
IN THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

ASTRAZENECA PHARMACEUTICALS LP; ASTRAZENECA AB;
ASTRAZENECA UK LTD,

Plaintiffs-Appellants,

v.

ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the
U.S. Department of Health and Human Services; UNITED STATES
DEPARTMENT OF HEALTH & HUMAN SERVICES; MEHMET C. OZ,
in his official capacity as Administrator of the Centers for Medicare and
Medicaid Services; CENTERS FOR MEDICARE AND MEDICAID
SERVICES,

Defendants-Appellees.

On Appeal from the United States District Court for
the District of Maryland
The Honorable Matthew J. Maddox, Jr. (No. 1:25-cv-4212)

JOINT APPENDIX

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TABLE OF CONTENTS

Order,	
Dist. Ct. Dkt. 52 (Aug. 19, 2026).....	JA1
District Court Docket Sheet.....	JA2
Complaint,	
Dist. Ct. Dkt. 1 (Dec. 19, 2025)	JA15
Notice of Appeal,	
Dist. Ct. Dkt. 53 (Aug. 21, 2026).....	JA61
Transcript of Motions Hearing Before Judge Maddox on August 19, 2026,	
Dist. Ct. Dkt. 54 (Aug. 24, 2026).....	JA65

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

**ASTRAZENECA PHARMACEUTICALS
LP, *et al.*,**

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., *et al.*,

Defendants.

Civ. No.: MJM-25-4212

* * * * *

ORDER

For the reasons stated on the record during the motions hearing on August 19, 2026, it is this 19th day of August, 2026, by the United States District Court for the District of Maryland, hereby ORDERED that:

1. Defendants' Motion to Dismiss pursuant to Federal Rule of Civil Procedure 12(b)(1) (ECF No. 32) is DENIED;
2. Plaintiffs' Motion for Summary Judgment (ECF No. 21) is DENIED;
3. Defendants' alternative Motion for Summary Judgment (ECF No. 32) is GRANTED;
4. Summary judgment is ENTERED in favor of Defendants; and
5. The Clerk of the Court SHALL CLOSE this case.

/S/
Matthew J. Maddox
United States District Judge

**U.S. District Court
District of Maryland (Baltimore)
CIVIL DOCKET FOR CASE #: 1:25-cv-04212-MJM**

AstraZeneca Pharmaceuticals LP et al v. Kennedy et al
Assigned to: Judge Matthew J. Maddox
Case in other court: Fourth Circuit Court of Appeals,
26-02165
Cause: 05:706 Judicial Review of Agency Action

Date Filed: 12/19/2025
Date Terminated: 08/20/2026
Jury Demand: None
Nature of Suit: 899 Other Statutes:
Administrative Procedures Act/Review or
Appeal of Agency Decision
Jurisdiction: U.S. Government Defendant

Plaintiff

AstraZeneca Pharmaceuticals LP

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V.

Defendant

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Defendant

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Amicus

**Biotechnology Innovation
Organization**

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Date Filed	#	Docket Text
12/19/2025	<u>1</u>	COMPLAINT <i>for Declaratory and Injunctive Relief</i> against All Defendants (Filing fee \$ 405 receipt number AMDDC–12431591.), filed by AstraZeneca AB, AstraZeneca Pharmaceuticals LP, AstraZeneca UK Ltd.. (Attachments: # <u>1</u> Civil Cover Sheet Civil Cover Sheet, # <u>2</u> Summons Summons to Defendant Kennedy, # <u>3</u> Summons Summons to Defendant Oz, # <u>4</u> Summons Summons to U.S. Attorney General Bondi, # <u>5</u> Summons Summons to U.S. States Attorney for District of Maryland – Hayes)(Pichini, Michael) (Entered: 12/19/2025)
12/19/2025	<u>2</u>	Local Rule 103.3 Disclosure Statement by AstraZeneca AB, AstraZeneca Pharmaceuticals LP, AstraZeneca UK Ltd. identifying Other Affiliate AstraZeneca PLC for AstraZeneca AB, AstraZeneca Pharmaceuticals LP, AstraZeneca UK Ltd..(Pichini, Michael) (Entered: 12/19/2025)
12/22/2025	<u>3</u>	Summons Issued 60 days as to Robert F. Kennedy, Jr, Mehmet Oz, U.S. Attorney and U.S. Attorney General (Entered: 12/22/2025)

01/05/2026	<u>4</u>	SUMMONS Returned Executed by AstraZeneca Pharmaceuticals LP, AstraZeneca AB, AstraZeneca UK Ltd.. Mehmet Oz served on 12/29/2025, answer due 2/27/2026.(Pichini, Michael) (Entered: 01/05/2026)
01/05/2026	<u>5</u>	SUMMONS Returned Executed by AstraZeneca Pharmaceuticals LP, AstraZeneca AB, AstraZeneca UK Ltd.. Robert F. Kennedy, Jr served on 12/29/2025, answer due 2/27/2026.(Pichini, Michael) (Entered: 01/05/2026)
01/05/2026	<u>6</u>	SUMMONS Returned Executed by AstraZeneca Pharmaceuticals LP, AstraZeneca AB, AstraZeneca UK Ltd.. U.S. Department of Health and Human Services served on 12/31/2025, answer due 3/2/2026.(Pichini, Michael) (Entered: 01/05/2026)
01/05/2026	<u>7</u>	SUMMONS Returned Executed by AstraZeneca Pharmaceuticals LP, AstraZeneca AB, AstraZeneca UK Ltd.. Centers for Medicare and Medicaid Services served on 12/29/2025, answer due 2/27/2026.(Pichini, Michael) (Entered: 01/05/2026)
01/05/2026	<u>8</u>	MOTION to Appear Pro Hac Vice for William T. Sharon (Filing fee \$100, receipt number AMDDC-12447058.) by AstraZeneca AB, AstraZeneca Pharmaceuticals LP, AstraZeneca UK Ltd. (Attachments: # <u>1</u> Attachment to Motion for Admission Pro Hac Vice)(Pichini, Michael) (Entered: 01/05/2026)
01/05/2026	<u>9</u>	MOTION to Appear Pro Hac Vice for Allon Kedem (Filing fee \$100, receipt number AMDDC-12447116.) by AstraZeneca AB, AstraZeneca Pharmaceuticals LP, AstraZeneca UK Ltd. (Attachments: # <u>1</u> Attachment to Motion for Admission Pro Hac Vice)(Pichini, Michael) (Entered: 01/05/2026)
01/05/2026	<u>10</u>	MOTION to Appear Pro Hac Vice for Catherine A. Brandon (Filing fee \$100, receipt number AMDDC-12447126.) by AstraZeneca AB, AstraZeneca Pharmaceuticals LP, AstraZeneca UK Ltd.(Pichini, Michael) (Entered: 01/05/2026)
01/05/2026	11	PAPERLESS ORDER granting <u>8</u> Motion to Appear Pro Hac Vice on behalf of William T. Sharon. Directing attorney William T. Sharon to register for pro hac vice filing in the District of Maryland through PACER at https://pacer.uscourts.gov/ if attorney has not already done so. The <i>Pro Hac Vice</i> option must be selected when registering. Signed by Clerk on 1/5/2026. (mh4s, Deputy Clerk) (Entered: 01/05/2026)
01/05/2026	12	PAPERLESS ORDER granting <u>9</u> Motion to Appear Pro Hac Vice on behalf of Allon Kedem. Directing attorney Allon Kedem to register for pro hac vice filing in the District of Maryland through PACER at https://pacer.uscourts.gov/ if attorney has not already done so. The <i>Pro Hac Vice</i> option must be selected when registering. Signed by Clerk on 1/5/2026. (mh4s, Deputy Clerk) (Entered: 01/05/2026)
01/05/2026	13	PAPERLESS ORDER granting <u>10</u> Motion to Appear Pro Hac Vice on behalf of Catherine A. Brandon. Directing attorney Catherine A. Brandon to register for pro hac vice filing in the District of Maryland through PACER at https://pacer.uscourts.gov/ if attorney has not already done so. The <i>Pro Hac Vice</i> option must be selected when registering. Signed by Clerk on 1/5/2026. (mh4s, Deputy Clerk) (Entered: 01/05/2026)
02/03/2026	<u>14</u>	NOTICE of Appearance by Dayna Kipnis on behalf of All Defendants (Kipnis, Dayna) (Entered: 02/03/2026)
02/04/2026	<u>15</u>	Joint MOTION to Vacate <i>Answer Deadlines and Set Summary Judgment Briefing Schedule</i> by AstraZeneca AB, AstraZeneca Pharmaceuticals LP, AstraZeneca UK Ltd. (Attachments: # <u>1</u> Text of Proposed Order to Joint Motion to Vacate Answer Deadlines and Set Summary Judgment Briefing Schedule)(Pichini, Michael) (Entered: 02/04/2026)

02/05/2026	<u>16</u>	ORDER granting Parties' <u>15</u> Joint Motion to Vacate Answer Deadlines and SetSummary Judgment Briefing Schedule; vacating Defendants' deadlines to answer or otherwise respond to complaint; vacating Defendants' obligations to file and serve the administrative record; adopting briefing deadlines and page limits as set forth re Motion and Cross Motion for Summary Judgment. Signed by Judge Matthew J. Maddox on 2/5/2026. (dass, Deputy Clerk) (Entered: 02/05/2026)
02/11/2026	<u>17</u>	NOTICE to Substitute Attorney (Pezzi, Stephen) (Entered: 02/11/2026)
02/12/2026	<u>18</u>	MARGINAL ORDER Approving <u>17</u> Notice to Substitute Attorney filed by Centers for Medicare and Medicaid Services, Robert F. Kennedy, Jr., Mehmet Oz, U.S. Department of Health and Human Services. Signed by Judge Matthew J. Maddox on 2/12/2026. (bas, Deputy Clerk) (Entered: 02/12/2026)
02/13/2026	<u>19</u>	Joint MOTION to Modify Scheduling Order re <u>16</u> Order on Motion to Vacate, by Centers for Medicare and Medicaid Services, Robert F. Kennedy, Jr, Mehmet Oz, U.S. Department of Health and Human Services (Attachments: # <u>1</u> Text of Proposed Order)(Pezzi, Stephen) (Entered: 02/13/2026)
02/18/2026	<u>20</u>	ORDER Granting <u>19</u> Joint Motion to Modify the Schedule. Signed by Judge Matthew J. Maddox on 2/18/2026. (bas, Deputy Clerk) (Entered: 02/19/2026)
02/27/2026	<u>21</u>	MOTION for Summary Judgment by AstraZeneca AB, AstraZeneca Pharmaceuticals LP, AstraZeneca UK Ltd. (Attachments: # <u>1</u> Memorandum in Support of Plaintiffs' Motion for Summary Judgment, # <u>2</u> Text of Proposed Order Granting Plaintiffs' Motion for Summary Judgment)(Pichini, Michael) (Entered: 02/27/2026)
03/04/2026	<u>22</u>	MOTION for Leave to File <i>Amicus Brief in Support of Plaintiffs' Motion for Summary Judgment (Unopposed)</i> by Bausch Health Companies Inc., Bristol Myers Squibb Company, Eli Lilly and Company, Johnson & Johnson, Sanofi–Aventis U.S. LLC, Biotechnology Innovation Organization (Attachments: # <u>1</u> Proposed amicus brief in support of Plaintiffs' Motion for Summary Judgment, # <u>2</u> Proposed Order)(Williams, Edward) (Entered: 03/04/2026)
03/04/2026	<u>23</u>	Local Rule 103.3 Disclosure Statement by Bausch Health Companies Inc., Biotechnology Innovation Organization, Bristol Myers Squibb Company, Eli Lilly and Company, Johnson & Johnson, Sanofi–Aventis U.S. LLC identifying Other Affiliate Sanofi S.A. for Sanofi–Aventis U.S. LLC.(Williams, Edward) (Entered: 03/04/2026)
03/04/2026	<u>24</u>	MOTION to Appear Pro Hac Vice for Cesar Lopez–Morales (Filing fee \$100, receipt number AMDDC–12589369.) by Bausch Health Companies Inc., Biotechnology Innovation Organization, Bristol Myers Squibb Company, Eli Lilly and Company, Johnson & Johnson, Sanofi–Aventis U.S. LLC(Williams, Edward) (Entered: 03/04/2026)
03/04/2026	<u>25</u>	MOTION to Appear Pro Hac Vice for Clement S. Roberts (Filing fee \$100, receipt number AMDDC–12589387.) by Bausch Health Companies Inc., Biotechnology Innovation Organization, Bristol Myers Squibb Company, Eli Lilly and Company, Johnson & Johnson, Sanofi–Aventis U.S. LLC(Williams, Edward) (Entered: 03/04/2026)
03/04/2026	<u>26</u>	MOTION to Appear Pro Hac Vice for Irena Royzman (Filing fee \$100, receipt number AMDDC–12589390.) by Bausch Health Companies Inc., Biotechnology Innovation Organization, Bristol Myers Squibb Company, Eli Lilly and Company, Johnson & Johnson, Sanofi–Aventis U.S. LLC(Williams, Edward) (Entered: 03/04/2026)

03/04/2026	<u>27</u>	MOTION to Appear Pro Hac Vice for Lauren Shepard (Filing fee \$100, receipt number AMDDC-12589398.) by Bausch Health Companies Inc., Biotechnology Innovation Organization, Bristol Myers Squibb Company, Eli Lilly and Company, Johnson & Johnson, Sanofi-Aventis U.S. LLC(Williams, Edward) (Entered: 03/04/2026)
03/05/2026	28	PAPERLESS ORDER granting <u>24</u> Motion to Appear Pro Hac Vice on behalf of Cesar A. Lopez-Morales. Directing attorney Cesar A. Lopez-Morales to register for pro hac vice filing in the District of Maryland through PACER at https://pacer.uscourts.gov/ if attorney has not already done so. The <i>Pro Hac Vice</i> option must be selected when registering. Signed by Clerk on 3/5/2026. (sj4s, Deputy Clerk) (Entered: 03/05/2026)
03/05/2026	29	PAPERLESS ORDER granting <u>25</u> Motion to Appear Pro Hac Vice on behalf of Clement Seth Roberts. Directing attorney Clement Seth Roberts to register for pro hac vice filing in the District of Maryland through PACER at https://pacer.uscourts.gov/ if attorney has not already done so. The <i>Pro Hac Vice</i> option must be selected when registering. Signed by Clerk on 3/5/2026. (sj4s, Deputy Clerk) (Entered: 03/05/2026)
03/05/2026	30	PAPERLESS ORDER granting <u>26</u> Motion to Appear Pro Hac Vice on behalf of Irena Royzman. Directing attorney Irena Royzman to register for pro hac vice filing in the District of Maryland through PACER at https://pacer.uscourts.gov/ if attorney has not already done so. The <i>Pro Hac Vice</i> option must be selected when registering. Signed by Clerk on 3/5/2026. (sj4s, Deputy Clerk) (Entered: 03/05/2026)
03/05/2026	31	PAPERLESS ORDER granting <u>27</u> Motion to Appear Pro Hac Vice on behalf of Lauren Shepard. Directing attorney Lauren Shepard to register for pro hac vice filing in the District of Maryland through PACER at https://pacer.uscourts.gov/ if attorney has not already done so. The <i>Pro Hac Vice</i> option must be selected when registering. Signed by Clerk on 3/5/2026. (sj4s, Deputy Clerk) (Entered: 03/05/2026)
03/27/2026	<u>32</u>	MOTION to Dismiss (<i>or, in the Alternative, for Summary Judgment</i>) and Opposition to Plaintiffs' Motion for Summary Judgment by Centers for Medicare and Medicaid Services, Robert F. Kennedy, Jr, Mehmet Oz, U.S. Department of Health and Human Services (Attachments: # <u>1</u> Memorandum in Support, # <u>2</u> Text of Proposed Order)(Pezzi, Stephen) (Entered: 03/27/2026)
04/27/2026	<u>33</u>	-FILED IN ERROR- RESPONSE re <u>32</u> MOTION to Dismiss (<i>or, in the Alternative, for Summary Judgment</i>) and Opposition to Plaintiffs' Motion for Summary Judgment, <u>21</u> MOTION for Summary Judgment and- <i>Plaintiff's reply in Support Thereof</i> filed by AstraZeneca AB, AstraZeneca Pharmaceuticals LP, AstraZeneca UK Ltd..(Pichini, Michael) Modified on 4/28/2026 (ols). (Entered: 04/27/2026)
04/28/2026	34	QC NOTICE: <u>33</u> Response, filed by AstraZeneca Pharmaceuticals LP, AstraZeneca AB, AstraZeneca UK Ltd. was filed incorrectly. <i>**Incorrect event used. Please refile using Responses and Replies > Reply to Response to Motion and enhance the text as needed to include that it is also a Response in Opposition. It has been noted as FILED IN ERROR, and the document link has been disabled.</i> (ols, Deputy Clerk) (Entered: 04/28/2026)
04/28/2026	<u>35</u>	REPLY to Response to Motion re <u>21</u> MOTION for Summary Judgment and <u>32</u> Opposition to Defendants' Motion to Dismiss/Motion for Summary Judgment filed by AstraZeneca AB, AstraZeneca Pharmaceuticals LP, AstraZeneca UK Ltd..(Pichini, Michael) (Entered: 04/28/2026)
05/20/2026	<u>36</u>	

		MOTION for Extension of Time to File Response/Reply <i>in Support of Defendants' Motion to Dismiss (or, in the alternative for Summary Judgment)</i> by Centers for Medicare and Medicaid Services, Robert F. Kennedy, Jr, Mehmet Oz, U.S. Department of Health and Human Services (Attachments: # <u>1</u> Text of Proposed Order)(Pezzi, Stephen) (Entered: 05/20/2026)
05/21/2026	<u>37</u>	RESPONSE in Opposition re <u>36</u> MOTION for Extension of Time to File Response/Reply <i>in Support of Defendants' Motion to Dismiss (or, in the alternative for Summary Judgment)</i> filed by AstraZeneca AB, AstraZeneca Pharmaceuticals LP, AstraZeneca UK Ltd..(Pichini, Michael) (Entered: 05/21/2026)
05/21/2026	<u>38</u>	ORDER granting in part <u>36</u> defendant's Motion for Extension of Time to File Response/Reply in support of <u>32</u> MOTION to dismiss (Or, In TheAlternative, For Summary Judgment), shall be filed no later than June 11, 2026. Signed by Judge Matthew J. Maddox on 5/21/2026. (bm5s, Deputy Clerk) (Entered: 05/22/2026)
06/11/2026	<u>39</u>	NOTICE of Appearance by Pardis Gheibi on behalf of All Defendants (Gheibi, Pardis) (Entered: 06/11/2026)
06/11/2026	<u>40</u>	REPLY to Response to Motion re <u>32</u> MOTION to Dismiss <i>(or, in the Alternative, for Summary Judgment) and Opposition to Plaintiffs' Motion for Summary Judgment</i> filed by Centers for Medicare and Medicaid Services, Robert F. Kennedy, Jr, Mehmet Oz, U.S. Department of Health and Human Services.(Gheibi, Pardis) (Entered: 06/11/2026)
06/26/2026	<u>41</u>	NOTICE by AstraZeneca AB, AstraZeneca Pharmaceuticals LP, AstraZeneca UK Ltd. <i>of Availability for Oral Argument</i> (Pichini, Michael) (Entered: 06/26/2026)
06/26/2026	<u>42</u>	PAPERLESS ORDER: A hearing on pending motions is scheduled for August 19, 2026, at 2:30 p.m., in Courtroom 5C. Signed by Judge Matthew J. Maddox on 6/26/2026. (Maddox, Matthew) (Entered: 06/26/2026)
06/30/2026	<u>43</u>	NOTICE of Appearance by Jedd Bellman on behalf of Bausch Health Companies Inc., Biotechnology Innovation Organization, Bristol Myers Squibb Company, Eli Lilly and Company, Johnson & Johnson, Sanofi–Aventis U.S. LLC (Bellman, Jedd) (Entered: 06/30/2026)
06/30/2026	<u>44</u>	MOTION to Withdraw as Attorney by Bausch Health Companies Inc., Biotechnology Innovation Organization, Bristol Myers Squibb Company, Eli Lilly and Company, Johnson & Johnson, Sanofi–Aventis U.S. LLC (Attachments: # <u>1</u> Text of Proposed Order)(Williams, Edward) (Entered: 06/30/2026)
07/01/2026	<u>45</u>	NOTICE of Appearance by Michael C Heyse on behalf of AstraZeneca AB, AstraZeneca Pharmaceuticals LP, AstraZeneca UK Ltd. (Heyse, Michael) (Entered: 07/01/2026)
07/13/2026	<u>46</u>	NOTICE by Centers for Medicare and Medicaid Services, Robert F. Kennedy, Jr, Mehmet Oz, U.S. Department of Health and Human Services (Attachments: # <u>1</u> Exhibit A)(Gheibi, Pardis) (Entered: 07/13/2026)
07/16/2026	<u>47</u>	RESPONSE re <u>46</u> Notice (Other) <i>and Notice of Further Authority</i> filed by All Plaintiffs. (Attachments: # <u>1</u> Exhibit Exhibit A, # <u>2</u> Exhibit Exhibit B)(Pichini, Michael) (Entered: 07/16/2026)
08/18/2026	<u>48</u>	NOTICE by Centers for Medicare and Medicaid Services, Robert F. Kennedy, Jr, Mehmet Oz, U.S. Department of Health and Human Services <i>NOTICE OF</i>

		<i>SUPPLEMENTAL AUTHORITY</i> (Attachments: # <u>1</u> Exhibit A)(Gheibi, Pardis) (Entered: 08/18/2026)
08/18/2026	<u>49</u>	ORDER granting <u>22</u> Motion for Leave to File an Amicus Brief in Support of Plaintiff's Motion for Summary Judgement. Signed by Judge Matthew J. Maddox on 8/18/2026. (bm5s, Deputy Clerk) (Entered: 08/19/2026)
08/19/2026	<u>50</u>	ORDER granting <u>44</u> Motion to Withdraw as Attorney. Attorney Edward Henderson Williams, II terminated. Signed by Judge Matthew J. Maddox on 8/19/2026. (bm5s, Deputy Clerk) (Entered: 08/19/2026)
08/19/2026	<u>51</u>	Motion Hearing held on 8/19/2026 re <u>21</u> MOTION for Summary Judgment filed by AstraZeneca Pharmaceuticals LP, AstraZeneca UK Ltd., AstraZeneca AB, <u>32</u> MOTION to Dismiss (<i>or, in the Alternative, for Summary Judgment</i>) and <i>Opposition to Plaintiffs' Motion for Summary Judgment</i> filed by Mehmet Oz, Robert F. Kennedy, Jr., U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services before Judge Matthew J. Maddox. (Russell Carrick – courtroom 5C)(Court Reporter: Amanda Longmore) (rc2s, Deputy Clerk) (Entered: 08/19/2026)
08/19/2026	<u>52</u>	ORDER denying <u>32</u> Defendants' Motion to Dismiss; denying <u>21</u> Plaintiffs' Motion for Summary Judgment; granting Defendants' alternative Motion for Summary Judgement; directing clerk to close this case.. Signed by Judge Matthew J. Maddox on 8/19/2026. (bm5s, Deputy Clerk) (Entered: 08/20/2026)
08/21/2026	<u>53</u>	NOTICE OF APPEAL as to <u>52</u> Order on Motion to Dismiss,, Order on Motion for Summary Judgment, by AstraZeneca AB, AstraZeneca Pharmaceuticals LP, AstraZeneca UK Ltd.. Filing fee \$ 605, receipt number AMDDC-12976439. (Attachments: # <u>1</u> Attachment 8.19.26 Court Order)(Heyse, Michael) (Entered: 08/21/2026)
08/24/2026	<u>54</u>	NOTICE OF FILING OF OFFICIAL TRANSCRIPT of Proceedings (Motions Hearing) held on 08/19/2026, before Judge Matthew J. Maddox. Court Reporter Amanda Longmore, Telephone number 4109624474; amanda_longmore@mdd.uscourts.gov. Total number of pages filed: 126. Transcript may be viewed at the court public terminal or purchased through the Court Reporter before the deadline for Release of Transcript Restriction. After that date it may be obtained from the Court Reporter or through PACER. Redaction Request due 9/14/2026. Redacted Transcript Deadline set for 9/24/2026. Release of Transcript Restriction set for 11/23/2026.(al6, Court Reporter) (Entered: 08/24/2026)
08/24/2026	<u>55</u>	Transmission of Notice of Appeal and Docket Sheet to US Court of Appeals re <u>53</u> Notice of Appeal. IMPORTANT NOTICE: To access forms which you are required to file with the United States Court of Appeals for the Fourth Circuit please go to http://www.ca4.uscourts.gov and click on Forms & Notices.(slss, Deputy Clerk) (Entered: 08/24/2026)
08/26/2026	<u>56</u>	USCA Case Number 26-2165 for <u>53</u> Notice of Appeal, filed by AstraZeneca UK Ltd., AstraZeneca Pharmaceuticals LP, AstraZeneca AB – Case Manager – T. Barton. (slss, Deputy Clerk) (Entered: 08/26/2026)

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

ASTRAZENECA PHARMACEUTICALS LP
1800 Concord Pike
Wilmington, Delaware 19850

and

ASTRAZENECA AB
S-151 85
Södertälje, Sweden

and

ASTRAZENECA UK LTD.
1 Francis Crick Avenue
Cambridge Biomedical Campus
Cambridge CB2 0AA
United Kingdom

Plaintiffs,

vs.

Civil Action No. _____

ROBERT F. KENNEDY, JR., in his official
capacity as Secretary of the U.S. Department of
Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

and

U.S. DEPARTMENT OF HEALTH AND HUMAN
SERVICES
200 Independence Avenue, SW
Washington, DC 20201

and

MEHMET OZ, in his official capacity as
Administrator of the Centers for Medicare and
Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

and

CENTERS FOR MEDICARE AND MEDICAID
SERVICES
7500 Security Boulevard
Baltimore, Maryland 21244

Defendants.

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiffs AstraZeneca Pharmaceuticals LP, AstraZeneca AB, and AstraZeneca UK Ltd.
(collectively, AstraZeneca) allege as follows:

INTRODUCTION

1. In the summer of 2022, Congress enacted legislation dramatically transforming Medicare, the Nation’s largest healthcare program. Since its creation decades ago, Medicare had reimbursed healthcare providers and drug dispensers for the cost of covered drugs at rates based on market forces. But as part of the Inflation Reduction Act of 2022 (IRA or Act), Pub. L. 117-169, Congress established a new system in which acquisition prices and reimbursement for selected pharmaceutical products instead will be imposed by the Secretary of the Department of Health and Human Services (HHS), under a program that the Act calls the “Drug Price Negotiation Program” (Program).

2. The Act gives the Secretary unilateral power over pharmaceutical prices—power that the Secretary must use to impose steep discounts on selected products. These products are subject to statutory price ceilings that embody deep cuts from current, market-based prices. But even more significantly, this government-imposed pricing generally has no floor; for almost any

drug selected under the Program, the Secretary could decide that Medicare should pay only a penny. No ordinary market actor brings that kind of leverage to the “negotiating” table.

3. In light of these draconian IRA-mandated price cuts, the Program carries monumental stakes for manufacturers—and has serious implications for medical innovation, provider and pharmacy reimbursements, and patient access. Studies indicate that the IRA will significantly curtail investment in medical research, to the detriment of patients.¹

4. Because the Act’s consequences are so severe, Congress limited and specified with precision the number of drugs that are subject to price caps under the IRA each year. For the Program’s first annual cycle, the statute directs the Secretary to select the ten “qualifying single source drugs” (QSSDs) that account for the highest total expenditures under Medicare; directs the Secretary to select fifteen more for its second cycle; directs the Secretary to select fifteen more for its third cycle; and directs the Secretary to select twenty more for its fourth and subsequent cycles. For each annual cycle, CMS must “publish a list of” the specified number of drugs—and no more. 42 U.S.C. § 1320f–1(a).

5. Yet in implementing the IRA, apparently CMS was not content with the existing scope of its already-sweeping power to dictate pharmaceutical prices. Rather, the agency sought to extend its authority even further, by expanding the stated numerical limit on the number of drugs eligible for price caps under the Program.

¹ Over the next decade, as many as 139 drugs are at risk of not being developed at all, meaning fewer innovative therapies for patients and their providers. *See* Vital Transformation, *IRA’s Impact on the US Biopharma Ecosystem* (June 1, 2023), <https://perma.cc/RRV5-DFGN>. These effects are already evident, with sharp cuts in early-stage investment. Since the IRA’s enactment, aggregate investment by small and mid-sized firms in new small-molecule medicines has declined by 68%. For treatments targeting diseases with a high proportion of Medicare beneficiaries, median investment size has dropped 74%. *See* Duane G. Schulthess et al., *The Inflation Reduction Act’s Impact Upon Early-Stage Venture Capital Investments*, 59 *Therapeutic Innovation & Regul. Sci.* 769 (2025), <https://doi.org/10.1007/s43441-025-00773-3>.

6. CMS has accomplished this power-grab by rewriting key statutory language. Under agency-issued guidance, CMS has redefined the term “qualifying single source drug” to sweep *multiple* products within each QSSD—in effect, treating two or more distinct drugs as a *single* QSSD.

7. There is nothing in the statute that permits the agency to redefine its terms in order to circumvent the clear limit on the number of drugs eligible for the Program. To the contrary, the Act makes clear that its numerical limits must be respected: It defines a QSSD as “[a] drug that *is approved* under” the Federal Food, Drug, and Cosmetic Act, but only if “at least 7 years will have elapsed since the date *of such approval*.” 42 U.S.C. § 1320f–1(e)(1)(A)(i)–(ii) (emphases added).

8. As the italicized language indicates, a QSSD must be a *single* drug subject to a *single* “approval.” The IRA provides that the relevant “approval” is the drug’s approval by the U.S. Food and Drug Administration (FDA) under a New Drug Application (NDA). The NDA is the fundamental building block of FDA’s framework for approving new drugs. FDA will approve an NDA only after a “long, comprehensive, and costly testing process” designed to determine whether the drug will be safe and effective to treat identified conditions in a specific patient population. *FTC v. Actavis, Inc.*, 570 U.S. 136, 142 (2013). And federal law attaches a host of consequences to NDA-approval, including permission to market the drug and a set period of exclusivity for most drugs that runs from the approval’s effective date.

9. The statutory QSSD definition accords with that understanding. A separate approval of an NDA (each “such approval”) potentially gives rise to a new QSSD, whose eligibility for the Program must be determined based on Medicare expenditures for *that* individual drug, and whose seven-year exemption period runs from FDA approval of *that* drug’s NDA. This straightforward reading of the text also makes good sense: FDA approval is grounded in substantial

safety and efficacy information—usually developed through years of clinical testing and millions, or even billions, of research dollars—justifying use of the drug for particular indications and particular patient populations.

10. Each “such approval” thus gives rise to a different FDA-approved drug, and hence a different potential QSSD, which must be considered on its own merits for potential selection for the Program, until the Act’s numerical threshold has been reached—but not beyond.

11. In guidance implementing the Program, however, CMS has sought to expand the numerical limit on eligible drugs by adopting an alternative definition of QSSD that contravenes the Act’s clear text. *See* Ctrs. for Medicare & Medicaid Servs., *Medicare Drug Price Negotiation Program: Final Guidance* (Oct. 2, 2024) (Final Guidance).² The guidance announces that the agency will “identify a potential qualifying single source drug using . . . all dosage forms and strengths of the drug with the same active moiety and the same holder of a New Drug Application (NDA), *inclusive of products that are marketed pursuant to different NDAs.*” *Id.* § 30.1 at 167 (emphasis added).

12. Under that approach, two or more *distinct* drugs that were evaluated and approved by FDA through different NDAs under entirely *separate* approval processes will nevertheless be

² On June 30, 2023, CMS issued guidance to govern the first cycle of the Program, which AstraZeneca has challenged in the U.S. District Court for the District of Delaware. *See* Am. Compl. *AstraZeneca Pharms. LP v. Becerra*, No. 23-CV-931, Dkt. 16 ¶¶ 47–48 (D. Del., Sept. 26, 2023). The court dismissed AstraZeneca’s APA claims for lack of standing. *AstraZeneca Pharms. LP v. Becerra*, 719 F. Supp. 3d 377, 387 (D. Del. 2024). AstraZeneca appealed that decision, and the Third Circuit affirmed. *See AstraZeneca Pharms. LP v. HHS*, 137 F.4th 116 (3d Cir. 2025). AstraZeneca has petitioned the U.S. Supreme Court for a writ of certiorari, which is currently pending. *See AstraZeneca Pharms. LP v. HHS*, No. 25-348 (S. Ct.). In September 2025, CMS issued guidance for the IRA’s third annual cycle, with price caps taking effect in 2028. *See* Ctrs. for Medicare & Medicaid Servs., *Medicare Drug Price Negotiation Program: Final Guidance* (Sept. 30, 2025), <https://edit.cms.gov/files/document/ipay-2028-final-guidance.pdf>.

treated collectively as a *single* QSSD, for purposes of selection under the Program, so long as they share the same “active moiety” and the same NDA-holder (which the agency refers to as the “primary manufacturer” of the selected drug). And the drugs will be combined for selection purposes even if they reflect significant ingredient or formulation differences warranting a new NDA, and even if they were approved at different times or to treat different diseases and different patient populations.

13. CMS’s approach of lumping together separately approved products is a transparent effort to nullify the central constraint on the Program’s scope. Since it allows two or more products approved under separate NDAs to be treated as a single QSSD, the agency’s approach facially contravenes the statute’s numerical limits on drug selection, with both the purpose and effect of applying the Program’s draconian price caps to a far broader range of products—including products that, standing alone, would not qualify for selection. 42 U.S.C. § 1320f–1(a).

14. CMS’s approach also means that even brand-new products could be subject to selection and negotiation *immediately* upon approval, contrary to the prohibition on selecting products until “at least 7 years will have elapsed since the date of [FDA] approval.” 42 U.S.C. § 1320f–1(e)(1)(A)(i)–(ii). Under the agency’s approach, if products that share the same active moiety are approved under more than one NDA, the clock would begin to run from when FDA approved the *first* NDA, rather than separate clocks that run for each product from the date of approval of its distinct NDA. The text of the statute does not permit CMS’s approach.

15. Moreover, *nothing* in the statute justifies CMS’s peculiar approach of aggregating together separately approved drugs based on a common active moiety and common identity of the NDA-holder—criteria that appear nowhere in the statute. CMS’s approach contravenes the statute’s clear instructions.

16. CMS’s approach is not just legally impermissible, but also practically harmful. It will discourage pharmaceutical manufacturers from investing time and money to discover whether an active moiety in an existing drug could be developed into a new product to treat different diseases or patient populations or to improve safety or efficacy. In the eyes of the agency, any Medicare expenditures for the new product approved under a separate NDA would be lumped together with expenditures for the existing product, thereby increasing the likelihood that the agency will select *both* products for the draconian Drug Price Negotiation Program—subjecting them to the Program’s steep cuts in payment and reimbursement, potentially on the very first day of a new product’s FDA approval. The agency’s approach thus incentivizes manufacturers *not to* innovate.

17. This harm is particularly acute for the development of oncology drugs, where post-approval research is critical for discovering additional uses for cancer medicines that can benefit more patients. In fact, among oncology drugs approved from 2000 to 2021, 57% of approved indications and 68% of industry-sponsored clinical trials occurred post-approval. Approximately half of these post-approval indications were in new oncology disease areas—thus delivering new treatment options for more cancer patients—and many occurred several years after the molecule’s initial approval. See Henry Grabowski et al., *Postapproval Innovation For Oncology Drugs And The Inflation Reduction Act*, 43 Health Affs. 1400 (2024), <https://bit.ly/4j8BJVQ>.

18. AstraZeneca asks this Court to set aside the section of the agency’s Final Guidance that eviscerates the statutory limit on the number of drugs eligible for the Program by redefining “qualifying single source drug” as including separately approved products that share the same active moiety and NDA-holder. Restoring fidelity to the statutory text will ensure that the agency

implements the Program within the parameters specified by the IRA, so that government-mandated price controls apply only to the number of drugs for which Congress actually authorized them.

JURISDICTION AND VENUE

19. This Court has jurisdiction pursuant to 28 U.S.C. § 1331 (action arising under the laws of the United States), 28 U.S.C. § 1346 (United States as a defendant), and 5 U.S.C. §§ 701-06 (Administrative Procedure Act). An actual controversy exists between the parties within the meaning of 28 U.S.C. § 2201(a), and this Court may grant declaratory relief, injunctive relief, and other appropriate relief pursuant to 28 U.S.C. §§ 2201-02 and 5 U.S.C. §§ 705-06.

20. Venue is proper in this Court under 28 U.S.C. § 1391(e) because this action seeks relief against federal agencies and officials acting in their official capacities, Defendant CMS is located within this District, and no real property is involved in the action.

PARTIES

21. Plaintiff AstraZeneca Pharmaceuticals LP, a limited partnership organized in Delaware with its principal place of business in Wilmington, Delaware, is a biopharmaceutical company focusing on the discovery, development, manufacturing, and commercialization of medicines.

22. Plaintiff AstraZeneca AB, a company operating and existing under the laws of Sweden, with its principal place of business at S-151 85 Södertälje, Sweden, is the corporate parent of AstraZeneca Pharmaceuticals LP.

23. Plaintiff AstraZeneca UK Ltd., a company operating and existing under the laws of the United Kingdom, with its principal place of business at 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge CB2 0AA, United Kingdom, is an indirect shareholder of AstraZeneca Pharmaceuticals LP.

24. Plaintiffs are referred to here collectively as “AstraZeneca.”

25. Defendant Robert F. Kennedy, Jr. is the Secretary of HHS. The IRA directs the Secretary to establish the Drug Price Negotiation Program. He is sued in his official capacity.

26. HHS is a department of the United States Government that is headquartered in Washington, D.C, and is responsible for the Centers for Medicare and Medicaid Services and the Medicare program.

27. Defendant the Centers for Medicare and Medicaid Services (CMS) is an executive agency within HHS that is headquartered in Maryland. CMS is responsible for administering the Medicare program and relevant statutory provisions challenged here.

28. Defendant Mehmet Oz is the Administrator of CMS. He administers the Program on behalf of the Secretary. He is sued in his official capacity.

BACKGROUND

FDA’s Drug Approval Process

29. All “new drugs” must be approved by FDA before being introduced into interstate commerce. 21 U.S.C. § 355(a). A manufacturer thus must submit a New Drug Application, or NDA, to request that FDA approve the drug.

30. As FDA has explained, the “goals of the NDA” are to allow the agency to determine (1) “[w]hether the drug is safe and effective in its proposed use(s), and whether the benefits of the drug outweigh the risks”; (2) “[w]hether the drug’s proposed labeling (package insert) is appropriate, and what it should contain”; and (3) “[w]hether the methods used in manufacturing the drug and the controls used to maintain the drug’s quality are adequate to preserve the drug’s identity, strength, quality, and purity.” FDA, *New Drug Application* (Jan. 21, 2022), <https://www.fda.gov/drugs/types-applications/new-drug-application-nda>.

31. Obtaining approval for an NDA involves a “long, comprehensive, and costly testing process.” *FTC v. Actavis, Inc.*, 570 U.S. 136, 142 (2013). Among other things, the manufacturer must submit “full reports of investigations” into the drug’s safety and effectiveness, “a full list of the articles used as components,” and a “full description” of how the drug is manufactured, processed, and packed. 21 U.S.C. § 355(b)(1). In other words, “[t]he documentation required in an NDA is supposed to tell the drug’s whole story.” *New Drug Application*.

32. If, at the end of this process, FDA is ultimately persuaded of the drug’s safety and efficacy, the manufacturer will receive “marketing approval.” 21 U.S.C. § 355(d). The date that such approval “shall be made effective” is fixed by statute according to specified criteria. *Id.* § 355(c)(3).

33. “FDA has interpreted the word ‘drug’ in the term ‘new drug’ to refer to the entire drug product and not just its active ingredient,” 86 Fed. Reg. 28605, 28606. Drugs with different “active ingredients” are thus typically considered for approval under separate NDAs.

34. But the agency also recognizes that even a single “active ingredient can have different effects on the body depending on the formulation of the drug and its route of administration.” FDA, *Guidance for Industry Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees*, 3 & n.7 (Dec. 2004) (*Separate Marketing Applications Guidance*), <https://www.fda.gov/media/72397/download>. “That is why when it reviews an application, FDA carefully evaluates, for each drug product, not only the active ingredient but also information about the drug’s formulation, route of administration, labeling, inactive ingredients, bioavailability, and manufacturing processes.” *Id.* FDA accordingly defines “drug product” in terms of its “finished dosage form, e.g., tablet, capsule, or solution, that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients,”

and also defines “drug substance” as the active ingredient intended to furnish pharmacological activity in the treatment of a disease. 21 C.F.R. § 314.3. This “product-specific interpretation of ‘new drug’ underpins FDA’s drug regulatory system” and “has significant implications for public health.” *Id.*

35. After an NDA has been approved, the manufacturer generally may not change any aspect of the drug, beyond the variations “already provided for in the NDA,” without providing notice to FDA. *Id.* § 314.70(a)(1)(i). Under FDA regulations, the type of FDA notice turns on the nature of the change and its potential effect on the approved drug. Changes are categorized as “minor,” “moderate,” or “major” based on whether a change has a minimal, moderate, or substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product as these factors relate to the safety or effectiveness of the drug. *Id.* § 314.70. For “minor” and “moderate” changes, sponsors are required to simply notify FDA of the change, following processes set forth in the regulations, and FDA approval is not required before the sponsor effects the change. *Id.* § 314.70(c)-(d).

36. For “major” changes to an existing drug, FDA regulations require sponsors to submit a “supplement” to the original NDA and to obtain approval from FDA before effecting the change. FDA refers to such supplements as “prior approval supplements.” *Id.* § 314.70(b). Under the regulations, changes requiring a prior approval supplement to the NDA include “changes in the qualitative or quantitative formulation of the drug product, including inactive ingredients, or in the specifications provided in the approved NDA” (with certain exceptions). *Id.* § 314.70(b)(2)(i).

37. Importantly, changes to a drug approved through a supplement are still considered part of the *existing* NDA. Thus, a supplement is approved under the existing NDA number, and is not assigned a new NDA number.

38. By contrast, there are certain types of changes to an approved drug that are so significant that FDA requires submission and approval of a new *separate and original NDA*, rather than a supplement to the existing NDA.

39. FDA’s policy for changes that rise to the level of requiring a separate original NDA is described in agency guidance. The agency’s *Separate Marketing Applications Guidance* describes different categories of changes and when such changes should be submitted in a separate original NDA instead of a supplement to an existing NDA.

40. Typically, a new NDA is required instead of a supplement when, for example, an applicant is seeking approval for a drug product that contains a different “active ingredient” than previously approved (whether or not the “active moiety”³ is different), a different “dosage form,” or a different “formulation” (*i.e.*, a drug’s active ingredient(s) in association with its inactive ingredients). *See* FDA, *Manual of Policies and Procedures 5018.2* (eff. Dec. 8, 2022), <https://www.fda.gov/media/94381/download>. By contrast, changes to dosage forms, strengths, and formulations may be encompassed within a single NDA under certain circumstances.

41. Consider dosage form—that is, a drug’s physical features, such as tablets, capsules, injectables, etc. *See* *Drugs@FDA Glossary of Terms* (2017), <https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms>. For dosage form changes to an approved drug,

³ As discussed below, an “active moiety” is the “molecule or ion that drives the action of the drug.” FDA, *Q&A: GFI #256 - Compounding Animal Drugs from Bulk Drug Substances* (Aug. 27, 2024), <https://bit.ly/4o5snL9>.

whether the sponsor should submit a supplement to the existing NDA or a separate original NDA turns on how the quantitative and qualitative formulation of the new dosage form compares to that of the previously approved product. A new dosage form can be approved through a *supplement* if the formulation of the new dosage form is “quantitatively and qualitatively identical” to that of the previously approved product. *Separate Marketing Applications Guidance* at 3. But if the formulation of the new dosage form *is not* “quantitatively and qualitatively identical” to that of the previously approved product, FDA recommends submission of a *separate original NDA*. *Id.*

42. Of particular relevance here, another type of change addressed in the guidance is a change in strength. For new strengths, whether a sponsor should submit a separate original NDA or a supplement turns on how the qualitative (but not quantitative) formulation of the new strength compares to that of the previously approved product. If the formulation of the new strength is “qualitatively identical” to that of the previously approved product, FDA recommends submission of a *supplement* provided the new strength is for the same dosage form and route of administration as the previously approved product. *Id.* at 3-4. If the formulation of the new strength is *not* “qualitatively identical” to that of the previously approved product, FDA recommends submission of a *separate original application*. *Id.* The guidance indicates FDA expects most strength changes can be submitted as a supplement, suggesting that most strength changes involve only quantitative formulation changes, not qualitative formulation changes. *See id.* at 5.

43. Whether a new “formulation” requires a new NDA or may be submitted through a supplement similarly depends on the circumstances. For example, “[a] change to an approved product . . . that changes . . . the formulation (e.g., different excipients) can be submitted as a supplement to an approved application” and “would not ordinarily warrant a new original

application unless it” results in a quantitative or qualitative change to the composition of an approved product to support “changes [to] the dosage form or route of administration.” *Id.*

44. New drugs regularly require new NDAs despite sharing an “active moiety” with a drug that has already been approved. For example, FDA has said that drugs with the same active moiety but different active ingredients are considered for approval under separate NDAs. That is because the agency requires submission of a separate NDA if an applicant develops a drug product with a different “active ingredient” than the applicant’s previously approved drug product, and two drugs can have different “active ingredients” despite having the same “active moiety.” There is a good reason for this difference: In determining a drug’s “active moiety,” FDA excludes appended portions of a drug that cause it to be a salt, ester, or other non-covalent derivative. *See* 21 C.F.R. § 314.3(b). In determining the “active ingredient,” by contrast, FDA includes those appended portions of a drug. *Id.* FDA defines “active ingredient” as “any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease.” *Id.* As a result, if an applicant develops two salts with different structures derived from the same active moiety (and the salts are the components intended to furnish pharmacologic action), FDA considers the salts to have *different* active ingredients and requires approval through *separate* NDAs.

