IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

TEVA PHARMACEUTICALS USA, INC., *et al.*,	)	
Plaintiffs,	)	
v.	)	Case No. 1:20-cv-00808 (BAH)
UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*,	)	
Defendants.	)	

MEMORANDUM IN SUPPORT OF UNOPPOSED
MOTION TO INTERVENE BY SANDOZ INC.

Sandoz Inc. ("Sandoz") respectfully submits this memorandum of law in support of its motion to intervene as a defendant. Sandoz seeks to intervene in this case because the relief sought by plaintiffs Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. (collectively, "Teva") would significantly impact Sandoz's own rights with respect to its competing generic products. Specifically, Teva seeks, among other things, a declaration that its glatiramer acetate product, sold under the brand name Copaxone®, is a "biological product" under the Public Health Services Act ("PHSA"), as amended by the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), and that its approved New Drug Application ("NDA") for Copaxone® is deemed a license for a biological product under the PHSA. Sandoz is the holder of two approved Abbreviated New Drug Applications ("ANDAs") for competing generic versions of Copaxone®—more affordable and automatically-substitutable medicines that Sandoz makes available to thousands of multiple sclerosis ("MS") patients that need them. Sandoz's commercial and regulatory rights in its ANDAs, and just as critically, patient access to this more affordable medicine, could be significantly affected by the outcome of this case.

Where, as here, one company seeks to impose barriers to competition by reversing lawful Agency action, courts routinely allow intervention by companies seeking to intervene to protect their legal and economic interests. *See, e.g.*, *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1078-79 (D.C. Cir. 2001); *Otsuka Pharm. Co. v. Burwell*, 302 F. Supp. 3d 375, 388 (D.D.C. 2016); *Biovail Corp. v. FDA*, 519 F. Supp. 2d 39, 43 (D.D.C. 2007); *Pfizer Inc. v. Shalala*, 1 F. Supp. 2d 38, 39 (D.D.C. 1998); *Eagle Pharm., Inc. v. Price*, 322 F.R.D. 48, 49-50 (D.D.C. 2017); *Apotex Inc. v. FDA*, 508 F. Supp. 2d 78, 80 n.2 (D.D.C. 2007). Sandoz has a considerable interest in the subject matter of this action that may not be adequately represented by the government defendants, U.S. Food and Drug Administration ("FDA"), Stephen M. Hahn, U.S. Department of Health and Human Services, and Alex M. Azar, II, (collectively, "Federal Defendants"), who have no commercial interest in the outcome. Therefore, the Court should grant Sandoz's timely motion to intervene as of right under Rule 24(a).

In the alternative, the Court should grant permissive intervention to Sandoz under Rule 24(b) because Sandoz's interests are implicated by Teva's action, and Sandoz's involvement would not prejudice the interests of any existing parties in the case. In particular, Sandoz's intervention would not delay this action because Sandoz will agree to follow the Scheduling Order previously entered by the Court and will file its cross motion for summary judgment, any opposition to Plaintiffs' motion, and reply on the same dates as the Federal Defendants. Sandoz also respectfully requests that, if intervention is granted, the Court waive the requirement of Local Civil Rule 7(j) and permit Sandoz to file its answer to the complaint on the same date as the Federal Defendants, *i.e.*, if this case is not resolved on cross-motions for summary judgment, twenty-one (21) days after the Court issues its summary-judgment ruling. (*See* Apr. 9, 2020 Minute Order).

Pursuant to Local Civil Rule 7(m), counsel for Sandoz conferred with counsel for Teva and the Federal Defendants regarding the relief sought in this motion. The Federal Defendants take no position on Sandoz's motion. Teva does not oppose Sandoz's motion to intervene, provided that Sandoz agrees to the existing schedule. As noted above, Sandoz has agreed to intervene on this basis. Accordingly, Sandoz's motion to intervene is unopposed and should be granted.

