

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

ASTRAZENECA PHARMACEUTICALS LP,

Plaintiff,

v.

XAVIER BECERRA, DANIEL J. BARRY,
DIANA ESPINOSA, U.S. DEPARTMENT OF
HEALTH AND HUMAN SERVICES, and
HEALTH RESOURCES AND SERVICES
ADMINISTRATION,

Defendants.

C.A. No. 21-27-LPS

MEMORANDUM ORDER

WHEREAS, in a memorandum opinion dated June 16, 2021, the Court held that AstraZeneca is “entitled to at least some relief” in this case (D.I. 78 at 1-2);

WHEREAS, in a corresponding order also dated June 16, 2021, the Court denied Defendants’ motion to dismiss (D.I. 55) with respect to the first three claims of AstraZeneca’s amended complaint and granted the motion solely with respect to the fourth claim, which AstraZeneca had withdrawn (*see* D.I. 79);

WHEREAS, the Court directed the parties to meet and confer regarding: (i) the precise relief to be granted to AstraZeneca given the Court’s analysis, (ii) what additional order the Court should enter, and (iii) the next steps in this case (*see id.*);

WHEREAS, on June 21, 2021, the parties submitted a joint status report outlining their positions on those issues (D.I. 82), which the Court has carefully considered;

NOW, THEREFORE, IT IS HEREBY ORDERED that:

1. It is **DECLARED** that HHS's withdrawal of the Opinion (*see* D.I. 81) does not moot this litigation. "It is well settled that a defendant's voluntary cessation of a challenged practice does not deprive a federal court of its power to determine the legality of the practice unless it is absolutely clear that the allegedly wrongful behavior could not reasonably be expected to recur." *Buckhannon Bd. & Care Home, Inc. v. W. Va. Dep't of Health & Human Resources*, 532 U.S. 598, 609 (2001) (internal quotation marks omitted); *see also Solar Turbines Inc. v. Seif*, 879 F.2d 1073, 1078-79 (3d Cir. 1989) (holding case not moot despite agency's withdrawal of administrative order because agency "ha[d] not altered its position on the merits"). Here, although HHS withdrew the Opinion, HHS has made it clear that its position on the 340B statute has not changed. (*See* D.I. 81-1 ("[HHS's general counsel] notes that its withdrawal of the Opinion does not impact the ongoing efforts of the Health Resources and Services Administration (HRSA) to enforce the obligations that 42 U.S.C. § 256b places on drug manufacturers"); *see also* D.I. 82 at 4 ("HRSA intends to continue enforcement proceedings against AstraZeneca pursuant to the 340B statute.)) Because HHS and its sub-agency, HRSA, intend to act in accordance with the withdrawn Opinion, this litigation is not moot. *See Solar Turbines*, 879 F.2d at 1079.¹

2. With respect to the third claim of the amended complaint, AstraZeneca's motion for summary judgment (D.I. 42) is **GRANTED**, and the government's motion for summary

¹ The government cites only one case in support of its argument that this litigation is now moot. (*See* D.I. 82 at 4) (citing *Marcavage v. Nat'l Park Serv.*, 666 F.3d 856, 861-62 (3d Cir. 2012)) In *Marcavage*, the Third Circuit determined that the alleged constitutional violations were unlikely to recur because the agency had amended the challenged regulations *before* the litigation. This case is different: HHS withdrew the Opinion only *after* the Court issued its memorandum opinion, and, as described above, HHS has indicated that its position on the 340B statute has not actually changed.

judgment (D.I. 55) is **DENIED**. Because the Court has concluded that AstraZeneca's claims are not moot, and given the Court's conclusions in the Opinion, the government agrees that this relief is proper. (*See* D.I. 82 at 6)

3. With respect to the first and second claims of the amended complaint, AstraZeneca's motion for summary judgment (D.I. 42) and the government's motion for summary judgment (D.I. 55) are **DENIED WITHOUT PREJUDICE**.

4. The Opinion issued by the general counsel of HHS on December 30, 2020, is **SET ASIDE** and **VACATED**.

The Court has considered the parties' other proposals (*see* D.I. 82 at 5-6), but it has determined that the relief granted in this Order is appropriate given the Court's conclusions in the June 16, 2021 Memorandum Opinion.

IT IS FURTHER ORDRED that the parties are directed to meet and confer regarding how this case will now proceed. No later than **July 6, 2021**, the parties shall submit a joint status report outlining their proposed schedule for: (i) AstraZeneca's filing of its second amended complaint, (ii) the government's filing of the administrative record regarding the Violation Letter, and (iii) both parties' filing and briefing of any forthcoming motions to dismiss, motions for summary judgment, or any other motions. Any proposed briefing schedule should take care to limit the number of requested pages to the minimum truly needed, and it should provide each party with at least one opportunity to respond in writing to the other party's arguments.

June 30, 2021
Wilmington, Delaware



HONORABLE LEONARD P. STARK
UNITED STATES DISTRICT JUDGE