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

)	
MSP RECOVERY CLAIMS, SERIES LLC.;	Civil Action No. :21-cv-
MSPA CLAIMS 1, LLC; MAO-MSO	
RECOVERY II, LLC, SERIES PMPI, a	
segregated series of MAO-MSO RECOVERY	
II, LLC; MSP RECOVERY CLAIMS SERIES)	
44, LLC, MSP RECOVERY CLAIMS PROV,)	
SERIES LLC, and MSP RECOVERY)	<u>COMPLAINT</u>
CLAIMS CAID, SERIES LLC,	
)	JURY TRIAL DEMANDED
PLAINTIFFS,	
)	
VS.	
)	
CELGENE CORPORATION AND BRISTOL-)	
MYERS SQUIBB COMPANY,	
MILERO SQUIDD COMITAIVI,	
DEPEND ANTE	
DEFENDANTS.)	

Plaintiffs MSP Recovery Claims, Series LLC, MSPA Claims 1, LLC and MAO-MSO Recovery II, LLC, Series PMPI, a segregated series of MAO-MSO Recovery II, LLC, MSP Recovery Series 44, LLC, MSP Recovery Claims PROV, Series LLC, and MSP Recovery Claims CAID, Series LLC (collectively referred to as "Plaintiffs" or "MSP" unless otherwise specifically identified hereby), through its attorneys, Santomassimo Davis LLP, by way of Complaint against Defendant Celgene Corporation ("Celgene") and Defendant Bristol-Myers Squibb Company ("Bristol-Myers Squibb") (collectively referred to as "Defendants") state as follows:



I. NATURE OF THE CASE

- 1. Plaintiffs bring this action against Celgene and its parent Bristol-Myers Squibb for violations of consumer protection and common law claims, arising out of Celgene's anticompetitive scheme that has prevented generic brands from entering the market to compete with Celgene's high-priced drugs Thalomid and Revlimid. The improper actions described below have allowed Celgene to maintain supracompetitive prices that thwart legitimate competition that would have benefited consumers and the public at large by drastically lowering the price of these medically necessary drugs. Celgene's misconduct is a textbook example of the type that is proscribed by both federal and state law and is emblematic of the historic and unprecedented increase in pharmaceutical drug costs. Plaintiffs' allegations are made on personal knowledge as to Plaintiffs, publicly available information and upon information and belief as to all other matters.
- 2. The subject drug Thalomid was originally developed, marketed, and sold under the brand name Thalidomide in the late 1950s and early 1960s as a sedative and anti-nausea medication. Thalidomide had catastrophic results "[w]hen taken by pregnant women for morning sickness, it caused missing limb parts in the fetus . . . as well as organ damage and death. Fifty years after the drug's heyday, the fear it inspired haunts arguments about the safety and regulation of medications . . . That tragedy is a major reason the Food and Drug Administration has as much authority over new drugs as it does today."
- 3. In 1998, Celgene obtained U.S. Food and Drug Administration ("FDA") approval to market Thalomid® (thalidomide) for a leprosy complication known as erythema nodosum leprosum ("ENL").
- 4. In 2005, Celgene successfully developed a thalidomide analog, Revlimid® (lenalidomide), and obtained FDA approval to market it for a specific chromosomal variant of

¹ Amanda Schaffer, *Thalidomide's Comeback*, Slate, Jan. 10, 2011, http://www.slate.com/articles/double_x/doublex/2011/01/thalidomides_comeback.html.



myelodysplastic syndromes ("MDS"). Celgene would go on to obtain FDA approvals for additional Revlimid indications, including for a subset of multiple myeloma ("MM") patients in 2006,² and later for a subset of mantle cell lymphoma ("MCL") patients in 2013.

- 5. However, unsatisfied with profits earned within the pharmaceutical legal and regulatory framework, Celgene commenced an anticompetitive scheme to illegally monopolize the market for Thalomid an Revlimid. Celgene constructed an impenetrable monopolistic fortress and engaged in a multi-prong scheme to unlawfully maintain an 100% share of the market for these two drugs by successfully interfering with competitors' efforts to develop and/or obtain FDA approval for generic versions of Thalomid and/or Revlimid at each progressive step of development.
- 6. As part of this anticompetitive scheme, plaintiffs allege that Celgene is: (1) manipulated the safety program designed to protect patients from thalidomide's and lenalidomide's teratogenic properties; (2) prevented pharmacies and ingredient suppliers from acting as alternative sources of samples for such would-be generic competitors; (3) fraudulently obtained various patents from the U.S. Patent and Trademark Office ("USPTO") for Thalomid and Revlimid and their associated safety distribution protocols; (4) serially commencing "sham" patent infringement lawsuits; and (5) filed baseless citizen petitions with the FDA to stymic generic approvals.
- 7. In the rare instances where Celgene's efforts failed to prevent a would-be competitor from prosecuting an Abbreviated New Drug Application ("ANDA"), and FDA approval of an ANDA for a generic version of Revlimid or Thalomid became possible, Celgene entered into confidential