ARGUMENT

Federal Rule of Civil Procedure 24 governs motions to intervene. This Rule allows "an absentee [to] be joined so that he may protect his interest which as a practical matter may be substantially impaired by the disposition of the action." FED. R. CIV. P. 24, advisory committee's note to 1966 amendment. Rule 24(a) provides for intervention as a matter of right, while Rule 24(b) allows permissive intervention. As explained below, Sandoz has the right to intervene in this action under Rule 24(a)(2). But, even if the Court finds Sandoz does not have the right to intervene under Rule 24(a)(2), the Court should permit Sandoz to intervene under Rule 24(b) based on the common issues of law and fact that Sandoz has identified with respect to the present action.

I. SANDOZ SHOULD BE PERMITTED TO INTERVENE AS A MATTER OF RIGHT UNDER RULE 24(a)(2).

Federal Rule of Civil Procedure 24(a)(2) states:

> (a) On timely motion, the court must permit anyone to intervene who . . .
>
> (2) claims an interest relating to the property or transaction that is the subject of the action, and is so situated that disposing of the action may as a practical matter impair or impede the movant's ability to protect its interest, unless existing parties adequately represent that interest.

FED. R. CIV. P. 24 (a)(2). In the D.C. Circuit, a non-party has a right to intervene if: (1) the motion to intervene was timely; (2) the applicant claims an interest relating to the property or transaction that is the subject of the action; (3) the applicant is so situated that the disposition of the action may as a practical matter impair or impede the applicant's ability to protect that interest; and (4) the applicant's interest is not adequately represented by existing parties. *See Fund for Animals, Inc. v. Norton*, 322 F.3d 728, 731 (D.C. Cir. 2003) (citations omitted); *see also Jones v. Prince George's Cty.*, 348 F.3d 1014, 1017 (D.C. Cir. 2003) (listing the four elements of Rule 24(a) as "timeliness, interest, impairment of interest, and adequacy of representation"). Sandoz satisfies each of the requirements for intervention under Rule 24(a)(2).

A. Sandoz's Motion to Intervene Is Timely.

This case has been pending for less than one month and Sandoz's timely motion will not delay the proceedings.

Teva filed its complaint on March 24, 2020. (D.I. 1). On April 9, 2020, the Court granted the parties' Joint Motion for Scheduling Order, setting forth a briefing schedule for the parties to file cross motions for summary judgment, and ordering the Federal Defendants to file an answer to Teva's complaint twenty-one (21) days after the Court issues its summary judgment ruling, if the case is not resolved by virtue of the Court's ruling. Sandoz thereafter promptly notified the parties of its intention to intervene and conferred with counsel for both Teva and the Federal Defendants as required by Local Civil Rule 7(m).

Sandoz's intervention will not delay the proceedings. If permitted to intervene, Sandoz will adhere to the existing scheduling order, will file its motion papers on the same dates as the Federal Defendants, and will coordinate with the Federal Defendants whenever possible.

Accordingly, Sandoz's motion is timely and will not delay these proceedings or otherwise prejudice any parties.

B. Sandoz Has a Substantial Interest in the Subject Matter of this Litigation.

Teva's complaint seeks to force FDA to convert Teva's NDA for Copaxone® into a deemed license under a Biologics License Application ("BLA") and place Copaxone® on the final list of "Approved NDAs for Biological Products That Will Be Deemed to Be BLAs." Teva's requested relief could similarly force FDA to convert all ANDAs and NDAs filed under 21 U.S.C. § 355(b)(2) referencing Copaxone® as the reference listed drug, such as Sandoz's ANDAs, into BLAs as well. (*See* Further Consolidated Appropriations Act, 2020, Pub. L. No. 116-94, § 607(2)(B)(iii), 133 Stat. 2534, 3127-28 (2019) ("Appropriations Act")). Sandoz therefore maintains a substantial interest in the subject matter of this litigation—indeed, an interest that is just as substantial as Teva's own interest.

