlimid in California by members of the Class.

c. D.C. Code §§ 28-4501, et seq., with respect to purchases of Thalomid and Revlimid in the District of Columbia by members of the Class.

d. Fla. Stat. §§ 501.201, et seq., with respect to purchases of Thalomid and Revlimid in Florida by members of the Class.

e. Hawaii Code §§ 480, et seq., with respect to purchases of Thalomid and Revlimid in Hawaii by members of the Class.

f. 740 Ill. Comp. Stat. 10/3, et seq., with respect to purchases of Thalomid and Revlimid in Illinois by members of the Class.

g. Iowa Code §§ 553.5 et seq., with respect to purchases of Thalomid and Revlimid in Iowa by members of the Class.

h. Kansas Stat. Ann. §§ 50-101, et seq., with respect to purchases of Thalomid and Revlimid in Kansas by members of the Class.

i. Me. Rev. Stat. Ann. 10, §§ 1101, et seq., with respect to purchases of Thalomid and Revlimid in Maine by members of the Class.

j. Mass. Gen. L. Ch. 93A, et seq., with respect to purchases of Thalomid and Revlimid in Massachusetts by members of the Class.

k. Mich. Comp. Laws Ann. §§ 445.771, et seq., with respect to purchases of Thalomid and Revlimid in Michigan by members of the Class.

l. Minn. Stat. §§ 325D.49, et seq., and Minn. Stat. § 8.31, et seq., with respect to purchases of Thalomid and Revlimid in Minnesota by members of the Class.

m. Miss. Code Ann. §§ 75-21-1, et seq., with respect to purchases of Thalomid and Revlimid in Mississippi by members of the Class.

n. Mo. Rev. Stat. §§ 416.011, et seq., with respect to purchase in Missouri by members of the Class.

o. Neb. Code Ann. §§ 59-801, et seq., with respect to purchases of Thalomid and Revlimid in Nebraska by members of the Class.

p. Nev. Rev. Stat. Ann. §§ 598A.060, et seq., with respect to purchases of Thalomid and Revlimid in Nevada by members of the Class.

q. N.H. Rev. Stat. Ann. §§ 356.1 et seq., with respect to purchases of Thalomid and Revlimid in New Hampshire by members of the Class.

r. N.M. Stat. Ann. §§ 57-1-1, et seq., with respect to purchases of Thalomid and Revlimid in New Mexico by members of the Class.

s. N.Y. Gen. Bus. Law §§ 340, et seq., with respect to purchases of Thalomid and Revlimid in New York by members of the Class.

t. N.C. Gen. Stat. §§ 75-2.1, et seq., with respect to purchases of Thalomid and Revlimid in North Carolina by members of the Class.

u. N.D. Cent. Code §§ 51-08.1-01, et seq., with respect to purchases of Thalomid and Revlimid in North Dakota by members of the Class.

v. Or. Rev. Stat. §§ 646.705, et seq., with respect to purchases of Thalomid and Revlimid in Oregon by members of the Class.

w. 10 L.P.R.A. §§ 257, et seq., with respect to purchases of Thalomid and Revlimid in Puerto Rico by members of the Class.

x. R.I. Gen. Laws §§ 6-36-1 et seq., with respect to purchases of Thalomid and Revlimid in Rhode Island by members of the Class.

y. S.D. Codified Laws §§ 37-1-3.1, et seq., with respect to purchases of Thalomid and Revlimid in South Dakota by members of the Class.

z. Tenn. Code Ann §§ 47-25-101, et seq., with respect to purchases of Thalomid and Revlimid in Tennessee by members of the Class.

aa. Utah code Ann. §§ 76-10-3101, et seq., with respect to purchases of Thalomid and Revlimid in Utah by members of the Class.

bb. Vt. Stat. Ann. 9, §§ 2451, et seq., with respect to purchases of Thalomid and Revlimid in Vermont by members of the Class.

cc. W.Va. Code §§ 47-18-1, et seq., with respect to purchases of Thalomid and Revlimid in West Virginia by members of the Class.

dd. Wis. Stat. §§ 133.01, et seq., with respect to purchases of Thalomid and Revlimid in Wisconsin by members of the Class.

CLAIM II

ATTEMPTED MONOPOLIZATION UNDER STATE LAW

296. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

297. Celgene, through its overarching anticompetitive scheme, specifically intended to maintain monopoly power in the relevant market. It was Celgene's conscious objective to control prices and/or to exclude competition in the relevant market.

298. The natural, intended, and foreseeable consequence of Celgene's overarching anticompetitive scheme was to control prices and exclude competition in the relevant market, to the extent it did not succeed.

