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Counsel for Plaintiff
Mylan Pharmaceuticals Inc.

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

MYLAN PHARMACEUTICALS INC.,	)	
Plaintiff,	)	
v.	)	Civil Action No. _____
CELGENE CORPORATION,	)	JURY TRIAL DEMANDED
Defendant.	)	*DOCUMENT FILED ELECTRONICALLY*

COMPLAINT

I. Nature of the Action

1. Plaintiff Mylan Pharmaceuticals Inc. ("Mylan"), a corporation organized and existing under the laws of West Virginia, having its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505, by way of complaint against the defendant Celgene Corporation ("Celgene'), having a principal place of business at 86 Morris Avenue, Summit, New Jersey 07901, alleges as follows:

2. In flagrant violation of federal and state antitrust laws, Celgene has unlawfully maintained monopolies over its two "lead" products—Thalomid and Revlimid—by preventing lower-priced generic competition from entering the market. While lower-priced generic competition would provide substantial cost-savings to the critically ill patients who must take these lifesaving drugs, Celgene is continuing to charge these patients monopoly prices. Indeed, by preventing generic entry, Celgene has been able to continue reaping as much as $170-310 per dose for Thalomid and $430 per dose for Revlimid,[1] or more than $200 million annually for Thalomid and $4 billion annually for Revlimid. This action seeks to stop Celgene from perpetuating this anticompetitive scheme which has resulted in depriving consumers from realizing the benefit from the lower-priced generic competition that federal and state laws were intended to foster.

3. Thalomid and Revlimid are drugs used by critically ill patients. Thalomid is the branded version of the pharmaceutical thalidomide; Revlimid is the branded version of the pharmaceutical lenalidomide. Thalomid is indicated for the treatment of debilitating and

[1] On information and belief, a typical Thalomid fill can cost from $4,800 (for 28 capsules of 50mg) to $8,864 or more (for 28 capsules of 200mg). A typical fill of Revlimid can cost $13,000 or more for 30 capsules. *See Thalidomides for Multiple Myeloma*, GoodRx, http://www.goodrx.com/multiple-myeloma/thalidomides (last visited April 2, 2014).

disfiguring lesions associated with erythema nodosum leprosum ("ENL"), a complication of Hansen's Disease, commonly known as leprosy. It is also indicated for the treatment of newly diagnosed multiple myeloma patients in combination with the pharmaceutical dexamethasone. Revlimid is indicated for the treatment of a subset of myelodysplastic syndromes ("MDS")—a group of disorders caused by poorly formed or dysfunctional blood cells.

4. Because of FDA imposed rigorous restrictions on the distribution of Thalomid and Revlimid, access to these drugs is highly restricted. For both products, the FDA conditioned Celgene's approval on the establishment of a risk management program, including a Risk Evaluation and Mitigation Strategies ("REMS") program, to ensure that there were appropriate safeguards in the use and distribution of these drugs. To meet these requirements, Celgene developed a restricted distribution program for Thalomid, known as the System for Thalidomide Education and Prescribing Safety ("S.T.E.P.S."). Similarly, for Revlimid, Celgene developed a REMS program called RevAssist.

5. In the legislation mandating the implementation of REMS programs for certain drugs, including Thalomid and Revlimid, Congress made clear that such programs were *not* to be used by branded drug makers as a tool to keep generic competitors out of the market. *See* Food Drug and Cosmetic Act §505-1(f)(8) (21 U.S.C. § 355-1). Despite this directive, however, this is precisely what Celgene has done with respect to its Thalomid and Revlimid products.

6. Under the Hatch-Waxman Act (a statutory scheme designed, in part, to encourage generic competition), a generic drug manufacturer can seek FDA approval for a generic version of a branded drug product by filing an Abbreviated New Drug Application ("ANDA"). Through the ANDA filing, a generic drug maker must demonstrate bioequivalence to the reference listed branded drug ("RLD") (*i.e.*, the branded drug to which the generic will be bioequivalent).

While, ordinarily, a generic manufacturer can obtain the necessary samples of the RLD for bioequivalence testing through normal distribution channels (*i.e.*, a wholesaler) simply by purchasing a sufficient quantity of the drug at market price, a generic firm may not do so for Thalomid and Revlimid because of the respective REMS programs for these drugs.

7. Celgene, a branded drug manufacturer, has used REMS as a pretext to prevent Mylan from acquiring the necessary samples to conduct bioequivalence studies, even after the FDA determined that Mylan's safety protocols were acceptable to conduct those studies. In furtherance of its scheme to monopolize and restrain trade, Celgene implemented certain distribution restrictions that significantly limit drug product availability. Indeed, Mylan had contacted known wholesale distributors throughout the years, in an effort to obtain Thalomid and Revlimid samples, however, those efforts were unsuccessful. Throughout this entire period, Celgene has engaged in a scheme (described at length below) to continuously prevent and/or stall all of Mylan's efforts to obtain samples of Thalomid and Revlimid. In so doing, Celgene prevented Mylan from obtaining any of the drug products necessary to conduct required bioequivalence testing.

8. Importantly, Celgene's playbook of obstructing its generic competitors by gaming the regulatory system is well-recognized. For example, in 2008, generic-drug maker Lannett Company, Inc. ("Lannett") accused Celgene of violating the antitrust laws by refusing to allow Lannett to purchase the Thalomid samples that it needed to conduct a bioequivalence study. The parties ultimately settled the lawsuit on confidential terms. Additionally, in June 2009, another generic manufacturer, Dr. Reddy's Laboratories, Inc. ("Dr. Reddy's"), submitted a Citizen Petition to the FDA complaining that Celgene was unlawfully blocking generic competition by refusing to supply Dr. Reddy's with Revlimid samples for bioequivalence testing. Indeed,

Celgene's anticompetitive conduct has even resulted in a Federal Trade Commission antitrust investigation into Celgene's efforts to foreclose generic competition to Thalomid and Revlimid by unreasonably restricting access to samples needed for bioequivalence testing.

9. The effect of Celgene's conduct is that no generic manufacturer, including Mylan, has been able to bring generic versions of Thalomid and/or Revlimid to market. Through its illegal actions, Celgene has foreclosed Mylan from even attempting to enter the market.

10. Having set up an unlawful barrier to competition for its "lead" products, Celgene is able to reap supracompetitive profits without the threat of generic competition. While critically ill patients are forced to pay between $5,000 and $9,000 for a monthly supply of Thalomid and about $13,000 for a monthly supply of Revlimid (prices that Celgene can dictate because it maintains a 100 percent market share), Celgene unjustly earns billions of dollars per year at the expense of the consumer. Indeed, since 2006, Celgene has made $20.9 billion from sales of Thalomid and Revlimid, amounts which accounted for 71 to 93 percent of Celgene's total yearly revenue.

11. As referenced above, such conduct harms consumers by denying them the substantial benefits of lower-priced generic competition and forces consumers and federal, state, and private payors to overspend on prescriptions for these products. Indeed, but for Celgene's unlawful conduct, consumers and federal, state, and private payors would have enjoyed lower-priced generic alternatives to Thalomid and Revlimid substantially earlier. Worse yet, left unchecked, there is no end in sight to Celgene's anticompetitive scheme to block generic competition to these products, to the detriment of Mylan and consumers of these products alike. Accordingly, to remedy Celgene's unlawful practices, Mylan files this action seeking declaratory relief, treble damages, costs of suit, attorneys' fees, and injunctive relief.

II. The Parties

12. Plaintiff Mylan is a corporation organized and existing under the laws of West Virginia, having its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

13. On information and belief, 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.

III. Jurisdiction and Venue

14. This action arises under the antitrust laws of the United States, including Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15(a) and 26, 28 U.S.C. § 2201, the New Jersey Antitrust Act, N.J. Stat. § 56:9, and New Jersey common law.

15. The actions complained of have occurred in and substantially affected interstate commerce. Specifically, Celgene is engaged in interstate commerce and in activities substantially affecting interstate commerce. Celgene's conduct alleged herein has a substantial effect on interstate commerce. Celgene's products are marketed and sold in more than fifty countries worldwide and covers all key pharmaceutical markets worldwide, including the United States. Doctors across the United States prescribe Thalomid and Revlimid to patients. Drug wholesalers and, ultimately, patients across the country purchase the drug.

16. Defendant may be found in, transacts business in, is headquartered in, and is subject to personal jurisdiction in the District of New Jersey.

17. This Court has subject matter jurisdiction based on 28 U.S.C. §§ 1331 and 1337(a), and 15 U.S.C. §§ 15 and 26. This Court has supplemental subject matter jurisdiction over the New Jersey state law claims pursuant to 28 U.S.C. § 1367(a).

18. The court also has jurisdiction under 28 U. S.C. §1332 (diversity jurisdiction), as the matter in controversy exceeds the sum or value of $75,000, exclusive of interest and costs, and complete diversity exists, as the parties reside in different states (Plaintiff is a West Virginia corporation, and upon information and belief, Celgene is a Delaware corporation with its principal place of business in New Jersey).

19. The violations of law alleged in this Complaint took place, in part, and have injured Mylan in this judicial district. Venue is therefore proper in the District of New Jersey pursuant to 15 U.S.C. §§ 15 and 22, and 28 U.S.C. § 1391.

IV. Statutory and Industry Background

20. The Federal Food, Drug and Cosmetic Act (the "Act"), 21 U.S.C. § 301 *et seq.*, as amended by the Drug Price Competition and Patent Restoration Act of 1984, codified at 21 U.S.C. § 355(j) and 35 U.S.C. § 271(e), commonly known as the "Hatch-Waxman Act," requires FDA approval before a company may market or sell a branded or generic pharmaceutical product in the United States.

21. As numerous courts and commentators have recognized, the Hatch-Waxman Act had one overarching purpose: to "get generic drugs into the hands of patients at reasonable prices – fast." *Andrx. Pharm., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 809 (D.C. Cir. 2001) (quoting *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991)); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1568 (Fed. Cir. 1997) ("[T]he purposes of the legislation are 'to make available more low cost generic drugs,'" and "provide regulatory relief, increase competition, economy in

government, and best of all, [allow] the American people [to] save money, and yet receive the best medicine that pharmaceutical science can provide.") (quoting *inter alia* Stmnt. on Signing S. 1583 Into Law, 20 Weekly Comp. Pres. Doc. 1359, 1360 (Sept. 24, 1984)).

22. The Hatch-Waxman Act, however, was not only designed for the benefit of generic drug companies. Instead, it was a carefully calibrated regulatory framework to facilitate the introduction of low cost generic drugs while preserving incentives for innovation. Thus, the Act similarly included changes that benefitted brand name drug manufacturers. Specifically, under the Act, brand manufacturers are entitled to five years of exclusivity for new drugs (defined as "new chemical entities") regardless of patent protection, *see* 21 U.S.C. § 355(c)(3)(E)(ii), and can also obtain up to five additional years of patent protection for their drugs in the event of delay in regulatory approval process, *see* 35 U.S.C. § 156. This was the central compromise behind the legislation: longer exclusivity and patent protection for brand name drugs, in exchange for faster and cheaper generic entry once the exclusivity periods and patent protection expired (or a patent was successfully challenged or designed around).

23. Congress coupled these protections for brand drugs with provisions directed at another "unintended distortion" created by the FDA approval process. Because generic firms must conduct bioequivalence testing with brand product before submitting an ANDA, the Act provides that it "shall not be an act of infringement to make, use, offer to sell, or sell . . . a patented invention . . . solely for uses reasonably related to the development and submission of information" for FDA approval.[2] This provision, known as the *Bolar* Amendment,[3] reflects

[2] 35 U.S.C. § 271(e)(1).

Congress's concern that if generic firms could not begin the testing necessary to submit an ANDA until the brand's patents had expired, the patentee's de facto monopoly would continue for an often substantial period until generic regulatory approval was obtained, amounting to an effective extension of the patent term. The *Bolar* Amendment addresses that problem by allowing generic firms to conduct testing with brand product before patent expiration.

24. To facilitate generic entry, rather than conduct full clinical trials, as is required for a New Drug Application, the statute only requires an ANDA filer to show that its drug is bioequivalent (within a defined range) to the RLD (e.g., the brand product).

25. Two drugs are considered bioequivalent if they contain the same active pharmaceutical ingredient and if there is no significant difference in the rate and extent to which the products are absorbed in the human body under similar experimental conditions, when administered in the same dose. *See* 21 U.S.C. § 355(j)(8)(B). If the generic drug is bioequivalent and is the same dosage strength and form as the RLD, it is deemed to be an "AB-rated equivalent" to the RLD. Many states have "automatic substitution" laws that require pharmacists to substitute AB-rated generic versions for prescriptions written for the RLD unless the prescribing physician specifically requests otherwise. Conversely, generic drugs that are not "AB-rated" to the reference listed branded drug cannot be automatically substituted for the RLD at the pharmacy level.

26. In order to perform the necessary bioequivalence testing between a proposed generic drug product and the RLD, the generic manufacturer needs to obtain samples of the

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[3] The provision overruled *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 856 (1984), in which the Federal Circuit had held that testing conducted to develop a generic drug was an act of infringement.

RLD. FDA's regulations also require that the party conducting bioequivalence testing retain reserve samples of batches of the proposed generic and RLD used to conduct the tests, in sufficient quantity for FDA to perform each test required in the application or supplemental application five times. The Hatch-Waxman framework, therefore, cannot function as Congress intended if generic firms are unable to access brand products.

27. For most drugs, a generic manufacturer can obtain adequate amounts of the RLD for bioequivalence testing and retained samples through normal distribution channels, such as through a wholesaler, simply by purchasing a sufficient quantity of the drug at market price.

28. However, some branded drugs are not available through such traditional means because they are associated with potential safety risks.

29. Specifically, the FDA manages risks related to pharmaceutical drugs. These efforts began with full-disclosure requirements requiring manufacturers to provide complete information about the drug product's indication, side effects, dosing, etc. to healthcare professionals. In the 1990s, the FDA began working with manufacturers to develop risk management programs for drugs with potentially dangerous side effects. In March 2005, FDA issued a final guidance document entitled "Guidance for Industry: Development and Use of Risk Minimization Action Plans." The guidance for Risk Minimization Action Plans ("RiskMAPs") gave manufacturers a broad set of tools to minimize product risk while preserving benefits ranging from distribution of educational materials to restrictions on distribution systems. As of February 2007, there were 30 drugs with some type of RiskMAP, most of which involved targeted education and outreach.

30. In September 2007, the Food and Drug Administration Amendments Act of 2007 ("FDAAA") gave the FDA authority to require REMS program for new drug products and

already approved products, if it determined that such a program is necessary to "ensure the benefits of the drug outweigh the risks of the drug." In addition to requirements such as a medication guide and package insert, the components of a REMS program (known as elements to assure safe use) can include potential restrictions on distribution of the drug, such as special certifications for practitioners, pharmacies, or healthcare settings that can dispense the drug, patient monitoring, and enrollment of eligible patients in a registry.