45. Likewise, new *dosage forms* often require new NDAs, irrespective of any shared active moiety or shared active ingredient, because developing a different dosage form generally entails adding, removing, or changing the ratios of inactive ingredients—thereby resulting in a formulation with “qualitative or quantitative” differences from that of the applicant’s previously approved dosage form. *Separate Marketing Applications Guidance* at 3 & n.7; *see* FDA, Manual of Policies and Procedures 5018.2 (eff. Dec. 8, 2022).

46. The NDA framework has significant implications for generic competition as well. “[O]nce the FDA has approved a brand-name drug for marketing, a manufacturer of a generic drug can obtain similar marketing approval through use of abbreviated procedures.” *Actavis*, 570 U.S. at 142. Under 21 U.S.C. § 355(j), a generic manufacturer may file an “Abbreviated New Drug Application,” or ANDA, showing that the generic has the same active ingredient, dosage form, strength, and route of administration as, and is bioequivalent to, a particular “listed” (*i.e.*, brand-name) NDA drug. *See id.* § 355(j)(2)(A)(i). As part of the ANDA, the applicant is required to identify the specific NDA that the ANDA references as the so-called “listed” drug. Food & Drug Admin., *Guidance for Industry, ANDA Submissions — Content and Format* (June 2019), available at <https://www.fda.gov/media/128127/download>.

The Inflation Reduction Act

47. Enacted in 1965, the Medicare program provides health insurance for individuals 65 years of age and older, some individuals with disabilities under age 65, and individuals with certain conditions such as end-stage renal disease. Medicare Part B generally provides eligible patients with insurance coverage for drugs and biologicals that are administered by physicians (or other health care providers). Medicare Part D provides eligible patients with insurance coverage for prescription drugs that are dispensed by pharmacies.

48. The Inflation Reduction Act of 2022 establishes a “Drug Price Negotiation Program” for setting acquisition prices and reimbursement rates under Medicare for a specified number of products per annual cycle.

CMS Selects a Specified Number of “Qualifying Single Source Drugs” for the Program

49. The IRA directs the Secretary to establish a “Drug Price Negotiation Program,” 42 U.S.C. § 1320f(a), which is administered by CMS. The Program is limited to Medicare Part D drugs for the first two annual cycles, after which CMS also may select Part B drugs. *Id.* § 1320f(b).

50. The statute sets forth a three-step process for the agency to select drugs for the Program.

51. **First**, CMS must identify “qualifying single source drugs” (QSSDs), which encompass many innovative first-in-class and best-in-class drug products. The statute defines a QSSD to include a drug product that is “a covered part D drug (as defined in [42 U.S.C. § 1395w–102(e)])” and:

(i) that *is approved* under section 355(c) of title 21 and is marketed pursuant to *such approval*;

(ii) for which, as of the selected drug publication date with respect to such initial price applicability year, *at least 7 years will have elapsed since the date of such approval*; and

(iii) that is not the listed drug for any drug that is approved and marketed under section 355(j) of title 21.

Id. § 1320f–1(e)(1)(A) (emphases added).⁴

52. **Second**, after identifying all QSSDs, CMS must determine which QSSDs qualify as “negotiation eligible drugs.” *Id.* § 1320f–1(d). To make this determination, CMS must rank QSSDs based upon each drug’s total expenditures under Medicare Part D or Part B, respectively, over the previous twelve-month period. *Id.* § 1320f–1(d)(1). Because only Part D drugs can be selected during the first two cycles, the agency ranks drugs only by Part D expenditures during these initial cycles. *Id.* § 1320f–1(d)(1)(A). The QSSDs that are among the top 50 highest

⁴ The IRA excludes certain drugs from the definition of QSSD, including “[c]ertain orphan drugs,” “[l]ow-spend Medicare drugs,” and “[p]lasma-derived products.” 42 U.S.C. § 1320f–1(e)(3).

expenditure Part D or Part B drugs, respectively, are known as “negotiation-eligible drugs.” *Id.* § 1320f–1(d).

53. When taking this second step of determining whether a QSSD ranks as a negotiation-eligible drug, the statute includes a “Use of Data” provision, which states:

In determining whether a qualifying single source drug satisfies any of the criteria described in paragraph (1) or (2) [*i.e.*, the criteria for negotiation-eligible drugs)], the Secretary shall use data that is aggregated across dosage forms and strengths of the drug, including new formulations of the drug, such as an extended release formulation, and not based on the specific formulation or package size or package type of the drug.

Id. § 1320f–1(d)(3)(B).

54. Thus, after the agency has identified each QSSD, the Use of Data provision instructs the agency to aggregate the approved dosage forms and strengths *within each* QSSD to determine whether the Medicare expenditures for that QSSD reach the top-50 threshold, at which point the QSSD becomes a negotiation-eligible drug.

55. ***Third***, the statute directs the agency to select a specified number of the highest-ranked negotiation-eligible drugs for the Program each year. *Id.* § 1320f–1(a)-(b). CMS was required to select *ten* Part D drugs during the first annual cycle, with price caps taking effect in 2026; and *fifteen* more during the second cycle, with price caps taking effect in 2027. *Id.* § 1320f–1(a)(1)-(2). After Part B drugs are added beginning in the third cycle, the statute directs CMS to select *fifteen* Part B or D drugs for price caps taking effect in 2028; and *twenty* more Part B or D drugs for the fourth cycle and each one thereafter. *Id.* § 1320f–1(a)(1), (3)-(4).

56. The drug-selection process is cumulative: Once a drug is selected, it remains a selected drug until a defined period after the agency determines that a generic version of the drug has been approved by the FDA and marketed “pursuant to such approval.” *Id.* § 1320f–1(c)(1)(B). The number of drugs subject to the Program thus mounts over time.

CMS Imposes “Maximum Fair Prices” Through So-Called “Negotiations”

57. Once innovative drugs are ranked and selected, the IRA directs the agency to “enter into agreements” with manufacturers, beginning the process through which CMS sets “maximum fair prices” (MFPs) for the selected drugs. *Id.* § 1320f–2(a)(1).

58. While the statute calls this process a “negotiation,” it is a negotiation only in name. In reality, the IRA enables CMS to *dictate* the MFP for a selected drug, and further *compels* the manufacturer to “agree” to it. *Id.* § 1320f–3(c).

59. To set (*i.e.*, dictate) the MFP, the IRA directs the agency to “develop and use a consistent methodology and process . . . for negotiations . . . that aims to achieve the *lowest* maximum fair price for each selected drug.” *Id.* § 1320f–3(b)(1) (emphasis added).

60. With a minor exception not relevant here, the law places no floor constraining the price CMS can impose; nor does it provide a clear standard for the agency to use in selecting prices. But it does impose caps on how high a price CMS can set, directing the Secretary to use the lowest number yielded by various alternative calculations specified by statute. *See, e.g., id.* § 1320f–3(b)(2)(F), (c).

61. As the last step in the price-setting process, the statute requires CMS to “compute and apply the [MFP] across different strengths and dosage forms of a selected drug.” *Id.* § 1320f–5(a)(2). Thus, CMS must adjust and apply the MFP to each strength and dosage form that falls under that selected drug (*i.e.*, to those strengths and dosage forms that were part of the QSSD identified in the first step of the selection process).

62. Once CMS has imposed an MFP for a selected drug, the manufacturer must provide “access to such price to” a wide variety of individuals and entities participating in Medicare. *Id.* § 1320f–2(a)(1). These participants include all eligible Medicare beneficiaries who are dispensed

drugs under Medicare Parts B and D; all “pharmacies, mail order services, and other dispensers” that dispense drugs to Medicare beneficiaries; and all “hospitals, physicians, and other providers of services and suppliers” that furnish or administer drugs to Medicare beneficiaries. *Id.* § 1320f–2(a)(1)(A)–(B); *id.* § 1320f(c)(2). Further, Medicare reimbursement rates for selected drugs are tied to the MFP. *See id.* § 1395w–102(d)(1)(D) (Part D negotiated price is capped at the maximum fair price plus any dispensing fee); *id.* § 1395w–3a(b)(1)(B) (provider payment amount for Part B selected drugs is the MFP plus six percent).

63. Manufacturers that fail to provide the required access to the MFP are subject to a civil monetary penalty of *ten times* the difference between the “price for such drug made available . . . by such manufacturer” and the MFP, multiplied by the total number of units sold. *Id.* § 1320f–6(a).

CMS Compels Participation in the Program Through a Hobson’s Choice: Threat of a Crippling “Excise Tax” or Complete Withdrawal from Medicare and Medicaid

64. Although the Drug Price Negotiation Program is designed to mimic a negotiation—including use of terms like “offer,” “counteroffer,” and “negotiation,” *id.* § 1320f–3—the statute uses these terms to conceal the true nature of the process. In reality, the Program is designed to coerce manufacturers to submit to government-imposed prices.

65. The Program is enforced through massive civil monetary penalties, *id.* § 1320f–6, and an “Excise Tax Imposed on Drug Manufacturers During Noncompliance Periods,” IRA § 11003. A manufacturer of a selected drug who fails to enter into a Program agreement (at the initiation of the “negotiation” period) or who fails “agree” to the ultimate price that CMS sets is subject to a steep and escalating daily penalty, 26 U.S.C. § 5000D(b), which under the statute *starts* at approximately 186% and escalates to 1,900% of *each sale* of the selected drug—not merely

Medicare sales, *id.* § 5000D(a).⁵ See Cong. Rsch. Serv., *Tax Provisions in the Inflation Reduction Act of 2022 (H.R. 5376)* 4 tbl. 2 (2022) (“The excise tax rate would range from 185.71% to 1,900% of the selected drug’s price depending on the duration of noncompliance.”). The excise-tax penalty thus represents a multiple of the manufacturer’s *total revenues* from the drug in question, not merely its profits. The penalty continues to accrue every day until the manufacturer acquiesces to CMS’s demands (or until the drug in question ceases to be a selected drug).

66. The “alternative” to the excise tax is for a manufacturer to exit Medicare and Medicaid with respect to *all* of its products—not just the selected drug. The IRA provides for the “[s]uspension” of the punitive excise-tax penalty, but only if the manufacturer terminates its Medicare Part D and Medicaid rebate agreements for *all* of the manufacturer’s drugs. 26 U.S.C. § 5000D(c). What is more, because a manufacturer must “have in effect a [Medicaid] rebate agreement” in order for a drug to be payable under Medicare Part B, terminating the Medicaid rebate agreement would also result in the manufacturer losing Part B coverage for all of its products. 42 U.S.C. § 1396r–8(a)(1). Thus, in order to suspend application of the tax penalty, a pharmaceutical manufacturer must entirely cease participation in both Medicare and Medicaid.⁶

⁵ The Internal Revenue Service has stated in a proposed rule that the excise tax will only apply to Medicare sales of the selected drug. See 90 Fed. Reg. 31 (Jan. 2, 2025). The statutory text, however, contains no such limitation.

⁶ Nor could these programs voluntarily cover the manufacturer’s products in the absence of these agreements. The IRA explicitly prohibits Part D plans from covering drugs of a manufacturer that has terminated its Part D agreement to suspend the excise tax. 42 U.S.C. § 1395w–153(c)(2). Although generally there is a narrow exception that allows Part D plans to cover drugs of a manufacturer without a Part D agreement if the agency determines that such drugs are “essential to the health” of Medicare beneficiaries, the IRA specifies that this exception does not apply if a manufacturer terminates its Medicare Part D agreement to avoid the excise tax. Likewise, covered outpatient drugs that do not fall under a Medicaid rebate agreement are not covered under the Medicaid Drug Rebate Program or Medicare Part B. *Id.* § 1396r–8(a)(1). Although there is an exception that allows Medicaid state plans to cover such a drug if the plan determines the drug is “essential to the health” of beneficiaries of their plan, the IRA prohibits Medicaid plans from covering the drug if a manufacturer terminates its Medicaid rebate agreement to avoid the excise tax. *Id.* § 1396r–8(a)(3).

67. Exiting the Medicare and Medicaid programs would not only be financially devastating for a manufacturer of a selected drug, but it would also jeopardize Medicare and Medicaid beneficiaries' access to *all* the manufacturer's medicines—not only the selected drug. The potential impact would be catastrophic, with Medicare and Medicaid accounting for nearly half of the U.S. prescription drug market. Cong. Budget Off., *Prescription Drugs: Spending, Use, and Prices* (Jan. 2022) at 8, <https://www.cbo.gov/publication/57050>.

CMS Program Guidance Seeks to Override the IRA's Defined Limits

68. On May 3, 2024, CMS issued draft guidance setting forth the agency's plan for implementing the Program during its second cycle—initial price applicability year 2027 (IPAY 2027)—for which the IRA directs CMS to select *fifteen* Part D drugs for “negotiation.” See Ctrs. for Medicare & Medicaid Servs., *Medicare Drug Price Negotiation Program: Draft Guidance* (May 3, 2024) (Draft Guidance). Although the statute does not contain any exceptions to the fifteen-drug limit or provide any basis to expand that number, CMS's draft guidance requires just that.

69. Specifically, CMS sought to override the IRA's express numerical limitation through Section 30 of its Draft Guidance, which articulates “the requirements governing the identification of qualifying single source drugs.” *Id.* § 30 at 5. In its Draft Guidance, CMS announced that it would “identify a potential qualifying single source drug using . . . all dosage forms and strengths of the drug with the same *active moiety* and the same holder of a New Drug Application (NDA), *inclusive of products that are marketed pursuant to different NDAs.*” *Id.* § 30.1 at 8 (footnote omitted) (emphases added).

70. The term “active moiety” does not appear in the IRA. According to FDA regulations implementing a *different* statute, the Federal Food Drug and Cosmetic Act (FDCA),

active moiety “is the molecule or ion . . . responsible for the physiological or pharmacological action of the drug substance.” 21 C.F.R. § 314.3. As discussed above, drugs that share an “active moiety” can still require distinct NDAs—for instance, when they contain different “active ingredients.” *See Separate Marketing Applications Guidance* at 3 & n.7. In other words, distinct drugs can *share* an active moiety yet have *different* active ingredients that require them to be approved under *separate* NDAs.

71. Thus, under the QSSD definition in CMS’s Draft Guidance, two or more *distinct* drugs with *different* active ingredients—evaluated and approved by the FDA under entirely separate processes at different times based on separate efficacy and safety data—could nevertheless be treated collectively as a *single* QSSD. So long as they share the same “active moiety” and have the same NDA-holder, CMS announced that it intended to aggregate their Medicare sales for purposes of selection under the Program. Draft Guidance § 30.2 at 14.

72. The agency also announced that, where two or more products with the same active moiety were approved under different NDAs, the clock would begin to run from the “earliest date of approval or licensure of the initial FDA application.” *Id.* § 30.1 at 10. As a result, a new product could be subject to selection, negotiation, and an MFP under the Program *immediately* upon FDA approval—so long as it shares an active moiety and NDA-holder with an older product—notwithstanding the IRA’s prohibition on selecting products until “at least 7 years will have elapsed since the date of such approval.” 42 U.S.C. § 1320f–1(e)(1)(A)(i)-(ii).

73. The agency acknowledged that the QSSD definition articulated in Section 30 was severely criticized, among other things, as “contradict[ing] the statute,” which “defines a qualifying single source drug in reference to a distinct NDA.” Final Guidance at 12. But when CMS finalized the guidance for the second cycle of selected drugs on October 2, 2024, it adopted

the interpretation of the QSSD definition in Section 30 without meaningful change. *See id.* § 30.1 at 167-68.

74. On January 17, 2025, CMS applied the Final Guidance to “publish a list of” ostensibly “fifteen” drugs for the second cycle. *See* 42 U.S.C. § 1320f–1(a). Instead of including only fifteen drugs, however, CMS exceeded that number by purporting to treat multiple drugs as single QSSDs. *See* Ctrs. for Medicare & Medicaid Servs., *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2027* (Jan. 17, 2025), <https://www.cms.gov/files/document/factsheet-medicare-negotiation-selected-drug-list-ipay-2027.pdf>.

Acalabrutinib Free Base and Acalabrutinib Maleate Salt

75. An illustration of this circumvention at work is how the Final Guidance lumps together two different drug products manufactured by AstraZeneca to treat certain forms of leukemia and lymphoma: acalabrutinib free base and acalabrutinib maleate salt. These drug products were approved by FDA years apart, pursuant to separate NDAs. Although the two drugs share an active moiety, they have different active ingredients and different dosage forms. And even beyond those distinctions, the two drugs differ in their formulations. As a result, they were *required* to be approved under distinct NDAs.

76. AstraZeneca developed acalabrutinib free base and acalabrutinib maleate salt to treat: (i) adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy; (ii) adult patients with previously untreated MCL who are ineligible for autologous hematopoietic stem cell transplantation, in combination with bendamustine and rituximab; and (iii) adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL). These products work by blocking the signal from a protein called Bruton tyrosine kinase, or BTK,

that leads to the growth of abnormal cancerous B cells (a type of white blood cells). By blocking BTK, these products help stop certain cancer cells from forming or growing and cause cancer cells to die. See AstraZeneca, *How Does Calquence Work?*, <https://perma.cc/U42V-H5SM>.

77. MCL and CLL/SLL are serious and life-threatening types of blood cancers. MCL is a rare and fast-growing subtype of B-cell non-Hodgkin lymphoma that is typically diagnosed at an advanced stage and associated with a high relapse rate. It is estimated that approximately 4,000 new cases of MCL are diagnosed each year. See Chan Yoon Cheah et al., *Mantle cell lymphoma*, 34 J. Clin. Oncol. 1256 (2016). CLL/SLL is a slow-growing cancer that affects B cells. CLL and SLL are distinguished by where cancer cells are mostly located; in CLL, cancer cells are found mostly in the blood and bone marrow, while in SLL, cancer cells are found mostly in the lymph nodes. See AstraZeneca, *What Should I Know About My Condition?*, <https://perma.cc/9XBF-E6YS>. CLL/SLL is the third-most common type of B-cell lymphoma, with approximately 18,740 people in the United States diagnosed with CLL/SLL each year. See Lymphoma Research Foundation, *Understanding Lymphoma and Chronic Lymphocytic Leukemia/ Small Lymphocytic Lymphoma (CLL/SLL)*, 154 (2023), <https://perma.cc/X4HH-89T4>.

78. MCL and CLL/SLL are rarely curable. Instead, the aim of treatment is to slow down progression of the disease, to relieve patients of symptoms, and, if possible, to increase overall survival.

79. In 2017, FDA granted an NDA, uniquely identified by the number 210259, for acalabrutinib free base to be marketed under the brand name CALQUENCE®. FDA initially approved acalabrutinib free base for treatment of adult patients with MCL who have received at least one prior therapy. Subsequently, AstraZeneca submitted certain supplements to the NDA to request additional indications. Today, acalabrutinib free base is indicated for the treatment of adult

patients with MCL who have received at least one prior therapy, transplant-ineligible adult patients with previously untreated MCL (in combination with bendamustine and rituximab), and adults patients with CLL or SLL.

80. Since the initial 2017 approval, the Prescribing Information for acalabrutinib free base has included a caution against co-administration with many common stomach acid-reducing medications, including proton pump inhibitors (PPIs), antacids, and H2-receptor antagonists (H2RAs), limiting the patient population able to benefit from it. Specifically, the Prescribing Information cautions to avoid co-administration of CALQUENCE® with PPIs and to stagger dosing with antacids and H2RAs.

81. Acid-reducing agents are among the most commonly prescribed medications in North America and Western Europe and are frequently used by cancer patients. One study estimated that, among cancer patients in the United States, between 20 and 33 percent had taken an acid-reducing agent within six months of their cancer diagnosis. Among patients with CLL in particular, the prevalence was between 18.5 and 21.9 percent. *See Gillian Smelick et al., Prevalence of acid-reducing agents (ARA) in cancer populations and ARA drug-drug interaction potential for molecular targeted agents in clinical development*, 10 Mol. Pharm. 4055 (2013).

82. This labeling cautioning against co-administration with many common stomach acid-reducing medications meant that the patient population able to benefit from acalabrutinib free base was significantly curtailed, or else it required patients to cease taking gastric-reducing agents or, with respect to certain medications, to adhere to particular dosing schedules to mitigate possible drug interactions.

83. Given these limitations, AstraZeneca invested substantial effort in developing a new product that would be just as effective as the free base but could also be taken along with

gastric acid-reducing agents. After years of research—and millions in R&D costs—AstraZeneca developed a new product that contains a new active ingredient (acalabrutinib maleate) and is administered through a dosage form with a new formulation (tablets). This new product was formulated to quickly and completely deliver the same amount of medicine across physiological pH levels, therefore allowing it to be taken along with gastric acid-reducing agents.

84. During development, AstraZeneca met with members of the FDA’s Office of New Drug Products to obtain feedback on its planned development for the new acalabrutinib maleate salt and the appropriate regulatory pathway for potentially obtaining FDA approval. Given the difference in active ingredient and in the qualitative and quantitative formulation of the new dosage form, FDA affirmed that AstraZeneca should submit acalabrutinib maleate salt to FDA via a separate original NDA pursuant to Section 505(b)(1) of the FDCA—which is the traditional approval pathway for new drugs and requires full reports of investigations of safety and effectiveness. *See Food & Drug Admin.*, April 17, 2019 Type C Meeting Minutes; *see also Separate Marketing Applications Guidance* at 3 & n.7 (“Every different active ingredient[] should be submitted in a separate original application,” even if they share “the same active moiety.”).

85. AstraZeneca submitted a new original NDA in accordance with FDA’s direction, including data supporting the safety and efficacy of acalabrutinib maleate salt and showing that a broader patient population would be able to benefit from acalabrutinib maleate salt as compared to the acalabrutinib free base. *See Shringi Sharma et al., Bioequivalence and Relative Bioavailability Studies to Assess a New Acalabrutinib Formulation That Enables Coadministration With Proton-Pump Inhibitors*, 11 Clin. Pharm. Drug Dev. 1294 (2022).

86. FDA approved the new NDA, uniquely identified by the number 216387, for the salt in 2022, concluding there was substantial data to support the effectiveness and safety of the

new product.⁷ Like the free base, acalabrutinib maleate salt is indicated for the treatment of adult patients with MCL who have received at least one prior therapy, transplant-ineligible adult patients with previously untreated MCL (in combination with bendamustine and rituximab), and adult patients with CLL or SLL. Importantly though, the label for acalabrutinib maleate salt does not include a caution against co-administration with gastric-reducing agents. Thus, unlike acalabrutinib free base, acalabrutinib maleate salt can be taken with acid-reducing agents such as PPIs, antacids, or H2-receptor antagonists without any dosing restrictions or modifications.

LEGAL ALLEGATIONS

CMS's Attempt to Override the IRA's Express Limits Plainly Exceeds Its Statutory Authority

87. As discussed, the IRA provides that “the Secretary shall select and publish a list of . . . 15 negotiation-eligible drugs” for IPAY 2027. 42 U.S.C. § 1320f–1(a). That instruction is clear, and Congress did not create any exceptions. In the Final Guidance, however, CMS sought to override that limit by redefining QSSD to group together *multiple* drugs.⁸ But nothing in the statute—either in the QSSD provision or elsewhere—allows the agency to ignore the numerical limit.

The IRA Defines QSSD by Reference to a Drug's NDA Approval

88. Just as the number “15” is unambiguous, the requirements for a QSSD are clear under the statute.

⁷ Because AstraZeneca sought approval for acalabrutinib salt for two different indications, FDA designated the NDA as two original applications for administrative purposes. FDA reviewed both applications under the same NDA number (216387). FDA designated the application for the CLL and SLL indication as “NDA 216387/Original 1,” and designated the application for the MCL indication as “NDA 216387/Original 2.”

⁸ On January 17, 2025, CMS published a list of drugs approved under *twenty-six* distinct NDAs. Among the twenty-six NDAs selected for the Program's second cycle, three have been administratively closed by the FDA. In any case, the number of drugs selected by CMS for the second cycle far exceeds the statutory limit of “15 negotiation-eligible drugs.” *Id.* § 1320f–1(a)(2).

89. The statute defines QSSD to include a drug that is “a covered part D drug (as defined in [42 U.S.C. § 1395w–102(e)])” and:

- (i) that is approved under section 355(c) of title 21 and is marketed pursuant to such approval;
- (ii) for which, as of the selected drug publication date with respect to such initial price applicability year, at least 7 years will have elapsed since the date of such approval; and
- (iii) that is not the listed drug for any drug that is approved and marketed under section 355(j) of title 21.

Id. § 1320f–1(e)(1)(A). Several aspects of this definition make clear that a QSSD is limited to a single drug approved under a single NDA.

90. Start with the requirement that the drug must be “a covered part D drug (as defined in [42 U.S.C. § 1395w–102(e)])”. The referenced provision defines a “covered part D drug” to mean, as relevant here, “a drug that may be dispensed only upon a prescription and that is described in subparagraph (A)(i), (A)(ii), or (A)(iii) of section 1396r–8(k)(2) of this title.” *Id.* § 1395w–102(e)(1)(A). And those references, in turn, define “covered outpatient drug” to mean a drug “which is approved for safety and effectiveness as a prescription drug under section 505 . . . of the Federal Food, Drug, and Cosmetic Act [*i.e.*, a brand-name drug or authorized generic] or which is approved under section 505(j) of such Act [*i.e.*, a generic drug].” *Id.* § 1396r–8(k)(2)(A)(i).

91. The IRA’s definition of a QSSD is thus limited to a drug “which is approved for safety and effectiveness as a prescription drug under section 505 . . . of the Federal Food, Drug, and Cosmetic Act.” *Id.* And Section 505 of the FDCA, which is codified at 21 U.S.C. § 355, lays out the FDA’s basic framework for approving and licensing new drugs: the NDA. In other words, the statutory definition of a QSSD is grounded in FDA’s framework for approving drug products, which distinguishes between drug products via distinct NDAs. By expressly defining a QSSD as a drug “which is approved” under the NDA-approval framework, Congress clearly intended that

CMS rely on this framework in distinguishing among QSSDs, making clear that a drug approved under its own NDA must also be treated as its own QSSD.

92. Other aspects of the QSSD definition further confirm that Congress intended to rely on the NDA-approval framework for distinguishing among QSSDs. Subparagraph (i) limits the definition to a drug that “is marketed pursuant to such approval.” Since the FDA’s approval of an NDA constitutes the requisite legal permission under which a drug “is marketed,” *id.* § 355(d), the term “such approval” (in the singular) must refer to the grant of the single, specific NDA that provides such permission. Conversely, a drug approved under a *different* NDA could not be described as being “marketed pursuant to such approval.” A drug approved under a separate NDA—under a separate *New Drug Application*—is just that: a new drug, which also must be a new QSSD.

93. Further, Subparagraph (ii) requires that at least seven years have elapsed between the grant of a drug’s NDA (“such approval”) and selection of the drug under the IRA. Congress established this timing to allow manufacturers a period of time to recoup their investment in developing the drug before becoming subjected to price controls, and to not interfere with common periods of marketing exclusivity that FDA may grant in association with its approval of an NDA. For example, New Chemical Entity (NCE) exclusivity runs for 5 years (which can effectively be extended up to 7.5 years under the Hatch-Waxman Act), *see* 21 U.S.C. § 355(j)(5); 21 C.F.R. § 314.108; new Clinical Investigation Exclusivity runs for three years, *see id.*; and orphan drug exclusivity runs for up to 7 years, *see* 21 U.S.C. § 360cc; 21 C.F.R. § 316.31. Since each NDA approval is made on a specific date, 21 U.S.C. § 355(c)(3), each “such approval” generates its own seven-year exemption period under the IRA.

94. Subparagraph (iii), which excludes brand-name drugs with an approved and marketed generic, accords with this reading as well. By excluding “the listed drug for any drug that is approved and marketed under section 355(j)”—*i.e.*, the brand-name drug that serves as the reference for an approved and marketed generic drug—the IRA necessarily uses “drug” to mean a product approved under a single, specific NDA. That is because, under the FDCA, the sponsor of a generic product applies for approval by identifying a *specific* NDA to serve as its “listed” (brand-name) reference drug. *Id.* § 355(j)(2)(A)(i). The FDA, in turn, approves a generic application based on that specific NDA, 21 C.F.R. § 314.92, and permission to market the generic drug remains tied to the listed drug’s NDA status, *id.* § 314.151. By excluding a “listed drug” from the QSSD definition, therefore, subparagraph (iii) confirms yet again that “drug” refers to a particular drug marketed pursuant to a specific NDA.

95. Congress’s decision to incorporate the NDA framework into the QSSD definition is unsurprising given FDA’s expertise in determining the features that distinguish individual drug products. Whether a particular product constitutes a distinct “drug” is a scientific determination “peculiarly suited to initial determination by the FDA.” *Weinberger v. Bentex Pharms., Inc.*, 412 U.S. 645, 653 (1973). Indeed, FDA has long understood the characteristics that make individual drugs distinct, which include “not only the active ingredient but also information about the drug’s formulation, route of administration, labeling, inactive ingredients, bioavailability, and manufacturing processes.” 86 Fed. Reg. at 28605, 28606. These determinations thus “ha[ve] significant implications for public health.” *Id.* Manufacturers, in turn, have long relied on FDA’s drug-approval framework as the basis for making decisions regarding research and development.

The Final Guidance Attempts to Override the Act’s Numerical Limits

96. Despite the IRA’s clear language, the Final Guidance seeks to expand the IRA’s numerical limits by defining QSSD in a different—and far broader—manner than the statute: “CMS will identify a potential qualifying single source drug using . . . *all* dosage forms and strengths of the drug with the same active moiety and the same holder of [an NDA], *inclusive of products that are marketed pursuant to different NDAs.*” Final Guidance § 30.1 at 167 (emphasis added) (footnote omitted). The Final Guidance thus groups together, into a single QSSD, separately approved drugs if they have (a) the same active moiety and (b) the same NDA-holder. The Final Guidance also provides that, in determining when the seven-year exemption period begins to run for a group of drugs that have different NDA-approval dates, “CMS will use the earliest date of approval or licensure of the initial FDA application number assigned to the NDA . . . holder for the active moiety.” *Id.* at 170.

97. The result of CMS’s approach is to group together *distinct* drugs, expanding the Act’s numerical limits and rendering drugs eligible for “negotiation” under the IRA in circumstances where the statute says they should *not* be eligible:

i. Whenever CMS treats two or more distinct drugs as a single QSSD, the number of drugs selected *always* will exceed the statutory limits on the number of drugs to be selected per cycle of price-setting under the IRA. For instance, even though Congress limited the first cycle to “10 negotiation-eligible drugs,” 42 U.S.C. § 1320f–1(a)(1), CMS in fact selected drugs approved under sixteen different NDAs. And even though the statute limits the second cycle to “15 negotiation-eligible drugs,” *id.* § 1320f–1(a)(2), CMS in fact selected drugs approved under twenty-six distinct NDAs.

ii. A drug may become negotiation-eligible significantly earlier in time than the statutorily prescribed seven-year exemption period, based on the earlier approval

date of a *different* drug. If “at least 7 years . . . have elapsed since the date of [NDA] approval” for one drug, *id.* § 1320f–1(e)(1)(A)(ii), but less than seven years have elapsed since the date of NDA approval for *other* drugs that share the same active moiety and NDA-holder, then the agency “will use the earliest date of approval” to determine whether the combined group qualifies as a QSSD. Final Guidance § 30.1 at 170. Indeed, a later-approved drug could even be subject to selection and negotiation *immediately* upon approval, if grouped together with another drug whose approval occurred more than seven years prior.

iii. Combining a drug’s Medicare expenditures together with the expenditures of one or more distinct drugs can also significantly increase the likelihood that the combined group ranks sufficiently high on the Medicare-expenditure list to trigger selection. Since negotiation-eligible drugs are “ranked” according to “the total expenditures for such drugs under” Medicare, and since CMS must “[s]elect from such ranked drugs . . . the negotiation-eligible drugs with the highest rankings,” 42 U.S.C. § 1320f–1(b)(1)(A)-(B), CMS’s approach of treating multiple drugs collectively makes it more likely that expenditures for the combined group will reach the threshold necessary for selection—including where none of the drugs would satisfy the threshold on its own.

98. To justify redefining QSSDs in this manner, the Final Guidance invokes language from two *different* statutory provisions—language that is noticeably absent from the statute’s definition of QSSD. The IRA’s “Use of Data” provision requires CMS, *after* determining whether a product qualifies as a QSSD, to then “aggregate data “across dosage forms and strengths of the drug” to determine whether total expenditures for that particular QSSD meet the threshold for

negotiation eligibility. *Id.* § 1320f–1(d)(3)(B). And among the “Administrative duties” imposed on the agency, CMS must “compute and apply the [MFP] across different strengths and dosage forms of a selected drug.” *Id.* § 1320f–5(a)(2). According to CMS’s Final Guidance, these “aggregation rules . . . necessarily establish[] that the negotiation procedures apply more broadly than to a distinct NDA.” Final Guidance at 13. But in fact, neither provision supports the agency’s approach.

99. Consider the “Use of Data” provision, which is found in subsection (d) of 42 U.S.C. § 1320f–1 and reads in full:

In determining whether a qualifying single source drug satisfies any of the criteria described in paragraph (1) or (2) [*i.e.*, the criteria for a negotiation-eligible drug)], the Secretary shall use data that is aggregated across dosage forms and strengths of the drug, including new formulations of the drug, such as an extended release formulation, and not based on the specific formulation or package size or package type of the drug.

42 U.S.C. § 1320f–1(d)(3)(B). This Use of Data provision cannot remotely be read as permitting the agency to group multiple different drugs together. As an initial matter, no such language appears in the statutory definition of QSSD, which is contained exclusively in a different subsection—subsection (e) of 42 U.S.C. § 1320f–1. The fact that Congress chose *not to* include the Use of Data provision in the QSSD definition itself undermines the agency’s attempt to insert it there.

100. The Use of Data provision’s text and operation also foreclose the government’s reading of it. Its stated function is to provide instructions, at the Program’s second stage of selection, as to whether a particular QSSD “satisfies any of the criteria” for negotiation-eligibility. *See supra* ¶¶ 53-54. The text specifies that “the Secretary shall use data that is aggregated across dosage forms and strengths” of a QSSD, “including new formulations *of the drug*, such as an extended-release formulation, and not based on the specific formulation or package size or package

type *of the drug*” in determining whether a QSSD satisfies any of the selection criteria. 42 U.S.C. § 1320f–1(d)(3)(B) (emphases added). The emphasized phrases (“of the drug”) show that this provision instructs the agency on how to aggregate across different dosage forms, strengths, and formulations of a particular QSSD. Identification of the relevant QSSD is thus a predicate determination; the “Use of Data” provision has effect only *after* the agency has identified the QSSD at the Program’s first stage. *See supra* ¶¶ 53–54. The Use of Data provision thus aggregates dosages forms and strengths only within a *previously identified* QSSD—that is, dosage forms and strengths of a drug that were approved under the same NDA. The provision has no bearing on whether a drug qualifies as a QSSD in the first place.

101. The other provision invoked by the Final Guidance, which requires CMS to “compute and apply the [MFP] across different strengths and dosage forms of a selected drug,” 42 U.S.C. § 1320f–5(a)(2), likewise does not support the agency’s attempt to group multiple drugs together. The compute-and-apply provision applies at the *last* step of price-setting: After CMS has identified all QSSDs, determined which of them are negotiation-eligible, selected the number of them appropriate for the annual cycle, and set each drug’s MFP, then CMS must “compute and apply” the MFP across different dosage forms and strengths of the drug. That requirement, however, has no relevance to the definition of a QSSD, which must be identified at the very *first* stage of price-setting. Like the Use of Data provision, the “compute and apply” instruction simply directs CMS to take an action with respect to those dosage forms and strengths that fall within a single QSSD—that is, to take action with respect to those dosage forms and strengths approved under the same NDA. This compute-and-apply instruction is not an invitation to expand the meaning of a QSSD beyond its statutory definition.

102. The Final Guidance nevertheless argues that the Use of Data and compute-and-apply provisions must be read to *implicitly* require aggregation of drugs approved under separate NDAs. “Because different dosage forms and strengths, as well as different formulations, containing the same active moiety / active ingredient may be approved . . . under multiple NDAs,” the agency contends, “the statutory negotiation procedures [must] apply more broadly than to a distinct NDA.” Final Guidance at 13. Otherwise, the agency concludes, the Use of Data and compute-and-apply provisions would be without “full effect.” *Id.*

103. The agency’s argument is a non-sequitur. While different dosage forms, strengths, and formulations are *sometimes* approved under multiple NDAs, that is not *always* the case: It is not uncommon for different dosage forms, strengths, and formulations of a drug to be encompassed within a single NDA. *See supra* ¶¶ 36-45. In such a case, the Use of Data provision ensures that all such forms, strengths, and formulations of a QSSD are aggregated for purposes of determining whether the drug is negotiation-eligible; and the compute-and-apply provision ensures that the MFP is applied to all of them. There is accordingly no need, in order to give these provisions “full effect,” to construe them as implicitly imposing an atextual reading on the QSSD definition.⁹ To the contrary, the fact that Congress expressly included certain

⁹ The agency also briefly argues that its approach is supported by 42 U.S.C. § 1320f-3(e)(1)(D), which requires CMS, “[f]or purposes of negotiating the maximum fair price of a selected drug . . . with the manufacturer of the drug,” to consider (among other factors) “applications and approvals under section 355(c) of title 21.” According to CMS, because Congress used “‘applications and approvals’ . . . in the plural, for the ‘drug,’ in the singular,” that must mean a single drug can include products approved under separate NDAs. Final Guidance at 13. But as noted above, a drug approved under a particular NDA is often associated with one or more “supplemental applications,” such as when a manufacturer seeks approval for a different strength that is supported by existing data. 21 U.S.C. § 355(c)(5); *see supra* ¶ 42. In such a case, there are multiple “applications and approvals under section 355(c) of title 21,” but only one “drug.” If anything, the agency’s emphasis on the “plural” use of “approvals” in Section 1320f-3(e)(1)(D) underscores the agency’s failure to acknowledge the *singular* use of “such approval” in the QSSD definition.

“aggregation” instructions elsewhere in the statute, yet *declined* to do so with respect to QSSDs, reinforces Congress’s intent to define QSSDs by each separate NDA approval.

104. Moreover, CMS has not attempted to—and cannot—justify the agency’s invention of two very different criteria for identifying individual QSSDs that appear nowhere in the statute: common active moiety and common NDA-holder.

105. The term “active moiety” has a well-established legal meaning. “*Active moiety* is the molecule or ion . . . responsible for the physiological or pharmacological action of the drug substance.” 21 C.F.R. § 314.3. If Congress intended for QSSDs to be grouped based on their active moiety, it could have included this term in the QSSD definition—but it did not. Congress is familiar with the term “active moiety,” which appears in five sections of the U.S. Code. *See* 21 U.S.C. §§ 355, 360b, 360n, 360ff, 360bbb-4a. The fact that the term “active moiety” does not appear in the QSSD definition—or, for that matter, anywhere in title 42 of the U.S. Code—is accordingly quite significant.

106. The agency’s use of “active moiety” is mirrored by the agency’s adoption of still another atextual requirement—namely, that the drugs must be manufactured by “the same holder of a New Drug Application (NDA).” Final Guidance § 30.1 at 167 (footnote omitted). CMS likely realized that it could not lump together drugs that share the same active moiety without risking the creation of multi-drug groups in which some of the drugs did *not* share the same manufacturer. That scenario would create numerous inconsistencies with the IRA’s so-called “negotiation” process, which requires CMS (*inter alia*) to sign an agreement to negotiate with “*the* manufacturer” of a selected drug, 42 U.S.C. § 1320f-2(a), (d) (emphasis added), to receive information relevant to the negotiation from “*the* manufacturer,” *id.* § 1320f-3(b)(2) (emphasis added), to negotiate for an MFP with “*the* manufacturer,” *id.* § 1320f-3(a) (emphasis added), and to ensure that “*the*

manufacturer” provides access to the resulting MFP, *id.* § 1320f–2(a)(2) (emphasis added). So CMS adopted the same-NDA-holder requirement as a workaround for these problems.

107. Yet CMS’s workaround, however much it solves the *practical* problems that the agency has created for itself, is entirely unmoored from the statutory definition of QSSD and the supposed textual justification for the same-active-moiety test, which is tied to the Use of Data and compute-and-apply provisions. Indeed, the very need to solve these practical problems via an atextual workaround is itself yet another indication of how far the agency’s approach deviates from the statute’s plain language.¹⁰

108. Ultimately, CMS’s reading of the IRA contravenes its plain text. The agency ignores key language and ascribes nonsensical meaning to key provisions. These linguistic gymnastics are intended to achieve an obvious goal: enabling the agency to set prices for more drugs than the IRA allows. But the “best reading” of a statute—which is the only “permissible” interpretation—is “the reading the court would [reach] if no agency were involved.” *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369, 400 (2024) (quotation marks omitted). Only a straightforward reading of the statute—one that limits a QSSD to those dosage forms and strengths approved under a *single* NDA, including its supplements—makes sense of all the statutory

¹⁰ The Final Guidance states that its approach “will decrease incentives for pharmaceutical manufacturers to engage in ‘product hopping,’” because it ensures that “a manufacturer is . . . limited in its ability to inappropriately exclude from the Negotiation Program drug products that might otherwise be eligible based on modest or minor modifications.” Final Guidance at 13. The guidance also states that “[r]educing ‘product hopping’ is consistent with the purpose of the statute, which is to ensure that the Negotiation Program delivers benefits to the Medicare program and its beneficiaries.” *Id.* But even accepting the agency’s assertion that one of the IRA’s goals is to reduce “product hopping”—despite the law’s failure to say so—that does not permit the agency to ignore clear numerical limits on its authority or to invent statutory terms and criteria that appear nowhere in the IRA’s text.

language and operates seamlessly through each step of the Program. No acrobatics or atextual criteria required.

109. By improperly redefining QSSD to circumvent the statutory requirement to “publish a list of” only fifteen drugs, the Final Guidance is facially unlawful. 42 U.S.C. § 1320f-1(a). Thus, CMS clearly exceeded its statutory authority.

The Agency’s Approach Harms Drug Innovation Generally and AstraZeneca in Particular

110. By aggregating multiple drugs approved under different NDAs, Section 30 disincentivizes innovation, to the detriment of patients, manufacturers, and the nation’s healthcare system. It will also have concrete negative effects on AstraZeneca specifically.

111. Pharmaceutical manufacturers like AstraZeneca discover and develop lifesaving and life-enhancing medicines that are distributed, prescribed, and used across the nation and around the world. Two therapy areas to which AstraZeneca devotes itself are Oncology and Rare Diseases. In Oncology, AstraZeneca focuses on some of the most hostile and hard-to-treat cancers including pancreatic cancer; certain blood cancers; and breast, lung, ovarian, and prostate cancers. AstraZeneca’s rare disease division, Alexion, is focused on transforming the lives of people affected by rare diseases, driving innovative research and development across new disease targets and modalities, and supporting access and advocating for the rare disease community.

112. The cost of developing such groundbreaking drugs is stunning. Pharmaceutical manufacturers expend vast amounts of time and resources to identify, test, and develop new drugs products, with the average cost of successfully bringing a drug to market now reaching \$2.3 billion. *See Deloitte, Seize the Digital Momentum: Measuring the Return from Pharmaceutical Innovation* 2022 at 12 (Jan. 2023), <https://perma.cc/XGN2-DE4M>. AstraZeneca in particular makes substantial investments in scientific innovation and pharmaceutical research; in 2024, the company

reported over \$13.6 billion in research and development expenses. *See* AstraZeneca Annual Report 6 (2024), <https://bit.ly/3XXhVef>.

113. Manufacturers who make these massive investments in hopes of developing new treatments for patients also face incredibly long odds. Only one compound in 5,000 that enters preclinical testing will achieve FDA approval, for a failure rate of 99.98%. Sandra Kraljevic et al., *Accelerating Drug Discovery*, 5 Eur. Mol. Bio. Org. Reps. 837, 837 (2004). Of the therapies approved for patient use, only one-third manage to cover their costs of development, much less to provide an economic return significant enough to allow for continued investment and innovation. *See* Vernon & Golec at 7. Pharmaceutical manufacturers like AstraZeneca therefore must make these high-risk up-front investments based on an uncertain prospect—that *if* they discover a compound, *if* it can be made into a drug that proves safe and efficacious, *if* it obtains regulatory approval, and *if* it reaches patients and fulfills a medical need, the product *might* earn market-based returns.

114. The interpretation of QSSD set forth in Section 30 significantly undermines incentives to research and develop new treatment applications, or to improve safety and efficacy for existing drugs. Under the agency’s improperly broad definition, it may not be feasible for manufacturers to invest the necessary resources—potentially billions of dollars of R&D costs and years of manpower—into researching whether an active moiety in an existing drug could also be used to treat a separate disease or could be reformulated to be safer or more effective for patients. If the manufacturer identifies such an application, under CMS’s approach, the new drug’s eligibility for CMS’s price “negotiation” program would be tied to the eligibility timeline of the earliest-existing drug with the same active moiety, limiting the manufacturer’s ability even to attempt to recoup its investment.

115. Indeed, Section 30 can actually act as a *disincentive* to innovate. As noted above, CMS's approach of treating multiple drugs collectively makes it more likely that Medicare expenditures for the combined group will reach the threshold necessary for selection. *See supra* ¶ 98.iii. As a result, where an earlier-developed drug would not satisfy the expenditure threshold on its own, a manufacturer who develops a new drug with the same active moiety runs the risk that any Medicare expenditures for the new drug will push the combination into the top ten, fifteen, or twenty QSSDs to be selected for that cycle. Given the draconian price cuts mandated by the IRA for selected drugs—which, under CMS's approach, would apply to both drugs—the manufacturer may well be better off *not* developing the new product. Thus, the harms of Section 30's approach are not limited to only those drugs selected for price-setting in the 2027 Program cycle.

