Frank R. Schirripa (<u>fschirripa@hrsclaw.com</u>) David R. Cheverie (<u>dcheverie@hrsclaw.com</u>) John A. Blyth (<u>jblyth@hrsclaw.com</u>) HACH ROSE SCHIRRIPA & CHEVERIE LLP 185 Madison Avenue, 14th Floor New York, NY 10016 Tel.: 212.213.8311 Fax: 212.779.0028

Brent W. Landau (<u>blandau@hausfeld.com</u>) HAUSFELD LLP 325 Chestnut Street, Suite 900 Philadelphia, PA 19106 Tel.: 215.985.3270 Fax: 215.985.3271

Counsel for Plaintiff and Proposed Class (Additional Counsel on Signature page)

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

International Union of Bricklayers and Allied Craft Workers Local 1 Health Fund, individually and on behalf of all others similarly situated,

Plaintiff,

v.

Celgene Corporation,

Defendant.

Civil Action No.

Class Action Complaint



Find authenticated court documents without watermarks at <u>docketalarm.com</u>.

TABLE OF CONTENTS

I.	NATU	RE OF THE ACTION1		
II.	JURIS	DICTION AND VENUE		
III.	THE I	ARTIES		
IV.	INDU	STRY BACKGROUND4		
	A.	Characteristics of the Pharmaceutical Marketplace4		
	B.	The Regulatory Structure for Approval of Generic Drugs, Listing Patent Information in the Orange Book, and the Substitution of Generic Drugs for Brand Name Drugs		
		1. The Hatch-Waxman Amendments		
		2. Requirements for Listing Patents in the Orange Book		
		3. Paragraph IV Certifications		
	C.	The Availability of Citizen Petitions to Delay The FDA Approval of Generic Drugs		
	D.	The Benefits of Generic Drugs		
	E.	The Impact of Authorized Generics		
V.	DEFENDANT'S ANTICOMPETITIVE CONDUCT			
	A.	Celgene's Monopolization through Anticompetitive Interference by Refusing to Sell to Generic Manufacturers		
		1. Celgene Prevents Barr from Obtaining Samples from Seratec by Entering into an Exclusive Supply Contract with Seratec		
		2. Celgene Refuses to Sell Samples to Lannett Despite FDA Approval to Do So		
		3. Celgene Refuses to Sell Samples to Mylan, Despite FDA Approval to Do So		
		4. Celgene Refuses to Sell Samples to Dr. Reddy's Laboratories, Despite FDA Approval to Do So		
	B.	Celgene Fraudulently Obtained Patents on Thalidomide and Lenalidomide to Obstruct Generic Competition and Maintain its Monopoly on Thalomid and Revlimid		

DOCKET

	C.	Celgene Files Litigation against Barr, Natco, Arrow, and Watson to Prevent or Delay Them from Marketing their Proposed ANDA Product in Competition with Celgene
		1. Celgene's Sham Litigation and Citizen Petition Against Barr490
		2. Celgene's Sham Litigation against Natco, Arrow, and Watson
	D.	Celgene's Settlements with Barr and Lannett Had Anticompetitive Effects55
	E.	Celgene's Scheme Was Intended To, And Did, Harm Competition and Delay Generic Entry
VI.	CLAS	S ACTION ALLEGATIONS
VII.	OTHE	ER FACTUAL ALLEGATIONS
	A.	Effects on Competition and Damages to Plaintiff and the Class
	B.	Effect on Interstate and Intrastate Commerce
	C.	Monopoly Power
VIII.	CLAI	MS FOR RELIEF634
IX.	DEM	AND FOR JUDGMENT74
X.	JURY	DEMAND

Plaintiff International Union of Bricklayers and Allied Craft Workers Local 1 Health Fund ("Plaintiff") brings this class action on behalf of itself and all other similarly situated end-payors against Celgene Corporation ("Celgene"). Based on personal knowledge as to facts pertaining to them, and upon information and belief as to all other matters, Plaintiff alleges as follows:

I. NATURE OF THE ACTION

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

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

3. Since 2006, Celgene has recorded \$20.9 billion from the sale of Thalomid and Revlimid combined, comprising between 71 and 93 percent of its annual revenues. A twenty-eight day supply of Thalomid can cost from between \$8,000 to \$10,000, and the same supply of Revlimid costs approximately \$15,000 to \$20,000. Celgene's revenues in 2013 from Revlimid were \$4,280,030,000, and \$244,500,000 from Thalomid. And Celgene has taken advantage of its market monopoly: when Thalomid first gained approval to enter the marketplace, it cost approximately \$6 per capsule; now, it costs between \$212 and \$357 per capsule. Celgene charges approximately \$500 per capsule of Revlimid.

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

- Using FDA safety requirements that were designed to ensure safe access to these dangerous drugs as a pretext to delay and indefinitely postpone the availability of cost-saving generic alternatives to these drugs;
- Fraudulently obtaining patents on the procedures to ensure safe use of Thalomid and Revlimid in order to block generic entrants from coming to market; and
- c. Engaging in sham litigation against any competitor who managed to obtain samples of Thalomid or Revlimid to do its generic bioequivalence testing.

5. Although existing federal law already forbids the use of safety regulations to deny generic drugmakers access to drugs, members of the United States House of Representatives have taken note of Celgene's anticompetitive actions, and introduced H.R. 5657, known as the Fair Access for Safe and Timely Generics Act, or FAST. FAST would require that brand-name manufacturers, as a condition of product approval, agree not to "adopt, impose or enforce any condition relating to the sale, resale or distribution" of REMS-restricted drugs that would prevent generics makers from obtaining needed samples. FAST purports to increase the penalties for conduct like Celgene's with Thalomid and Revlimid.

6. Celgene's anticompetitive tactics to block generic entry have caused Plaintiff and the class of end-payors it seeks to represent (as defined below) to pay higher prices to treat the dangerous conditions (leprosy and multiple myeloma) that Thalomid and Revlimid address.

7. Plaintiff brings this action as a class action on behalf of all consumers and third party payors (collectively, "End-Payors") in certain states, the District of Columbia, and Puerto Rico who indirectly purchased, paid and/or provided reimbursement for Thalomid and/or Revlimid, other than for re-sale since November 7, 2010 (see Class Definition below).

DOCKET A L A R M



Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.