31. Congress included a specific provision in the FDAAA mandating that REMS programs must not be used by branded drug makers as a tool to keep generic competitors out of the market. Specifically, FDC Act § 505-1(f)(8) states: "No holder of an approved covered application shall use any element to assure safe use required by [FDA] under [FDC Act § 505-1(f)] to block or delay approval of an application under Section 505(b)(2) or to prevent application of such element under [FDC Act § 505-1(i)(1)(B)] to a drug that is the subject of an [ANDA]." The FDA has further recognized that the REMS provision should not be used to prevent generic companies from obtaining necessary RLD samples to conduct bioequivalence testing. In a February 12, 2007 letter to Mylan regarding Celgene's refusal to provide samples of a branded product subject to a REMS program, the FDA stated:

> The agency is aware that [the brand] has expressed concern that providing [the RLD] to a generic drug manufacturer (or its agent) for use in bioequivalence studies would interfere with [the brand's] ability to track dispensing of the drug and undermine the [REMS] program. It is 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 [REMS] program to prevent manufacturers of generic drugs from obtaining [RLD] for use in bioequivalence testing necessary to obtain approval of an abbreviated new drug application for [generic RLD].

The letter further stated that the FDA would not consider the provision of samples of an RLD to a generic manufacturer a REMS violation, and therefore would not impose any penalties for such conduct. To classify the provision of samples to a generic as a REMS violation would

"frustrate" the "intention of Congress in enacting the Generic Drug Approval Provisions in Section 505(j) . . ." of the Hatch-Waxman Act.

32. Despite the plain language of FDAAA and the FDA's stated position, the practice of using REMS to block the procurement of samples for bioequivalence testing continues, as branded drug manufacturers have determined that they can use elements of a REMS program as an excuse to restrict competition.

33. If successful, conduct of the type alleged in this case threatens to undermine the careful balance created by the Hatch-Waxman Act and potentially preserve a brand firm's monopoly indefinitely.

V. Benefits of Generic Competition

34. Generic drugs are typically sold at substantial discounts from the price of the branded RLD. The first generic drug that enters the market is generally priced at a significant discount to the RLD and, as additional generic drugs enter the market, generic drug prices may fall to as low as five percent of the branded RLD's price.

35. Generic drug competition generates large savings for consumers and federal, state, and private payors. A 2004 FDA study found that consumers whose needs can be fully satisfied with generic drugs could enjoy reductions of 52 percent in their daily medication costs. More recently, a study commissioned by the Generic Pharmaceutical Association found that generic drugs saved the U.S. health care system $1 trillion from 2002 to 2011.[4] The study also cites data from the federal Centers for Medicare & Medicaid Services establishing that, for every

[4] Generic Pharmaceutical Association Online, New Study Finds Generic Prescription Drugs Saved Consumers and the U.S. Health Care System 1 Trillion over Past Decade, http://www.gphaonline.org/gpha-media/press/new-study-finds-generic-prescription-drugs-saved-consumers-and-the-u-s-health-care-system-1-trillion-over-past-decade.

two percent increase in generic utilization, Medicaid saves an additional $1.3 billion annually. An even more recent study revealed that in 2011 alone, the use of generic drugs generated an estimated $192 billion in total consumer savings.[5]

VI. Relevant Market and Market Power

Thalidomide Market

36. The relevant market in which to assess the anticompetitive effects of Celgene's conduct concerning Thalomid is the market for thalidomide capsule products, including Thalomid and bioequivalent, FDA-approved generic thalidomide capsule products.

37. The generic thalidomide product developed by Mylan would be, upon final FDA approval, bioequivalent to Thalomid. Thalidomide capsule products, including Celgene's branded Thalomid, are not reasonably interchangeable with other products due to, for example, price, use, qualities, characteristics, and/or distinct customers or end uses. The availability of other treatments (if any) indicated for (1) patients with newly diagnosed multiple myeloma (in combination with dexamethasone), or (2) certain conditions associated with ENL, an inflammatory complication of leprosy that results in painful and disfiguring skin lesions, is not sufficient to prevent the anticompetitive effects of Celgene's conduct.

38. Generic thalidomide products would be priced substantially below the price Celgene charges for Thalomid. Upon entry of generic thalidomide capsule products, these products would divert substantial sales from Thalomid, which would benefit consumers, patients, and government programs (such as Medicare and Medicaid).

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[5] Generic Pharmaceutical Association, *Generic Drug Savings in the U.S.* 2 (4th ed. 2012).

39. A small, but significant, non-transitory price increase above the competitive level for Thalomid by Celgene would not have caused a loss of sales sufficient to make the price increase unprofitable.

40. Thalomid price levels did not exhibit significant, positive cross-elasticity of demand with respect to price with any other product.

41. Such products comprise a distinct relevant product market for antitrust purposes. Thus, the relevant product market in which to assess the anticompetitive effects of Celgene's conduct is the market for Thalomid and its bioequivalent ANDA generic products (the "Thalidomide Market").

42. The relevant geographic market in which to assess the anticompetitive effects of Celgene's conduct is the United States. FDA's elaborate regulatory process for approving drugs for sale in the United States, and the fact that the marketing, sales, and distribution of pharmaceuticals occur on a nationwide basis, establish the boundaries of the geographic market.

43. There are substantial barriers to entry into the Thalidomide Market, including FDA's regulatory requirements and the substantial time and expense required to develop an ANDA generic product bioequivalent to Thalomid. Moreover, through its anticompetitive, exclusionary conduct, Celgene has erected additional, artificial barriers to entry in the Thalidomide Market. For instance, Celgene has raised the cost of entry into the market by requiring potential competitors to incur the costs and delays resulting from Celgene's conduct, including but not limited to preventing Mylan from obtaining RLD samples.

44. Celgene is the only company with an FDA-approved thalidomide product. As a result, at all times relevant to this Complaint, Celgene has possessed monopoly power and market power in the Thalidomide Market with a market share of 100 percent. Celgene has

sufficient monopoly power and market power to keep prices of products in the Thalidomide Market artificially high and quantities artificially low.

45. Celgene has used its monopoly power and market power to foreclose or otherwise adversely affect competition in the Thalidomide Market by causing output to be artificially low, raising competitors' costs and/or keeping the market price for products in the Thalidomide Market above a competitive level.

Lenalidomide Market

46. The relevant market in which to assess the anticompetitive effects of Celgene's conduct concerning Revlimid is the market for lenalidomide capsule products, including Revlimid and bioequivalent, FDA-approved generic lenalidomide capsule products.

47. The generic lenalidomide product developed by Mylan would be, upon final FDA approval, bioequivalent to Revlimid. Lenalidomide capsule products, including Revlimid, are not reasonably interchangeable with other products due to, for example, price, use, qualities, characteristics, and/or distinct customers or end uses. The availability of other treatments (if any) indicated for (1) multiple myeloma (in combination with dexamethasone) in patients who have received at least one prior therapy, or (2) a subset of MDS – a group of disorders caused by poorly formed or dysfunctional blood cells, is not sufficient to prevent the anticompetitive effects of Celgene's conduct.

48. Generic lenalidomide products would be priced substantially below the price Celgene charges for Revlimid. Upon entry of generic lenalidomide capsule products, these products would divert substantial sales from Revlimid, which would benefit consumers, patients, and government programs (such as Medicare and Medicaid).

49. A small, but significant, non-transitory price increase above the competitive level for Revlimid by Celgene would not have caused a loss of sales sufficient to make the price increase unprofitable.

50. Revlimid price levels did not exhibit significant, positive cross-elasticity of demand with respect to price with any other product.

51. Such products comprise a distinct relevant product market for antitrust purposes. Thus, the relevant product market in which to assess the anticompetitive effects of Celgene's conduct is the market for Revlimid and its bioequivalent ANDA generic products (the "Lenalidomide Market") (collectively, the Thalidomide Market and Lenalidomide Market are the "Relevant Markets").

52. The relevant geographic market in which to assess the anticompetitive effects of Celgene's conduct is the United States. FDA's elaborate regulatory process for approving drugs for sale in the United States, and the fact that the marketing, sales, and distribution of pharmaceuticals occur on a nationwide basis, establish the boundaries of the geographic market.

53. There are substantial barriers to entry into the Lenalidomide Market, including FDA's regulatory requirements and the substantial time and expense required to develop an ANDA generic product bioequivalent to Revlimid. Moreover, through its anticompetitive, exclusionary conduct, Celgene has erected additional, artificial barriers to entry in the Lenalidomide Market. For instance, Celgene has raised the cost of entry into the market by requiring potential competitors to incur the costs and delays resulting from Celgene's conduct, including but not limited to preventing Mylan from obtaining RLD samples.

54. Celgene is the only company with an FDA-approved lenalidomide product. As a result, at all times relevant to this Complaint, Celgene has possessed monopoly power in the

Lenalidomide Market with a market share of 100 percent. Celgene has sufficient monopoly power and market power to keep prices of products in the Lenalidomide Market artificially high and quantities artificially low.

55. Celgene has used its monopoly power and market power to foreclose or otherwise adversely affect competition in the Lenalidomide Market by causing output to be artificially low, raising competitors' costs and/or keeping the market price for products in the Lenalidomide Market above a competitive level.

VII. Background on Thalidomide and Lenalidomide

56. Celgene is a multinational integrated biopharmaceutical company, incorporated in 1986 as a Delaware Corporation. Celgene is primarily engaged in the discovery, development and commercialization of therapies designed to treat cancer and other severe, immune, inflammatory conditions.

57. Celgene's commercially marketed products are Revlimid, Thalomid, Vidaza, Abraxane, Istodax, Pomalyst/Imnovid and azacitidine for injection (a generic version of Vidaza). Celgene also licenses Focalin XR and the entire Ritalin family rights to Novartis Pharma AG. Of these, both Revlimid and Thalomid reap sales in the billions of dollars every year, and have constituted between 71 and 75 percent of Celgene's total sales for the past three years.[6]

Thalidomide

58. Thalidomide is a drug that was originally marketed as a sedative. By 1957, thalidomide was sold over-the-counter in Germany. By 1960, it was sold throughout Europe and South America, in Canada, and in many other parts of the world. In September of 1960,

[6] Celgene Corporation, Annual Report (Form 10-K) (Feb. 13, 2014).

Richardson-Merrell, a pharmaceutical company based in Cincinnati, submitted an application to the FDA in an effort to introduce thalidomide into the United States, which was ultimately withdrawn.

59. In July 1998, the FDA approved thalidomide for the first time in the United States under the brand name Thalomid, manufactured by Celgene. It was approved for one condition only: treatment of the debilitating and disfiguring lesions associated with ENL, a complication of Hansen's Disease, commonly known as leprosy.

60. The FDA conditioned approval of thalidomide for leprosy on rigorous restrictions on the distribution of thalidomide to prevent it from being prescribed or taken improperly.

61. In May 2006, Celgene received an additional approval from the FDA to market Thalomid for treatment in combination with dexamethasone for newly diagnosed multiple myeloma patients.

62. As stated above, Celgene derives millions of dollars from sales of Thalomid. In 2013, Celgene's sales of Thalomid were over $240 million.[7] In 2008, Celgene's sales of Thalomid reached a high of $504.7 million.[8]

63. Thalomid is only available through a REMS program known as S.T.E.P.S. S.T.E.P.S. is Celgene's education and restricted distribution program for Thalomid. Among other things, S.T.E.P.S. requires prescribers, patients, and dispensing pharmacies to participate in a registry, and a prescription cannot be filled unless the physicians, patients, and pharmacies have been registered, trained, and meet all qualification criteria.

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[7] Celgene Corporation, Annual Report (Form 10-K) (Feb. 12, 2013).

[8] Celgene Corporation, Annual Report (Form 10-K) (Feb. 17, 2009).

64. As a result of the S.T.E.P.S. program, generic companies requiring Thalomid samples to conduct bioequivalence testing can only obtain supply from Celgene.

65. While Celgene uses S.T.E.P.S. as part of the overall anticompetitive scheme to deny access to RLD samples to potential competitors, it had provided Thalomid on numerous occasions to non-competitor research organizations for the purpose of conducting clinical studies using the drugs.[9] For example, in 2012, Celgene provided Thalomid to researchers at the Johns Hopkins University School of Medicine in order to conduct a clinical trial to demonstrate an effective treatment for cough among idiopathic pulmonary fibrosis (IPF) patients. Notably, Celgene did so without any "role in the study design, conduct, analysis, or manuscript preparation."[10]

Lenalidomide

66. Lenalidomide is an analogue of thalidomide. In December 2005, Celgene received approval from the FDA to market lenalidomide under the brand name Revlimid for the treatment of a subset of MDS–a group of disorders caused by poorly formed or dysfunctional blood cells. As with thalidomide, the FDA conditioned approval on restrictions on the distribution of lenalidomide to prevent it from being prescribed or taken improperly.

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[9] U.S. National Institutes of Health, Clinical Trials, http://clinicaltrials.gov/ct2/home (search '"thalomid" and "celgene"') (last visited March 9, 2014).

[10] John Hopkins Medicine, Thalidomide Relieves Disabling Cough and Improves Quality of Life for People with Deadly Lung Disease, Study Shows, Sept. 18, 2012, http://www.hopkinsmedicine.org/news/media/releases/thalidomide_relieves_disabling_cough_and_improves_quality_of_life_for_people_with_deadly_lung_disease_study_shows ("Celgene Corporation provided both the funding for the trial and the study medication but had no role in the study design, conduct, analysis, or manuscript preparation.").

67. In June 2006, Celgene received additional approval from the FDA to market Revlimid for treatment in combination with dexamethasone for multiple myeloma patients who have received at least one prior therapy.

68. As stated above, Revlimid is one of Celgene's "lead" products. Celgene's sales of Revlimid were $3.2 billion[11] and $3.77 billion[12] in 2011 and 2012, respectively. In 2013, Celgene's sales of Revlimid reached $4.28 billion.[13]

69. Revlimid is only available through a REMS program known as RevAssist, which was developed by Celgene and implemented at the commercial launch of Revlimid in December 2005. RevAssist is Celgene's education and restricted distribution program for Revlimid. Among other things, RevAssist requires prescribers, patients, and dispensing pharmacies to participate in a registry, and a prescription cannot be filled unless the physicians, patients, and pharmacies have been registered, trained, and meet all qualification criteria. The RevAssist program was developed to address warnings with respect to fetal exposure.

70. As a result of the RevAssist program, generic companies requiring Revlimid samples to conduct bioequivalence testing can only obtain supply from Celgene.

