No. _____

In the Supreme Court of the United States

ASTRAZENECA PHARMACEUTICALS LP; ASTRAZENECA AB,

Applicants,

v.

SECRETARY UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ADMINISTRATOR CENTERS FOR MEDICARE & MEDICAID SERVICES.

APPLICATION FOR AN EXTENSION OF TIME TO FILE A PETITION FOR A WRIT OF CERTIORARI

To the Honorable Samuel Alito, Associate Justice of the Supreme Court of the United States and Circuit Justice for the United States Court of Appeals for the Third Circuit:

1. Pursuant to Supreme Court Rule 13.5 and 28 U.S.C. § 2101(c), Applicants AstraZeneca Pharmaceuticals LP and AstraZeneca AB (collectively, AstraZeneca) respectfully request a 45-day extension of time, to and including September 20, 2025, within which to file a petition for a writ of certiorari. The United States Court of Appeals for the Third Circuit issued an opinion on May 8, 2025. A copy of the opinion is attached as Exhibit A. This Court's jurisdiction would be invoked under 28 U.S.C. § 1254(1).

2. Absent an extension, a petition for a writ of certiorari would be due on August 6, 2025. This application is being filed more than ten days before that date, and no prior application has been made in this case.

3. AstraZeneca is a world-leading pharmaceutical company that creates medicines to treat serious diseases. AstraZeneca aims to provide patients with access to its medications today, and to continue funding innovative, life-saving medical advancements for tomorrow. That life-saving and innovative work requires tremendous investment: AstraZeneca spends billions on research and development, and any given drug can take years to develop before it is approved—if it is approved at all. As a result of that investment and those attendant risks, AstraZeneca has received numerous patents that protect its innovations. Those patents, alongside regulatory exclusivity periods, allow AstraZeneca to recoup its investments based on the prevailing market-dictated price. Rigorous enforcement of patent rights and the ability to sell drugs at market prices is essential to the continued investment necessary to develop and market new drug products.

4. The government has upended this regime. In the Inflation Reduction Act of 2022 (IRA), Congress implemented the so-called "Drug Price Negotiation Program," a Medicare price-fixing regime that forces manufacturers like AstraZeneca to sell their patented drugs at government-dictated prices. See 42 U.S.C. § 1320f *et seq.* Under the Program, the Centers for Medicare & Medicaid Services (CMS) must identify and select a designated number of drugs each year for which to "negotiate" a price cap for prescription drugs dispensed to Medicare-eligible individuals. See *id.* § 1320f-1. Nothing about this "negotiation" mirrors a typical commercial negotiation over a product's sales price. For

starters, negotiation is mandatory: Manufacturers must sign an agreement by a date certain to participate in the negotiation process. See *id.* § 1320f-2. In addition, although the Program nominally allows CMS and the manufacturer to jointly determine the negotiated price, the statute directs CMS to "achieve the lowest maximum fair price for each selected drug." *Id.* § 1320f-3(b)(1).

5. Manufacturers that do not wish to participate in the Program are out of luck. Refusing to negotiate with CMS or to agree to CMS's offered price triggers a daily penalty beginning at 185% of the drug's price and quickly escalating to 1,900%. See Cong. Rsch. Serv., No. R47202, Tax Provisions in the Inflation Reduction Act of 2022 (H.R. 5376), at 4 tbl. 2 (Aug. 10, 2022); 26 U.S.C. § 5000D(a)-(b). There are only two ways to "suspen[d]" this oppressive penalty: A manufacturer can acquiesce to CMS's price or it can terminate "all applicable agreements" to sell every single one of its eligible drugs as part of Medicare and Medicaid, which would leave huge swaths of the country without access to any of the manufacturer's medications. 26 U.S.C. § 5000D(c).

6. To make matters worse, the IRA deprives manufacturers of any procedural protections. CMS need not go through notice-and-comment rulemaking, and there is no process for manufacturers to ask CMS to reconsider its decision to select a manufacturer's drug for "negotiation" under the Program or the price cap CMS has set. The IRA also expressly precludes "administrative or judicial review" of CMS's decision to select certain drugs for negotiation and CMS's offer price. 42 U.S.C. § 1320f-7.