Teva's argument hinges on a dispute over FDA's interpretation and application of 42 U.S.C. § 262, which defines the term "biological product" to include, *inter alia*, a "protein" or "analogous product," and FDA's own rulemaking which further defines the term "protein." 42 U.S.C. § 262(i)(1); *see also* 21 C.F.R. § 600.3(h)(6). Specifically, Teva alleges that its Copaxone® product is a "protein," or at the very least an "analogous product," and therefore a "biological product" under the statute. Teva thus argues that its Copaxone® NDA should have been "deemed to be a license" under the transition rules of the BPCIA. (D.I. 1). But, to date, FDA has not transitioned Teva's NDA to a licensed BLA.

Sandoz has significant, cognizable interests in the subject matter of this action, both from a regulatory and commercial standpoint. Sandoz has been marketing its approved generic glatiramer acetate products for years. FDA approved Sandoz's ANDA for a 20 mg/mL glatiramer acetate product on April 16, 2015, and Sandoz launched that competing, more affordable generic product two months later on June 18, 2015. A few years later, FDA approved Sandoz's ANDA for a 40 mg/mL glatiramer acetate product on February 12, 2018, and Sandoz

launched that generic product immediately thereafter as well. Sandoz, moreover, has already spent more than *10 years* defending itself against patent infringement lawsuits brought by Teva—including claims involving process patents—each time achieving a successful outcome allowing it to enter and stay on the market to provide MS patients with immediate access to more affordable glatiramer medicines. *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335 (Fed. Cir. 2015); *Teva Pharm. USA, Inc. v. Sandoz Inc.*, 906 F.3d 1013 (Fed. Cir. 2018).

How FDA interprets the BPCIA and applies the transition rules to products previously approved under NDAs has a direct effect on Sandoz, as Sandoz's own applications will also be subject to any potential transition under the statute. More plainly, if FDA is forced to transition Teva's NDA to a licensed BLA, FDA would be expected to similarly transition Sandoz's glatiramer acetate ANDAs to BLAs, and Sandoz's own applications would thereafter be governed by the statutory provisions of the PHSA (42 U.S.C. § 262) instead of the Federal Food, Drug, and Cosmetic Act ("FFDCA") under 21 U.S.C. § 355(j). (*See* Appropriations Act at § 607(2)(B)(iii)). This, in turn, could have a marked impact on Sandoz's rights in its ANDAs, and patient access to these generic products, as explained below.

C. Sandoz's Interests Will Be Affected by the Disposition of this Action.

Sandoz's interests in maintaining the approval of its ANDAs under the FFDCA and continuing to market its generic glatiramer acetate products under such ANDAs may be severely affected by the disposition of this action. *First*, as noted above, if Teva's requested relief is granted, Sandoz's applications would no longer be expected to be governed by the approval and marketing requirements under the FFDCA; instead, they would be governed by a distinctly different set of requirements governing so-called "biosimilar" or "interchangeable biosimilar" products under the PHSA. *Second*, Teva's requested relief would cause significant commercial

harm to Sandoz, as well as harm to the MS patients that rely on Sandoz's more affordable generic products. Any or all of these interests justify intervention as of right.

By virtue of FDA's approval of Sandoz's glatiramer acetate ANDA products as therapeutically equivalent to Copaxone®, Sandoz's generic products may be automatically substituted at the pharmacy for Copaxone®. *Bristol-Myers Squibb Co. v. Shalala*, 892 F. Supp. 295, 296 (D.D.C. 1995) (noting that a therapeutic equivalence rating "allows pharmacists to substitute the generic version of the [drug] for the original product"); *see also Warner-Lambert Co. v. Shalala*, 202 F.3d 326, 327-28 (D.C. Cir. 2000) (acknowledging that drugs that are not considered "therapeutically equivalent" to the referenced brand drug "cannot take advantage of state pharmacy laws that deem such products substitutable"). This ability to be substituted for the branded counterpart is critical not only to a generic product's success, but for patient access at the pharmacy as well. *Warner-Lambert*, 202 F.3d at 328 ("Substitutability is competitively important."); *see also Meijer, Inc. v. Warner Chilcott Holdings Co.*, 246 F.R.D. 293, 297 (D.D.C. 2007) (noting that "almost all states and the District of Columbia encourage generic competition through laws that allow pharmacists to substitute brand-name drugs with their AB-rated generic equivalents, unless a physician directs or the patient requests otherwise").