116. But as it pertains to the 2027 Program cycle, the harms caused by CMS's approach are clearly illustrated by its effect on two products manufactured by AstraZeneca to treat certain forms of blood cancer, acalabrutinib free base and acalabrutinib maleate salt, both of which are marketed under the tradename CALQUENCE®.

117. The FDA granted an NDA for acalabrutinib free base in 2017. But the label for this product cautioned to avoid co-administration with many common stomach acid-reducing medications, significantly limiting the patient population able to benefit from acalabrutinib. AstraZeneca accordingly invested substantial resources into developing a new drug, acalabrutinib maleate salt, that has the same treatment efficacy as acalabrutinib but can also be taken along with gastric acid-reducing agents. At FDA's direction, AstraZeneca submitted a new original NDA for acalabrutinib maleate salt and obtained approval for this new product on August 3, 2022. Given the broader (but overlapping) patient population able to use acalabrutinib maleate salt, AstraZeneca ceased distribution of acalabrutinib free base in the United States at the end of 2022.

118. Under the IRA, acalabrutinib maleate salt cannot qualify as a QSSD until at least February 1, 2030, because that is the first selection date that will take place seven years after the NDA approval for acalabrutinib maleate salt, and acalabrutinib maleate salt may only be “marketed pursuant to such approval”—*i.e.*, pursuant to the approval of the 2022 NDA. 42 U.S.C. § 1320f–1(e)(1)(A)(ii).

119. Yet on January 17, 2025, CMS, applying Section 30 of the Final Guidance, treated the two separately approved products (acalabrutinib free base and acalabrutinib maleate salt) as a single QSSD and selected both of them for the IRA’s so-called “negotiation” process.

120. Section 30’s improper interpretation of the statute thus has caused, and will continue to cause, concrete harm to AstraZeneca. AstraZeneca has been forced to participate in a sham “negotiation,” which resulted in CMS setting a Medicare price for two distinct products—acalabrutinib free base and acalabrutinib maleate salt—neither of which independently meets the statutory requirements for selection. Acalabrutinib maleate salt thus became subject to the IRA’s price-setting process less than three years after its approval as new drug by FDA, rather than the seven-year exemption period prescribed by Congress. And the agency imposed a price cap for acalabrutinib free base, even though that product was not eligible for the Program based on its Medicare expenditures. The government-imposed price is set to be \$8,600 for a 30 day-equivalent supply, a steep cut from the current, market-based prices for these products.

121. AstraZeneca has no feasible alternative. As the Congressional Budget Office recognized when analyzing an earlier draft of the IRA, the excise tax is so steep that no manufacturer could realistically pay it. *See* Cong. Budget Off., *CBO’s Model of Drug Price Negotiations Under the Elijah E. Cummings Lower Drug Costs Now Act* (Feb. 2021), <https://www.cbo.gov/system/files/2021-02/56905-Drug-Price-Negotiations.pdf> (“CBO and the

staff of the Joint Committee on Taxation (JCT) expect that a manufacturer would remove its drug from the U.S. market rather than pay the excise tax.”). Moreover, exiting Medicare and Medicaid with respect to all of its products is entirely unfeasible for AstraZeneca, as it would leave millions of patients without access to necessary medications and decimate AstraZeneca’s business; Medicare and Medicaid collectively account for approximately more than 40% of the company’s gross revenues in the U.S.

CLAIM FOR RELIEF
(Contrary to Law and *Ultra Vires*)

122. AstraZeneca realleges and incorporates by reference all prior and subsequent paragraphs.

123. The Administrative Procedure Act (APA) requires courts to “hold unlawful and set aside” agency action that is “not in accordance with law” or is “in excess of statutory jurisdiction, authority, or limitations.” 5 U.S.C. § 706(2)(A), (C). “The APA, in short, incorporates the traditional understanding of the judicial function, under which courts must exercise independent judgment in determining the meaning of statutory provisions.” *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369, 394 (2024). The “command of the APA” thus is “that ‘the reviewing court’—not the agency whose action it reviews—is to ‘decide all relevant questions of law’ and ‘interpret statutory provisions.’” *Id.* at 398 (quoting 5 U.S.C. § 706) (ellipsis omitted).

124. Further, an agency has no power to act unless Congress confers power upon it. *See City of Arlington v. FCC*, 569 U.S. 290, 299 (2013); *see also La. Pub. Serv. Comm’n v. FCC*, 476 U.S. 355, 374 (1986) (explaining that “an agency literally has no power to act . . . unless and until Congress confers power upon it”). Thus, an agency’s actions are *ultra vires* when it “exceed[s] the scope of its delegated authority or violate[s] a clear statutory mandate.” *Hanauer v. Reich*, 82 F.3d 1304, 1307 (4th Cir. 1996).

125. CMS’s redefinition of QSSD, requiring the publication of a list of more than “15 negotiation-eligible drugs” for the Program’s second cycle, is contrary to law, exceeds the agency’s statutory authority and is *ultra vires*. 42 U.S.C. § 1320f–1(a)(2).

126. By redefining QSSD as “all dosage forms and strengths of the drug with the same active moiety and the same holder of [an NDA], *inclusive of products that are marketed pursuant to different NDAs*,” Final Guidance § 30.1 at 167 (emphasis added) (footnote omitted), CMS’s Final Guidance facially contravenes the statutory text and (i) the IRA’s numerical limits on drugs selected per cycle; (ii) the seven-year exemption period for newly approved drugs; and (iii) eligibility requirements for selecting only those drugs with the highest Medicare spending.

127. First, CMS’s definition contravenes the statutory requirement that a QSSD received approval under a single NDA, causing CMS to exceed the statutory limits on the number of drugs to be selected per cycle of price-setting under the IRA. *See* 42 U.S.C. §§ 1320f–1(a).

128. Second, in determining when the seven-year exemption period begins to run for a group of drugs that have different NDA-approval dates, “CMS will use the earliest date of approval or licensure of the initial FDA application number assigned to the NDA . . . holder for the active moiety.” Final Guidance at 170. By permitting drugs to become negotiation-eligible based on the earlier approval date of a *different* drug, CMS’s Final Guidance is irreconcilable with the statutorily prescribed seven-year exemption period. *See* 42 U.S.C. § 1320f–1(e)(1)(A)(ii).

129. Finally, CMS’s approach contradicts the IRA’s requirement to rank drugs for negotiation eligibility according to “the total [Medicare] expenditures for such drugs.” 42 U.S.C. § 1320f–1(b)(1)(A)-(B). CMS’s approach instead combines particular drugs’ Medicare expenditures with the expenditures of other, different drugs. This atextual approach impermissibly

increases the likelihood that a particular drug will be selected—as part of a combined group—for “negotiation.”

130. CMS’s Final Guidance therefore is *ultra vires*, not in accordance with law, and in excess of statutory jurisdiction, authority, or limitations.

PRAYER FOR RELIEF

NOW, THEREFORE, AstraZeneca requests a judgment in its favor against Defendants as follows:

1. Declare that Section 30.1 of the Final Guidance was promulgated in violation of the APA;
2. Declare that Section 30.1 of the Final Guidance is not in accordance with law and was promulgated in excess of statutory jurisdiction, authority, or limitations;
3. Declare that Section 30.1 of the Final Guidance is *ultra vires* and unenforceable;
4. Set Section 30.1 of the Final Guidance aside;
5. Enjoin CMS from enforcing Section 30.1 of the Final Guidance;
6. Enjoin CMS from expanding the IRA’s scope by exceeding the numerical limits on drug selection;
7. Require CMS to comply with 42 U.S.C. § 1320f–1(a)(2) by publishing a list of no more than fifteen negotiation-eligible drugs with respect to initial price applicability year 2027;
8. Award AstraZeneca reasonable attorneys’ fees and costs, plus interest accruing thereon, under 28 U.S.C. § 2412; and
9. Grant such other and further relief as the Court may deem appropriate.

Dated: December 19, 2025

Respectfully submitted,

/s/ Michael A. Pichini

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** Application to be admitted pro hac vice
forthcoming*

Counsel for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that this document will be served on Defendants in accordance with Fed.

R. Civ. P. 4.

/s/ Michael A. Pichini

Michael A. Pichini

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

ASTRAZENECA PHARMACEUTICALS LP,
ASTRAZENECA AB, and ASTRAZENECA UK
LTD.,

Plaintiffs,

vs.

ROBERT F. KENNEDY, JR., in his official
capacity as Secretary of the U.S. Department of
Health and Human Services; the U.S.
DEPARTMENT OF HEALTH AND HUMAN
SERVICES; MEHMET OZ, in his official capacity
as Administrator of the Centers for Medicare and
Medicaid Services; and the CENTERS FOR
MEDICARE AND MEDICAID SERVICES,

Defendants.

Civil Action No. 25-cv-4212

NOTICE OF APPEAL

Notice is hereby given that Plaintiffs, AstraZeneca Pharmaceuticals LP, AstraZeneca AB, and AstraZeneca UK Ltd., appeal to the United States Court of Appeals for the Fourth Circuit regarding this Court's Order dated August 19, 2026 (a copy of which is attached hereto), denying Plaintiffs' motion for summary judgment and granting the motion for summary judgment of Defendants Robert F. Kennedy, Jr., in his official capacity as Secretary of the United States Department of Health and Human Services, the United States Department of Health and Human Services, Dr. Mehmet Oz, in his official capacity as Administrator of the Centers for Medicare and Medicaid Services, and the Centers for Medicare and Medicaid Services.

Dated: August 21, 2026

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CERTIFICATE OF SERVICE

I hereby certify that this document will be served on Defendants in accordance with Fed.

R. Civ. P. 5(a).

/s/ Michael C. Heyse

Michael C. Heyse

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

**ASTRAZENECA PHARMACEUTICALS
LP, *et al.*,**

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., *et al.*,

Defendants.

Civ. No.: MJM-25-4212

* * * * *

ORDER

For the reasons stated on the record during the motions hearing on August 19, 2026, it is this 19th day of August, 2026, by the United States District Court for the District of Maryland, hereby ORDERED that:

1. Defendants' Motion to Dismiss pursuant to Federal Rule of Civil Procedure 12(b)(1) (ECF No. 32) is DENIED;
2. Plaintiffs' Motion for Summary Judgment (ECF No. 21) is DENIED;
3. Defendants' alternative Motion for Summary Judgment (ECF No. 32) is GRANTED;
4. Summary judgment is ENTERED in favor of Defendants; and
5. The Clerk of the Court SHALL CLOSE this case.

/S/

Matthew J. Maddox
United States District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
NORTHERN DIVISION

ASTRAZENECA)
PHARMACEUTICALS LP, et al.,)
Plaintiffs,)

vs.)

ROBERT F. KENNEDY, JR., in)
his Official Capacity as)
Secretary of the U.S.)
Department of Health and)
Human Services, et al.,)
Defendants.)

CIVIL CASE NO.
1:25-cv-04212-MJM

WEDNESDAY, AUGUST 19, 2026
Courtroom 5C
Baltimore, Maryland

TRANSCRIPT OF PROCEEDINGS
MOTIONS HEARING
BEFORE THE HONORABLE MATTHEW J. MADDOX

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(Computer-aided Transcription of Stenotype Notes)
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P R O C E E D I N G S

(2:33 p.m.)

THE COURT: Could I have Mr. Carrick please call the case?

THE CLERK: Your Honor, calling the case of AstraZeneca Pharmaceuticals, LP, et al., versus Kennedy, et al., Case Number MJM-25-cv-4212. The case is called for a motions hearing. And if the plaintiff counsel could put their appearance on the record, please.

MR. KEDEM: Hello, Your Honor. Allon Kedem for AstraZeneca.

THE COURT: Good afternoon.

MR. SHARON: William Sharon for AstraZeneca.

THE COURT: Good afternoon.

MR. HEYST: Michael Heyst for AstraZeneca.

THE COURT: Hello.

THE CLERK: Defense?

MR. PEZZI: Good afternoon, Your Honor. Stephen Pezzi from the Department of Justice on behalf of defendants.

THE COURT: Good afternoon.

MS. GHEIBI: Good afternoon, Your Honor. Pardis Gheibi from DOJ on behalf of defendants.

THE COURT: All right. Good afternoon. Thank you all. So let's see here. Give me one moment.

So just to set the stage here, the plaintiffs in this

1 case, AstraZeneca Pharmaceuticals LP, AstraZeneca AB, and
2 AstraZeneca UK Ltd. -- well, collectively referred to as the
3 plaintiffs or as AstraZeneca collectively, initiated this civil
4 action against the U.S. Secretary of Health and Human Services,
5 the U.S. Department of Health and Human Services, the
6 Administrator of the Centers for Medicare & Medicaid Services,
7 or CMS, and CMS itself, I will collectively refer to as the
8 defendants.

9 The plaintiffs here allege that guidance promulgated and
10 issued by CMS is contrary to the statutory definition of the
11 term "qualifying single source drug" as used in the Inflation
12 Reduction Act, or the IRA. Therefore, plaintiffs contend CMS's
13 guidance is not in accordance with law, is beyond the agency's
14 authority in violation of the Administrative Procedure Act, and
15 is ultra vires.

16 Pending before the Court now is AstraZeneca's Motion for
17 Summary Judgment at ECF Number 21; the defendants' Motion to
18 Dismiss or in the alternative for summary judgment at ECF
19 Number 32.

20 Now, I'm going to lay out some more background, and I'll
21 invite counsel to let me know if you disagree with anything
22 that I am saying here at the outset of your oral argument, but
23 one of the issues that we have in this case, and I see there
24 being two primary issues.

25 The first issue, or one issue, rather, is whether CMS

1 exceeded its statutory authority by issuing guidance that a
2 qualifying single source drug, or QSSD, will be identified,
3 quote, "using for drug products all dosage forms and strengths
4 of the drug with the same active moiety," I think is the word,
5 "and the same holder of the New Drug Application, or NDA,
6 includes products that are marketed pursuant to different
7 NDAs."

8 Cast differently, the issue is whether CMS guidance on
9 identifying QSSDs runs contrary to the statutory definition of
10 that term in the IRA, specifically § 1320f-1(e)(1) of Title 42
11 of the U.S. Code. AstraZeneca argues that the guidance is
12 unlawful under the APA and is ultra vires and therefore it must
13 be set aside and denied implementation and enforcement by court
14 order, and the defendants, of course, dispute those claims.

15 The other issue is whether § 1320f-7(2) deprives federal
16 courts of jurisdiction to hear the plaintiffs' challenge to the
17 final guidance. Now, I've identified that jurisdictional issue
18 second for convenience, but that issue, of course, is a
19 threshold issue that will need to be addressed either before or
20 in connection with the merits of the plaintiffs' challenge.

21 Now, I'll note, as counsel are aware, just yesterday the
22 U.S. Court of Appeals for the D.C. Circuit issued its decision
23 in Teva Pharmaceuticals USA v. Kennedy. That's Appeal Number
24 25-5425. And two issues presented in that case are virtually
25 identical to the two issues I've just described in the instant

1 case.

2 I'll note that Parts I(A) and I(B)(1) of the Teva decision
3 outline the relevant statutory and regulatory background as it
4 concerns the Medicare program, the IRA, and the Drug Price
5 Negotiation Program, as well as the final guidance that CMS
6 issued, which the plaintiffs challenge here.

7 I think that D.C. Circuit's summary of the statutory and
8 regulatory background is concise and it's accurate, and I would
9 be inclined to incorporate it here by reference.

10 Now, as it concerns this case, there don't appear to be
11 any material facts that are in dispute. On January 17th, 2025,
12 CMS applied the final guidance to publish a list of drugs for
13 the second annual cycle of the program. In accordance with the
14 guidance, that list treated multiple FDA-approved drug products
15 as single QSSDs.

16 Now, according to AstraZeneca, CMS's final guidance
17 impermissibly seeks to expand the IRA's numerical limits by
18 defining a QSSD in a different or broader manner than the IRA.
19 This broad interpretation has resulted in two of AstraZeneca's
20 separately FDA-approved products being treated as a single QSSD
21 and selected for the program's negotiation process.

22 Those products are -- I'm going to have trouble
23 pronouncing this -- I think it's acalabrutinib free base, the
24 same word maleate salt, and both are marketed under the brand
25 name Calquence.

1 The plaintiffs claim that the former drug product is
2 ineligible for the program based on its Medicare expenditures
3 and the latter drug product only received FDA approval in 2022
4 and therefore it should not be treated as a QSSD.

5 Plaintiff contends that CMS's reading of the IRA
6 contravenes its plain text and that CMS has undermined
7 incentives to research and develop new treatment applications
8 or to improve safety and efficacy of existing drugs, and its
9 issued final guidance is ultra vires.

10 And I believe that that's the substance of its claims, and
11 there may be more to it, of course, but I want to check with
12 each counsel whether or not you have any disputes, and I'll
13 invite you to raise those disputes in connection with your oral
14 argument.

15 Now, as I noted, there's a jurisdictional issue here.
16 Defendants are resting on that claiming that the Court lacks
17 jurisdiction pursuant to a jurisdiction-stripping statute.
18 And, of course, in every case it's the plaintiff's obligation
19 to establish jurisdiction and plaintiff filed the opening
20 motion seeking summary judgment, so my inclination would be to
21 hear from plaintiffs first on both issues and then, you know,
22 I'll kind of defer to you, more or less, in terms of your
23 preparation as to whether or not you want to separate the two
24 issues out or address them at the same time.

25 MR. KEDEM: Thank you, Your Honor. May I speak from

1 the podium?

2 THE COURT: You may.

3 MR. KEDEM: So thank you again, Your Honor. Very
4 much appreciate the opportunity to address you today and want
5 to express our particular appreciation for your willingness to
6 schedule this hearing promptly in light of the upcoming
7 statutory deadline.

8 I think the way that we would be inclined to handle
9 things, subject to the Court's direction, is to start with a
10 sort of affirmative presentation regarding the argument that we
11 are making, which I think then can feed into the jurisdictional
12 issue.

13 I have short slide presentation. You should have hard
14 copies of it. We have copies as well for your Clerk. We gave
15 it to opposing counsel. And I guess now would be a good time
16 to ask -- yeah, there we go.

17 THE COURT: well, just double-checking, I have one
18 hard copy up here. You said there was a second one?

19 MR. KEDEM: Yeah. My co-counsel can bring you
20 another one.

21 THE COURT: Perfect.

22 MR. SHARON: Here are a few.

23 THE COURT: I got one. Thank you.
24 whenever you're ready.

25 MR. KEDEM: The IRA strikes a balance. Congress

1 sought to lower prices for certain drugs but without stifling
2 innovation.

3 To accomplish these twin goals, Congress identified
4 qualifying drugs by incorporating the existing NDA approval
5 regime and setting a seven-year clock. Only a drug that is
6 approved under that regime and is marketed pursuant to such
7 approval can qualify and, importantly, only if at least seven
8 years have elapsed since, quote, "the date of such approval."
9 Those instructions can only be read one way. To be a
10 qualifying drug, at least seven years have to have passed since
11 the date of the drug's NDA approval.

12 AstraZeneca begins with this definition. If you read this
13 definition, you know a qualifying drug has a single NDA. The
14 Government, by contrast, bypasses the qualifying drug
15 definition in favor of an active moiety definition.

16 To get there, the Government does something
17 counterintuitive. It starts with ancillary provisions outside
18 the QSSD definition, in other subsections in other statutory
19 sections entirely and then tries to reverse-engineer them back
20 into the qualifying drug definition.

21 That has a lot of problems, one of which is that all of
22 those provisions kick in only after a qualifying drug has been
23 identified and all of them, every single one of them, is
24 completely consistent with our reading of qualifying drug as
25 having a single NDA.

1 The Government has another problem, though. Even those
2 ancillary provisions don't get you to active moiety. They talk
3 about aggregating across dosage forms and strengths, but active
4 moiety is a much different and far, far broader concept, and
5 even though the IRA is an incredibly detailed reticulated
6 scheme, the term "active moiety" appears nowhere within it,
7 even though it does appear in other statutes.

8 So starting with an overview of the IRA's three steps. So
9 the first step is to identify qualifying drugs, or qualifying
10 single source drug, or QSSDs; the second, to determine which of
11 those qualifying drugs counts as eligible for negotiation, what
12 the statute refers to as negotiation-eligible drugs; and the
13 third is to take those negotiation-eligible drugs to select a
14 certain number of them and engage in a price setting process
15 through negotiation of a maximum fair price that applies to the
16 drug.

17 Now, we, of course, begin by interpreting the QSSD
18 definition under the QSSD definition (e)(1), and we'll run
19 through it very briefly, but we are focusing on (e)(1)(A), the
20 three Romanettes underneath it. All three of these we believe
21 clearly show that each drug has its own NDA.

22 So starting with the first romanette, a drug, in order to
23 be a QSSD, has to be approved under § 355(c) and marketed
24 pursuant to such approval. So 355(c) is the part of the FDCA
25 that authorizes a drug to be approved for marketing by FDA, and

1 the marketing authority is obviously a point back to such
2 approval. So we're talking about a drug that is approved under
3 this provision and marketed pursuant to such approval. Such
4 has to refer back to this original approval.

5 Next is romanette (ii), and we think this is really the
6 most important provision. So the safeguard for innovation
7 under this statutory scheme is that a drug cannot be selected
8 for price caps under the IRA within seven years. And here is
9 the instruction, the key instruction for how to figure out what
10 that seven-year period entails:

11 You need to know when are you starting the clock for a
12 particular drug. And what it says is at least seven years have
13 to have elapsed since the date of such approval. And, again,
14 we the date of such approval has to point back to the singular
15 date on which the NDA for the drug was approved. Again, it has
16 to be the same reference to such approval as in the prior
17 Romanette, and there is only one date for a particular original
18 NDA for each drug. You have to have some way to know exactly
19 when the seven-year clock starts, which is something that you
20 always do when there's a one-to-one correspondence between a
21 drug and its NDA.

22 we'll get to this in a second, but under the Government's
23 interpretation, by contrast, you can have a drug that spans
24 multiple products that are approved under different NDAs, all
25 of which happened on different dates, and there's no

1 instruction about what to do in that situation which is, I
2 think, a pretty clear sign that the statute doesn't contemplate
3 it ever happening.

4 And then, finally, the third romanette talks about the
5 drug not being the listed drug for any drug approved and
6 marketed under § 355(j).

7 So here, a listed drug is a reference to a brand-name drug
8 that is listed in the FDA's orange book, which, if you can get
9 a print version, actually has an orange color. You can also go
10 online and look at it. And it basically lists drugs according
11 to their NDAs and has their original NDA approval date. And
12 there is always a correspondence between a generic drug and the
13 nongeneric branding version, and that correspondence is based
14 on the NDA. So a generic drug is allowed to be marketed as a
15 generic under the original NDA of the brand-name drugs.

16 So we think that's a pretty straightforward indication in
17 several different respects that the statute is contemplating a
18 drug being identified based on its original NDA.

19 Now we're turning briefly to the Government's
20 interpretation and all of the different problems that arise
21 when you abandon what the QSSD definition actually provides.
22 So --

23 THE COURT: Before you get to that, can I pick up on
24 that last romanette?

25 MR. KEDEM: Please.

1 THE COURT: So my understanding is that that
2 reference to a listed drug is referring to a statutory term
3 that's defined in § 355(j)(2).

4 MR. KEDEM: That's correct.

5 THE COURT: And there's nothing in 355 nor in 1320f-1
6 that takes that definition to place any restriction on the
7 definition of QSSD in the IRA. Am I correct about that?

8 MR. KEDEM: So there's nothing further in 1320f-1, I
9 think that that's correct. The reference to listed drug is a
10 reference within § 355 to FDA's responsibility to essentially
11 publish a list of drugs whose NDAs have been approved.

12 So FDA -- the way that FDCA works is, you submit an
13 application to be able to market a drug. If it's approved,
14 you've got authorization to market the drug, and FDA
15 periodically has to publish a list of all the drugs that have
16 been approved to be marketed, and that's what we're talking
17 about here, and the generic version is tied to a listed
18 version.

19 THE COURT: Okay. And the QSSD, the only
20 significance that that has for this case is that the QSSD must
21 exclude those listed drugs.

22 MR. KEDEM: So QSSD excludes drugs that have a
23 generic version. But I think that the reason that it matters
24 for our dispute is that -- and we'll get into this a little bit
25 later -- is that there is a generic version for each NDA. We

1 don't have a situation where there's a generic version for
2 multiple NDAs, but under the Government's interpretation of the
3 word "drug" you might have three different products approved
4 under three different NDAs, and you might have a generic
5 version for one of them but not for the other two, or for two
6 of them but not the third, and then you have a confusing
7 situation about what happens in that situation.

8 THE COURT: All right. Have they I guess promulgated
9 any list of drugs for negotiation that raise that tension that
10 you're pointing out?

11 MR. KEDEM: They have. I can check. I'm not sure
12 specifically. What they've said in their guidance is if there
13 is a generic version of any of the products, then we're not
14 going to treat that as a qualifying drug.

15 So, in other words, if there is Product A, B, and C,
16 according to CMS, whenever there's a generic version of any of
17 them it knocks out the entire group.

18 And I'm actually just about to sort of explain why that
19 causes a lot of practical problems, if you'll allow me to.

20 THE COURT: But just so I'm clear --

21 MR. KEDEM: Sure.

22 THE COURT: -- they have not included any of those
23 drugs that raise that issue that you point out.

24 MR. KEDEM: That's correct. But I think the fact
25 that such problems arise under their interpretation is strong

1 evidence that it's not the right way to read the statute. It
2 makes a lot more sense, if you've got Products A, B, and C,
3 when there's a generic version of A, it knocks out A, or if
4 there's a generic version of C, it knocks out C. It doesn't
5 make sense for a generic version of C to knock out A, B, and C
6 if there's no generic version of A.

7 THE COURT: Isn't the note -- I mean, I guess the
8 underlying policy consideration is as long as there's generic
9 competitors, that's reason to exclude it from the negotiation
10 program.

11 MR. KEDEM: Sure. So why don't I just jump a little
12 bit ahead --

13 THE COURT: Yeah.

14 MR. KEDEM: -- and sort of illustrate what I'm
15 talking about.

16 THE COURT: Sure.

17 MR. KEDEM: So here is a timeline problem, which I
18 think you've seen from our brief, where drugs can be approved
19 at different times and the seven-year clock has to start from
20 somewhere. And so CMS says, well, we're starting the clock
21 from the earliest date. So in this instance, they treat
22 Product A as starting the clock in 2015 even though Drug C is
23 within the seven-year period of exclusivity. So they just made
24 that up. The statute doesn't say the earliest date. They just
25 say that's what we're going to go with.

1 But you could also have a problem where in one scenario
2 there's a generic version of Drug A for these three drugs, and
3 you think this isn't so bad because A is the one who started
4 the clock and A is the one that knocks out the eligibility of
5 this entire group, according to the Government's reading.

6 But consider a different scenario where B is the generic.
7 So the Government says the clock starts in 2015 with Product A,
8 but nevertheless the fact that there's a generic version of B
9 and only B knocks out the entire suite of drugs. Now A, B, and
10 C are no longer eligible under the Government's view for
11 qualifying -- to be qualifying drugs or be price setting under
12 the IRA. And, again, we don't think that that makes sense.

13 It's a lot more sensible as the IRA suggests in the QSSD
14 definition that it's whether you are the listed drug for that
15 particular product, not the listed drug for another product
16 that happens to share the same active moiety. But it creates
17 even more problems beyond that.

18 So here, for instance, you can imagine a scenario where
19 almost all of the spending is coming from Drug C. So that's
20 the drug the Government really wants to lower the price of
21 because it's driving a lot of their expenditures. And yet,
22 imagine a situation where there's a generic version only of
23 Drug A, and so the cheap -- the generic version of a drug that
24 has almost no spending can knock out the eligibility of the
25 entire group. Again, that doesn't make a lot of sense, and you

1 wouldn't have that problem if you treated each generic drug as
2 tied to a specific NDA of each QSSD.

3 And then one other problem which, again, appears in our
4 brief, under the Government's reading, because you're
5 aggregating, you're oftentimes disincentivizing manufacturers
6 to come up with new products.

7 So if you have Products A and B that keep you under the
8 threshold but there's another product that could be great for
9 patients, save lives, Product C that would also have
10 expenditures that would push you over the threshold, because
11 all of those are going to be grouped together under the
12 Government's interpretation, you have a strong incentive not to
13 develop that product to the harm of patients everywhere.

14 So, again, the goal of the IRA is to lower prices without
15 stifling innovation, but their interpretation has that effect.

16 THE COURT: But isn't there a form of innovation that
17 may be incentivized through this scheme the way that the CMS
18 interprets the term?

19 Specifically, I'm referring to the active moiety and the
20 innovative action in the private sector might be the discovery
21 of new molecules, new active moieties, essentially. It seems
22 to provide an incentive for that, does it not, because then you
23 have a new drug?

24 MR. KEDEM: Yeah. So I guess I would say it doesn't
25 eliminate the existing incentive to find a new active moiety.

1 You don't need the IRA for that. The IRA is basically only
2 downside for manufacturers because all it does is cap prices
3 pretty substantially. I mean, we're talking reductions of
4 two-thirds or more.

5 And so it is true that if you develop a product with a new
6 active moiety, then you are free from that downside, but it's
7 not as if the IRA helps create an incentive for that. You
8 already have an incentive to develop that product.

9 And there's also, just from a patient's perspective, the
10 patient doesn't care about active moiety, doesn't even know
11 what an active moiety is. What they care about is whether a
12 drug has been developed that treats a new condition, extends to
13 a new patient population, has a new way of -- and, you know,
14 that there's some new benefit to it.

15 And that, I think, goes to something I'm sure we're going
16 to talk about, which is when do you have a drug approved under
17 a new NDA versus a supplement to an existing NDA.

18 If a drug is sufficiently new, it's going to be approved
19 under a new NDA as opposed to a supplement to an existing NDA
20 under FDA's own guidance.

21 THE COURT: While we're on the topic of policy
22 considerations here, how do you see that factoring into the
23 decision that I make? Because, really, it's up to Congress to
24 decide what the policy is; I just interpret statutes.

25 MR. KEDEM: I totally agree with you, Your Honor, and

1 I think, you know, all of these sort of policy considerations,
2 I think is the reason that they matter is the Government's
3 interpretation leads to all sorts of illogical conclusions,
4 that if Congress had specified, that would be one thing, but
5 there is not a hint in the QSSD that Congress wanted any of
6 those things to be true.

7 And I think maybe that's a good interp- -- it's a good
8 transition, perhaps, to just talking about the Government's
9 interpretation, and I think the most sort of notable thing, you
10 know, as we go back to the overview of the different steps of
11 the IRA is, you would think that the Government would start
12 with the qualifying drug definition in interpreting qualifying
13 drug. It doesn't. It starts at Steps 2 and 3 with ancillary
14 provisions that do other things.

15 And I think there are a few things to understand about the
16 Government's interpretation, and I am prepared to walk through
17 it in as much detail as you would like.

18 But I think just as an overview, all three of the
19 provisions, use of data, applications and approval, and compute
20 and apply that the Government relies on, all of them start with
21 prefatory clauses that make very clear that those provisions
22 apply to do a specific thing at a step after you have already
23 figured out what a qualifying drug is.

24 So you start at Step 1, what's a qualifying drug, and you
25 run through those three romanettes to figure out whether you

1 satisfy all three criteria. If not, you're not a qualifying
2 drug.

3 Then at Step 2 you take all the qualifying drugs and you
4 stack them up and you see which are the 50 highest-spend
5 qualifying drugs and that -- and those are negotiation
6 eligible.

7 And so Step 2, including the use of data provision, says
8 in determining whether a qualifying single source drug is
9 negotiation eligible, they have to use data aggregated across
10 dosage forms and strengths. But that prefatory clause tells
11 you the function of that provision, and there's a similar one
12 for the other two provisions.

13 But, next, the thing that each of these provisions that
14 the Government relies on instructs you to do are perfectly
15 consistent with AstraZeneca's interpretation.

16 So let's take the use of data provision as an example.

17 What it says is when trying to figure out which of the
18 qualifying drugs that you've identified has the top 50
19 expenditures, use data aggregated across dosage forms and
20 strengths of the drug.

21 Now, that is perfectly consistent with our reading because
22 you can have one drug approved under an NDA that has
23 supplemental forms of it approved under supplemental NDAs that
24 might be different against dosage or strength. So you might
25 have a regular strength and an extra strength. They're both

1 approved under the same NDA and so they're the same drug, but
2 the extra strength version was approved in a later supplemental
3 NDA.

4 And so this says you better count both the original form
5 and the supplement and the extra strength form when you are
6 counting up expenditures for that drug. That's a perfectly
7 reasonable instruction.

8 THE COURT: Before I forget, can I ask a question?

9 MR. KEDEM: Please. Always.

10 THE COURT: What determines whether you supplement
11 versus file a new application?

12 MR. KEDEM: Right, great question. So the answer is
13 there's FDA guidance about that.

14 So FDA guidance, and it's really complicated and I had a
15 lot of people explain it to me, but basically it's if it's
16 sufficiently different you need to file a new NDA, but if it's
17 not sufficiently different, you file it as a supplement.

18 And just to give you a little bit of context, for our two
19 products, for the free base version and the maleate salt
20 version, FDA told us to file the maleate salt version under a
21 new NDA. It said it was sufficiently different that it
22 justified a new NDA. But FDA itself has guidance and makes the
23 call. So they don't have to file an application. If you try
24 and file a new NDA and they think that's inappropriate, they do
25 what's called a "Refuse to File" or they can just reject your

1 application. Obviously, you can go to court and try and
2 challenge it under their guidance, but ultimately it's the
3 agency's call.

4 And so that, I think, speaks to a lot of what the
5 Government refers to as product-hopping concerns, which is
6 where a manufacturer might try and manipulate things. FDA is
7 the one who has the guidance about when you file as a new NDA
8 versus under an existing NDA and, you know, we don't think
9 product hopping is actually a concern. The statute doesn't say
10 anything about it, but even insofar as it was a concern, that's
11 the answer to it.

12 THE COURT: But under the FDA guidance you could have
13 two different dosages, strength levels for the same drug that
14 get filed as two different NDAs, correct?

15 MR. KEDEM: So my understanding is, in some
16 circumstances, let's say you're talking about an oral
17 suspension that is designed for children that might be
18 sufficiently different that FDA says we want you to file this
19 as a new NDA, and in that instance, yeah, it would be filed as
20 a new drug, and in that case it would just be a separate drug
21 and you wouldn't aggregate across those two.

22 what this says is, aggregated across dosage forms and
23 strengths of the drug, and it's -- "the drug" is a reference to
24 the qualifying single source drug whose data you are trying to
25 aggregate. And so you have to start with the question in

1 step 1, what's the drug. Once you know that, all the different
2 dosage forms and strengths of that drug, you aggregate that
3 data.

4 The other provisions that the Government relies on are
5 sort of to the same effect. So applications and approvals for
6 the drug, the Government says, well, the word "drug" there is
7 singular; "applications" and "approvals" is plural, so it must
8 be that you have multiple applications and approvals for a
9 single drug. And we say, yes, exactly, you can have one
10 original NDA but multiple supplements -- supplemental
11 applications that are approved and, for that reason, when you
12 are negotiating the maximum fair price, you have to consider
13 data from those applications and approvals.

14 That's very different, though, from saying that you have
15 to consider applications and approvals from what is essentially
16 a different drug. So it's consistent with our reading as well,
17 and the same is true for "compute" and "apply."

18 But I think another important thing to understand about
19 all three of these provisions is, even if you accepted
20 everything else the Government said, it still wouldn't get you
21 to active moiety because if you look at all of these terms,
22 active moiety is not there.

23 So let's talk about dosage forms and strengths. Active
24 moiety is not dosage forms and strengths. It's a very, very
25 different concept. In fact, dosage forms and strengths is one

1 of the smaller distinctions between drugs. A bigger
2 distinction is different active ingredient, and an even bigger
3 distinction is different active moiety. You can have drugs
4 that are the same active moiety that are different active
5 ingredients.

6 And just to sort of give you an example of products that
7 are pretty disparate and yet still have the same active moiety
8 and therefore would be the same active -- same drug under the
9 Government's reading, we've got Prograf and Protopic. One is a
10 pill to prevent organ rejection and people who go through, you
11 know, kidney transplants and other transplants, and another is
12 a topical ointment to treat eczema, but they share the same
13 active moiety so the Government would treat them as one drug.

14 Now, the Government has this workaround where they say,
15 well, if it's a different manufacturer, then we won't treat it
16 as the same drug even though the statute under their reading
17 would treat it as the same drug, but you can imagine Astellas
18 sells Prograf to LEO Pharmaceuticals. In that case they would
19 be treated as the same drug by the Government and would be
20 subject to the same maximum fair price under the IRA. And,
21 honestly, it doesn't really make a lot of sense. Obviously
22 these two were approved under different NDAs.

23 So with that, I'm prepared to sort of walk through other
24 features of the statutory interpretation of qualifying single
25 source drug or the Government's interpretation. I have a whole

1 bunch more slides where I sort of in painstaking detail sort of
2 talk about all the different parts of the Government's
3 interpretation, but I won't do that unless it would be useful
4 to Your Honor.

5 THE COURT: well, I mean, just to guide you a little
6 bit --

7 MR. KEDEM: Sure.

8 THE COURT: -- it may be that there was an elephant
9 born yesterday in the D.C. Circuit.

10 MR. KEDEM: Sure, yes.

11 THE COURT: If you want to tell me how that --

12 MR. KEDEM: Yes.

13 THE COURT: -- elephant is wrong and how I should
14 send it out of the courtroom --

15 MR. KEDEM: Yes.

16 THE COURT: -- it probably would be the most useful
17 thing to do because I think it was very persuasive.

18 MR. KEDEM: well, I appreciate that, Your Honor, and
19 I really appreciate it.

20 So I would point to four aspects of the decision. These
21 are the top four parts that I think are off.

22 First is, somewhat oddly, the Court didn't start with the
23 qualifying drug definition. It didn't even acknowledge
24 romanettes (i) or (iii) at all, which we think there's a lot of
25 language there which is very directly pointing to the fact that

1 it's just applications. It is each drug under its own NDA.

2 Second, when it did get to romanette (ii), it rejected it
3 basically by saying that Teva's argument begged the question
4 that Teva's argument about romanette (ii) only worked if you
5 started with the premise that different drugs required a
6 different NDA. And just going back to romanette (ii), I don't
7 think that that's a defensible argument.

8 So what romanette (ii) says is the date of such approval.
9 The Supreme Court has told us when you have the definite
10 Article, the date, paired with the word "such," that always
11 means or essentially always means something specific.

12 And there is only one specific thing that it could be
13 pointing to here to start the clock, and that is the date of
14 such approval, which suggests that there has to be a single
15 approval.

16 So I don't think it begs the question to say you cannot
17 read this and think that a drug has multiple dates of such
18 approval. So that I think is the main error of the D.C.
19 Circuit, you know, which I think it came to in part because it
20 didn't start with the QSSD.

21 But the next error is, it said that the ancillary
22 provisions somehow lead to the Government's interpretation even
23 though the D.C. Circuit acknowledged that they didn't foreclose
24 Teva's interpretation; in other words, it acknowledged that
25 Teva could explain how those provisions had meaningful work to

1 do even under a one-NDA interpretation. It just said, well,
2 they sit uneasily because they would be surplusage.

3 And what the D.C. Circuit said is, look, if you already
4 knew that each drug included everything under an NDA, why would
5 you tell -- why would you need an instruction about aggregating
6 across dosage forms and strengths because those dosage forms
7 and strengths are usually going to already be included within
8 the same NDA.

9 And our response is, that is a belt-and-suspenders
10 approach that tells you, look, manufacturers, don't even try
11 and argue. If you have a drug that has a regular strength and
12 an extra-strength version, those are just changes in dosage
13 form or strength or extended release version, they all get
14 aggregated, don't try and argue otherwise, it's belt and
15 suspenders.

16 But whatever surplusage problem we have under our
17 interpretation, the Government has a much worse surplusage
18 problem because, again, remember, active moiety is a much
19 broader basis for grouping different drug products. And so
20 whatever surplusage there might be within an NDA product,
21 there's a much bigger surplusage problem if you're grouping
22 everything that has active moiety because then obviously you're
23 going to group things together that have different dosage forms
24 and strengths.

25 And then, finally, the D.C. Circuit did not even

1 acknowledge, much less explain, how you get from those
2 ancillary provisions to an active moiety interpretation.
3 Again, those ancillary provisions, they refer to dosage forms
4 and strengths and extended release formula. They don't say
5 anything about active moiety, even though there are a ton of
6 other statutes that actually do refer to active moiety.

7 And so even if you took everything else that the
8 Government said at face value and you sort of
9 reverse-engineered these ancillary provisions back through the
10 steps to the qualifying single source drug definition, that
11 still wouldn't get you to an interpretation in which products
12 are grouped together according to active moiety. It would at
13 most say they should be grouped together according to dosage
14 forms and strengths.

15 THE COURT: Okay. I'm not sure that your argument
16 just now addressed the point I'm about to make, but I think the
17 argument is more so the fact that those later provisions make
18 reference to all dosages and strengths suggest that you -- that
19 the original drug, the drug that's referenced in the QSSD
20 definition can have multiple usages and strengths.

21 MR. KEDEM: Yes.

22 THE COURT: And then they are working from the
23 proposition that you could have multiple dosages and strengths
24 that are spread across multiple NDAs.

25 MR. KEDEM: Right. So, sure, and why don't I go back

1 to that language because I agree with you that that is the
2 argument and I think it's not at all a problem on our side.

3 So in order for that to be a problem for us, it has to be
4 true that we just can't account for a situation in which a
5 product has multiple dosage forms and strengths within the same
6 drug. But we can. It happens all the time. You'll have one
7 product approved under an original NDA and then different
8 dosage forms and strengths of the same product that are
9 approved under supplemental NDAs.

10 So, according to our interpretation, they're still the
11 same drug because you still just have one NDA. So you have the
12 regular version and the extended release version or the regular
13 version and the extra strength form. And so what this
14 instruction tells you to do under our interpretation is, you
15 use data that is aggregated across all of those when you are
16 figuring out whether that drug is on the top 50 list.

17 what you don't do is take other drugs that have other NDAs
18 and combine them just because they happen to be variations in
19 dosage form and strength. So, in other words --

20 THE COURT: But doesn't the provision that the
21 negotiation eligibility step, doesn't the provision that
22 governs that step suggest that that is exactly what you have to
23 do or what you should do?

24 MR. KEDEM: No, Your Honor, and here's why. So it
25 says, "In determining whether a qualifying single source drug

1 is negotiation eligible, use data aggregated across and
2 formulations of the drug."

3 So the word "of the drug," you still have to know what is
4 the drug that you're aggregating with respect to, and there's
5 no mystery here, it's the qualifying single source drug. You
6 are determining whether the qualifying single source drug is
7 negotiation eligible. And so, again, it only tells you to
8 aggregate within the drug, the thing that you identified in
9 step 1.

10 THE COURT: Here's another point.

11 MR. KEDEM: Please.

12 THE COURT: This may respond to the point that you
13 were making earlier about two radically different drugs that
14 happen to have the same active moiety.

15 They're marketed by two different manufacturers in most
16 cases, I would assume; you have one that's a cream that treats
17 one condition, you have one that's a powder that treats some
18 other condition.

19 MR. KEDEM: Sure.

20 THE COURT: But your reading of the CMS's
21 interpretation would tend to group these as long as they were
22 put out by the same manufacturer.

23 MR. KEDEM: That's correct. I don't think the
24 Government disputes us on that point.

25 THE COURT: But, I mean, as I would say it, as a

1 layperson at least, there's not just a variation in dosage and
2 strength that separates these two drugs. They don't -- at
3 step 2 it wouldn't make sense to combine those two because --

4 MR. KEDEM: I agree with you.

5 THE COURT: -- they don't vary in that way. Their
6 variations are more significant than that.

7 MR. KEDEM: Right.

8 THE COURT: And so wouldn't that be a limiting
9 principle that keeps CMS from grouping drugs that don't belong
10 together?

11 MR. KEDEM: So, Your Honor, if you were to adopt that
12 and say, look, AstraZeneca, we reject a lot of your reading, we
13 think anything that is a variation in terms of dosage form and
14 strength has to be aggregated, that still wouldn't get you to
15 active moiety.

16 So just to go back to Prograf. So Prograf, these are not
17 variations in terms of dosage form and strength, but they do
18 share an active moiety. So under the Government's
19 interpretation they would be grouped together, but I think per
20 what you just said now you could say, look, I am reading the
21 dosage forms and strengths instruction to say any dosage form
22 and strengths get grouped together. But that would only group
23 together by dosage form and strength; it would not group
24 together by active moiety.

25 And so you would say Prograf and Protopic, those are

1 different drugs, but Protopic and Protopic extended, you know,
2 release or something -- there is not actually a Protopic
3 extended release as far as I know, but let's say there were,
4 that would be grouped together.

5 So that would be a different interpretation than us, it
6 would be a different interpretation than the Government. We
7 think that would be obviously a lot more in line with the
8 statute. It would be accepting a premise that we think is
9 wrong that the Step 2 can inform Step 1, but even assuming you
10 accepted that, it would not get you to active moiety.

11 THE COURT: Right, but if I was to adopt that
12 limitation, I'm not sure it would be proper for me to do
13 anything about it at that stage because that's not really what
14 your controversy is.

15 MR. KEDEM: well, respectfully, I think it would
16 require you to set aside the guidance because I think you would
17 be determining that the guidance is not consistent with the
18 statute. If the guidance had said we will group together
19 products that are different only in formulations and strengths,
20 then I agree with you, you wouldn't have a basis to set that
21 aside if you adopted that reading. But that's not what the
22 guidance says. It says we're grouping together by active
23 moiety.

