IN THE
SUPREME COURT OF THE UNITED STATES

No. 22A846

SHIRE US INC; SHIRE LLC,

Applicants,

v.

MARK BLACKBURN,

Respondent.

APPLICATION TO THE HON. JUSTICE CLARENCE THOMAS FOR A SECOND EXTENSION OF TIME WITHIN WHICH TO FILE A PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

Pursuant to Supreme Court Rule 13(5), Shire US Inc and Shire LLC[1] ("Applicants") hereby move for an additional extension of time of 30 days, up to and including June 4, 2023, for the filing of a petition for a writ of certiorari. Unless an extension is granted, the deadline for filing the petition for certiorari will be May 5, 2023.

In support of this request, Applicants state as follows:

1. The United States Court of Appeals for the Eleventh Circuit rendered its decision on November 7, 2022 (Exhibit 1) and denied a timely petition for rehearing on January 5, 2023 (Exhibit 2). Applicants filed an application to extend

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[1] In July 2020, Shire US Inc and Shire LLC merged into Takeda Pharmaceuticals U.S.A., Inc.

the time to file a petition by 30 days on March 21, 2023, and Justice Thomas granted that extension on March 29, 2023. This Court has jurisdiction under 28 U.S.C. §1254(1).

2. This case concerns whether federal law preempts a state-law failure-to-warn claim that implicates the "Highlights" section of a prescription pharmaceutical drug label. The Highlights section of a drug label contains important information for prescribing the drug safely and effectively, *see* 21 C.F.R. §201.57(a), and the FDA requires drug manufacturers to obtain agency approval before making any changes to that section, *see id.* §314.70(b)(2)(v)(C) (identifying "[a]ny change to the information required by §201.57(a)" as one of the "[c]hanges requiring supplement submission and approval prior to distribution of the product made using the change"). Accordingly, if a plaintiff brings a state-law claim asserting that a drug manufacturer had a state-law duty to independently change the Highlights section, that claim is squarely preempted. *See, e.g.*, *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 623-24 (2011) (preemption exists "when a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency").

3. Applicants manufacture Lialda, a drug indicated for the induction of remission in patients with active, mild to moderate ulcerative colitis and for the maintenance of remission of ulcerative colitis; in 2016, Mark Blackburn ("Respondent") sued Applicants, alleging that he developed kidney disease after he was prescribed Lialda to treat Crohn's disease. Ex. 1 at 2. Respondent asserted a

state-law cause of action claiming that he would not have developed kidney disease if Applicants had independently altered the Highlights section of Lialda's label to include different warnings from those approved by the FDA, and Applicants subsequently sought summary judgment on federal preemption grounds. *See* Ex. 1 at 2, 8.

4. In the decision below, the Eleventh Circuit found that Respondent's state-law failure-to-warn cause of action is not preempted. Although the court acknowledged that 21 C.F.R. §314.70(b)(2)(v)(C) "requires a supplement for '[a]ny change to the information required by' the Highlights section," it concluded that this case turns on 21 C.F.R. §314.70(b)(2)(v)(A), which "exempts" from the prior-approval requirement "'[c]hanges in labeling … described in'" 21 C.F.R. §314.70(c)(6)(iii)—also known as the "changes-being-effected" regulation. Ex. 1 at 8. In the court's view, under the changes-being-effected regulation and without obtaining prior FDA approval, Applicants could have "add[ed] or strengthen[ed] an instruction" on Lialda's label "about dosage and administration." Ex. 1 at 8. As the court failed to recognize, however, the changes-being-effected regulation expressly states that it does *not* apply—and thus prior FDA approval remains necessary—when changes to the Highlights section are at issue. *See* 21 C.F.R. §314.70(c)(6)(iii) ("The agency may designate a category of changes for the purpose of providing that, in the case of a change in such category, the holder of an approved NDA may commence distribution of the drug product involved upon receipt by the agency of a supplement for the change. These changes include, but are not limited to … [c]hanges in the labeling to

reflect newly acquired information, *except for changes to the information required in §201.57(a) of this chapter* [the regulation governing the Highlights section of a drug's label] *(which must be made under paragraph (b)(2)(v)(C) of this section* [the regulation requiring a pre-approval supplement to change a drug's label])" (emphasis added)).

5. The Eleventh Circuit's decision thus is plainly wrong and inconsistent with this Court's precedent, as commentators have recognized. *See, e.g.*, James M. Beck, *Blackburn—That's Just Plain Wrong* (Dec. 19, 2022), https://bit.ly/3TlFWs4. That decision, moreover, will have far-reaching consequences, as it will compel drug manufacturers to make potentially risky changes to the Highlights sections of drug labels and will expose drug manufacturers to meritless state-law claims that are clearly preempted.

6. Applicants recently retained the undersigned counsel to prepare a petition for certiorari, and because counsel was not involved in the proceedings below, additional time is needed to fully examine the record and research the legal issues presented in this case.

7. Undersigned counsel also has substantial briefing obligations in other matters between now and the current due date of the petition, including a reply brief in support of a motion to dismiss in *Smartmatic USA Corp. v. Fox Corp.*, No. 151136/2021 (N.Y. Sup. Ct.) (due April 30, 2023); a response brief in *National Shooting Sports Found. v. Att'y Gen of N.J.*, No. 23-1214 (3d Cir.) (due May 1, 2023); and a reply brief in support of a motion to reargue in *Smartmatic USA Corp. v. Fox Corp.*, No. 2022-01291 (N.Y. App. Div.) (due May 5, 2023).

8. Applicants therefore request a modest second extension to allow for the preparation of a petition that fully addresses the important and far-reaching issues raised by the decision below.

WHEREFORE, for the foregoing reasons, Applicants request that an extension of time up to and including June 4, 2023, be granted within which Applicants may file a petition for a writ of certiorari.

Respectfully submitted,

ERIN E. MURPHY
Counsel of Record
CLEMENT & MURPHY, PLLC
706 Duke Street
Alexandria, VA 22314
(202) 742-8900
erin.murphy@clementmurphy.com
Counsel for Applicants

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