Biosimilar products, on the other hand, do not enjoy the same market advantages as therapeutically equivalent ANDA products. As Teva readily admits, "a biosimilar cannot be *substituted* for a reference product 'without the intervention of the health care provider who prescribed the reference product,' unless FDA takes the further step of deeming the biosimilar to be 'interchangeable.'" (D.I. 1, at ¶ 35 (citing 42 U.S.C. § 262(i)(3)) (emphasis original)). To date, no interchangeable biosimilars have been approved by FDA. Thus, to the extent FDA were to transition Sandoz's ANDAs to BLAs, yet delay in making an interchangeability determination

with respect to Sandoz's glatiramer acetate products, Sandoz would lose its ability to compete effectively in the market with Copaxone®. And just as critically, MS patients would be deprived of automatic substitution at the pharmacy for a more affordable generic alternative. For these reasons, Sandoz's interests, and the interests of MS patients and payors, will be directly and economically affected by the disposition of this action.

D. The Current Parties Do Not Adequately Represent Sandoz's Interests.

Finally, the existing parties cannot adequately represent Sandoz's interests, and therefore, intervention under Rule 24(a)(2) is warranted. *See Trbovich v. United Mine Workers of Am.*, 404 U.S. 528, 538 n.10 (1972) ("The requirement of the Rule is satisfied if the applicant shows that representation of his interest 'may be' inadequate; and the burden of making that showing should be treated as minimal."). Teva's interests in this litigation are directly adverse to Sandoz's. The Federal Defendants have no economic interest in this matter and likely must weigh their own interests in responding to Teva's action, such as enforcing the FFDCA and PHSA and their own regulations. Sandoz, moreover, has no assurance that any of the Federal Defendants will consider Sandoz's commercial interests or seek to protect against the potentially significant economic losses Sandoz will suffer. Moreover, if it cannot intervene, Sandoz may lose the opportunity to appeal this Court's decision or to participate in any appeal. Only by participating in this case can Sandoz ensure that its interests are protected.

II. ALTERNATIVELY, SANDOZ SHOULD BE PERMITTED TO INTERVENE UNDER RULE 24(b).

Should the Court conclude that Sandoz is not entitled to intervene as a matter of right under Rule 24(a)(2), Sandoz respectfully requests this Court's permission to intervene under Rule 24(b). Permissive intervention is warranted upon a timely motion where the movant "has a claim or defense that shares with the main action a common question of law or fact." FED. R.

CIV. P. 24(b)(1)(B). As set forth above, Sandoz's timely motion to intervene will not delay the proceedings. Further, Sandoz has raised a common question of law and/or fact in its interest in having its ANDA continue to be governed under the statutory framework of the FFDCA rather than the PHSA. Whether FDA is forced to deem Copaxone® (and any generic equivalents) licensed under a BLA bears directly on Sandoz's two approved ANDAs. Accordingly, Sandoz requests that this Court, at a minimum, allow it to intervene permissively in this action.

III. CONCLUSION.

For the foregoing reasons, Sandoz respectfully requests that the Court grant its motion to intervene as a defendant in this action.

Dated: April 17, 2020

Respectfully submitted,

By: */s/ William A. Rakoczy*

William A. Rakoczy
D.C. Bar No. 489082
Lara E. FitzSimmons
Rachel P. Waldron
Trang H. Lin
Chris P. Galligan
RAKOCZY MOLINO MAZZOCHI SIWIK LLP
6 West Hubbard Street, Suite 500
Chicago, IL 60654
(312) 222-6301
(312) 222-6321 (facsimile)
wrakoczy@rmmslegal.com
lfitzsimmons@rmmslegal.com
rwaldron@rmmslegal.com
tlin@rmmslegal.com
cgalligan@rmmslegal.com

Counsel for Proposed Intervenor-Defendant, Sandoz Inc.