71. While Celgene uses RevAssist as part of the overall anticompetitive scheme to deny access to RLD samples to potential competitors, it had provided Revlimid on numerous occasions to non-competitor research organizations for the purpose of conducting clinical studies using the drugs.[14] For example, on information and belief, Celgene provided Revlimid to

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[11] Celgene Corporation, Annual Report (Form 10-K) (Feb. 13, 2014).

[12] *Id.*

[13] *Id.*

[14] U.S. National Institutes of Health, Clinical Trials, http://clinicaltrials.gov/ct2/home (search '"revlimid" and "celgene"') (last visited March 9, 2014).

international researchers at Intergroupe Francophone du Myelome, University Hospital of Toulouse, and Groupe Francophone Des Myelodysplasies, as well as the National Cancer Institute and Eastern Cooperative Oncology Group in 2010. In 2011, Celgene provided Revlimid to the Mayo Clinic and MD Anderson Cancer Center in Houston, TX and undertook a phase II investigator-initiated study of Revlimid in combination with Avastin (bevacizumab), a drug manufactured by Genentech. Generally, Celgene had previously stated that Revlimid and its compounds were subject to over a 100 clinical trials. *Id*.

VIII. Defendant's Unlawful Conduct

72. In order to protect itself from competition, Celgene devised an anticompetitive scheme to prevent Mylan and others from ever attempting to file thalidomide or lenalidomide ANDAs by requiring its wholesale distributors and specially certified pharmacies to withhold samples of Thalomid and Revlimid and by refusing to sell these samples to Mylan itself. Celgene used its tactics to deny Mylan access to Thalomid samples for years, and subsequently has incorporated Revlimid into its anticompetitive scheme and used the same tactics to deny Mylan access to Revlimid as well.

Mylan's Initial Request for Thalomid

73. In September 2003, Mylan began efforts to develop a generic equivalent to Celgene's branded Thalomid.

74. Before submitting its ANDA, a generic manufacturer typically must perform bioequivalence studies and validation testing to be included in the ANDA for FDA approval. In order to develop its generic version of thalidomide and file its ANDA, Mylan needed to secure samples of Thalomid for use in bioequivalence studies.

75. Mylan initially attempted to obtain Thalomid samples through normal wholesale distribution channels but was unable to do so as a result of S.T.E.P.S. 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. On May 3, 2005, having received no response to its previous request, Mylan once again contacted Celgene through a third party, repeating its request to purchase Thalomid capsules for bioequivalence testing.

76. Roughly one and a half months later, on June 21, 2005, Celgene responded. Celgene confirmed 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. Celgene further stated that it was against policy to deal with intermediaries in the provision of Thalomid.

77. On September 2, 2005, Mylan reached out directly to Celgene and asked 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 capsules for bioequivalence testing, noting that "obtaining samples through other traditional channels is nearly impossible."

78. On October 20, 2005, Celgene confirmed its receipt of Mylan's September 2, 2005 letter. In its response, Celgene stated that, "[g]iven the importance and uncompromising requirement to ensure that THALOMID is dispensed strictly and only via our proprietary System for Thalidomide Education and Prescribing Safety (S.T.E.P.S.) risk management program, and due to our responsibility under that program to ensure, to the maximum extent possible, that the drug is used appropriately so as to avoid fetal exposure, we require additional time to more fully

assess our position." Celgene concluded by assuring Mylan that "a complete response will be sent upon thorough consideration of the request."

79. On December 19, 2005, Celgene sent its "complete" response to Mylan's September 2, 2005 request, indicating that Celgene would need FDA's agreement to allow samples to be distributed outside of the S.T.E.P.S. program. In this correspondence, Celgene specifically suggested to Mylan to contact the FDA – "[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." Celgene further stated that if 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."

FDA Determines that Mylan's Safety Protocols Are Acceptable to Acquire Thalomid Samples from Celgene

80. Following Celgene's "recommendation," on January 11, 2006, Mylan submitted a letter to the FDA. Among other things, Mylan requested the FDA's assistance in obtaining supplies of Thalomid capsules for bioequivalence testing. Mylan acknowledged the requirements of the S.T.E.P.S. program, and that "it is not possible to obtain the needed THALOMID supplies directly from the supplier [Celgene]."

81. Mylan explained that it had requested the supplies directly from Celgene as recommended by the FDA's Office of Generic Drugs ("OGD"), and in response Celgene stated that it required a written recommendation from the FDA prior to Celgene's further consideration of Mylan's request. Mylan then specifically requested that the FDA provide Celgene with written authorization for Celgene to provide Mylan with the requested quantity of Thalomid capsules.

82. To aid the FDA's determination as to whether or not to authorize Mylan's request, Mylan attached to the letter its proposed protocols for the planned bioequivalence studies noting that these studies "will only enroll healthy vasectomized males and females not of child-bearing potential." Mylan also highlighted its familiarity with the S.T.E.P.S. program and experience with restrictive and complex risk management programs.

83. In a letter dated February 12, 2007, the FDA responded to Mylan and provided comments to Mylan's January 11, 2006 submission. In its letter, the FDA explained that an effective way to ensure the safety of subjects in proposed thalidomide bioequivalence studies is for the generic manufacturer to submit an investigational new drug application ("IND") or a study protocol that FDA would review to "ensure that all appropriate safeguards for a clinical investigation with thalidomide are in place." The FDA further stated that:

> These safeguards would represent a substitute for the controls present in the S.T.E.P.S. program
>
> [. . .]
>
> 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. (emphasis supplied)

84. Following FDA's guidance, on May 1, 2007, Mylan submitted the requested safety protocols for its thalidomide bioequivalence study protocols to FDA for its review. Mylan's submission, which ran 141 pages in total, included the following materials:

- Proposed study protocol entitled "Single-Dose Fasting Bioequivalence Study of Thalidomide Capsules (200 mg; Mylan) and Thalomid Capsules (200 mg; Celgene) in Healthy Male Subjects";
- Proposed study protocol entitled "Single-Dose Fed Bioequivalence Study of Thalidomide Capsules (200 mg; Mylan) and Thalomid Capsules (200 mg; Celgene) in Healthy Male Subjects";
- Proposed Volunteer Consent Form, used to inform potential volunteers about the risks and benefits of a research study and to ask potential volunteers to consent to participate in the study;
- Annotated version of proposed study protocol entitled "Single-Dose Fasting Bioequivalence Study of Thalidomide Capsules (200 mg; Mylan) and Thalomid Capsules (200 mg; Celgene) in Healthy Male Subjects." This version indicated where each of the FDA's recommendations had been incorporated into Mylan's study protocol, for the purpose of facilitating the Agency's review;
- Annotated version of proposed study protocol entitled "Single-Dose Fed Bioequivalence Study of Thalidomide Capsules (200 mg; Mylan) and Thalomid Capsules (200 mg; Celgene) in Healthy Male Subjects." This version indicated where each of the FDA's recommendations had been

incorporated into Mylan's study protocol, for the purpose of facilitating the Agency's review; and

- Annotated version of proposed Volunteer Consent Form. This version indicated where each of the FDA's recommendations had been incorporated into Mylan's study protocol, for the purpose of facilitating the Agency's review.

85. Mylan again requested that the FDA provide its written confirmation upon review and a determination that Mylan's safeguards are acceptable. Mylan explained that "[t]his written confirmation will then be forwarded to Celgene with our request for the required number of samples of the reference product (Thalomid Capsules) needed for conducting bioequivalence, dissolution, and stability testing."

86. On September 11, 2007, the FDA responded to Mylan's proposed safety protocols. The FDA informed Mylan that its protocols had been reviewed by the Division of Bioequivalence ("DBE") and that Mylan's thalidomide protocols were "acceptable." The FDA's response also included additional "recommendations" that Mylan would need to follow in conducting its studies. However, the FDA did not require Mylan to re-submit its protocols to include these additional recommendations. Rather, the FDA indicated that once these additional recommendations were implemented by Mylan in conjunction with the already submitted protocols, the combined protocols would meet the FDA standards.

87. By letter dated November 16, 2007, Mylan informed Celgene that the FDA deemed Mylan's safety protocols acceptable and repeated its request for Thalomid samples. Mylan stated that "upon the guidance of FDA, this letter confirms that Mylan has received affirmation from the Agency indicating that Mylan's proposed bioequivalence study protocols

regarding Thalidomide Capsules provide adequate safety measures to ensure the safety of subjects."

88. The letter further stated that "it is Mylan's understanding that the Agency has informed Celgene that the FDA intends to exercise enforcement discretion to permit Celgene to provide another drug manufacturer with Thalomid" for the purpose of conducting bioequivalence testing. Given that any "concerns" expressed by Celgene in previous correspondences had been appropriately addressed, Mylan reiterated its request for thalidomide samples, and assured Celgene that it was prepared to pay full value for the samples.

89. Nearly three weeks passed with no response from Celgene. On December 4, 2007, Mylan sent a follow-up letter to Celgene regarding the status of supply of Thalomid capsules. This letter noted that Mylan had "not received a response as requested in the [November 16, 2007] letter."

Celgene's First Set of Additional Requests to Acquire Thalomid Samples After the FDA Determines Mylan's Protocols to Be Acceptable to Ensure Safety

90. Finally, nearly two months later – and more than three years after Mylan's initial attempt to secure Thalomid samples from Celgene – Celgene responded with a letter on January 8, 2008 confirming receipt of Mylan's November 16, 2007 letter.

91. Celgene acknowledged, as indicated previously by Mylan, that the FDA had "issued a letter [to Celgene] regarding the transfer of a limited amount of Thalomid for testing purposes." Celgene's letter further quotes the FDA letter as stating:

> [T]he agency intends to exercise its enforcement discretion to permit Celgene to provide to another drug manufacturer (or its agent) 500 units of Thalomid . . . 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.

92. The FDA's authorization – following its review and acceptance of Mylan's safety protocols – should have been more than sufficient for Celgene to provide Mylan with the requested samples, but Celgene asserted that it was "prohibited" from providing the requested Thalomid and then for the first time made arbitrary and onerous information requests from Mylan. The pretext for this "prohibition" was a discrepancy in the amount of capsules requested by Mylan and the amount permitted by the FDA correspondence. This issue was resolved readily by Mylan agreeing to limit its request to the 500 capsules permitted by FDA, which Mylan did on June 27, 2008.

93. Celgene reiterated the importance of public safety, claiming that its "concerns about distributing Thalomid outside of the S.T.E.P.S. program are independent of FDA's regulatory oversight." That is, although the government agency that was specifically authorized to review drug safety had thoroughly reviewed Mylan's proposed safety protocols, and clearly agreed to the distribution of Thalomid samples to Mylan outside of the S.T.E.P.S. program, Celgene somehow viewed itself as having the authority to second-guess the FDA's decision.

94. Recognizing that Mylan's actions to date had effectively addressed any potential regulatory and safety issues surrounding the distribution of Thalomid, Celgene grasped for additional "issues" to use as justifications for its refusal to deal. For example, Celgene's January 8, 2008 letter vaguely pointed to the existence of "significant business and liability concerns" without further explanation, and without offering to discuss what specific safeguards would satisfactorily address these concerns.

95. Instead, Celgene requested that Mylan produce to Celgene voluminous documents and information – ten categories in total – that were not reasonably necessary for Celgene to provide Thalomid to Mylan. On the whole, Celgene's requests were irrelevant, overly broad,

unduly burdensome, and animated solely by Celgene's desire to preserve and extend its thalidomide monopoly by preventing generic competition.

96. For example, one request sought Mylan's policies for the "storage and use of hazardous substances," without limitation. Another requested information about "any enforcement actions or complaints" involving Mylan's clinical research associates.

97. Celgene even included an extraordinarily broad request for Mylan's "history of compliance with FDA regulatory requirements for the previous five years, including warning letters and FDA Form 483's." Form 483 inspection reports are used by the FDA in routine inspections manufacturing facilities. Given that Mylan was going to be using the Thalomid samples for testing, not manufacturing, there is no plausible reason for the reports to have had any bearing on a legitimate evaluation of Mylan's request for samples.

98. Moreover, Celgene did not commit to providing any samples of Thalomid to Mylan for use in bioequivalence testing, even in the event that Mylan did respond completely to the onerous and overbroad requests for documents and information. Rather, the January 8, 2008 letter merely stated that upon Mylan's compliance, "Celgene will reconsider Mylan's request accordingly."

99. Knowing full well that it had given Mylan no guarantees or certainties regarding the supply of Thalomid, Celgene also asked whether Mylan's product liability insurance covered thalidomide.

100. Notably, at no point during the parties' correspondence, spanning a period of over three years, did Celgene explicitly state its refusal to sell Thalomid samples to Mylan. Indeed, in its January 8, 2008 letter, Celgene informed Mylan that "Celgene does not believe that it is appropriate to transfer Thalomid capsules to Mylan *at this time*" (emphasis supplied), leaving

open the possibility that it would at some point in the future. Celgene's pattern of conduct was to continually condition the provision of Thalomid samples upon Mylan's willingness to meet the largely arbitrary and increasingly burdensome requirements Celgene set forth.

101. Celgene did not make its requests for information (or even hint at them) until more than three years had passed since Mylan's initial attempt to secure Thalomid samples. Celgene's letter and requests were plainly a pretext to allow Celgene to delay, and continue depriving Mylan of samples, with the aim of foreclosing potential competition.

Confidentiality Agreement

102. In a letter to Celgene dated February 25, 2008, Mylan highlighted the odd timing of Celgene's requests – "We do find it curious that [you are] asking for these voluminous and proprietary materials only now, many months after our initial exchange of correspondence . . . in which [Celgene] made no mention of wanting to review such items."

103. Mylan also explicitly stated its suspicions "that Celgene is using these information requests as a pretext to continue to delay generic competition to Thalomid," but for the sake of avoiding further delay, Mylan agreed to "immediately deliver" all of the information Celgene had requested, on a confidential basis. To that end, Mylan enclosed with its letter a standard three-page confidentiality agreement for Celgene's review and execution. The requested materials had been assembled, and Mylan was prepared to produce it to Celgene as soon as Celgene executed the agreement.

104. Celgene took nearly two months to respond. On April 18, 2008, Celgene proposed edits to the confidentiality agreement. Mylan quickly accepted Celgene's edits, and Celgene responded that it would execute the revised agreement.

105. Then another month and a half went by with no word from Celgene. In early June 2008, Celgene proposed additional edits to the revised agreement, which Mylan again accepted.

106. Celgene finally executed the confidentiality agreement on June 24, 2008. Celgene's lack of responsiveness added approximately four more months of delay to what had become a nearly four-year long exchange.

