# U.S. District Court District of Columbia (Washington, DC) CIVIL DOCKET FOR CASE #: 1:21-cv-01479-DLF

NOVARTIS PHARMACEUTICALS CORPORATION v. ESPINOSA et al Assigned to: Judge Dabney L. Friedrich Cases: 1:21-cv-02608-DLF 1:21-cv-01686-DLF 1:21-cv-02826-DLF 1:22-cv-02893-DLF 1:22-cv-01986-DLF Case in other court: 21-05299

Cause: 05:0706 Judicial Review of Agency Actions

## **Plaintiff**

# NOVARTIS PHARMACEUTICALS CORPORATION

Date Filed: 05/31/2021 Date Terminated: 11/05/2021 Jury Demand: None Nature of Suit: 890 Other Statutory Actions Jurisdiction: U.S. Government Defendant

## represented by Susan Cook

HOGAN LOVELLS US LLP 555 Thirteenth Street, NW Washington, DC 20004 (202) 637-6684 Fax: (202) 637-5910 Email: susan.cook@hoganlovells.com *ATTORNEY TO BE NOTICED* 

## **Catherine Emily Stetson**

HOGAN LOVELLS US LLP 555 Thirteenth Street, NW Washington, DC 20004 (202) 637-5491 Fax: (202) 637-5910 Email: cate.stetson@hoganlovells.com *ATTORNEY TO BE NOTICED* 

V.

# <u>Defendant</u>

# **DIANA ESPINOSA**

in her official capacity as ACTING ADMINISTRATOR, HEALTH RESOURCES AND SERVICES ADMINISTRATION

# represented by Jody D. Lowenstein

U.S. DEPARTMENT OF JUSTICE Federal Programs Branch 1100 L St. NW Washington, DC 20005 202-598-9280 Email: jody.d.lowenstein@usdoj.gov *LEAD ATTORNEY ATTORNEY TO BE NOTICED* 

# <u>Defendant</u>

11/1/22, 5:13 PM Case 1:21-cv-01479-DLF Docu <b>XAVIER BECERRA</b> #21-5304 Document #19 in his official capacity as SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES		<b>avel defaults22</b> Page 2 of 10 Filed: 11/01/2022 Page 2 of 10 (See above for address) <i>LEAD ATTORNEY</i> <i>ATTORNEY TO BE NOTICED</i>
<u>Movant</u> AMERICAN HOSPITAL ASSOCIATION	represented by	William Barnett Schultz ZUCKERMAN SPAEDER LLP 1800 M St. NW Suite 1000 Washington, DC 20036 202-778-1800 Fax: 202-822-8106 Email: wschultz@zuckerman.com <i>LEAD ATTORNEY</i> <i>ATTORNEY TO BE NOTICED</i>
<u>Movant</u> 340B HEALTH	represented by	William Barnett Schultz (See above for address) <i>LEAD ATTORNEY</i> <i>ATTORNEY TO BE NOTICED</i>
<u>Movant</u> AMERICA'S ESSENTIAL HOSPITALS	represented by	William Barnett Schultz (See above for address) <i>LEAD ATTORNEY</i> <i>ATTORNEY TO BE NOTICED</i>
<u>Movant</u> ASSOCIATION OF AMERICAN MEDICAL COLLEGES	represented by	William Barnett Schultz (See above for address) LEAD ATTORNEY ATTORNEY TO BE NOTICED

Movant CHILDREN'S HOSPITAL ASSOCIATION

### **Movant**

AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS

# <u>Amicus</u>

# NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS

# represented by William Barnett Schultz

represented by William Barnett Schultz

(See above for address)

LEAD ATTORNEY

(See above for address) LEAD ATTORNEY ATTORNEY TO BE NOTICED

ATTORNEY TO BE NOTICED

#### represented by Ronald S. Connelly

POWERS, PYLES, SUTTER & VERVILLE 1501 M Street, NW 7th Floor

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Filed: 11/01/2022 Page 3 of 10 (202) 872-6762 Fax: (202) 785-1756 Email: ron.connelly@ppsv.com LEAD ATTORNEY ATTORNEY TO BE NOTICED

