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Attorneys for Plaintiff Federal Trade Commission

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

FEDERAL TRADE COMMISSION,

Plaintiff,

v.

ALLERGAN PLC,

ALLERGAN FINANCE LLC,

WATSON LABORATORIES, INC.,

ENDO INTERNATIONAL PLC,

and

ENDO PHARMACEUTICALS INC.,

Defendants.

Case No. 17-cv-00312

COMPLAINT FOR INJUNCTIVE AND OTHER EQUITABLE RELIEF

Plaintiff, the Federal Trade Commission ("FTC"), by its designated attorneys, petitions this Court, pursuant to Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), for a permanent injunction and other equitable relief against Defendants Endo Pharmaceuticals Inc.; Endo International plc; Watson Laboratories, Inc.; Allergan Finance LLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.); and Allergan plc[1] to undo and prevent their unfair methods of competition in or affecting commerce in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), and an acquisition in violation of Section 7 of the Clayton Act, 15 U.S.C. § 18.

I. Nature of the Case

1. This antitrust case challenges anticompetitive reverse-payment agreement between Endo and Watson to obstruct lower-cost generic competition to Lidoderm, Endo's most important branded prescription drug product. In 2011, Endo generated more than $825 million from Lidoderm, a lidocaine patch, comprising 30% of Endo's total annual revenues. The threat of generic entry to Lidoderm posed significant financial risks for the company. Endo knew that generic competition would decimate its Lidod

9. Defendant Watson’s acquisition of an exclusive field-of-use license constitutes an acquisition subject to Section 7 of the Clayton Act, 15 U.S.C. § 18.

10.

(commonly known as the Orange Book) within 30 days of issuance of the patent. 21 C.F.R. § 314.53.

20. A company seeking to market a generic version of a branded drug may file an Abbreviated New Drug Application ("ANDA") with the FDA. The generic applicant must demonstrate that its generic drug is therapeutically equivalent to the brand-name drug that it references and for which it seeks to be a generic substitute. Upon showing that the generic drug is therapeutically equivalent to the already-approved branded drug, the generic company may rely on the studies submitted in connection with the already-approved branded drug's NDA to establish that the generic drug is safe and effective. 21 U.S.C. § 355(j)(2)(A)(iv).

21. The FDA assigns a generic drug an "AB" rating if it is therapeutically equivalent to a brand-name drug. An AB-rated generic drug is the same as a brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use. A generic drug also must contain identical amounts of the same active ingredient(s) as the brand-name drug, although its inactive ingredients may vary.

22. When a brand-name drug is covered by one or more patents listed in the Orange Book, a company seeking to market a generic version of that drug before the patents expire must make a "paragraph IV certification" in its ANDA certifying that the patents are invalid, unenforceable, and/or will not be infringed by the generic drug.

23. If a company makes a paragraph IV certification, it must notify the patent holder of its certification. If the patent holder initiates a patent infringement suit against the company within 45 days of receiving such notice, the FDA may not grant final approval of the ANDA until the earliest of: (1) patent expiry; (2) district court resolution of the patent litigation in favor of the generic company; or (3) the expiration of an automatic 30-month stay.

24. The Hatch-Waxman Act provides the first generic company or companies filing an ANDA containing a paragraph IV certification ("first filer") with a period of protection from competition with other ANDA filers. This is referred to as the "180-day exclusivity" or "first-filer exclusivity" period. The Supreme Court observed that the 180-day exclusivity period "can prove valuable, possibly worth several hundred million dollars" to the first filer.

incentives to make price comparisons.

C. Competition from lower-priced generic drugs saves American consumers billions of dollars a year

30. The Hatch-Waxman Act and state substitution laws have succeeded in facilitating generic competition and generating large savings for patients, healthcare plans, and federal and state governments. The first generic competitor's product is typically offered at a 20% to 30% discount to the branded product. Subsequent generic entry creates greater price competition with discounts reaching 85% or more off the brand price. According to a 2010 Congressional Budget Office report, the retail price of a generic is 75% lower, on average, than the retail price of a brand-name drug. In 2015 alone, the Generic Pharmaceutical Association reported that use of generic versions of brand-name drugs saved the U.S. healthcare system $227 billion.

31. Because of these price advantages and cost savings, many third-party payers of prescription drugs (e.g., health insurance plans and Medicaid programs) have adopted policies to encourage the substitution of AB-rated generic drugs for their branded counterparts. As a result of these policies and lower prices, many consumers routinely switch from a branded drug to an AB-rated generic drug upon its introduction. Consequently, AB-rated generic drugs typically capture over 80% of a branded drug's unit and dollar sales within six months of market entry.

32. Consumers also benefit from competition between an authorized generic drug and an ANDA-based generic drug. Empiri

generic lidocaine patch sales forecasts and budgets for the period beginning in late 2012 or early 2013.

49. Launching Watson's generic Lidoderm product upon FDA approval would likely require an at-risk launch. In addressing that possibility for generic Lidoderm, Watson Pharma's CEO, Paul Bisaro, publicly stated that Watson has "never been shy" about launching at risk and that these launch preparations were not a "bluff," but a genuine commitment to launch a generic Lidoderm product upon FDA approval, even if the patent litigation had not yet concluded:

> Just for the record and this is an important point, to demonstrate our commitment to this product we've built onto our facility in Salt Lake. We spent $40 million and we're buying raw material today [February 2012], so we're spending millions of dollars preparing for this launch. So this is not a bluff; it's true.

