

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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TEVA PHARMACEUTICALS USA,))
INC.,))
))
Plaintiff,))
))
v.)	Civil Action No. 09-1111 (RMC)
))
KATHLEEN SEBELIUS, Secretary of))
Health and Human Services, <i>et al.</i> ,))
))
Defendants.))
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ORDER

On March 16, 2010, this Court ordered as follows:

It is hereby

ORDERED AND DECLARED that Teva has not forfeited its right to 180-day marketing exclusivity for generic losartan potassium products under 21 U.S.C. § 355(j)(5)(D)(i)(I); and it is

FURTHER ORDERED that the Food and Drug Administration (“FDA”) is ENJOINED from approving any Abbreviated New Drug Application (“ANDA”), *see* 21 U.S.C. § 355(j), for a generic version of Cozaar®¹ 25mg, 50mg, and 100mg tablets other than Teva’s ANDA No. 07-6958 prior to the conclusion of Teva’s 180-day period of marketing exclusivity; and it is

FURTHER ORDERED that the FDA is ENJOINED from approving any ANDA for a generic version of Hyzaar® 50mg/12.5mg and 100mg/25mg tablets other than Teva’s ANDA No. 07-7157 prior to the conclusion of Teva’s 180-day period of marketing exclusivity.

¹ Merck and Co., Inc., holds two approved New Drug Applications, *see* 21 U.S.C. § 355(a) & (b), relating to losartan potassium/hydrochlorothiazide tablets, which it commercially markets under the brand name Cozaar® and Hyzaar®.

See Order [Dkt. #28]. Defendants now move to clarify, alter, or amend the March 16 Order asserting that the “further ordered” paragraphs rule out the possibility that Teva’s exclusivity could be found to be forfeited under one of the other five forfeiture events provided for in the governing statute, 21 U.S.C. § 355(j)(5)(D)(i)(II) - (VI). They ask that the Order be amended to delete the “further ordered” paragraphs.

Teva objects, asserting that Defendants plan to declare that Teva forfeited its right to 180-day marketing exclusivity for generic losartan potassium products under the sixth forfeiture event, *see* 21 U.S.C. § 355(j)(5)(D)(i)(VI), because the patent that is the subject of the paragraph IV certification has expired due to the brand manufacturer’s failure to pay maintenance fees.² Teva complains that Defendants raised this issue for the first time before the Circuit in opposing Teva’s request for an emergency mandate.³ Without commenting on this new issue, the Circuit granted the emergency mandate. Teva argues (1) that the granting of the mandate reveals the Circuit’s rejection of the subparagraph VI forfeiture claim and (2) that the Circuit’s holding that the failure to market provision does not permit a brand manufacturer to unilaterally vitiate a generic’s exclusivity by delisting a patent under forfeiture event (I) applies with equal force to the claim Defendants make with regard to forfeiture event (VI). *See Teva Pharmaceuticals USA, Inc. v. Sebelius*, Nos. 09-5281 & 09-5308, 2010 WL 695446, * 14-15 (D.C. Cir. Mar. 2, 2010).

Defendants’ motion to amend the March 16 Order is well-founded. The precise issue of a possible subparagraph VI forfeiture was not raised in the Complaint, and it was not addressed

² The FDA opened the issue of a subparagraph VI forfeiture for comments under public docket number FCA-2010-N-0134 and plans to make a decision on March 26, 2010.

³ The Circuit issued the mandate in this case on March 12, 2010.

by the Circuit in its March 2 Opinion or its March 12 mandate.⁴

Accordingly, Defendants' motion to amend [Dkt. # 29] is **GRANTED**; and it is

FURTHER ORDERED that this Court's March 16 Order [Dkt. # 28] is amended to provide as follows: it is hereby **ORDERED AND DECLARED** that Teva has not forfeited its right to 180-day marketing exclusivity for generic losartan potassium products under 21 U.S.C. § 355(j)(5)(D)(i)(I).

Accordingly, this case is closed. This is a final appealable order. *See* Fed. R. App. P. 4(a).

SO ORDERED.

Date: March 26, 2010

/s/
ROSEMARY M. COLLYER
United States District Judge

⁴ If Defendants declare that Teva forfeited its exclusivity via one of the other five forfeiture events provided for in the statute, 21 U.S.C. § 355(j)(5)(D)(i)(II) - (VI), Teva may litigate the issue in a new lawsuit, filed as a case related to this one.