107. On June 27, 2008, Mylan responded to Celgene by letter and produced all of the materials requested by Celgene on January 8, 2008. Mylan did so notwithstanding the fact that Mylan believed that much of the information requested by Celgene was not relevant to the provision of samples of Thalomid for bioequivalence testing and even though "Mylan already has satisfied the FDA's stringent requirements as part of its regulatory oversight for the proposed study . . ." The documentation provided by Mylan ran over 180 pages and provided detailed information including the following:

- Mylan's intended risk management measures;
- Evidence of liability insurance sufficient to cover events associated with thalidomide;
- Qualifications of Mylan's clinical research associates, including any enforcement actions or complaints involving those associates;
- Procedures for monitoring and handling adverse events;
- Procedures for minimizing risk and adverse reactions;
- Procedures for investigating complaints;
- Mylan's history of compliance with FDA regulatory requirements (including warning letters and FDA Form 483's) for the past five years;

- Mylan's Contract Research Organization's ("CRO") history of compliance with FDA, a CRO to be used by Mylan to conduct the bioequivalence study;
- regulatory requirements (including warning letters and FDA Form 483's) for the past five years;
- Policies for biohazard handling and disaster recovery plans;
- Policies for the storage and use of hazardous substances;
- Plans for handling and tracking the chain of custody and use of Thalomid capsules;
- History of product loss due to improper handling or tracking; and
- Other organization(s) that will be involved in the handling of Thalomid on behalf of Mylan.

108. Further, Mylan stated that it was willing to enter into an indemnification arrangement to indemnify Celgene for any liability resulting from Mylan's studies. Mylan noted that "[g]iven the length of time that has passed since making this request due to Celgene's delay in executing the confidentiality agreement, we expect Celgene has drafted an indemnification arrangement and can send immediately for Mylan's review."

109. As a result of Mylan's willingness to enter into such an arrangement, Mylan did not believe responding to Celgene's information requests was still necessary, but chose to do so anyway, in the interest of avoiding further delay. Agreeing to indemnify Celgene for any liability resulting from Mylan's studies would sufficiently and wholly address Celgene's purported concerns about safety and render Celgene's voluminous information requests redundant. Regardless, in the interest of demonstrating full cooperation and avoiding further

delay, Mylan chose to enter an indemnification arrangement as well as comply with Celgene's various requests.

110. Mylan concluded its letter by urging Celgene to "move forward expeditiously to avoid further delay," noting that "almost four years have passed since Mylan initially contacted Celgene about obtaining Thalomid." Mylan made clear to Celgene that any further delay in the provision of supply would "only serve to underscore that Celgene's objective is delay rather than any legitimate business justification."

111. Nearly a month passed with no response from Celgene. On July 25, 2008, Mylan sent a follow-up letter to Celgene regarding the status of supply of Thalomid capsules. In the letter Mylan remarked that Celgene had had "ample time" to review the provided information.

112. On August 1, 2008, Celgene sent a letter to Mylan indicating that Celgene was "carefully reviewing" the materials Mylan had submitted on June 27, 2008. Celgene acknowledged Mylan's willingness to enter into an indemnification agreement. While Celgene had not yet prepared such an agreement, Celgene stated that it was willing to do so, and expected "to be in a position to forward a draft to you by August 15."

Draft Indemnification Agreement

113. On August 15, 2008 Celgene provided Mylan with a draft indemnification agreement. After reviewing the draft indemnification agreement, Mylan sent a letter to Celgene on October 10, 2008, expressing concerns over certain of the overly broad terms in the agreement.

114. Mylan also took issue with a provision relating to its maintenance of insurance coverage. The provision not only required Mylan to maintain insurance for an unnecessarily

long duration, but also restricted Mylan from taking any actions relating to insurance coverage without the prior written approval of Celgene.

115. In its letter, Mylan clarified that it was willing to enter into a reasonable indemnification arrangement despite the fact that it believed such an arrangement was unnecessary in light of the FDA's finding that Mylan's proposed study protocols were acceptable to ensure safety.

116. Mylan stated that it was "willing to accept all *reasonable* terms" in Celgene's draft indemnification agreement, and enclosed a revised draft striking out certain of the more onerous and unreasonable provisions. Mylan also reminded Celgene that it had fully responded to every request made by Celgene in its January 8, 2008 letter, and that the parties had now reached the four year anniversary date of Mylan's initial request to Celgene.

117. Despite Mylan's having provided all of the documents and information requested by Celgene, Celgene refused to provide the Thalomid samples necessary for bioequivalence testing. Rather, Celgene continued to throw new unreasonable and numerous demands at Mylan to further delay Mylan's ability to develop its thalidomide product.

Celgene's Second Set of Additional Requests to Acquire Thalomid Samples After the FDA Determines Mylan's Protocols to Be Acceptable to Ensure Safety

118. On October 31, 2008, Celgene sent a letter to Mylan responding to Mylan's October 1, 2008 letter, and requesting even more information. Even though Mylan had already submitted proof of liability insurance sufficient to cover events associated with thalidomide, Celgene now demanded additional evidence from Mylan's and its CRO's insurance providers. Celgene also rejected Mylan's proposed revisions to the draft indemnification agreement, claiming that they did not "adequately protect Celgene's interests."

119. Remarkably, Celgene took the position for the first time – after having engaged in extended interaction with Mylan for over four years – that it somehow had "no legal obligation" to provide Mylan with Thalomid samples, despite the fact that Celgene controlled the only supply of a resource necessary and absolutely essential for conducting legally mandated bioequivalence studies.

120. On April 20, 2009, Mylan responded to Celgene by acquiescing to each of the demands and requests outlined in Celgene's October 31, 2008 letter. Mylan dropped its own proposed revisions to the draft indemnification agreement and accepted those proposed by Celgene. Mylan also enclosed certificates of insurance from both Mylan and its CRO's underwriters, addressing Celgene's request for additional coverage information.

121. Mylan at this point had unquestionably satisfied all of the demands that Celgene had imposed, notwithstanding the fact that most of Celgene's demands were not relevant to the provision of Thalomid samples.

Celgene's Third Set of Additional Requests to Acquire Thalomid Samples After the FDA Determines Mylan's Protocols to Be Acceptable to Ensure Safety

122. On June 24, 2009, Celgene responded to Mylan's submission of coverage information by requesting that Mylan produce even more additional materials – in nine categories, to be exact. Celgene stated that "[t]hese issues must be adequately addressed before Celgene will release Thalomid samples to Mylan or any other company."

123. Interestingly, Celgene suggested that it was merely following guidance from the FDA, which had "indicated that there is a zero tolerance [sic] for fetal exposure to thalidomide." While acknowledging the significance of the FDA in such matters, Celgene stubbornly ignored (or refused to take into consideration) the fact that FDA had already found Mylan's testing

protocols to be acceptable and sufficient to provide safety measures, and had agreed to the distribution of thalidomide to Mylan outside of the S.T.E.P.S. program.

124. Instead, Celgene issued another list of requests and demanded that Mylan comply "as quickly as possible." Celgene's demands for further information and materials were related to the following categories:

- Sufficiency of the FDA acceptance of Mylan's protocol for thalidomide bioequivalence testing;
- Additional evidence of insurance coverage;
- Procedures for disposal of unused Thalomid;
- Clarification of history of product loss due to improper handling or tracking;
- Whether any of Mylan's studies will be conducted in California;
- Additional evidence of compliance with FDA regulatory requirements over the past five years;
- Additional information regarding Mylan's CRO's activities that are unrelated to Mylan or thalidomide; and
- Confirmation of the continued accuracy of Mylan's past submissions.

125. In addition to requests for information and materials, Celgene's letter requested that Mylan and Mylan's CRO agree to change their respective insurance coverage from claims-made policies to occurrence-based policies and flatly rejected Mylan's proposed edits to the indemnification agreement, which Mylan already agreed to drop in its April 20, 2009 letter.

126. This latest round of requests by Celgene were, like the requests made in January 8, 2008, overbroad, unduly burdensome, and for the most part not relevant to the provision of samples of Thalomid for bioequivalence testing. This new set of requests was also redundant,

asking for information that Mylan had already provided, or vaguely questioning the accuracy of such information. For example, one of the requests sought evidence of FDA approval of Mylan's testing protocol – information that Celgene already had in its possession.

127. Notably, after all of these delay tactics, Celgene still held out the possibility that it would sell Thalomid samples to Mylan. In its letter, Celgene stated clearly that it "remains willing to provide Thalomid samples to Mylan."

128. After attempting to engage with Celgene for almost five years in order to procure Thalomid samples necessary for bioequivalence testing – developing and refining FDA-approved safety protocols, undertaking substantial efforts to collect materials from numerous sources within the Company and from its agents, and complying with increasingly unreasonable and irrelevant requests – Mylan recognized that further engagement with Celgene would be fruitless as each attempt to comply with Celgene's demands would simply be met with further requests and delay.

129. Celgene's sustained course of conduct, motivated solely by anticompetitive intent, is aimed specifically at delaying indefinitely Mylan's ability to conduct the bioequivalence testing necessary to obtain approval of a generic thalidomide product.

Mylan's Efforts to Develop Generic Revlimid

130. When Mylan considered filing an ANDA for lenalidomide and requested from Celgene Revlimid samples necessary for a bioequivalence study (after unsuccessfully trying to obtain samples through wholesale distributors), Celgene stayed true to its scheme and sent Mylan down a nearly identical path of delay.

131. In January 2009, Mylan began efforts to develop a generic equivalent to Celgene's Revlimid.

132. To conduct bioequivalence testing, Mylan needed to procure samples of Revlimid. Similar to Thalomid, Revlimid is not available through normal wholesale distribution channels, and can only be purchased from Celgene. However, after Mylan's difficulty with Celgene over an exhausting period of five years, which ended in Mylan's complete inability to obtain samples of Thalomid, Mylan concluded that any efforts to obtain supply of Revlimid from Celgene at that time would be fruitless.

133. Nonetheless, Mylan chose to proceed with all necessary steps to allow it to move forward with bioequivalence testing should it be able to obtain supply.

134. During the period of August 2009 to May 2012, Mylan undertook to prepare safety protocols consistent with provision of Celgene's RevAssist REMS program for Revlimid. Mylan completed preparation of those protocols, which included safeguards consistent with the RevAssist program.

FDA Determines Mylan's Lenalidomide Protocols to Be Acceptable to Ensure Safety

135. On August 24, 2012, Mylan submitted its lenalidomide safety protocols to the FDA for review. Mylan's submission included the following materials:

- Proposed study protocol entitled "Single-Dose Fed Bioequivalence Study of Lenalidomide Capsules (25 mg; Mylan) to Revlimid Capsules (25 mg; Celgene) in Healthy Adult Male Volunteers";
- Proposed study protocol entitled "Single-Dose Fasting Bioequivalence Study of Lenalidomide Capsules (25 mg; Mylan) to Revlimid Capsules (25 mg; Celgene) in Healthy Adult Male Volunteers";

- Proposed study protocol entitled "Single-Dose Fasting Bioequivalence Study of Lenalidomide Capsules (15 mg; Mylan) to Revlimid Capsules (15 mg; Celgene) in Healthy Adult Male Volunteers";
- Proposed Volunteer Consent Forms for all three aforementioned studies, used to inform potential volunteers about the risks and benefits of a research study and to ask potential volunteers to consent to participate in the study;
- A document entitled "Important Information and Warnings for Female Sexual Partners of Men Participating in the Lenalidomide Research Study," warning female sexual partners of male volunteers that lenalidomide can be present in semen and that therefore they should not have unprotected sex while the male is in the study and for 4 weeks after the study is completed.

136. In correspondence with Mylan on October 1, 2012, the FDA informed Mylan that the DBE had completed its review and found Mylan's protocols "acceptable" for the purpose of demonstrating bioequivalence. FDA further provided additional comments and recommendations from the Division of Clinical Review that Mylan needed to follow based on a comparison of Mylan's protocols and Celgene's RevAssist program.

137. FDA's correspondence also addressed the possibility of Mylan receiving "assistance" from the FDA's OGD in obtaining Revlimid:

> If you still desire assistance from the OGD in obtaining the Reference Listed Drug Revlimid, please submit for review the revised lenalidomide protocols, the informed consents for these protocols and all informational materials that will be distributed by the study investigators, pharmacists and/or subjects. *At your request and after the OGD has determined that the submitted documents are acceptable, the OGD will notify the sponsor of the RLD that it has received sufficient assurance that the lenalidomide BE studies will be conducted in such a manner as to ensure the safety of the subjects, and that the sponsor of the RLD may provide you or your agent with the RLD for the purpose of conducting bioequivalence (including dissolution) testing.* (emphasis supplied)

138. On November 19, 2012, Mylan responded by supplying the additional information requested by FDA's Division of Clinical Review in its October 1, 2012 letter and by confirming that it had incorporated the FDA's recommendations into Mylan's testing protocols.

139. With respect to the issue of Revlimid supply raised by the FDA, Mylan confirmed its continued desire to develop a generic lenalidomide product by replying that it "does still desire OGD's assistance in obtaining the Reference Listed Drug, Revlimid, so that we can conduct the necessary chemistry and bioequivalence testing" to support the future filing of an ANDA.

140. In its letter of November 19, 2012, Mylan also granted permission to the Office of Generic Drugs to notify Celgene once Mylan's protocols were approved.

141. On February 28, 2013, the FDA replied to Mylan asking for additional documentation and identifying a few minor recommendations, including changes to the informed consent form. Mylan responded on May 7, 2013, implementing suggested changes and providing additional documentation.

142. Ultimately, on July 29, 2013, Mylan received approval from the FDA's Office of Generic Drugs. The FDA determined that the protocols submitted by Mylan were "adequate safeguards that serve as an appropriate substitute for the controls present in the FDA mandated Revlimid REMS program for ensuring patient safety." Further, the FDA noted that "Mylan provided the OGD with permission to send a correspondence to the Reference Listed Drug ("RLD") holder [Celgene] requesting that they provide Mylan with 500 capsules of each strength of Revlimid for the purpose of conducting bioequivalence (including dissolution) testing."

Celgene's First Set of Requests to Acquire Revlimid Samples Notwithstanding FDA's Impending Determination that Mylan's Protocols Are Acceptable to Ensure Safety

143. On May 1, 2013, in anticipation of FDA's impending determination that Mylan's lenalidomide bioequivalence study protocols are acceptable to ensure safety, Mylan sent a letter to Celgene. In this letter, Mylan informed Celgene that Mylan was close to receiving the FDA's decision and requested to purchase Revlimid samples. Mylan requested 500 capsules each of the 2.5 mg, 5 mg, 10 mg, 15 mg and 25 mg strengths offered to pay market value for the capsules.

144. On May 14, 2013, Celgene responded stating that it must wait until the FDA grants final approval to Mylan before providing samples, and further requesting nine types of additional information from Mylan.

145. Staying true to its anticompetitive scheme, the request portion of Celgene's May 14, 2013 letter was nearly identical to its January 8, 2008 letter asking Mylan to provide voluminous information even after the FDA approved Mylan's thalidomide study safety protocols.

