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UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

MOLINA HEALTHCARE INC., Plaintiff, vs. JAZZ PHARMACEUTICALS, INC.; JAZZ PHARMACEUTICALS IRELAND LIMITED; JAZZ PHARMACEUTICALS PUBLIC LIMITED COMPANY; HIKMA PHARMACEUTICALS PLC; HIKMA PHARMACEUTICALS USA INC.; HIKMA LABS, INC.; EUROHEALTH (USA), INC.; AMNEAL PHARMACEUTICALS LLC; PAR PHARMACEUTICAL, INC.; LUPIN LTD.; LUPIN PHARMACEUTICALS INC.; LUPIN INC., Defendants.	Case No. COMPLAINT JURY TRIAL DEMANDED

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1. Plaintiff Molina Healthcare Inc. ("Molina" or "Plaintiff") brings this action against Defendants Jazz Pharmaceuticals, Inc., Jazz Pharmaceuticals Ireland Limited, Jazz Pharmaceuticals Public Limited Company, Hikma Pharmaceuticals plc, Hikma Pharmaceuticals USA Inc., Hikma Labs, Inc., Eurohealth (USA), Inc., Amneal Pharmaceuticals LLC, Par Pharmaceutical, Inc., Lupin Ltd., Lupin Pharmaceuticals Inc., and Lupin Inc., (collectively, "Defendants") for violations of antitrust, consumer protection, and common laws. Plaintiff's claims concern Defendants' scheme to restrain competition for branded Xyrem and its AB rated generic bioequivalents in the United States. Defendants, the brand manufacturer of Xyrem and several competitors, abused the patent laws for profit by allocating the market for a drug that was invented nearly 150 years ago. Sodium oxybate, sold under the brand name Xyrem (also known as γ-hydroxybutyric acid (GHB)) is a naturally occurring substance found in the central nervous system. Xyrem is manufactured by Jazz Pharmaceuticals, Inc and its affiliates ("Jazz"). Xyrem has historically been Jazz's main source of revenue, making up 70% or more of its revenues since 2007. Jazz's growth and profits have been entirely linked to its ability to increase prices on Xyrem and keep the market to itself. To prevent generic competition and unlawfully maintain this monopoly, Jazz first manipulated an FDA safety program meant to mitigate safety risks of certain drugs ("REMS"); engaged in sham patent litigation; abused the REMS process to further frustrate generic competitors; and finally agreed with other Defendants to delay generic entry in exchange for allocating the generic market for AB-rated generic Xyrem. All the while, Jazz imposed a series of grotesque price hikes that would have been impossible had generic entry been successful. This scheme caused Plaintiff to pay inflated prices for Xyrem from July 17, 2017 through the present, until the anticompetitive effects of the Defendants' unlawful conduct cease.

I. INTRODUCTION

2. This litigation challenges a comprehensive anticompetitive scheme to suppress generic competition for Xyrem, a leading treatment of narcolepsy. Defendants abused an FDA drug safety program called "Risk Evaluation and Mitigation Strategy," engaged in sham patent litigation, and entered into reverse payments to generic manufacturers to preserve their monopoly in Xyrem. Through this

scheme Defendants suppressed generic competition and raised the price of Xyrem 841% between 2007 and 2014. Third-party payors such as Plaintiff footed the bill for this manipulation.

3. Sodium oxybate, the active ingredient in Xyrem, is a central nervous system depressant that has been widely available in the United States since the 1960s. Sodium oxybate is the chemically derived version of γ-Hydroxybutyric acid (GHB), which occurs naturally in human bodies' central nervous systems, as well as wine, beef, small citrus fruits, and almost all animals.[1]

4. Narcolepsy is a disorder characterized by excessive daytime sleepiness ("EDS") and intermittent manifestations of REM sleep during wakefulness. In 1994, the Food and Drug Administration's ("FDA") Orphan Products Development Division and a non-profit advocacy organization approached a small Minnesota-based drug company, Orphan Medical, to suggest the development of sodium oxybate for treatment of cataplexy, which is a common symptom of narcolepsy manifested by sudden episodes of bilateral skeletal muscle weakness induced by an emotional trigger such as laughter, anger, embarrassment, or surprise.

5. Orphan Medical began development of what would become Xyrem and, in 2002, obtained FDA approval to market sodium oxybate for the treatment of cataplexy associated with narcolepsy in adults. Orphan branded its product Xyrem. In 2005, Orphan Medical obtained FDA approval to market Xyrem for EDS associated with narcolepsy in adults. Until 2021, Xyrem was the only drug approved by the FDA to treat both EDS and cataplexy associated with narcolepsy. In 2020, the FDA also approved Jazz's follow-on sodium oxybate product, Xywav, for the treatment of those conditions.

6. In 2005, Jazz Pharmaceuticals, Inc. acquired Orphan Medical. "The acquisition was unprofitable at first …. By 2009, Jazz was on the verge of bankruptcy. … Jazz responded by replacing its management team."[2] Jazz then began a series of epic price hikes. In May of 2014, Bloomberg published a ranking of drug price increases from 2007 to 2014. Xyrem ranked first with an overall

[1] "Gamma-hydroxybutyric acid (GHB), Critical Review Report," World Health Organization Expert Committee on Drug Dependence (2012); https://www.who.int/medicines/areas/quality_safety/4.1GHBcritical_review.pdf

[2] *In re Xyrem Antitrust Litig.*, Case No. 5:20-md-02966-LHK, ECF No. 138, at 2 (N.D. Cal. Aug. 13, 2021).

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