

**UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF MISSISSIPPI
NORTHERN DIVISION**

GENBIOPRO, INC.

PLAINTIFF

V.

CIVIL ACTION NO. 3:20-CV-00652-HTW-LGI

**DR. THOMAS DOBBS, STATE HEALTH OFFICER
OF THE MISSISSIPPI DEPARTMENT OF HEALTH,
IN HIS OFFICIAL CAPACITY**

DEFENDANTS

**GENBIOPRO, INC.’S MEMORANDUM IN SUPPORT OF ITS
MOTION FOR LEAVE TO FILE AMENDED COMPLAINT**

Pursuant to Federal Rule of Civil Procedure 15(a)(2) and Local Rule 15, Plaintiff, GenBioPro, Inc. (“GBP”), seeks leave to file its Proposed Amended Complaint (“PAC”) to add allegations related to Mississippi’s “Trigger Law,” MISS. CODE ANN. § 41-41-45, which went into effect on July 7, 2022.

Under Rule 15 a “court should freely give leave [to amend pleadings] when justice so requires[.]” which it does here. Fed. R. Civ. P. 15(a)(2). As explained below, the Mississippi Trigger Law effectively bans nearly all abortions in Mississippi, including medicated abortions. That ban prevents GBP from selling its product in Mississippi and prevents access to a medication that the Food and Drug Administration (“FDA”), after exhaustive review, has deemed safe and effective.

Although GBP’s claims remain the same, GBP did not directly address the Trigger Law—which was not in effect at the time—in its original Complaint. GBP thus seeks leave to timely address the recent change in Mississippi’s abortion regulations.

I. BACKGROUND

GBP filed its Complaint on October 9, 2020 (ECF No. 1). GBP's Complaint, as filed, challenged Mississippi's laws that restrict access to mifepristone, including the Women's Health Defense Act of 2013, S.B. 2795, 2013 Reg. Sess. (Miss. 2013) (codified as amended at MISS. CODE ANN. §§ 41-41-101–117), and other then-existing regulations governing who may prescribe mifepristone and under what conditions.

In response, on November 6, 2020, Defendant moved to dismiss GBP's claims pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6). Def.'s Mot. to Dismiss (Nov. 6, 2020), ECF No. 8. The Court heard oral argument on Defendant's Motion to Dismiss on March 25, 2021 and June 8, 2022. Discovery was stayed pending the resolution of the motion to dismiss, Order Staying Disc. & Case Mgmt. Conf. (Nov. 18, 2020), ECF No. 11, and the Parties have not yet engaged in a Case Management Conference or discussed a proposed Scheduling Order.

A. Mississippi Trigger Law

In 2007, the State of Mississippi passed a trigger law, which established a path to ban all abortions in the state if the Supreme Court overruled *Roe v. Wade*, 410 U.S. 113 (1973). *See* MISS. CODE ANN. § 41-41-45. On July 7, 2022, in the wake of the Supreme Court's ruling in *Dobbs v. Jackson Women's Health Organization*, No. 19-1392, 579 U.S. ____ (2022), the law went into effect. The Trigger Law provides that “[n]o abortion shall be performed or induced in the State of Mississippi, except . . . where necessary for the preservation of the mother's life or where the pregnancy was caused by rape.” MISS. CODE ANN. § 41-41-45(2).

The Trigger Law defines abortion as “the use or prescription of any instrument, medicine, drug or any other substance or device to terminate the pregnancy of a woman. . . .” *Id.* § 41-41-45(1). Thus, except in rare circumstances, the Trigger Law bans prescribing mifepristone for its FDA-approved use to terminate an early pregnancy.

B. Proposed Amendment to Plaintiff's Complaint

GBP alleged in its Complaint that certain Mississippi laws and regulations, including the Women's Health Defense Act of 2013, are unconstitutional. Specifically, GBP alleged that the Mississippi laws violate the Supremacy Clause, U.S. CONST. art. VI, cl. 2, and the Commerce Clause, U.S. CONST. art. I, § 8, cl. 3, because they impose restrictions on who may prescribe mifepristone and under what circumstances, which conflict with the FDA's approved regimen and Risk Evaluation and Mitigation Strategy for mifepristone. Now, GBP seeks to amend its Complaint in order to include allegations related to the Mississippi Trigger Law, its impact on GBP's ability to sell mifepristone in Mississippi, and the conflict the Trigger Law amplifies between Mississippi's regulations and the FDA's intended access to and approved regimen for mifepristone.