146. As was the case with Mylan's requests for Thalomid samples, the information requested by Celgene related almost entirely to purported safety concerns that have been already reviewed and addressed by the FDA. Specifically, the requests asked for the following information:

- intended risk management measures, especially regarding the prevention of fetal exposure;
- insurance information;
- clinical research organization information;

- Mylan's and its safety monitoring activities; information on historical FDA Form 483s and related remedial actions;
- information relating to Mylan's and its CRO's policies for biohazard handling, disaster recovery plans, and storage and use policies; and
- information on how capsules will be handled, dispensed, administered and tracked.

147. Celgene's May 14, 2013 letter further conditioned the provision of Revlimid samples on execution of a supply agreement, which would have to include indemnification terms.

148. In sum, with its May 14, 2013 letter, Celgene signaled to Mylan its intent—to repeat the *nine year long* delay campaign Celgene undertook in response to Mylan's request for Thalomid samples. While Mylan understood that by means of its May 14, 2013 letter Celgene constructively refused to provide Mylan with Revlimid samples, it took additional steps to respond to Celgene's requests.

149. On January 13, 2014, Mylan submitted to the OGD, at the OGD's request, a Disclosure Authorization allowing the OGD to contact Celgene and share with it the fact that the FDA had received a request from Mylan for assistance in obtaining supplies of lenalidomide for the purpose of bioequivalence testing and that Mylan "has submitted for FDA's review study protocols that include safety precautions for testing comparable to those set forth in the FDA-mandated REMS for Revlimid."

150. On March 11, 2014, following the FDA's final endorsement of its safety protocols, Mylan sent a letter to Celgene. In this letter, Mylan informed Celgene that the FDA has found its lenalidomide bioequivalence study safety protocols to be acceptable to ensure

safety. Mylan also notified Celgene that it will not "reengage in the back-and-forth correspondence initiated by Celgene over a more than three year period when Mylan similarly sought samples of thalidomide" and asked Celgene to provide samples by March 14, 2014.

151. In the last ditch effort to obtain Revlimid samples, Mylan in its March 11, 2014 letter also attached an indemnification agreement containing terms agreeable to Mylan for execution by Celgene that "reflect[ed] the numerous terms Mylan acceded to as part of the [the thalidomide] negotiations, and which provide sufficient protection to any legitimate concerns Celgene may have regarding indemnification."

152. On March 20, 2014, Celgene responded to Mylan's March 11, 2014 letter without providing the Revlimid samples requested, but rather requesting eight categories of information. As with its prior requests for information relating to both Thalomid and Revlimid, Celgene requested extensive information pertaining to safety issues already subject to FDA review.

153. First, in its March 20, 2014 letter, Celgene sought from Mylan a written confirmation from the FDA that Celgene is allowed to sell Revlimid samples to Mylan. Celgene made this demand despite noting in its letter that Mylan received "FDA's approval of [its] protocols." Indeed, as part of its March 11, 2014 letter, Mylan had provided FDA's approval letter to Celgene, which stated that Mylan's " protocols are safe to proceed" and "include adequate safeguards that serve as an appropriate substitute for the controls present in the . . . Revlimid REMS." The FDA letter further confirmed that "on November 19, 2012, Mylan provided the OGD with permission to send correspondence to [Celgene] requesting that it provide Mylan with 500 capsules of each strength of Revlimid for the purpose of conducting bioequivalence (including dissolution) testing."

154. Second, Celgene requested information relating to safety issues that already were subject to FDA review in determining that Mylan's lenalidomide bioequivalence protocols were acceptable. In particular, Celgene demanded the following information:

- a copy of the FDA approved protocols and informed consent;
- information about Mylan's CRO and the CRO's qualifications;
- Mylan's and its CRO's procedures for safety monitoring and adverse event reporting;
- all risk management procedures that will be employed by Mylan and its CRO;
- FDA enforcement histories (previous three years) for Mylan and its CRO, including Form 483 's and related remedial actions; and
- policies and procedures for biohazard handling, disaster recovery, and storage and use of lenalidomide products.

155. Third, Celgene made an entirely new request erecting yet another barrier to Mylan's development of generic lenalidomide. Specifically, Celgene stated that "[e]vidence of IRB approval will be required prior to placing an order for Revlimid for the *in vivo* bioequivalence study." This new request, which had not been made previously by Celgene for either Thalomid or Revlimid, was introduced for purposes of delaying provision of the FDA authorized samples of Revlimid to Mylan. First, Institutional Review Boards or "IRBs" are multidisciplinary boards that review the manner in which a clinical ("in vivo") study is conducted for both safety and ethical considerations. However, IRB review would not even occur for Mylan's bioequivalence studies until *after* Mylan received samples and conducted further development work (including laboratory "in vitro" testing) on its generic form of Revlimid. Thus, Celgene's request for "evidence" of IRB approval is premature. Second, and in

line with Celgene's prior pattern of conduct of requesting information relating to safety issues subject to FDA review, IRB review likewise is within the FDA's purview. The FDA provides guidelines to IRBs, has the authority to audit IRBs, and confirms appropriate IRB review prior to approving a product for marketing. As Celgene knows well, the FDA determined that Mylan's lenalidomide safety protocols were acceptable and that Revlimid samples should be made available to Mylan prior to and separate from IRB approval. Specifically, the FDA in its July 29, 2013 letter to Mylan committed to direct Celgene to "provide Mylan with 500 capsules of each strength of Revlimid for the purpose of conducting bioequivalence (including dissolution) testing" while expressly recognizing in the same letter that IRB approval was a separate requirement. Specifically, the FDA recognized that IRB approval had not yet occurred in stating that "[a]cceptance of this protocol by OGD should be considered independently of an IRB's acceptance of the same protocol, and should not influence the decision of an IRB to accept the protocol." Celgene, thus, by requesting "evidence" of IRB approval from Mylan again seeks to impose its own regulatory requirement on Mylan – a regulatory requirement not imposed by the actual regulator, the FDA. This request is clearly intended to provide further grounds for Celgene to delay provision of the FDA authorized Revlimid samples to Mylan.

156. Finally, with regard to Mylan's proposed indemnification terms submitted as an attachment to Mylan's March 11, 2014 letter, Celgene failed to sign the agreement. Instead, Celgene stated that it would only consider entering into such terms after it receives the eight categories of information requested and only "upon [Celgene's] satisfactory review" of that information. Celgene refused to sign the terms despite the fact that Celgene stated that after review of the information requested it would provide a supply agreement that would include

"indemnification provisions *substantially* similar to the indemnification provisions you proposed."

157. In sum, Celgene's March 20, 2014 letter continues its pattern of refusing to provide Mylan with product samples necessary to conduct FDA authorized bioequivalence studies. Celgene's sustained course of conduct, motivated by anticompetitive intent, is aimed specifically at delaying indefinitely Mylan's ability to conduct the bioequivalence testing necessary to obtain approval of a generic lenalidomide product.

VIII. The Anticompetitive Effects of Defendant's Conduct

158. Because Mylan cannot obtain Thalomid or Revlimid inside or outside Celgene's REMS programs, Celgene's agreements with its wholesale distributors, specially certified pharmacies, and other third parties clearly have an anticompetitive impact on the markets for thalidomide and lenalidomide. These agreements preclude access to the samples necessary for bioequivalence testing, prevent any ANDA filings, and therefore thwart entry into the markets for thalidomide and lenalidomide. Nor are the restrictions on distribution reasonably necessary to achieve legitimate ends given that the FDA found Mylan's testing protocols to be sufficient to ensure safety. Celgene's restrictions, as applied to Mylan, are a mere pretext to eliminate competition.

159. Competition in the thalidomide and lenalidomide markets is restricted due to the need for FDA approval before a competitor may market a generic substitute product rated as therapeutically equivalent to Thalomid or to Revlimid. In addition, prior to submitting an application to FDA for approval, a drug company incurs significant costs and requires significant knowledge and time in order to formulate and develop a drug for FDA approval.

160. Notably, on information and belief, Celgene offers its products at a retail price to customers who are willing to abide by certain safety protocols, yet it is unwilling to sell those same products at retail prices to Mylan. Further, on information and belief, Celgene has required that all of its customers agree not to resell its retail products to "unapproved" buyers, including Mylan.

161. On information and belief, Celgene on numerous occasions provided Thalomid and Revlimid to non-competitor research organizations for the purpose of conducting clinical studies using the drugs. Specifically, Celgene has frequently allowed access to Thalomid and Revlimid samples—directly or indirectly—to other organizations, for the purpose of conducting clinical studies. Mylan seeks only to be treated the same way Celgene has treated the sponsors of these other studies.

162. For example, Celgene provided Thalomid to the Johns Hopkins University School of Medicine in order to conduct a 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. Generally, Celgene suggests that it had provided Revlimid in over a 100 clinical studies.

163. On information and belief, the organizations who conducted the clinical studies referenced above did not obtain Thalomid and Revlimid samples through Celgene's REMS programs.

164. There is only one plausible explanation for Celgene's willingness to allow access to such samples to these entities, on one hand, and its steadfast refusal to allow access to such

samples to Mylan, on the other hand: a desire to "block or delay" generic competition, in violation of FDC Act § 505-1(f)(8) and the antitrust laws.

165. Celgene's anticompetitive practices have had a direct, substantial and adverse effect on Mylan and competition by monopolizing and maintaining monopoly power, artificially creating barriers to entry, and foreclosing competition in the Thalidomide and Lenalidomide Markets. But for Celgene's conduct, Mylan would have been able to compete for sales within the Relevant Markets substantially earlier. In particular, absent Celgene's conspiracy and anticompetitive refusal to deal, Mylan estimates it would have filed an ANDA for thalidomide years earlier and entered the market years earlier, offering patients a low-cost generic option for Thalomid. Similarly, but for Celgene's anticompetitive conduct, Mylan would not have been delayed in preparation of its lenalidomide ANDA.

166. Because Mylan's competing thalidomide and lenalidomide capsule products would be priced below Celgene's Thalomid and Revlimid, Mylan would make significant sales immediately upon entry into the Relevant Markets.

167. Celgene's anticompetitive conduct has impeded and continues to delay the sale of generic thalidomide and lenalidomide capsules in the Relevant Markets, and thus has allowed (and will continue to allow) Celgene to maintain and extend its monopoly power in the Relevant Markets and to sell Thalomid and Revlimid at artificially inflated monopoly prices.

168. This conduct has harmed the competitive process and allowed Celgene to perpetuate supracompetitive prices from wholesalers, retailers, and consumers. But for Celgene's anticompetitive conduct, consumers and federal, state, and private payors would have enjoyed the benefits of lower-priced generic competition years earlier. Instead, as a result of Celgene's strategies to thwart generic entry, consumers and federal, state, and private payors

have been (and/or will continue to be) forced to pay monopoly rents for Celgene's branded Thalomid and Revlimid without the ability to select lower-priced generic alternatives.

169. Celgene's anticompetitive practices have had a direct, substantial and adverse effect on Mylan and competition by monopolizing and maintaining monopoly power, artificially creating barriers to entry, and foreclosing competition in the Relevant Markets.

170. There are no procompetitive justifications, countervailing efficiencies, increases in consumer welfare, or legitimate business reasons for Celgene's conduct.

171. Mylan has extensive experience in the pharmaceutical industry, including obtaining approval for ANDAs and marketing generic pharmaceutical products.

172. Mylan has a history of achieving high approval rates for its ANDAs.

173. Mylan has sufficient financial capacity to enter the Relevant Markets.

174. Mylan has taken actual and substantial affirmative steps toward attempting to develop its generic thalidomide and lenalidomide capsule products and, but for Celgene's anticompetitive conduct, would have received regulatory approval for this product.

175. Mylan has expended substantial labor and sums of money in developing its generic thalidomide and lenalidomide capsule products, and otherwise preparing to enter the Relevant Markets.

Need for Injunctive Relief

176. Mylan repeats and re-alleges the allegations of paragraphs 1-175 as if fully set forth herein.

177. Mylan has a reasonable probability of success on the merits.

178. Mylan's right to relief in the form of access to sufficient samples of Thalomid and Revlimid to enable Mylan to perform bioequivalence testing in support of an ANDA is clear.

179. Specifically, Mylan is entitled to a mandatory immediate injunction pursuant to 15 U.S.C. § 26 and Fed. R. Civ. P. 65, requiring Celgene to permit Mylan to purchase samples of Thalomid and Revlimid.

180. Celgene's conduct as outlined above has directly, proximately, and foreseeably caused irreparable injuries, or threatens to cause irreparable injury to, Mylan in at least the following ways:

a. Mylan cannot obtain samples of Thalomid and Revlimid to conduct its bioequivalence testing in order to enter into the Relevant Markets; and

b. Mylan will expend substantial sums to undertake litigation in an effort to obtain samples of Thalomid and Revlimid to conduct its bioequivalence testing; and

c. Mylan stands to lose millions of dollars in profits from lost sales by virtue of its foreclosure from and/or delayed entry into the Relevant Markets.

181. The actual and threatened injury to competition flows directly from Mylan's actual and threatened injuries, and both Mylan's actual and threatened injuries and the actual and threatened injury to competition result from Celgene's anticompetitive conduct.

182. The actual and threatened injury to Mylan resulting from Celgene's wrongful conduct constitutes antitrust injury.

183. Mylan does not have an adequate remedy at law.

184. As a result of Celgene's alleged unlawful conduct, as alleged herein, Mylan will continue to suffer immediate and irreparable harm that cannot be fully remedied by money damages.

185. Granting immediate injunctive relief to Mylan will not result in greater harm to Celgene.

186. Granting immediate injunctive relief to Mylan will be in the public interest, as it will finally allow the development of lower-cost, generic thalidomide and lenalidomide products, important drugs used to treat serious diseases, resulting in competition in the Relevant Markets.

FIRST COUNT
Sherman Act Section 2—Thalomid
Monopolization, Attempted Monopolization and Conspiracy to Monopolize

187. Mylan repeats and re-alleges the allegations of paragraphs 1-186 as if fully set forth herein.

188. The Thalidomide Market is the relevant market.

189. Celgene possesses monopoly power in the Thalidomide Market. This market is characterized by significant entry barriers.

190. This claim arises under the Sherman Act, 15 U.S.C. § 2, and the Clayton Act, 15 U.S.C. §§ 15, 26, and seeks a judgment that Celgene has violated Section 2 of the Sherman Act, 15 U.S.C. § 2, by monopolizing, attempting to monopolize and conspiring to monopolize the Thalidomide Market.

191. Through the foregoing acts, Celgene, unlawfully and in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, has used, is using and, if not restrained by this Court, will continue to use its power in the Thalidomide Market to monopolize, attempt to monopolize, and conspire to monopolize the Thalidomide Market.