299. There was a substantial and real chance, a reasonable likelihood, and/or a dangerous probability that Celgene will succeed in and achieve its goal of maintaining monopoly power in the relevant market.

300. As a direct and proximate result of Celgene's illegal and monopolistic conduct, Plaintiffs and the Classes were harmed as aforesaid.

301. By engaging in the foregoing conduct, Celgene has intentionally and wrongfully attempted to monopolize the relevant market in violation of the following state laws:

a. Arizona Rev. Stat. §§ 44-1401, et seq., with respect to purchases of Thalomid and Revlimid in Arizona by members of the Class.

b. Cal. Bus. & Prof Code §§ 17200, et seq., and California common law with respect to purchases of Thalomid and Revlimid in California by members of the Class.

c. D.C. Code §§ 28-4501, et seq., with respect to purchases of Thalomid and Revlimid in the District of Columbia by members of the Class.

d. Fla. Stat. §§ 501.201, et seq., with respect to purchases of Thalomid and Revlimid in Florida by members of the Class.

e. Hawaii Code §§ 480, et seq., with respect to purchases of Thalomid and Revlimid in Hawaii by members of the Class.

f. 740 Ill. Comp. Stat. 10/3, et seq., with respect to purchases of Thalomid and Revlimid in Illinois by members of the Class.

g. Iowa Code §§ 553.5 et seq., with respect to purchases of Thalomid and Revlimid in Iowa by members of the Class.

h. Kansas Stat. Ann. §§50-101, et seq., with respect to purchases of Thalomid and Revlimid in Kansas by members of the Class.

i. Me. Rev. Stat. Ann. 10, §§ 1101, et seq., with respect to purchases of Thalomid and Revlimid in Maine by members of the Class.

j. Mich. Comp. Laws Ann. §§ 445.771, et seq., with respect to purchases of Thalomid and Revlimid in Michigan by members of the Class.

k. Minn. Stat. §§ 325D.49, et seq., and Minn. Stat. § 8.31, et seq., with respect to purchases of Thalomid and Revlimid in Minnesota by members of the Class.

l. Miss. Code Ann. §§ 75-21-1, et seq., with respect to purchases of Thalomid and Revlimid in Mississippi by members of the Class.

m. Mo. Rev. Stat. §§ 416.010, et seq., with respect to purchases of Thalomid and Revlimid in Missouri by members of the Class.

n. Neb. Code Ann. §§ 59-801, et seq., with respect to purchases of Thalomid and Revlimid in Nebraska by members of the Class.

o. Nev. Rev. Stat. Ann. §§ 598A.060, et seq., with respect to purchases of Thalomid and Revlimid in Nevada by members of the Class.

p. N.H. Rev. Stat. Ann. §§ 356.1, et seq., with respect to purchases of Thalomid and Revlimid in New Hampshire by members of the Class.

q. N.Y. Gen. Bus. Law §§ 340, et seq., with respect to purchases of Thalomid and Revlimid in New York by members of the Class.

r. N.M. Stat. Ann. §§ 57-1-1, et seq., with respect to purchases of Thalomid and Revlimid in New Mexico by members of the Class.

s. N.C. Gen. Stat. §§ 75-1, et seq., with respect to purchases of Thalomid and Revlimid in North Carolina by members of the Class.

t. N.D. Cent. Code §§ 51-08.1-03, et seq., with respect to purchases of Thalomid and Revlimid in North Dakota by members of the Class.

u. Or. Rev. Stat. §§ 646.705, et seq., with respect to purchases of Thalomid and Revlimid in Oregon by members of the Class.

v. 10 L.P.R.A. §§ 257, et seq., with respect to purchases of Thalomid and Revlimid in Puerto Rico by members of the Class.

w. R.I. Gen. Laws §§ 6-36-1 et seq., with respect to purchases of Thalomid and Revlimid in Rhode Island by members of the Class.

x. S.D. Codified Laws §§ 37-1-3.1, et seq., with respect to purchases of Thalomid and Revlimid in South Dakota by members of the Class.

y. Utah code Ann. §§ 76-10-3101, et seq., with respect to purchases of Thalomid and Revlimid in Utah by members of the Class.

z. Vt. Stat. Ann. 9, §§ 2451, et seq., with respect to purchases of Thalomid and Revlimid in Vermont by members of the Class.

aa. Tenn. Code Ann §§ 47-25-101, et seq., with respect to purchases of Thalomid and Revlimid in Tennessee by members of the Class.

bb. W.Va. Code §§ 47-18-1, et seq., with respect to purchases of Thalomid and Revlimid in West Virginia by members of the Class.

cc. Wis. Stat. §§ 133.01, et seq., with respect to purchases of Thalomid and Revlimid in Wisconsin by members of the Class.