## Amicus

# RYAN WHITE CLINICS FOR 340B ACCESS

## represented by Ronald S. Connelly

(See above for address) LEAD ATTORNEY ATTORNEY TO BE NOTICED

## Amicus

# LITTLE RIVERS HEALTH CARE, INC.

## represented by Ronald S. Connelly

(See above for address) LEAD ATTORNEY ATTORNEY TO BE NOTICED

# <u>Amicus</u>

**WOMENCARE, INC.,** *doing business as* FAMILYCARE HEALTH CENTER

# represented by Ronald S. Connelly

(See above for address) LEAD ATTORNEY ATTORNEY TO BE NOTICED

Date Filed	#	Docket Text
05/31/2021	1	COMPLAINT against XAVIER BECERRA, DIANA ESPINOSA (Filing fee \$ 402 receipt number ADCDC-8491700) filed by NOVARTIS PHARMACEUTICALS CORPORATION. (Attachments: # 1 Civil Cover Sheet, # 2 Exhibit 1, # 3 Exhibit 2, # 4 Exhibit 3, # 5 Summons Espinosa, # 6 Summons Garland, # 7 Summons Becerra, # 8 Summons Phillips)(Stetson, Catherine) (Entered: 05/31/2021)
05/31/2021	2	LCvR 26.1 CERTIFICATE OF DISCLOSURE of Corporate Affiliations and Financial Interests by NOVARTIS PHARMACEUTICALS CORPORATION (Stetson, Catherine) (Entered: 05/31/2021)
06/01/2021	3	NOTICE of Appearance by Susan Cook on behalf of NOVARTIS PHARMACEUTICALS CORPORATION (Cook, Susan) (Entered: 06/01/2021)
06/01/2021		Case Assigned to Judge Christopher R. Cooper. (zsb) (Entered: 06/01/2021)
06/01/2021	4	SUMMONS (4) Issued Electronically as to XAVIER BECERRA, DIANA ESPINOSA, U.S. Attorney and U.S. Attorney General (Attachment: # <u>1</u> Notice and Consent)(adh, ) (Entered: 06/01/2021)
06/02/2021	5	MOTION for Preliminary Injunction by NOVARTIS PHARMACEUTICALS CORPORATION. (Attachments: # <u>1</u> Memorandum in Support, # <u>2</u> Declaration, # <u>3</u> Text of Proposed Order)(Stetson, Catherine) (Entered: 06/02/2021)
06/07/2021	<u>6</u>	Case randomly reassigned to Judge Dabney L. Friedrich. Judge Christopher R. Cooper is no longer assigned to the case. (ztnr) (Entered: 06/07/2021)
06/07/2021	7	RETURN OF SERVICE/AFFIDAVIT of Summons and Complaint Executed as to the United States Attorney. Date of Service Upon United States Attorney on 6/4/2021.