24 So Prograf and Protopic, according to the Government, are
25 one drug, and I think you would need to say I'm setting aside

1 the guidance on the basis that it is misaligned with the
2 statute's instruction to group only with respect to
3 formulations and strengths.

4 THE COURT: I don't see anything in their guidance
5 that's at odds with what I'm saying because they say that a
6 QSSD -- a QSSD gets identified for drug products by -- well, it
7 says all dosage forms and strengths of the drug with the same
8 active moiety. So --

9 MR. KEDEM: Yes.

10 THE COURT: -- it's not just the active moiety that's
11 the limiting -- that's limiting in terms of how drugs get
12 grouped together, but it's also variation in dosages -- in
13 dosage forms and strengths.

14 MR. KEDEM: Right.

15 THE COURT: So if you have two different drugs that
16 are not variations in dosage form and strength, even under the
17 guidance as currently drafted it wouldn't get grouped together.
18 Am I mistaken?

19 MR. KEDEM: So I think you are mistaken. Obviously
20 my friend from the Government can speak to this.

21 My understanding is that the Government groups together
22 all products with the same active moiety irrespective of
23 whether they are variations from one another in terms of dosage
24 forms and strengths.

25 So just to give you a very concrete example, which is in

1 some sense at issue here, the free base and the maleate salt
2 are not variations in terms of dosage forms and strengths.
3 They don't even share the same active ingredient. And so --

4 THE COURT: well, it seems, then, you don't have a
5 beef with the guidance, you have a beef with how they applied
6 it in your case.

7 MR. KEDEM: So, you know, again, you should ask the
8 Government how they read the guidance and whether they read the
9 guidance the same way I do. We read the guidance as saying,
10 and I'm pretty sure the Government does as well, that things
11 that differ from one another in respects other than dosage
12 forms and strength, if they share an active moiety, are still
13 treated as one drug.

14 THE COURT: Where does it say that in the guidance?

15 MR. KEDEM: So I will -- I can pull up what the
16 guidance says.

17 THE COURT: I'll try to pull up my copy while you're
18 doing that.

19 MR. KEDEM: So it says all dosage forms and strengths
20 of the drug. It doesn't say that only if they vary in terms of
21 their dosage form and strength.

22 So, in other words, it will use -- just to be -- give you
23 another example, all dosage forms and strengths of Prograf and
24 all dosage form and strengths of Protopic, but it will combine
25 those into one drug.

1 THE COURT: where does it say it will combine those
2 into one drug?

3 MR. KEDEM: It says -- so as I read that instruction
4 and, you know, again, Your Honor, if you want to say that this
5 is the right interpretation, and the Government can tell you if
6 it's incorrect, I read it as saying all products that are the
7 same moiety, whatever variations they have in terms of dosage
8 forms and strengths are all treated as a single qualifying
9 single source drug.

10 THE COURT: I think that's stretching the reading. I
11 mean, it's butchering that first sentence, I think. You have
12 to rearrange the words of that first sentence in order to get
13 to that reading. I'll ask the Government what their position
14 on it is.

15 MR. KEDEM: Okay. Again, I don't want to speak for
16 the Government, but my strong suspicion, and, you know, part of
17 the reason I know that is because they grouped together the
18 free base and the salt even though they are not variations in
19 terms of dosage forms and strengths, and no one thought that
20 they were doing anything other than applying the guidance in a
21 faithful manner. Everyone was on the same page about that,
22 and, you know --

23 THE COURT: well, that seems to be the kind of
24 challenge that you're disclaiming here.

25 MR. KEDEM: Okay. Fair enough. Let me give you one

1 other reason, I think, and, again, the Government can clarify.

2 One other reason I think we know that that's not how
3 they're doing it is they've got this separate manufacturer
4 instruction, which is just not necessary if you're talking
5 about variations. Like you don't run into a situation where
6 one manufacturer sells the original version and a different
7 manufacturer does the extended release version.

8 THE COURT: What's the instruction that you're
9 referring to?

10 MR. KEDEM: So their instruction is that they will --
11 it -- they have their instruction about only treating it as the
12 same drug if it's made by the same manufacturer.

13 THE COURT: Well, sure, because they can only
14 negotiate with one party.

15 MR. KEDEM: No, no, I understand that's the reason
16 for it, but I think it's also a signal if you're not talking
17 about products where it's just the small variations in terms of
18 dosage forms and strengths.

19 THE COURT: Well, I think there's a reading of the
20 statute that mandates them to restrict it to one manufacturer,
21 is there not, at the third step?

22 MR. KEDEM: So, yeah, I mean, so we think it's pretty
23 direct if you just look at the romanettes because each NDA only
24 is held by one manufacturer. They sort of back into it through
25 later steps. I think we're on the same page about that, but we

1 take that as evidence for our reading.

2 But I think the only point I'm trying to make here is if
3 you're -- if you think that the Government is just saying
4 dosage forms and strengths of the same product are the only
5 thing that gets grouped together, you wouldn't really need a
6 separate manufacturer instruction because that just doesn't
7 come up as far as I know.

8 THE COURT: Okay. I understand what you're saying.

9 MR. KEDEM: So I'm happy to pause or answer any
10 further questions about the statutory interpretation.

11 THE COURT: No, I think you were ticking through your
12 problems with the Teva decision. If there were any other ones
13 that --

14 MR. KEDEM: Sure. So I would identify all four of
15 those. I think the fourth one is the one we were just talking
16 about, that, you know, at most it would say aggregate across
17 dosage forms and strengths, not against products that have
18 different active moiety.

19 Insofar as Your Honor wanted to adopt that reading, then I
20 do think it would require setting the guidance aside but, you
21 know, it would be a -- you know, welcome for Your Honor to
22 speak with the Government about that.

23 I'm happy, now that we've sort of elucidated the nature of
24 the controversy, to talk, if it would be helpful, about
25 judicial review bars, any questions that you might have there.

1 THE COURT: Okay. Before we turn to that, let me see
2 if there were any other questions I wanted to ask you on the
3 merits.

4 There was another point but I think I may raise it later.
5 We can move onto jurisdiction if you'd like.

6 MR. KEDEM: Sure, Your Honor. So just very --
7 obviously, Your Honor is very familiar with the arguments. I
8 think just as a framing matter, judicial review bars are read
9 incredibly narrowly. I think that's especially true when
10 you're talking about a question of statutory interpretation.

11 The Government here concedes all we have is a single pure
12 statutory interpretation argument. For that reason, we think
13 it falls within the heartland of the merger rule that the D.C.
14 Circuit has repeatedly upheld, including in a recent case in
15 Ardelyx that we filed a supplemental notice about. The Fourth
16 Circuit itself adopted the merger principle in the Arlington
17 Hospital case.

18 In all of those instances they have what we have here,
19 which is a provision that bars certain agency decisions made
20 under certain provisions, and the challenger has an argument
21 that, well, you didn't actually make the decision under that
22 statutory provision.

23 So in Ardelyx, the bar was against challenging CMS's
24 identification of renal dialysis services, and the manufacturer
25 said, well, our drug isn't a renal dialysis service, and the

1 D.C. Circuit said that challenge merges with the question of
2 whether the bar covers it and so we can examine the merits.

3 The same is true in Arlington Hospital. That was a
4 provision that bars review of CMS decisions not to make payment
5 for certain personal comfort items listed in § 1395. The
6 hospital was allowed by the Fourth Circuit to argue, well,
7 telephones aren't personal covered -- aren't personal comfort
8 items because they're not listed in § 1395.

9 We have a challenge, a statutory challenge of exactly the
10 same nature. We are arguing that the Government never made a
11 qualification -- never made a determination of qualifying
12 single source drugs under subsection (e) and that merges with
13 the merits.

14 So I'm happy to pause there on the merger doctrine if you
15 have any questions.

16 THE COURT: well, I'll ask the same question. I
17 mean, the Teva decision also analyzed jurisdiction. It came
18 out in favor of your position, but it didn't do it through a
19 merger doctrine. Do you have any, I guess, difference of
20 agreement as to how the D.C. Circuit got there?

21 MR. KEDEM: Yeah. So it was an interesting decision.
22 It actually cited a couple merger cases, including the
23 Southwest Airlines case which features so prominently in our
24 reply brief and it sort of draws out on some of those
25 principles, but you're right that the focus of it was really on

1 the question whether the determination is the sort of selecting
2 of the 15 drugs, which it said it was, as opposed to, you know,
3 all of the statutory interpretations that go into it. And we
4 actually think the merger doctrine's sort of a straightforward
5 way to get there. We do agree with its analysis, though, and
6 essentially they get you to the same place.

7 THE COURT: Okay. All right. Anything else?

8 MR. KEDEM: Nothing further, unless Your Honor has
9 additional questions.

10 THE COURT: Not at this time.

11 MR. KEDEM: Thank you, Your Honor.

12 THE COURT: Thank you.

13 Okay. I'm sorry, ma'am, if you could help me with the
14 pronunciation of your last name again.

15 MS. GHEIBI: Sure, Your Honor. Gheibi.

16 THE COURT: Gheibi, okay. Thank you.

17 MS. GHEIBI: Thank you, Your Honor.

18 If permissible, I'd like to take the jurisdictional
19 question and then my colleague Stephen Pezzi will address the
20 statutory question.

21 THE COURT: That works.

22 MS. GHEIBI: So as Your Honor acknowledged, yesterday
23 there was a bit of an elephant born in Teva, so I'll start with
24 the elephant.

25 There, the Court disagreed with us on the jurisdictional

1 question, and we obviously maintain that the Court was wrong.
2 It created a circuit split with the Third Circuit in Novo and
3 we think the Third Circuit's approach is not only more
4 consistent with the text of the review preclusion, but it's
5 actually more consistent with the Supreme Court's decision in
6 Doe versus Mullin which came out a few months ago. We filed a
7 supplemental authority there.

8 But I will discuss Teva and why it's wrong, but before I
9 do that, I'd like to sort of flag the D.C. Circuit's own
10 description of its case law toward the end where it sort of
11 confronts Novo. What it says is, and I'm quoting, "But our
12 approach in construing review bars has long differed from our
13 sister circuits."

14 And that's exactly right. The D.C. Circuit's
15 interpretation of review preclusions is unique, and that is
16 true even in the merger context, which I will get to. These
17 are different theories, we acknowledge that, and we'll discuss
18 why the merger theory is unique to the D.C. Circuit and the
19 Fourth Circuit has not, in fact, adopted it.

20 But I do think that Teva's analysis of the jurisdictional
21 question needs to be examined in light of its own recognition
22 that it is applying the uniquely D.C. Circuit case law.

23 And that paragraph that -- the following paragraph then
24 talks about the fact that the Third Circuit's adopting a
25 different interpretation that comes from Bakran, and it cites

1 to a dissenting opinion, interestingly enough, from the D.C.
2 Circuit that sort of says -- by Judge Henderson that explains
3 that there are other circuits that have taken a different
4 approach, and one of those circuits is the Fourth Circuit in a
5 case called Lee versus USCIS. We've cited it on Page 13 of our
6 opening brief. We cited it for a slightly different
7 proposition. But be that as it may, the case is binding.

8 And I'm happy to get into why Lee versus USCIS came out
9 the way it did but, again, I think it is important to
10 acknowledge that the D.C. Circuit itself has acknowledged that
11 it's unique when it comes to reviewing these review
12 preclusions.

13 But going to the question that was presented in Lee versus
14 USCIS, there the review preclusion precluded -- it was framed
15 in exactly the same way. It precluded review of any judgment
16 regarding the granting of relief under section, among other
17 sections, 1255. So it had the same sort of under -- under
18 clause, under Section X.

19 THE COURT: If you could please give me the citation
20 to the Lee case.

21 MS. GHEIBI: Sure. That case is 592 F.3d 612. It's
22 a case from 2010, which notably postdates Arlington Hospital,
23 the case plaintiff cited in their opening brief by a few
24 decades.

25 But there, so it had a review preclusion that had this

1 under clause. The plaintiff there had claimed that the
2 Government essentially misinterpreted the word "beneficiary" in
3 that provision.

4 So § 1255 had the word "beneficiary" in it, and Lee said
5 that the Government is misinterpreting the word "beneficiary."
6 And the Fourth Circuit said -- the Fourth Circuit still decided
7 the claim raised in this APA action falls squarely within the
8 scope of this particular review preclusion, and importantly it
9 says, "Although Lee's claim in his Amended Complaint is
10 carefully worded to avoid expressly challenging the denial of
11 his application for adjustment of status, that is clearly what
12 Lee seeks to do."

13 And that's exactly what's going on here. AstraZeneca has
14 carefully worded its challenge as trying to find some hook in
15 the guidance. It's saying, no, no, no, we're not challenging
16 the determination of our drug, we're challenging the
17 interpretation that CMS has adopted in its guidance. But that
18 was precisely the type of maneuvering that the Fourth Circuit
19 itself has rejected and so have other circuits.

20 Now, we acknowledge the D.C. Circuit obviously did not do
21 that yesterday, but the D.C. Circuit is unique in that sense.
22 And not only that, but we also think the D.C. Circuit's opinion
23 is not consistent with Doe versus Mullin, and I think the best
24 sort of way to analyze that inconsistency is to just look at
25 the basis for which Teva attempts to distinguish Mullin. And

1 if I may just go through the basis very quickly.

2 So it identifies essentially three different reasons as to
3 why Mullin is different. I'm looking at Page 20 and 21 of the
4 Teva opinion. And the first basis is that it says in Mullin
5 the Supreme Court was examining a review preclusion that
6 included the phrase "with respect to" and "any." So it
7 borrowed any determination with respect to.

8 So, first of all, the word "any," the Supreme Court does
9 not find that word to be relevant to its analysis at all. The
10 phrase "with respect to," what the Supreme Court does there is
11 it uses the phrase "with respect to" to say that it just
12 confirms its interpretation.

13 So after it analyzes the word "determination," its
14 ordinary meaning pursuant to dictionary definition, it says it
15 could mean that final determination itself or it could mean the
16 subsidiary determinations up until the determination. That's
17 essentially the interpretation that Novo adopted prior to
18 Mullin, of course, but it was the same reasoning.

19 And then the Supreme Court says, not only is it common to
20 use the word "determination" in this broad sense, but other
21 terms in the judicial review bar, particularly the phrase "with
22 respect to," support this broad understanding.

23 So there, the Supreme Court was just saying that the
24 phrase "with respect to" just supports its broader
25 understanding. And we know that "with respect to" was not

1 determinative in that case because of the way the Supreme Court
2 distinguishes McNary. And the following page, where the
3 Supreme Court spends one paragraph distinguishing McNary, the
4 review preclusion there says "review of a determination
5 respecting an application for adjustment of status under some
6 program."

7 "Because this provision" -- this is directly quoting,
8 "Because this provision referred to a 'single act,' a ruling on
9 an individual application," then it was interpreted narrowly.
10 And the only phrase the Supreme Court emphasizes from the
11 provision in McNary is "an application." So what the Supreme
12 Court found relevant there was that the subject of the
13 determination, determination of "an application" was singular.

14 Here, the subject of the determination is plural.
15 Congress barred judicial review of the determination of
16 qualifying single source drugs.

17 So under that reasoning, McNary's analysis is not
18 applicable here, and yet Teva applied it here. And the basis
19 Teva provides as to why it wasn't applicable in Mullin and why
20 it's applicable to this provision is that towards the end it
21 says, well, in that case there was the phrase "with respect to"
22 and that doesn't appear here. But interestingly enough, in
23 McNary, Congress used the phrase "respecting" which is
24 interchangeable with "with respect to."

25 But, again, what the Supreme Court found relevant was not

1 the respecting or with respect to or the determination, it was
2 the subject of the determination, is it plural or is it
3 singular. In McNary it was singular; here it's plural.

4 So again, that's the second basis for which Teva
5 distinguishes it. We think that's demonstrably an incorrect
6 reading of Mullin, if you will. Mullin is very clear about
7 what it finds relevant about McNary and is the fact that the
8 subject of the determination, "an application" is singular.

9 And then the third basis for why Teva distinguishes Mullin
10 is it says -- the objections in Mullin, it says -- I'm
11 quoting -- "Those objections went to the Secretary's exercise
12 of discretion."

13 And then at the bottom of that paragraph says, "Its claim
14 therefore concerns the scope" -- talking about Teva --
15 "concerns the scope of CMS's statutory authority, not the
16 quality of reasoning underlying any such determination."

17 So it distinguished Mullin saying that there plaintiffs
18 were challenging the Secretary's exercise of discretion, but
19 here there's a sort of statutory challenge to exceed the
20 statutory authority. That is also incorrect.

21 In Mullin, the plaintiffs there did have a statutory
22 challenge. And I'm now reading from the plaintiffs' brief,
23 they identified a particular subsection that required the
24 Secretary to only issue his designation or termination after
25 consultation with appropriate agencies. That was a statutory

1 requirement.

2 Then they said, "Thus, the statutorily mandated
3 consultation is necessarily antecedent to rather than a
4 component of the Secretary's determination." They said a court
5 can therefore evaluate the legal sufficiency of the purported
6 consultation.

7 So once again, Mullin there also raises statutory
8 challenge. So we think all the three bases for which Teva
9 purported to distinguish Mullin cannot withstand scrutiny, and
10 Mullin's interpretation -- or rather Novo's, the Third
11 Circuit's application of this statutory preclusion is more
12 consistent with Mullin.

13 And the D.C. Circuit attempts to distinguish Novo by
14 saying in that case the Court was -- or rather plaintiffs were
15 challenging a specific determination just the sort of grouping
16 of their drugs, whereas Teva was challenging CMS's guidance,
17 the sort of definition that is also inaccurate.

18 Novo, there the plaintiffs were challenging a definition.
19 Just to read directly from the Novo plaintiffs' brief, they
20 said Congress did not authorize CMS to rewrite the IRA's
21 statutory definitions. The Novo -- the Third Circuit in Novo
22 explicitly said, and I'm quoting here, "Here, CMS adopted a
23 definition of qualifying single source drug that led the agency
24 to group Novo Nordisk products together and ultimately selected
25 them for negotiation as one drug. We, therefore, cannot review

1 CMS's determinations or the internal processes CMS used to make
2 them."

3 So in that way, the challenge presented by the plaintiffs
4 in Novo and the challenge presented by plaintiffs here is
5 exactly the same posture. And that was the case in Teva, it's
6 a clear circuit split, and we think that this Court should --
7 we respectfully urge the Court to follow the Third Circuit's
8 path, which is not only more consistent with the precedent
9 outside of the D.C. Circuit, but it's also more consistent with
10 the Supreme Court's decision in Mullin.

11 And one aspect of Mullin that we think is particularly
12 relevant here is the fact that Mullin was very careful to
13 acknowledge that allowing plaintiffs to create a sort of
14 distinction, which AstraZeneca is trying to do here saying
15 we're not challenging a determination, we're just challenging
16 the way in which the agency got there, the methodology, that
17 allows for, quote/unquote, clever lawyering to maneuver around
18 a review bar.

19 And so in that sense, I mean, Teva did not really
20 acknowledge that. All Teva said was, well, plaintiffs can't
21 bring a challenge to the determination itself but they can
22 challenge the process in which CMS gets there or the
23 interpretations or definitions adopted by CMS.

24 But the reality is that every manufacturer, just like
25 AstraZeneca, just like the other manufacturers we're seeing

1 bring these suits, can just reframe their challenge to the
2 determination in a way that essentially vacates the
3 determination.

4 I mean, it is not a coincidence that if the Court adopts
5 AstraZeneca's interpretation, Calquence will not be included in
6 the negotiation program. That is not an accident. That is by
7 design. They are designing their statutory questions in a way
8 that gets them the result they want, that gets this Court to
9 vacate a determination that that Congress precluded it from
10 reviewing, but then they're just finding some statutory hook
11 for it the way opposing counsel was trying to find a statutory
12 hook for it in the CMS guidance in real time. And that's what
13 we're seeing manufacturers do, and that's exactly the type of
14 clever lawyering that the Supreme Court wanted to prevent.

15 THE COURT: What, then, actually prevents CMS from
16 rewriting the statute?

17 MS. GHEIBI: So Congress precluded it, and here's
18 what I will say about that is that type of challenge to CMS's
19 misinterpreting the statute, that is precluded, and that is
20 exactly the type of argument that the plaintiffs made in Mullin
21 and the Supreme Court rejected it.

22 The Supreme Court discussed this towards the end of the
23 jurisdictional analysis essentially saying that, well,
24 plaintiffs complain that the Secretary can make a designation
25 or termination by just flipping a coin and it can designate 50

1 countries at the same time.

2 The Supreme Court said regardless of whether or not those
3 are reviewable, we're not going to opine on whether or not
4 there could be some way to review those. Congress made the
5 choice to preclude review, and so if and when that happens it
6 is up to Congress to fix it. That is, after all, the whole
7 point of the review preclusion.

8 And what I will say about those farfetched hypotheticals,
9 plaintiffs are trying to provoke alarm about these sort of
10 farfetched hypotheticals where we have this rogue CMS that goes
11 around, designates hundreds of drugs at the same time, picks a
12 drug that was just announced yesterday and says it's been seven
13 years. Congress could have very reasonably concluded that the
14 chances of a rogue CMS is very low.

15 But what is far more likely is that manufacturers such as
16 AstraZeneca with a ton of resources and a ton of incentives
17 will try to litigate this program, essentially nullify it or
18 kneecap the program through litigation. And, in fact, that is
19 precisely what we're seeing. This is AstraZeneca's second
20 lawsuit despite the review preclusion. But be that as it may,
21 it was perfectly reasonable for Congress to make that judgment.
22 And if and when they're confronted with the sort of rogue CMS
23 scenario, which, again, seems very unlikely, but if that
24 hypothetical comes to pass, Congress can then address it.
25 That's up to Congress.

1 But Congress doesn't legislate based on farfetched
2 hypotheticals. It legislates based on the realities on the
3 ground, and we think that its decision to preclude review is
4 consistent with the realities on the ground. It wanted this
5 program to be immune from judicial second-guessing. It wanted
6 to prevent exactly the type of scrutiny here.

7 And the plaintiffs have these slides showing the
8 different -- talking about the difference between active moiety
9 versus active ingredient, and my colleague will discuss that in
10 detail, but that's exactly the type of thing that Congress
11 thought should not be subject to judicial second-guessing.
12 These are not things that should be decided by lawyers and
13 judges using canons of statutory interpretation, but rather by
14 CMS.

15 And again, if and when CMS steps out of line in a way that
16 alarms Congress, that is Congress's responsibility, and, again,
17 that comes from Mullin itself.

18 And one other thing I will note about Mullin is that the
19 plaintiffs there presented their argument as this is just a
20 challenge to the way in which the agency gets there. It's not
21 a challenge to the determination. And they continue to hammer
22 in the point that the nature of their challenges were such that
23 it was not dispositive on the unreviewable determination.

24 So they said, if the Court accepts plaintiffs'
25 interpretation that the Secretary should have consulted with

1 other agencies but it failed to do so, it doesn't mean that the
2 designation will get vacated. What will happen is that the
3 Secretary will just have to go through the lawful process and
4 then she can make the same determination that it did
5 previously. So it wasn't going to be decisive on the
6 determination. The Supreme Court still rejected it.

7 what's telling is that in this case it will be decisive on
8 the determination because the CMS is -- or rather the IRA
9 negotiation program is quite formulaic. And CMS is instructed
10 to identify a certain number of drugs that are the most
11 expensive and it has to be 7 years or 11 years, sort of very
12 formulaic standards.

13 The only real dispute will ever be about the
14 interpretation. So if the interpretation is up for dispute, if
15 the interpretation is subject to judicial second-guessing, then
16 the, quote/unquote, determinations will be decided in federal
17 courts by judges, not by CMS. And it leaves a serious question
18 as to what, if anything, will still be subject to the review
19 preclusion.

20 I mean, Your Honor expressed concern about what type of
21 thing could be reviewed by the Court. The problem with
22 plaintiffs' interpretation, at least in this particular
23 context, is that if this Court adopts Teva's interpretation,
24 the Courts are allowed to make the determination as to what the
25 interpretation is, then there is nothing left for CMS to really

1 decide, that it would just be left with nothing but the sort of
2 formulaic application.

3 In this case, for instance, if the Court sides with
4 AstraZeneca on the interpretation, the determination is set. I
5 mean, there is no -- there's virtually no discretion left for
6 CMS at that point, and so clearly as to how that will leave the
7 review preclusion with anything to do.

8 So in that sense we respectfully disagree with Teva and we
9 think the Third Circuit's approach was far more consistent
10 with, again, interpretation of the text and the Supreme Court's
11 decision in Mullin.

12 But I will -- also like to address this merger theory. So
13 the merger theory is, at least, based on our understanding,
14 rather unique to the D.C. Circuit, the COMSAT cases and
15 whatnot.

16 The Arlington Hospital case plaintiffs have cited, that
17 case does not actually address the merger theory. It just
18 says, like on the review preclusion is from 1981, I believe, or
19 1984, rather, and it says we agree with the District Court, the
20 District Court was correct. It draws a footnote saying that
21 other circuits agreed. So it doesn't engage in any analysis.

22 They cite another case, the Garcia versus Barr case. That
23 case actually did not even include an express review
24 preclusion. That was a question of implicit review preclusion.
25 That analysis is completely different.

1 But what I will say about Arlington Hospital is to the
2 extent the merger theory makes sense is present in situations
3 where there is a dispute about the category of determination
4 that the agency engaged in.

5 So, for instance, if CMS decides tomorrow that AstraZeneca
6 is completely barred from the negotiation program and it says
7 that debarment is subject to the review preclusion, this Court
8 can under the merger theory examine the scope of the review
9 preclusion and say, wait a minute, this is not the type of
10 determination that Congress wanted subject to the review
11 preclusion, that there's three types of sort of selection
12 determination, determination of qualifying single source drug
13 and whatnot that Congress wanted precluded. Debarment is not
14 one of them.

15 But here nobody disputes about the type of determination
16 that AstraZeneca takes issue with. The type of determination
17 here is a qualifying single source drug. The way AstraZeneca
18 is presenting the merger theory is it's saying, uh-huh, it is
19 not truly a determination under the review preclusion unless
20 it's a lawful determination under the review preclusion.

21 It's essentially trying to smuggle in a lawfulness inquiry
22 into this categorical inquiry. So we think that's a
23 misapplication of the merger theory.

24 And notably, Teva cited to the merger cases, but, as Your
25 Honor acknowledged, Teva didn't engage with the merger theory

1 in this context, and -- but plaintiffs' theory which we think,
2 again, extends the merger theory beyond its bounds by trying to
3 smuggle in a lawfulness inquiry into this categorical inquiry,
4 I mean, it raises serious questions about whether or not any of
5 these cases, including Mullin, were decided correctly.

6 So if I look at Lee versus USCIS, the case we just
7 discussed, in that case the provision also said it precluded
8 any judgment regarding the granting of relief under Subsection
9 [sic] 1255. Under AstraZeneca's theory for the Court to
10 determine, wait a minute, is this truly a judgment under
11 § 1255, it first has to determine whether or not it was lawful
12 under 1255. And in order to determine whether or not it was
13 lawful under 1255, it had to address Lee's claim about whether
14 or not USCIS interpreted "beneficiary" correctly.

15 But even applying that theory to Mullin itself, Mullin --
16 the review preclusion in Mullin said there's no judicial review
17 of any determination of the agency, fill-in-the-blank agency,
18 with respect to the designation -- designation or termination
19 or extension of a designation of a foreign state under this
20 subsection.

21 Now, interestingly, enough, that subsection included the
22 statutory requirement that the agency engage in consultations
23 with other agencies.

24 Now, under AstraZeneca's theory, the Supreme Court, for
25 the Supreme Court to decide whether or not this was truly a

1 determination under this subsection, it had to determine
2 whether or not DHS complied with the statutory requirement.
3 But, of course, no one raised that argument. As we understand
4 it no party even raised that argument, and none of the Supreme
5 Court Justices even entertained that argument, including the
6 dissent, and we don't think that's because of the lack of legal
7 talent. To be frank, we think that has to do with the fact
8 that that theory is so expansive that it would write away so
9 many review preclusions.

10 I mean, Congress routinely cross-references other
11 provisions, it routinely uses this under clause. The job of
12 that under clause is to identify the categories of
13 determinations that are subject to a review preclusion. It's
14 not there to sort of open the door for the Court to engage in
15 some sort of a lawfulness determination.

16 So to the extent that there is any merger theory that's
17 applicable in the Fourth Circuit or even consistent with
18 Mullin, that's the way in which it has to be interpreted
19 because it's really difficult to reconcile AstraZeneca's
20 expansive view of this merger theory with Mullin itself or,
21 quite frankly, all the other review preclusions that include
22 this under provision.

23 In Arlington Hospital, so just going back to Arlington
24 Hospital, the Fourth Circuit case they do identify, in that
25 case the Court was engaging in that categorical analysis, the

1 District Court. I mean, it's consistent. Again, the Fourth
2 Circuit didn't engage in any sort of meaningful analysis, but
3 it's -- a finding of jurisdiction was consistent with this
4 categorical approach because there, the review preclusion
5 said -- it basically barred certain payments and whatnot,
6 because such items are listed in Subsection (x). So it
7 identifies a subsection and it said the items were listed in
8 Subsection (x). And Subsection (x) then identified a certain
9 list of items, and the Court said, well, I have to go look at
10 the list to figure out whether or not this is the type of
11 payment that falls within the scope of the review preclusion.
12 That makes sense. That's still a categorical approach. That's
13 not a lawfulness approach. That's a categorical approach. And
14 that is going to be rare because there's rarely going to be a
15 dispute about the parties over the categorical nature of the
16 agency determination.

17 There's always going to be a dispute over the lawfulness
18 or rather any time there's a statutory complaint, there's
19 always going to be a dispute about the lawfulness, but rarely
20 are the parties going to disagree.

21 So in my hypothetical, it would be the debarment scenario.
22 That's rare, but if and when that comes up, this merger theory
23 would have some pull. Here it doesn't. So, respectfully, we
24 would maintain that the merger theory is not applicable here
25 either, if the Court's so inclined to even invoke it.

1 But unless the Court has any questions.

2 THE COURT: All right. Let's see.

3 You were focused on the merger theory as a distinction
4 between D.C. Circuit law and other circuits.

5 MS. GHEIBI: Yes.

6 THE COURT: But I guess there were broader principles
7 that were focused on the Teva decision that do seem to apply
8 across multiple circuits, even if the Third -- it didn't --
9 perhaps the Third Circuit -- I'm not sure if the Third
10 Circuit's an outlier in this respect. I just noted that even
11 the Fourth Circuit seems to suggest that, again, there's a
12 strong presumption of reviewability and therefore in a
13 situation where there's any ambiguity or there's any doubt, you
14 resolve it in favor of review.

15 MS. GHEIBI: Yes, Your Honor, and we don't think here
16 there is any doubt, the same way that Mullin concluded that
17 there was no doubt there. Here, again, we think Congress could
18 not have been more clear, it's barring a review of the
19 determination of qualifying single source drugs in the plural
20 under subsection (e). It's identifying the type of thing it
21 doesn't want subject to judicial review.

22 And using sort of the standard canvas of statutory
23 interpretation and the guidance from the Supreme Court, the
24 fact that the subject of the determination is plural here is a
25 clear distinction between McNary, the fact that the word

1 "determination" was just interpreted by the Supreme Court a few
2 months ago, and the Supreme Court there said that
3 "determination" is rather broad, it could have two different
4 definitions, it could have final decision or all the
5 subsidiaries leading up to it, but it essentially said in the
6 administrative law context that's a distinction without a
7 difference because in the administrative law context the
8 subsidiary decisions merge into the final determination. So if
9 you can't challenge the final determination, if Congress said
10 no review of the final determination, there's no review over
11 the subsidiary determinations either.

12 And what I will say about the D.C. Circuit precedent that,
13 yes, it does differ on the merger rule, but as Teva
14 acknowledged, it also differs with this respect on its ruling
15 that you can -- that when Congress bars the final determination
16 it doesn't bar the subsidiary determinations, or rather the
17 interpretations leading up to it.

18 The D.C. Circuit there acknowledged that in that respect
19 they also differ from their sister circuits. That's the
20 dissenting opinion I was talking about. They cite to a
21 dissenting opinion from Judge Henderson and they very
22 transparently acknowledge that, yes, other circuits have taken
23 a different approach and essentially said, be that as it may,
24 we're reaching a different decision.

25 So we would maintain it is not the Third Circuit that's

1 the outlier, it's the D.C. Circuit that's the outlier. And
2 that's not us saying it, that's the D.C. Circuit saying it.
3 They're acknowledging that they are an outlier. And we think
4 that Novo's interpretation is far more consistent with the
5 out-of-D.C.-Circuit case law -- or, sorry, Novo's
6 interpretation, yes.

7 THE COURT: And the only Fourth Circuit case that you
8 cited just now in your presentation was Lee, but I'm not sure
9 that I followed you. You referenced Lee a couple of times but
10 the earlier point that you referenced Lee you seemed to be
11 citing it in support of your position that if the Fourth
12 Circuit was to take a side on this now dispute between the
13 Third Circuit and the D.C. Circuit, it would take the Third
14 Circuit side?

15 MS. GHEIBI: Yes.

16 THE COURT: What is there in Lee that suggests that?

17 MS. GHEIBI: I'm sorry?

18 THE COURT: What is there in Lee that suggests that?

19 MS. GHEIBI: So it's the quote that I read from
20 basically saying Lee -- what Lee tried to do is he challenged
21 the term "beneficiary" as it appears in Subsection [sic] 1255,
22 and the Court there said the claim still squarely falls within
23 the review preclusion and it said, "Although Lee's claim in his
24 Amended Complaint is carefully worded to avoid expressly
25 challenging the denial of his application for adjustment of

1 status, that is clearly what Lee seeks to do." And then it
2 goes on to say that Lee's complaint in that district -- is that
3 the district director made a faulty eligibility determination
4 under Subsection 1255(i) and that faulty eligibility
5 determination from Lee's brief is the beneficiary
6 interpretation, and it says that determination was the sole
7 basis of denial of Lee's application and cannot be divorced
8 from the denial itself.

9 Here, the Government's, or CMS's interpretation of a
10 qualifying single source drug was essentially the sole basis
11 for including AstraZeneca in the list. As we just discussed,
12 if the Court adopts AstraZeneca's interpretation, they're not
13 going to be included in the list. So the sole basis for why
14 they're identified as a qualifying single source drug, the sole
15 basis why they're selected for the program as far as
16 interpretive question is concerned is what they challenge.

17 So, I mean, it just so happens -- I mean, again, like we
18 said, it's not an accident that they're challenging the thing
19 that if the Court sides with them on, lucky for them, their
20 drug is not part of the negotiation program. That's exactly
21 what Lee was trying to do. Instead of challenging the
22 unreviewable determination, it tried to come at it collaterally
23 by saying, wait a minute, the Government is misinterpreting
24 this provision, it's misinterpreting "beneficiary." And the
25 Fourth Circuit saw right through that. It said, although

1 you're trying to carefully maneuver your way around it, you're
2 clearly trying to challenge what you're not permitted to
3 challenge.

4 Now, we acknowledge that other -- that the rest of the
5 opinion, and Lee sort of talks about the nuances and the
6 complexities of that particular statute and whatnot, but the
7 premise is the same. The premise is that the Court is sort of
8 acknowledging that this sort of clever maneuvering can't get
9 past the fact that what plaintiff is trying to challenge is the
10 unreviewable determination itself. They can't just cleverly
11 plead around it. And that is particularly potent in the
12 particular -- the Drug Negotiation Program, the IRA context,
13 because, as we said, this particular program is very formulaic.
14 I mean, once we get past the interpretive questions, the
15 determination as to the drugs is set because Congress says pick
16 the most expensive drugs.

17 Now, if the Courts get to decide what is a qualifying
18 single source drug through the sort of interpretive
19 maneuvering, that manufacturers will raise, continue to raise,
20 we expect, then those determinations are going to be
21 effectively made here in these courtrooms as opposed to the CMS
22 headquarters, and then it raises questions about, well, what is
23 the purpose of the review preclusion? What was Congress trying
24 to do if not shield these determinations from judicial
25 second-guessing?

1 THE COURT: In your discussion of Doe v. Mullin you
2 were taking a different read than the D.C. Circuit took by I
3 guess sort of casting their focus --

4 MS. GHEIBI: Yes.

5 THE COURT: -- on the "with respect to" language as a
6 secondary consideration in the Supreme Court's case. And I may
7 have misheard you, but you seem to be linking that "respect to"
8 language back to the statute at issue in this case, but I might
9 have misheard you because it's not this there, I don't think.

10 MS. GHEIBI: No, Your Honor. I may have misspoken.

11 THE COURT: okay.

12 MS. GHEIBI: I'm linking it back to the provision in
13 McNary.

14 THE COURT: okay.

15 MS. GHEIBI: So the provision in McNary said -- had
16 barred the review of a determination respecting an application.
17 Now, obviously "respecting" and "with respect to" are
18 synonymous. But McNary took a narrow interpretation while
19 Mullin took a broad interpretation, and the material
20 distinction between those two provisions is that in McNary, at
21 least that's what the Supreme Court said, that in McNary the
22 subject of the determination was singular. It was a
23 determination of "an application." The Supreme Court
24 highlights that "an application" part.

25 Here -- so by analogy, here the subject of the

1 determination is plural. Congress barred review of the
2 determination of qualifying single source drugs.

3 THE COURT: Determination's not plural.

4 MS. GHEIBI: I'm sorry?

5 THE COURT: Determination is not plural.

6 MS. GHEIBI: And it wasn't plural in Mullin either,
7 and yet the Supreme Court found that it was broad, again, just
8 taking the Supreme Court's analysis there.

9 THE COURT: But it said any determination, which I
10 think it's not plural in a formal sense, I don't think, but
11 when you're saying any determination with respect to, you're
12 talking about multiple determinations.

13 MS. GHEIBI: what I will say is that the word "any"
14 was not the textual hook for the Supreme Court. The textual
15 hook for the Supreme Court was the word "determination," and
16 then it said that that determination is supported by "with
17 respect to."

18 But obviously, we know that "with respect to" is not
19 decisive because "respecting" appears in McNary. And McNary
20 came out the other way, and what the Supreme Court said about
21 McNary, the basis for which it distinguished it, was that there
22 the subject of the determination was singular.

23 I mean, whether or not that's accurate or not, that is the
24 Supreme Court's analysis. It says a provision governing
25 statute barring, quote, "review of a determination respecting

1 an application for adjustment of status under..." And then
2 "an application" is emphasized and says "because this provision
3 referred to a single act, i.e., a ruling on an individual
4 application," the Court held what it did. It sort of
5 interpreted narrowly.

6 So it's not us saying that the singular versus plural is
7 relevant. It's the Supreme Court saying it. So in that --
8 that's what I meant by "with respect to" versus here we have
9 "of" as opposed to "with respect to." What we're trying to
10 argue is that "with respect to" in Mullin was not decisive, it
11 couldn't have been, because if it was then the Supreme Court
12 would have had no answer for McNary because it also used
13 "respecting."

14 THE COURT: All right. I understand now. Was there
15 anything further?

16 MS. GHEIBI: No, I think -- oh, yes, ultra vires
17 review.

18 So plaintiffs have also raised a claim under ultra vires.
19 As we've cited from the Supreme Court case in 2025, the Supreme
20 Court said in -- sorry, the name of the case is escaping me --
21 the Nuclear Regulatory Commission versus Texas, it said that
22 ultra vires review is not available when there's an express
23 statutory preclusion. Plaintiffs say that's dicta. We would
24 disagree. I mean, the Court there was just articulating the
25 standard.

1 But dicta or not, the Fourth Circuit has since reiterated
2 that standard in a case we also cite, Sustainability Institute
3 versus Trump, it's a 2026 case from the Fourth Circuit. The
4 citation to that is 165 F.4th 817. And it essentially says
5 that when there's an express review preclusion there's no ultra
6 vires review available. And that really makes sense because an
7 ultra vires review is really intended for situations in which
8 there is no cause of action, effectively, that there's
9 nothing --

10 So, for instance, we'll sometimes see it in an APA context
11 when some final agency action. So they can't bring an APA suit
12 but they've identified some explicit statutory prohibition and
13 they'll raise this as a, quote/unquote, Hail Mary is what
14 Supreme Court referred to it as. It doesn't really make sense
15 here because the dispute is whether or not there's an express
16 review preclusion.

17 If the Court sides with plaintiffs on that, then they
18 would just have a straightforward APA suit. There would be no
19 need to assert it as an ultra vires claim, so we would say
20 because the review preclusion is express, they also don't have
21 an ultra vires review.

22 THE COURT: All right. Thanks very much.

23 MS. GHEIBI: Thank you.

24 MR. PEZZI: Good afternoon, Your Honor. Stephen
25 Pezzi from the Department of Justice on behalf of the

1 defendants.

2 Obviously, the Government believes that there's a
3 jurisdictional problem here, but were the Court to reach the
4 merits, we think CMS's interpretation of the statute is the
5 best one.

6 I would like to start with -- I don't have my own slides,
7 but I do have my own hypotheticals.

8 So imagine three children, I have three children each
9 going to the doctor, taking -- you know, they have some sort of
10 illness, everybody is handed some Tylenol. The youngest kid
11 can take it in the liquid suspension; the middle kid a chewable
12 tablet; the oldest kid is maybe old enough to actually swallow
13 a pill.

14 Everyone would agree that that is the same drug in the
15 colloquial sense in the ordinary meaning of the word "drug,"
16 even if they are presented in different forms. It's not a
17 perfect hypothetical because obviously Tylenol is an
18 over-the-counter medication and never be subject for that
19 reason.

20 But the point I'm trying to make is there's an ordinary
21 understanding of the word "drug" that I think plaintiffs
22 omitted entirely in their presentation that I think is worth
23 the Court considering and that the D.C. Circuit did just
24 consider yesterday.

25 So the provision defining qualifying single source drug

1 that plaintiffs spent most of their presentation discussing, it
2 actually starts with the word "a drug" and the word "drug" is
3 not separately defined in the statute.

4 And so we think the fact that the Government's
5 interpretation is far more consistent with the ordinary meaning
6 of the word "drug" than plaintiffs' informs how the -- what
7 plaintiffs refer to as ancillary provisions, which I will get
8 to in a minute, we don't think they're ancillary at all, all
9 need to be sort of interpreted as one cohesive whole.

10 I think my friend on the other side said that patients
11 don't care about active moiety, and maybe that's correct and
12 I'm sure that's correct in most cases, but patients certainly
13 don't care about the difference between a New Drug Application
14 and a Supplemental New Drug Application, and it is telling how
15 critical that very subtle, very complicated distinction is to
16 plaintiffs' interpretation of what Congress did here, and I
17 think it can be illustrated in the following sense.

18 There's a lot of talk in the briefs about aggregation and
19 whether the statute requires aggregation of drugs or different
20 forms of drugs when determining what is a qualifying single
21 source drug or a negotiation-eligible drug.

22 Actually, everyone agrees that aggregation is required.
23 Plaintiffs think that aggregation is required. They just think
24 that aggregation is required within the same New Drug
25 Application and stopping right there.

1 They think that, you know, if there's a Supplemental New
2 Drug Application filed, there's also aggregation across -- to
3 that Supplemental New Drug Application. The only difference is
4 that they think Congress limited that aggregation to the
5 original New Drug Application and any supplements rather than a
6 truly New Drug Application. And there is just absolutely
7 nothing in the text of the statute that would indicate that.

8 The best plaintiffs have is language in a different
9 statute entirely, the Food, Drug & Cosmetic Act. That's a
10 statute that was enacted, in its original form, I think in the
11 1930s and obviously has gone through many changes and trials
12 and tribulations over the proceeding near century.

13 But the Inflation Reduction Act is a different statute
14 using different language passed for different purposes. And
15 so, unless Congress had explicitly, you know, said that we need
16 to be borrowing every single jot and tittle of the Food, Drug &
17 Cosmetic Act and how we interpret the Inflation Reduction Act,
18 there's just no basis for that here.

19 Now, to get to that result, plaintiffs -- well, before I
20 get to, I think, some of my additional concerns with
21 plaintiffs' interpretation, I do just want to lay out, I know
22 Your Honor's familiar both from the briefing and from
23 plaintiffs' presentation with the basics of the Government's
24 interpretation. But, to be clear, there are multiple
25 indications in the relevant subsections of the very statute

1 that created the negotiation program, not another statute, that
2 Congress fully expected and anticipated the very sort of
3 aggregation decisions that CMS is making now and that are now
4 the subject of litigation in this case and others.

5 And so in 1320f-1(d)(3)(B), Congress is expressly to
6 consider data across dosage forms and strengths of the drug,
7 comma, including new formulations of the drug, comma, such as
8 an extended release formulation and not based on the specific
9 formulation or package type of a drug.

10 1320f-3(e)(1)(D), when talking about the offer price for
11 the negotiations, talks about, quote, "applications and
12 approvals," plural, "under § 355(c) of Title 21 or § 262(a) of
13 this Title for the drug," singular. So that's Congress
14 explicitly acknowledging that one drug may have multiple
15 applications and approvals.

16 And then 42 U.S.C. 1320f-5(a)(2) talking about how to set
17 an maximum fair price -- or, excuse me -- how a maximum fair
18 price is applicable to certain drugs, again uses some of the
19 same language about different strengths and dosage forms of a
20 selected drug and not based on the specific formulation or
21 package size or package type of such drug.

22 So, I mean, that language obviously creates a very
23 significant problem for some of plaintiffs' arguments here and
24 so they -- they're good lawyers and they have arguments as to
25 each of them as to why they think that somehow that is still

1 consistent with their interpretation. None of them ultimately
2 work.

3 So I'll start with, for example, 1320f-3(e)(1)(D). This
4 is the provision applications and approvals for one drug. I
5 mean, that is clearly contemplating multiple applications,
6 plural, and multiple approvals, plural, for one drug.