The PAC incorporates allegations related to the Trigger Law, support for which is based on the facts and legal theories already pleaded in GBP's Complaint. The PAC neither removes any of the allegations already in GBP's Complaint nor changes any of the issues or theories of liability pleaded in the Complaint.

Along with its Trigger Law allegations, GBP's PAC includes minor amendments to reflect changes to the FDA's approved regimen for mifepristone that the FDA has stated are forthcoming. As of April 2021, the FDA no longer requires mifepristone to be dispensed in-person, and GBP's PAC accounts for that change. GBP has also included information related to its Prescriber Agreement with Planned Parenthood Southeast, Inc., which was previously submitted in a letter to the Court following the March 25, 2021 hearing. U. Gwyn Williams Letter to Hon. Henry T. Wingate (Apr. 1, 2021), ECF No. 18.

II. ARGUMENT

Federal Rule of Civil Procedure 15(a)(2)’s liberal standard warrants granting GBP leave to amend. Pursuant to Rule 15(a)(2), when justice so requires, “[t]he court should freely give leave” to allow a party to amend its pleading. As Rule 15(a)(2) “evinces a bias in favor of granting leave to amend[,]” *Carroll v. Fort James Corp.*, 470 F.3d 1171, 1175 (5th Cir. 2006) (quoting *Dussouy v. Gulf Coast Inv. Corp.*, 660 F.2d 594, 597–98 (5th Cir. 1981)), “District Courts therefore need a substantial reason to deny a party the opportunity to amend.” *Courson v. Cordis Corp.*, No. 3:17-cv-00186, 2018 WL 3058867, at *4 (N.D. Miss. June 20, 2018) (citing *Smith v. EMC Corp.*, 393 F.3d 590, 595 (5th Cir. 2004)). Courts are to consider five factors when deciding whether leave should be granted: (1) undue delay; (2) bad faith or dilatory motive; (3) repeated failure to cure deficiencies by previous amendments; (4) undue prejudice to the opposing party; and (5) futility of the amendment. *Rozenzweig v. Azurix Corp.*, 332 F.3d 854, 864 (5th Cir. 2003) (citing *Foman v. Davis*, 371 U.S. 178, 182 (1962)).

None of the factors that could warrant denying GBP’s Motion are present here: GBP has not engaged in undue delay, bad faith, or repeated amendments, Defendant will not be prejudiced by GBP’s PAC, and GBP’s PAC is not futile. Accordingly, the Court should grant GBP’s Motion for Leave to Amend its Complaint.

First, GBP’s motion is timely. GBP informed the Court that it would seek leave to amend before the Trigger Law went into effect. As of the Court-ordered deadline for this filing, Order (July 11, 2022), ECF. No. 37, the Trigger Law has been in effect for two weeks.

Second, GBP cannot be accused of acting in bad faith: the recent change in Mississippi’s abortion regulations was entirely outside GBP’s control.

Third, GBP has not previously sought to amend its Complaint. GBP seeks only to amend its Complaint now so that its pleadings accurately reflect the full extent of the Mississippi laws that restrict access to GBP's product.

Fourth, GBP's PAC will not prejudice Defendant. This litigation is still only at the pleading stage and the Trigger Law implicates the same legal issues as those already raised in GBP's Complaint. The Parties have not yet participated in a Case Management Conference, engaged in any discovery, or even begun to deal with the merits of GBP's claims. *See Courson*, 2018 WL 3058867, at *5 ("Importantly, allowing Plaintiff to amend her complaint would not prejudice Defendant because the Court has yet to set any deadlines in this case."). If GBP is granted leave to amend, the same issues—whether GBP has standing and whether GBP has adequately pleaded its preemption and Commerce Clause claims—would remain before the Court on Defendant's Motion to Dismiss.

