UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

In re

GLUMETZA ANTITRUST LITIGATION.

No. C 19-05822 WHA
No. C 19-06138 WHA
No. C 19-06839 WHA
No. C 19-07843 WHA
No. C 19-08155 WHA
No. C 20-01198 WHA
No. C 20-05251 WHA

(Consolidated)

This Document Relates to:

ALL ACTIONS.

ORDER RE SUMMARY JUDGMENT

INTRODUCTION

In a secret pharmaceutical-patent infringement settlement agreement, concealed from the district judge, brand and generic manufacturers of the type 2 diabetes drug Glumetza allegedly pledged not to compete with each other by agreeing to not introduce a generic version of the drug for several years. So, while generic competition should have driven drug prices *down*, the brand manufacturer instead hiked prices *up*. The generic manufacturer belatedly entered the market at premium pricing, and, as a result, the conspiring manufacturers allegedly extracted huge sums of money from consumers. In this resulting antitrust action, a certified class of direct purchasers move for partial summary judgment that our defendant brand and generic manufacturers wielded market power. For their part, defendants move for summary judgment,

STATEMENT

An estimated thirty million Americans suffer from type 2 diabetes. The condition, "caused by the combination of insulin resistance . . . and deficient insulin secretion," causes an alarming array of complications. Those with diabetes face nearly twice the average risk of stroke and heart disease. They may suffer foot ulcers that take months or years to heal, or may require amputation. Around forty percent suffer some degree of kidney disease, with one percent suffering kidney failure. In fact, "[p]ersons with diabetes make up the fastest growing group of kidney dialysis and transplant recipients in the United States." "Diabetes is the leading cause of new cases of blindness among adults aged 18–64 years." And, in 2017, diabetes was estimated to be the seventh leading cause of death in the United States. CTRS. DISEASE CTRL. & PREV., NAT'L DIABETES STATS. RPT. 12 (2020), https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf; NAT'L INST. OF DIABETES & DIGESTIVE & KIDNEY DISEASES, DIABETES IN AMERICA, ch. 1, pp. 2–3, ch. 22, p. 1, fact sheet (3d ed. 2018), https://www.niddk.nih.gov/about-niddk/strategic-plans-reports/diabetes-in-america-3rd-edition.

Fortunately, modern medicine offers a battery of remedial medications. One such drug, metformin hydrochloride, helps control blood-sugar levels. Following approval by the Food and Drug Administration in June 2005, defendant Depomed, Inc. launched a new extended-release version of metformin in late 2006. Glumetza, introduced first in 500 mg and later in 1000 mg tablets, extended the release of metformin over a prolonged period by disbursing the active drug into a polymeric matrix. In the stomach, the metformin would more slowly diffuse out of the matrix and ensure its smooth delivery into the bloodstream over time, without the usual initial spike and later lull in drug level, to offer consistent blood-sugar control.

Depomed obtained several patents covering the developments embodied in Glumetza, United States Patent Nos. 6,340,475 and 6,635,280, which expired in September 2016, No. 6,488,962, which expired in June 2020, and No. 6,723,340, which will expire in October 2021. Depomed listed these patents as covering Glumetza in the FDA's "Orange Book." U.S. DEP'T

HEATH & HUM. SERVS., FDA, APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (41st ed. 2021), https://www.fda.gov/media/71474/download.

In 2009, defendants Lupin Pharmaceuticals, Inc. and Lupin Limited filed an Abbreviated New Drug Application with the FDA, seeking to manufacture and market generic versions of both 500 mg and 1000 mg Glumetza. Lupin certified to the FDA that Depomed's patents were either invalid or not infringed, yet Depomed sued anyway in November 2009, asserting several claims from the '475, '280, and '962 patents (it also asserted but later dropped the '340 patent). The case came before the Honorable Phyllis J. Hamilton of our district. Following a year of litigation, Judge Hamilton held a *Markman* hearing in January 2011 and issued a claim construction order in May. The parties fought for the rest of that year, but, before filing dispositive motions, settled in February 2012. As far as the parties told the judge, they would simply go their separate ways and Lupin would launch its generic on February 1, 2016. *Depomed, Inc. v. Lupin Pharms., Inc.*, No. C 09-05587 PJH, Dkt. No. 152 (N.D. Cal. Mar. 27, 2012). This, our plaintiffs now allege, concealed an underlying unlawful conspiracy.

* * *

Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984, more commonly known as the Hatch-Waxman Act, to lower pharmaceutical drug prices by speeding generics to market. In general, a pharmaceutical drug must undergo a grueling — and costly — testing regimen to obtain FDA approval to market. To ease generic entry, however, the Act permits a generic drug manufacturer to file an Abbreviated New Drug Application (ANDA) to piggyback on the approval efforts of the underlying brand-name drug that uses the same active ingredient and to which the proposed generic is biologically equivalent. The Act then implements a network of interlocking incentives to encourage faster introduction of these low-cost generics into the pharmaceutical market, yet still drive new drug development. *See FTC v. Actavis*, 570 U.S. 136, 142 (2013); 21 U.S.C. §§ 355(j)(2)(A)(ii), (iv).

