UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Joseph J. Simons, Chairman**
Noah Joshua Phillips
Rohit Chopra
Rebecca Kelly Slaughter
Christine S. Wilson

In the Matter of **WATSON PHARMACEUTICALS INC.,** **a corporation;** **ACTAVIS INC.,** **a corporation;** **ACTAVIS PHARMA HOLDING 4 EHF.,** **a private limited liability company;** **and** **ACTAVIS S.Á.R.L.,** **a limited liability corporate entity.**	**DOCKET NO. C-4373**

ORDER REOPENING AND MODIFYING ORDER

On October 22, 2018, Teva Pharmaceutical Industries Ltd. ("Teva") filed a petition ("Petition") pursuant to Section 5(b) of the Federal Trade Commission Act, 15 U.S.C. § 45(b), and Section 2.51(b) of the Commission's Rules of Practice and Procedure, 16 C.F.R. § 2.51(b), requesting that the Commission reopen and modify the Commission's order in Docket No. C-4373 ("Order"). Teva is the successor to Watson Pharmaceuticals Inc. ("Watson") and Actavis Inc. ("Actavis"), the Respondents to the Order. Teva filed the Petition at the request of Pfizer Inc. ("Pfizer").

The Order remedied the anticompetitive effects in twenty-one pharmaceutical markets resulting from Watson's acquisition of Actavis, including the market for extended release acute pain treatment served by branded Embeda®,[1] which Pfizer and Actavis were developing and manufacturing prior to the acquisition pursuant to an exclusive agreement. At the time of the acquisition, Pfizer had recalled Embeda, but was planning to reintroduce it to the market after reformulating the product. Watson was one of only a few companies that appeared likely to enter with a generic version of Embeda. As part of the Commission's remedy, Watson/Actavis

[1] The Order refers to Embeda® as Morphine Sulphate Naltrexone Extended Release Products. Order ¶ I.FFF.

and Pfizer amended the Development and Manufacturing Services Agreement between Actavis and Pfizer ("Agreement") in several respects, including to remove impediments to entry by a generic Embeda (*e.g.*, by eliminating Actavis' right of first refusal to market an authorized generic) and to foster Pfizer's relaunch of Embeda and eventual independence from supply from Actavis (*e.g.*, by transferring manufacturing rights back to Pfizer). The Order provided that Pfizer would continue to have a supply of Embeda from Actavis to allow Pfizer to relaunch Embeda pursuant to the amended Agreement, but consistent with limiting continuing entanglements to the extent deemed necessary, included a four-year limitation on the Respondents' obligation to supply Embeda to Pfizer following its relaunch of Embeda.[2]

In January 2015, Pfizer reintroduced Embeda to the market, and in February 2016, exercised its right to extend the supply of Embeda pursuant to the amended Agreement for two one-year periods. Despite its best efforts, however, Pfizer will be unable to complete the manufacturing technology transfer to another manufacturing site before expiration of the extended supply term of Embeda on December 31, 2018. The reason is because extended release products like Embeda are complex and difficult to manufacture, and Embeda, which includes morphine sulphate, has abuse deterrent properties that make manufacturing especially difficult. According to the Petition, Pfizer needs a further extension of the supply of Embeda to allow it to complete its ongoing efforts to transfer the manufacture of Embeda to another manufacturing site. However, this extension is prevented by the Order language limiting extensions of the supply term to four years after relaunch.

In August 2016, Teva acquired Allergan, which included the merged Watson/Actavis, and became a successor-Respondent under the Order. Teva's Petition states that Teva is planning to launch a generic version of Embeda in the foreseeable future.[3] However, there currently is no FDA-approved generic version of Embeda on the market, and if Pfizer will be unable to continue to market branded Embeda upon the expiration of Teva's supply of Embeda, which will leave health care providers and their patients with no supply of Embeda as an option for acute pain treatment. At Pfizer's request, Teva and Pfizer have negotiated a further extension of the amended Agreement (*i.e.*, the Proposed Fourth Amendment to the Development and Manufacturing Services Agreement, which would extend the term of Teva's supply of Embeda beyond the Order's four-year limit).

In its Petition, Teva requests that the Commission eliminate the Order's four-year limit on the term of Embeda supply by Actavis (now Teva) based on changed conditions of fact and because the proposed modification would be in the public interest. For the reasons stated herein, the Commission has determined to grant Teva's Petition.

[2] *See* Order ¶ I.III.6 (Definition of Morphine Sulphate Naltrexone Extended Release Product Assets (*i.e.*, Embeda) includes a four-year limit on Pfizer's right to extend supply agreement from date of first commercial sale of Embeda as reformulated and relaunched).
[3] Petition at 6, 12.