7 Plaintiffs' response is that that only means Supplemental
8 New Drug Applications rather than a truly New Drug Application.
9 There is no reason to believe that based on the text of the
10 statute. There's just nothing in the statute that limits it as
11 such and, in fact, there's a textual indication to the
12 contrary. It's applications and approvals under § 355(c) of
13 Title 21 or § 262(a). Those cross-references are about the
14 approval process for all New Drug Applications, not just
15 Supplemental New Drug Applications.

16 And so limiting the understanding in a way that plaintiffs
17 would ask this Court to limit it would be entirely unmoored
18 from that textual cross-reference. It would also just be an
19 extraordinarily surprising and counterintuitive way for
20 Congress to achieve this very significant change in everyone's
21 understanding about what a drug would be, especially given the
22 very explicit language in that provision and some of the others
23 that I pointed to clearly contemplating this sort of
24 aggregation.

25 And, again, everyone agrees that as long as it's within

1 the same New Drug Application or even a Supplemental New Drug
2 Application that sort of aggregation is required. Plaintiffs'
3 NDA-specific limitation is just entirely created by AstraZeneca
4 and by some of the other manufacturers who have tried to make
5 this argument thus far unsuccessfully in every case.

6 The reason why we should not, absent a clear indication
7 from Congress, import every single jot and tittle of the Food,
8 Drug & Cosmetic Act to the Inflation Reduction Act is because
9 those are very different statutes passed for very different
10 reasons.

11 It makes perfect sense that when the FDA is approving a
12 new drug or a Supplemental New Drug Application or a change in
13 how a drug is marketed, even down to a new label on a
14 prescription drug gets FDA approval. I mean, the purpose of
15 the Food, Drug & Cosmetic Act is to ensure that prescription
16 drugs are safe and effective for patients, and so even, you
17 know, relatively subtle changes in a drug could be worthy of
18 FDA consideration and regulatory scrutiny.

19 Now, the Inflation Reduction Act has a very different
20 goal. It's about saving money for the American people and
21 Medicare beneficiaries and getting Medicare off this sort of
22 unsustainable path it has been on with escalating prescription
23 drug costs, and the approach that Congress took in that statute
24 was to identify the drugs that were most costly to the Medicare
25 program.

1 And if it were so simple to evade selection simply by
2 submitting two separate, you know, New Drug Applications for an
3 alleged innovation in your drug rather than, you know, going
4 through a supplement, it would be very, very trivial to turn
5 this into what the District Court in Teva called a
6 self-defeating statute, and there's just no reason to think
7 that that's what Congress did here.

8 THE COURT: well, plaintiffs' portrayal of the
9 process is that it's basically dictated by the FDA. Is that
10 not correct?

11 I mean, the decision as to whether or not to file a new
12 application versus to supplement an old one is something that
13 the FDA decides.

14 MR. PEZZI: So it is certainly a topic that is in FDA
15 guidance. There is -- so there is FDA guidance on this
16 subject. It is not always the clearest or most prescriptive
17 guidance, as I think my friend on the other side essentially
18 acknowledged.

19 Now, AstraZeneca says in this case, and I have no reason
20 to doubt, although I don't think it's clear in the record that,
21 you know, in this case FDA suggested to them that they should
22 proceed by two separate applications. And I know that that
23 happens sometimes. It does not happen every time, and the
24 reasons why something may be submitted in a separate
25 application or a supplemental application can -- it can come

1 down to just a discretionary decision of the manufacturer
2 itself, you know, how it looks at the guidance, there might not
3 always be an indication from the FDA.

4 So this is not something that has a clear statutory answer
5 in a lot of cases, and so suggesting that these massive
6 distinctions between which drugs will be in the program and out
7 of the program turn on this sort of fuzzy and subjective
8 back-and-forth between the FDA and the company based on FDA
9 guidance that has changed significantly over the years. I
10 think that's another powerful indication that plaintiffs' line,
11 which is New Drug Applications and Supplemental New Drug
12 Application isn't the right one.

13 I mean, if Congress had wanted to do that, of course, it
14 very easily could have, and then we would respect that choice.
15 There's just no textual indication in the text of the statute
16 that that's what was happening here --

17 THE COURT: So you're saying ultimately --

18 MR. PEZZI: -- as an example. Sorry.

19 THE COURT: I'm sorry to cut you off. But you're
20 saying basically the drug manufacturer has some agency here and
21 exercises some discretion as to when a new NDA will be filed
22 versus an old one being supplemented such that in light of this
23 new statute the IRA and CMS's implementation of it, they could
24 elude the negotiation program by just deciding to bring a new
25 version of an old drug to market through a new NDA and getting

1 approval for that and then draw all the customers away from the
2 old drug to the new drug and therefore raise, I guess, the
3 revenues associated with that and the expenditures associated
4 with that, and CMS couldn't do anything about it because the
5 old drug now has lost its customers and, you know, the new drug
6 is the one that's driving all of the expenditures, and CMS
7 wouldn't be able to do anything about it because it's a new NDA
8 and therefore it can't be grouped with the old drug even though
9 essentially it is the old drug.

10 MR. PEZZI: Yes, Your Honor. Now, to be clear, I
11 don't want to overstate this point. I mean, plaintiffs are
12 certainly right at a high-level generality that the FDA has a
13 very important role to play in that process. I don't want to
14 suggest that FDA, you know, never cares whether something is a
15 New Drug Application or a supplement. It does care. But it is
16 absolutely the case, as Your Honor said, that it is often the
17 case that manufacturers do have some agency on that choice, and
18 we think that undermines plaintiffs' position here.

19 The -- oh, an important example, I think, is an extended
20 release formulation. The reason that that's a good example is
21 because that one actually appears in the text of the statute as
22 an example offered by Congress. So in some of the provisions
23 that I quoted from earlier and that are heavily featured in our
24 brief, Congress goes out of the way to say, you know, new
25 formulation of the drug, comma, such as extended release

1 formulation. An extended release formulation, as I understand
2 it, is very often the sort of new formulation that results in a
3 New Drug Application rather than a supplement.

4 And so it would be odd to think as plaintiffs do that when
5 Congress was making all these references to new formulations it
6 only had supplements in mind and then it just chose a really
7 poor example, if that's the case, of an extended release
8 formulation because that, if anything, it's sort of the
9 opposite expectation is that that's one of the more common
10 examples in which FDA will say, you know, a New Drug
11 Application is required. And so it's just hard to imagine that
12 Congress would have chosen that example if the line that
13 Congress intended to draw without saying so explicitly was
14 plaintiffs' line.

15 Plaintiffs' response to I think really the entirety of
16 these statute provisions that I just went through, call them I
17 think ancillary provisions in the slide deck today. I mean,
18 again, they're in 1320f, f-1, f-3, and f-5, which are all
19 substantive provisions about how drugs are selected for the
20 negotiation program. That doesn't strike me as ancillary at
21 all.

22 what is ancillary are the attenuated cross-references that
23 underlie plaintiffs' position. So the entirety of their -- if
24 you ask plaintiffs, you know, okay, you say the line is
25 NDA-specific and even certain types of NDAs and you said where

1 do you get that from, I think their -- the only answer I've
2 seen in the briefs and the only answer I heard today is
3 multiple degrees of cross-references, first from the qualifying
4 single source drug definition to the Medicare Drug Rebate
5 Program references a covered Part D drug. That, in turn, has
6 an eventual cross-reference to the Food, Drug & Cosmetic Act,
7 as we talked about.

8 That is really an ancillary provision if we're going to be
9 labeling Congress's choices in that way. And again, once you
10 get there, it's not like there's something that, you know,
11 distinguishes supplements from new applications in a way that
12 would be relevant to the definition of a qualifying single
13 source drug.

14 I mean, we think what Congress was doing with that
15 cross-reference was much less dramatic. It was making clear
16 that this is a program that covers drugs that Medicare pays
17 for, prescription drugs that Medicare pays for, I should say.

18 And so, you know, there's a lot of experimental drugs out
19 there, there's drugs that are approved only in Europe or Asia
20 that are not yet approved in the U.S. They are not covered by
21 the program and those cross-references make that clear because
22 those are not FDA-approved drugs. But to hinge the entirety of
23 plaintiffs' understanding on those cross-references I think is
24 unsupportable.

25 THE COURT: what did you make of the discussion I had

1 with Mr. Kedem about the limiting principle that I perceived in
2 the guidance as written?

3 In other words, they are making the argument that active
4 moiety is not a sufficient limiting principle because you could
5 have two radically different drugs that have the same active
6 moiety and they shouldn't be grouped together, but then I read
7 the first sentence of the provision that they are challenging
8 is including the limiting principle of variation of dosages and
9 strengths.

10 Am I reading it correctly?

11 MR. PEZZI: So I think I would say this. I think if
12 I understood plaintiffs correctly, the Government and
13 plaintiffs agree on what the guidance does. We -- although I
14 very much disagree with some of the statements that were made
15 about the slide that was before Your Honor and the implication
16 of the slides, I actually would like to address that very
17 briefly.

18 THE COURT: You're talking about the slide with the
19 picture of the two?

20 MR. PEZZI: Yes. I'm not sure this is the most
21 important issue in the case, but because there was significant
22 discussion of it, I just want to make sure that everybody's
23 clear about what the Government's position is and is not.

24 Sorry, I don't think there's page numbers, but I just want
25 to...

1 okay. It's the first slide after the section "CMS's
2 active moiety definition is illogical."

3 THE COURT: Right. I have it.

4 MR. PEZZI: So this -- so this slide shows Prograf
5 and Protopic. I think it was suggested multiple times that the
6 Government would consider this one drug. The Government
7 considered this two drugs, and I think so would plaintiffs. I
8 mean, for one reason, it's two different manufacturers. So one
9 is Astellas, one is LEO Pharma.

10 THE COURT: Setting that aside, you know, like
11 Mr. Kedem said, one company bought the other one.

12 MR. PEZZI: Yes. So if they were the same
13 manufacturer, they very well might be the same drug.

14 The other thing I want to say about this slide, though,
15 which I think is important to keep in mind, I think the crux of
16 plaintiffs' argument as to why this is some sort of shocking
17 edge case for an outlying hypothetical that illustrates the
18 problems with the Government's position is that there's two
19 different indications for this drug that, you know, to a
20 layperson, certainly to me, like sound quite different, organ
21 rejection and eczema.

22 The indication for which the drug is approved by the FDA
23 or not approved by the FDA has nothing to do with the
24 definition of a qualifying single source drug, and I think
25 that's true also under plaintiffs' position.

1 That could be very significant, again, in FDA's regulatory
2 practice as to whether someone, you know, is properly selling
3 or prescribing drugs. There's also, like, off-label uses of
4 prescription drugs. It's an entirely separate, complicated
5 area of the law that has very little to do with the Inflation
6 Reduction Act, unless I'm misunderstanding the point.

7 Now, ultimately, I mean, when you look at the pictures,
8 it's a little hard to see, but Prograf -- I've never heard of
9 Prograf and Protopic -- or maybe they were mentioned once in
10 the briefs -- they both seem to be tacrolimus. One is a
11 topical ointment, one is a pill. And so, I mean, ultimately we
12 stand by the notion that if two people are taking tacrolimus,
13 one in the pill and one in an ointment, they are taking the
14 same drug within the meaning of the Inflation Reduction Act,
15 and we think that is indicated by, you know, all of the
16 statutory language that we referenced here. So, I mean, I
17 think --

18 THE COURT: That's because the essential
19 pharmacological element is the same, meaning the active moiety
20 is the same between the two?

21 MR. PEZZI: Essentially, Your Honor, that's right. I
22 mean, the agency's focus has been on active moiety, and I think
23 the D.C. Circuit's decision yesterday, although we obviously
24 have our disagreements with the jurisdictional discussion, I
25 think does do a good job on the merits of explaining, you know,

1 I think the language and the opinions that people take drugs,
2 not NDAs.

3 And the thing that, you know, my kids care about when they
4 have a fever is the acetaminophen and the Tylenol, and the
5 thing that someone cares about when they take Calquence is the
6 acalabrutinib.

7 And so, I mean, the two drugs that we're talking about
8 here, which AstraZeneca markets as Calquence and Calquence,
9 which I don't think is a coincidence, I mean, they're both 100
10 milligrams of acalabrutinib used to treat I think the same
11 condition. It is true that there is some minor chemical
12 variation and it also may be true that that minor chemical
13 variation matters to the FDA's regulatory practice about
14 whether you can sell one without getting approval from the
15 other, but that does not answer the question of whether it
16 matters to Congress's judgment that, you know, it should be
17 included in this program as one of the costliest drugs to
18 Medicare.

19 And accepting plaintiffs' interpretation would
20 significantly undermine what Congress thought it was
21 accomplishing, including by the very text that I started with
22 in those multiple provisions within the -- within the
23 discussion of the drug selection process.

24 So plaintiffs' argument I think primarily -- there's very
25 little in the way of an explanation as to why Congress or why

1 we should think that the line Congress intended to draw was
2 NDAs or NDAs plus supplemental NDAs, and it is mostly about
3 trying to identify problems with the Government's
4 interpretation or some sort of logical incoherencies that, you
5 know, render the Government's interpretation problematic. All
6 of those things are either not problems or they are problems
7 that equally plague AstraZeneca's interpretation.

8 So one we already touched on. I mean, the briefs go on
9 and on about this same holder limitation that they say is
10 atextual, you know, because the guidance requires different
11 NDAs to be held by the same manufacturer, essentially.

12 I mean, for one thing, I think everyone agrees on that
13 understanding, and I think plaintiffs' agreed on that again
14 today. The statute contemplates negotiation with one
15 manufacturer, not, you know, a consortium of competing
16 manufacturers. It couldn't negotiate with two different
17 manufacturers that are competitors on one price. It just
18 doesn't make sense. And then there's clear textual indication
19 to the contrary, repeated references to "the manufacturer."

20 So I think it's common ground between the parties that,
21 you know, CMS shouldn't be selecting drugs on the basis of, you
22 know, adding up expenditures from different manufacturers and
23 the agencies not doing that. So I don't think that's any
24 reason to reject the Government's interpretation.

25 They spend a lot of time talking about use of the word

1 "drug," singular. I already pointed to some of the textual
2 issues with that approach. Again, the statute contemplates
3 that applications and approvals, plural, need to be considered
4 for the drug, singular.

5 But at a higher level of generality, I mean, we agree that
6 we're talking about selecting a -- you know, a singular drug.
7 The whole dispute is how you do that and what is a drug and
8 what is not a drug and where you draw the line. And again, our
9 line focuses on active moiety in the case of drugs, active
10 ingredient in the case of biological products. Their line
11 focuses on new drug applications but we think the CMS's
12 understanding is a far better interpretation of the statute and
13 certainly when considered as one cohesive whole.

14 And then I think the last one is the generic competition
15 provisions. You know, a drug is no longer a qualifying single
16 source drug if it has meaningful generic competition, and the
17 relevant language, you know, about seven years from such
18 approval, I mean, again, that is entirely consistent with the
19 Government's interpretation as well.

20 whether there's a New Drug Application and a Supplemental
21 New Drug Application, those also happen on two different dates.
22 So the exact same question arises as to whether, you know, are
23 you counting from the first date or the second date, and I
24 think it's clear from the statutory text you count from the
25 earlier date, which is the Government's interpretation.

1 We know this from, again, the statute says to, quote,
2 "include new formulations of the drug." I mean, obviously a
3 new formulation is different from an old formulation. The
4 passage of time is inherent in the word "new," and so I think
5 to the extent that's a problem, it's a problem with both
6 interpretations but we think the statute answers the question
7 anyway, so it's not a -- it's not a real problem.

8 And with the Court's indulgence, unless Your Honor has any
9 other questions.

10 I mean, the last thing I would say is, you know, this is
11 the same question that the District Court in Teva looked at,
12 that the D.C. Circuit panel yesterday in Teva looked at. All
13 four of those judges came to the same conclusion.

14 We think reading the statute as a whole, the best
15 interpretation is not allowing the sometimes very subtle
16 differences between one form of drug and another to defeat the
17 statutory criteria that Congress set forth for determining what
18 is and is not a qualifying single source drug, and I think even
19 if the Court was concerned about the Government's
20 interpretation, plaintiffs' interpretation that focuses on an
21 NDA or different types of NDAs is even further afield from the
22 statutory text. So we think our position is well grounded in
23 that text, but certainly there's no basis to adopt an
24 NDA-specific understanding of the statute.

25 And unless Your Honor has other questions.

1 THE COURT: All right. Thank you, Mr. Pezzi.

2 MR. PEZZI: Thank you, Your Honor.

3 THE COURT: Mr. Kedem, was there anything you wanted
4 to say in rebuttal? I'd just ask you to keep your comments
5 brief.

6 MR. KEDEM: Understood. Thank you, Your Honor. I am
7 happy to go in whichever order you would prefer.

8 THE COURT: well, whatever order you'd like is fine.

9 MR. KEDEM: Okay. well, since Mr. Pezzi just spoke,
10 why don't I address the merits really quickly.

11 I want to address this sort of ordinary understanding
12 argument that we hear for the very first time at oral argument.
13 I don't think it works for a number of reasons. He says, look,
14 everyone thinks of Tylenol the same, whether it's the chewable,
15 the liquid, the pill version. I don't think if you asked a
16 hundred people they would think Protopic, an organ rejection
17 drug, is the same as Prograf, an eczema medication.

18 I also think if you asked a hundred people to define the
19 word "drug," not a single of them -- a single person would come
20 up with the active moiety definition.

21 But, honestly, it really just doesn't matter because this
22 is not an ordinary language case. This is a case in which
23 Congress went to painstaking lengths to set out a definition of
24 what a qualifying drug is in Subsection (e). And so there is a
25 reticulated definition. It does not include active moiety.

1 And so this plain language interpretation doesn't make sense.

2 He says, look, patients don't care about New Drug
3 Applications. Congress obviously cared about New Drug
4 Applications and it's not in these, like, buried in
5 cross-references.

6 Again, if you go to the slide that lays out subsection (e)
7 with all three romanettes, we're not looking at
8 cross-references here. Romanette (i) says a drug that is
9 approved under § 355 of Title 21. That's the provision for
10 approval of New Drug Applications. It is marketed pursuant to
11 such approval. Seven years will have lapsed since the date of
12 such approval, and it is not the listed drug for any drug
13 approved and marketed under 355(j). Again, generic drugs are
14 approved and marked with respect to a listed drug approved
15 under an NDA. So these are not cross-references. This is the
16 sum and substance of the qualifying drug definition.

17 And the most remarkable thing I think I heard from the
18 Government was almost no engagement with the text of
19 subsection (e) itself. The closest we got was Mr. Pezzi's
20 statement that, well, look, even if it says the date of such
21 approval, seven years have to have lapsed since the date of
22 such approval, well, you know, you still know that you're going
23 to have subsequent approvals because you've got different
24 dosage forms and strengths.

25 That may be true, but you still don't know what the date

1 of such approval is. That can only be a reference to one
2 single approval. And under our interpretation, consistent with
3 all of the other romanettes, that is the approval of the NDA.

4 It is true that you can have supplemental approvals at
5 different times, but that's not the date of such approval, and
6 you don't start the clock from those subsequent approvals.
7 That is clear only under a one-drug, one-NDA interpretation.
8 Otherwise, it's just the Government reading in the earliest
9 where it doesn't belong.

10 There is no language that gets you there. They just chose
11 that because it allows them to group as many drugs as possible,
12 drugs even that were approved, products that were approved a
13 year ago get grouped with drug products that were approved 10
14 to 15 to 20 years earlier, not because of anything the statute
15 says, just because it allows a broader grouping and therefore,
16 you know, more price setting.

17 And that's -- I'm sorry.

18 THE COURT: I just want to -- I mean, I'm sort of
19 chomping at sort of trying out an analogy with you.

20 MR. KEDEM: Sure.

21 THE COURT: And I was searching for an analogy to the
22 situation in order to better understand the parties' arguments.

23 And one that I came up with is if we were to look at the
24 word "book," and say you had a statute that told the Librarian
25 of Congress that they could negotiate the prices of certain

1 books with publishers.

2 MR. KEDEM: Right.

3 THE COURT: And then it had a definition for the
4 certain types of books that may be subject --

5 MR. KEDEM: Yes.

6 THE COURT: -- to this negotiation program. And in
7 that definition it made reference to the process by which a
8 book obtains an ISBN.

9 MR. KEDEM: Um-hmm.

10 THE COURT: Now, I just received today, it's still in
11 plastic, I haven't opened it yet, it's from the Fourth Circuit.
12 It's the Fourth Circuit's Criminal Handbook. It has an ISBN on
13 it. This is the 2026 edition. We also have the 2025 edition
14 that has a different ISBN.

15 MR. KEDEM: Sure. Right.

16 THE COURT: But I think viewed from a certain
17 perspective, you could say that they're the same book.

18 MR. KEDEM: Yeah.

19 THE COURT: I mean, they are -- they're different
20 editions of the same book.

21 MR. KEDEM: Sure.

22 THE COURT: But you have this reference in the
23 statute, this hypothetical statute, to the process of obtaining
24 an ISBN just to make sure that, you know, this is a book that
25 went through that process. And this defines the type of book

1 that the Librarian in Congress may subject to negotiation.

2 we might have some ambiguity about whether or not book --
3 a specific book has to be tied to a specific ISBN or whether it
4 could apply across multiple ISBNs.

5 MR. KEDEM: Can --

6 THE COURT: As I understand it, a paperback might
7 have a different ISBN than a hardcover and so forth.

8 MR. KEDEM: So --

9 THE COURT: But then we may have -- let me just
10 finish the analogy.

11 Then we have another provision later on that talks about
12 the process by which the negotiation has to play out, and that
13 later-on provision makes reference to the fact that there are
14 multiple editions and multiple versions of a book.

15 MR. KEDEM: Yeah.

16 THE COURT: And when you collect the data, in order
17 to determine a negotiation offer, you have to consider an
18 aggregation of all these different things.

19 MR. KEDEM: Right.

20 THE COURT: And then that might reasonably inform how
21 the word "book" is defined at the first step, would it not?

22 MR. KEDEM: So I think that it would, but I think it
23 leads towards our interpretation, not theirs.

24 THE COURT: Okay.

25 MR. KEDEM: I'm not super familiar with the ISBN, but

1 I'm going to take as a given that basically every different
2 version, paperback, non-paperback, might have a different ISBN.

3 So let's say you had a statute that said you need to
4 figure out what the relevant book is, and everyone sort of
5 understands you've got an original version of it, which there
6 is some original registration date for it. That's, let's say,
7 when your copyright attaches. And then there might be a
8 paperback version of the book or, you know, e-Kindle version of
9 the book or something like that. Let's say maybe those get
10 different ISBNs.

11 But there's also a statutory provision that says whether
12 you are eligible for price setting depends on the date of
13 approval of the book, or copyright approval of the book or
14 whatever it is.

15 I think then you would understand, okay, I now know what
16 makes up a book. A book is something that has a copyright
17 approval, that happens at time one, and then the paperback
18 version gets swept into it, the Kindle version gets swept into
19 it.

20 But if it differs in terms of the original copyright
21 version, then it's no longer the same book, even if it's the
22 same publisher, even if maybe it's the same author, doesn't
23 matter, other variations don't count. That's essentially what
24 we have here.

25 what we are saying is that the original version of the

1 product which gets its original NDA, that's when you start the
2 clock and every single update of that, supplemental versions or
3 otherwise, gets swept within it.

4 And my friend expressed a policy concern about product
5 hopping, basically. He didn't call it that, but that's
6 basically his concern, that manufacturers will manipulate the
7 process. And he said, look, they have a little bit of agency
8 about following FDA's guidance.

9 And I suppose that's true, you could submit as a new NDA
10 if you want to, but the FDA can say no, don't do that, we're
11 not filing this, or we'll file it but we're going to reject it.
12 So ultimately he acknowledges it's up to FDA's guidance to
13 determine whether it is.

14 So I don't actually think even if the statute cared about
15 product hopping, which there's no indication it does, I still
16 don't think that there's a problem here because of FDA's
17 control over the process.

18 So, you know, to take your analogy, I think it's a good
19 one and it's a sort of good translation, but I think it leads
20 to our view because --

21 THE COURT: well, I'm not sure how much you do
22 copyright law, but my understanding is the copyright attaches
23 when the book is written.

24 MR. KEDEM: Right.

25 THE COURT: which means that if you have subsequent

1 editions of the same book, there's not like a new --

2 MR. KEDEM: Right. So that's -- that I think makes
3 it a perfect analogy.

4 So if the price setting regime for books said, look, we
5 are only going to do price setting for books based on the date
6 of the copyright approval of the book, I think that would
7 strongly indicate to you that you need to group together things
8 based on when they were copyrighted and what was copyrighted.

9 And so the original version of the book would be grouped
10 together with the paperback version and the kindle version or
11 whatever, but you would not group according to other criteria,
12 active moiety criteria, like is it the same author, is it the
13 same publishing house, or anything else that doesn't directly
14 appear in the statute, and you would know from the date of such
15 copyright approval provision that there was one date and one
16 very specific date and it was specified.

17 And that is all we're asking you to do is to say there are
18 several references in romanette (i), (ii), and (iii) to the NDA
19 approval process. That is the approval with respect to which
20 you market, that is the date that you have to tie the
21 seven-year clock to, that is what you tie the listed -- that is
22 the listed drug with respect to generic drug, and so that's how
23 we do it.

24 THE COURT: All right. Did you have a response to
25 the jurisdictional argument that you heard?

1 MR. KEDEM: Sure. With respect to the jurisdictional
2 argument, first of all, the strong default is there is judicial
3 review that gets turbocharged when you're talking about a
4 question of statutory interpretation.

5 What I heard from my friend from the Government was
6 essentially, do you really want courts making these
7 determinations? Shouldn't it be made by CMS?

8 When it comes to statutory determinations, yes, it is
9 emphatically the province of the Court to decide what the
10 statute means. And I don't think there's any indication that
11 Congress wanted CMS to be able to redefine seven years as five
12 years or, you know, two different drugs as one different drug.

13 They refer to a number of cases, none of which dealt with
14 merger doctrine. Lee versus USCIS, which we deal with in
15 Footnote 4 of our reply brief, was not a merger doctrine case.
16 Doe versus Mullin was not a merger doctrine case and did not
17 involve a statutory interpretation claim of the sort that were
18 at issue here.

19 My friend says, look, what even would this judicial review
20 provision bar if you applied the merger doctrine? And I think
21 the answer is pretty clear, it would bar, as the D.C. Circuit
22 explained in Ardelyx, it would still bar procedural and
23 arbitrary and capricious claims of the sort that were at issue
24 in Doe versus Mullin.

25 And, in addition, we just agree with the D.C. -- so even

1 with respect to the inextricably intertwined argument, which is
2 a distinct argument that the D.C. Circuit relied on, we think
3 that the distinctions that it drew with Mullin are good ones.

4 It talked about one decision that gets made each year, the
5 determination of 15 or 20, depending on the year, single source
6 drugs -- I'm sorry, drugs that are selected for negotiation.
7 So it is a singular determination of with respect to multiple
8 drugs, but it's still a determination of drugs.

9 That is very different from an interpretation of the
10 statute and, insofar as Mullin recognized, you can read the
11 word "determination" narrowly or broadly. There it said, look,
12 we're going to read it broadly because it said any
13 determination with respect to, which has a broadening effect.
14 Here, by contrast, we don't have "with respect to" and we're
15 just talking about statutory interpretation cases.

16 Arlington Hospital, although it did not use the term
17 "merger doctrine," if you read the District Court's decision,
18 which the Court of Appeals endorsed, that was very clearly a
19 merger doctrine case. They essentially said if something does
20 not qualify as the type of decision that is articulated in the
21 statutory provision at issue, then it is not covered by the
22 judicial review bar.

23 That is exactly the argument we are making, that they did
24 not make a determination under Subsection (e). They made a
25 determination under language -- active moiety language of their

1 own creation.

2 Finally, just returning very briefly to the merits, I
3 think you heard my friend from the Government say they read the
4 Government's -- they read the CMS guidance the same way that we
5 read the CMS guidance, meaning that they will group things
6 together by active moiety no matter what else, regardless of
7 any other variations.

8 If you think that the statute is best read to say it is
9 only variations in strengths or formulas that are grouped
10 together irrespective of NDA, then you would articulate that
11 and you would set the agency guidance aside because it is
12 inconsistent with that, as both sides agree.

13 And, finally, Your Honor -- unless you have something
14 further?

15 THE COURT: well, I'll just ask that question when
16 you get up.

17 MR. KEDEM: Okay. One final point, we very much
18 appreciate Your Honor holding this hearing promptly. We would
19 respectfully request that any ruling take into consideration
20 the upcoming statutory deadline.

21 THE COURT: what is that deadline?

22 MR. KEDEM: January 1st is when the price setting
23 goes into effect.

24 THE COURT: All right. Thank you.

25 MR. KEDEM: Thank you, Your Honor.

1 THE COURT: I was looking at Mr. Pezzi when I said I
2 was going to ask that question when he gets up.

3 MR. PEZZI: Absolutely.

4 THE COURT: I'm assuming he was going to get up.
5 were you going to get up anyway?

6 MR. PEZZI: I'm happy to, Your Honor.

7 THE COURT: Okay.

8 MR. PEZZI: However Your Honor would like us to
9 proceed.

10 THE COURT: All right. So maybe we should begin with
11 that question.

12 I mean, it's not clear to me that the interpretation that
13 I was placing on the table is at odds with the guidance, but
14 what's your position on that last argument that Mr. Kedem made?

15 MR. PEZZI: Yeah. So I definitely did not agree with
16 the most recent formulation that was stated during the
17 rebuttal, which I think was some version of the Government
18 agrees that it groups together anything by active moiety
19 regardless of any other characteristics. That certainly goes
20 too far.

21 what I do think we agree on and what I think the briefs
22 accurately reflect is how the guidance works and that it is
23 focused on active moiety. It discusses dosage form and
24 strength. There are other ways, though, in which a drug -- in
25 which different drug products could vary beyond dosage form and

1 strength.

2 So, for example, formulation or method of administration
3 or extended release formulation. And, again, some of those are
4 from the statutory text, like an extended release formulation.

5 So I think in a technical sense an extended release
6 formulation might be a new formulation rather than a different
7 dosage form or strength in, you know, FDA regulatory parlance,
8 and so I think that is the issue that created some confusion
9 earlier in the argument.

10 We certainly do not think that the guidance could or
11 should be vacated on that basis. And, to be clear, it's
12 absolutely not an argument that plaintiffs have raised here.
13 So I just wanted to be clear about that given some of the
14 language in the rebuttal.

15 THE COURT: Okay.

16 MR. PEZZI: I'm certainly happy to address any other
17 questions Your Honor may have, and I'm sure Ms. Gheibi is also
18 happy to address any further questions Your Honor may have
19 about jurisdiction.

20 I mean, I don't think I have a lot more to add beyond what
21 we have already addressed, and I don't want to keep Your Honor
22 and the rest of the courtroom here all day for no good reason,
23 but...

24 THE COURT: No, that's fine. If you don't have any
25 rebuttal on anything that Mr. Kedem said, that's fine. You

1 don't -- I'm not going to -- I don't have any questions for you
2 so I'm not going to require you to make a rebuttal
3 presentation.

4 MR. PEZZI: Okay. Thank you.

5 THE COURT: Ms. Gheibi, did you have anything that
6 you wanted to say in rebuttal on the jurisdictional issue?

7 MS. GHEIBI: No, Your Honor. Unless the Court has
8 any questions for me, we'll rest.

9 THE COURT: Okay. I'm going to take a brief recess.
10 I'll see whether or not I can be so prompt as to make an oral
11 ruling and make a decision during the recess in that regard as
12 to whether I can rule at this time or not.

13 we'll take recess of ten minutes.

14 (A recess was taken from 4:45 p.m. to 4:59 p.m.)

15 THE COURT: And I recognize the hour's what it is,
16 but in the interest of expediency, I would like to make an oral
17 ruling here, if I can.

18 I did have a question that I should have asked Mr. Pezzi,
19 actually, when he was standing up in the form of rebuttal.

20 You heard Mr. Kedem's argument with respect to -- his
21 textual argument with respect to the date of such approval. I
22 wanted to hear what CMS's read of that provision is.

23 MR. PEZZI: Yes. Certainly, Your Honor.

24 CMS in its guidance makes clear -- so I'd like to answer
25 that in two ways: One is how the guidance treats that issue;

1 and then, two, what we think it means or perhaps more precisely
2 does not mean for the statutory interpretation of the dispute
3 that is now before Your Honor.

4 So how the guidance treats that issue is it looks at the
5 earliest approval of any relevant NDA approvals here. Now,
6 obviously we have a disagreement with plaintiffs about whether
7 we're limited to aggregation in one NDAs or multiple NDAs or
8 just the supplemental NDAs, but the guidance makes clear that
9 it's the earliest relevant date.

10 Now, plaintiffs I think latch onto that to suggest that
11 there is, you know, a problem with the Government's
12 interpretation of the statute. We don't think that's the case.
13 Obviously, we have all our sort of bigger picture, wholistic
14 arguments which is to zero in on two that I think are
15 specifically relevant to this wrinkle.

16 One is the statute talks about including new formulations,
17 and so, again, inherent in the word "new" is the passage of
18 time, so Congress shouldn't be surprised that there might be
19 more than one relevant approval date.

20 And then two is, again, I think to the extent this is a
21 problem, it is also a problem of AstraZeneca's interpretation
22 because even they acknowledge that aggregation is required if
23 the new NDA is a supplement to the previous NDA and, of course,
24 that supplement is approved on a later date.

25 THE COURT: All right. Okay. Thank you. You did

1 make that argument. I just wasn't clear about its connection
2 to the argument on the date, but that's helpful. Thank you.

3 Give me one moment, please.

4 (Pause in Proceedings.)

5 THE COURT: All right. Thank you for your patience.

6 The defendants here have moved to dismiss AstraZeneca's
7 claim pursuant to Rule 12(b)(1) arguing that the IRA's judicial
8 review provision in § 1320f-7(2) bars AstraZeneca's statutory
9 challenge because the Act's bar on judicial review of CMS's
10 drug selection determination extends to the process CMS used to
11 make those determinations.

12 After review of the authorities cited by the parties,
13 including the D.C. Circuit's reasoning in Teva Pharmaceuticals
14 which issued yesterday, the Court finds that it does have
15 jurisdiction to review AstraZeneca's claim. I find Teva to be
16 persuasive on this point, and its reasoning on the
17 jurisdictional issue is correct and applicable here.

18 A federal court must have subject matter jurisdiction, of
19 course, to decide any case before it. If it doesn't have it,
20 then it must dismiss the case, but Congress may limit subject
21 matter jurisdiction of the federal courts and it may do that
22 through a jurisdiction-stripping statute or statutes that limit
23 judicial review.

24 But, in this context, there is a strong presumption that
25 Congress intends judicial review of administrative action, and

1 I'm citing Bowen v. Michigan Academy, 476 U.S. 667.

2 Fundamental principles of administrative law establish
3 that when confronted with a challenge to an agency statutory
4 interpretation, a District Court must independently determine
5 for itself whether the agency's interpretation is correct.

6 That's the McLaughlin case from the Supreme Court.

7 Because the Court is not bound by an agency's
8 interpretation, it must determine the meaning of the law under
9 ordinary principles of statutory interpretation, affording
10 appropriate respect to the agency's interpretation. This role
11 persists even when the statute delegates discretionary
12 authority to the Executive Branch.

13 And there I'm citing Trump v. Cook, a recent Supreme Court
14 case.

15 To interpret a statute, the Court must first look at its
16 language, giving the words their ordinary meaning. The Court
17 also has an interpretive duty to give effect whenever possible
18 to a statute's every clause and word.

19 That's the Lara-Aguilar case from the Fourth Circuit in
20 2018.

21 Given the strong presumption of reviewability, when the
22 statutory provision is reasonably susceptible to divergent
23 interpretation, the Court must adopt the reading that accords
24 with the basic principle that Executive determinations
25 generally are subject to judicial review.

1 That's the case Guerrero Lasprilla v. Barr. That's a
2 Supreme Court case from 2020.

3 The burden of rebutting the presumption in favor of
4 judicial review is a heavy burden. The presumption can only be
5 overcome by clear and convincing evidence of congressional
6 intent to preclude judicial review. The presumption can be
7 rebutted when a statute's language or structure demonstrates
8 that Congress wanted an agency to police its own conduct.

9 When a statute expressly prohibits judicial review, the
10 presumption of reviewability requires it to be read narrowly.

11 There I am citing the D.C. Circuit, the El Paso case
12 that's cited in Teva, but there's also a Third Circuit case
13 that stands for the same proposition, United States v. Dohou.
14 That's D-o-h-o-u, a Third Circuit case from 2020.

15 Here, § 1320f-7(2) provides that there shall be no
16 administrative or judicial review of the determination of
17 qualifying single source drugs under § 1320f-1(e) of this Title
18 or the determination of negotiation-eligible drugs.

19 Based on this text, the object of the review bar in each
20 instance is the determination. That term describes a single
21 discrete act rather than a group of decisions or practice or
22 procedure employed in making the decisions. On that I'm
23 quoting Teva.

24 And I happen to agree with Teva. Black's Law Dictionary
25 defines "determination" as the act of deciding something

1 officially, especially a final decision by a court or
2 administrative agency.

3 It's a discrete act. The presumption of reviewability,
4 again, requires the Court to read this word narrowly. And I am
5 fully -- I'm giving full recognition and consideration of the
6 Supreme Court's decision in Mullin v. Doe, but I don't find
7 that it's applicable here in the context of this statute given
8 the context of the word "determination."

9 There were other indicators within the statutory phrase
10 that included the word "determination" in Mullin that suggested
11 the broader ruling and I think led to the Supreme Court's
12 determination that it should be read broadly in the context of
13 that case.

14 But in the context of this case, expanding the meaning of
15 the term to encompass the process by which the determination is
16 made would go beyond the strict bounds of the
17 jurisdiction-stripping statute.

18 As the D.C. Circuit has explained, allowing CMS's
19 interpretation of the judicial review provision to stand would
20 permit CMS to shield its interpretations of the IRA by
21 embedding its interpretation of the relevant term and to each
22 drug evaluation and then calling the whole package a
23 determination.

24 Such a reading of the statute is not what Congress
25 authorized is my finding. So for those reasons, I will reject

1 the defendants' reading of that jurisdiction-limiting statute.

2 Now, I believe generally the Teva decision adequately
3 addresses the defendants' jurisdictional arguments, but given
4 that we're in the Fourth Circuit here, some reference was made
5 to Fourth Circuit precedent. As to the Lee decision, I think
6 it's distinguishable from this case and it doesn't save the
7 defendants' position on jurisdiction.

8 The complaint in the instant case is, on its face, an
9 attack on the final guidance on its face. It may be that
10 AstraZeneca was injured through the determination made as to
11 Calquence, but I don't see any indication in the complaint that
12 it was manipulated to avoid attacking that determination. The
13 complaint instead attacks the guidance and the interpretation
14 of the IRA reflected in that guidance.

15 So that's my ruling on the jurisdictional issue, so the
16 Rule 12(b)(1) motion will be denied.

17 But turning to the merits, both parties have moved for
18 summary judgment. AstraZeneca argues that it's entitled to
19 judgment as a matter of law because CMS's final guidance
20 contravenes the IRA whereas the defendants argue that they are
21 entitled to judgment as a matter of law because the guidance
22 comports with the IRA.

23 I do find that summary judgment should be awarded to the
24 defendants largely for the same decisions cited by the Teva
25 decision.

1 Here, the CMS's final guidance instructs the agency to
2 identify a potential qualifying single source drug using all
3 dosage forms and strengths of the drug with the same active
4 moiety and the same holder of an NDA inclusive of products that
5 are marketed pursuant to different NDAs.

6 The Court finds that this approach aligns with the
7 statutory scheme established by Congress, including the
8 definition of a QSSD as reflected in § 1320f-1(e)(1).

9 To quote Teva, "in negotiating a maximum fair price, CMS
10 must consider applications and approvals under § 355(c) of
11 Title 21." The terms "application" and "approvals" are plural;
12 the term "the drug" is singular. The negotiation provision
13 then recognizes that a single drug can have multiple
14 corresponding approvals and applications. Moreover, Congress
15 referred generally to applications and approvals under
16 § 355(c). Separate NDAs are applications under § 355(c).

17 The surrounding provisions make that point even clearer as
18 reflected in the Teva decision and its discussion of the
19 provisions at 1320f-1(d)(3)(B) and § 1320f-5(a)(2). I do find
20 that the D.C. Circuit reasoning in Teva is persuasive and I
21 adopt it here.

22 The Court is unpersuaded by AstraZeneca's product-specific
23 reasons of the QSSD provision. In AstraZeneca's view, the IRA
24 defines a QSSD as a drug approved by an NDA in support of that
25 interpretation. The plaintiffs point out that the IRA's

1 aggregation provision operates after CMS identifies a
2 qualifying single source drug, but the Court declines to read
3 that provision in isolation, as did the D.C. Circuit.

4 Reading it together with the other provisions I just
5 cited, the Court agrees with the D.C. Circuit that
6 subsection (e) supplies the conditions for qualification while
7 § 1320f-1(d)(3)(B) tells CMS what formulations belong to the
8 drug, whose expenditures it must calculate. Nothing in either
9 provision draws a line at the edge of an NDA.

10 Adopting the D.C. Circuit's reasoning, this Court finds
11 that AstraZeneca's contention that older QSSDs cannot be
12 grouped with recently FDA-approved drugs under the IRA to be
13 incorrect because the seven-year requirement imposed in the
14 QSSD definition measures the age of the drug once it has been
15 identified. That's to quote the Teva decision.

16 The IRA does not require each NDA to be treated as a
17 separate statutory drug. AstraZeneca's argument that the final
18 guidance's inclusion of active moiety in its QSSD
19 identification provision reflects a rewriting of the IRA's
20 definition of that term, I find that that argument fails
21 because the term "active moiety" does comport with the ordinary
22 meaning of the word "drug." As the D.C. Circuit pointed out in
23 Teva, active moiety has long played a key role in determining
24 when a drug is new and when it, instead, uses the approved
25 moiety in a new way.

1 AstraZeneca emphasizes the fact that the IRA does not use
2 the term "active moiety" at any point, arguing that that
3 omission reflects a congressional intent of some sort. Here,
4 AstraZeneca misapplies the relevant canon of interpretation.
5 The Supreme Court has recently reiterated that "where Congress
6 includes particular language in one section of a statute but
7 omits it in another section of the same Act, it is generally
8 presumed that Congress acts intentionally and purposefully in
9 the disparate inclusion or exclusion."

10 There, I'm quoting from *City and County of San*
11 *Francisco v. EPA*, 604 U.S. 334.

12 But this principle of statutory interpretation does not
13 apply here because AstraZeneca acknowledges Congress did not
14 use the term 'active moiety' at all in the IRA; therefore, its
15 omission from the QSSD definition in subsection (e)(1)(D) is of
16 no interpretive consequence or significance.

17 As to the plaintiffs' textual argument regarding the date
18 of NDA approval, CMS's best interpretation is that the date
19 referenced is the earlier date or the earliest date a drug with
20 the same active moiety obtained NDA approval, and I find that
21 to be the best interpretation because it contemplates the
22 required passage of time reflected in the seven-year provision
23 of the QSSD definition and the aggregation of subsequent
24 approvals for new formulations reflected in other provisions
25 that govern the Drug Negotiation Program.

1 AstraZeneca criticizes the CMS's decision to count two
2 drugs with the same active moiety as a single QSSD only if they
3 share the same NDA holder, characterizing the agency's approach
4 as an ad hoc interpretation. But CMS's requirement that the
5 drugs share the same NDA holder accords with the IRA's repeated
6 direction that CMS negotiate with the manufacturer of a
7 selected drug.

8 There I'm quoting from Teva again.

9 The word "manufacturer" is used in the singular throughout
10 § 1320f-3(e), while the same provision uses the words
11 "applications" and "approvals" under § 355(c) in the plural.

12 AstraZeneca argues that CMS's definition would render
13 other provisions of the IRA which instruct CMS to consider --
14 I'm sorry -- it would render -- there's a superfluous problem
15 in that CMS's definition would render other provisions of the
16 IRA superfluous.

17 According to AstraZeneca, the instruction with regards to
18 applications and approvals would already be subsumed by the
19 definition of a QSSD that includes multiple drugs with
20 different NDAs, so if Congress had intended that, then it would
21 have said that.

22 But as the D.C. Circuit pointed out, the IRA's provisions
23 govern different decisions made at different points in the
24 negotiation program. These decisions include selection,
25 negotiation offer, and application of the final negotiated

1 price as reflected in f-1(d)(3)(B), f-3(e)(1)(D), and
2 f-5(a)(2).

3 And I also find that the Generix decision cited by
4 plaintiffs do not support their position. There, the Supreme
5 Court construed the term "drug" in the context of the FDCA and
6 held that the term encompassed an entire drug product,
7 including both its active and inactive ingredients.

8 The Court, however, expressly declined to decide whether
9 two products containing the same active ingredients but
10 differing in other respects would in some circumstances
11 constitute the same drug.

12 Thus, Generix does not establish that the NDA's
13 application number determines whether two products constitute
14 the same drug under the IRA, and I believe that the Teva court
15 came to the same determination.

16 So for all of those reasons, the Court rejects
17 AstraZeneca's statutory challenge and will grant summary
18 judgment in favor of the defendants, and I'll enter a brief
19 order reflecting that ruling and close the case.

20 Was there anything else that we should address before we
21 conclude here? Mr. Kedem?

22 MR. KEDEM: No, Your Honor.

23 THE COURT: All right. Thank you.

24 Anything from you, Mr. Pezzi?

25 MR. PEZZI: Nothing from defendants, Your Honor.

1 THE COURT: All right. Thank you, and I want to
2 thank you again for your patience. I understand we've moved
3 past the hour of 5 o'clock, and I want to thank you all for the
4 quality of your briefing and your presentations today. It's
5 much appreciated. Enjoy the rest of your day.

