
United States Court of Appeals for the Third Circuit

BRISTOL MYERS SQUIBB COMPANY,

Plaintiff-Appellant,

v.

XAVIER BECERRA, *ET AL.*,

Defendants-Appellees.

JANSSEN PHARMACEUTICALS, INC.,

Plaintiff-Appellant,

v.

XAVIER BECERRA, *ET AL.*,

Defendants-Appellees.

On Appeal from the United States District Court for the
District of New Jersey, Nos. 3:23-cv-03335 & 3:23-cv-03818

MOTION TO EXPEDITE

Robert A. Long, Jr.
Kevin F. King
Michael M. Maya
Bradley K. Ervin
COVINGTON & BURLING LLP
850 Tenth Street, NW
Washington, D.C. 20001-4956

Noel J. Francisco
Yaakov M. Roth
Brett A. Shumate
JONES DAY
51 Louisiana Avenue, N.W.
Washington, D.C. 20001

Toni-Ann Citera
Rajeev Muttreja
JONES DAY
250 Vesey Street
New York, NY 10281

May 15, 2024

Counsel for Janssen Pharmaceuticals, Inc.

Counsel for Bristol Myers Squibb Company

(Additional counsel listed on signature page)

Pursuant to Federal Rule of Appellate Procedure 27 and Local Appellate Rule 4.1, Appellants Bristol Myers Squibb Company (“BMS”) and Janssen Pharmaceuticals, Inc. (“Janssen”) respectfully request that the Court expedite the briefing, argument, and disposition of these consolidated appeals concerning the constitutionality of the Drug Price Negotiation Program (the “Program”) in the Inflation Reduction Act (the “IRA”), given the national importance and time-sensitivity of the issues presented. Counsel for BMS and Janssen have conferred with counsel for the Government regarding this motion. The Government consents to this motion only insofar as it requests the briefing schedule agreed upon by the parties; the Government otherwise defers to the Court with respect to when it hears argument and renders a decision.

BACKGROUND

In August 2022, Congress enacted the “Drug Price Negotiation Program” as part of the IRA. The statute exposes drug manufacturers to enormous financial penalties or withdrawal from Medicare and Medicaid—neither of which is a real option—as a means of coercing them into participating in the Program and providing Medicare beneficiaries with “access” to medicines selected by the Centers for Medicare and Medicaid Services (“CMS”), at below-market prices dictated by CMS. In addition, the IRA requires the manufacturers of chosen drugs (on pain of additional penalties) to participate in faux “negotiations” with CMS, and to publicly affirm that they have “agreed” that the Government-set price is the “maximum fair price” for their products.

These consolidated appeals, filed by BMS and Janssen, concern the constitutionality of this unprecedented Program.

BMS and Janssen manufacture medicines—Eliquis and Xarelto, respectively—that were chosen by CMS for the Program. The mandated “negotiations” with CMS are already underway for each of BMS and Janssen regarding these drugs, which are among the Nation’s most widely used medicines. The manufacturers must reach an “agreement” with the Government by August 1, 2024, which is when the “negotiation period” ends. The Government will then announce to the public the “maximum fair price” of these medicines by September 1, 2024, and the Government-dictated price for these medicines will become effective January 1, 2026. *See* 42 U.S.C. §§ 1320f(d), 1320f–1(a)(1).

Meanwhile, additional BMS and Janssen medicines are projected to be swept into the Program’s subsequent cycles, to which the Government will add new medicines each year. And based on how the Program operates, BMS and Janssen are making decisions now about discovery, research, and development funding for medicines that are years or decades away from reaching the market. *See* Decl. of Christopher T. Mancill ¶¶ 40–45, BMS D. Ct. Doc. 36-1 (“Mancill Decl.”).

BMS and Janssen separately challenged the Program’s constitutionality in the District of New Jersey, asserting claims under the Fifth and First Amendments. Compl., BMS D. Ct. Doc. 1; Compl., Janssen D. Ct. Doc. 1. The manufacturers and the Government cross-moved for summary judgment without discovery, and those

motions were argued together on March 7, 2024. BMS D. Ct. Docs. 36, 38, 107; Janssen D. Ct. Doc. 30, 33. On April 29, 2024, the District Court denied the manufacturers' motions and granted the Government's cross-motions, issuing an opinion and the final judgments now on appeal. BMS D. Ct. Docs. 110, 111; Janssen D. Ct. Docs. 98, 99. The District Court held that: (i) the Program does not effectuate a physical taking of BMS's and Janssen's property under the Fifth Amendment; (ii) the Program does not violate BMS's and Janssen's First Amendment rights by compelling their speech; and (iii) the Program does not violate the unconstitutional conditions doctrine. Opinion, BMS D. Ct. Doc. 110.

BMS immediately filed a notice of appeal to this Court. BMS D. Ct. Doc. 113. Janssen filed a notice of appeal the next day. Janssen D. Ct. Doc. 100. This Court consolidated the appeals when docketing them.

ARGUMENT

This Court may “expedite the consideration of any action ... if good cause therefor is shown.” 28 U.S.C. § 1657(a); *see* L.A.R. 4.1 (a motion to expedite shall “set[] forth the exceptional reason that warrants expedition”). Good cause exists here.