² Under the FDA's orphan drug exclusivity program, 21 U.S.C. §§ 360aa-cc, the FDA may not approve a generic equivalent for a specific indication or "rare disease" that a brand drug is FDA-approved to treat for a period of seven (7) years. MM is such a "rare disease." Therefore, until May 25, 2013, the FDA could not approve a generic thalidomide for the treatment of MM. It could, nevertheless, approve generic thalidomide for the treatment of other indications. This is known as a "skinny label."



settlements with its competitors that, upon information and belief, included anti-competitive "pay-for-delay" reverse payments. The federal government has routinely criticized – and challenged in court – the same sort of anticompetitive practices in which Celgene engages.³

- 8. In 2006, a month's supply of Revlimid cost \$6,195.⁴ In 2010, the price was about \$8,000 for a one-month supply. Now, a twenty-eight (28) day supply of Revlimid costs patients and their health insurers as much as \$20,000, and a twenty-eight (28) day supply of Thalomid costs them as much as \$10,000. In 2016, Celgene's total revenue was \$11.23 billion, of which \$6.97 billion was from Revlimid and \$152.10 million was from Thalomid. When Thalomid first entered the market, it cost approximately \$6 per capsule. In 2014, its price soared to as much as \$357 per capsule.
- 9. In the last ten (10) years, as a result of Celgene's anticompetitive conduct to eliminate/limit generic alternatives from the market, Celgene has been able to routinely increase its prices either once or twice per year.
- 10. Celgene's illicit and monopolistic efforts with respect to Thalomid and Revlimid have been enormously profitable. Between 2006 and 2016, Celgene recorded \$35.60 billion of Revlimid sales and \$3.65 billion of Thalomid sales, yielding the following respective annual sales:⁵

2016 2015 2014 2013 2012 2011 2010 2009 2008 2007

Revlimid 6974M 5800M 4980M 4280M 3770M 3210M 2470M 1706M 1325M 774M 321M

⁵ Net product sales figures drawn from Celgene's Annual Reports/Form 10-K filings for fiscal years ending 2007-2016.



³ See, e.g., Federal Trade Commission, Pay for Delay: How Drug Company Pay-Offs Cost Consumers Billions (Jan. 2010), https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf.

⁴ Alison Kodjak, *How A Drugmaker Gamed The System to Keep Generic Competition Away* (May 17, 2018), https://www.npr.org/sections/health-shots/2018/05/17/571986468/how-a-drugmaker-gamed-the-system-to-keep-generic-competition-away.

Thalomid 152M 185M 221M 245M 302M 339M 387M 437M 505M 447M

- 11. In December 2016, Revlimid was the second-highest grossing drug worldwide.⁶ For the year ended December 31, 2020, Bristol-Myers Squibb reported that Revlimid revenue had grown to more than \$12.1 billion worldwide, including more than \$8.29 billion in the United States.⁷
- 12. There has never been a generic substitute for Revlimid or Thalomid available in the U.S., enabling Celgene to price the drugs at levels unrestrained by generic competition.
- 13. Celgene's anticompetitive tactics to block generic entry have caused Plaintiffs to pay supracompetitive prices for these drugs in violation of various federal antitrust laws, states' antitrust, consumer protection, trade practices, and insurance fraud laws.
- 14. Plaintiffs seek to recover incurred civil damages and over payments made on behalf of their Assignors who purchased or otherwise provided reimbursement for Thalomid and/or Revlimid, which was prescribed and dispensed to Plaintiffs' Assignors' Enrollees as well as injunctive relief.

II. JURISDICTION AND VENUE

15. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1337 as well as 15 U.S.C. §§ 15 and 26. Plaintiffs assert federal claims for treble damages, injunctive relief and costs of suit, including reasonable attorneys' fees, against Defendants under Section 2 of the Sherman Act, 15 U.S.C. § 2, and Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15 and 26.

 $^{^{7}\}$ https://news.bms.com/news/details/2021/Bristol-Myers-Squibb-Reports-Fourth-Quarter-and-Full-Year-Financial-Results-for-2020/default.aspx.



⁶ Amy Brown, *EP Vantage 2017 Preview* (Dec. 2016), http://info.evaluategroup.com/rs/607-YGS-364/images/EPV2017Prev.pdf.

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