/1/22, 5:13 PM USCA		1:21-cv-01479-DLF Documbiant & Countribady 1 and 2 Page 4 of 10 21-5304 Answer due for ALE FEDERAL DEFENDANCES by 8/3/2027. (Coor, Susan) (Entered: 06/07/2021)
06/07/2021		MINUTE ORDER. Upon consideration of the parties' <u>5</u> Joint Proposed Briefing Schedule, it is ORDERED that the following schedule shall govern future proceedings: the defendants shall certify the administrative record on or before June 11, 2021; the defendants shall file their combined opposition to plaintiff's motion for preliminary injunction and cross-motion for summary judgment on or before June 28, 2021; the plaintiff shall file its combined reply in support of its motion for preliminary injunction and opposition to defendants' motion for summary judgment on or before July 9, 2021; and the defendants shall file their reply in support of their cross-motion on or before July 16, 2021. On or before June 10, 2021, the parties shall inform the Courtroom Deputy of the times both parties are available for a hearing on July 28, July 29, and July 30, 2021. So Ordered by Judge Dabney L. Friedrich on June 7, 2021. (lcdlf2) (Entered: 06/07/2021)
06/07/2021	<u>8</u>	STANDARD ORDER for Civil Cases. See text for details. Signed by Judge Dabney L. Friedrich on June 7, 2021. (lcdlf2) (Entered: 06/07/2021)
06/07/2021		Set/Reset Deadlines: Administrative Record due by 6/11/2021. Cross Motions due by 6/28/2021. Response to Cross Motions due by 7/9/2021. Reply to Cross Motions due by 7/16/2021. Responses due by 6/28/2021 Replies due by 7/9/2021. (zjch) (Entered: 06/08/2021)
06/11/2021	2	NOTICE of Appearance by Jody D. Lowenstein on behalf of All Defendants (Lowenstein, Jody) (Entered: 06/11/2021)
06/11/2021	<u>10</u>	MOTION for Leave to File <i>Manually the Administrative Record</i> by XAVIER BECERRA, DIANA ESPINOSA. (Attachments: # <u>1</u> Index for Certified Administrative Record, # <u>2</u> Certification for Administrative Record, # <u>3</u> Text of Proposed Order) (Lowenstein, Jody) (Entered: 06/11/2021)
06/16/2021		MINUTE ORDER granting the defendants' <u>10</u> Motion to File Manually the Administrative Record. The defendants are ORDERED to file the administrative record manually by providing it to the Clerk of Court in electronic form. The defendants are FURTHER ORDERED to file through CM/ECF a joint appendix containing the portions of the administrative record cited by the parties at the close of briefing on the defendants' forthcoming motion for summary judgment. So Ordered by Judge Dabney L. Friedrich on June 16, 2021. (lcdlf2) (Entered: 06/16/2021)
06/17/2021	11	RETURN OF SERVICE/AFFIDAVIT of Summons and Complaint Executed on United States Attorney General. Date of Service Upon United States Attorney General 06/14/2021. (Kilgore, Harrison) (Entered: 06/17/2021)
06/28/2021	12	Consent MOTION for Leave to File <i>Amicus Brief in Support of Defendants</i> by AMERICAN HOSPITAL ASSOCIATION, 340B HEALTH, AMERICA'S ESSENTIAL HOSPITALS, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, CHILDREN'S HOSPITAL ASSOCIATION, AMERICAN SOCIETY OF HEALTH- SYSTEM PHARMACISTS. (Attachments: # 1 Exhibit Amicus Brief, # 2 Exhibit Testoni Declaration, # 3 Text of Proposed Order Proposed Order)(Schultz, William) (Entered: 06/28/2021)
06/28/2021	<u>13</u>	MOTION for Summary Judgment by XAVIER BECERRA, DIANA ESPINOSA. (Attachments: # <u>1</u> Memorandum in Support of Motion for Summary Judgment and in Opposition to Motion for Preliminary Injunction, # <u>2</u> Exhibit Declaration of Kate Talmor, # <u>3</u> Text of Proposed Order)(Lowenstein, Jody) (Entered: 06/28/2021)
06/28/2021	14	Memorandum in opposition to re 5 MOTION for Preliminary Injunction and in Support