50. Endo was closely monitoring the steps Watson was taking to prepare for a generic lidocaine patch launch and Watson's public statements about the likelihood of such a launch. Endo expected that competition from a generic product would lead to rapid and dramatic declines in the company's Lidoderm revenues. During the first year after generic entry, Endo predicted that its branded Lidoderm revenues would decrease by at least $500 million. Watson similarly forecasted a sharp decline in branded Lidoderm sales after a generic product entered the market.

51. In late June 2011, Watson Labs prevailed with respect to claim construction of the '529 patent. As the Patent Case Management Judicial Guide notes, "The construction of patent claims plays a critical role in nearly every patent case. It is central to evaluation of infringement and validity, and can affect or determine the outcome of other significant issues such as unenforceability, enablement, and remedies."

52. Shortly after the adverse claim construction decision, Endo filed a separate federal court action against Watson Labs alleging that its generic product infringed three additional patents that Endo had subsequently acquired—U.S. Patent Nos. 5,741,510 (the "'510 patent"), 6,096,333 (the "'333 patent"), and 6,096,334 (the "'334 patent"). Of these three patents, Endo

listed only the ’510 patent in the Orange Book. No 30-month stay resulted from this later patent litigation.

53. A six-day trial on the ’529 patent infringement claims occurred in February 2012. Coming out of that trial, Watson was confident in its litigation position.

C. Endo paid Watson to abandon its patent challenge and refrain from competing until September 2013

54. On May 28, 2012, Endo and Watson settled both Lidoderm patent litigations (“the Lidoderm Agreement”) before a final decision was issued in either cas [redacted]

55. The Lidoderm Agreement required (i) Watson to abandon the patent challenge and (ii) Watson Pharma and all its subsidiaries to refrain from initiating future patent challenges relating to Lidoderm or from launching any generic version of Lidoderm for more than a year, until September 15, 2013. In exchange, Endo agreed to pay the Watson entities through two separate components. First, Endo committed not to sell an authorized generic version of Lidoderm for up to 7½ months following Wats

57. Endo had the legal right and financial incentive to compete with an authorized generic version of Lidoderm as soon as Watson entered with its generic Lidoderm product. Under the Lidoderm Agreement, however, Endo agreed not to compete with an authorized generic version of Lidoderm for 7½ months [lesindho0.0014 TJ 0.0005 T9

71. Endo's payment to Watson cannot be justified solely as compensation for services to be performed by Watson. In fact, Watson provided no services to Endo in exchange for the Lidoderm Agreement payment worth hundreds of millions of dollars.

eliminating the risk that Watson would have ma

Endo's monopoly profits. Each did so conscious of the fact that this agreement would greatly enrich them at the expense of consumers.

97. Defendants have the incentive, opportunity, and demonstrated interest to continue to enter other reverse-payment agreements in the future. Endo and Watson each continue to develop and manufacture pharmaceutical products. Defendants are regularly involved in

period for generic Lidoderm. Under the Hatch-Waxman Act, the FDA was prohibited by law from approving any other generic version of Lidoderm until the 180-day exclusivity period had expired or been forfeited. Endo, however, was legally entitled to market an authorized generic version of its own Lidoderm product at any time, including during the first-filer's exclusivity period.

102. Before the Lidoderm Agreement, Endo was planning to launch an authorized generic as soon as Watson launched its generic lidocaine patch. Under its agreement with Teikoku, Endo had the exclusive right to sell an authorized generic version of Lidoderm in the United States. Endo also had the financial incentive to do so. As soon as Watson entered with its generic product, Endo could sell an authorized generic to compete for sales to generic lidocaine users, while preserving branded Lidoderm sales for the minority of users who were willing to pay more for the branded product. Endo estimated that it could make more than $150 million in net sales during the first year after generic entry by selling an authorized generic in competition with Watson.

103. Under the Lidoderm Agreement, however, Watson acquired an exclusive field-of-use license that prevented Endo from launching an authorized generic until May 2014. By eliminating the potential competition between Endo's authorized generic and Watson's generic version of Lidoderm, this acquisition substantially reduced competition in the market for generic lidocaine patches.

104. As a result of Endo and Watson's conduct, competition between generic lidocaine patches was delayed for 7½ months until May 2014. Absent Endo's commitment not to compete with an authorized generic, Endo would have launched an authorized generic at or near the time of Watson's generic lidocaine patch entry. Endo's authorized generic entry would have resulted in significantly lower prices for generic lidocaine patches and hundreds of millions of dollars in savings for generic lidocaine patch purchasers. Instead, Endo and Watson shared additional profits at the expense of consumers.

105. Upon termination of the exclusive field-of-use license, Endo immediately launched a Lidoderm authorized generic through its subsidiary, Qualitest. Competition from

Section 7 of the Clayt[illegible]

15 U.S.C. § 18;

4. That Defendants [illegible]

[illegible] form of substan[illegible]

[illegible] with an authorized generic version of its

product for some period of time; or

[illegible]

Defendants' violations of

Section 5(a) of the FTC Act [illegible]

[illegible]

Bureau of Competition

[illegible]

[illegible]EFER

Attorneys for Plaintiff

Federal Trade Commission

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