UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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ANNIE TUMMINO, *et al.*,

Plaintiffs,

MEMORANDUM & ORDER

- against -

No. 12-CV-763 (ERK)(VVP)

MARGARET HAMBURG, Commissioner of Food and Drugs, *et al.*

Defendants.

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KORMAN, J.:

I filed an opinion today in which I reversed the decision of the Food and Drug Administration ("FDA") denying a Citizen Petition seeking over-the-counter access to Plan B for women of all ages and remanded to the FDA with instructions to grant it. Familiarity with the facts and background set out in that opinion is assumed. I write here to address the motion of Teva Women's Health, Inc. ("Teva") to "intervene in support of neither party and for the limited purpose of defending its statutory right to marketing exclusivity," or, failing that, to have its brief considered as an *amicus* brief. Teva's Mot. to Intervene at 1, Case No. 12-cv-763, Doc. No. 22.

Some brief background is necessary. Under the Food Drug and Cosmetic Act ("FDCA"), a drug manufacturer who submits studies to obtain approval of a switch application from prescription to over-the-counter sale is entitled to three years in which it has the exclusive right to market the drug. The right of exclusivity is contingent upon the approval of the switch application and a finding by the FDA that the studies were "essential" to its approval. The purpose underlying this exclusivity provision, according to both the FDA and Teva, is "to encourage and reward drug manufacturers who devote the time and expense to clinical trials

necessary to approve changes to a drug product." *Id.*; Teva's Proposed Mem. Of Law in Resp. to Order to Show Cause at 11, Case No. 12-cv-763, Doc. No. 22-2.

In this case, the FDA conceded that the actual use and label studies submitted by Teva were sufficient to justify a complete over-the-counter switch, although it suggested that the label comprehension study was not essential. Nevertheless, Teva's application was not approved and it was not granted exclusivity. As the Citizen Petition Denial Letter explained, the "FDA's final determination on exclusivity was not made because FDA determines whether to grant exclusivity *after product approval*." Citizen Petition Denial Letter at 9 n.4 (emphasis added). Nor is Teva currently marketing Plan B One-Step for universal over-the-counter access. Thus, the policy justification underlying the exclusivity provision of the FDCA does not apply here. Indeed, Teva's position will not be affected whether the case is decided in favor of the FDA or the plaintiffs—in either case, it will not enjoy exclusivity.

Moreover, Teva has chosen not to appeal the denial of the Plan B One-Step SNDA; rather, it claims to be involved in "active dialogue with the FDA right now," and it has acquiesced in the suggestion that it could still appeal if the FDA should adhere to its position. Apr. 27, 2012 Hr'g Tr. at 22:9-10, Case No. 12-cv-763, Doc. No. 84. The availability of an alternative means of protecting its interests in a separate action is alone sufficient to justify denial of Teva's motion to intervene. 7C Wright, Miller & Kane, Federal Practice and Procedure § 1908.2, at 378-84 (3d ed. 2007).

This consideration aside, Teva's motion to intervene "for limited purposes in support of neither party" is fundamentally illogical because the purpose of intervention under Rule 24 is for the intervenor to "come in as a party" in its own right, not to support one side or another. 7C Wright, Miller & Kane, Federal Practice and Procedure § 1901, at 257 (3d ed. 2007); *see also*

Schneider v. Dumbarton Developers, Inc., 767 F.2d 1007, 1017 (D.C. Cir. 1985) ("When a party intervenes, it becomes a full participant in the lawsuit and is treated just as if it were an original party."). This explains the Rule's requirement that that proposed intervenor file its own "pleading that sets out the claim or defense for which intervention is sought." Fed. R. Civ. P. 24(c). Teva's motion to intervene for "limited purposes" is plainly not allowed by the Rule. *See N.Y. News, Inc. v. Newspaper and Mail Deliverers' Union of N.Y.*, 139 F.R.D. 291, 293 (S.D.N.Y. 1991) ("[I]t is clear that the Federal Rules do not anticipate limited, 'special status' intervenors.")

Indeed, the failure to file a pleading by itself may be "fatal" to the motion. *See Abramson v. Pennwood Inv. Corp.*, 392 F.2d 759, 761 (2d Cir. 1968) (affirming district court's denial of motion to intervene for failure to file a pleading); *see also Berbungs Und Commerz Union Austalt v. Collectors' Guild, Ltd.*, 782 F. Supp. 870, 874 (S.D.N.Y. 1991) ("A motion to intervene must be accompanied by a pleading . . . ."); *Retired Chicago Police Ass'n v. City of Chicago*, 7 F.3d 584, 595 (7th Cir. 1993) (rule is "unambiguous" in requiring the proposed intervenor to submit a pleading). Teva's memorandum of law, submitted with its motion for intervention, is not a pleading because the only filing properly characterized as a "pleading" is a complaint or an answer. Fed. R. Civ. P. 7(a).

Finally, I have no power to grant a period of exclusivity. Indeed, I do not have subject-matter jurisdiction to review the denial of Teva's SNDA for the purpose of granting it any relief, much less granting a period of exclusivity that only the FDA can grant when it approves an application after finding that the studies submitted by the sponsor are essential. Under these circumstances, intervention would be pointless.

CONCLUSION

Teva's motion to intervene is denied. Nevertheless, I grant its application for *amicus curiae* status and I have treated its memorandum as such.

SO ORDERED.

Brooklyn, New York
April 4, 2013

Edward R. Korman

Edward R. Korman
Senior United States District Judge