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06/29/2021		MINUTE ORDER. Upon consideration of the American Hospital Association, et al.'s 12 Consent Motion for Leave to File an Amicus Brief in Support of the Defendants, it i ORDERED that the motion is GRANTED. So Ordered by Judge Dabney L. Friedrich on June 29, 2021. (lcdlf2) (Entered: 06/29/2021)
07/02/2021	15	Unopposed MOTION for Leave to File <i>Amicus Curiae Brief</i> by NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS, RYAN WHITE CLINICS FOR 340B ACCESS, LITTLE RIVERS HEALTH CARE, INC., WOMENCARE, INC.,. (Attachments: # <u>1</u> Exhibit Amicus Brief, # <u>2</u> Exhibit Index of Exhibits, # <u>3</u> Exhibit A. Glover Decl., # <u>4</u> Exhibit B. Johnson Decl., # <u>5</u> Exhibit C. Dickerson Decl., # <u>6</u> Exhibit D. Auclair Decl., # <u>7</u> Exhibit E. Slingerland Decl., # <u>8</u> Exhibit LCvR 7.1 Certificate, # <u>9</u> Text of Proposed Order)(Connelly, Ronald) (Entered: 07/02/2021)
07/02/2021	<u>16</u>	NOTICE of Appearance by Ronald S. Connelly on behalf of LITTLE RIVERS HEALTH CARE, INC., RYAN WHITE CLINICS FOR 340B ACCESS, WOMENCARE, INC., (Connelly, Ronald) (Entered: 07/02/2021)
07/07/2021		MINUTE ORDER. Upon consideration of the National Association of Community Health Centers, et al.'s <u>15</u> Unopposed Motion for Leave to File an Amicus Curiae Brief in Support of the Defendants' Motion for Summary Judgment, it is ORDERED that the motion is GRANTED. So Ordered by Judge Dabney L. Friedrich on July 7, 2021. (lcdlf2) (Entered: 07/07/2021)
07/07/2021	21	AMICUS BRIEF by LITTLE RIVERS HEALTH CARE, INC., NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS, RYAN WHITE CLINICS FOR 340B ACCESS, WOMENCARE, INC.,. (Attachment: # <u>1</u> Exhibits)(eg) (Entered 07/15/2021)
07/07/2021	22	LCvR 26.1 CERTIFICATE OF DISCLOSURE of Corporate Affiliations and Financial Interests by LITTLE RIVERS HEALTH CARE, INC., NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS, RYAN WHITE CLINICS FOR 340B ACCESS, WOMENCARE, INC., (eg) (Entered: 07/15/2021)
07/09/2021		MINUTE ORDER. Upon review of the complaints and filings in Novartis Pharmaceuticals Corp. v. Espinosa, 1:21-cv-01686-DLF, and United Therapeutics Corp v. Espinosa, 1:21-cv-01479-DLF, the Court has determined that it would be most efficient to consider the motions in these cases simultaneously. Accordingly, the Court directs the parties in both cases to confer and inform the Court, on or before July 14, 2021, (1) whether the parties consent to consolidating consideration of the plaintiffs' motions for a preliminary injunction with an expedited ruling on the parties' cross- motions for summary judgment, see Fed. R. Civ. P. 65(a)(2), and (2) if so, whether the current briefing schedules should be modified. If the parties agree that the Court should consolidate the motions and issue a ruling on the merits, the Court will set a joint hearing on the cross-motions for summary judgment no later than October 2021. So Ordered by Judge Dabney L. Friedrich on July 9, 2020. (lcdlf3) (Entered: 07/09/2021)
07/09/2021	<u>17</u>	REPLY to opposition to motion re <u>5</u> MOTION for Preliminary Injunction filed by NOVARTIS PHARMACEUTICALS CORPORATION. (Stetson, Catherine) (Entered: 07/09/2021)
07/09/2021	<u>18</u>	Memorandum in opposition to re <u>13</u> MOTION for Summary Judgment filed by NOVARTIS PHARMACEUTICALS CORPORATION. (Attachments: # <u>1</u> Text of Proposed Order)(Stetson, Catherine) (Entered: 07/09/2021)
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07/09/2021		Set/Reset Deadlines: Status Report due by 7/14/2021 (zjch) (Entered: 07/12/2021)
07/14/2021	20	Joint STATUS REPORT by NOVARTIS PHARMACEUTICALS CORPORATION. (Stetson, Catherine) (Entered: 07/14/2021)
07/15/2021		MINUTE ORDER. Upon review of the parties' joint status reports in Novartis Pharmaceuticals Corp. v. Espinosa, No. 1:21-cv-01479-DLF, and United Therapeutics Corp. v. Espinosa, No. 1:21-cv-01686-DLF, and with the consent of the plaintiff in Novartis, the Court will consolidate a decision on the motion for a preliminary injunction filed in Novartis with a ruling on the parties' cross-motions for summary judgment. The Court will also expedite consideration of the parties' cross-motions for summary judgment in both cases and schedule a joint motions hearing in October, once the Court's trial schedule is set. Accordingly, on or before September 15, 2021, the parties in both cases shall inform the Courtroom Deputy of three dates (and times) in October on which all parties are available for a hearing. The hearing set for July 28, 2021, at 9:30 a.m. in Novartis is VACATED. The defendants' obligation to file answers in both cases is stayed pending resolution of the motions for summary judgment. If the parties in United Therapeutics wish to modify the briefing schedule, they shall jointly file a proposed briefing schedule with briefing to be completed no later than September 24, 2021. So Ordered by Judge Dabney L. Friedrich on July 15, 2021. (lcdlf3) (Entered 07/15/2021)
07/15/2021		Set/Reset Deadlines: Inform the Courtroom Deputy of available dates by 9/15/2021. (zjch) (Entered: 07/15/2021)
07/15/2021		Set/Reset Deadlines: Briefing Schedule due by 9/24/2021. (zjch) (Entered: 07/22/2021)
07/16/2021	23	REPLY to opposition to motion re <u>13</u> MOTION for Summary Judgment filed by XAVIER BECERRA, DIANA ESPINOSA. (Lowenstein, Jody) (Entered: 07/16/2021)
07/16/2021	24	Memorandum in opposition to re <u>19</u> MOTION for Summary Judgment filed by XAVIER BECERRA, DIANA ESPINOSA. (Lowenstein, Jody) (Entered: 07/16/2021)
07/16/2021	25	JOINT APPENDIX of the Certified Administrative Record by XAVIER BECERRA, DIANA ESPINOSA. (Attachments: # 1 Index of Joint Appendix, # 2 Part I, # 3 Part II, # 4 Part III, # 5 Part IV)(Lowenstein, Jody) (Entered: 07/16/2021)
09/15/2021		NOTICE of Hearing: Motion Hearing set for 10/12/2021 at 11:00 AM via video before Judge Dabney L. Friedrich. (zjch, ) (Entered: 09/15/2021)
09/23/2021	<u>26</u>	NOTICE of Defendants' Recent Enforcement Action Referral by NOVARTIS PHARMACEUTICALS CORPORATION (Attachments: # <u>1</u> Exhibit)(Stetson, Catherine) (Entered: 09/23/2021)
09/23/2021		MINUTE ORDER. On July 15, 2021, with the consent of both parties pursuant to their <u>20</u> Joint Status Report, the Court vacated the preliminary injunction hearing and consolidated a ruling on the preliminary injunction with a ruling on summary judgment cross-motions in October. Pursuant to plaintiff's <u>26</u> Notice, it appears to the Court that the government is taking steps to initiate an enforcement action against the plaintiff in the interim. It is hereby ORDERED that the defendant respond to plaintiff's <u>26</u> Notice and SHOW CAUSE why the Court should not temporarily restrain the defendant from bringing an enforcement action against the plaintiff until the October 12, 2021, Motions Hearing. Defendants shall file this response today, September 23, 2021. So Ordered by Judge Dabney L. Friedrich on September 23, 2021. (lcdlf3) (Entered: 09/23/2021)