6 (The proceedings concluded at 5:17 p.m.)

7 CERTIFICATE OF OFFICIAL REPORTER

8 I, Amanda L. Longmore, Registered Professional Reporter
9 and Federal Certified Realtime Reporter, in and for the United
10 States District Court for the District of Maryland, do hereby
11 certify, pursuant to 28 U.S.C. § 753, that the foregoing is a
12 true and correct transcript of the stenographically-reported
13 proceedings held in the above-entitled matter and that the
14 transcript page format is in conformance with the regulations
15 of the Judicial Conference of the United States.

16 Dated this 23rd day of August 2026

17 -S-

18 _____
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Motions, Hearing, 8/19/26

'active' [1] - 106:14 'single' [1] - 44:8 1 [4] - 18:24; 22:1; 29:9; 31:9 10 [1] - 86:13 100 [1] - 80:9 11 [1] - 51:11 12(b)(1) [2] - 99:7; 103:16 1255 [7] - 41:17; 42:4; 54:9; 11-13; 59:21 1255(i) [1] - 60:4 13 [1] - 41:5 1320f [1] - 75:18 1320f-1 [2] - 12:5, 8 1320f-1(d)(3)(B) [3] - 69:5; 104:19; 105:7 1320f-1(e) [1] - 101:17 1320f-1(e)(1) [1] - 4:10 1320f-1(e)(1) [1] - 104:8 1320f-3(e) [1] - 107:10 1320f-3(e)(1)(D) [1] - 69:10 1320f-3(e)(1)(D) [1] - 70:3 1320f-5(a)(2) [1] - 69:16 1320f-5(a)(2) [1] - 104:19 1320f-7(2) [3] - 4:15; 99:8; 101:15 1395 [2] - 38:5, 8 15 [3] - 39:2; 86:14; 93:5 165 [1] - 65:4 17th [1] - 5:11 1930s [1] - 68:11 1981 [1] - 52:18 1984 [1] - 52:19 1st [1] - 94:22 2 [5] - 18:13; 19:3, 7; 30:3; 31:9 20 [3] - 43:3; 86:14; 93:5 2010 [1] - 41:22 2015 [2] - 14:22; 15:7 2018 [1] - 100:20 2020 [2] - 101:2, 14 2022 [1] - 6:3	2025 [3] - 5:11; 64:19; 87:13 2026 [2] - 65:3; 87:13 21 [6] - 3:17; 43:3; 69:12; 70:13; 85:9; 104:11 25-5425 [1] - 4:24 262(a) [1] - 69:12 262(a) [1] - 70:13 2:33 [1] - 2:2 3 [1] - 18:13 32 [1] - 3:19 334 [1] - 106:11 355 [3] - 12:5, 10; 85:9 355(c) [6] - 9:23; 69:12; 70:12; 104:10; 107:11 355(c) [2] - 104:16 355(j) [2] - 11:6; 85:13 355(j)(2) [1] - 12:3 4 [1] - 92:15 42 [2] - 4:10; 69:16 476 [1] - 100:1 4:45 [1] - 97:14 4:59 [1] - 97:14 50 [4] - 19:4, 18; 28:16; 48:25 592 [1] - 41:21 604 [1] - 106:11 612 [1] - 41:21 667 [1] - 100:1 7 [1] - 51:11 817 [1] - 65:4 AB [1] - 3:1 abandon [1] - 11:21 able [3] - 12:13; 74:7; 92:11 absent [1] - 71:6 absolutely [4] - 68:6; 74:16; 95:3; 96:12 Academy [1] - 100:1 acalabrutinib [3] - 5:23; 80:6, 10 accepted [2] - 22:19; 31:10 accepting [2] - 31:8; 80:19 accepts [1] - 50:24 accident [2] - 48:6; 60:18 accomplish [1] - 8:3	accomplishing [1] - 80:21 accordance [2] - 3:13; 5:13 according [10] - 5:16; 11:10; 13:16; 15:5; 27:12; 28:10; 31:24; 91:11; 107:17 accords [2] - 100:23; 107:5 account [1] - 28:4 accurate [2] - 5:8; 63:23 accurately [1] - 95:22 acetaminophen [1] - 80:4 achieve [1] - 70:20 acknowledge [10] - 24:23; 27:1; 40:17; 41:10; 42:20; 47:13; 20; 58:22; 61:4; 98:22 acknowledged [8] - 25:23; 39:22; 41:10; 53:25; 58:14, 18; 72:18 acknowledges [2] - 90:12; 106:13 acknowledging [3] - 59:3; 61:8; 69:14 act [5] - 44:8; 64:3; 101:21, 25; 102:3 Act [14] - 3:12, 14; 68:9, 13, 17; 71:8, 15, 19; 76:6; 79:6, 14; 106:7 Act's [1] - 99:9 action [6] - 3:4; 16:20; 42:7; 65:8, 11; 99:25 active [66] - 4:4; 8:15; 9:2, 6; 15:16; 16:19, 21, 25; 17:6, 10-11; 22:21-23; 23:2-4, 7-8, 13; 26:18, 22; 27:2, 5-6, 12; 29:14; 30:15, 18, 24; 31:10, 22; 32:8,	10, 22; 33:3, 12; 36:18; 50:8; 67:11; 77:3, 5; 78:2; 79:19, 22; 82:9; 84:20, 25; 91:12; 93:25; 94:6; 95:18, 23; 104:3; 105:18, 21, 23; 106:2, 20; 107:2; 108:7, 9 acts [1] - 106:8 ad [1] - 107:4 add [1] - 96:20 adding [1] - 81:22 addition [1] - 92:25 additional [2] - 39:9; 68:20 address [13] - 6:24; 7:4; 39:19; 49:24; 52:12, 17; 54:13; 77:16; 84:10; 96:16, 18; 108:20 addressed [3] - 4:19; 27:16; 96:21 addresses [1] - 103:3 adequately [1] - 103:2 adjustment [4] - 42:11; 44:5; 59:25; 64:1 administration [1] - 96:2 Administrative [1] - 3:14 administrative [6] - 58:6; 99:25; 100:2; 101:16; 102:2 administrator [1] - 3:6 adopt [6] - 30:11; 31:11; 36:19; 83:23; 100:23; 104:21 adopted [7] - 31:21; 37:16; 40:19; 42:17; 43:17; 46:22; 47:23 adopting [2] - 40:24; 105:10 adopts [3] - 48:4; 51:23; 60:12 affording [1] -	100:9 afield [1] - 83:21 afternoon [7] - 2:12, 14, 18, 20-21, 23; 65:24 age [1] - 105:14 agencies [4] - 45:25; 51:1; 54:23; 81:23 agency [18] - 37:19; 46:23; 47:16; 50:20; 53:4; 54:17, 22; 56:16; 65:11; 73:20; 74:17; 90:7; 94:11; 100:3; 101:8; 102:2; 104:1 agency's [7] - 3:13; 21:3; 79:22; 100:5, 7, 10; 107:3 aggregate [5] - 21:21, 25; 22:2; 29:8; 36:16 aggregated [7] - 19:9, 19; 21:22; 26:14; 28:15; 29:1; 30:14 aggregating [4] - 9:3; 16:5; 26:5; 29:4 aggregation [15] - 67:18, 22-24; 68:2, 4; 69:3; 70:24; 71:2; 88:18; 98:7, 22; 105:1; 106:23 ago [3] - 40:6; 58:2; 86:13 agree [14] - 17:25; 28:1; 30:4; 31:20; 39:5; 52:19; 66:14; 77:13; 82:5; 92:25; 94:12; 95:15, 21; 101:24 agreed [2] - 52:21; 81:13 agreement [1] - 38:20 agrees [5] - 67:22; 70:25; 81:12; 95:18; 105:5 Aguilar [1] - 100:19 ahead [1] - 14:12 Airlines [1] -	38:23 al [2] - 2:6 alarm [1] - 49:9 alarms [1] - 50:16 aligns [1] - 104:6 allege [1] - 3:9 alleged [1] - 72:3 Allon [1] - 2:10 allow [1] - 13:19 allowed [3] - 11:14; 38:6; 51:24 allowing [3] - 47:13; 83:15; 102:18 allows [3] - 47:17; 86:11, 15 almost [3] - 15:19, 24; 85:18 alternative [1] - 3:18 ambiguity [2] - 57:13; 88:2 Amended [2] - 42:9; 59:24 American [1] - 71:20 analogy [6] - 62:25; 86:19, 21; 88:10; 90:18; 91:3 analysis [11] - 39:5; 40:20; 43:9; 44:17; 48:23; 52:21, 25; 55:25; 56:2; 63:8, 24 analyze [1] - 42:24 analyzed [1] - 38:17 analyzes [1] - 43:13 ancillary [13] - 8:17; 9:2; 18:13; 25:21; 27:2, 9; 67:7; 75:17, 20, 22; 76:8 announced [1] - 49:12 annual [1] - 5:13 answer [10] - 20:12; 21:11; 36:9; 64:12; 73:4; 76:1; 80:15; 92:21; 97:24 answers [1] - 83:6 antecedent [1] - 46:3
--	--	--	---	--	---

Motions, Hearing, 8/19/26

anticipated [1] - 69:2 anyway [2] - 83:7; 95:5 APA [5] - 4:12; 42:7; 65:10, 18 Appeal [1] - 4:23 Appeals [2] - 4:22; 93:18 appear [4] - 5:10; 9:7; 44:22; 91:14 appearance [1] - 2:9 applicable [8] - 44:18-20; 55:17; 56:24; 69:18; 99:17; 102:7 application [26] - 12:13; 20:11, 23; 21:1; 42:11; 44:5, 9, 11, 13; 45:8; 46:11; 52:2; 59:25; 60:7; 62:16, 23-24; 64:1, 4; 72:12, 25; 104:11; 107:25; 108:13 Application [18] - 4:5; 67:13, 25; 68:2, 5-6; 70:8; 71:1, 12; 73:12; 74:15; 75:3, 11; 82:20 applications [30] - 6:7; 18:19; 22:5, 7-8, 11, 13, 15; 25:1; 69:11, 15; 70:4, 8, 12, 14-15; 72:2, 22; 73:11; 76:11; 82:3, 11; 85:3; 104:10, 14-16; 107:11, 18 Applications [2] - 85:4, 10 applied [4] - 5:12; 33:5; 44:18; 92:20 applies [1] - 9:15 apply [6] - 18:20, 22; 22:17; 57:7; 88:4; 106:13 applying [3] - 34:20; 40:22; 54:15 appreciate [4] - 7:4; 24:18;	94:18 appreciation [1] - 7:5 approach [14] - 26:10; 40:3, 12; 41:4; 52:9; 56:4, 12-13; 58:23; 71:23; 82:2; 104:6; 107:3 appropriate [2] - 45:25; 100:10 approval [44] - 6:3; 8:4, 7-8, 11; 9:24; 10:2-4, 13-14, 16; 11:11; 18:19; 25:8, 14-15, 18; 70:14; 71:14; 74:1; 80:14; 82:18; 85:10-12, 21-22; 86:1-3, 5; 89:13, 17; 91:6, 15, 19; 97:21; 98:5, 19; 106:18, 20 approvals [22] - 22:5, 7-8, 13, 15; 69:12, 15; 70:4, 6, 12; 82:3; 85:23; 86:4, 6; 98:5; 104:10, 14-15; 106:24; 107:11, 18 approved [40] - 5:14, 20; 8:6; 9:23, 25; 10:2, 15, 24; 11:5; 12:11, 13, 16; 13:3; 14:18; 17:16, 18; 19:22; 20:1; 22:11; 23:22; 28:7, 9; 76:19, 22; 78:22; 85:9, 13-14; 86:12; 98:24; 104:24; 105:12, 24 approving [1] - 71:11 arbitrary [1] - 92:23 Ardelyx [3] - 37:15, 23; 92:22 area [1] - 79:5 argue [5] - 26:11, 14; 38:6; 64:10; 103:20 argues [3] - 4:11;	103:18; 107:12 arguing [3] - 38:10; 99:7; 106:2 argument [37] - 3:22; 6:14; 7:10; 25:3, 7; 27:15, 17; 28:2; 37:12, 20; 48:20; 50:19; 55:3-5; 71:5; 77:3; 78:16; 80:24; 84:12; 91:25; 92:2; 93:1, 23; 95:14; 96:9, 12; 97:20; 99:1; 105:17, 20; 106:17 arguments [6] - 37:7; 69:23; 86:22; 98:14; 103:3 arise [2] - 11:20; 13:25 arises [1] - 82:22 Arlington [8] - 37:16; 38:3; 41:22; 52:16; 53:1; 55:23; 93:16 Article [1] - 25:10 articulate [1] - 94:10 articulated [1] - 93:20 articulating [1] - 64:24 Asia [1] - 76:19 aside [7] - 4:13; 31:16, 21, 25; 36:20; 78:10; 94:11 aspect [1] - 47:11 aspects [1] - 24:20 assert [1] - 65:19 associated [2] - 74:3 assume [1] - 29:16 assuming [2] - 31:9; 95:4 Astellas [2] - 23:17; 78:9 AstraZeneca [32] - 2:6, 11, 13, 15; 3:1-3; 4:11; 5:16; 8:12; 30:12; 42:13; 47:14, 25;	49:16; 52:4; 53:5, 16-17; 60:11; 71:3; 72:19; 80:8; 103:10, 18; 106:1, 4, 13; 107:1, 12, 17 AstraZeneca's [19] - 3:16; 5:19; 19:15; 48:5; 49:19; 54:9, 24; 55:19; 60:12; 81:7; 98:21; 99:6, 8, 15; 104:22; 105:11, 17; 108:17 atextual [1] - 81:10 attaches [2] - 89:7; 90:22 attack [1] - 103:9 attacking [1] - 103:12 attacks [1] - 103:13 attempts [2] - 42:25; 46:13 attenuated [1] - 75:22 author [2] - 89:22; 91:12 authorities [1] - 99:12 authority [7] - 3:14; 4:1; 10:1; 40:7; 45:15, 20; 100:12 authorization [1] - 12:14 authorize [1] - 46:20 authorized [1] - 102:25 authorizes [1] - 9:25 available [2] - 64:22; 65:6 avoid [3] - 42:10; 59:24; 103:12 awarded [1] - 103:23 aware [1] - 4:21 back-and-forth [1] - 73:8 background [3] - 3:20; 5:3, 8 bad [1] - 15:3 Bakran [1] - 40:25 balance [1] - 7:25 bar [11] - 37:23;	38:2; 43:21; 47:18; 58:16; 92:20-22; 93:22; 99:9; 101:19 Barr [1] - 52:22 barr [1] - 101:1 barred [5] - 44:15; 53:6; 56:5; 62:16; 63:1 barring [2] - 57:18; 63:25 bars [7] - 36:25; 37:8, 19; 38:4; 40:12; 58:15; 99:8 base [4] - 5:23; 20:19; 33:1; 34:18 based [13] - 6:2; 11:13, 18; 50:1; 52:13; 69:8, 20; 70:9; 73:8; 91:5, 8; 101:19 bases [1] - 46:8 basic [1] - 100:24 basics [1] - 68:23 basis [18] - 26:19; 31:20; 32:1; 42:25; 43:1, 4; 44:18; 45:4, 9; 60:7, 10, 13, 15; 63:21; 68:18; 81:21; 83:23; 96:11 beef [2] - 33:5 begged [1] - 25:3 begin [2] - 9:17; 95:10 begins [1] - 8:12 begs [1] - 25:16 behalf [3] - 2:19, 22; 65:25 believes [1] - 66:2 belong [3] - 30:9; 86:9; 105:7 belt [2] - 26:9, 14 belt-and-suspenders [1] - 26:9 beneficiaries [1] - 71:21 beneficiary [7] - 42:2, 4-5; 54:14; 59:21; 60:5, 24 benefit [1] - 17:14 best [7] - 42:23; 66:5; 68:8; 83:14; 94:8; 106:18, 21	better [3] - 20:4; 82:12; 86:22 between [14] - 10:20; 11:12; 23:1; 50:8; 57:4, 25; 59:12; 62:20; 67:13; 73:6, 8; 79:20; 81:20; 83:16 beyond [6] - 3:13; 15:17; 54:2; 95:25; 96:20; 102:16 bigger [4] - 23:1; 26:21; 98:13 binding [1] - 41:7 biological [1] - 82:10 bit [6] - 12:24; 14:12; 20:18; 24:6; 39:23; 90:7 Black's [1] - 101:24 blank [1] - 54:17 book [23] - 11:8; 86:24; 87:8, 17, 20, 24-25; 88:2, 14, 21; 89:4, 8-9, 13, 16, 21; 90:23; 91:1, 6, 9 books [4] - 87:1, 4; 91:4 born [2] - 24:9; 39:23 borrowed [1] - 43:7 borrowing [1] - 68:16 bottom [1] - 45:13 bought [1] - 78:11 bound [1] - 100:7 bounds [2] - 54:2; 102:16 Bowen [1] - 100:1 Branch [1] - 100:12 brand [3] - 5:24; 11:7, 15 brand-name [2] - 11:7, 15 branding [1] - 11:13 brief [13] - 14:18; 16:4; 38:24; 41:6, 23; 45:22; 46:19; 60:5; 74:24; 84:5; 92:15; 97:9; 108:18
--	---	---	---	---	---

Motions, Hearing, 8/19/26

briefing [1] - 68:22 briefly [4] - 9:19; 11:19; 77:17; 94:2 briefs [5] - 67:18; 76:2; 79:10; 81:8; 95:21 bring [5] - 7:19; 47:21; 48:1; 65:11; 73:24 broad [6] - 5:19; 43:20, 22; 58:3; 62:19; 63:7 broadening [1] - 93:13 broader [7] - 5:18; 9:4; 26:19; 43:24; 57:6; 86:15; 102:11 broadly [3] - 93:11; 102:12 bunch [1] - 24:1 burden [2] - 101:3 buried [1] - 85:4 but.. [1] - 96:23 butchering [1] - 34:11 bypasses [1] - 8:14 calculate [1] - 105:8 Calquence [6] - 5:25; 48:5; 80:5, 8; 103:11 cannon [1] - 106:4 cannons [1] - 50:13 cannot [6] - 10:7; 25:16; 46:9, 25; 60:7; 105:11 canvas [1] - 57:22 cap [1] - 17:2 capricious [1] - 92:23 caps [1] - 10:8 care [7] - 17:10; 67:11, 13; 74:15; 80:3; 85:2 cared [2] - 85:3; 90:14 careful [1] - 47:12 carefully [4] - 42:10, 14; 59:24; 61:1 cares [2] - 74:14; 80:5 Carrick [1] - 2:3	case [79] - 2:4, 7; 3:1, 23; 4:24; 5:1, 10; 6:18; 12:20; 21:20; 23:18; 33:6; 37:14, 17; 38:23; 40:10, 22; 41:5, 7, 20-23; 44:1, 21; 46:14; 47:5; 51:7; 52:3, 16-17, 22-23; 54:6; 55:24; 59:5, 7; 62:6, 8; 64:19; 65:2; 69:4; 71:5; 72:19, 21; 74:16; 75:7; 77:21; 78:17; 82:9; 84:22; 92:15; 93:19; 98:12; 99:19; 100:6, 14, 19; 101:1, 11-12, 14; 102:13; 103:6, 8; 108:19 Case [1] - 2:7 cases [9] - 29:16; 38:22; 52:14; 53:24; 54:5; 67:12; 73:5; 92:13; 93:15 cast [1] - 4:8 casting [1] - 62:3 categorical [7] - 53:22; 54:3; 55:25; 56:4, 12-13, 15 categories [1] - 55:12 category [1] - 53:3 causes [1] - 13:19 Centers [1] - 3:6 century [1] - 68:12 certain [13] - 8:1; 9:14; 37:19; 38:5; 51:10; 56:5, 8; 69:18; 75:25; 86:25; 87:4, 16 certainly [10] - 67:12; 72:14; 74:12; 78:20; 82:13; 83:23; 95:19; 96:10, 16; 97:23 challenge [28] - 4:16, 20; 5:6;	21:2; 34:24; 38:1, 9; 42:14; 45:19, 22; 46:8; 47:3, 21-22; 48:1, 18; 50:20; 58:9; 60:16; 61:2, 9; 99:9; 100:3; 108:17 challenged [1] - 59:20 challenger [1] - 37:20 challenges [1] - 50:22 challenging [14] - 37:23; 42:10, 15-16; 45:18; 46:15, 18; 47:15; 59:25; 60:18, 21; 77:7 chances [1] - 49:14 change [2] - 70:20; 71:12 changed [1] - 73:9 changes [3] - 26:12; 68:11; 71:17 characteristics [1] - 95:19 characterizing [1] - 107:3 cheap [1] - 15:23 check [2] - 6:11; 13:11 checking [1] - 7:17 chemical [2] - 80:11 chewable [2] - 66:11; 84:14 children [3] - 21:17; 66:8 choice [3] - 49:5; 73:14; 74:17 choices [1] - 76:9 chomping [1] - 86:19 chose [2] - 75:6; 86:10 chosen [1] - 75:12 Circuit [64] - 4:22; 24:9; 25:19, 23; 26:3, 25; 37:14, 16; 38:1, 6, 20; 40:2, 18-19, 22; 41:2, 4, 10; 42:6, 18, 20-21;	46:13, 21; 47:9; 52:14; 55:17, 24; 56:2; 57:4, 9, 11; 58:12, 18, 25; 59:1, 7, 12-14; 60:25; 62:2; 65:1, 3; 66:23; 83:12; 87:11; 92:21; 93:2; 100:19; 101:11, 14; 102:18; 103:4; 104:20; 105:3, 5, 22; 107:22 circuit [2] - 40:2; 47:6 Circuit's [14] - 5:7; 40:3, 9, 14, 24; 42:22; 46:11; 47:7; 52:9; 57:10; 79:23; 87:12; 99:13; 105:10 circuits [9] - 40:13; 41:3; 42:19; 52:21; 57:4, 8; 58:19, 22 circumstances [2] - 21:16; 108:10 citation [2] - 41:19; 65:4 cite [3] - 52:22; 58:20; 65:2 cited [13] - 38:22; 41:5, 23; 52:16; 53:24; 59:8; 64:19; 99:12; 101:12; 103:24; 105:5; 108:3 cites [1] - 40:25 citing [4] - 59:11; 100:1, 13; 101:11 City [1] - 106:10 civil [1] - 3:3 claim [12] - 6:1; 42:7, 9; 45:13; 54:13; 59:22; 64:18; 65:19; 92:17; 99:7, 15 claimed [1] - 42:1 claiming [1] - 6:16 claims [3] - 4:14; 6:10; 92:23 clarify [1] - 35:1 clause [6] - 19:10; 41:18; 42:1;	55:11; 100:18 clauses [1] - 18:21 clear [26] - 11:2; 13:20; 18:21; 45:6; 47:6; 57:18, 25; 68:24; 71:6; 72:20; 73:4; 74:10; 76:15, 21; 77:23; 81:18; 82:24; 86:7; 92:21; 95:12; 96:11, 13; 97:24; 98:8; 99:1; 101:5 clearer [1] - 104:17 clearest [1] - 72:16 clearly [8] - 9:21; 42:11; 52:6; 60:1; 61:2; 70:5, 23; 93:18 Clerk [1] - 7:14 CLERK [2] - 2:5, 17 clever [3] - 47:17; 48:14; 61:8 cleverly [1] - 61:10 clock [12] - 8:5; 10:11, 19; 14:19, 22; 15:4, 7; 25:13; 86:6; 90:2; 91:21 close [1] - 108:19 closest [1] - 85:19 CMS [49] - 3:7, 10, 25; 4:8; 5:5, 12; 6:6; 13:16; 14:20; 16:17; 30:9; 38:4; 42:17; 46:20, 22; 47:1, 22-23; 48:12, 15; 49:10, 14, 22; 50:14; 51:8, 17, 25; 52:6; 53:5; 61:21; 69:3; 74:4, 6; 81:21; 92:7, 11; 94:4; 97:24; 99:10; 102:20; 104:9; 105:1, 7; 107:6, 13 CMS's [24] - 3:12; 5:16; 6:5; 29:20; 37:23; 45:15; 46:16; 47:1;	48:18; 60:9; 66:4; 73:23; 78:1; 82:11; 97:22; 99:9; 102:18; 103:19; 104:1; 106:18; 107:1, 4, 12, 15 co [1] - 7:19 co-counsel [1] - 7:19 Code [1] - 4:11 cohesive [2] - 67:9; 82:13 coin [1] - 48:25 coincidence [2] - 48:4; 80:9 collaterally [1] - 60:22 colleague [2] - 39:19; 50:9 collect [1] - 88:16 collectively [3] - 3:2, 7 colloquial [1] - 66:15 color [1] - 11:9 combine [4] - 28:18; 30:3; 33:24; 34:1 comfort [2] - 38:5, 7 coming [1] - 15:19 comma [3] - 69:7; 74:25 comments [1] - 84:4 Commission [1] - 64:21 common [3] - 43:19; 75:9; 81:20 company [2] - 73:8; 78:11 competing [1] - 81:15 competition [2] - 82:14, 16 competitors [2] - 14:9; 81:17 complain [1] - 48:24 complaint [5] - 56:18; 60:2; 103:8, 11, 13 Complaint [2] - 42:9; 59:24 completely [3] - 8:24; 52:25; 53:6
---	---	---	--	---	---

Motions Hearing, 8/19/26

complexities [1] - 61:6 complicated [3] - 20:14; 67:15; 79:4 complied [1] - 55:2 component [1] - 46:4 comport [1] - 105:21 comports [1] - 103:22 compute [2] - 18:19; 22:17 COMSAT [1] - 52:14 concedes [1] - 37:11 concept [2] - 9:4; 22:25 concern [5] - 21:9; 51:20; 90:4, 6 concerned [2] - 60:16; 83:19 concerns [6] - 5:4, 10; 21:5; 45:14; 68:20 concise [1] - 5:8 conclude [1] - 108:21 concluded [2] - 49:13; 57:16 conclusion [1] - 83:13 conclusions [1] - 18:3 concrete [1] - 32:25 condition [4] - 17:12; 29:17; 80:11 conditions [1] - 105:6 conduct [1] - 101:8 confirms [1] - 43:12 confronted [2] - 49:22; 100:3 confronts [1] - 40:11 confusing [1] - 13:6 confusion [1] - 96:8 Congress [65] - 7:25; 8:3; 17:23; 18:4; 44:15, 23;	46:20; 48:9, 17; 49:4, 6, 13, 21, 24-25; 50:1, 10, 16; 53:10, 13; 55:10; 57:17; 58:9, 15; 61:15, 23; 63:1; 67:16; 68:4, 15; 69:2, 5, 13; 70:20; 71:7, 23; 72:7; 73:13; 74:22, 24; 75:5, 12-13; 76:14; 80:20, 25; 81:1; 83:17; 84:23; 85:3; 86:25; 88:1; 92:11; 98:18; 99:20, 25; 101:8; 102:24; 104:7, 14; 106:5, 8, 13; 107:20 Congress's [3] - 50:16; 76:9; 80:16 congressional [2] - 101:5; 106:3 connection [3] - 4:20; 6:13; 99:1 consequence [1] - 106:16 consider [9] - 15:6; 22:12, 15; 66:24; 69:6; 78:6; 88:17; 104:10; 107:13 consideration [5] - 14:8; 62:6; 71:18; 94:19; 102:5 considerations [2] - 17:22; 18:1 considered [3] - 78:7; 82:3, 13 considering [1] - 66:23 consistent [21] - 8:24; 19:15, 21; 22:16; 31:17; 40:4; 42:23; 46:12; 47:8; 50:4; 52:9; 55:17; 56:1, 3; 59:4; 67:5; 70:1; 82:18; 86:2 consortium [1] - 81:15 constitute [2] - 108:11, 13 construed [1] -	108:5 construing [1] - 40:12 consultation [3] - 45:25; 46:3, 6 consultations [1] - 54:22 consulted [1] - 50:25 containing [1] - 108:9 contemplate [1] - 11:2 contemplates [3] - 81:14; 82:2; 106:21 contemplating [3] - 11:17; 70:5, 23 contend [1] - 3:12 contends [1] - 6:5 contention [1] - 105:11 context [14] - 20:18; 40:16; 51:23; 54:1; 58:6; 61:12; 65:10; 99:24; 102:7, 12, 14; 108:5 continue [2] - 50:21; 61:19 contrary [4] - 3:10; 4:9; 70:12; 81:19 contrast [3] - 8:14; 10:23; 93:14 contravenes [2] - 6:6; 103:20 control [1] - 90:17 controversy [2] - 31:14; 36:24 convenience [1] - 4:18 convincing [1] - 101:5 cook [1] - 100:13 copies [2] - 7:14 copy [2] - 7:18; 33:17 copyright [8] - 89:7, 13, 16, 20; 90:22; 91:6, 15 copyrighted [2] - 91:8 correct [12] - 12:4, 7, 9; 13:24; 21:14; 29:23; 52:20;	67:11; 72:10; 99:17; 100:5 correctly [4] - 54:5, 14; 77:10, 12 correspondence [3] - 10:20; 11:12 corresponding [1] - 104:14 Cosmetic [5] - 68:9, 17; 71:8, 15; 76:6 costliest [1] - 80:17 costly [1] - 71:24 costs [1] - 71:23 counsel [7] - 2:8; 3:21; 4:21; 6:12; 7:15, 19; 48:11 count [4] - 20:4; 82:24; 89:23; 107:1 counter [1] - 66:18 counterintuitive [2] - 8:17; 70:19 counting [2] - 20:6; 82:23 countries [1] - 49:1 counts [1] - 9:11 County [1] - 106:10 couple [2] - 38:22; 59:9 course [10] - 4:14, 18; 6:11, 18; 9:17; 43:18; 55:3; 73:13; 98:23; 99:19 Court [91] - 3:16; 4:22; 6:16; 24:22; 25:9; 39:25; 40:1; 43:5, 8, 10, 19, 23; 44:1, 3, 10, 12, 25; 46:14; 47:6; 48:4, 8, 14, 21-22; 49:2; 50:24; 51:6, 21, 23; 52:3, 19-20; 54:9, 24-25; 55:5, 14, 25; 56:1, 9; 57:1, 23; 58:1; 59:22; 60:12, 19; 61:7; 62:21, 23; 63:7, 14-15, 20; 64:4, 7, 11, 19-20,	24; 65:14, 17; 66:3, 23; 70:17; 72:5; 83:11, 19; 92:9; 93:18; 97:7; 99:14; 100:4, 6-7, 13, 15-16, 23; 101:2; 102:4; 104:6, 22; 105:2, 5, 10; 106:5; 108:5, 8, 16 court [7] - 4:13; 21:1; 46:4; 53:7; 99:18; 102:1; 108:14 COURT [119] - 2:3, 12, 14, 16, 20, 23; 7:2, 17, 21, 23; 11:23; 12:1, 5, 19; 13:8, 20, 22; 14:7, 13, 16; 16:16; 17:21; 20:8, 10; 21:12; 24:5, 8, 11, 13, 16; 27:15, 22; 28:20; 29:10, 12, 20, 25; 30:5, 8; 31:11; 32:4, 10, 15; 33:4, 14, 17; 34:1, 10, 23; 35:8, 13, 19; 36:8, 11; 37:1; 38:16; 39:7, 10, 12, 16, 21; 41:19; 48:15; 57:2, 6; 59:7, 16, 18; 62:1, 5, 11, 14; 63:3, 5, 9; 64:14; 65:22; 72:8; 73:17, 19; 76:25; 77:18; 78:3, 10; 79:18; 84:1, 3, 8; 86:18, 21; 87:3, 6, 10, 16, 19, 22; 88:6, 9, 16, 20, 24; 90:21, 25; 91:24; 94:15, 21, 24; 95:1, 4, 7, 10; 96:15, 24; 97:5, 9, 15; 98:25; 99:5; 108:23 Court's [12] - 7:9; 40:5; 47:10; 52:10; 56:25; 62:6; 63:8, 24; 83:8; 93:17; 102:6, 11	courtroom [2] - 24:14; 96:22 courtrooms [1] - 61:21 courts [4] - 4:16; 51:17; 92:6; 99:21 Courts [2] - 51:24; 61:17 covered [4] - 38:7; 76:5, 20; 93:21 covers [2] - 38:2; 76:16 cream [1] - 29:16 create [2] - 17:7; 47:13 created [4] - 40:2; 69:1; 71:3; 96:8 creates [2] - 15:16; 69:22 creation [1] - 94:1 criminal [1] - 87:12 criteria [4] - 19:1; 83:17; 91:11 critical [1] - 67:15 criticizes [1] - 107:1 cross [12] - 55:10; 70:13, 18; 75:22; 76:3, 6, 15, 21, 23; 85:5, 8, 15 cross-reference [3] - 70:18; 76:6, 15 cross-references [9] - 55:10; 70:13; 75:22; 76:3, 21, 23; 85:5, 8, 15 crux [1] - 78:15 customers [2] - 74:1, 5 cut [1] - 73:19 cycle [1] - 5:13 D.C [44] - 4:22; 5:7; 24:9; 25:18, 23; 26:3, 25; 37:13; 38:1, 20; 40:9, 14, 18, 22; 41:1, 10; 42:20-22; 46:13; 47:9; 52:14; 57:4; 58:12, 18; 59:1, 13; 62:2; 66:23; 79:23; 83:12; 92:21, 25; 93:2; 99:13;
---	---	--	--	---	--

Motions, Hearing, 8/19/26

101:11; 102:18; 104:20; 105:3, 5, 10, 22; 107:22 data [12] - 18:19; 19:7, 9, 16, 19; 21:24; 22:3, 13; 28:15; 29:1; 69:6; 88:16 date [36] - 8:8, 11; 10:13-15, 17; 11:11; 14:21, 24; 25:8, 10, 13; 82:23, 25; 85:11, 20-21, 25; 86:5; 89:6, 12; 91:5, 14-16, 20; 97:21; 98:9, 19, 24; 99:2; 106:17 dates [3] - 10:25; 25:17; 82:21 deadline [3] - 7:7; 94:20 deal [1] - 92:14 dealt [1] - 92:13 debarment [3] - 53:7, 13; 56:21 decades [1] - 41:24 decide [7] - 17:24; 52:1; 54:25; 61:17; 92:9; 99:19; 108:8 decided [4] - 42:6; 50:12; 51:16; 54:5 decides [2] - 53:5; 72:13 deciding [2] - 73:24; 101:25 decision [31] - 4:22; 5:2; 17:23; 24:20; 36:12; 37:21; 38:17, 21; 40:5; 47:10; 50:3; 52:11; 57:7; 58:4, 24; 72:11; 73:1; 79:23; 93:4, 17, 20; 97:11; 102:1, 6; 103:2, 5, 25; 104:18; 105:15; 107:1; 108:3 decisions [9] - 37:19; 38:4; 58:8; 69:3; 101:21; 103:24; 107:23	decisive [4] - 51:5, 7; 63:19; 64:10 deck [1] - 75:17 declined [1] - 108:8 declines [1] - 105:2 default [1] - 92:2 defeat [1] - 83:16 defeating [1] - 72:6 defendants [11] - 2:19, 22; 3:8; 4:14; 6:16; 66:1; 99:6; 103:20, 24; 108:18, 25 defendants' [4] - 3:17; 103:1, 3, 7 defense [1] - 2:17 defensible [1] - 25:7 defer [1] - 6:22 define [1] - 84:18 defined [3] - 12:3; 67:3; 88:21 defines [3] - 87:25; 101:25; 104:24 defining [2] - 5:18; 66:25 definite [1] - 25:9 definitely [1] - 95:15 definition [40] - 3:10; 4:9; 8:12, 15, 18, 20; 9:18; 11:21; 12:6; 15:14; 18:12; 24:23; 27:10, 20; 43:14; 46:17, 23; 76:4, 12; 78:2, 24; 84:20, 23, 25; 85:16; 87:3, 7; 104:8; 105:14, 20; 106:15, 23; 107:12, 15, 19 definitions [3] - 46:21; 47:23; 58:4 degrees [1] - 76:3 delegates [1] - 100:11 demonstrably [1] - 45:5 demonstrates [1] - 101:7 denial [4] - 42:10; 59:25; 60:7	denied [2] - 4:13; 103:16 Department [3] - 2:19; 3:5; 65:25 deprives [1] - 4:15 described [1] - 4:25 describes [1] - 101:20 description [1] - 40:10 design [1] - 48:7 designate [1] - 48:25 designates [1] - 49:11 designation [6] - 45:24; 48:24; 51:2; 54:18 designed [1] - 21:17 designing [1] - 48:7 despite [1] - 49:20 detail [3] - 18:17; 24:1; 50:10 detailed [1] - 9:5 determination [89] - 38:11; 39:1; 42:16; 43:7, 13, 15-16, 20; 44:4, 13-15; 45:1, 8, 16; 46:4, 15; 47:15, 21; 48:2, 9; 50:21, 23; 51:4, 6, 8, 24; 52:4; 53:3, 10, 12, 15-16, 19-20; 54:17; 55:1, 15; 56:16; 57:19, 24; 58:1, 3, 8-10, 15; 60:3, 5-6, 22; 61:10, 15; 62:16, 22-23; 63:1, 5, 9, 11, 15-16, 22, 25; 93:5, 7-8, 11, 13, 24-25; 99:10; 101:16, 18, 20, 25; 102:8, 10, 12, 15, 23; 103:10, 12; 108:15 determination's [1] - 63:3 determinations	[13] - 43:16; 47:1; 51:16; 55:13; 58:11, 16; 61:20, 24; 63:12; 92:7; 99:11; 100:24 determinative [1] - 44:1 determine [9] - 9:10; 54:10-12; 55:1; 88:17; 90:13; 100:4, 8 determines [2] - 20:10; 108:13 determining [7] - 19:8; 28:25; 29:6; 31:17; 67:20; 83:17; 105:23 develop [4] - 6:7; 16:13; 17:5, 8 developed [1] - 17:12 DHS [1] - 55:2 dialysis [2] - 37:24 dicta [2] - 64:23; 65:1 dictated [1] - 72:9 Dictionary [1] - 101:24 dictionary [1] - 43:14 differ [3] - 33:11; 58:13, 19 differed [1] - 40:12 difference [5] - 38:19; 50:8; 58:7; 67:13; 68:3 differences [1] - 83:16 different [93] - 4:6; 5:18; 9:4; 10:24; 11:17, 20; 13:3; 14:19; 15:6; 18:10; 19:24; 20:16, 21; 21:13, 18; 22:1, 14, 16, 25; 23:2-4, 15, 22; 24:2; 25:5; 26:19, 23; 28:7; 29:13, 15; 31:1, 5-6, 19; 32:15; 35:6; 36:18; 40:17, 25; 41:3, 6; 43:2; 50:8; 52:25; 58:3, 	23-24; 62:2; 66:16; 67:19; 68:8, 13-14; 69:19; 71:9, 19; 77:5; 78:8, 19-20; 81:10, 16, 22; 82:21; 83:3, 21; 85:23; 86:5; 87:14, 19; 88:7, 18; 89:1, 10; 92:12; 93:9; 95:25; 96:6; 104:5; 107:20, 23 differently [1] - 4:8 differing [1] - 108:10 differs [2] - 58:14; 89:20 difficult [1] - 55:19 direct [1] - 35:23 direction [2] - 7:9; 107:6 directly [4] - 24:25; 44:7; 46:19; 91:13 director [1] - 60:3 disagree [5] - 3:21; 52:8; 56:20; 64:24; 77:14 disagreed [1] - 39:25 disagreement [1] - 98:6 disagreements [1] - 79:24 disclaiming [1] - 34:24 discovery [1] - 16:20 discrete [2] - 101:21; 102:3 discretion [4] - 45:12, 18; 52:5; 73:21 discretionary [2] - 73:1; 100:11 discuss [3] - 40:8, 17; 50:9 discussed [3] - 48:22; 54:7; 60:11 discusses [1] - 95:23 discussing [1] - 67:1 discussion [6] -	62:1; 76:25; 77:22; 79:24; 80:23; 104:18 disincentivizing [1] - 16:5 dismiss [3] - 3:18; 99:6, 20 disparate [2] - 23:7; 106:9 dispositive [1] - 50:23 dispute [13] - 4:14; 5:11; 12:24; 51:13; 53:3; 56:15, 17, 19; 59:12; 65:15; 82:7; 98:2 disputes [4] - 6:12; 29:24; 53:15 dissent [1] - 55:6 dissenting [3] - 41:1; 58:20 distinct [1] - 93:2 distinction [8] - 23:2; 47:14; 57:3, 25; 58:6; 62:20; 67:15 distinctions [3] - 23:1; 73:6; 93:3 distinguish [3] - 42:25; 46:9, 13 distinguishable [1] - 103:6 distinguished [2] - 45:17; 63:21 distinguishes [4] - 44:2; 45:5, 9; 76:11 distinguishing [1] - 44:3 district [2] - 60:2 District [7] - 52:19; 56:1; 72:5; 83:11; 93:17; 100:4 divergent [1] - 100:22 divorced [1] - 60:7 doctor [1] - 66:9 doctrine [8] - 38:14, 19; 92:14-16, 20; 93:17, 19 doctrine's [1] - 39:4 doe [2] - 92:16; 102:6
--	--	---	--	---	---

Motions, Hearing, 8/19/26

Doe [4] - 40:6; 42:23; 62:1; 92:24 DOHOU [1] - 101:14 Dohou [1] - 101:13 DOJ [1] - 2:22 door [1] - 55:14 dosage [47] - 4:3; 9:3; 19:10, 19, 24; 21:22; 22:2, 23-25; 26:6, 12, 23; 27:3, 13; 28:5, 8, 19; 30:1, 13, 17, 21, 23; 32:7, 13, 16, 23; 33:2, 11, 19, 21, 23-24; 34:7, 19; 35:18; 36:4, 17; 69:6, 19; 85:24; 95:23, 25; 96:7; 104:3 dosages [5] - 21:13; 27:18, 23; 32:12; 77:8 double [1] - 7:17 double- checking [1] - 7:17 doubt [4] - 57:13, 16-17; 72:20 down [2] - 71:13; 73:1 downside [2] - 17:2, 6 drafted [1] - 32:17 dramatic [1] - 76:15 draw [4] - 74:1; 75:13; 81:1; 82:8 draws [3] - 38:24; 52:20; 105:9 drew [1] - 93:3 driving [2] - 15:21; 74:6 Drug [32] - 4:5; 5:4; 14:22; 15:2, 19, 23; 67:13, 24; 68:2, 5-6, 9, 16; 70:8; 71:1, 8, 12, 15; 73:11; 74:15; 75:3, 10; 76:4, 6; 82:20; 85:3, 10; 106:25 drug [212] - 3:11; 4:2-4; 5:14; 6:1, 3; 8:5, 10, 13-14, 20, 22,	24; 9:10, 16, 21-22, 25; 10:2, 7, 12, 15, 18, 21, 23; 11:5, 7, 12, 14, 18; 12:2, 9, 13-14; 13:3, 14; 15:14, 20, 23; 16:1, 23; 17:12, 16, 18; 18:12, 23-24; 19:2, 8, 20, 22; 20:1, 6; 21:13, 20, 23-24; 22:1, 6, 9, 16; 23:8, 13, 16-17, 19, 25; 24:23; 25:1, 17; 26:4, 11, 19; 27:10, 19; 28:6, 11, 16, 25; 29:2-6, 8; 31:25; 32:6; 33:13, 20, 25; 34:2, 9; 35:12; 37:25; 42:16; 46:23, 25; 49:12; 53:12, 17; 60:10, 14, 20; 61:12, 18; 66:14, 21, 25; 67:2, 6, 21; 69:6, 9, 13-14, 20-21; 70:4, 6, 8, 14-15, 21; 71:12-14, 17, 23; 72:2; 73:11, 20, 25; 74:2, 5, 8-9, 25; 76:4, 13; 78:6, 13, 19, 22, 24; 79:14; 80:23; 82:1, 4, 6-8, 11, 15-16; 83:2, 16, 18; 84:17, 19, 24; 85:2, 8, 12, 14, 16; 86:7, 13; 91:22; 92:12; 95:24; 99:10; 102:22; 104:2, 12-13, 24; 105:2, 8, 14, 17, 22, 24; 106:19; 107:7; 108:5, 11, 14 drug's [1] - 8:11 drugs [78] - 5:12; 6:8; 8:1, 4; 9:9, 11-13; 11:10, 15; 12:11, 15, 21-22; 13:9, 23; 14:18; 15:2, 9, 11; 19:3, 5, 18;	23:1, 3; 25:5; 28:17; 29:13; 30:2, 9; 31:1; 32:11, 15; 38:12; 39:2; 44:16; 46:16; 49:11; 51:10; 57:19; 61:15; 63:2; 67:19; 69:18; 71:16, 24; 73:6; 75:19; 76:16-19, 22; 77:5; 78:7; 79:3; 80:1, 7, 17; 81:21; 82:9; 85:13; 86:11; 92:12; 93:6, 8; 101:17; 105:12; 107:2, 5, 19 during [2] - 95:16; 97:11 duty [1] - 100:17 e [3] - 57:20; 84:24; 93:24 e(1) [1] - 9:18 e(1)(A) [1] - 9:19 e(1)(D) [1] - 106:15 e-Kindle [1] - 89:8 earliest [6] - 14:21, 24; 86:8; 98:5, 9; 106:19 easily [1] - 73:14 ECF [2] - 3:17 eczema [3] - 23:12; 78:21; 84:17 edge [2] - 78:17; 105:9 edition [2] - 87:13 editions [3] - 87:20; 88:14; 91:1 effect [5] - 16:15; 22:5; 93:13; 94:23; 100:17 effective [1] - 71:16 effectively [2] - 61:21; 65:8 efficacy [1] - 6:8 either [6] - 4:19; 56:25; 58:11; 63:6; 81:6; 105:8 El [1] - 101:11 elapsed [2] - 8:8; 10:13 element [1] - 79:19	elephant [4] - 24:8, 13; 39:23 eligibility [5] - 15:4, 24; 28:21; 60:3 eligible [11] - 9:11-13; 15:10; 19:6, 9; 29:1, 7; 67:21; 89:12; 101:18 eliminate [1] - 16:25 elucidated [1] - 36:23 elude [1] - 73:24 embedding [1] - 102:21 emphasized [1] - 64:2 emphasizes [2] - 44:10; 106:1 emphatically [1] - 92:9 employed [1] - 101:22 enacted [1] - 68:10 encompass [1] - 102:15 encompassed [1] - 108:6 end [3] - 40:10; 44:20; 48:22 endorsed [1] - 93:18 enforcement [1] - 4:13 engage [6] - 9:14; 52:21; 53:25; 54:22; 55:14; 56:2 engaged [1] - 53:4 engagement [1] - 85:18 engaging [1] - 55:25 engineer [1] - 8:19 engineered [1] - 27:9 ensure [1] - 71:15 entails [1] - 10:10 enter [1] - 108:18 entertained [1] - 55:5 entire [5] - 13:17; 15:5, 9, 25; 108:6 entirely [7] - 8:19;	66:22; 68:9; 70:17; 71:3; 79:4; 82:18 entirety [3] - 75:15, 23; 76:22 entitled [2] - 103:18, 21 EPA [1] - 106:11 equally [1] - 81:7 error [2] - 25:18, 21 escalating [1] - 71:22 escaping [1] - 64:20 especially [3] - 37:9; 70:21; 102:1 essential [1] - 79:18 essentially [23] - 12:10; 16:21; 22:15; 25:11; 39:6; 42:2; 43:2, 17; 48:2, 23; 49:17; 53:21; 58:5, 23; 60:10; 65:4; 72:17; 74:9; 79:21; 81:11; 89:23; 92:6; 93:19 establish [3] - 6:19; 100:2; 108:12 established [1] - 104:7 et [2] - 2:6 Europe [1] - 76:19 evade [1] - 72:1 evaluate [1] - 46:5 evaluation [1] - 102:22 eventual [1] - 76:6 everywhere [1] - 16:13 evidence [3] - 14:1; 36:1; 101:5 exact [1] - 82:22 exactly [14] - 10:18; 22:9; 28:22; 38:9; 40:14; 41:15; 42:13; 47:5; 48:13, 20; 50:6, 10; 60:20; 93:23 examine [2] - 38:2; 53:8 examined [1] -	40:21 examining [1] - 43:5 example [12] - 19:16; 23:6; 32:25; 33:23; 70:3; 73:18; 74:19, 22; 75:7, 12; 96:2 examples [1] - 75:10 exceed [1] - 45:19 exceeded [1] - 4:1 exclude [2] - 12:21; 14:9 excludes [1] - 12:22 exclusion [1] - 106:9 exclusivity [1] - 14:23 excuse [1] - 69:17 Executive [2] - 100:12, 24 exercise [2] - 45:11, 18 exercises [1] - 73:21 existing [6] - 6:8; 8:4; 16:25; 17:17, 19; 21:8 expand [1] - 5:17 expanding [1] - 102:14 expansive [2] - 55:8, 20 expect [1] - 61:20 expectation [1] - 75:9 expected [1] - 69:2 expediency [1] - 97:16 expenditures [9] - 6:2; 15:21; 16:10; 19:19; 20:6; 74:3, 6; 81:22; 105:8 expensive [2] - 51:11; 61:16 experimental [1] - 76:18 explain [4] - 13:18; 20:15; 25:25; 27:1 explained [2] - 92:22; 102:18 explaining [1] - 79:25 explains [1] - 41:2
--	---	--	--	---	--