CLAIM III

UNFAIR AND DECEPTIVE TRADE PRACTICES UNDER STATE LAW

302. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

303. Defendant engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the state consumer protection statutes listed below. As a direct and proximate result of Defendant's

anticompetitive, deceptive, unfair, unconscionable, and fraudulent conduct, Plaintiffs and class members were deprived of the opportunity to purchase a generic version of Thalomid and Revlimid and forced to pay higher prices for each drug.

304. There was and is a gross disparity between the price that Plaintiff and the class members paid and pay for the brand Thalomid and Revlimid product and the value received, given that a much cheaper substitute generic product should be available, and prices for brand Thalomid and Revlimid should be much lower, but for Defendant's unlawful conduct.

305. By engaging in the foregoing conduct, Defendant have engaged in unfair competition or deceptive acts and practices in violation of the following state laws:

a. Ark. Code §§ 4-88-101, et seq., with respect to purchases of Thalomid and Revlimid in Arkansas by members of the Class.

b. Ariz. Code §§ 44-1255, et seq., with respect to purchases of Thalomid and Revlimid in Arizona by members of the Class.

c. Cal. Bus. & Prof Code §§ 17200, et seq., with respect to purchases of Thalomid and Revlimid in California by members of the Class.

d. D.C. Code §§ 28-3901, et seq., with respect to the purchases of Thalomid and Revlimid in the District of Columbia.

e. Fla. Stat. §§ 501.201, et seq., with respect to purchases of Thalomid and Revlimid in Florida by members of the Class.

f. Idaho Code §§ 48-601, et seq., with respect to the purchases of Thalomid and Revlimid in Idaho by members of the Class.

g. 815 ILCS §§ 505/1, et seq., with respect to the purchases of Thalomid and Revlimid in Illinois by members of the Class.

h. 5 Me. Rev. Stat. §§ 205-A, et seq., with respect to the purchases of Thalomid and Revlimid in Maine by members of the Class.

i. Mich. Stat. §§ 445.901, et seq., with respect to purchases of Thalomid and Revlimid in Michigan by members of the Class.

j. Minn. Stat. §§ 325F.68, et seq., and Minn. Stat. § 8.31, et seq., with respect to purchases of Thalomid and Revlimid in Minnesota by members of the Class.

k. Missouri Stat. §§ 407.010, et seq., with respect to purchases of Thalomid and Revlimid in Missouri by members of the Class.

l. Neb. Rev. Stat. §§ 59-1601, et seq., with respect to purchases of Thalomid and Revlimid in Nebraska by members of the Class.

m. Nev. Rev. Stat. §§ 598.0903, et seq., with respect to purchases of Thalomid and Revlimid in Nevada by members of the Class.

n. N.H. Rev. Stat. §§ 358-A, et seq., with respect to purchases of Thalomid and Revlimid in New Hampshire by members of the Class.

o. N.M. Stat. §§ 57-12-1, et seq., with respect to purchases of Thalomid and Revlimid in New Mexico by members of the Class.

p. N.Y. Gen. Bus. Law §§ 349, et seq., with respect to purchases of Thalomid and Revlimid in New York by members of the Class.

q. N.C. Gen. Stat. §§ 75-1, et seq., with respect to purchases of Thalomid and Revlimid in North Carolina by members of the Class.

r. Or. Rev. Stat. §§ 646.605, et seq., with respect to purchases of Thalomid and Revlimid in Oregon by members of the Class.

s. 73 Pa. Stat. Ann. §§ 201-1, et seq., with respect to purchases of Thalomid and Revlimid in Pennsylvania by members of the Class.

t. R.I. Gen. Laws §§ 6-13.1-1, et seq., with respect to purchases of Thalomid and Revlimid in Rhode Island by members of the Class

u. S.D. Code Laws §§ 37-24-1, et seq., with respect to purchases of Thalomid and Revlimid in South Dakota by members of the Class.

v. Utah Code §§13-11-1, et seq., with respect to purchases of Thalomid and Revlimid in Utah by member of the Class.

w. Va. Code Ann. §§ 59.1-196, et seq., with respect to purchases of Thalomid and Revlimid in Virginia by members of the Class.

x. West Virginia Code §§ 46A-6-101, et seq., with respect to purchases of Thalomid and Revlimid in West Virginia by members of the Class.