7. AstraZeneca, which manufactures a drug that has been selected for price regulation under this regime, challenged the Program as violating AstraZeneca's due

process rights. AstraZeneca explained that the Program deprives AstraZeneca of its investment-backed patent rights and the right to sell its drug at market prices, without providing even the most rudimentary procedural safeguards.

8. The district court rejected AstraZeneca's claim. In its view, because participation in Medicare is voluntary, AstraZeneca does not have the right to control the prices it charges on patented drugs.

9. The Third Circuit affirmed. The panel recognized that "[t]he Due Process Clause protects property interests that are created and defined . . . by federal statute," and that "patent rights exist to permit greater profits during a product's exclusivity period to incentivize innovation." Ex. A at 19. But the court brushed aside AstraZeneca's interests in those patents on the theory that "[t]here is no protected property interest in selling goods" "at a market rate." *Ibid.* In so doing, the Third Circuit purported to distinguish this Court's decision in *Bowles* v. *Willingham*, which upheld a wartime rent-control statute against a due process challenge precisely because the statute allowed for judicial review. 321 U.S. 503, 519-522 (1944). That statute empowered the government to "fix maximum rents for housing accommodations in any . . . area where defense activities have resulted or threaten to result in an increase in the rents for housing accommodations." *Id.* at 512-513. A landlord challenged the statute under the Fifth Amendment, but this Court held that post-deprivation "judicial review" "satisfie[d] the requirements of due process." *Id.* at 520. Here, however, judicial review and other basic procedural protections are notably absent under the Program. Yet the Third Circuit deemed that immaterial on the theory that *Bowles* involved "private housing transactions," whereas the Program here supposedly "only sets

prices for drugs *that CMS pays for*." Ex. A at 20-21. But the Program is not a mere reimbursement schedule that determines how much the government will pay; in an exercise of coercive regulatory power, the Program caps the prices that AstraZeneca may charge private purchasers in commercial transactions to which the government is not a party.

10. This case raises an exceptionally important question warranting this Court's review: Whether the Drug Price Negotiation Program deprives manufacturers of interests in their patented drugs and the freedom to offer them at market prices that are protected by the Due Process Clause.

11. The answer to that question has significant implications for all segments of industry. The decision below jeopardizes the important rights that patents provide and, in turn, the innovation and development that patents incentivize. Equally concerning, the decision gives the government carte blanche to set prices without any procedural safeguards—not even judicial review—so long as it acts not only as a price regulator, but also as a market participant. That turns constitutional principles on their head; due process protections are *more* important in that scenario—not less. The Program at issue here is a perfect illustration: No ordinary market participant has the power to fine a private party into oblivion or to cut off access to the market if the property-holder refuses to participate in a price-fixing regime. Certiorari is warranted to restore the important property protections that patent-holders have traditionally enjoyed, and to make clear that the Due Process Clause applies when the government exercises sovereign authority to regulate private transactions, even if the government also exercises market power in other respects as well.

12. Applicants respectfully request an extension of time to file a petition for a writ of certiorari. Counsel was retained in this matter after the panel issued its decision, and a 45-day extension would allow counsel sufficient time to fully examine the decision's consequences, research and analyze the issues presented, and prepare the petition for filing. Additionally, the undersigned counsel has numerous other pending matters that would interfere with counsel's ability to file the petition on or before August 6, 2025.

13. *Wherefore*, Applicants respectfully request that an order be entered extending the time to file a petition for a writ of certiorari to and including September 20, 2025.

Dated: July 24, 2025

Respectfully Submitted,

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Supreme Court Rule 29.6, Applicants make the following disclosures: AstraZeneca Pharmaceuticals LP is a Delaware limited partnership. AstraZeneca Pharmaceuticals LP's general partner is AstraZeneca AB, a Swedish corporation. AstraZeneca Pharmaceuticals LP's sole limited partner is Zeneca Inc., a Delaware corporation. AstraZeneca PLC, a publicly-held company, is the ultimate parent company of AstraZeneca Pharmaceuticals LP, AstraZeneca AB, and Zeneca, Inc. No other publicly held company owns 10% or more of the voting interest in AstraZeneca Pharmaceuticals LP or AstraZeneca AB.

Dated: July 24, 2025

Allon Kedem

Counsel for Applicants