

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.