BACKGROUND

The Order arose from settlement of the Commission's investigation into Watson's acquisition of Actavis in 2012. At the time of the investigation, Watson was one of a limited number of likely potential suppliers of a generic equivalent of Pfizer's branded product, Embeda. Pfizer was in an exclusive Development and Manufacturing Services Agreement with Actavis to produce Embeda. Embeda is an extended-release opioid pain reliever that has specific abuse-deterrent technology and is difficult to manufacture. Actavis had previously supplied Pfizer from an Actavis site, but at the time of the Order Pfizer had recalled Embeda and was working with Actavis to remediate issues with the product so Pfizer could reintroduce it from the Actavis site.

The Order's purpose, *inter alia*, was to "to create a viable and effective competitor, that is independent of Respondents" in the "research, Development, and manufacture" and the "distribution, sale, and marketing" of Embeda and its generic equivalents.[4] To remedy the effects of the acquisition in the relevant acute pain treatment market, the Commission required the merging parties to restructure the Agreement in such a way as to protect the potential competition between Pfizer's Embeda (and any authorized generic version of this product) and Watson's generic equivalent of Embeda that was in development. The Order provided Pfizer with what appeared to be sufficient time to resolve the manufacturing issues that had caused the recall of Embeda, re-introduce Embeda from the Actavis site, and move production of this difficult-to-manufacture product away from its competitor, Watson/Actavis. It was anticipated that Pfizer would need a significant amount of time to do this, and four years appeared to be sufficient at the time. As a part of the Commission's remedy, Watson/Actavis and Pfizer removed certain provisions in the Agreement in order to allow Watson to develop, manufacture, and market a generic Embeda. The Order's limitation on the continued supply of Embeda to Pfizer pursuant to the Agreement assured this would not act as a disincentive for Watson/Actavis to continue to develop and introduce its own directly competing product. Accordingly, the Order limited the supply term to four years after Pfizer's reintroduction of Embeda to the market.

Thus, the Order required the Respondents, in relevant part, to grant Pfizer: (i) an extended-term supply agreement to enable Pfizer to reintroduce Embeda to the market, but limited Pfizer's right to extend the supply to four years after relaunch, and provide Pfizer with time to relocate production after the relaunch of Embeda; (ii) the option to move production of Embeda out of the Respondents' site at the time of Pfizer's choosing; (iii) assistance from the Respondents with the transfer of the manufacturing technology related to Embeda to an alternate manufacturing site; (iv) the right to terminate the agreement at will; and (v) protections from the Respondents unilaterally terminating the agreement.[5]

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4 Order ¶ IV.E.

5 Order ¶¶ IV.A. and I.III.

STANDARD TO REOPEN AND MODIFY

Section 5(b) of the Federal Trade Commission Act, 15 U.S.C. § 45(b) provides that the Commission shall reopen an order to consider whether it should be modified if the respondent "makes a satisfactory showing that changed conditions of law or fact" so require.[6] A satisfactory showing sufficient to require reopening is made when a request to reopen identifies significant changes in circumstances and shows that the changes either eliminate the need for the order or make continued application of it inequitable or harmful to competition.[7]

Section 5(b) also provides that the Commission may reopen and modify an order when, although changed circumstances would not require reopening, the Commission determines that the public interest so requires. Respondents are therefore invited in petitions to reopen to show how the public interest warrants the requested modification.[8] In the case of "public interest" requests, FTC Rule of Practice § 2.51(b), 16 C.F.R. § 2.51(b), requires an initial "satisfactory showing" of how the modification would serve the public interest before the Commission determines whether to reopen an order.

A "satisfactory showing" requires, with respect to public interest requests, that the petitioner make a *prima facie* showing of a legitimate public interest reason or reasons justifying relief. A request to reopen and modify will not contain a "satisfactory showing" if it is merely conclusory or otherwise fails to set forth by affidavit(s) specific facts demonstrating in detail the reasons why the public interest would be served by the modification.[9] This showing requires the requester to demonstrate, for example, that there is a more effective or efficient way of achieving the purposes of the order, that the order in whole or part is no longer needed, or that there is some other clear public interest that would be served if the Commission were to grant the requested relief. In addition, this showing must be supported by evidence that is credible and reliable.

If, after determining that the requester has made the required showing, the Commission decides to reopen the order, the Commission will then consider and balance all of the reasons for and against modification. In no instance does a decision to reopen an order oblige the Commission to modify it,[10] and the burden remains on the requester in all cases to demonstrate why the order should be reopened and modified. The petitioner's burden is not a light one in view of the public interest in repose and the finality of Commission orders.[11] All information

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6 *See Supplementary Information, Amendment to* 16 CFR 2.51(b), ("Amendment"), 65 Fed. Reg. 50636, August 21, 2000.