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/1/22, 5:13 PM 09/23/2020A	-	1:21-cv-01479-DLF Document a Courribad va da labe 2 Page 7 of 10 2NOTICE in Response to the Court's September 23, 2021 Minute Order and Plaintiff's Notice of Defendants' Recent Enforcement Action Referral by XAVIER BECERRA, DIANA ESPINOSA re Order,, Set Deadlines,., (Lowenstein, Jody) (Entered: 09/23/2021)
09/24/2021		MINUTE ORDER. In light of the defendants' <u>27</u> Response, and in particular, its representation that "[t]he administrative process that OIG is required to follow before it may issue a final, effective decision imposing penalties on a manufacturer for knowing and intentional overcharges under the 340B Program cannot be completed in the 19-day period between now and the October 12, 2021 motions hearing," the Court DENIES the plaintiff's request to hold a telephonic status conference today. As previously scheduled, a hearing on the pending motions will be held on October 12, 2021, at 11 a.m. via videoconference. So Ordered by Judge Dabney L. Friedrich on September 24, 2021. (lcdlf3) (Entered: 09/24/2021)
10/12/2021		Minute Entry for proceedings held before Judge Dabney L. Friedrich: Motion Hearing held on 10/12/2021 re (19 in 1:21-cv-01479-DLF) MOTION for Summary Judgment filed by NOVARTIS PHARMACEUTICALS CORPORATION, (14 in 1:21-cv-01686- DLF) MOTION for Summary Judgment filed by UNITED THERAPEUTICS CORPORATION, (13 in 1:21-cv-01479-DLF) MOTION for Summary Judgment filed by XAVIER BECERRA, DIANA ESPINOSA, (16 in 1:21-cv-01686-DLF) MOTION for Summary Judgment filed by XAVIER BECERRA, U.S. HEALTH RESOURCES AND SERVICES ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, DIANA ESPINOSA. Court Reporter Sara Wick. (zjch, ) (Entered: 10/12/2021)
10/25/2021	28	TRANSCRIPT OF MOTIONS HEARING before Judge Dabney L. Friedrich held on 10/12/2021. Page Numbers: 1-62. Date of Issuance: 10/25/2021. Court Reporter: Sara Wick, telephone number 202-354-3284. Transcripts may be ordered by submitting the Transcript Order Form
		For the first 90 days after this filing date, the transcript may be viewed at the courthouse at a public terminal or purchased from the court reporter referenced above. Aft er 90 days, the transcript may be accessed via PACER. Other transcript formats, (multi-page, condensed, CD or ASCII) may be purchased from the court reporter.
		<b>NOTICE RE REDACTION OF TRANSCRIPTS:</b> The parties have twenty-one days to file with the court and the court reporter any request to redact personal identifiers from this transcript. If no such requests are filed, the transcript will be made available to the public via PACER without redaction after 90 days. The policy, which includes the five personal identifiers specifically covered, is located on our website at www.dcd.uscourts.gov.
		Redaction Request due 11/15/2021. Redacted Transcript Deadline set for 11/25/2021. Release of Transcript Restriction set for 1/23/2022.(Wick, Sara) (Entered: 10/25/2021)
11/02/2021	<u>29</u>	NOTICE OF SUPPLEMENTAL AUTHORITY by XAVIER BECERRA, DIANA ESPINOSA (Attachments: # <u>1</u> Exhibit Lilly Order on SJ)(Lowenstein, Jody) (Entered: 11/02/2021)
11/04/2021	30	RESPONSE re <u>29</u> NOTICE OF SUPPLEMENTAL AUTHORITY filed by NOVARTIS PHARMACEUTICALS CORPORATION. (Attachments: # <u>1</u> Exhibit 1, # <u>2</u> Exhibit 2) (Stetson, Catherine) (Entered: 11/04/2021)
11/05/2021	31	ORDER denying defendants' <u>13</u> Motion for Summary Judgment and granting in part and denying in part plaintiff's <u>19</u> Motion for Summary Judgment. See text for details.