192. Celgene knowingly and intentionally engaged in an anticompetitive scheme designed to unlawfully "block or delay approval," 21 U.S.C. § 355-1(f)(8), of an AB-rated generic version of Thalomid, and thus to willfully to maintain its monopoly power. Specifically,

Celgene prohibits access to bioequivalence samples using its S.T.E.P.S. program as a pretext. The FDA has determined Mylan's bioequivalence testing safety protocols to be sufficient to ensure safety, and Mylan notified Celgene of the FDA's determination. Additionally, Mylan, at Celgene's request, provided voluminous documentation detailing safety procedures and safeguards that would be implemented during Mylan's bioequivalence testing. Also, on several occasions, Mylan offered to pay retail prices for any samples Celgene would be willing to provide. In light of the above, Celgene's continued refusal to provide samples demonstrates predatory intent and has the effect of excluding potential competitors while preserving Celgene's dominant position.

193. By means of its refusal to deal, Celgene has acted for the specific purpose of monopolizing the Thalidomide Market.

194. Further, Celgene intentionally and wrongfully maintained its monopoly power with respect to Thalomid by entering into unlawful agreements with wholesale distributors and its S.T.E.P.S.-certified pharmacies, under which such participants agreed with Celgene not to supply Thalomid to any entity that does not have Celgene's approval.

195. Celgene intentionally and wrongfully maintained its monopoly power with respect to Thalomid by entering into unlawful agreements with wholesale distributors and its "specially certified" pharmacies, under which such participants agree with Celgene not to supply Thalomid to any entity that does not have Celgene's approval.

196. Celgene's conduct has no procompetitive, legitimate business justification. Celgene's conduct can be explained only by anticompetitive motives, and a desire to foreclose competition in the Thalidomide Market. Celgene's purported justifications are pretextual.

197. To the extent there are legitimate business justifications for Celgene's exclusionary conduct, Celgene's anticompetitive conduct is not necessary to serve those justifications.

198. Celgene currently enjoys a monopoly in the Thalidomide Market, and there is a dangerous probability Celgene will succeed in maintaining its monopoly by means of its unlawful conduct.

199. By its scheme, Celgene intentionally and wrongfully maintained its monopoly power with respect to thalidomide in violation of Section 2 of the Sherman Act. As a result of Celgene's unlawful maintenance of monopoly power, Mylan has suffered and will continue to suffer injury to its business and property, including lost profits, out-of-pocket costs, and lost business opportunities.

200. The foregoing acts and practices have harmed consumers and competition.

201. Celgene's conduct occurred in, and has had a substantial effect on, interstate commerce.

202. Celgene's anticompetitive and exclusionary conduct has directly and proximately caused injury to Mylan's business and property, as set forth above. Mylan's injury is the type the antitrust laws are intended to prohibit and thus constitutes antitrust injury.

203. Celgene's unlawful conduct continues and, unless restrained, will continue. Thus, unless the activities complained of are enjoined, Mylan will suffer immediate and irreparable injury for which Mylan is without an adequate remedy at law.

204. Mylan is entitled to a judgment that Celgene has violated Section 2 of the Sherman Act; to the damages it suffered as a result of that violation, to be trebled in accordance

with the Clayton Act, 15 U.S.C. § 15, plus interest; to its costs and attorneys' fees; and to an injunction restraining Celgene's continued violations.

SECOND COUNT
Sherman Act Section 2—Revlimid
Monopolization, Attempted Monopolization and Conspiracy to Monopolize

205. Mylan repeats and re-alleges the allegations of paragraphs 1-204 as if fully set forth herein.

206. The Lenalidomide Market is the relevant market.

207. Celgene possesses monopoly power in the Lenalidomide Market. This market is characterized by significant entry barriers.

208. This claim arises under the Sherman Act, 15 U.S.C. § 2, and the Clayton Act, 15 U.S.C. §§ 15, 26, and seeks a judgment that Celgene has violated Section 2 of the Sherman Act, 15 U.S.C. § 2, by monopolizing, attempting to monopolize and conspiring to monopolize the Lenalidomide Market.

209. Through the foregoing acts, Celgene, unlawfully and in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, has used, is using and, if not restrained by this Court, will continue to use its power in the Lenalidomide Market to monopolize, attempt to monopolize, and conspire to monopolize the Lenalidomide Market.

210. Celgene knowingly and intentionally engaged in an anticompetitive scheme designed to unlawfully "block or delay approval," 21 U.S.C. § 355-1(f)(8), of an AB-rated generic version of Revlimid, and thus to willfully to maintain its monopoly power.

211. Specifically, Celgene prohibits access to bioequivalence samples using its RevAssist program as a pretext. The FDA has determined Mylan's bioequivalence testing safety protocols to be sufficient to ensure safety, and Mylan notified Celgene of the FDA's

determination. Mylan has offered to pay retail prices for any samples Celgene would be willing to provide. In light of the above, Celgene's refusal to provide samples demonstrates predatory intent and has the effect of excluding potential competitors while preserving Celgene's dominant position.

212. By means of its refusal to deal, Celgene has acted for the specific purpose of monopolizing Lenalidomide Market.

213. Further, Celgene intentionally and wrongfully maintained its monopoly power with respect to Revlimid by entering into unlawful agreements with wholesale distributors and its RevAssist certified pharmacies, under which such participants agree with Celgene not to supply Revlimid to any entity that does not have Celgene's approval.

214. Celgene intentionally and wrongfully maintained its monopoly power with respect to Revlimid by entering into unlawful agreements with wholesale distributors and its "specially certified" pharmacies, under which such participants agree with Celgene not to supply Revlimid to any entity that does not have Celgene's approval.

215. Celgene's conduct has no procompetitive, legitimate business justification. Celgene's conduct can be explained only by anticompetitive motives, and a desire to foreclose competition in the Lenalidomide Market. Celgene's purported justifications are pretextual.

216. To the extent there are legitimate business justifications for Celgene's exclusionary conduct, Celgene's anticompetitive conduct is not necessary to serve those justifications.

217. Celgene currently enjoys a monopoly in the Lenalidomide Market, and there is a dangerous probability Celgene will succeed in maintaining its monopoly by means of its unlawful conduct.

218. By its scheme, Celgene intentionally and wrongfully maintained its monopoly power with respect to lenalidomide in violation of Section 2 of the Sherman Act. As a result of Celgene's unlawful maintenance of monopoly power, Mylan has suffered and will continue to suffer injury to its business and property, including lost profits, out-of-pocket costs, and lost business opportunities.

219. The foregoing acts and practices have harmed consumers and competition.

220. Celgene's conduct occurred in, and has had a substantial effect on, interstate commerce.

221. Celgene's anticompetitive and exclusionary conduct has directly and proximately caused injury to Mylan's business and property, as set forth above. Mylan's injury is the type the antitrust laws are intended to prohibit and thus constitutes antitrust injury.

222. Celgene's unlawful conduct continues and, unless restrained, will continue. Thus, unless the activities complained of are enjoined, Mylan will suffer immediate and irreparable injury for which Mylan is without an adequate remedy at law.

223. Mylan is entitled to a judgment that Celgene has violated Section 2 of the Sherman Act; to the damages it suffered as a result of that violation, to be trebled in accordance with the Clayton Act, 15 U.S.C. § 15, plus interest; to its costs and attorneys' fees; and to an injunction restraining Celgene's continued violations.

THIRD COUNT
Sherman Act Section 2—Thalomid
Denial of an Essential Facility or Resource Necessary to Compete

224. Mylan repeats and re-alleges the allegations of paragraphs 1-223 as if fully set forth herein.

225. This claim arises under the Sherman Act, 15 U.S.C. § 2, and the Clayton Act, 15 U.S.C. §§ 15, 26, and seeks a judgment that Celgene has violated Section 2 of the Sherman Act, 15 U.S.C. § 2, by monopolizing, attempting to monopolize, and conspiring to monopolize the Thalidomide Market by denying its competitors access to an essential facility or resource required to compete in the relevant market.

226. Celgene possesses monopoly power in the Thalidomide Market. This market is characterized by significant entry barriers.

227. A monopolist's denial to competitors of access to its essential goods, services or resources has been held to violate § 2.

228. FDA-approved Thalomid is an essential resource for the bioequivalence testing required to obtain FDA approval of a generic thalidomide product and thus Celgene's distribution of Thalomid is an essential facility for the production of generic thalidomide.

229. Mylan is unable practically or reasonably to duplicate the essential facility or resource for the purpose of conducting bioequivalence studies that will meet FDA requirements. Nor can Thalomid samples useable for FDA-approved bioequivalence studies be obtained from another source.

230. By refusing to provide samples of its Thalomid to Mylan, despite the FDA's acceptance of Mylan's safety protocols, Mylan's general assurances and representations that safety procedures would be followed, and Mylan's willingness to pay for the samples, for use in bioequivalence testing necessary to obtain approval of an ANDA for a thalidomide product, Celgene has controlled and is controlling an "essential resource" and "essential facility" for the development of that resource, thereby precluding or significantly delaying the development of

Mylan's generic thalidomide product in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

231. Celgene has denied, and continues to deny the use of the essential facility or resource of Thalomid samples to Mylan, a potential competitor in the Thalidomide Market.

232. Providing Mylan with Thalomid samples would be feasible. Celgene could simply sell Thalomid to Mylan at or near the market price it provides to other customers. No ongoing supervision by the court would be required to enforce such an order, especially in light of Mylan's safety assurances.

233. Celgene has no legitimate, procompetitive justification for sacrificing profits by refusing to sell Thalomid to Mylan at its market price. Celgene's purported justifications are pretextual.

234. To the extent there are legitimate business justifications for Celgene's exclusionary conduct, Celgene's anticompetitive conduct is not necessary to serve those justifications.

235. By its denial of access to an essential facility or resource necessary to compete in the relevant market, Celgene has intentionally and wrongfully maintained its monopoly power with respect to thalidomide in violation of Section 2 of the Sherman Act.

236. Celgene's unlawful monopoly as set forth above has had the following effects, among others:

a. Competition in the manufacture and sale of thalidomide was restrained, suppressed and eliminated; and

b. Purchasers of Thalomid were deprived of the benefits of free and open competition, and the availability of a lower cost generic thalidomide product, in the purchase of Thalomid; and

c. Celgene sold its Thalomid at artificially high and noncompetitive price levels.

237. Celgene's anticompetitive and exclusionary conduct has directly and proximately caused injury to Mylan's business and property, as set forth above. Mylan's injury is the type the antitrust laws are intended to prohibit and thus constitutes antitrust injury.

238. As a result of Celgene's unlawful denial of access to an essential facility or resource, Mylan has suffered and will continue to suffer injury to its business and property, including lost profits, out-of-pocket costs, and lost business opportunities.

239. Celgene's unlawful conduct continues and, unless restrained, will continue. Unless the activities complained of are enjoined, Mylan will suffer immediate and irreparable injury for which Mylan is without an adequate remedy at law.

240. Mylan is entitled to a judgment that Celgene has violated Section 2 of the Sherman Act; to the damages it has suffered as a result of that violation, to be trebled in accordance with the Clayton Act, 15 U.S.C. § 15, plus interest; to its costs and attorneys' fees; and to an injunction restraining Celgene's continued violations.

FOURTH COUNT
Sherman Act Section 2—Revlimid
Denial of an Essential Facility or Resource Necessary to Compete

241. Mylan repeats and re-alleges the allegations of paragraphs 1-240 as if fully set forth herein.

242. This claim arises under the Sherman Act, 15 U.S.C. § 2, and the Clayton Act, 15 U.S.C. §§ 15, 26, and seeks a judgment that Celgene has violated Section 2 of the Sherman Act, 15 U.S.C. § 2, by monopolizing, attempting to monopolize, and conspiring to monopolize the Lenalidomide Market by denying its competitors access to an essential facility or resource required to compete in the relevant market.

243. Celgene possesses monopoly power in the Lenalidomide Market. This market is characterized by significant entry barriers.

244. A monopolist's denial to competitors of access to its essential goods, services or resources has been held to violate § 2.

245. FDA-approved Revlimid is an essential resource for the bioequivalence testing required to obtain FDA approval of a generic lenalidomide product and thus Celgene's distribution of Revlimid is an essential facility for the production of generic lenalidomide.

246. Mylan is unable practically or reasonably to duplicate the essential facility or resource for the purpose of conducting bioequivalence studies that will meet FDA requirements. Nor can Revlimid samples useable for FDA-approved bioequivalence studies be obtained from another source.

247. By refusing to provide samples of its Revlimid to Mylan, despite the FDA's acceptance of Mylan's safety protocols, Mylan's general assurances and representations that safety procedures would be followed, and Mylan's willingness to pay for the samples, for use in bioequivalence testing necessary to obtain approval of an ANDA for a lenalidomide product, Celgene has controlled and is controlling an "essential resource" and "essential facility" for the development of that resource, thereby precluding or significantly delaying the development of

Mylan's generic lenalidomide product in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

248. Celgene has denied, and continues to deny the use of the essential facility or resource of Revlimid samples to Mylan, a potential competitor in the Lenalidomide Market.

249. Providing Mylan with Revlimid samples would be feasible. Celgene could simply sell Revlimid to Mylan at or near the market price it provides to other customers. No ongoing supervision by the court would be required to enforce such an order, especially in light of Mylan's safety assurances.

250. Celgene has no legitimate, procompetitive justification for sacrificing profits by refusing to sell Revlimid to Mylan at its market price. Celgene's purported justifications are pretextual.

251. To the extent there are legitimate business justifications for Celgene's exclusionary conduct, Celgene's anticompetitive conduct is not necessary to serve those justifications.

252. By its denial of access to an essential facility or resource necessary to compete in the Lenalidomide Market, Celgene has intentionally and wrongfully maintained its monopoly power with respect to lenalidomide in violation of Section 2 of the Sherman Act.

253. Celgene's unlawful monopoly as set forth above has had the following effects, among others:

a. Competition in the manufacture and sale of lenalidomide was restrained, suppressed and eliminated; and

b. Purchasers of Revlimid were deprived of the benefits of free and open competition, and the availability of a lower cost generic lenalidomide product, in the purchase of Revlimid; and

c. Celgene sold its Revlimid at artificially high and noncompetitive price levels.

254. Celgene's anticompetitive and exclusionary conduct has directly and proximately caused injury to Mylan's business and property, as set forth above. Mylan's injury is the type the antitrust laws are intended to prohibit and thus constitutes antitrust injury.

255. As a result of Celgene's unlawful denial of access to an essential facility or resource, Mylan has suffered and will continue to suffer injury to its business and property, including lost profits, out-of-pocket costs, and lost business opportunities.

256. Celgene's unlawful conduct continues and, unless restrained, will continue. Unless the activities complained of are enjoined, Mylan will suffer immediate and irreparable injury for which Mylan is without an adequate remedy at law.