The ANDA relieves generic drug manufacturers of a significant burden by, in practical effect, placing it on brand manufacturers. So, to ensure generics cannot immediately hop

aboard and profit from a brand manufacturers' costly investment, the ANDA scheme relies on, among others, patents to temporarily exclude generic manufacturers from use of the novel drug ingredient itself or its new formulation, delivery mechanism, or form of treatment. H. Hovenkamp, *Anticompetitive Patent Settlements & the Supreme Court's Actavis Decision*, 15 MINN. J.L. SCI. & TECH. 3, 10–11 (2014). Recognizing that the long FDA approval process would otherwise eat into a substantial portion of a patent's twenty-year term, the Act provides for up to a five-year extension of a drug patent's term. *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 644 (2d Cir. 2015). The Act adds a further layer to drug-patent protection, requiring an ANDA application to certify that the relevant patents have either expired or will expire before the generic reaches the market, or that the patents are either invalid or not infringed. *Actavis*, 570 U.S. at 143; 21 U.S.C. § 355(j)(2)(A)(vii)(I)–(IV).

Balancing this patent protection with its overall goal of expediting generic entry, the Act encourages generic manufacturers to challenge weak validity or infringement cases. *See King Drug Co. v. SmithKline Beecham Corp.*, 791 F.3d 388, 394 (3d Cir. 2015). The first generic to file an ANDA including a certification of invalidity or noninfringement (the "Paragraph IV" approach) wins 180 days of generic exclusivity, meaning that once it gains FDA approval and enters the market, the FDA can't approve any other generics during that time. This, however, doesn't stop the brand from launching its own "authorized generic" to win some market share back from the first filer, and the first filer can lose the exclusivity if fails to market promptly after a later generic filer gains FDA approval. But the exclusivity period can be "worth several hundred million dollars" to the first-filer generic and outweigh the risk of infringement suit. *Actavis*, 570 U.S. at 143–44; *In re Wellbutrin XL Antitrust Litig.*, 868 F.3d 132, 144 fn. 7 (3d Cir. 2017); *See Teva Pharm. v. Crawford*, 410 F.3d 51, 55 (D.C. Cir. 2005); 21 U.S.C. § 355(j)(5)(B)(iv), (D).

To ease timely judicial resolution of ANDA patent challenges, a Paragraph IV certification operates as a technical act of patent infringement. And, to encourage prompt commencement, the Hatch-Waxman Act imposes a thirty-month stay against FDA approval of the ANDA if the patent owner sues within forty-five days' notice of the certification. If a court

resolves the infringement suit during that time, the FDA follows that result. If not, the FDA will then be free to approve the ANDA at the expiration of the statutory stay. *Actavis*, 570 U.S. at 143; 21 U.S.C. § 355(j)(5)(B)(iii); 35 U.S.C. § 271(e)(2)(A).

With FDA approval, a generic drug may enter the market. Though, if the infringement suit remains ongoing, the launch is commonly referred to as "at risk," given the brand manufacturer might still win a judgment of infringement, damages (perhaps enhanced for willfulness), and, where appropriate, an injunction. *Wellbutrin*, 868 F.3d at 168 fn. 59; 35 U.S.C. §§ 283–84. But once a generic drug makes it to market, the FDA's Orange Book broadcasts its availability to the public as an alternative to the underlying brand drug. All fifty states and the District of Columbia have some form of mandatory or permissive drug substitution law to help shift consumers from expensive brand drugs to their cheaper generics, without another visit to the doctor. *See Schneiderman*, 787 F.3d at 644–45.

This scheme is *supposed* to expedite our access to cheaper generics. But the pharmaceutical industry found a way around it. In some infringement cases, the brand manufacturer (the *patent owner*) pays the generic (the *accused infringer*) to settle. This may seem topsy-turvy but the patent owner actually comes out ahead. In exchange, the first-filer generic manufacturer agrees to stay off the market for a few years. So, instead of expedited generic entry, the brand maintains its monopoly and cuts the supposed-generic a share of the profits.

In 2013, the United States Supreme Court found that these "pay for delay" schemes can violate federal antitrust law. True, a patent gives a brand drug the power to exclude competition within the bounds of the claims for its twenty-year term. But by paying the *accused infringer* to stay out of the market, the brand in essence concedes the weakness of the patent's validity or infringement case against the ANDA. Thus, the settlement suppresses generic competition and does so outside the bounds of the brand manufacturer's patent protection. *See Actavis*, 570 U.S. at 147–49, 153–58.

Our plaintiffs allege just a scheme here. The stipulated dismissal in 2012, which the parties submitted to Judge Hamilton and which they characterized as permitting Lupin's early

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