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Attorneys for Plaintiffs Centene Corporation, WellCare Health Plans, Inc., New York Quality Healthcare Corporation dba Fidelis Care, and Health Net, LLC

UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

CENTENE CORPORATION; WELLCARE HEALTH PLANS, INC.; NEW YORK QUALITY HEALTHCARE CORPORATION dba FIDELIS CARE; and HEALTH NET, LLC,

Plaintiffs,

v.

MERCK & COMPANY, INC.; MERCK SHARP & DOHME CORPORATION; SCHERING-PLOUGH CORPORATION; SCHERING CORPORATION; and GLENMARK PHARMACEUTICALS LTD.,

Defendants.

Civil Action No.

COMPLAINT

JURY TRIAL DEMANDED



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Plaintiffs Centene Corporation ("Centene"), WellCare Health Plans, Inc. ("WellCare"), New York Quality Healthcare Corporation dba Fidelis Care ("Fidelis"), and Health Net, LLC ("Health Net") (collectively, "Plaintiffs" or the "Centene Companies") bring this antitrust action against Merck & Company, Inc., Merck Sharp & Dohme Corporation, Schering-Plough Corporation, and Schering Corporation (collectively, "Merck"); and Glenmark Pharmaceuticals Ltd. ("Glenmark", with Merck, "Defendants"), seeking damages resulting from Defendants' anticompetitive conduct. Based on the investigation of counsel, and upon information and belief as to all other matters, the Centene Companies allege as follows:

NATURE OF THE CASE

- 1. Heart disease is the leading cause of death in the United States, accounting for 1 out of every 4 deaths. One of the major risk factors for heart disease is high cholesterol. In the United States, more than 93 million adults have cholesterol levels higher than 200 mg/dL and nearly 29 million have cholesterol levels exceeding 240 mg/dL. Pharmaceutical companies have developed a litany of statins and other lipid-regulating drugs to treat this condition. And these companies have reaped enormous profits from their efforts. In 2011 alone, sales of cholesterol regulating drugs exceeded \$39.1 billion per year.
- 2. Merck has developed and marketed several blockbuster cholesterol-reducing drugs. Indeed, two of its drugs Zetia, the first drug in a new class of lipid-lowering medications, and Vytorin, a fixed-dosed combination pill comprised of Zetia and simvastatin (generic Zocor) have been among the best-selling cholesterol treatment drugs over the past fifteen years, each consistently generating more than \$1 billion in sales per year (and more than

² See Centers for Disease Control and Prevention, *High Cholesterol Facts* (Sept. 8, 2020), available at https://www.cdc.gov/cholesterol/facts.htm.



¹ See Centers for Disease Control and Prevention, *Heart Disease* (Oct. 22, 2020), available at https://www.cdc.gov/heartdisease/index.htm.

\$2 billion in some years). As a result, when the new chemical exclusivity period on Zetia was nearing its end, and generic manufacturers were poised to enter with competing drugs, Merck took aggressive measures to protect its profits.

- 3. Seeing an opportunity to capitalize on Zetia's loss of exclusivity, Glenmark, a manufacturer of generic drugs, was the first company to file an Abbreviated New Drug Application ("ANDA") seeking to launch a generic to compete with Zetia. Shortly after the ANDA was filed, Merck sued Glenmark, alleging that Glenmark's generic would infringe one of Merck's patents covering Zetia. Merck later admitted its lawsuit had no merit because it had failed to disclose prior art to the United States Patent and Trademark Office ("USPTO") that would have resulted in the denial of patent protection for Zetia. But simply by initiating the litigation, Merck triggered a 30-month stay, which precluded the Food & Drug Administration ("FDA") from granting final approval of Glenmark's ANDA.
- 4. Glenmark responded to Merck's lawsuit by asserting several meritorious affirmative defenses and counterclaims. Despite being put on notice of the various defects in its patent infringement claim, Merck did not dismiss its meritless litigation; rather, it continued to prosecute its action to blockade Glenmark's competition. During the course of the litigation, Merck and Glenmark discussed potential settlement. When they were unable to reach an agreement, Glenmark asked the court to rule on its pending motions for partial summary judgment. After the court granted in part and denied in part Glenmark's motions, Glenmark entered into a Marketing and Distribution Agreement (the "Distribution Agreement") with Par Pharmaceutical, Inc. ("Par"). Under the terms of the Distribution Agreement, Par would be the exclusive distributor for Glenmark's generic Zetia, and it would share in all potential Zetia settlement proceeds and profits on sales of Glenmark's generic Zetia in the United States.



- 5. Approximately seven days after Glenmark executed the Distribution Agreement with Par, Glenmark and Merck settled their action. This settlement, along with Merck's pursuit of litigation to enforce a patent it knew was invalid, was at the heart of Merck's and now Glenmark's anticompetitive scheme to deprive the market of generic competition. Pursuant to their settlement agreement, Glenmark agreed to drop its meritorious claims and defenses against Merck and delay its launch of generic Zetia for nearly five years. In exchange, Merck agreed to refrain from competing with Glenmark by not introducing its own authorized generic ("AG") version of Zetia during Glenmark's 180-day period of first-filer exclusivity. Par played an integral role in negotiating these terms.
- 6. As a result of Merck's monopolistic scheme and its anticompetitive agreement with Glenmark, Merck reaped billions of dollars in additional sales of Zetia and Vytorin.

 Glenmark also reaped millions of dollars in additional profits once its product finally reached the market. Meanwhile, health plans, like the Centene Companies, were forced to significantly overpay for Zetia and Vytorin because there were no generic equivalents of Zetia. By the time Glenmark finally entered the market with its generic on December 12, 2016, the Centene Companies had overpaid by hundreds of millions of dollars for their members' Zetia and Vytorin prescriptions. And the Centene Companies continued to overpay, due to the delay-inflated drug prices and the lack of competition associated with Merck's agreement not to launch an AG.
- 7. If Merck had not failed to disclose prior art to the USPTO and not brought or maintained its frivolous patent litigation blocking generic competition, or Merck, Glenmark, and Par had not conspired to allocate the market for Zetia via their anticompetitive settlement agreement, both Merck and Glenmark would have launched generic versions of Zetia at least as early as December 2011. And, six months later, additional generics would have entered the



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