257. Mylan is entitled to a judgment that Celgene has violated Section 2 of the Sherman Act; to the damages it has suffered as a result of that violation, to be trebled in accordance with the Clayton Act, 15 U.S.C. § 15 plus interest; to its costs and attorneys' fees; and to an injunction restraining Celgene's continued violations.

FIFTH COUNT
Sherman Act Section 1—Thalomid
Contract, Combination or Conspiracy in Restraint of Trade

258. Mylan repeats and re-alleges the allegations of paragraphs 1-257 as if fully set forth herein.

259. This claim arises under the Sherman Act, 15 U.S.C. § 1, and the Clayton Act, 15 U.S.C. §§ 15, 26, and seeks a judgment that Celgene has violated Section 1 of the Sherman Act, 15 U.S.C. § 1, by conspiring, combining and/or agreeing to restrain trade in the Thalidomide Market.

260. Through the foregoing acts, Celgene, unlawfully and in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1, has acted pursuant to a contract, combination or conspiracy in order to, and with the likely effect of, unreasonably restraining trade in the Thalidomide Market.

261. In order to protect itself from competition, Celgene devised an anticompetitive scheme to prevent Mylan and others from ever attempting to file thalidomide ANDAs by requiring its wholesale distributors and specially certified pharmacies to withhold samples of Thalomid and by refusing to sell these samples to Mylan itself.

262. Specifically, Celgene has entered into unlawful agreements with wholesale distributors to limit distribution of Thalomid to only those entities Celgene permits under its S.T.E.P.S. program. Celgene has also entered into unlawful agreements with each of its S.T.E.P.S.-certified entities, including pharmacies, under which such participants agree not to supply thalidomide to any entity without Celgene's approval. On information and belief, Celgene uses these and similar agreements to exercise complete control over the distribution of Thalomid.

263. Each of these agreements constitute contracts, combinations and conspiracies that substantially, unreasonably, and unduly restrain trade in the relevant market, and harmed Mylan thereby.

264. There is no legitimate, procompetitive business justification for Celgene's agreements with S.T.E.P.S.-certified distributors that outweighs the anticompetitive effect of

these agreements. Celgene's purported justifications are pretextual. Even if there was some business justification, the agreements are broader than necessary to achieve such a purpose.

265. The foregoing acts and practices have harmed consumers and competition.

266. Celgene's conduct occurred in, and has had a substantial effect on, interstate commerce.

267. As a result of Celgene's conduct, Mylan has suffered and will continue to suffer injury to its business and property, including lost profits, out-of-pocket costs, and lost business opportunities.

268. Celgene's anticompetitive and exclusionary conduct has directly and proximately caused injury to Mylan's business and property, as set forth above. Mylan's injury is the type the antitrust laws are intended to prohibit and thus constitutes antitrust injury.

269. Celgene's unlawful conduct continues and, unless restrained, will continue. Thus, unless the activities complained of are enjoined, Mylan will suffer immediate and irreparable injury for which Mylan is without an adequate remedy at law.

270. Mylan is entitled to a judgment that Celgene has violated Section 1 of the Sherman Act; to the damages it suffered as a result of that violation, to be trebled in accordance with the Clayton Act, 15 U.S.C. § 15, plus interest; to its costs and attorneys' fees; and to an injunction restraining Celgene's continued violations.

SIXTH COUNT
Sherman Act Section 1—Revlimid
Contract, Combination or Conspiracy in Restraint of Trade

271. Mylan repeats and re-alleges the allegations of paragraphs 1-270 as if fully set forth herein.

272. This claim arises under the Sherman Act, 15 U.S.C. § 1, and the Clayton Act, 15 U.S.C. §§ 15, 26, and seeks a judgment that Celgene has violated Section 1 of the Sherman Act, 15 U.S.C. § 1, by conspiring, combining and/or agreeing to restrain trade in the Lenalidomide Market.

273. Through the foregoing acts, Celgene, unlawfully and in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1, has acted pursuant to a contract, combination or conspiracy in order to, and with the likely effect of, unreasonably restraining trade in the Lenalidomide Market.

274. In order to protect itself from competition, Celgene devised an anticompetitive scheme to prevent Mylan and others from ever attempting to file lenalidomide ANDAs by requiring its wholesale distributors and specially certified pharmacies to withhold samples of Revlimid and by refusing to sell these samples to Mylan itself.

275. Specifically, Celgene has entered into unlawful agreements with wholesale distributors to limit distribution of Revlimid to only those entities Celgene permits under its RevAssist program. Celgene has also entered into unlawful agreements with each of its RevAssist-certified entities, including pharmacies, under which such participants agree not to supply lenalidomide to any entity without Celgene's approval. On information and belief, Celgene uses these and similar agreements to exercise complete control over the distribution of Revlimid.

276. Each of these agreements constitute contracts, combinations and conspiracies that substantially, unreasonably, and unduly restrain trade in the relevant market, and harmed Mylan thereby.

277. There is no legitimate, procompetitive business justification for Celgene's agreements with RevAssist-certified distributors that outweighs the anticompetitive effect of these agreements. Celgene's purported justifications are pretextual. Even if there was some business justification, the agreements are broader than necessary to achieve such a purpose.

278. The foregoing acts and practices have harmed consumers and competition.

279. Celgene's conduct occurred in, and has had a substantial effect on, interstate commerce.

280. As a result of Celgene's conduct, Mylan has suffered and will continue to suffer injury to its business and property, including lost profits, out-of-pocket costs, and lost business opportunities.

281. Celgene's anticompetitive and exclusionary conduct has directly and proximately caused injury to Mylan's business and property, as set forth above. Mylan's injury is the type the antitrust laws are intended to prohibit and thus constitutes antitrust injury.

282. Celgene's unlawful conduct continues and, unless restrained, will continue. Unless the activities complained of are enjoined, Mylan will suffer immediate and irreparable injury for which Mylan is without an adequate remedy at law.

283. Mylan is entitled to a judgment that Celgene has violated Section 1 of the Sherman Act; to the damages it suffered as a result of that violation, to be trebled in accordance with the Clayton Act, 15 U.S.C. § 15, plus interest; to its costs and attorneys' fees; and to an injunction restraining Celgene's continued violations.

SEVENTH COUNT
Sherman Act Section 1— Thalomid and Revlimid
Contract, Combination or Conspiracy in Restraint of Trade

284. Mylan repeats and re-alleges the allegations of paragraphs 1-283 as if fully set forth herein.

285. This claim arises under the Sherman Act, 15 U.S.C. § 1, and the Clayton Act, 15 U.S.C. §§ 15, 26, and seeks a judgment that Celgene has violated Section 1 of the Sherman Act, 15 U.S.C. § 1, by conspiring, combining and/or agreeing to restrain trade in the Relevant Markets.

286. Through the foregoing acts, Celgene, unlawfully and in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1, has acted pursuant to a contract, combination or conspiracy in order to, and with the likely effect of, unreasonably restraining trade in the Relevant Markets.

287. Celgene engaged in an illegal conspiracy to preclude Mylan from obtaining samples necessary to conduct generics' bioequivalence studies in an effort to thwart lower-cost competition.

288. In order to protect itself from competition, Celgene devised an anticompetitive scheme to prevent Mylan and others from ever attempting to file thalidomide or lenalidomide ANDAs by requiring its wholesale distributors and specially certified pharmacies to withhold samples of Thalomid and Revlimid and by refusing to sell these samples to Mylan itself. Celgene used its tactics to deny Mylan access to Thalomid samples for years, and subsequently has incorporated Revlimid into its anticompetitive scheme and used the same tactics to deny Mylan access to Revlimid as well.

289. In furtherance of this conspiracy, Celgene has entered into unlawful agreements with wholesale distributors to limit distribution of Thalomid and Revlimid to only those entities

Celgene permits under its S.T.E.P.S and RevAssist programs. Celgene has also entered into unlawful agreements with each of its S.T.E.P.S- and RevAssist-certified entities, including pharmacies, under which such participants agree not to supply thalidomide or lenalidomide to any entity without Celgene's approval. On information and belief, Celgene uses these and similar agreements to exercise complete control over the distribution of Thalomid and Revlimid.

290. Each of these agreements, and the agreements collectively, constitute contracts, combinations and conspiracies that substantially, unreasonably, and unduly restrain trade in the Relevant Markets, and harmed Mylan thereby.

291. Celgene's pattern of conduct in engaging in precisely the same conduct in regards to Revlimid as it had done previously concerning Thalomid is indicative of Celgene's long standing anticompetitive scheme to prevent Mylan and others entering the Relevant Markets.

292. There is no legitimate, procompetitive business justification for Celgene's agreements with S.T.E.P.S- and RevAssist- certified distributors that outweighs the anticompetitive effect of these agreements. Celgene's purported justifications are pretextual. Even if there was some business justification, the agreements are broader than necessary to achieve such a purpose.

293. The foregoing acts and practices have harmed consumers and competition.

294. Celgene's conduct occurred in, and has had a substantial effect on, interstate commerce.

295. As a result of Celgene's conduct, Mylan has suffered and will continue to suffer injury to its business and property, including lost profits, out-of-pocket costs, and lost business opportunities.

296. Celgene's anticompetitive and exclusionary conduct has directly and proximately caused injury to Mylan's business and property, as set forth above. Mylan's injury is the type the antitrust laws are intended to prohibit and thus constitutes antitrust injury.

297. Celgene's unlawful conduct continues and, unless restrained, will continue. Unless the activities complained of are enjoined, Mylan will suffer immediate and irreparable injury for which Mylan is without an adequate remedy at law.

298. Mylan is entitled to a judgment that Celgene has violated Section 1 of the Sherman Act; to the damages it suffered as a result of that violation, to be trebled in accordance with the Clayton Act, 15 U.S.C. § 15, plus interest; to its costs and attorneys' fees; and to an injunction restraining Celgene's continued violations.

EIGHTH COUNT
The New Jersey Antitrust Act, Sections 56:9-3 and 56:9-4 – Thalomid

299. Mylan repeats and re-alleges the allegations of paragraphs 1-298 as if fully set forth herein.

300. This claim arises under the New Jersey Antitrust Act, N.J. Stat. Ann. § 56:9 et seq, and seeks a judgment that Celgene's conduct as alleged herein violates the New Jersey Antitrust Act, N.J. Stat. Ann. § 56:9-4 and § 56:9-3.

Section 56:9-4, Monopolization

301. Celgene's conduct as alleged herein constitutes monopolization, attempted monopolization, and conspiracy to monopolize, in violation of N.J. Stat. Ann. § 56:9-4.

302. Specifically, Celgene's agreements with wholesale distributors and pharmacies to restrict distribution of Thalomid, as well as its refusal to sell Thalomid samples to Mylan at their market price, are calculated to maintain monopoly power in the relevant markets, in violation of N.J. Stat. Ann. § 56:9-4.

Section 56:9-4, Monopolization by Denial of an Essential Facility

303. In addition, Celgene's conduct as alleged herein constitutes monopolization, attempted monopolization, and conspiracy to monopolize by denial of an essential facility or resource necessary to compete, in violation of N.J. Stat. Ann. § 56:9-4.

304. Specifically, Celgene's control over, and denial of access to competitors, of the essential, non-duplicable resource of Thalomid samples, when granting such access would be feasible, is calculated to maintain monopoly power in the relevant markets, in violation of N.J. Stat. Ann. § 56:9-4.

Section 56:9-3, Agreement in Restraint of Trade

305. Celgene's conduct as alleged herein constitutes a contract, combination, or conspiracy in restraint of trade or commerce, in violation of N.J. Stat. Ann. § 56:9-3.

306. Specifically, Celgene's agreements and contracts with wholesale distributors and "specially certified" pharmacies prohibiting sales of Thalomid to Celgene's competitors are contracts, combinations, and conspiracies in restraint of trade or commerce, in violation of N.J. Stat. Ann. § 56:9-3.

307. Similarly, Celgene's agreements and contracts with S.T.E.P.S-certified distribution partners, limiting sales of Thalomid to entities approved by Celgene are contracts, combinations, and conspiracies in restraint of trade or commerce, in violation of N.J. Stat. Ann. § 56:9-3.

* * *

308. The foregoing acts and practices, and the continuing course of Celgene's anticompetitive conduct, have harmed consumers and competition.

309. Celgene's anticompetitive and exclusionary conduct has directly and proximately caused injury to Mylan's business and property, as set forth above. Mylan's injury is the type the antitrust laws are intended to prohibit and thus constitutes antitrust injury.

310. Celgene's unlawful conduct continues and, unless restrained, will continue.

311. Unless the activities complained of are enjoined, Mylan will suffer immediate and irreparable injury for which Mylan is without an adequate remedy at law.

312. Mylan is entitled to a judgment that Celgene has violated Sections 56:9-3 and 56:9-4 of the New Jersey Antitrust Act; to the damages it suffered as a result of that violation, to be trebled in accordance with N.J. Stat. Ann. § 56:9-12, plus interest; to its costs and attorneys' fees; and to an injunction restraining Celgene's continued violations.

NINTH COUNT
The New Jersey Antitrust Act, Sections 56:9-3 and 56:9-4 – Revlimid

313. Mylan repeats and re-alleges the allegations of paragraphs 1-312 as if fully set forth herein.

314. This claim arises under the New Jersey Antitrust Act, N.J. Stat. Ann. § 56:9 et seq, and seeks a judgment that Celgene's conduct as alleged herein violates the New Jersey Antitrust Act, N.J. Stat. Ann. § 56:9-4 and § 56:9-3.

Section 56:9-4, Monopolization

315. Celgene's conduct as alleged herein constitutes monopolization, attempted monopolization, and conspiracy to monopolize, in violation of N.J. Stat. Ann. § 56:9-4.

316. Specifically, Celgene's agreements with wholesale distributors and pharmacies to restrict distribution of Revlimid, as well as its refusal to sell Revlimid samples to Mylan at their market price, are calculated to maintain monopoly power in the relevant markets, in violation of N.J. Stat. Ann. § 56:9-4.

Section 56:9-4, Monopolization by Denial of an Essential Facility

317. In addition, Celgene's conduct as alleged herein constitutes monopolization, attempted monopolization, and conspiracy to monopolize by denial of an essential facility or resource necessary to compete, in violation of N.J. Stat. Ann. § 56:9-4.

318. Specifically, Celgene's control over, and denial of access to competitors, of the essential, non-duplicable resource of Revlimid samples, when granting such access would be feasible, is calculated to maintain monopoly power in the relevant markets, in violation of N.J. Stat. Ann. § 56:9-4.

Section 56:9-3, Agreement in Restraint of Trade

319. Celgene's conduct as alleged herein constitutes a contract, combination, or conspiracy in restraint of trade or commerce, in violation of N.J. Stat. Ann. § 56:9-3.

