

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

EAGLE PHARMACEUTICALS, INC., :
 :
 : Civil Action No. 16-790 (GK)
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 Plaintiff, :
 :
 :
 v. :
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 :
 THOMAS PRICE, in his official :
 Capacity as Secretary of :
 Health and Human Services; :
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 :
 U.S. DEPARTMENT OF HEALTH AND :
 HUMAN SERVICES; :
 :
 :
 SCOTT GOTTLIEB, in his :
 official capacity as :
 Commissioner of the U.S. Food :
 and Drug Administration; :
 :
 :
 U.S. FOOD AND DRUG :
 ADMINISTRATION, :
 :
 :
 Defendants. :
 :

MEMORANDUM OPINION

This matter is before the Court on Apotex, Inc.'s Motion to Intervene. Upon consideration of the Motion [Dkt. No. 48], Opposition [Dkt. No. 50], Reply [Dkt. No. 51], the entire record herein, and for the reasons discussed below, the Court concludes that the Motion should be granted.

I. BACKGROUND

In the underlying case, Plaintiff Eagle Pharmaceuticals, Inc. ("Eagle") brings suit against the U.S. Department of Health and Human Services, the U.S. Food and Drug Administration, and their respective directors (collectively "Federal Defendants") following the denial to Eagle of a seven-year period of orphan drug exclusivity for the cancer treatment drug, Bendeka. On October 7, 2016, the Parties completed summary judgment briefing. Apotex, a producer of a generic form of Bendeka, has filed an Abbreviated New Drug Application ("ANDA") for its generic product that is currently pending before the FDA and seeks to intervene in this case to safeguard its ability to market and produce its generic product.

II. DISCUSSION

Apotex has moved to intervene as of right, pursuant to Federal Rule of Civil Procedure 24(a)(2) "to participate and to protect its interests in this case and also to preserve its rights to participate in any appeal...or to file its own notice of appeal in the event of an adverse decision." Mot. at 3.

Under Rule 24(a)(2), an intervening party must demonstrate: (1) that its motion is timely; (2) that it has a cognizable interest in the property or transaction at issue; (3) that the

interest will be impaired or impeded if intervention is denied; and (4) that the applicant's interest is not adequately represented by an existing party. Fund for Animals, Inc. v. Norton, 322 F.3d 728, 731 (D.C. Cir. 2003). Nor is the Court persuaded that Apotex's intervention would cause unnecessary delay in disposition of the case. The Court concludes, for the following reasons, that Apotex has met these requirements.

Regarding the first requirement, Eagle primarily points to the fact that it filed its Complaint in April 2016 and completed summary judgment briefing in October 2016 to argue that intervention is untimely. See Opp. at 1. Although Eagle is correct that this case has been pending for over a year, "the amount of time which has elapsed since the litigation began is not in itself the determinative test of timeliness." Natural Resources Defense Counsel v. Costle, 561 F.2d 904, 907 (D.C. Cir. 1977). Instead, timeliness "is to be determined from all the circumstances, including the purpose for which intervention is sought ... and the improbability of prejudice to those already in the case." Id.

The circumstances in this case favor a finding that the Motion is timely. Apotex filed the Motion only a month after receiving notice from the FDA that its ANDA had been accepted. It is logical that Apotex would wait to ensure that it had cleared the first

hurdle in its path to market its generic product before seeking to intervene in a case that could directly affect its interests. Eagle's arguments to the contrary overlook the Hatch-Waxman Act regulatory framework concerning ANDAs.¹

Moreover, Apotex's intervention would not prejudice the existing parties or cause an unnecessary delay in the disposition of this case. If permitted to intervene, Apotex "seek[s] to defer filing an answer until resolution of the pending summary judgment motions." Mot. at 2-3. As such, the Court assumes that Apotex is not requesting to submit additional motions concerning the pending summary judgment pleadings. Federal Defendants have not opposed Apotex's request to intervene or otherwise suggested that they would be harmed by the addition of Apotex to the case.

Rule 24(a)(2) also requires that the applicant for intervention demonstrate a cognizable or legally protected interest in the action. In its Opposition, Eagle does not appear to dispute that Apotex has a cognizable interest in opposing a competitor's efforts to obtain orphan drug exclusivity over a product for which Apotex has produced a generic. See generally Opp. Indeed, if Eagle prevails on the merits in this case, Apotex

¹ Notably, the cases upon which Eagle relies to argue that the Motion is untimely do not concern ANDAs.

will be foreclosed from marketing its generic product until 2022.

See Mot. at 5.

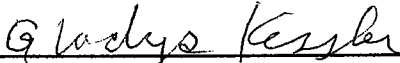
Furthermore, Rule 24(a)(2) requires that the cognizable interest of the applicant for intervention will be impaired or impeded if intervention is denied. Given the present posture of this Motion, the answer to that question is related to the fourth requirement of Rule 24(a), namely that no party in the action can be an adequate representative of the applicant's interests. As Apotex emphasizes, it need only "show[] that representation of [its] interest 'may be' inadequate; and the burden of making that showing should be treated as minimal." Trbovich v. United Mine Workers of Am., 404 U.S. 528, 538 n.10 (1972). Because Apotex's specific financial interest in the grant or denial of Eagle's orphan drug exclusivity is not an interest shared by the general public, the Federal Defendants are not in a position to adequately represent Apotex's interests. See Apotex Inc. v. U.S. Food & Drug Admin., 508 F. Supp. 2d 78, 80 n.2 (D.D.C. 2007). The Court recognizes that if Eagle prevails on the merits in the case and the Federal Defendants elect not to appeal, Apotex would have no appeal in which to intervene at a later date. See Reply at 5.

Accordingly, the Court finds that Apotex has sufficiently demonstrated that it may intervene as a right pursuant to Rule 24(a)(2).²

III. CONCLUSION

For the foregoing reasons, Apotex's Motion to Intervene shall be **granted**. An Order shall accompany this Memorandum Opinion.

August 30, 2017



Gladys Kessler
United States District Judge

Copies to: attorneys on record via ECF

² Because the Court concludes that Apotex may intervene as a right, it need not consider Rule 24(b)'s permissive intervention standards.