

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF CONNECTICUT

BOEHRINGER INGELHEIM  
PHARMACEUTICALS, INC.,

*Plaintiff,*

v.

UNITED STATES DEPARTMENT of  
HEALTH and HUMAN SERVICES *et al.*,

*Defendants.*

Civil Action No. 3:23-CV-01103-RNC

**PLAINTIFF BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.’S**  
**MOTION FOR SUMMARY JUDGMENT**

Plaintiff Boehringer Ingelheim Pharmaceuticals, Inc. (“BI”) respectfully requests that this court enter an Order, pursuant to Rule 56 of the Federal Rules of Civil Procedure, granting summary judgment for BI and against Defendants Department of Health and Human Services (“HHS”), Xavier Becerra (in his official capacity as Secretary of HHS), Centers for Medicare and Medicaid Services (“CMS”), and Chiquita Brooks-LaSure (in her official capacity as Administrator of CMS) on the claims in this action (BI’s Counts I-VI). The reasons for this Motion, as set forth more fully in the accompanying Memorandum of Law, the Declaration of Christine Marsh, and the Declaration of James T. Shearin, are that no genuine issues of material fact exist regarding any of these claims, and that BI is entitled to judgment as a matter of law.<sup>1</sup>

---

<sup>1</sup> On September 13, 2023, Plaintiff and Defendants filed a joint scheduling motion advising that “this case presents legal questions regarding the constitutionality of a federal statute (and related administrative action), which can properly be resolved through dispositive motions, without need for discovery” and without need for “separate statements of undisputed material facts.” Dkt. 16 at 1–3. The Court granted that motion in a minute order issued on September 15, 2023, stating

ORAL ARGUMENT REQUESTED

BI is entitled to judgment as a matter of law on its Due Process claim (Count I) because the Drug Price Negotiation Program (“Program”) of the Inflation Reduction Act of 2022 (“IRA”) fails to provide core procedural safeguards. Specifically, the Program deprives BI of the opportunity to be heard by an impartial decisionmaker, prohibits all judicial and administrative review of key CMS actions in implementing the Program, allows CMS to ignore BI’s arguments and evidence during the “negotiations,” denies BI the right to review and respond to the evidence on which CMS relies in imposing a “maximum fair price,” and lacks discernible standards to guide CMS’s action in establishing the “maximum fair price.”

BI is entitled to judgment as a matter of law on its Takings claim (Count II) because the Program effects a physical taking of BI’s Jardiance<sup>®</sup> tablets without just compensation. In particular, the Program appropriates BI’s rights to possess and dispose of its property by granting Medicare participants a right to “access” Jardiance<sup>®</sup> products on terms unilaterally established by CMS, and to which BI would never voluntarily agree.

BI is entitled to judgment as a matter of law on its First Amendment claim (Count III) because the Program compels BI to sign an “agreement” endorsing the Government’s views regarding the Program, which BI does not share, including that BI voluntarily “agrees” to participate in the Program, that the Program involves arms-length “negotiations,” and that the prices set by the “negotiations” will be “fair.” By mandating that BI express those messages, the Program transgresses the rule that the Government “cannot tell people that there are things they must say” without “plainly violat[ing] the First Amendment.” *New Hope Fam. Servs., Inc. v. Poole*, 966 F.3d 145 (2d Cir. 2020).

---

(among other things) that “[u]nless and until ordered to do so in the future, the parties need not file Local Rule 56(a) statements of undisputed facts.”

BI is entitled to judgment as a matter of law on its Eighth Amendment claim (Count IV) because the fines imposed in the event BI does not participate in the Program are unconstitutionally excessive. Those fines, which reach 1900 percent of a manufacturer's U.S. gross revenues for the selected drug (and would result in penalties of more than \$5.5 billion per week in BI's case), are unconstitutional because they impose an "exceedingly heavy burden" on regulated parties and are not proportional to the Government's interests in carrying out the Program. *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 565 (2012).

BI is entitled to judgment as a matter of law on its Unconstitutional Conditions claim (Count V) because even if the Program were voluntary (which it is not), it unconstitutionally conditions continued participation in Medicare and Medicaid on BI's relinquishing of its constitutional rights. There is no connection or proportionality between participation in the Program with respect to Medicare pricing for a single selected drug on the one hand, and the sweeping conditions imposed by the Program regarding broader participation in Medicare and Medicaid for all of BI's drug products on the other hand. *See Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 606 (2013).

BI is entitled to judgment as a matter of law on its claim under the Administrative Procedure Act and the Medicare Act because CMS issued its Manufacturer Agreement, which establishes key Program requirements and thus constitutes a legislative rule, without providing manufacturers (including BI) with an opportunity to comment on the Agreement's terms. *See, e.g., Am. Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1053-54 (D.C. Cir. 1987).

WHEREFORE, for the reasons set forth above and in the accompanying Memorandum of Law and declarations, BI respectfully requests that the Court enter judgment on behalf of BI on all claims in the Complaint.

BI further requests that the Court expedite its disposition of this case. By August 1, 2024, in the absence of judicial intervention, BI will be required to sign a further agreement adopting a “maximum fair price” for Jardiance<sup>®</sup>. *See* 42 U.S.C. §§ 1320f(d)(2)(B), 1320f(b)(4)(B), 1320f-3(a)(1). Given the irreparable harm that would result from that agreement, BI respectfully requests that the Court hold oral argument on the parties’ cross-motions for summary judgment promptly after the close of briefing and issue a ruling on those motions before the August 1, 2024 deadline.

Respectfully submitted,

/s/ James T. Shearin

Robert A. Long, Jr. (*pro hac vice*)  
Kevin F. King (*pro hac vice*)  
Thomas Brugato (*pro hac vice*)  
Michael M. Maya (*pro hac vice*)  
COVINGTON & BURLING LLP  
850 Tenth Street, NW  
Washington, DC 20001-4956  
Tel.: (202) 662-6000  
Fax: (202) 662-6291

James T. Shearin [01326]  
Marcy Tench Stovall [14238]  
PULLMAN & COMLEY, LLC  
850 Main Street  
P.O. Box 7006  
Bridgeport, CT 06601-7006  
Juris No. 47892  
Tel.: (203) 330-2000  
Fax: (203) 576-8888  
jtshearin@pullcom.com

*Counsel for Plaintiff*  
*Boehringer Ingelheim Pharmaceuticals, Inc.*