320. Specifically, Celgene's agreements and contracts with wholesale distributors and "specially certified" pharmacies prohibiting sales of Revlimid to Celgene's competitors are contracts, combinations, and conspiracies in restraint of trade or commerce, in violation of N.J. Stat. Ann. § 56:9-3.

321. Similarly, Celgene's agreements and contracts with RevAssist-certified distribution partners, limiting sales of Revlimid to entities approved by Celgene are contracts, combinations, and conspiracies in restraint of trade or commerce, in violation of N.J. Stat. Ann. § 56:9-3.

* * *

322. The foregoing acts and practices, and the continuing course of Celgene's anticompetitive conduct, have harmed consumers and competition.

323. Celgene's anticompetitive and exclusionary conduct has directly and proximately caused injury to Mylan's business and property, as set forth above. Mylan's injury is the type the antitrust laws are intended to prohibit and thus constitutes antitrust injury.

324. Celgene's unlawful conduct continues and, unless restrained, will continue.

325. Unless the activities complained of are enjoined, Mylan will suffer immediate and irreparable injury for which Mylan is without an adequate remedy at law.

326. Mylan is entitled to a judgment that Celgene has violated Sections 56:9-3 and 56:9-4 of the New Jersey Antitrust Act; to the damages it suffered as a result of that violation, to be trebled in accordance with N.J. Stat. Ann. § 56:9-12, plus interest; to its costs and attorneys' fees; and to an injunction restraining Celgene's continued violations.

TENTH COUNT
The New Jersey Antitrust Act, Sections 56:9-3 and 56:9-4 - Thalomid and Revlimid

327. Mylan repeats and re-alleges the allegations of paragraphs 1-326 as if fully set forth herein.

328. This claim arises under the New Jersey Antitrust Act, N.J. Stat. Ann. § 56:9 et seq, and seeks a judgment that Celgene's conduct as alleged herein violates the New Jersey Antitrust Act, N.J. Stat. Ann. § 56:9-4 and § 56:9-3.

Section 56:9-4, Monopolization

329. Celgene's conduct as alleged herein constitutes monopolization, attempted monopolization, and conspiracy to monopolize, in violation of N.J. Stat. Ann. § 56:9-4.

330. Specifically, Celgene's agreements with wholesale distributors and pharmacies to restrict distribution of Thalomid and Revlimid, as well as its refusal to sell Thalomid and Revlimid samples to Mylan at their market price, are calculated to maintain monopoly power in the relevant markets, in violation of N.J. Stat. Ann. § 56:9-4.

Section 56:9-4, Monopolization by Denial of an Essential Facility

331. In addition, Celgene's conduct as alleged herein constitutes monopolization, attempted monopolization, and conspiracy to monopolize by denial of an essential facility or resource necessary to compete, in violation of N.J. Stat. Ann. § 56:9-4.

332. Specifically, Celgene's control over, and denial of access to competitors, of the essential, non-duplicable resource of Thalomid and Revlimid samples, when granting such access would be feasible, is calculated to maintain monopoly power in the relevant markets, in violation of N.J. Stat. Ann. § 56:9-4.

Section 56:9-3, Agreement in Restraint of Trade

333. Celgene's conduct as alleged herein constitutes a contract, combination, or conspiracy in restraint of trade or commerce, in violation of N.J. Stat. Ann. § 56:9-3.

334. Specifically, Celgene's agreements and contracts with wholesale distributors and "specially certified" pharmacies prohibiting sales of Thalomid and Revlimid to Celgene's competitors are contracts, combinations, and conspiracies in restraint of trade or commerce, in violation of N.J. Stat. Ann. § 56:9-3.

335. Similarly, Celgene's agreements and contracts with S.T.E.P.S- and RevAssist-certified distribution partners, limiting sales of Thalomid and Revlimid to entities approved by Celgene are contracts, combinations, and conspiracies in restraint of trade or commerce, in violation of N.J. Stat. Ann. § 56:9-3.

* * *

336. The foregoing acts and practices, and the continuing course of Celgene's anticompetitive conduct, have harmed consumers and competition.

337. Celgene's anticompetitive and exclusionary conduct has directly and proximately caused injury to Mylan's business and property, as set forth above. Mylan's injury is the type the antitrust laws are intended to prohibit and thus constitutes antitrust injury.

338. Celgene's unlawful conduct continues and, unless restrained, will continue.

339. Unless the activities complained of are enjoined, Mylan will suffer immediate and irreparable injury for which Mylan is without an adequate remedy at law.

340. Mylan is entitled to a judgment that Celgene has violated Sections 56:9-3 and 56:9-4 of the New Jersey Antitrust Act; to the damages it suffered as a result of that violation, to be trebled in accordance with N.J. Stat. Ann. § 56:9-12, plus interest; to its costs and attorneys' fees; and to an injunction restraining Celgene's continued violations.

ELEVENTH COUNT
Common Law of the State of New Jersey—Thalomid
Unfair Competition

341. Mylan repeats and re-alleges the allegations of paragraphs 1-340 as if fully set forth herein.

342. By reason of the foregoing unlawful, predatory and anticompetitive acts as alleged herein, Celgene has engaged in unfair competition and/or unfair trade practices in violation of the common law of the State of New Jersey.

343. As a result of the foregoing, Mylan has been injured in its business and/or property and is entitled to damages, attorneys' fees, costs of suit and other appropriate relief.

TWELFTH COUNT
Common Law of the State of New Jersey—Revlimid
Unfair Competition

344. Mylan repeats and re-alleges the allegations of paragraphs 1-343 as if fully set forth herein.

345. By reason of the foregoing unlawful, predatory and anticompetitive acts as alleged herein, Celgene has engaged in unfair competition and/or unfair trade practices in violation of the common law of the State of New Jersey.

346. As a result of the foregoing, Mylan has been injured in its business and/or property and is entitled to damages, attorneys' fees, costs of suit and other appropriate relief.

THIRTEENTH COUNT
Common Law of the State of New Jersey—Thalomid and Revlimid
Unfair Competition

347. Mylan repeats and re-alleges the allegations of paragraphs 1-346 as if fully set forth herein.

348. By reason of the foregoing unlawful, predatory and anticompetitive acts as alleged herein, Celgene has engaged in unfair competition and/or unfair trade practices in violation of the common law of the State of New Jersey.

349. As a result of the foregoing, Mylan has been injured in its business and/or property and is entitled to damages, attorneys' fees, costs of suit and other appropriate relief.

FOURTEENTH COUNT
Common Law of the State of New Jersey—Thalomid
Tortious Interference with an Economic Advantage

350. Mylan repeats and re-alleges the allegations of paragraphs 1-349 as if fully set forth herein.

351. Celgene develops and sells pharmaceutical products in the commerce of the State of New Jersey.

352. Celgene's conduct gives rise to common law liability for tortious interference with prospective business relations and economic advantage.

353. Mylan has a reasonable expectation of economic advantage from a prospective economic relationship with third parties, including distributors, pharmacies and individuals suffering from multiple myeloma and ENL, all of which would purchase generic thalidomide drug products.

354. Celgene has been aware of Mylan's intention to submit an ANDA for a generic thalidomide drug product since at least October 2004. Accordingly, Celgene is aware of Mylan's reasonable expectation of economic advantage from sales of generic thalidomide.

355. Celgene has intentionally and maliciously interfered with Mylan's reasonable expectation of economic advantage from sales of a generic thalidomide drug product by refusing to sell Mylan samples of Thalomid for bioequivalence testing required to obtain FDA approval of a generic thalidomide drug product. Celgene does not have a legitimate, pro-competitive business purpose for refusing to sell Mylan samples of Thalomid.

356. If Celgene had not interfered, Mylan would not be delayed in entering the relevant market and would receive the anticipated benefit of sales and profits from generic entry.

357. Celgene's tortious interference has directly and proximately caused injury to Mylan' business and property, including but not limited to lost profits and lost business opportunities.

FIFTEENTH COUNT
Common Law of the State of New Jersey—Revlimid
Tortious Interference with an Economic Advantage

358. Mylan repeats and re-alleges the allegations of paragraphs 1-357 as if fully set forth herein.

359. Celgene develops and sells pharmaceutical products in the commerce of the State of New Jersey.

360. Celgene's conduct gives rise to common law liability for tortious interference with prospective business relations and economic advantage.

361. Mylan has a reasonable expectation of economic advantage from a prospective economic relationship with third parties, including distributors, pharmacies and individuals suffering multiple myeloma whose disease has been treated at least once in the past and patients with transfusion-dependent due to MDS, all of which would purchase generic lenalidomide drug products.

362. Celgene has been aware of Mylan' intention to submit an ANDA for a generic lenalidomide drug product since at least May 2013. Accordingly, Celgene is aware of Mylan's reasonable expectation of economic advantage from sales of generic lenalidomide.

363. Celgene has intentionally and maliciously interfered with Mylan's reasonable expectation of economic advantage from sales of a generic lenalidomide drug product by refusing to sell Mylan samples of Revlimid for bioequivalence testing required to obtain FDA approval of a generic lenalidomide drug product. Celgene does not have a legitimate, pro-competitive business purpose for refusing to sell Mylan samples of Revlimid.

364. If Celgene had not interfered, Mylan would not be delayed in entering the relevant market and would receive the anticipated benefit of sales and profits from generic entry.

365. Celgene's tortious interference has directly and proximately caused injury to Mylan' business and property, including but not limited to lost profits and lost business opportunities.

SIXTEENTH COUNT
Common Law of the State of New Jersey— Thalomid and Revlimid
Tortious Interference with an Economic Advantage

366. Mylan repeats and re-alleges the allegations of paragraphs 1-365 as if fully set forth herein.

367. Celgene develops and sells pharmaceutical products in the commerce of the State of New Jersey.

368. Celgene's conduct gives rise to common law liability for tortious interference with prospective business relations and economic advantage.

369. Mylan has a reasonable expectation of economic advantage from a prospective economic relationship with third parties, including distributors, pharmacies and individuals suffering from multiple myeloma and ENL, all of which would purchase generic thalidomide drug products.

370. Mylan has a reasonable expectation of economic advantage from a prospective economic relationship with third parties, including distributors, pharmacies and individuals suffering multiple myeloma whose disease has been treated at least once in the past and patients with transfusion-dependent due to MDS, all of which would purchase generic lenalidomide drug products.

371. Celgene has been aware of Mylan' intention to submit an ANDA for a generic lenalidomide drug product since at least May 2013. Accordingly, Celgene is aware of Mylan's reasonable expectation of economic advantage from sales of generic lenalidomide.

372. Celgene has been aware of Mylan' intention to submit an ANDA for a generic thalidomide drug product since at least October 2004. Accordingly, Celgene is aware of Mylan's reasonable expectation of economic advantage from sales of generic thalidomide.

373. Celgene has intentionally and maliciously interfered with Mylan's reasonable expectation of economic advantage from sales of generic thalidomide and lenalidomide drug products by refusing to sell Mylan samples of Thalomid or Revlimid for bioequivalence testing required to obtain FDA approval of generic thalidomide or lenalidomide drug product. Celgene does not have a legitimate, pro-competitive business purpose for refusing to sell Mylan samples of Thalomid or Revlimid.

374. If Celgene had not interfered, Mylan would not be delayed in entering the relevant market and would receive the anticipated benefit of sales and profits from generic entry.

375. Celgene's tortious interference has directly and proximately caused injury to Mylan' business and property, including but not limited to lost profits and lost business opportunities.

SEVENTEENTH COUNT
Declaratory Judgment Pursuant to 28 U.S.C. §§ 2201-2202

376. Mylan repeats and re-alleges the allegations of paragraphs 1-375 as if fully set forth herein.

377. This cause of action arises under 28 U.S.C. §§ 2201-2202.

378. Mylan has made every good faith effort to obtain the subject samples only to be stonewalled by Celgene in refusing to provide same as part of its overall anticompetitive scheme as alleged herein. Based on the foregoing facts, and as a result of the unwillingness and refusal of Celgene to supply the subject samples that are essential to Mylan's ability to compete in the relevant markets, there is at this time an actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment that exists between Mylan and Celgene, regarding, inter alia, the

requirements of Celgene to provide Mylan sufficient samples of Thalomid and Revlimid so that Mylan can perform bioequivalence testing.

379. Under the totality of circumstances alleged herein, and because there is a strong public interest in resolving the issues herein, there is a case and controversy between the parties having adverse legal interests that warrants the immediate issuance of a declaratory judgment.

380. Therefore, Mylan seeks an immediate declaratory judgment pursuant to 28 U.S.C. § 2201 in its favor and against Celgene under each of the applicable causes of action alleged herein, declaring that Celgene is required to sell Mylan sufficient samples of Thalomid and Revlimid so that Mylan can perform bioequivalence testing.

Prayer for Relief

WHEREFORE, Mylan respectfully requests judgment in its favor and against Celgene as follows:

a. Preliminary and permanent mandatory injunctive relief pursuant to 15 U.S.C. § 26, Fed. R. Civ. P. 65, and N.J. Stat. Ann. § 56:9-10 compelling Celgene to sell Mylan sufficient quantities of Thalomid and Revlimid at market prices so that Mylan can perform bioequivalence testing;

b. Compensatory damages for Mylan's lost sales of generic thalidomide and lenalidomide, and profits on those sales, that are caused by Mylan's delay in submitting an ANDA;

c. Treble damages pursuant to 15 U.S.C. § 15 and N.J. Stat. Ann § 56:9-12;

d. An award of attorney's fee and costs pursuant to 28 U.S.C. § 15 and N.J. Stat. Ann. § 56:9-12;

e. An immediate declaratory judgment pursuant to 28 U.S.C. § 2201;

f. A declaration that Celgene is required to sell Mylan sufficient samples of Thalomid and Revlimid so that Mylan can perform bioequivalence testing; and

g. Such other and further relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Mylan Pharmaceuticals Inc. demands a trial by jury as to all issues of right to a jury.

Dated: April 3, 2014

Respectfully submitted,

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LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, the undersigned counsel for Plaintiff hereby states that the matter in controversy is not the subject of any other pending actions, arbitrations and/or administrative proceedings.

Dated: April 3, 2014

Respectfully submitted,

SAIBER LLC
Attorneys for Plaintiff
Mylan Pharmaceuticals Inc.

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LOCAL CIVIL RULE 201.1 CERTIFICATION

Pursuant to Local Civil Rule 201.1, the undersigned counsel for Plaintiff hereby states that it seeks injunctive and declaratory relief as well as monetary damages greater than $150,000, and therefore this action is not appropriate for compulsory arbitration.

Dated: April 3, 2014

SAIBER LLC
Attorneys for Plaintiff
Mylan Pharmaceuticals Inc.

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