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11/05/2021	32	MEMORANDUM OPINION regarding parties' Motions for Summary Judgment. See text for details. Signed by Judge Dabney L. Friedrich on November 5, 2021. (lcdlf3) (Entered: 11/05/2021)
12/28/2021	33	NOTICE OF APPEAL TO DC CIRCUIT COURT as to <u>32</u> Memorandum & Opinion, Terminate Deadlines, <u>31</u> Order on Motion for Summary Judgment, by XAVIER BECERRA, DIANA ESPINOSA. Fee Status: No Fee Paid. Parties have been notified. (Lowenstein, Jody) (Entered: 12/28/2021)
12/29/2021	34	Transmission of the Notice of Appeal, Order Appealed (Memorandum Opinion), and Docket Sheet to US Court of Appeals. The Court of Appeals docketing fee was not paid because the appeal was filed by the government re <u>33</u> Notice of Appeal to DC Circuit Court. (zjf) (Entered: 12/29/2021)
12/30/2021		USCA Case Number 21-5299 for <u>33</u> Notice of Appeal to DC Circuit Court filed by XAVIER BECERRA, DIANA ESPINOSA. (zeg) (Entered: 01/05/2022)
10/27/2022	35	ORDER of USCA as to (33 in 1:21-cv-01479-DLF) Notice of Appeal to DC Circuit Court filed by XAVIER BECERRA, DIANA ESPINOSA ; USCA Case Number 21- 5299. (zed) (Entered: 10/28/2022)
10/31/2022	36	ORDER in response to the limited <u>35</u> remand from the Court of Appeals for the District of Columbia Circuit. See text for details. Signed by Judge Dabney L. Friedrich on October 31, 2022. (lcdlf3) (Entered: 10/31/2022)