Finally, as to futility, GBP's motion to amend is not futile because, like GBP's Complaint, the PAC sets forth a full and thorough factual basis for GBP's preemption and Commerce Clause claims that meets the requirements of Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6). An amendment is only considered futile if "the amended complaint would fail to state a claim upon which relief could be granted." *Stripling v. Jordan Prod. Co., LLC*, 234 F.3d 863, 873 (5th Cir. 2000) (collecting cases). "If a proposed amendment is not *clearly* futile, then denial of leave to amend is improper." *Moore v. Dallas Indep. Sch. Dist.*, 557 F. Supp. 2d 755, 759 (N.D. Tex. 2008) (emphasis in original) (quoting 6 CHARLES ALAN WRIGHT, ARTHUR R. MILLER & MARY KAY KANE, FEDERAL PRACTICE AND PROCEDURE § 1487 (2d ed. 1990)), *aff'd*, 370 F. App'x 455 (5th Cir. 2010).

GBP's proposed amendments are not futile. In its PAC, GBP pleads that the Trigger Law operates as a de facto ban on mifepristone and renders it essentially impossible for GBP to operate in Mississippi. Though GBP maintains that its Complaint sufficiently pleaded both standing and GBP's preemption and Commerce Clause claims, the near-total ban on medicated abortion makes GBP's standing, preemption, and Commerce Clause claims all the more clear. Indeed, while Defendant argued that GBP's alleged, pre-ban injury was "speculative," when asked if a ban with criminal penalties would manifest a different approach to standing, Defendant informed this Court that a "ban would make it a different case . . . the complete inability to enter the market per se . . . may change the calculus" for standing. *See* Tr. of Mot. to Dismiss Hr'g (via Zoom) ("Mot. to Dismiss Hr'g") at 34:3–6 (June 8, 2022).

Similarly, as to Plaintiff's substantive allegations, though the merits are not yet at issue, the Parties have repeatedly argued the significance of *Zogenix, Inc. v. Patrick*, in which the Massachusetts district court found that a state ban of an FDA-approved product was preempted by federal law. No. 14-11689, 2014 WL 1454696, at *1–2 (D. Mass. Apr. 15, 2014). Defendant has attempted to distinguish *Zogenix* on the grounds that *Zogenix* concerned a complete ban, whereas Defendant argued the Mississippi regulations do not constitute a ban. *See, e.g.*, Mot. Hr'g Tr. at 13:8–25 (Mar. 25, 2021), ECF No. 28 (counsel for Defendant arguing, "[n]ow, the main point about *Zogenix* that is important here is that Mississippi law does not ban the use of mifepristone, nor do Mississippi laws constitute a de facto ban on the use of mifepristone."); Mot. to Dismiss Hr'g at 33:9–17 (counsel for Defendant stating, "the hypothetical of a ban is inapposite here, so that really should carry no weight. There is no ban here. And at issue in the *Zogenix* case itself was the Court was considering whether the Massachusetts regulation was a ban or not a ban. . . . So to conflate a ban with Mississippi's regulations is simply an inapt hypothetical").

The ban is no longer hypothetical: the Trigger Law prohibits the use of mifepristone to terminate a pregnancy in all but the narrowest of circumstances. The ban forecloses GBP from selling its product in Mississippi and creates an even more stark conflict with the FDA's approved regimen for mifepristone. GBP's allegations are thus fortified by the Trigger Law and justice warrants that GBP be granted leave to amend its Complaint to include such allegations.

Fundamentally, though GBP's legal arguments remain the same, judicial economy will be served if the Court is able to consider the impact of the de facto medicated abortion ban when it rules on Defendant's motion to dismiss. GBP seeks only to ensure that the Trigger Law is squarely included in its allegations, given its significance for GBP's claims.

III. CONCLUSION

For the foregoing reasons, GBP respectfully requests that this Court grant GBP leave to file its Amended Complaint.

Dated: July 21, 2022

Respectfully submitted,

GENBIOPRO, INC.

By Its Attorneys,

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CERTIFICATE OF SERVICE

I certify that I have this day electronically filed the foregoing with the Clerk of the Court using the ECF system which served a copy upon all counsel of record who have registered with that system.

This the 21st day of July, 2022.

/s/ J. Carter Thompson, Jr.

J. CARTER THOMPSON, JR.