Most fundamentally, the parties and the public alike have a strong interest in adjudicating the constitutionality of this major, novel Program before the Government-mandated prices take effect on January 1, 2026. BMS and Janssen therefore respectfully request a decision from this Court by early 2025, so that en banc and/or Supreme Court review can be sought and obtained, if necessary, without the need to seek emergency

relief. The proposed briefing schedule, followed by prompt oral argument (if the Court deems it appropriate), is intended to accommodate that timing.

Moreover, the Program is *already* causing ongoing and escalating constitutional and financial harm to BMS and Janssen. BMS and Janssen have been compelled, by the threat of enormous penalties, to enter faux “negotiations” with CMS and, by August 2024, will be forced to sign “agreements” declaring the prices dictated by CMS to be the “maximum fair prices” for their medicines. The manufacturers assert that this compelled speech violates the First Amendment, which amounts to irreparable harm. *Elrod v. Burns*, 427 U.S. 347, 373 (1976) (plurality op.). In addition, other BMS and Janssen medicines are projected to be selected for subsequent cycles of the Program,¹ and the manufacturers must make critical decisions today about their portfolios—including what products and indications to develop—under that unconstitutional shadow. Mancill Decl. ¶¶ 40–45 (noting a registrational study BMS has decided not to pursue as a result of the IRA).

The Government does not oppose the proposed briefing schedule, for good reason. This appeal presents purely legal questions, which have been extensively briefed and argued by the Government in numerous cases across the Nation. *See supra* n.1. And the Government has not opposed similar requests to expedite consideration of

¹ *See* Sean Dickson & Inmaculada Hernandez, *Drugs Likely Subject to Medicare Negotiation, 2026–2028*, 29 J. Mgmt. Care Spec. Pharm. 229, 231–32 (Mar. 2023), *available at* <https://www.jmcp.org/doi/epdf/10.18553/jmcp.2023.29.3.229?role=tab>.

other challenges to the Program. *See, e.g.*, Stipulated & Proposed Order, *AstraZeneca Pharms. LP v. Becerra*, No. 1:23-cv-00931 (D. Del. Sept. 18, 2023) (not opposing plaintiff's request that district court rule "on or before March 1, 2024"); Unopposed Motion to Expedite Briefing and Argument, *Nat'l Infusion Center Ass'n v. Becerra*, No. 24-50180 (5th Cir. Mar. 22, 2024). The only other court of appeals to consider a challenge to the Program also expedited its consideration of that appeal. *See* Order, *Nat'l Infusion Ctr. Ass'n v. Becerra*, No. 24-50180 (5th Cir. Apr. 1, 2024).

CONCLUSION AND PROPOSED SCHEDULE

For these reasons, BMS and Janssen respectfully request that the Court expedite the briefing, argument, and disposition of these related appeals. Appellants propose, and the Government consents to, the following briefing schedule:

Appellants' Opening Briefs: July 12, 2024.

The Government's Opposition Brief: September 9, 2024.

Appellants' Reply Briefs: October 2, 2024.

BMS and Janssen are available to appear for oral argument at the Court's earliest convenience following the conclusion of briefing.

Dated: May 15, 2024

Respectfully submitted,

/s/ Kevin F. King

Robert A. Long, Jr.

Kevin F. King

Michael M. Maya

Bradley K. Ervin

COVINGTON & BURLING LLP

850 Tenth Street, NW

Washington, D.C. 20001-4956

/s/ Yaakov M. Roth

Noel J. Francisco

Yaakov M. Roth

Brett A. Shumate

Charles E.T. Roberts

John Henry Thompson

Louis J. Capozzi III

JONES DAY

51 Louisiana Avenue, N.W.

Washington, D.C. 20001

Toni-Ann Citera

Rajeev Muttreja

JONES DAY

250 Vesey Street

New York, NY 10281

Jeffrey J. Greenbaum

Katherine M. Lieb

SILLS CUMMIS & GROSS P.C.

One Riverfront Plaza

Newark, New Jersey 07102

Counsel for Janssen Pharmaceuticals, Inc.

Counsel for Bristol Myers Squibb Company

COMBINED CERTIFICATIONS

1. Pursuant to Third Circuit L.A.R. 28.3(d), at least one of the attorneys whose names appear on this motion, including the undersigned, is a member in good standing of the bar of this Court.
2. This motion complies with the type-volume limitation of Fed. R. App. P. 27(d)(2) because it contains 1,144 words, excluding the parts of the documented exempted by Fed. R. App. P. 32(f).
3. This motion complies with the typeface and type-style requirements of Fed. R. App. P. 32(a)(5) and Fed. R. App. P. 32(a)(6) because it has been prepared in a 14-point proportionally spaced typeface (Garamond) using Microsoft Word.
4. That on May 15, 2024, I caused the foregoing to be filed with the Clerk of Court using the CM/ECF System, and all counsel of record in this case is a Filing User who will receive notice of such filing.

Dated: May 15, 2024

/s/ Yaakov M. Roth

Yaakov M. Roth