7 S. Rep. No. 96-500, 96th Cong., 2d Sess. 9 (1979) (significant changes or changes causing unfair disadvantage); *Louisiana-Pacific Corp.*, Docket No. C-2956, Letter to John C. Hart (June 5, 1986), at 4 (unpublished) ("Hart Letter"); *see also United States v. Louisiana-Pacific Corp.*, 967 F.2d 1372, 1376-77 (9th Cir. 1992).

8 Hart Letter at 5; 16 C.F.R. § 2.51.

9 16 C.F.R. § 2.51.

10 *See Louisiana-Pacific*, 967 F.2d at 1376-77 (reopening and modification are independent determinations).

11 *See Federated Department Stores, Inc. v. Moitie*, 425 U.S. 394 (1981) (strong public interest considerations support repose and finality).

and material that the requester wishes the Commission to consider shall be contained in the request at the time of filing.[12]

THE PUBLIC INTEREST WARRANTS REOPENING AND MODIFYING THE ORDER

The Commission has determined that the public interest requires that the Order be reopened and modified to eliminate the Order's four-year limit on the term of Embeda supply by Actavis (now Teva) to Pfizer. Because the Commission has determined that Teva has made a satisfactory showing that the public interest would be served by the modification Teva requests in its Petition, there is no need for the Commission to consider whether changed conditions of fact would justify the requested Order modification.

The Commission finds that since the Order was issued, Pfizer reintroduced Embeda in 2015 from an Actavis manufacturing site and has been actively working to move production of Embeda to an alternate manufacturing site. Although Pfizer has performed many of the steps necessary to gain FDA approval to manufacture Embeda at this alternate site, it has not successfully completed all of these steps. Further, Pfizer will not complete this manufacturing transfer before the current term of the supply agreement with Teva expires.

Teva has also continued to develop Watson's generic equivalent of Embeda as contemplated by the Order, and states in its Petition that it plans to introduce its generic version of Embeda in the foreseeable future.[13] Teva thus remains a potential competitor to Pfizer in the relevant Complaint market.[14] Both Pfizer's progress toward moving production of Embeda away from its competitor and Teva's progress toward producing a generic version of Embeda demonstrate significant progress toward achieving the independent competition in the relevant acute pain treatment market contemplated by the Order.

Teva has demonstrated that the modification to the Order it requests in its Petition – eliminating the four-year limit on the supply of Embeda to Pfizer – would serve the clear public interest in achieving the contemplated remedial purposes of Order, and that the continued application of the Order's four-year limit on the term of Embeda supply would be harmful to the public interest. The purpose of the Order is to maintain competition in the market for the Embeda product and generic equivalents of Embeda. However, Pfizer will not complete the process of gaining FDA approval for an alternate manufacturing site before the current Embeda supply term expires. If Pfizer is unable to obtain a sufficient further extension of the supply agreement, Embeda will not remain on the market because there currently are no FDA-approved therapeutic equivalents of Embeda – a result directly contrary to the remedial purposes of the Order.

Accordingly, the Commission has determined to reopen and modify the Order to eliminate the four-year limitation on the Respondents' obligation to supply Embeda to Pfizer.

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12 16 C.F.R. § 2.51(b).

13 Petition at 6, 12.

14 *See* Complaint ¶ 24.

CONCLUSION

Having found that it is in the public interest to grant Teva's Petition, the Commission has determined to reopen and modify the Order. Accordingly:

IT IS ORDERED that this matter be, and it hereby is reopened; and

IT IS FURTHER ORDERED that Paragraph I.III.6. of the Order is revised to remove the language that is struck through below:

> rights to extend the requirement for Respondents to supply the Morphine Sulphate Naltrexone Extended Release Product to Pfizer ~~for term not to exceed four (4) years from the date of first commercial sale of the Morphine Sulphate Naltrexone Extended Release Product as reformulated and relaunched after the Acquisition Date~~; *provided, however,* that, if the relaunch of the Morphine Sulphate Naltrexone Extended Release Product does not occur within three (3) years of the date of the Morphine Sulphate Naltrexone Extended Release Product Divestiture Agreement, then this requirement for Respondents' to supply such Product to Pfizer shall expire three (3) years from the date of the Morphine Sulphate Naltrexone Extended Release Product Divestiture Agreement; . . .

IT IS FURTHER ORDERED that Paragraph I.III.6. of the Order now reads:

> rights to extend the requirement for Respondents to supply the Morphine Sulphate Naltrexone Extended Release Product to Pfizer; *provided, however,* that, if the relaunch of the Morphine Sulphate Naltrexone Extended Release Product does not occur within three (3) years of the date of the Morphine Sulphate Naltrexone Extended Release Product Divestiture Agreement, then this requirement for Respondents' to supply such Product to Pfizer shall expire three (3) years from the date of the Morphine Sulphate Naltrexone Extended Release Product Divestiture Agreement; . . .

By the Commission, Commissioner Wilson recused.

Donald S. Clark
Secretary

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ISSUED: December 17, 2018