Motions, Hearing, 8/19/26

explanation [1] - 80:25	17:22	56:10; 89:4	92:15	framing [1] - 37:8	- 8:14, 16; 9:1; 15:7, 20; 18:11, 20; 19:14; 21:5; 22:4, 6, 20; 23:13, 19; 26:17; 27:8; 29:24; 31:6, 24; 32:20; 33:8, 10; 34:5, 13, 16; 35:1; 36:3, 22; 37:11; 38:10; 42:2, 5; 60:23; 66:2; 77:12; 78:6; 85:18; 86:8; 92:5; 94:3; 95:17
explicit [2] - 65:12; 70:22	facts [1] - 5:11	figured [1] - 18:23	footnote [1] - 52:20	Francisco [1] - 106:11	Government's [28] - 10:22; 11:19; 13:2; 15:5, 10; 16:4, 12; 18:2, 8, 16; 23:9, 25; 24:2; 25:22; 30:18; 60:9; 67:4; 68:23; 77:23; 78:18; 81:3, 5, 24; 82:19, 25; 83:19; 94:4; 98:11
explicitly [4] - 46:22; 68:15; 69:14; 75:13	failed [1] - 51:1	figuring [1] - 28:16	foreclose [1] - 25:23	frank [1] - 55:7	governs [1] - 28:22
express [6] - 7:5; 52:23; 64:22; 65:5, 15, 20	fails [1] - 105:20	file [11] - 20:11, 16-17, 20, 23-25; 21:7, 18; 72:11; 90:11	foreign [1] - 54:19	frankly [1] - 55:21	grant [1] - 108:17
expressed [2] - 51:20; 90:4	fair [7] - 9:15; 22:12; 23:20; 34:25; 69:17; 104:9	filed [7] - 6:19; 21:14, 19; 37:15; 40:6; 68:2; 73:21	forget [1] - 20:8	free [5] - 5:23; 17:6; 20:19; 33:1; 34:18	granting [2] - 41:16; 54:8
expressly [5] - 42:10; 59:24; 69:5; 101:9; 108:8	faithful [1] - 34:21	filing [1] - 90:11	form [19] - 16:16; 20:4; 26:13; 28:13, 19; 30:13, 17, 21, 23; 32:16; 33:21, 24; 68:10; 83:16; 95:23, 25; 96:7; 97:19	friend [7] - 32:20; 67:10; 72:17; 90:4; 92:5, 19; 94:3	great [2] - 16:8; 20:12
extended [14] - 26:13; 27:4; 28:12; 31:1, 3; 35:7; 69:8; 74:19, 25; 75:1, 7; 96:3	falls [4] - 37:13; 42:7; 56:11; 59:22	fill [1] - 54:17	formal [1] - 63:10	full [1] - 102:5	ground [3] - 50:3; 81:20
extends [3] - 17:12; 54:2; 99:10	familiar [3] - 37:7; 68:22; 88:25	fill-in-the-blank [1] - 54:17	former [1] - 6:1	fully [2] - 69:2; 102:5	grounded [1] - 83:22
extension [1] - 54:19	far [12] - 9:4; 31:3; 36:7; 49:15; 52:9; 59:4; 60:15; 67:5; 71:5; 82:12; 95:20	final [19] - 4:17; 5:5, 12, 16; 6:9; 43:15; 58:4; 8-10, 15; 65:11; 94:17; 102:1; 103:9, 19; 104:1; 105:17; 107:25	forms [36] - 4:3; 9:3; 19:10, 19, 23; 21:22; 22:2, 23-25; 26:6, 23; 27:3, 14; 28:5, 8; 30:21; 32:7, 13, 24; 33:2, 12, 19, 23; 34:8, 19; 35:18; 36:4, 17; 66:16; 67:20; 69:6, 19; 85:24; 104:3	function [1] - 19:11	group [15] - 13:17; 15:5, 25; 26:23; 29:21; 30:22; 31:18; 32:2; 46:24; 86:11; 91:7, 11; 94:5; 101:21
extent [4] - 53:2; 55:16; 83:5; 98:20	farfetched [3] - 49:8, 10; 50:1	finally [4] - 11:4; 26:25; 94:2, 13	formula [1] - 27:4	fundamental [1] - 100:2	grouped [16] - 16:11; 27:12; 30:19, 22; 31:4; 32:12, 17; 34:17; 36:5; 74:8; 77:6; 86:13; 91:9; 94:9; 105:12
extra [5] - 19:25; 20:2, 5; 26:12; 28:13	faulty [2] - 60:3	fine [3] - 84:8; 96:24	formulaic [4] - 51:9, 12; 52:2; 61:13	fuzzy [1] - 73:7	grouping [6] - 26:19, 21; 30:9; 31:22; 46:15; 86:15
extra-strength [1] - 26:12	favor [5] - 8:15; 38:18; 57:14; 101:3; 108:18	finish [1] - 88:10	formulas [1] - 94:9	Garcia [1] - 52:22	groups [2] -
extraordinarily [1] - 70:19	FDA [33] - 5:14, 20; 6:3; 9:25; 12:12, 14; 20:13, 20, 22; 21:6, 12, 18; 71:11, 14, 18; 72:9, 13-15, 21; 73:3, 8; 74:12, 14; 75:10; 76:22; 78:22; 90:10; 96:7; 105:12	first [18] - 3:25; 6:21; 9:9, 22; 24:22; 34:11; 43:4, 8; 54:11; 76:3; 77:7; 78:1; 82:23; 84:12; 88:21; 92:2; 100:15	formulation [17] - 69:8, 20; 74:20, 25; 75:1, 8; 83:3; 95:16; 96:2-4, 6	generality [2] - 74:12; 82:5	
f-1 [1] - 75:18	FDA-approved [4] - 5:14, 20; 76:22; 105:12	five [1] - 92:11	formulations [9] - 29:2; 31:19; 32:3; 69:7; 75:5; 83:2; 98:16; 105:7; 106:24	generally [4] - 100:25; 103:2; 104:15; 106:7	
f-1(d)(3)(B) [1] - 108:1	FDCA [3] - 9:24; 12:12; 108:5	fix [1] - 49:6	forth [3] - 73:8; 83:17; 88:7	generic [25] - 11:12, 14-15; 12:17, 23, 25; 13:1, 4, 13, 16; 14:3-6, 8; 15:2, 6, 8, 22-23; 16:1; 82:14, 16; 85:13; 91:22	
f-3 [1] - 75:18	featured [1] - 74:23	flag [1] - 40:9	four [4] - 24:20; 36:14; 83:13	Generix [2] - 108:3, 12	
f-3(e)(1)(D) [1] - 108:1	features [2] - 23:24; 38:23	flipping [1] - 48:25	fourth [1] - 36:15	GHEIBI [21] - 2:21; 39:15, 17, 22; 41:21; 48:17; 57:5, 15; 59:15, 17, 19; 62:4, 10, 12, 15; 63:4, 6, 13; 64:16; 65:23; 97:7	
f-5 [1] - 75:18	federal [4] - 4:15; 51:16; 99:18, 21	focus [3] - 38:25; 62:3; 79:22	Fourth [21] - 37:15; 38:6; 40:19; 41:4; 42:6, 18; 55:17, 24; 56:1; 57:11; 59:7, 11; 60:25; 65:1, 3; 87:11; 100:19; 103:4	Gheibi [5] - 2:22; 39:15; 96:17; 97:5	
f-5(a)(2) [1] - 108:2	feed [1] - 7:11	focused [3] - 57:3, 7; 95:23	framed [1] - 41:14	given [6] - 70:21; 89:1; 96:13; 100:21; 102:7; 103:3	
F.3d [1] - 41:21	fever [1] - 80:4	focuses [3] - 82:9, 11; 83:20		goal [2] - 16:14; 71:20	
F.4th [1] - 65:4	few [5] - 7:22; 18:15; 40:6; 41:23; 58:1	focusing [1] - 9:19		goals [1] - 8:3	
face [3] - 27:8; 103:8	figure [5] - 10:9; 18:25; 19:17;	follow [1] - 47:7		govern [2] - 106:25; 107:23	
fact [18] - 13:24; 15:8; 22:25; 24:25; 27:17; 40:19, 24; 45:7; 47:12; 49:18; 55:7; 57:24; 61:9; 67:4; 70:11; 88:13; 106:1		followed [1] - 59:9		governing [1] - 63:24	
factoring [1] -		following [4] - 40:23; 44:2; 67:17; 90:8		Government [44]	

Motions Hearing, 8/19/26

32:21; 95:18 Guerrero [1] - 101:1 guess [8] - 7:15; 13:8; 14:7; 16:24; 38:19; 57:6; 62:3; 74:2 guessing [4] - 50:5, 11; 51:15; 61:25 guidance [65] - 3:9, 13; 4:1, 8, 11, 17; 5:5, 12, 14, 16; 6:9; 13:12; 17:20; 20:13, 22; 21:2, 7, 12; 31:16-18, 22; 32:1, 4, 17; 33:5, 8-9, 14, 16; 34:20; 36:20; 42:15, 17; 46:16; 48:12; 57:23; 72:15, 17; 73:2, 9; 77:2, 13; 81:10; 90:8, 12; 94:4, 11; 95:13, 22; 96:10; 97:24; 98:4, 8; 103:9, 13-14, 19, 21; 104:1 guidance's [1] - 105:18 guide [1] - 24:5 hail [1] - 65:13 hammer [1] - 50:21 handbook [1] - 87:12 handed [1] - 66:10 handle [1] - 7:8 happy [8] - 36:9, 23; 38:14; 41:8; 84:7; 95:6; 96:16, 18 hard [4] - 7:13, 18; 75:11; 79:8 hardcover [1] - 88:7 harm [1] - 16:13 headquarters [1] - 61:22 Health [2] - 3:4 hear [4] - 4:16; 6:21; 84:12; 97:22 heard [7] - 76:2; 79:8; 85:17; 91:25; 92:5;	94:3; 97:20 hearing [3] - 2:8; 7:6; 94:18 heartland [1] - 37:13 heavily [1] - 74:23 heavy [1] - 101:4 held [4] - 35:24; 64:4; 81:11; 108:6 hello [2] - 2:10, 16 help [1] - 39:13 helpful [2] - 36:24; 99:2 helps [1] - 17:7 Henderson [2] - 41:2; 58:21 HEYST [1] - 2:15 Heyst [1] - 2:15 high [1] - 74:12 high-level [1] - 74:12 higher [1] - 82:5 highest [1] - 19:4 highest-spend [1] - 19:4 highlights [1] - 62:24 hinge [1] - 76:22 hint [1] - 18:5 hmm [1] - 87:9 hoc [1] - 107:4 holder [5] - 4:5; 81:9; 104:4; 107:3, 5 holding [1] - 94:18 honestly [2] - 23:21; 84:21 Honor [47] - 2:5, 10, 18, 21; 6:25; 7:3; 17:25; 24:4, 18; 28:24; 30:11; 34:4; 36:19, 21; 37:6; 39:8, 11, 15, 17, 22; 51:20; 53:25; 57:15; 62:10; 65:24; 74:10, 16; 77:15; 79:21; 83:8, 25; 84:2, 6; 94:13, 18, 25; 95:6, 8; 96:17, 21; 97:7, 23; 98:3; 108:22, 25 Honor's [1] - 68:22 hook [5] - 42:14; 48:10, 12; 63:14	hopping [4] - 21:5, 9; 90:5, 15 hospital [1] - 38:6 Hospital [8] - 37:17; 38:3; 41:22; 52:16; 53:1; 55:23; 93:16 hour's [1] - 97:15 house [1] - 91:13 Human [2] - 3:4 hundred [2] - 84:16, 18 hundreds [1] - 49:11 hypothetical [5] - 49:24; 56:21; 66:17; 78:17; 87:23 hypotheticals [4] - 49:8, 10; 50:2; 66:7 I(A) [1] - 5:2 I(B)(1) [1] - 5:2 i.e [1] - 64:3 identical [1] - 4:25 identification [2] - 37:24; 105:19 identified [13] - 4:2, 17; 8:3, 23; 11:18; 19:18; 29:8; 32:6; 45:23; 56:8; 60:14; 65:12; 105:15 identifies [3] - 43:2; 56:7; 105:1 identify [8] - 9:9; 36:14; 51:10; 55:12, 24; 71:24; 81:3; 104:2 identifying [2] - 4:9; 57:20 ii [6] - 10:5; 25:2, 4, 6, 8; 91:18 iii [2] - 24:24; 91:18 illness [1] - 66:10 illogical [2] - 18:3; 78:2 illustrate [1] - 14:14 illustrated [1] - 67:17 illustrates [1] - 78:17 imagine [5] -	15:18, 22; 23:17; 66:8; 75:11 immune [1] - 50:5 impermissibly [1] - 5:17 implementation [2] - 4:13; 73:23 implication [1] - 77:15 implicit [1] - 52:24 import [1] - 71:7 important [7] - 10:6; 22:18; 41:9; 74:13, 19; 77:21; 78:15 importantly [2] - 8:7; 42:8 imposed [1] - 105:13 improve [1] - 6:8 inaccurate [1] - 46:17 inactive [1] - 108:7 inappropriate [1] - 20:24 inactive [5] - 16:12, 22, 25; 17:7 incentives [2] - 6:7; 49:16 incentivized [1] - 16:17 inclination [1] - 6:20 inclined [3] - 5:9; 7:8; 56:25 include [5] - 52:23; 55:21; 83:2; 84:25; 107:24 included [9] - 13:22; 26:4, 7; 43:6; 48:5; 54:21; 60:13; 80:17; 102:10 includes [3] - 4:6; 106:6; 107:19 including [13] - 19:7; 37:14; 38:22; 54:5; 55:5; 60:11; 69:7; 77:8; 80:21; 98:16; 99:13; 104:7; 108:7 inclusion [2] - 105:18; 106:9	inclusive [1] - 104:4 incoherencies [1] - 81:4 inconsistency [1] - 42:24 inconsistent [1] - 94:12 incorporate [1] - 5:9 incorporating [1] - 8:4 incorrect [4] - 34:6; 45:5, 20; 105:13 incredibly [2] - 9:5; 37:9 independently [1] - 100:4 indicate [2] - 68:7; 91:7 indicated [1] - 79:15 indication [11] - 11:16; 70:11; 71:6; 73:3, 10, 15; 78:22; 81:18; 90:15; 92:10; 103:11 indications [2] - 68:25; 78:19 indicators [1] - 102:9 individual [2] - 44:9; 64:3 indulgence [1] - 83:8 ineligible [1] - 6:2 inextricably [1] - 93:1 Inflation [7] - 3:11; 68:13, 17; 71:8, 19; 79:5, 14 inform [2] - 31:9; 88:20 informs [1] - 67:6 ingredient [4] - 23:2; 33:3; 50:9; 82:10 ingredients [3] - 23:5; 108:7, 9 inherent [2] - 83:4; 98:17 initiated [1] - 3:3 injured [1] - 103:10 innovation [5] - 8:2; 10:6; 16:15; 72:3	innovative [1] - 16:20 inquiry [4] - 53:21; 54:3 insofar [3] - 21:10; 36:19; 93:10 instance [7] - 14:21; 15:18; 21:19; 52:3; 53:5; 65:10; 101:20 instances [1] - 37:18 instant [2] - 4:25; 103:8 instead [3] - 60:21; 103:13; 105:24 Institute [1] - 65:2 instruct [1] - 107:13 instructed [1] - 51:9 instruction [15] - 10:9; 11:1; 20:7; 26:5; 28:14; 30:21; 32:2; 34:3; 35:4, 8, 10-11; 36:6; 107:17 instructions [1] - 8:9 instructs [2] - 19:14; 104:1 intended [4] - 65:7; 75:13; 81:1; 107:20 intends [1] - 99:25 intent [2] - 101:6; 106:3 intentionally [1] - 106:8 interchangeable [1] - 44:24 interest [1] - 97:16 interesting [1] - 38:21 interestingly [3] - 41:1; 44:22; 54:21 internal [1] - 47:1 interp [1] - 18:7 interpret [3] - 17:24; 68:17; 100:15 interpretation [99] - 5:19; 10:23;
---	---	---	--	---	--

Motions, Hearing, 8/19/26

11:20; 13:2, 25; 16:12, 15; 18:3, 9, 16; 19:15; 23:24; 24:3; 25:22, 24; 26:1, 17; 27:2, 11; 28:10, 14; 29:21; 30:19; 31:5; 34:5; 36:10; 37:10, 12; 40:15, 25; 42:17; 43:12, 17; 46:10; 48:5; 50:13, 25; 51:14, 22-23, 25; 52:4, 10; 57:23; 59:4, 6; 60:6, 9, 12; 62:18; 66:4; 67:5, 16; 68:21, 24; 70:1; 80:19; 81:4, 7, 24; 82:12, 19, 25; 83:15, 20; 85:1; 86:2, 7; 88:23; 92:4, 17; 93:9, 15; 95:12; 98:2, 12, 21; 100:4, 8-10, 23; 102:19, 21; 103:13; 104:25; 106:4, 12, 18, 21; 107:4 interpretations [5] - 39:3; 47:23; 58:17; 83:6; 102:20 interpreted [6] - 44:9; 54:14; 55:18; 58:1; 64:5; 67:9 interpreting [2] - 9:17; 18:12 interpretive [5] - 60:16; 61:14, 18; 100:17; 106:16 interprets [1] - 16:18 intertwined [1] - 93:1 invite [2] - 3:21; 6:13 invoke [1] - 56:25 involve [1] - 92:17 IRA [32] - 3:12; 4:10; 5:4, 18; 6:5; 7:25; 9:5; 10:8; 12:7; 15:12; 16:14;	17:1, 7; 18:11; 23:20; 51:8; 61:12; 73:23; 102:20; 103:14, 20, 22; 104:23; 105:12, 16; 106:1, 14; 107:13, 16; 108:14 IRA's [8] - 5:17; 9:8; 46:20; 99:7; 104:25; 105:19; 107:5, 22 irrespective [2] - 32:22; 94:10 ISBN [8] - 87:8, 12, 14, 24; 88:3, 7, 25; 89:2 ISBNs [2] - 88:4; 89:10 isolation [1] - 105:3 issue [24] - 3:25; 4:8, 15, 17-19; 6:15; 7:12; 13:23; 33:1; 45:24; 53:16; 62:8; 77:21; 92:18, 23; 93:21; 96:8; 97:6, 25; 98:4; 99:17; 103:15 issued [5] - 3:10; 4:22; 5:6; 6:9; 99:14 issues [7] - 3:23; 4:24; 6:21, 24; 82:2 issuing [1] - 4:1 items [5] - 38:5, 8; 56:6, 9 itself [15] - 3:7; 20:22; 37:16; 41:10; 42:19; 43:15; 47:21; 50:17; 54:15; 55:20; 60:8; 61:10; 73:2; 85:19; 100:5 January [2] - 5:11; 94:22 job [2] - 55:11; 79:25 jot [2] - 68:16; 71:7 Judge [2] - 41:2; 58:21 judges [3] - 50:13; 51:17; 83:13	judgment [13] - 3:17; 6:20; 41:15; 49:21; 54:8, 10; 80:16; 103:18, 21, 23; 108:18 judicial [23] - 36:25; 37:8; 43:21; 44:15; 50:5, 11; 51:15; 54:16; 57:21; 61:24; 92:2, 19; 93:22; 99:7, 9, 23, 25; 100:25; 101:4, 6, 9, 16; 102:19 jump [1] - 14:11 jurisdiction [15] - 4:16; 6:17, 19; 37:5; 38:17; 56:3; 96:19; 99:15, 18, 21-22; 102:17; 103:1, 7 jurisdiction- limiting [1] - 103:1 jurisdiction- stripping [3] - 6:17; 99:22; 102:17 jurisdictional [15] - 4:17; 6:15; 7:11; 39:18, 25; 40:20; 48:23; 66:3; 79:24; 91:25; 92:1; 97:6; 99:17; 103:3, 15 Justice [2] - 2:19; 65:25 justices [1] - 55:5 justified [1] - 20:22 KEDEM [75] - 2:10; 6:25; 7:3, 19, 25; 11:25; 12:4, 8, 22; 13:11, 21, 24; 14:11, 14, 17; 16:24; 17:25; 20:9, 12; 21:15; 24:7, 10, 12, 15, 18; 27:21, 25; 28:24; 29:11, 19, 23; 30:4, 7, 11; 31:15; 32:9, 14, 19; 33:7, 15, 19; 34:3, 15, 25; 35:10, 15, 22;	36:9, 14; 37:6; 38:21; 39:8, 11; 84:6, 9; 86:20; 87:2, 5, 9, 15, 18, 21; 88:5, 8, 15, 19, 22, 25; 90:24; 91:2; 92:1; 94:17, 22, 25; 108:22 Kedem [7] - 2:10; 77:1; 78:11; 84:3; 95:14; 96:25; 108:21 Kedem's [1] - 97:20 keep [4] - 16:7; 78:15; 84:4; 96:21 keeps [1] - 30:9 Kennedy [2] - 2:6; 4:23 key [2] - 10:9; 105:23 kick [1] - 8:22 kid [3] - 66:10 kidney [1] - 23:11 kids [1] - 80:3 kind [2] - 6:22; 34:23 Kindle [2] - 89:8; 91:10 kindle [1] - 89:18 kneecap [1] - 49:18 knock [2] - 14:5; 15:24 knocks [5] - 13:17; 14:3; 15:4, 9 label [2] - 71:13; 79:3 labeling [1] - 76:9 lack [1] - 55:6 lacks [1] - 6:16 language [21] - 24:25; 28:1; 62:5, 8; 68:8, 14; 69:19, 22; 70:22; 79:16; 80:1; 82:17; 84:22; 85:1; 86:10; 93:25; 96:14; 100:16; 101:7; 106:6 lapsed [2] - 85:11, 21 Lara [1] - 100:19 Lara-Aguilar [1] - 100:19 largely [1] -	103:24 Lasprilla [1] - 101:1 last [5] - 11:24; 39:14; 82:14; 83:10; 95:14 latch [1] - 98:10 later-on [1] - 88:13 latter [1] - 6:3 law [13] - 3:13; 40:10, 22; 57:4; 58:6; 59:5; 79:5; 90:22; 100:2, 8; 103:19, 21 Law [1] - 101:24 lawful [4] - 51:3; 53:20; 54:11, 13 lawfulness [6] - 53:21; 54:3; 55:15; 56:13, 17, 19 lawsuit [1] - 49:20 lawyering [2] - 47:17; 48:14 lawyers [2] - 50:12; 69:24 lay [2] - 3:20; 68:21 layperson [2] - 30:1; 78:20 lays [1] - 85:6 lead [1] - 25:22 leading [2] - 58:5, 17 leads [3] - 18:3; 88:23; 90:19 least [7] - 8:7, 10; 10:12; 30:1; 51:22; 52:13; 62:21 leave [1] - 52:6 leaves [1] - 51:17 led [2] - 46:23; 102:11 Lee [19] - 41:5, 8, 13, 20; 42:4, 12; 54:6; 59:8-10, 16, 18, 20; 60:1, 21; 61:5; 92:14; 103:5 Lee's [6] - 42:9; 54:13; 59:23; 60:2, 5, 7 left [3] - 51:25; 52:1, 5 legal [2] - 46:5; 55:6 legislate [1] - 50:1 legislates [1] -	50:2 lengths [1] - 84:23 LEO [2] - 23:18; 78:9 less [3] - 6:22; 27:1; 76:15 level [2] - 74:12; 82:5 levels [1] - 21:13 librarian [2] - 86:24; 88:1 light [3] - 7:6; 40:21; 73:22 likely [1] - 49:15 limit [3] - 70:17; 99:20, 22 limitation [3] - 31:12; 71:3; 81:9 limited [2] - 68:4; 98:7 limiting [8] - 30:8; 32:11; 70:16; 77:1, 4, 8; 103:1 limits [2] - 5:17; 70:10 line [11] - 31:7; 50:15; 73:10; 75:12, 14, 24; 81:1; 82:8-10; 105:9 linking [2] - 62:7, 12 liquid [2] - 66:11; 84:15 list [10] - 5:12, 14; 12:11, 15; 13:9; 28:16; 56:9; 60:11, 13 listed [17] - 11:5, 7-8; 12:2, 9, 17, 21; 15:14; 38:5, 8; 56:6; 85:12, 14; 91:21 lists [1] - 11:10 litigate [1] - 49:17 litigation [2] - 49:18; 69:4 lives [1] - 16:9 logical [1] - 81:4 look [20] - 11:10; 22:21; 26:3, 10; 30:12, 20; 35:23; 42:24; 54:6; 56:9; 79:7; 84:13; 85:2, 20; 86:23; 90:7; 91:4; 92:19; 93:11; 100:15
--	---	--	---	---	---

Motions, Hearing, 8/19/26

looked [2] - 83:11 looking [3] - 43:3; 85:7; 95:1 looks [2] - 73:2; 98:4 lost [1] - 74:5 low [1] - 49:14 lower [3] - 8:1; 15:20; 16:14 LP [2] - 2:6; 3:1 Ltd [1] - 3:2 lucky [1] - 60:19 ma'am [1] - 39:13 main [1] - 25:18 maintain [3] - 40:1; 56:24; 58:25 maleate [4] - 5:24; 20:19; 33:1 mandated [1] - 46:2 mandates [1] - 35:20 maneuver [2] - 47:17; 61:1 maneuvering [3] - 42:18; 61:8, 19 manipulate [2] - 21:6; 90:6 manipulated [1] - 103:12 manner [2] - 5:18; 34:21 manufacturer [20] - 21:6; 23:15; 29:22; 35:3; 6-7, 12, 20, 24; 36:6; 37:24; 47:24; 73:1, 20; 78:13; 81:11, 15, 19; 107:6, 9 manufacturers [15] - 16:5; 17:2; 26:10; 29:15; 47:25; 48:13; 49:15; 61:19; 71:4; 74:17; 78:8; 81:16, 22; 90:6 marked [1] - 85:14 market [4] - 12:13; 73:25; 91:20 marketed [13] - 4:6; 5:24; 8:6; 9:23; 10:3; 11:6, 14; 12:16; 29:15; 71:13; 85:10, 13; 104:5	marketing [2] - 9:25; 10:1 markets [1] - 80:8 Mary [1] - 65:13 massive [1] - 73:5 material [2] - 5:11; 62:19 matter [9] - 18:2; 37:8; 84:21; 89:23; 94:6; 99:18, 21; 103:19, 21 matters [3] - 12:23; 80:13, 16 maximum [6] - 9:15; 22:12; 23:20; 69:17; 104:9 McLaughlin [1] - 100:6 McNary [16] - 44:2, 11, 23; 45:3, 7; 57:25; 62:13, 15, 18, 20-21; 63:19, 21; 64:12 McNary's [1] - 44:17 mean [48] - 14:7; 17:3; 24:5; 29:25; 34:11; 35:22; 38:17; 43:15; 47:19; 48:4; 51:1, 20; 52:5; 54:4; 55:10; 56:1; 60:17; 61:14; 63:23; 64:24; 69:22; 70:5; 71:14; 72:11; 73:13; 74:11; 75:17; 76:14; 78:8; 79:7, 11, 16, 22; 80:7, 9; 81:8, 12; 82:5, 18; 83:2, 10; 86:18; 87:19; 95:12; 96:20; 98:2 meaning [10] - 43:14; 66:15; 67:5; 79:14, 19; 94:5; 100:8, 16; 102:14; 105:22 meaningful [3] - 25:25; 56:2; 82:16 means [6] - 25:11; 70:7; 90:25; 92:10; 98:1	meant [1] - 64:8 measures [1] - 105:14 Medicaid [1] - 3:6 Medicare [10] - 3:6; 5:4; 6:2; 71:21, 24; 76:4, 16-17; 80:18 medication [2] - 66:18; 84:17 mentioned [1] - 79:9 merge [1] - 58:8 merger [30] - 37:13, 16; 38:14, 19, 22; 39:4; 40:16, 18; 52:12, 17; 53:2, 8, 18, 23-25; 54:2; 55:16, 20; 56:22, 24; 57:3; 58:13; 92:14-16, 20; 93:17, 19 merges [2] - 38:1, 12 merits [9] - 4:20; 37:3; 38:2, 13; 66:4; 79:25; 84:10; 94:2; 103:17 method [1] - 96:2 methodology [1] - 47:16 Michael [1] - 2:15 Michigan [1] - 100:1 middle [1] - 66:11 might [19] - 13:3; 16:20; 19:24; 21:6, 17; 26:20; 36:25; 62:8; 73:2; 78:13; 88:2, 6, 20; 89:2, 7; 96:6; 98:18 milligrams [1] - 80:10 mind [2] - 75:6; 78:15 minor [2] - 80:11 minute [4] - 53:9; 54:10; 60:23; 67:8 minutes [1] - 97:13 misaligned [1] - 32:1 misapplication [1] - 53:23 misapplies [1] -	106:4 misheard [2] - 62:7, 9 misinterpreted [1] - 42:2 misinterpreting [4] - 42:5; 48:19; 60:23 misspoken [1] - 62:10 mistaken [2] - 32:18 misunderstandi ng [1] - 79:6 MJM-25-cv-4212 [1] - 2:7 moieties [1] - 16:21 moiety [59] - 4:4; 8:15; 9:2, 4, 6; 15:16; 16:19, 25; 17:6, 10-11; 22:21, 24; 23:3, 7, 13; 26:18, 22; 27:2, 5-6, 12; 29:14; 30:15, 18, 24; 31:10, 23; 32:8, 10, 22; 33:12; 34:7; 36:18; 50:8; 67:11; 77:4, 6; 78:2; 79:19, 22; 82:9; 84:20, 25; 91:12; 93:25; 94:6; 95:18, 23; 104:4; 105:18, 21, 23, 25; 106:2, 20; 107:2 moiety [1] - 106:14 molecules [1] - 16:21 moment [2] - 2:24; 99:3 money [1] - 71:20 months [2] - 40:6; 58:2 moreover [1] - 104:14 most [15] - 10:6; 18:9; 24:16; 27:13; 29:15; 36:16; 51:10; 61:16; 67:1, 12; 71:24; 72:16; 77:20; 85:17; 95:16 mostly [1] - 81:2 motion [4] - 3:16; 6:20; 103:16	motions [1] - 2:8 move [1] - 37:5 moved [2] - 99:6; 103:17 MR [97] - 2:10, 13, 15, 18; 6:25; 7:3, 19, 22, 25; 11:25; 12:4, 8, 22; 13:11, 21, 24; 14:11, 14, 17; 16:24; 17:25; 20:9, 12; 21:15; 24:7, 10, 12, 15, 18; 27:21, 25; 28:24; 29:11, 19, 23; 30:4, 7, 11; 31:15; 32:9, 14, 19; 33:7, 15, 19; 34:3, 15, 25; 35:10, 15, 22; 36:9, 14; 37:6; 38:21; 39:8, 11; 65:24; 72:14; 73:18; 74:10; 77:11, 20; 78:4, 12; 79:21; 84:2, 6, 9; 86:20; 87:2, 5, 9, 15, 18, 21; 88:5, 8, 15, 19, 22, 25; 90:24; 91:2; 92:1; 94:17, 22, 25; 95:3, 6, 8, 15; 96:16; 97:4, 23; 108:22, 25 MS [21] - 2:21; 39:15, 17, 22; 41:21; 48:17; 57:5, 15; 59:15, 17, 19; 62:4, 10, 12, 15; 63:4, 6, 13; 64:16; 65:23; 97:7 Mullin [40] - 40:6; 42:23, 25; 43:3, 18; 44:19; 45:6, 9-10, 17, 21; 46:7, 9, 12; 47:10-12; 48:20; 50:17; 52:11; 54:5, 15-16; 55:18, 20; 57:16; 62:1, 19; 63:6; 64:10; 92:16, 24; 93:3, 10; 102:6, 10 Mullin's [1] - 46:10 multiple [26] -	5:14; 10:24; 13:2; 22:8, 10; 25:17; 27:20, 23-24; 28:5; 57:8; 63:12; 68:24; 69:14; 70:5; 76:3; 78:5; 80:22; 88:4, 14; 93:7; 98:7; 104:13; 107:19 must [11] - 4:12; 12:20; 22:7; 99:18, 20; 100:4, 8, 15, 23; 104:10; 105:8 mystery [1] - 29:5 name [5] - 5:25; 11:7, 15; 39:14; 64:20 narrow [1] - 62:18 narrowly [6] - 37:9; 44:9; 64:5; 93:11; 101:10; 102:4 nature [4] - 36:23; 38:10; 50:22; 56:15 NDA [64] - 4:5; 8:4, 11, 13, 25; 9:21; 10:15, 18, 21; 11:11, 14-15, 18; 12:25; 16:2; 17:17, 19; 19:22; 20:1, 3, 16, 21-22, 24; 21:7, 19; 22:10; 25:1, 6; 26:1, 4, 8, 20; 28:7, 11; 35:23; 71:3; 73:21, 25; 74:7; 75:25; 83:21, 24; 85:15; 86:3, 7; 90:1, 9; 91:18; 94:10; 98:5, 23; 104:4, 24; 105:9, 16; 106:18, 20; 107:3, 5 NDA's [1] - 108:12 NDA-specific [3] - 71:3; 75:25; 83:24 NDAs [25] - 4:7; 10:24; 11:11; 12:11; 13:2, 4; 19:23; 21:14; 23:22; 27:24; 28:9, 17; 75:25;
---	--	--	--	---	---

Motions, Hearing, 8/19/26

80:2; 81:2, 11; 83:21; 98:7; 104:5, 16; 107:20 near [1] - 68:12 necessarily [1] - 46:3 necessary [1] - 35:4 need [13] - 4:19; 10:11; 17:1; 20:16; 26:5; 31:25; 36:5; 65:19; 67:9; 68:15; 82:3; 89:3; 91:7 needs [1] - 40:21 negotiate [4] - 35:14; 81:16; 86:25; 107:6 negotiated [1] - 107:25 negotiating [2] - 22:12; 104:9 negotiation [32] - 5:21; 9:11-13, 15; 13:9; 14:9; 19:5, 9; 28:21; 29:1, 7; 46:25; 48:6; 51:9; 53:6; 60:20; 61:12; 67:21; 69:1; 73:24; 75:20; 81:14; 87:6; 88:1, 12, 17; 93:6; 101:18; 104:12; 107:24 Negotiation [2] - 5:5; 106:25 negotiation- eligible [4] - 9:12; 67:21; 101:18 negotiations [1] - 69:11 never [5] - 38:10; 66:18; 74:14; 79:8 nevertheless [1] - 15:8 New [20] - 4:5; 67:13, 24; 68:1, 3, 5-6; 70:8; 71:1, 12; 73:11; 74:15; 75:3, 10; 82:20; 85:3, 10 new [56] - 6:7; 16:6, 21, 23, 25; 17:5, 12-14, 17-19; 20:11,	16, 21-22, 24; 21:7, 19-20; 69:7; 70:8, 14-15; 71:12; 72:2, 11; 73:11, 21, 23-25; 74:2, 5, 7, 24; 75:2, 5; 76:11; 82:11; 83:2-4; 85:2; 90:9; 91:1; 96:6; 98:16, 23; 105:24; 106:24 next [3] - 10:5; 19:13; 25:21 nobody [1] - 53:15 non [1] - 89:2 non-paperback [1] - 89:2 none [3] - 55:4; 70:1; 92:13 nongeneric [1] - 11:13 Nordisk [1] - 46:24 notable [1] - 18:9 notably [2] - 41:22; 53:24 note [4] - 4:21; 5:2; 14:7; 50:18 noted [2] - 6:15; 57:10 nothing [11] - 12:5, 8; 39:8; 51:25; 52:1; 65:9; 68:7; 70:10; 78:23; 105:8; 108:25 notice [1] - 37:15 notion [1] - 79:12 Novo [10] - 40:2, 11; 43:17; 46:13, 18-19, 21, 24; 47:4 Novo's [3] - 46:10; 59:4 nowhere [1] - 9:6 nuances [1] - 61:5 Nuclear [1] - 64:21 nullify [1] - 49:17 Number [4] - 2:7; 3:17, 19; 4:23 number [5] - 9:14; 51:10; 84:13; 92:13; 108:13 numbers [1] - 77:24 numerical [1] -	5:17 object [1] - 101:19 objections [2] - 45:10 obligation [1] - 6:18 obtained [1] - 106:20 obtaining [1] - 87:23 obtains [1] - 87:8 obviously [20] - 10:1; 21:1; 23:21; 26:22; 31:7; 32:19; 37:7; 40:1; 42:20; 62:17; 63:18; 66:2, 17; 68:11; 69:22; 79:23; 83:2; 85:3; 98:6, 13 odd [1] - 75:4 oddly [1] - 24:22 odds [2] - 32:5; 95:13 off-label [1] - 79:3 offer [3] - 69:10; 88:17; 107:25 offered [1] - 74:22 officially [1] - 102:1 often [2] - 74:16; 75:2 oftentimes [1] - 16:5 ointment [3] - 23:12; 79:11, 13 old [9] - 66:12; 72:12; 73:22, 25; 74:2, 5, 8-9; 83:3 older [1] - 105:11 oldest [1] - 66:12 omission [2] - 106:3, 15 omits [1] - 106:7 omitted [1] - 66:22 once [6] - 22:1; 46:7; 61:14; 76:9; 79:9; 105:14 one [102] - 2:24; 3:23, 25; 7:17, 20, 23; 8:9, 21, 23; 10:17, 20; 13:5; 15:1, 3-4; 16:3; 18:4; 19:11, 22; 21:7;	22:9, 25; 23:9, 13; 25:12; 26:1; 28:6, 11; 29:16; 31:25; 32:23; 33:11, 13, 25; 34:2, 19, 25; 35:2, 6, 14, 20, 24; 36:15; 41:4; 44:3; 46:25; 47:11; 50:18; 53:14; 55:3; 66:5; 67:9; 69:14; 70:4, 6; 72:12; 73:12, 22; 74:6, 21; 75:9; 78:6, 8-9, 11; 79:10, 13; 80:14, 17; 81:8, 12, 14, 17; 82:13; 83:16; 86:1, 7, 23; 89:17; 90:19; 91:15; 92:12; 93:4; 94:17; 97:25; 98:7, 16, 19; 99:3; 106:6 one-drug [1] - 86:7 one-NDA [2] - 26:1; 86:7 one-to-one [1] - 10:20 ones [2] - 36:12; 93:3 online [1] - 11:10 open [1] - 55:14 opened [1] - 87:11 opening [3] - 6:19; 41:6, 23 operates [1] - 105:1 opine [1] - 49:3 opinion [6] - 41:1; 42:22; 43:4; 58:20; 61:5 opinions [1] - 80:1 opportunity [1] - 7:4 opposed [4] - 17:19; 39:2; 61:21; 64:9 opposing [2] - 7:15; 48:11 opposite [1] - 75:9 oral [6] - 3:22; 6:13; 21:16; 84:12; 97:10, 16	orange [2] - 11:8 order [10] - 4:14; 9:22; 28:3; 34:12; 54:12; 84:7; 86:22; 88:16; 108:19 ordinary [9] - 43:14; 66:15, 20; 67:5; 84:11, 22; 100:9, 16; 105:21 organ [3] - 23:10; 78:20; 84:16 original [18] - 10:4, 17; 11:11, 15, 18; 20:4; 22:10; 27:19; 28:7; 35:6; 68:5, 10; 89:5, 20, 25; 90:1; 91:9 otherwise [3] - 26:14; 86:8; 90:3 out-of-D.C.- Circuit [1] - 59:5 outlier [4] - 57:10; 59:1, 3 outline [1] - 5:3 outlying [1] - 78:17 outset [1] - 3:22 outside [2] - 8:17; 47:9 over-the- counter [1] - 66:18 overcome [1] - 101:5 overstate [1] - 74:11 overview [3] - 9:8; 18:10, 18 own [9] - 9:21; 17:20; 25:1; 40:9, 21; 66:6; 94:1; 101:8 p.m [3] - 2:2; 97:14 package [4] - 69:9, 21; 102:22 page [4] - 34:21; 35:25; 44:2; 77:24 Page [2] - 41:5; 43:3 painstaking [2] - 24:1; 84:23 paired [1] - 25:10 panel [1] - 83:12 paperback [6] -	88:6; 89:2, 8, 17; 91:10 paragraph [4] - 40:23; 44:3; 45:13 Pardis [1] - 2:21 parlance [1] - 96:7 Part [1] - 76:5 part [5] - 9:24; 25:19; 34:16; 60:20; 62:24 particular [11] - 7:5; 10:12, 17; 15:15; 42:8; 45:23; 51:22; 61:6, 12-13; 106:6 particularly [3] - 43:21; 47:11; 61:11 parties [5] - 56:15, 20; 81:20; 99:12; 103:17 parties' [1] - 86:22 parts [2] - 24:2, 21 Parts [1] - 5:2 party [2] - 35:14; 55:4 Paso [1] - 101:11 pass [1] - 49:24 passage [3] - 83:4; 98:17; 106:22 passed [3] - 8:10; 68:14; 71:9 past [2] - 61:9, 14 path [2] - 47:8; 71:22 patience [1] - 99:5 patient [2] - 17:10, 13 patient's [1] - 17:9 patients [6] - 16:9, 13; 67:10, 12; 71:16; 85:2 pause [2] - 36:9; 38:14 Pause [1] - 99:4 payment [2] - 38:4; 56:11 payments [1] - 56:5 pays [2] - 76:16 pending [1] - 3:16
---	---	--	---	--	--