## **UNITED STATES DISTRICT COURT** FOR THE DISTRICT OF COLUMBIA

NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. No. 21-cv-1479 (DLF) DIANA ESPINOSA, Acting Administrator, Health Resources and Services Administration, et al., Defendants. UNITED THERAPEUTICS CORPORATION, Plaintiff, v.

No. 21-cv-1686 (DLF)

DIANA ESPINOSA, Acting Administrator, Health Resources and Services Administration, et al.,

Defendants.

## ORDER

The case is before the Court on a remand from the U.S. Court of Appeals for the District of Columbia Circuit "for the limited purpose of explaining whether it contemplates any further proceedings on the claim for injunctive relief or whether the district court's decision is final." D.C. Cir. Order at 3, Dkt. 35. The Court's decision was final. It contemplated no additional proceedings.

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In its November 5, 2021 Memorandum Opinion, Dkt. 32, and accompanying Order, Dkt. 31, the Court granted in part and denied in part the plaintiffs' Motions for Summary Judgment. The Court also stated that it denied the defendants' Motions for Summary Judgment. Order, Dkt. 31. This was incorrect. The Court should have framed its order as one denying in part *and granting in part* the defendants' Motions for Summary Judgment.

The Court denied the manufacturers certain declaratory and injunctive relief that they requested. Namely, the Court declined to declare either that Section 340B permits the manufacturers' *specific* conditions on offers of 340B-priced drugs, or that HRSA can never initiate a successful future enforcement action against the manufacturers. *See* Compl. at 25, Dkt. 1 (*Novartis*); Compl. at 51, Dkt. 1 (*United Therapeutics*). In doing so, the Court necessarily granted in part the defendants' motions for summary judgment, but it did not reach the merits of either issue. When the Court stated that it would not issue this requested relief "at this time," Mem. Op. at 20, Dkt. 32, the Court merely intended to leave open the possibility that, in a future case, the parties could persuade a court that Section 340B either permits or prohibits the specific conditions at issue.

For the above reasons, as corrected, the Court's November 5, 2021 Memorandum Opinion, Dkt. 32, and Order, Dkt. 31, are the Court's final decision in this case.

obuy L. Friedrich BNEY L. FRIEDRICH

DABNEY L. FRIEDRICH United States District Judge

October 31, 2022