CLAIM IV

INJUNCTIVE RELIEF UNDER SECTION 16 OF THE CLAYTON ACT FOR CELGENE'S VIOLATIONS OF SECTION 2 OF THE SHERMAN ACT

306. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

307. Plaintiffs' allegations described herein and in claims I through III comprise of Section 1 and 2 of the Sherman Act, as well as state laws supra.

308. Plaintiffs and the members of the proposed Injunction Class seek equitable and injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable laws, to correct for the anticompetitive market effects

caused by the unlawful conduct of Defendant, and other relief so as to assure that similar anticompetitive conduct does not reoccur in the future.

CLAIM V

UNJUST ENRICHMENT UNDER STATE LAW

309. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

310. Defendants have benefited from monopoly profits on the sale of Thalomid and Revlimid resulting from the unlawful and inequitable acts alleged in this Complaint.

311. Defendant's financial benefit resulting from its unlawful and inequitable acts is traceable to overpayments for Thalomid and Revlimid by Plaintiffs and members of the Unjust Enrichment Damages Class.

312. Plaintiffs and the Unjust Enrichment Damages Class have conferred upon Defendant an economic benefit, in the nature of profits resulting from unlawful overcharges and monopoly profits, to the economic detriment of Plaintiffs and the Unjust Enrichment Damages Class.

313. It would be futile for Plaintiffs and the Unjust Enrichment Damages Class to seek a remedy from any party with whom they have privity of contract.

314. It would be futile for Plaintiffs and the Unjust Enrichment Damages Class to seek to exhaust any remedy against the immediate intermediary in the chain

of distribution from which it indirectly purchased Thalomid and Revlimid, as they are not liable and would not compensate Plaintiffs for unlawful conduct caused by Defendant.

315. The economic benefit of overcharges and monopoly profits derived by Defendant through charging supracompetitive and artificially inflated prices for Thalomid and Revlimid is a direct and proximate result of Defendant's unlawful practices.

316. The financial benefits derived by Defendant rightfully belong to Plaintiffs and the Damages Class, as Plaintiffs and the Damages Class paid anticompetitive and monopolistic prices during the Class Period, inuring to the benefit of Defendant.

317. It would be inequitable under unjust enrichment principles under the law of the District of Columbia and the laws of all states and territories in the United States, except Ohio and Indiana, for Defendant to be permitted to retain any of the overcharges for Thalomid and Revlimid derived from Defendant's unfair and unconscionable methods, acts, and trade practices alleged in this Complaint.

318. Defendants are aware of and appreciate the benefits bestowed upon it by Plaintiffs and the Unjust Enrichment Damages Class.

319. Defendant should be compelled to disgorge in a common fund for the benefit of Plaintiff and the Unjust Enrichment Damages Class all unlawful or inequitable proceeds it received.

320. A constructive trust should be imposed upon all unlawful or inequitable sums received by Defendant traceable to Plaintiffs and the Unjust Enrichment Damages Class.

321. Plaintiffs and the Unjust Enrichment Damages Class have no adequate remedy at law.

IX. DEMAND FOR JUDGMENT

WHEREFORE, Plaintiffs, on behalf of themselves and the proposed Classes, respectfully prays that the Court:

A. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a) and (b)(3), and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the Classes, and declare Plaintiffs the representatives of the Classes;

B. Enter joint and several judgments against Defendant and in favor of Plaintiffs and the Classes;

C. Declare the acts alleged herein to be unlawful under the state statutes set forth above, and the common law of unjust enrichment of the states and territories set forth above;

D. Permanently enjoin Defendant pursuant to sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15 (a) and 26, from continuing their unlawful contact, so as to assure that similar anticompetitive conduct does not continue to occur in the future;

E. Grant Plaintiffs and the Damage Classes equitable relief in the nature of disgorgement, restitution, and the creation of a constructive trust to remedy Defendant's unjust enrichment;

F. Award Plaintiffs and the Damages Classes damages as provided by law in an amount to be determined at trial;

G. Award the Damages Classes damages and, where applicable, treble, multiple, punitive, and/or other damages, in an amount to be determined at trial, including interest;

H. Award Plaintiffs and the Classes their costs of suit, including reasonable attorneys' fees as provided by law; and

I. Grant such other further relief as is necessary to correct for the anticompetitive market effects caused by Defendant's unlawful conduct, as the Court deems just.

X. JURY DEMAND

322. Pursuant to Fed. Civ. P. 38, Plaintiffs, on behalf of themselves and the proposed Classes, demand a trial by jury on all issues so triable.

Respectfully submitted:

Dated: June 14, 2017

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