Motions, Hearing, 8/19/26

people [7] - 20:15; 23:10; 71:20; 79:12; 80:1; 84:16, 18 per [1] - 30:19 perceived [1] - 77:1 perfect [4] - 7:21; 66:17; 71:11; 91:3 perfectly [4] - 19:14, 21; 20:6; 49:21 perhaps [3] - 18:8; 57:9; 98:1 period [2] - 10:10; 14:23 periodically [1] - 12:15 permissible [1] - 39:18 permit [1] - 102:20 permitted [1] - 61:2 persists [1] - 100:11 person [1] - 84:19 personal [3] - 38:5, 7 perspective [2] - 17:9; 87:17 persuasive [3] - 24:17; 99:16; 104:20 PEZZI [19] - 2:18; 65:24; 72:14; 73:18; 74:10; 77:11, 20; 78:4, 12; 79:21; 84:2; 95:3, 6, 8, 15; 96:16; 97:4, 23; 108:25 Pezzi [8] - 2:19; 39:19; 65:25; 84:1, 9; 95:1; 97:18; 108:24 Pezzi's [1] - 85:19 Pharma [1] - 78:9 Pharmaceutical s [4] - 2:6; 3:1; 4:23; 23:18 pharmaceuticals [1] - 99:13 pharmacologica l [1] - 79:19 phrase [9] - 43:6, 10-11, 21, 24; 44:10, 21, 23; 102:9	pick [2] - 11:23; 61:15 picks [1] - 49:11 picture [2] - 77:19; 98:13 pictures [1] - 79:7 pill [5] - 23:10; 66:13; 79:11, 13; 84:15 place [2] - 12:6; 39:6 placing [1] - 95:13 plague [1] - 81:7 plain [2] - 6:6; 85:1 plaintiff [6] - 2:8; 6:5, 19; 41:23; 42:1; 61:9 plaintiff's [1] - 6:18 plaintiffs [42] - 2:25; 3:3, 9, 12; 5:6; 6:1, 21; 45:17, 21; 46:14, 18; 47:3, 13, 20; 48:20, 24; 49:9; 50:7, 19; 52:16; 64:18, 23; 65:17; 66:21; 67:1, 7, 23; 68:8, 19; 70:16; 74:11; 75:4, 24; 77:12; 78:7; 96:12; 98:6, 10; 104:25; 108:4 plaintiffs' [28] - 4:16, 20; 45:22; 46:19; 50:24; 51:22; 54:1; 67:6, 16; 68:21, 23; 69:23; 70:7; 71:2; 72:8; 73:10; 74:18; 75:14, 23; 76:23; 78:16, 25; 80:19, 24; 81:13; 83:20; 106:17 plastic [1] - 87:11 play [2] - 74:13; 88:12 played [1] - 105:23 plead [1] - 61:11 plural [18] - 22:7; 44:14; 45:2; 57:19, 24; 63:1, 3, 5-6, 10; 64:6;	69:12; 70:6; 82:3; 104:11; 107:11 plus [1] - 81:2 podium [1] - 7:1 point [22] - 10:1, 14; 13:23; 24:20; 27:16; 29:10, 12, 24; 36:2; 37:4; 49:7; 50:22; 52:6; 59:10; 66:20; 74:11; 79:6; 94:17; 99:16; 104:17, 25; 106:2 pointed [4] - 70:23; 82:1; 105:22; 107:22 pointing [3] - 13:10; 24:25; 25:13 points [1] - 107:23 police [1] - 101:8 policy [5] - 14:8; 17:21, 24; 18:1; 90:4 poor [1] - 75:7 population [1] - 17:13 portrayal [1] - 72:8 position [12] - 34:13; 38:18; 59:11; 74:18; 75:23; 77:23; 78:18, 25; 83:22; 95:14; 103:7; 108:4 possible [2] - 86:11; 100:17 postdates [1] - 41:22 posture [1] - 47:5 potent [1] - 61:11 potential [1] - 104:2 powder [1] - 29:17 powerful [1] - 73:10 practical [1] - 13:19 practice [3] - 79:2; 80:13; 101:21 precedent [3] - 47:8; 58:12; 103:5	precisely [3] - 42:18; 49:19; 98:1 preclude [3] - 49:5; 50:3; 101:6 precluded [7] - 41:14; 48:9, 17, 19; 53:13; 54:7 preclusion [29] - 40:4; 41:14, 25; 42:8; 43:5; 44:4; 46:11; 49:7, 20; 51:19; 52:7, 18, 24; 53:7, 9, 11, 19-20; 54:16; 55:13; 56:4, 11; 59:23; 61:23; 64:23; 65:5, 16, 20 preclusions [4] - 40:15; 41:12; 55:9, 21 prefatory [2] - 18:21; 19:10 prefer [1] - 84:7 premise [4] - 25:5; 31:8; 61:7 preparation [1] - 6:23 prepared [2] - 18:16; 23:23 prescribing [1] - 79:3 prescription [5] - 71:14, 22; 76:17; 79:4 prescriptive [1] - 72:16 present [1] - 53:2 presentation [7] - 7:10, 13; 59:8; 66:22; 67:1; 68:23; 97:3 presented [6] - 4:24; 41:13; 47:3; 50:19; 66:16 presenting [1] - 53:18 presumed [1] - 106:8 presumption [8] - 57:12; 99:24; 100:21; 101:3, 6, 10; 102:3 pretty [7] - 11:2, 16; 17:3; 23:7; 33:10; 35:22; 92:21	prevent [3] - 23:10; 48:14; 50:6 prevents [1] - 48:15 previous [1] - 98:23 previously [1] - 51:5 price [18] - 9:14; 10:8; 15:11, 20; 22:12; 23:20; 69:10, 17-18; 81:17; 86:16; 89:12; 91:4; 94:22; 104:9; 108:1 Price [1] - 5:4 prices [4] - 8:1; 16:14; 17:2; 86:25 primarily [1] - 80:24 primary [1] - 3:24 principle [7] - 30:9; 37:16; 77:1, 4, 8; 100:24; 106:12 principles [4] - 38:25; 57:6; 100:2, 9 print [1] - 11:9 private [1] - 16:20 problem [21] - 9:1; 14:17; 15:1; 16:1, 3; 26:16, 18, 21; 28:2; 51:21; 66:3; 69:23; 83:5, 7; 90:16; 98:11, 21; 107:14 problematic [1] - 81:5 problems [10] - 8:21; 11:20; 13:19, 25; 15:17; 36:12; 78:18; 81:3, 6 procedural [1] - 92:22 procedure [1] - 101:22 Procedure [1] - 3:14 proceed [2] - 72:22; 95:9 proceeding [1] - 68:12 Proceedings [1] - 99:4	process [17] - 5:21; 9:14; 47:22; 51:3; 70:14; 72:9; 74:13; 80:23; 87:7, 23, 25; 88:12; 90:7, 17; 91:19; 99:10; 102:15 processes [1] - 47:1 Product [2] - 14:22; 15:7 product [22] - 6:1, 3; 13:15; 15:15; 16:8, 13; 17:5, 8; 21:5, 9; 26:20; 28:5, 7-8; 36:4; 90:1, 4, 15; 104:22; 108:6 product-hopping [1] - 21:5 product-specific [1] - 104:22 products [29] - 4:3, 6; 5:14, 20, 22; 10:24; 13:3, 13; 14:2; 16:6; 20:19; 23:6; 26:19; 27:11; 31:19; 32:6, 22; 34:6; 35:17; 36:17; 46:24; 82:10; 86:12; 95:25; 104:4; 108:9, 13 Prograf [11] - 23:9, 18; 30:16, 25; 31:24; 33:23; 78:4; 79:8; 84:17 program [26] - 5:4, 13; 6:2; 14:10; 44:6; 48:6; 49:17; 50:5; 51:9; 53:6; 60:15, 20; 61:12; 69:1; 71:25; 73:6, 24; 75:20; 76:16, 21; 80:17; 87:6; 107:24 Program [3] - 5:5; 76:5; 106:25 program's [1] - 5:21 prohibition [1] - 65:12
---	--	--	---	---	---

Motions Hearing 8/19/26

prohibits [1] - 101:9 prominently [1] - 38:23 prompt [1] - 97:10 promptly [2] - 7:6; 94:18 promulgated [2] - 3:9; 13:8 pronouncing [1] - 5:23 pronunciation [1] - 39:14 proper [1] - 31:12 properly [1] - 79:2 proposition [3] - 27:23; 41:7; 101:13 Protopic [10] - 23:9; 30:25; 31:1, 24; 33:24; 78:5; 79:9; 84:16 provide [1] - 16:22 provides [3] - 11:21; 44:19; 101:15 province [1] - 92:9 provision [46] - 10:3, 6; 19:7, 11, 16; 28:20; 37:19, 22; 38:4; 42:3; 44:7, 11, 20; 54:7; 55:22; 60:24; 62:12, 15; 63:24; 64:2; 66:25; 70:4, 22; 76:8; 77:7; 85:9; 88:11, 13; 89:11; 91:15; 92:20; 93:21; 97:22; 99:8; 100:22; 102:19; 104:12, 23; 105:1, 3, 9, 19; 106:22; 107:10 provisions [33] - 8:17, 22; 9:2; 18:14, 19, 21; 19:12; 22:4, 19; 25:22, 25; 27:2, 9, 17; 37:20; 55:11; 62:20; 67:7; 74:22; 75:16, 19; 80:22; 82:15; 104:17, 19; 105:4; 106:24;	107:13, 15, 22 provoke [1] - 49:9 publish [3] - 5:12; 12:11, 15 publisher [1] - 89:22 publishers [1] - 87:1 publishing [1] - 91:13 pull [3] - 33:15, 17; 56:23 pure [1] - 37:11 purported [2] - 46:5, 9 purpose [2] - 61:23; 71:14 purposefully [1] - 106:8 purposes [1] - 68:14 pursuant [9] - 4:6; 6:17; 8:6; 9:24; 10:3; 43:14; 85:10; 99:7; 104:5 push [1] - 16:10 put [2] - 2:8; 29:22 QSSD [29] - 4:2; 5:18, 20; 6:4; 8:18; 9:17, 23; 11:21; 12:7, 19-20, 22; 15:13; 16:2; 18:5; 25:20; 27:19; 32:6; 104:8, 23-24; 105:14, 18; 106:15, 23; 107:2, 19 QSSDs [4] - 4:9; 5:15; 9:10; 105:11 qualification [2] - 38:11; 105:6 qualify [2] - 8:7; 93:20 qualifying [54] - 3:11; 4:2; 8:4, 10, 13-14, 20, 22, 24; 9:9, 11; 13:14; 15:11; 18:12, 23-24; 19:1, 3, 5, 8, 18; 21:24; 23:24; 24:23; 27:10; 28:25; 29:5; 34:8; 38:11; 44:16; 46:23;	53:12, 17; 57:19; 60:10, 14; 61:17; 63:2; 66:25; 67:20; 76:3, 12; 78:24; 82:15; 83:18; 84:24; 85:16; 101:17; 104:2; 105:2 quality [1] - 45:16 questions [16] - 36:10, 25; 37:2; 38:15; 39:9; 48:7; 54:4; 57:1; 61:14, 22; 83:9, 25; 96:17; 97:1, 8 quickly [2] - 43:1; 84:10 quite [3] - 51:9; 55:21; 78:20 quote [8] - 4:3; 8:8; 59:19; 63:25; 69:11; 83:1; 104:9; 105:15 quote/unquote [3] - 47:17; 51:16; 65:13 quoted [1] - 74:23 quoting [7] - 40:11; 44:7; 45:11; 46:22; 101:23; 106:10; 107:8 radically [2] - 29:13; 77:5 raise [8] - 6:13; 13:9, 23; 37:4; 61:19; 65:13; 74:2 raised [5] - 42:7; 55:3; 64:18; 96:12 raises [3] - 46:7; 54:4; 61:22 rare [2] - 56:14, 22 rarely [2] - 56:14, 19 rather [17] - 3:25; 46:3, 10, 14; 50:13; 51:8; 52:14, 19; 56:18; 58:3, 16; 68:5; 70:8; 72:3; 75:3; 96:6; 101:21 reach [1] - 66:3 reaching [1] -	58:24 read [26] - 8:9, 12; 14:1; 25:17; 33:8; 34:3, 6; 37:8; 46:19; 59:19; 62:2; 77:6; 93:10, 12, 17; 94:3-5, 8; 97:22; 101:10; 102:4, 12; 105:2 reading [26] - 6:5; 8:24; 15:5; 16:4; 19:21; 22:16; 23:9, 16; 29:20; 30:12, 20; 31:21; 34:10, 13; 35:19; 36:1, 19; 45:6, 22; 77:10; 83:14; 86:8; 100:23; 102:24; 103:1; 105:4 ready [1] - 7:24 real [3] - 48:12; 51:13; 83:7 realities [2] - 50:2, 4 reality [1] - 47:24 really [21] - 10:5; 15:20; 17:23; 20:14; 23:21; 24:19; 31:13; 36:5; 38:25; 47:19; 51:25; 55:19; 65:6, 14; 75:6, 15; 76:8; 84:10, 21; 92:6 rearrange [1] - 34:12 reason [18] - 12:23; 14:9; 18:2; 22:11; 34:17; 35:1, 15; 37:12; 66:19; 70:9; 71:6; 72:6, 19; 74:20; 78:8; 81:24; 96:22 reasonable [2] - 20:7; 49:21 reasonably [3] - 49:13; 88:20; 100:22 reasoning [7] - 43:18; 44:17; 45:16; 99:13, 16; 104:20; 105:10 reasons [7] - 43:2; 71:10; 72:24; 84:13;	102:25; 104:23; 108:16 Rebate [1] - 76:4 rebuttal [7] - 84:4; 95:17; 96:14, 25; 97:2, 6, 19 rebutted [1] - 101:7 rebutting [1] - 101:3 received [2] - 6:3; 87:10 recent [3] - 37:14; 95:16; 100:13 recently [2] - 105:12; 106:5 recess [4] - 97:9, 11, 13 recognition [2] - 40:21; 102:5 recognize [1] - 97:15 recognized [1] - 93:10 recognizes [1] - 104:13 reconcile [1] - 55:19 record [2] - 2:9; 72:20 redefine [1] - 92:11 Reduction [7] - 3:12; 68:13, 17; 71:8, 19; 79:6, 14 reductions [1] - 17:3 refer [6] - 3:7; 10:4; 27:3, 6; 67:7; 92:13 reference [16] - 5:9; 10:16; 11:7; 12:2, 9-10; 21:23; 27:18; 70:18; 76:6, 15; 86:1; 87:7, 22; 88:13; 103:4 referenced [5] - 27:19; 59:9; 79:16; 106:19 references [13] - 55:10; 70:13; 75:5, 22; 76:3, 5, 21, 23; 81:19; 85:5, 8, 15; 91:18 referred [5] - 3:2; 44:8; 64:3; 65:14; 104:15	referring [3] - 12:2; 16:19; 35:9 refers [2] - 9:12; 21:5 reflect [1] - 95:22 reflected [6] - 103:14; 104:8, 18; 106:22, 24; 108:1 reflecting [1] - 108:19 reflects [2] - 105:19; 106:3 reframe [1] - 48:1 refuse [1] - 20:25 regard [1] - 97:11 regarding [4] - 7:10; 41:16; 54:8; 106:17 regardless [3] - 49:2; 94:6; 95:19 regards [1] - 107:17 regime [3] - 8:5; 91:4 registration [1] - 89:6 regular [4] - 19:25; 26:11; 28:12 Regulatory [1] - 64:21 regulatory [6] - 5:3, 8; 71:18; 79:1; 80:13; 96:7 reiterated [2] - 65:1; 106:5 reject [5] - 20:25; 30:12; 81:24; 90:11; 102:25 rejected [4] - 25:2; 42:19; 48:21; 51:6 rejection [3] - 23:10; 78:21; 84:16 rejects [1] - 108:16 relatively [1] - 71:17 release [14] - 26:13; 27:4; 28:12; 31:2; 35:7; 69:8; 74:20, 25; 75:1, 7; 96:3 relevant [17] - 5:3;
--	--	---	--	---	--

Motions, Hearing, 8/19/26

43:9; 44:12, 25; 45:7; 47:12; 64:7; 68:25; 76:12; 82:17; 89:4; 98:5, 9, 15, 19; 102:21; 106:4 relied [1] - 93:2 relief [2] - 41:16; 54:8 relies [3] - 18:20; 19:14; 22:4 remarkable [1] - 85:17 remember [1] - 26:18 renal [2] - 37:24 render [4] - 81:5; 107:12, 14 repeated [2] - 81:19; 107:5 repeatedly [1] - 37:14 reply [2] - 38:24; 92:15 request [1] - 94:19 require [4] - 31:16; 36:20; 97:2; 105:16 required [9] - 25:5; 45:23; 67:22-24; 71:2; 75:11; 98:22; 106:22 requirement [5] - 46:1; 54:22; 55:2; 105:13; 107:4 requires [4] - 67:19; 81:10; 101:10; 102:4 research [1] - 6:7 resolve [1] - 57:14 resources [1] - 49:16 respect [37] - 29:4; 32:2; 43:6, 10-11, 22, 24-25; 44:21; 24; 45:1; 54:18; 57:10; 58:14, 18; 62:5, 7, 17; 63:11, 17-18; 64:8-10; 73:14; 85:14; 91:19, 22; 92:1; 93:1, 7, 13-14; 97:20; 100:10 respectfully [5] -	31:15; 47:7; 52:8; 56:23; 94:19 respecting [8] - 44:5, 23; 45:1; 62:16; 63:19, 25; 64:13 respects [3] - 11:17; 33:11; 108:10 respond [1] - 29:12 response [4] - 26:9; 70:7; 75:15; 91:24 responsibility [2] - 12:10; 50:16 rest [3] - 61:4; 96:22; 97:8 resting [1] - 6:16 restrict [1] - 35:20 restriction [1] - 12:6 result [2] - 48:8; 68:19 resulted [1] - 5:19 results [1] - 75:2 reticulated [2] - 9:5; 84:25 returning [1] - 94:2 revenues [1] - 74:3 reverse [2] - 8:19; 27:9 reverse-engineer [1] - 8:19 reverse-engineered [1] - 27:9 review [74] - 36:25; 37:8; 38:4; 40:4, 12, 15; 41:11, 14-15, 25; 42:8; 43:5, 21; 44:4, 15; 46:25; 47:18; 49:4, 7, 20; 50:3; 51:18; 52:7, 18, 23-24; 53:7, 10, 19-20; 54:16; 55:9, 13, 21; 56:4, 11; 57:14, 18, 21; 58:10; 59:23; 61:23; 62:16; 63:1, 25; 64:17, 22; 65:5-7, 16, 20-21; 92:3, 19;	93:22; 99:8, 12, 15, 23, 25; 100:25; 101:4, 6, 9, 16, 19; 102:19 reviewability [4] - 57:12; 100:21; 101:10; 102:3 reviewable [1] - 49:3 reviewed [1] - 51:21 reviewing [2] - 41:11; 48:10 rewrite [1] - 46:20 rewriting [2] - 48:16; 105:19 rogue [3] - 49:10, 14, 22 role [3] - 74:13; 100:10; 105:23 romanette [10] - 9:22; 10:5; 11:4, 24; 25:2, 4, 6, 8; 85:8; 91:18 Romanette [1] - 10:17 romanettes [5] - 18:25; 24:24; 35:23; 85:7; 86:3 Romanettes [1] - 9:20 routinely [2] - 55:10 rule [3] - 37:13; 58:13; 97:12 Rule [2] - 99:7; 103:16 ruling [9] - 44:8; 58:14; 64:3; 94:19; 97:11, 17; 102:11; 103:15; 108:19 run [3] - 9:18; 18:25; 35:5 runs [1] - 4:9 safe [1] - 71:16 safeguard [1] - 10:6 safety [1] - 6:8 salt [5] - 5:24; 20:19; 33:1; 34:18 San [1] - 106:10 satisfy [1] - 19:1 save [2] - 16:9; 103:6 saving [1] - 71:20 saw [1] - 60:25	scenario [5] - 15:1, 6, 18; 49:23; 56:21 schedule [1] - 7:6 scheme [4] - 9:6; 10:7; 16:17; 104:7 scope [5] - 42:8; 45:14; 53:8; 56:11 scrutiny [3] - 46:9; 50:6; 71:18 searching [1] - 86:21 second [13] - 4:18; 5:13; 7:18; 9:10; 10:22; 25:2; 45:4; 49:19; 50:5, 11; 51:15; 61:25; 82:23 second-guessing [4] - 50:5, 11; 51:15; 61:25 secondary [1] - 62:6 Secretary [5] - 3:4; 45:24; 48:24; 50:25; 51:3 Secretary's [3] - 45:11, 18; 46:4 section [4] - 41:16; 78:1; 106:6 Section [1] - 41:18 sections [2] - 8:19; 41:17 sector [1] - 16:20 see [11] - 2:24; 3:23; 17:22; 19:4; 32:4; 37:1; 57:2; 65:10; 79:8; 97:10; 103:11 seeing [3] - 47:25; 48:13; 49:19 seeking [1] - 6:20 seeks [3] - 5:17; 42:12; 60:1 seem [3] - 57:7; 62:7; 79:10 select [1] - 9:13 selected [8] - 5:21; 10:7; 46:24; 60:15; 69:20; 75:19;	93:6; 107:7 selecting [3] - 39:1; 81:21; 82:6 selection [5] - 53:11; 72:1; 80:23; 99:10; 107:24 self [1] - 72:6 self-defeating [1] - 72:6 sell [1] - 80:14 selling [1] - 79:2 sells [2] - 23:18; 35:6 send [1] - 24:14 sense [22] - 14:2, 5; 15:12, 25; 23:21; 30:3; 33:1; 42:21; 43:20; 47:19; 52:8; 53:2; 56:12; 63:10; 65:6, 14; 66:15; 67:17; 71:11; 81:18; 85:1; 96:5 sensible [1] - 15:13 sentence [3] - 34:11; 77:7 separate [10] - 6:23; 21:20; 35:3; 36:6; 72:2, 22, 24; 79:4; 104:16; 105:17 separately [2] - 5:20; 67:3 separates [1] - 30:2 serious [2] - 51:17; 54:4 service [1] - 37:25 Services [3] - 3:4 services [1] - 37:24 set [10] - 2:25; 4:13; 31:16, 20; 52:4; 61:15; 69:16; 83:17; 84:23; 94:11 setting [11] - 8:5; 9:14; 15:11; 31:25; 36:20; 78:10; 86:16; 89:12; 91:4; 94:22 seven [17] - 8:5, 7, 10; 10:8, 10, 12, 19; 14:19,	23; 49:12; 82:17; 85:11, 21; 91:21; 92:11; 105:13; 106:22 seven-year [8] - 8:5; 10:10, 19; 14:19, 23; 91:21; 105:13; 106:22 several [2] - 11:17; 91:18 shall [1] - 101:15 share [7] - 15:16; 23:12; 30:18; 33:3, 12; 107:3, 5 SHARON [2] - 2:13; 7:22 Sharon [1] - 2:13 shield [2] - 61:24; 102:20 shocking [1] - 78:16 short [1] - 7:13 show [1] - 9:21 showing [1] - 50:7 shows [1] - 78:4 sic [2] - 54:9; 59:21 side [5] - 28:2; 59:12, 14; 67:10; 72:17 sides [4] - 52:3; 60:19; 65:17; 94:12 sign [1] - 11:2 signal [1] - 35:16 significance [2] - 12:20; 106:16 significant [5] - 30:6; 69:23; 70:20; 77:21; 79:1 significantly [2] - 73:9; 80:20 similar [1] - 19:11 simple [1] - 72:1 simply [1] - 72:1 single [51] - 3:11; 4:2; 5:15, 20; 8:13, 23, 25; 9:10; 19:8; 21:24; 22:9; 23:24; 25:14; 27:10; 28:25; 29:5; 34:8; 37:11; 38:12; 44:16; 46:23;
---	--	---	---	---	--

Motions, Hearing 8/19/26

53:12, 17; 57:19; 60:10, 14; 61:18; 63:2; 64:3; 66:25; 67:20; 68:16; 71:7; 76:4, 12; 78:24; 82:15; 83:18; 84:19; 86:2; 90:2; 93:5; 101:17, 20; 104:2, 13; 105:2; 107:2 singular [16] - 10:14; 22:7; 44:13; 45:3, 8; 62:22; 63:22; 64:6; 69:13; 82:1, 4, 6; 93:7; 104:12; 107:9 sister [2] - 40:13; 58:19 sit [1] - 26:2 situation [9] - 11:1; 13:1, 7; 15:22; 28:4; 35:5; 57:13; 86:22 situations [2] - 53:2; 65:7 size [1] - 69:21 slide [8] - 7:13; 75:17; 77:15, 18; 78:1, 4, 14; 85:6 slides [4] - 24:1; 50:7; 66:6; 77:16 slightly [1] - 41:6 small [1] - 35:17 smaller [1] - 23:1 smuggle [2] - 53:21; 54:3 sole [4] - 60:6, 10, 13 someone [2] - 79:2; 80:5 sometimes [3] - 65:10; 72:23; 83:15 somewhat [1] - 24:22 somewhere [1] - 14:20 sorry [11] - 39:13; 59:5, 17; 63:4; 64:20; 73:18; 77:24; 86:17; 93:6; 107:14 sort [60] - 7:10; 13:18; 14:14;	18:1, 9; 22:5; 23:6, 23; 24:1; 27:8; 35:24; 36:23; 38:24; 39:1, 4; 40:9; 41:2, 17; 42:24; 45:19; 46:15, 17; 47:13; 49:9, 22; 51:11; 52:1; 53:11; 55:14; 56:2; 57:22; 61:5, 7-8, 18; 62:3; 64:4; 66:9; 67:9; 69:2; 70:23; 71:2, 21; 73:7; 75:2, 8; 78:16; 81:4; 84:11; 86:18; 89:4; 90:19; 92:17, 23; 98:13; 106:3 sorts [1] - 18:3 sought [1] - 8:1 sound [1] - 78:20 source [32] - 3:11; 4:2; 9:10; 19:8; 21:24; 23:25; 27:10; 28:25; 29:5; 34:9; 38:12; 44:16; 46:23; 53:12, 17; 57:19; 60:10, 14; 61:18; 63:2; 66:25; 67:21; 76:4, 13; 78:24; 82:16; 83:18; 93:5; 101:17; 104:2; 105:2 Southwest [1] - 38:23 spans [1] - 10:23 speaks [1] - 21:4 specific [14] - 16:2; 18:22; 25:11; 46:15; 69:8, 20; 71:3; 75:25; 83:24; 88:3; 91:16; 104:22 specifically [4] - 4:10; 13:12; 16:19; 98:15 specified [2] - 18:4; 91:16 spend [2] - 19:4; 81:25 spending [2] - 15:19, 24 spends [1] - 44:3	spent [1] - 67:1 split [2] - 40:2; 47:6 spread [1] - 27:24 squarely [2] - 42:7; 59:22 stack [1] - 19:4 stage [2] - 2:25; 31:13 stand [2] - 79:12; 102:19 standard [3] - 57:22; 64:25; 65:2 standards [1] - 51:12 standing [1] - 97:19 stands [1] - 101:13 start [14] - 7:9; 14:19; 18:11, 20, 24; 21:25; 24:22; 25:13, 20; 39:23; 66:6; 70:3; 86:6; 90:1 started [3] - 15:3; 25:5; 80:21 starting [5] - 9:8, 22; 10:11; 14:20, 22 starts [5] - 8:17; 10:19; 15:7; 18:13; 67:2 state [1] - 54:19 statement [1] - 85:20 statements [1] - 77:14 States [1] - 101:13 statues [1] - 71:9 status [4] - 42:11; 44:5; 60:1; 64:1 statute [61] - 6:17; 9:12; 11:2, 17; 14:1, 24; 21:9; 23:16; 31:8, 18; 35:20; 48:16, 19; 61:6; 62:8; 63:25; 66:4; 67:3, 19; 68:7, 9-10, 13, 25; 69:1; 70:10; 71:23; 72:6; 73:15, 23; 74:21; 75:16; 81:14; 82:2, 12; 83:1, 6, 14, 24; 86:14, 24;	87:23; 89:3; 90:14; 91:14; 92:10; 93:10; 94:8; 98:12, 16; 99:22; 100:11, 15; 101:9; 102:7, 17, 24; 103:1; 106:6 statute's [3] - 32:2; 100:18; 101:7 statutes [4] - 9:7; 17:24; 27:6; 99:22 statutorily [1] - 46:2 statutory [58] - 3:10; 4:1, 9; 5:3, 7; 7:7; 8:18; 10:7; 12:2; 23:24; 36:10; 37:10, 12, 22; 38:9; 39:3, 20; 45:15, 19-21, 25; 46:7, 11, 21; 48:7, 10-11; 50:13; 54:22; 55:2; 56:18; 57:22; 64:23; 65:12; 73:4; 79:16; 82:24; 83:17, 22; 89:11; 92:4, 8, 17; 93:15, 21; 94:20; 96:4; 98:2; 99:8; 100:3, 9, 22; 102:9; 104:7; 105:17; 106:12; 108:17 Step [8] - 18:24; 19:3, 7; 22:1; 29:9; 30:3; 31:9 step [6] - 9:9; 18:22; 28:21; 35:21; 88:21 Stephen [3] - 2:18; 39:19; 65:24 steps [5] - 9:8; 18:10; 27:10; 35:25; 50:15 Steps [1] - 18:13 stifling [2] - 8:1; 16:15 still [20] - 22:20; 23:7; 27:11; 28:10; 29:3; 30:14; 33:12; 42:6; 51:6, 18;	56:12; 59:22; 69:25; 85:22, 25; 87:10; 90:15; 92:22; 93:8 stopping [1] - 67:25 straightforward [3] - 11:16; 39:4; 65:18 strength [21] - 19:24; 20:2, 5; 21:13; 26:11-13; 28:13, 19; 30:2, 14, 17, 23; 32:16; 33:12, 21; 95:24; 96:1, 7 strengths [41] - 4:3; 9:3; 19:10, 20; 21:23; 22:2, 23-25; 26:6, 24; 27:4, 14, 18, 20, 23; 28:5, 8; 30:21; 31:19; 32:3, 7, 13, 24; 33:2, 19, 23-24; 34:8, 19; 35:18; 36:4, 17; 69:6, 19; 77:9; 85:24; 94:9; 104:3 stretching [1] - 34:10 strict [1] - 102:16 strike [1] - 75:20 strikes [1] - 7:25 stripping [3] - 6:17; 99:22; 102:17 strong [7] - 13:25; 16:12; 34:16; 57:12; 92:2; 99:24; 100:21 strongly [1] - 91:7 structure [1] - 101:7 subject [25] - 7:9; 23:20; 44:12, 14; 45:2, 8; 50:11; 51:15, 18; 53:7, 10; 55:13; 57:21, 24; 62:22, 25; 63:22; 66:18; 69:4; 72:16; 87:4; 88:1; 99:18, 20; 100:25 subjective [1] - 73:7	submit [2] - 12:12; 90:9 submitted [1] - 72:24 submitting [1] - 72:2 subsection [6] - 38:12; 45:23; 54:20; 55:1; 56:7 Subsection [13] - 54:8; 56:6, 8; 57:20; 59:21; 60:4; 84:24; 85:6, 19; 93:24; 105:6; 106:15 subsections [2] - 8:18; 68:25 subsequent [4] - 85:23; 86:6; 90:25; 106:23 subsidiaries [1] - 58:5 subsidiary [4] - 43:16; 58:8, 11, 16 substance [2] - 6:10; 85:16 substantially [1] - 17:3 substantive [1] - 75:19 subsumed [1] - 107:18 subtle [3] - 67:15; 71:17; 83:15 sufficiency [1] - 46:5 sufficient [1] - 77:4 sufficiently [5] - 17:18; 20:16, 21; 21:18 suggest [5] - 27:18; 28:22; 57:11; 74:14; 98:10 suggested [3] - 72:21; 78:5; 102:10 suggesting [1] - 73:5 suggests [4] - 15:13; 25:14; 59:16, 18 suit [2] - 65:11, 18 suite [1] - 15:9 suits [1] - 48:1 sum [1] - 85:16 summary [7] -
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Motions, Hearing, 8/19/26

3:17; 5:7; 6:20; 103:18, 23; 108:17 super [1] - 88:25 superfluous [2] - 107:14, 16 supplement [11] - 17:17, 19; 20:5, 10, 17; 72:4, 12; 74:15; 75:3; 98:23 Supplemental [3] - 67:14; 68:1, 3 supplemental [18] - 19:23; 20:2; 22:10; 28:9; 37:15; 40:7; 70:7, 15; 71:1, 12; 72:25; 73:11; 81:2; 82:20; 86:4; 90:2; 98:8 supplemented [1] - 73:22 supplements [4] - 22:10; 68:5; 75:6; 76:11 supplies [1] - 105:6 support [4] - 43:22; 59:11; 104:24; 108:4 supported [1] - 63:16 supports [1] - 43:24 suppose [1] - 90:9 Supreme [46] - 25:9; 40:5; 43:5, 8, 10, 19, 23; 44:1, 3, 10-11, 25; 47:10; 48:14, 21-22; 49:2; 51:6; 52:10; 54:24; 55:4; 57:23; 58:1; 62:6, 21, 23; 63:7, 14-15, 20, 24; 64:7, 11, 19; 65:14; 100:6, 13; 101:2; 102:6, 11; 106:5; 108:4 surplusage [5] - 26:2, 16-17, 20 surprised [1] - 98:18 surprising [1] - 70:19	surrounding [1] - 104:17 susceptible [1] - 100:22 suspenders [2] - 26:9, 15 suspension [2] - 21:17; 66:11 suspicion [1] - 34:16 Sustainability [1] - 65:2 swallow [1] - 66:12 swept [3] - 89:18; 90:3 synonymous [1] - 62:18 table [1] - 95:13 tablet [1] - 66:12 tacrolimus [2] - 79:10, 12 talent [1] - 55:7 talks [6] - 11:4; 40:24; 61:5; 69:11; 88:11; 98:16 technical [1] - 96:5 telephones [1] - 38:7 ten [1] - 97:13 tend [1] - 29:21 tension [1] - 13:9 term [17] - 3:11; 4:10; 9:6; 12:2; 16:18; 59:21; 93:16; 101:20; 102:15, 21; 104:12; 105:20; 106:2, 14; 108:5 termination [3] - 45:24; 48:25; 54:18 terms [14] - 6:22; 22:21; 30:13, 17; 32:11, 23; 33:2, 20; 34:7, 19; 35:17; 43:21; 89:20; 104:11 Teva [41] - 4:23; 5:2; 25:25; 36:12; 38:17; 39:23; 40:8; 42:25; 43:4; 44:18; 45:4, 9, 14; 46:8, 16; 47:5, 19-20; 52:8; 53:24;	57:7; 58:13; 72:5; 83:11; 99:13, 15; 101:12, 23-24; 103:2, 24; 104:9, 18, 20; 105:15, 23; 107:8; 108:14 Teva's [5] - 25:3, 24; 40:20; 51:23 Texas [1] - 64:21 text [14] - 6:6; 40:4; 52:10; 68:7; 70:9; 73:15; 74:21; 80:21; 82:24; 83:22; 85:18; 96:4; 101:19 textual [9] - 63:14; 70:11, 18; 73:15; 81:18; 82:1; 97:21; 106:17 THE [121] - 2:3, 5, 12, 14, 16-17, 20, 23; 7:2, 17, 21, 23; 11:23; 12:1, 5, 19; 13:8, 20, 22; 14:7, 13, 16; 16:16; 17:21; 20:8, 10; 21:12; 24:5, 8, 11, 13, 16; 27:15, 22; 28:20; 29:10; 12, 20, 25; 30:5, 8; 31:11; 32:4, 10, 15; 33:4, 14, 17; 34:1, 10, 23; 35:8, 13, 19; 36:8, 11; 37:1; 38:16; 39:7, 10, 12, 16, 21; 41:19; 48:15; 57:2, 6; 59:7, 16, 18; 62:1, 5, 11, 14; 63:3, 5, 9; 64:14; 65:22; 72:8; 73:17, 19; 76:25; 77:18; 78:3, 10; 79:18; 84:1, 3, 8; 86:18, 21; 87:3, 6, 10, 16, 19, 22; 88:6, 9, 16, 20, 24; 90:21, 25; 91:24; 94:15, 21, 24; 95:1, 4, 7, 10; 96:15, 24; 97:5,	9, 15; 98:25; 99:5; 108:23 theirs [1] - 88:23 theories [1] - 40:17 theory [20] - 40:18; 52:12, 17; 53:2, 8, 18, 23, 25; 54:1, 9, 15, 24; 55:8, 16, 20; 56:22, 24; 57:3 therefore [12] - 3:12; 4:12; 6:4; 23:8; 45:14; 46:5, 25; 57:12; 74:2, 8; 86:15; 106:14 they've [3] - 13:12; 35:3; 65:12 thinks [1] - 84:14 Third [14] - 40:2, 24; 46:10, 21; 47:7; 52:9; 57:9; 58:25; 59:13; 101:12, 14 third [6] - 9:13; 11:4; 13:6; 35:21; 45:9; 57:8 thirds [1] - 17:4 three [16] - 9:8, 20; 13:3; 15:2; 18:18, 25; 19:1; 22:19; 43:2; 46:8; 53:11; 66:8; 85:7 threshold [3] - 4:19; 16:8, 10 throughout [1] - 107:9 ticking [1] - 36:11 tie [2] - 91:20 tied [3] - 12:17; 16:2; 88:3 timeline [1] - 14:17 Title [7] - 4:10; 69:12; 70:13; 85:9; 101:17; 104:11 tittle [2] - 68:16; 71:7 to.. [1] - 77:25 today [5] - 7:4; 75:17; 76:2; 81:14; 87:10 together [25] - 16:11; 26:23;	27:12; 30:10, 19, 22-24; 31:4, 18, 22; 32:12, 17, 21; 34:17; 36:5; 46:24; 77:6; 91:7, 10; 94:6, 10; 95:18; 105:4 tomorrow [1] - 53:5 ton [3] - 27:5; 49:16 took [5] - 27:7; 62:2, 18-19; 71:23 top [3] - 19:18; 24:21; 28:16 topic [2] - 17:21; 72:14 topical [2] - 23:12; 79:11 totally [1] - 17:25 touched [1] - 81:8 toward [1] - 40:10 towards [3] - 44:20; 48:22; 88:23 transition [1] - 18:8 translation [1] - 90:19 transparently [1] - 58:22 transplants [2] - 23:11 treat [7] - 13:14; 14:21; 23:12, 15, 17; 80:10 treated [8] - 5:14, 20; 6:4; 16:1; 23:19; 33:13; 34:8; 105:16 treating [1] - 35:11 treatment [1] - 6:7 treats [5] - 17:12; 29:16; 97:25; 98:4 trials [1] - 68:11 tribulations [1] - 68:12 tried [3] - 59:20; 60:22; 71:4 tries [1] - 8:19 trivial [1] - 72:4 trouble [1] - 5:22 true [13] - 17:5; 18:6; 22:17; 28:4; 37:9; 38:3; 40:16; 78:25;	80:11; 85:25; 86:4; 90:9 truly [5] - 53:19; 54:10, 25; 68:6; 70:8 Trump [2] - 65:3; 100:13 try [7] - 20:23; 21:1, 6; 26:10, 14; 33:17; 49:17 trying [18] - 19:17; 21:24; 36:2; 42:14; 47:14; 48:11; 49:9; 53:21; 54:2; 60:21; 61:1, 9, 23; 64:9; 66:20; 81:3; 86:19 turbocharged [1] - 92:3 turn [4] - 37:1; 72:4; 73:7; 76:5 turning [2] - 11:19; 103:17 twin [1] - 8:3 two [41] - 3:24; 4:24; 5:19; 6:23; 13:5; 17:4; 19:12; 20:18; 21:13, 21; 23:22; 29:13, 15; 30:2; 32:15; 58:3; 62:20; 72:2, 22; 77:5, 19; 78:7, 18; 79:12, 20; 80:7; 81:16; 82:21; 92:12; 97:25; 98:1, 14, 20; 107:1; 108:9, 13 two-thirds [1] - 17:4 Tylenol [4] - 66:10, 17; 80:4; 84:14 type [16] - 42:18; 48:13, 18, 20; 50:6, 10; 51:20; 53:9, 15-16; 56:10; 57:20; 69:9, 21; 87:25; 93:20 types [4] - 53:11; 75:25; 83:21; 87:4 U.S [7] - 3:4; 4:11, 22; 76:20; 100:1; 106:11 U.S.C [1] - 69:16 UK [1] - 3:2
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Motions, Hearing, 8/19/26

ultimately [7] - 21:2; 46:24; 70:1; 73:17; 79:7, 11; 90:12 ultra [10] - 3:15; 4:12; 6:9; 64:16, 18, 22; 65:5, 7, 19, 21 um-hmm [1] - 87:9 under [88] - 4:12; 5:24; 8:6; 9:18, 23; 10:2, 7-8, 22, 24; 11:6, 15; 13:2, 4, 25; 15:10; 16:4, 7, 11; 17:16, 19-20; 19:22; 20:1, 20; 21:2, 8, 12; 23:8, 16, 20, 22; 25:1; 26:1, 4, 16; 28:7, 9, 14; 30:18; 32:16; 37:20; 38:12; 41:16-18; 42:1; 44:5, 17; 53:8, 19-20; 54:8-10, 12-13, 19, 24; 55:1, 11-12, 22; 57:20; 60:4; 64:18; 69:12; 70:12; 78:25; 85:9, 13, 15; 86:2, 7; 93:24; 100:8; 101:17; 104:10, 15-16; 105:12; 107:11; 108:14 under.. [1] - 64:1 underlie [1] - 75:23 underlying [2] - 14:8; 45:16 undermine [1] - 80:20 undermined [1] - 6:6 undermines [1] - 74:18 underneath [1] - 9:20 understood [2] - 77:12; 84:6 uneasily [1] - 26:2 unique [5] - 40:15, 18; 41:11; 42:21; 52:14 uniquely [1] -	40:22 United [1] - 101:13 unlawful [1] - 4:12 unless [10] - 24:3; 39:8; 53:19; 57:1; 68:15; 79:6; 83:8, 25; 94:13; 97:7 unlikely [1] - 49:23 unmoored [1] - 70:17 unpersuaded [1] - 104:22 unreviewable [3] - 50:23; 60:22; 61:10 unsuccessfully [1] - 71:5 unsupportable [1] - 76:24 unsustainable [1] - 71:22 up [27] - 7:18; 11:23; 14:24; 16:6; 17:23; 19:4; 20:6; 33:15, 17; 36:7; 43:16; 49:6, 25; 51:14; 56:22; 58:5, 17; 81:22; 84:20; 86:23; 89:16; 90:12; 94:16; 95:2, 4-5; 97:19 upcoming [2] - 7:6; 94:20 update [1] - 90:2 upheld [1] - 37:14 urge [1] - 47:7 USA [1] - 4:23 usages [1] - 27:20 USCIS [6] - 41:5, 8, 14; 54:6, 14; 92:14 useful [2] - 24:3, 16 uses [6] - 43:11; 55:11; 69:18; 79:3; 105:24; 107:10 vacate [1] - 48:9 vacated [2] - 51:2; 96:11 vacates [1] - 48:2 value [1] - 27:8 variation [6] - 30:1, 13; 32:12;	77:8; 80:12 variations [13] - 28:18; 30:6, 17; 32:16, 23; 33:2; 34:7, 18; 35:5, 17; 89:23; 94:7, 9 vary [3] - 30:5; 33:20; 95:25 version [43] - 11:9, 13; 12:17, 23, 25; 13:1, 5, 13, 16; 14:3-6; 15:2, 8, 22-23; 20:2, 19-20; 26:12; 28:12; 35:6; 73:25; 84:15; 89:2, 5, 8, 18, 21, 25; 91:9; 95:17 versions [2] - 88:14; 90:2 versus [21] - 2:6; 17:17; 20:11; 21:8; 40:6; 41:5, 8, 13; 42:23; 50:9; 52:22; 54:6; 64:6, 8, 21; 65:3; 72:12; 73:22; 92:14, 16, 24 view [4] - 15:10; 55:20; 90:20; 104:23 viewed [1] - 87:16 violation [1] - 3:14 vires [10] - 3:15; 4:12; 6:9; 64:16, 18, 22; 65:6, 19, 21 virtually [2] - 4:24; 52:5 wait [3] - 53:9; 54:10; 60:23 walk [2] - 18:16; 23:23 wants [1] - 15:20 ways [2] - 95:24; 97:25 welcome [1] - 36:21 whatnot [4] - 52:15; 53:13; 56:5; 61:6 whereas [2] - 46:16; 103:20 whichever [1] - 84:7 whole [7] - 23:25;	49:6; 67:9; 82:7, 13; 83:14; 102:22 wholistic [1] - 98:13 William [1] - 2:13 willingness [1] - 7:5 withstand [1] - 46:9 word [34] - 4:4; 5:24; 13:3; 22:6; 25:10; 29:3; 42:2, 4-5; 43:8, 13, 20; 57:25; 63:13, 15; 66:15, 21; 67:2, 6; 81:25; 83:4; 84:19; 86:24; 88:21; 93:11; 98:17; 100:18; 102:4, 8, 10; 105:22; 107:9 worded [3] - 42:10, 14; 59:24 words [8] - 13:15; 25:24; 28:19; 33:22; 34:12; 77:3; 100:16; 107:10 workaround [1] - 23:14 works [4] - 12:12; 39:21; 84:13; 95:22 worse [1] - 26:17 worth [1] - 66:22 worthy [1] - 71:17 wrinkle [1] - 98:15 write [1] - 55:8 written [2] - 77:2; 90:23 x) [2] - 56:6, 8 year [11] - 8:5; 10:10, 19; 14:19, 23; 86:13; 91:21; 93:4; 105:13; 106:22 years [14] - 8:8, 10; 10:8, 12; 49:13; 51:11; 73:9; 82:17; 85:11, 21; 86:14; 92:11 yesterday [9] - 4:21; 24:9; 39:22; 42:21; 49:12; 66:24; 79:23; 83:12;	99:14 youngest [1] - 66:10 zero [1] - 98:14 § [26] - 4:10, 15; 9:23; 11:6; 12:3, 10; 38:5, 8; 42:4; 54:11; 69:12; 70:12; 85:9; 99:8; 101:15, 17; 104:8, 10, 16, 19; 105:7; 107:10
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CERTIFICATE OF SERVICE

I hereby certify that on October 5, 2026, I electronically filed the foregoing document and accompanying materials with the United States Court of Appeals for the Fourth Circuit by using the appellate CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

/s/ Allon Kedem
Allon Kedem

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