

**IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT**

ASTRAZENECA PHARMACEUTICALS, LP, *ET AL.*,

Plaintiffs-Appellants,

v.

No. 24-1819

XAVIER BECERRA, *ET AL.*,

Defendants-Appellees.

**CONSENT MOTION TO ENTER PROPOSED BRIEFING SCHEDULE
AND SET CASE FOR ARGUMENT ALONGSIDE
TWO RELATED APPEALS**

1. Pursuant to Federal Rules of Appellate Procedure 26(b) and 27, Plaintiffs-Appellants AstraZeneca Pharmaceuticals LP and AstraZeneca AB (collectively, AstraZeneca) hereby move this Court to modify the current briefing schedule to better align this case with the deadlines in two related appeals: *Bristol Myers Squibb Co. v. Becerra*, No. 24-1820 (3d Cir.) (“*BMS*”), and *Janssen Pharmaceuticals, Inc. v. Becerra*, No. 24-1821 (3d Cir.). AstraZeneca further moves this Court to set this case for argument on the same date as *BMS* and *Janssen*. The Government consents to these requests.

2. This case involves a challenge to the Medicare Drug Price Negotiation Program (the “Program”), which Congress enacted as part of the Inflation Reduction Act (IRA) in 2022. The statute sets forth a complex scheme that

requires manufacturers of certain drugs to “negotiate” with the Centers for Medicare & Medicaid Services (CMS) to set what the IRA refers to as a “maximum fair price” for their products. *See, e.g.*, 42 U.S.C. §§ 1320f(3), 1320f-2(a)(1); 1320f-3(a)(1). CMS has also imposed new, a-textual Program requirements through Guidance. *See CMS, Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2026* (June 30, 2023).

3. AstraZeneca’s drug FARXIGA[®] (dapagliflozin) has been selected for negotiation for initial price applicability year 2026. *CMS, Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026* (August 2023). By statute, AstraZeneca and the Government must reach an “agreement” by August 1, 2024, when the “negotiation period” ends. The Government will announce the “maximum fair price” it has established for FARXIGA by September 1, 2024, and the Government-dictated price will become effective on January 1, 2026. *See* 42 U.S.C. §§ 1320f(d), 1320f-1(a)(1).

4. AstraZeneca has no choice but to comply with these deadlines. Failure to accept the Government’s proffered “maximum fair price” by August 1 or to offer FARXIGA at the Government-mandated price by January 1, 2026 will expose AstraZeneca to draconian daily penalties based on its revenues for the drug. *See* 26 U.S.C. § 5000D(a)-(b).

5. In addition, AstraZeneca is making decisions now about research, development, and investments into new therapeutic treatment options for FARXIGA and other drug products. Those decisions would be impacted if AstraZeneca were to succeed on its claims in this appeal. *See* Decl. of Jim Ader, D. Ct. Dkt. 60.

6. AstraZeneca challenged CMS's Guidance as unlawful and arbitrary and capricious under the Administrative Procedure Act (APA). *See* D. Ct. Dkts. 16, 19. AstraZeneca also argued that the Program violates its Fifth Amendment procedural due process rights. *See id.* The District Court dismissed AstraZeneca's APA arguments for lack of standing and dismissed its due process claim on the merits. *See* D. Ct. Dkt. 70. AstraZeneca appealed.

7. Several other manufacturers whose drugs have been selected for negotiation for initial price applicability year 2026 have also challenged the Program on various grounds, including BMS and Janssen. BMS and Janssen asserted claims under the Fifth Amendment Takings Clause, the First Amendment, and the unconstitutional conditions doctrine, all of which the U.S. District Court for the District of New Jersey rejected. BMS and Janssen's appeals are currently pending before this Court in two consolidated cases. *See BMS*, No. 24-1820 (3d Cir.); *Janssen*, No. 24-1821 (3d Cir.).

8. This Court recently granted BMS’s and Janssen’s motion to “expedite the briefing, argument, and disposition of [their] consolidated appeals” in light of “the national importance and time-sensitivity of the issues presented” and entered the following briefing schedule:

Appellants’ Opening Brief due July 12, 2024

Government’s Response Brief due September 9, 2024

Appellants’ Reply Brief due October 2, 2024

Order, *BMS*, No. 24-1820, Dkt. 24 (3d Cir. May 23, 2024); *see* Mot. to Expedite 1, *BMS*, No. 24-1820, Dkt. 17 (3d Cir. May 15, 2024).

9. In light of the overlap between AstraZeneca’s appeal and BMS’s and Janssen’s appeals, and in aid of judicial economy, AstraZeneca respectfully requests that the Court modify the current briefing schedule to align the deadlines in this case with *BMS* and *Janssen* and to set all three cases for argument before the same panel, on the same day. Specifically, AstraZeneca requests that the briefing schedule be modified as follows:

Brief	Current Deadline	Proposed New Deadline	Extension Requested
Appellant’s Opening Brief	June 25, 2024	July 15, 2024	20 days
Government’s Response Brief	July 25, 2024	September 12, 2024	29 days
Appellant’s Reply Brief	August 15, 2024	October 7, 2024	4 days

AstraZeneca is likewise available to “appear for oral argument at the Court’s earliest convenience following the conclusion of briefing.” Mot. to Expedite 6, *BMS*, No. 24-1820, Dkt. 17.

10. Setting these three related cases for argument on the same day will benefit both the Court and the parties. It would allow one panel to resolve all three appeals, which involve overlapping issues arising under the same complex statutory scheme. Contemporaneous argument would also permit the Court to issue its decision in this case on the same timeline as in *BMS* and *Janssen*, ideally by early 2025. That would allow AstraZeneca ample time to pursue any further review and relief as necessary prior to January 1, 2026—the date on which the “negotiated price” for FARXIGA will become effective.

11. Good cause exists for extending AstraZeneca’s opening brief deadline. Over the next several weeks, Ms. Stetson, counsel of record, is occupied with briefing deadlines for a variety of matters, including: filing a reply in support of a petition for a writ of certiorari in *Brandon Council v. United States*, No. 23-953 (U.S.), on June 14; a petition for a writ of certiorari in *Sony Music Ent., et al. v. Cox Commc’ns, LLC, et al.*, No. 21-1168 (4th Cir.), on June 17; a response brief in *Sony Music Ent., et al. v. Cox Commc’ns, Inc.*, No. 22-1451 (4th Cir.), on June 21; and a brief in opposition in *Smith & Wesson Brands, Inc., et al. v. Estados Unidos Mexicanos*, No. 23-1141 (U.S.), on July 3.

12. Neither party has previously sought an extension of any briefing deadlines in this case.

For these reasons, AstraZeneca requests that this Court grant the consent motion, enter the proposed briefing schedule, and set this case for argument alongside *BMS* and *Janssen*.

May 31, 2024

Respectfully submitted,

/s/ Catherine Stetson

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1. This document complies with the type-volume limitation of Fed. R. App. P. 27(d)(2)(A) because it contains 1,031 words, exclusive of those items listed in Fed. R. App. P. 27(a)(2)(B) and Fed. R. App. P. 32(f).

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/s/ Catherine Stetson
Catherine E. Stetson

CERTIFICATE OF SERVICE

I hereby certify that on May 31, 2024, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Third Circuit using the appellate CM/ECF system. Counsel for all parties to the case are registered CM/ECF users and will be served by the appellate CM/ECF system.

/s/ Catherine Stetson
Catherine E. Stetson